Evaluation of the Aerosols Dispensers Directive 75/324/EC

Final report, 24 March 2017

ENTR/172/PP/2012/FC – Lot 4

Jacek Walendowski
Judith Vermeer
Paresa Markianidou
Nora Schiemann
Pierre Pouppez de Kettenis
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E-MAIL: GROW-PRESSURE-EQUIPMENT@EC.EUROPA.EU

European Commission
B-1049 Brussels

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Directorate-General for Internal Market, Industry, Entrepreneurship, and SMEs
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2017

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ABBREVIATIONS

ADD – Aerosol Dispensers Directive.

ADR – European Agreement on International Carriage of Dangerous Goods by Road.

ASEAN – Association of Southeast Asian Nations.

ATEX – Equipment for potentially explosive atmospheres.

ATP – Adaptation to Technical Progress.

BAM – German Federal Institute of Material Testing.

CAPEX – Capital Expenditures.

CEN – The European Committee for Standardisation.

CIRCABC – Communication and Information Resource Centre for Administrations, Businesses and Citizens.

COTIF – Convention concerning the International Carriage of Dangerous Goods by Rail.

EBITDA – Earnings Before Interest, Taxes, Depreciation and Amortisation.

EEN – Enterprise Europe Network.

FCs – Fluorocarbons.

FEA – European Aerosol Federation.

IATA – International Air Transport Association.

ICAO – The International Civil Aviation Organisation.

IPRED – Intellectual Property Rights Enforcement Directive.

NLF – New legislative framework.

OPEX – Operating Expenses.

PAIR – Plastic Aerosols Independent Review.

PED – Pressure Equipment Directive.

PET – polyethylene terephthalate.

RAPEX – The Rapid Alert System for non-food dangerous products.

RID – Regulations concerning the International Carriage of Dangerous Goods by Rail.

SPVD – Simple Pressure Vessels Directive.

TPED – Transportable Pressure Equipment Directive.

UN GHS – The United Nations Globally Harmonised System of Classification and Labelling of Chemicals.

VOCs – Volatile organic compounds.

1. EXECUTIVE SUMMARY

1.1. THE AEROSOL DISPENSERS DIRECTIVE

The Aerosol Dispensers Directive (ADD) (75/324/EEC) is one of the oldest EU legislations related to product safety. This Directive includes specific requirements related to pressure hazard and flammability as well as a general obligation to analyse all hazards which could apply to an aerosol dispenser product. Based on such analysis, the aerosol is designed, constructed and tested accordingly to fulfil the appropriate safety requirements concerning its use.

The ADD has two objectives:

1. Guaranteeing that products within the scope of the ADD are safe for consumers / other users in respect of hazards related to pressure and where appropriate, flammability and inhalation.
2. Securing the free movement of aerosol dispensers throughout the EU. As such, Member States must allow the marketing on their territory of aerosol dispensers that comply with ADD.

The ADD is a so-called "old approach" directive including very detailed technical requirements regarding labelling, manufacturing, and testing, etc. The Directive has never seen a complete revision, but several amendments were made over time. These modifications were of technical nature to accommodate changes in technology (e.g. allowing safely increasing the pressure in containers resulting in better performance of the aerosol dispenser products) or to ensure coherence with other legislation (e.g. related to the labelling requirements of the Regulation on classification, labelling and packaging of substances and mixtures, known also as the CLP Regulation).

1.2. OBJECTIVES AND APPROACH TO THIS EVALUATION

Since its adoption in 1975, the ADD has not been subject to a formal evaluation. While the overall perception of the Directive is positive, the European Commission felt that a rigorous evaluation should assess whether this perception reflects the real situation. The evaluation aimed at assessing the relevance, effectiveness, efficiency, coherence, and EU added-value of the ADD. It covered the EU28 Member States.

The evaluation relied on data from several primary and secondary data sources. These consisted of desk research (including a full market analysis of the European aerosols sector), interviews with key stakeholders (European and national authorities, industry, and consumer organisations), a targeted online survey for economic operators, and an open public consultation.

1.3. MAIN FINDINGS AND CONCLUSIONS

1.3.1. Relevance

The findings of this evaluation suggest that the dual objective of the ADD is still highly relevant to the needs of aerosol dispenser industry in Europe. Product safety of aerosol dispensers and a smooth functioning of the EU internal market are still seen as important objectives to be pursued and safeguarded at EU level.

There have been several technological advancements in the field, including the development of new materials for aerosol dispensers (plastics/PET plastic aerosol technology), alternative propellants, new products based on innovative technologies, development of new valves and dispensing systems, etc. The amendments to technological progress played an important role in keeping the Directive up to date with these developments. Article 5 of the ADD lays down the procedure to adapt the Annexes of the ADD to technical progress. While this procedure was considered lengthy, in general national authorities felt that this was justified by the safety aspects in question. In absence of the Adaptation to Technical Progress (ATP) procedure any change to the Directive would require a full legislative procedure which would be even more time and resource consuming.

1.3.2. Effectiveness

The evaluation found the ADD to be effective. While the achievement of the Directive's objectives is hard to measure and depends on multiple external factors, stakeholders (both national authorities and industry representatives) believed that it had made significant contributions to the safety of users and the smooth functioning of the EU internal market. The Directive has been successful in harmonising rules and requirements in relation to aerosol dispensers between EU Member States, thereby facilitating intra-Union trade and guaranteeing an adequate safety level for consumers. Based on the information available, there seem to have been rarely any cases in which compliant aerosols were refused in Member States based on provisions related to the Directive. Moreover, based on the information collected as part of this evaluation, there had been very few reported incidents with aerosol dispensers. The incidents that did take place were often due to misuse of products.

Most national authorities and industry representatives indicated that the provisions, requirements, and methods outlined in the Annexes of the Directive are effective. The wording and content of the Directive are sufficiently clear. While the Directive is very technical in nature, generally industry knows and understands the Directive very well.

Nevertheless, there were some issues that did come up during the evaluation and can be summarised as follows:

- First, there is a disagreement among industry stakeholders in relation to the appropriateness and relevance of Annex Section 5 – the special provisions applying to plastic aerosol dispensers. In total, 43% of the survey respondents, predominantly aerosol fillers, felt that provisions limiting the maximum content were no longer appropriate or relevant, while 24% felt that provisions applying to plastic aerosol dispensers are appropriate and still relevant. No stakeholder group stands out as leaning towards either one and responses are rather mixed. A possible interpretation could be that this is dependent on the extent that companies have already been considering the introduction of plastic aerosols who would hence be more inclined to find provisions no longer appropriate or relevant. This is likely related to the on-going discussions to adapt these provisions.
- Second, it was argued that the alternative tests were expensive (more expensive than the hot water bath test). In addition, there was a need to obtain permission from the relevant national authorities, and there were considerable technical challenges to be overcome in order to successfully implement alternative test methods.
- Third, some economic operators criticised the requirement that the percentage of flammable content needed to be labelled on products even if those products were classified as being non-flammable (Article 8 1a of the ADD). Labelling of

the percentage of flammable content has several disadvantages. First, concentrations are integral parts of formula and linked to specific substances, in this case all substances which are classified as flammable. This means, that parts of the formula are being publicly available. Secondly, if the formula is subject to minor changes in the concentration of flammable substances, the entire artwork definitely needs to be changed. Although these changes do not have an impact on the ingredients declaration that does not require exact percentages, the changes in artwork of printed cans are expensive. To sum up, the evaluation finds no evidence suggesting that this a major issue that would have a negative influence on the effectiveness of ADD. It is also important to note that there are no issues with the requirement to place a warning of flammability for aerosol dispensers classified as flammable.

It should be noted that most of these issues were considered to be minor and did not cause any serious problems to the ADD's effectiveness in practice. The issue of plastics though was considered to be more serious by the economic operators consulted as part of this evaluation.

There have also been very few (potential) barriers to the application of the Directive in practice. Moreover, none of the barriers were considered significant problems, nor was there enough evidence to show that issues actually hinder the effective application of the Directive in practice.

Lastly, the evaluation found one positive unexpected/unintended impact, which is the fact that the rules and requirements of the Directive are used and taken over by many non-EU countries, such as Brazil, China and India (with the exclusion of two important countries, namely the US and Canada).

1.3.3. Efficiency

The Directive was considered to be efficient, by national authorities as well as economic operators. None of the Member State representatives that we spoke to were able to estimate the costs imposed by the ADD on *national authorities*. However, they anonymously stated that the cost imposed by the Directive (e.g. caused by the transposition of amendments of the Directive or communication to industry) on their national authority was very low.

The assessment of costs on *economic operators* was also difficult, as most of the costs were made as part of broader industry and/or company standards and as a response to the requirements of various other legislations. The attribution hence of the costs to the ADD in the strict sense are minimal. Subsequently, the cost assessment performed relied on the assumption that the costs provided are independent of their attribution to the ADD and instead the question formulated as the costs to produce ADD compliant aerosols. Based on this assumption, the cost of ADD, as a % share of production cost per unit, has been estimated at ca. 5% for can manufacturers and fillers and below 5% for valve manufacturers. With a total production cost per unit of output of the finished aerosol dispenser ranging between €0.14 to €1 the cost due to ADD ranges from €0.007 to €0.05.

Both national authorities and economic operators considered costs associated to ADD to be proportionate to the benefits.

1.3.4. Coherence

The ADD can be considered coherent with legislation at national level. The evaluation did not identify any inconsistencies, overlaps, contradictions, or gaps between the ADD and national legislation.

At EU level, the ADD forms part of the EU legislative framework for equipment presenting a pressure hazard. All Directives that fall under this framework pursue the same objective, namely to enhance consumer and user safety and to facilitate the internal market. In addition, there are several other pieces of legislation that are relevant at EU level. The ADD was found to be coherent with most of these pieces of legislation. The evaluation did not identify any overlaps or contradictions between the ADD and these other pieces of legislation. One exception to this was the CLP Regulation. With the introduction of this Regulation on the classification, labelling, and packaging of products in 2008, some overlaps and inconsistencies were created with the labelling criteria that were laid down in the ADD. These overlaps refer to the hazard statements (CLP, Section 2.11) and classification of flammable aerosols (CLP, Table 2.2.1 in Section 2.2.2. Classification Criteria). In practice, there have been some issues because the CLP had not been initially fully in line with the needs and practices for aerosol products. The problems have gradually been removed in various steps through adaptations of the CLP and the ADD. Currently, there are no remaining issues at the level of ADD. Another incoherence concerns the labelling of volume and weight, which is mandatory by ADD but referring to Council Directive 2007/45/EC laying down the rules on nominal quantities for prepacked products repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC" further in this report referred to as the "Nominal Quantities Directive 2007/45/EC"[1], it is only mandatory to label the filling volume.

During one of the interviews with the economic operators it was pointed to a reference in ADD to the inhalation of the spray which overlaps with other sectoral legislations (i.e. Regulation EC No. 1223/2009 on cosmetic products). Nevertheless, it needs to be acknowledged that there is no practical consequence resulting from the existing provision.

Recently, some of the discussions around the ADD have revolved around the question whether the ADD should be aligned with the New Legislative Framework (NLF). One national representative argued that the Commission should consider aligning the Directive to the NLF.

At international level, the ADD was also found to be largely coherent with the existing agreements. One exception to this is the European Agreement on International Carriage of Dangerous Goods by Road (ADR). The evaluation identifies a number of differences between the ADR and ADD, however, it should be noted that these issues did not represent problems in practice. For example, while the ADR allows lower temperature of tests (30°C) for certain products, the ADD mentions the alternative test method. In this context, it has to be remembered that the alternative test method is costly because of a requirement to have in place the accredited quality system and the infrastructure installed. The ADR has also a specific exemption concerning hot-water bath test for aerosol products required to be sterile which does not exist in ADD.

This could have a potential influence when selling the products outside the EU market. However, it is possible to produce aerosol products in Europe which do not comply

[1] Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products.

with the ADD and transport them to countries outside the EU because ADD only applies to products to be placed on the market in the European Union.

1.3.5. EU Added Value

The better functioning of the internal market was seen by most of the consulted public authorities and industry representatives as one of the most important added values of the ADD. They considered that there was a clear value of harmonisation of safety, testing and labelling requirements at European level. The industry representatives felt that non-harmonised national legislation would hinder the free movement of aerosol dispenser products, hamper innovation, drive the costs and increase the administrative burden for the industry.

There is also an EU added value in relation to consumer protection. The Directive provides strict safety requirements that help to ensure a high level of consumer safety in relation to aerosol dispenses across the Union. Moreover, the safety of aerosol dispensers is not only of interest to consumers of aerosol dispensers, but also of paramount importance to the whole sector. A failure of a product of one company would jeopardise the reputation of the entire industry. It should be noted that while the aerosol industry in Europe would most likely not take any risks when it comes to the safety of their aerosol dispensers (due to the reputational risks involved), there is more concern among economic operators when it comes to aerosol dispensers that are imported from countries outside the Union.

2. INTRODUCTION

2.1. PURPOSE OF THE EVALUATION

The Aerosol Dispensers Directive has not been subject to a formal evaluation since its adoption in 1975. From the outset of the evaluation, the overall perception of the performance of the Directive was positive. There were hardly any reported safety issues over the last 10 years and there were no cases of barriers to trade reported to the European Commission. The sector seemed to operate smoothly within the current legal framework.

The objective of the evaluation is to assess whether the Directive is meeting its objectives of guaranteeing free circulation of aerosol dispensers within the EU while ensuring a high degree of safety for consumers, during production, transport and storage. Furthermore, ADD should be verified whether it contains all relevant information, criteria and requirements, whether there are overlaps, incoherent information or contradictions to other directives or regulations.

Information was collected from stakeholders, including:

- economic operators and their associations;
- public authorities; and
- consumers/users and their associations.

This was being done via different techniques such as:

- interviews;
- a targeted consultation of economic operators; and
- public online consultation.

Additional sources were literature (publications, books, legal frameworks, FEA standards, public standards for selected countries in Europe and globally) as well as consultation by experts.

The aim is to assess the extent to which the Directive has been successful in effectiveness, efficiency, relevance (given the needs and its objectives), coherence and achieving EU added-value. The evaluation was carried out during the period from November 2015 until March 2017 by the team from Technopolis Group reinforced by consultants with specific expertise in the field of aerosol dispensers to facilitate the analysis of the technical aspects which were raised during the consultations and interviews.

The evaluation final report will be presented and discussed in the Commission's working group related to the ADD and with all relevant stakeholders. The final report of this study will also be made publicly available. It will provide crucial input to possible future policy initiatives in the field of aerosol dispensers legislation in the European Union.

2.2. SCOPE OF THE EVALUATION

The scope of the evaluation will be an overall evaluation of the performance of the Directive. The results and findings of the evaluations will provide information to the Commission services as to whether a revision of the ADD is required. The evaluation covers all Member States and the period 2005 to 2015, although in specific cases it was necessary to take into account the situation before this period in order to be able to evaluate some aspects. The study focused on aspects regulated by the ADD itself. A clear distinction is made between aspects in the scope of the Directive and those governed by other legislation applying to aerosol dispensers but which are outside the scope of this evaluation (such as for example packaging, environmental, foodstuff or pharmaceuticals) Specifically this concerns aspects of hygiene, specification of raw materials that can be part of aerosol formulations, specific test methods concerning product performance, efficacy, claim substantiation, toxicological profiles, environmental aspects, like recycling, waste and waste management, etc.

A high number of different economic operators are involved in the development and distribution of the aerosol products. They represent the persons responsible for marketing of aerosols and their professional associations where specific industry standards are being created and aligned, e.g. dimension of cans, orifices, valve diameters, actuation forces, pressure resistance levels of standard packaging, etc. Most important stakeholders are the economic operators and their professional associations, the public authorities and the users of these products (i.e. consumer or industrial users and their professional associations).

3. BACKGROUND TO THE INITIATIVE

3.1. DESCRIPTION OF THE INITIATIVE AND ITS OBJECTIVES

The Aerosol Dispensers Directive (ADD) (75/324/EEC) is one of the oldest EU legislations related to product safety. The Directive has two objectives which are fulfilled by technical harmonisation at the European level:

- Guaranteeing those products within the scope of the directive will be **safe for consumers and other users** in respect of hazards related to pressure and where appropriate, flammability and inhalation.

- Securing the **free movement** of aerosol dispensers throughout the EU. As such, Member States must allow the marketing on their territory of aerosol dispensers that comply with the directive.

The ADD defines aerosol dispensers as: "any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

In summary, the key characteristics of an aerosol dispenser can be summarised as follows:

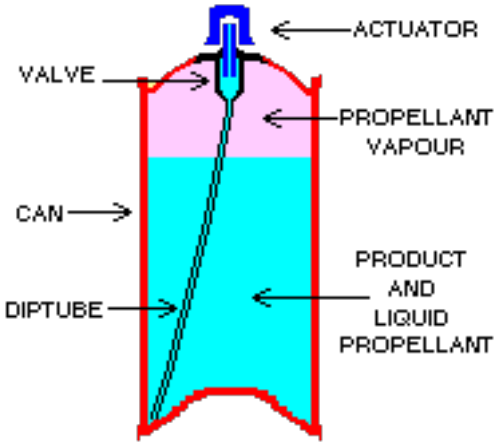
- they operate under pressure which creates a hazard which must be addressed in the design, manufacturing and testing of the product;

- they use a propellant which can be flammable or not flammable (adding a safety hazard which must be properly addressed);
- they have an active component (deodorants/antiperspirants, food, paint, etc.); and
- they have a release device (valve).

A typical **aerosol dispenser** is based on a dispensing system, typically a container filled with an aerosol and a propellant. Aerosols are a mixture of liquid and/or solid particles suspended in air or gas, whereas propellants are chemicals that generate pressure and push the content out of the container where it is suspended as very fine particles, droplets, or foam.

The aerosol dispenser is composed of a container (can, bottle), the actuator (button), a valve, a propellant (a liquefied or compressed gas) and the actual active product. The container is made from metal (tin plated steel or aluminium), plastic or glass and holds the propellant and the product. Within the container, the propellant exerts pressure on the product. When the actuator is pressed by the user, the pressure will force the product out of the container (See Figure 1).

Figure 1 Aerosol dispensing system



The valve body acts as a mixing chamber for the product and the propellant. An efficient aerosol product requires solutions with a complex interplay between propellant, active component, solvent, operational parameters (such as pressure) and valve design. For a number of applications, the valve is the crucial component. For example, the finer the mist, the better, thus, R&D has focussed on the valve, in order to produce finer aerosols or to be able to diffuse foams.

In terms of technical components, one can distinguish the production of the can or bottle and thus take into account the basic material such as plastic, tin plate, aluminium, or (to a very limited extend) glass, and the design and production of the valve (again a mix of plastics and metals). The recycling rates nowadays for tin plate and aluminium are almost at 100% level, although there is no direct recycling of aerosol containers into aerosol containers. Waste is being recycled into other useful things, e.g. tools, construction, household devices, etc. As the market share of plastic aerosol dispensers is still marginal, there is no data on their recycling. However for

plastics in general and as pointed in the Commission roadmap of the Communication on Plastics in a Circular Economy published in January 2017[2], reuse and recycling of end-of life plastics remains very low. In 2014, the EU generated about 25 million tonnes of post-consumer plastic waste of which only 30% was recycled.

More detailed information about the challenges such as the quality of the spray and its performance during use is presented in Annex 3.

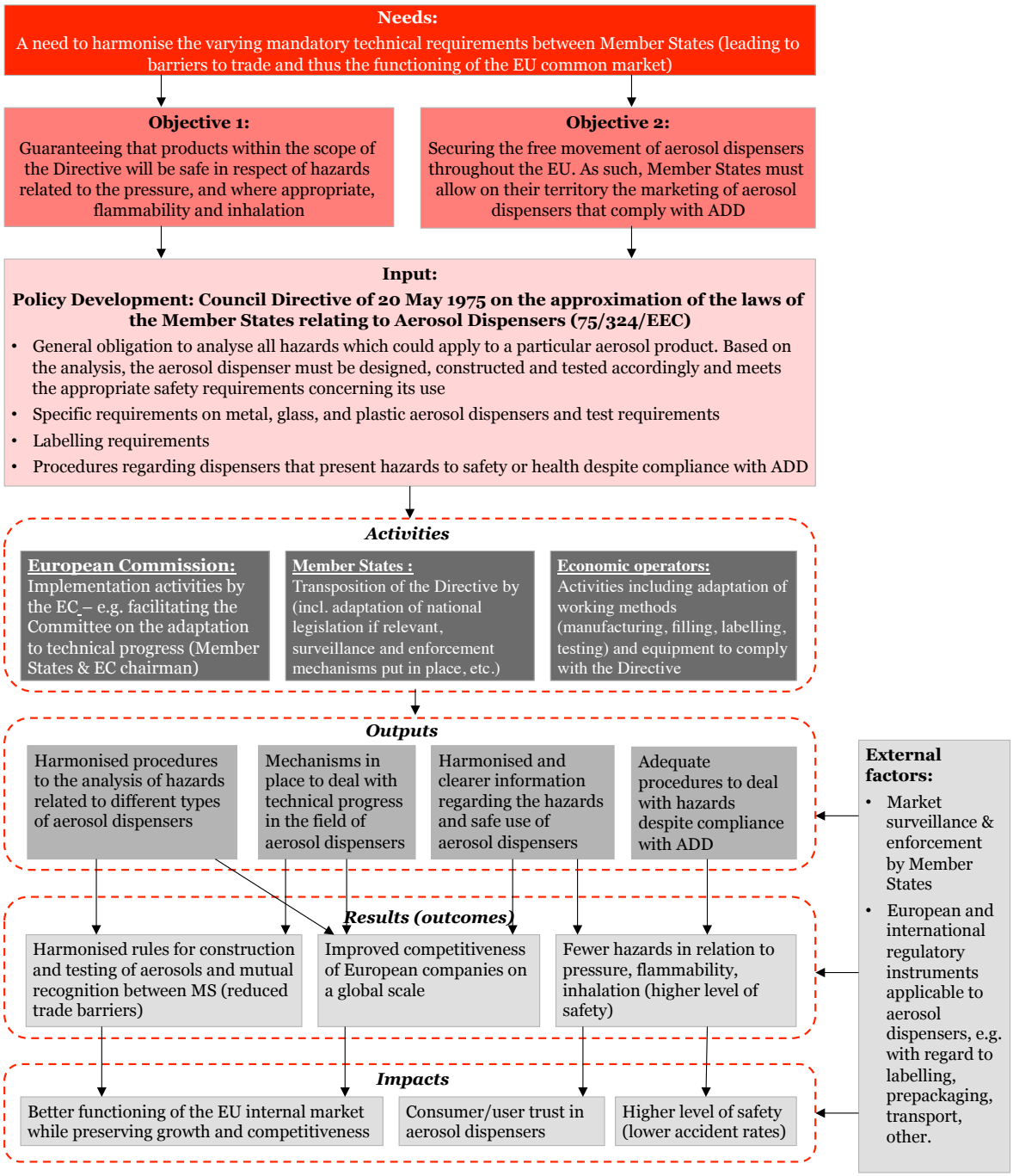
The starting point for the evaluation of the ADD was to develop an intervention logic model. Based on the Commission Guidelines on Better Regulation (May 2015)[3], this is a model of causality that presents the links between the needs and objectives on the one hand, and the intended activities, outputs, results, and impacts of the Directive on the other.

As shown in Figure 2, the intervention logic for the Directive provided the overall framework in which the achievements of the Directive were assessed by the evaluation.

[2] See: http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_39_plastic_strategy_en.pdf

[3] See: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

Figure 2 Intervention logic of the Aerosols Dispenser Directive



3.2. BASELINE

Prior to 1975 all Member States had their own national legislations in relation to hazard of aerosol dispensers due to pressure, flammability, and inhalation. Therefore, there was only harmonisation of rules and requirements as established by the industry itself, which needed to be taken to national level and then aligned in each Member State. As stated in the Directive itself, differences in mandatory technical specifications between the Member States were hindering trade within the Community. Economic operators selling their products across the European Community had to comply with varying safety requirements depending on the national legislations (nine Member States).

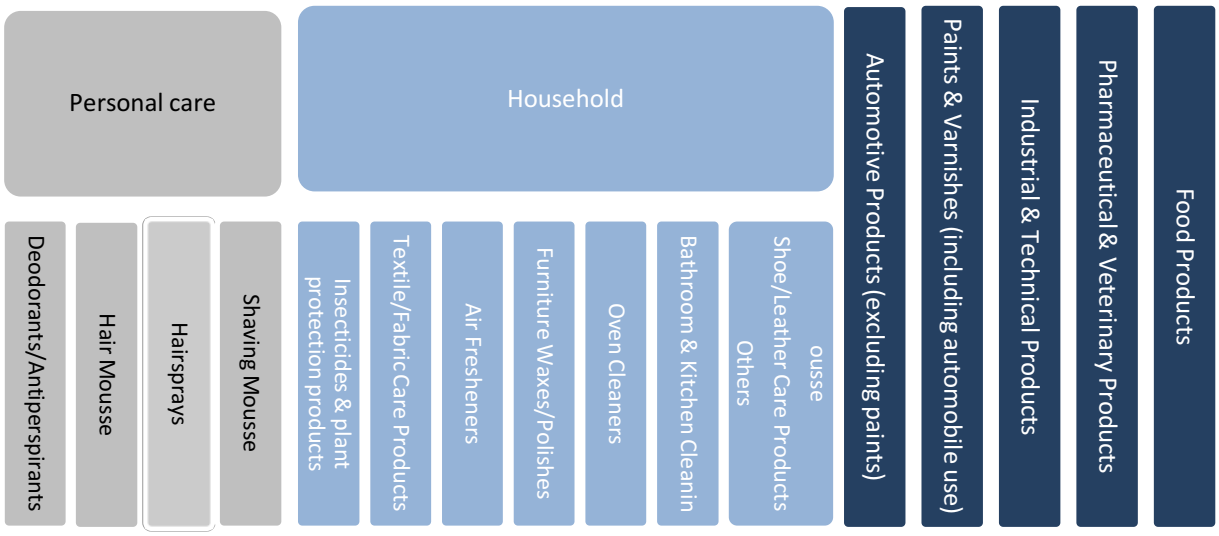
The justification of the creation and implementation of the Directive from 1975 onwards was twofold. On the one hand, the Directive aimed to continue **consumer welfare** (by ensuring a high level of consumer safety) in relation to aerosol dispensers. On the other hand, based on the notions of mutual recognition and free movement of goods, the Directive sought to strengthen the **single market** by ensuring that those aerosol dispensers compliant with ADD would be allowed on the markets of all Member States. In practice, this meant that Member States were free to adopt the specifications of the ADD in addition to or in place of their current legislation in this area. In addition, they were no longer allowed to pose any barriers to the marketing of aerosol dispensers that are complaint with the ADD coming from other Member States.

3.3. MARKET ANALYSIS

3.3.1. Aerosol Market

The aerosol market can be distinguished in terms of **production of cans by type of material** i.e. steel, aluminium, glass, synthetic materials (for instance plastic) and different types of technology/design i.e. special aerosol containers (bag on valve, bi-compartmented etc.). The containers are available in various shapes, size, and appearance with different decorative effects suiting a particular application. The **main product groups** are summarised in Figure 3.

Figure 3 Product group breakdown



Source: FEA; compilation: Technopolis Group.

3.3.2. Aerosol value chain

The relevant industries in the aerosol **value chain** include:

1. **Manufacturers of cans**

   Subgroups: slug producers, plate producers, manufacturers of machines for welding, extrusion, blow moulding and equipment for testing, manufacturers of coatings.

2. **Manufacturers of valves**

   Subgroups: plate producers, manufacturers of machines for moulding etc. and test equipment, manufacturers of coatings.

3. **Filling industry**

   Subgroups: manufacturers of filling lines (liquid filling, crimping/clinching, gas filling), test equipment (water bath, leak detector etc.), users/manufacturers of aerosol packs, product development.

   Indirect suppliers of actives, propellants and solvents – primary in product development.

4. **Marketing/sales/distribution** - the persons responsible for marketing

   Subgroups: as above - often part of the filling industry, product development.

To facilitate the understanding of the aerosols value chain we list below descriptions of the different industries' components.

Figure 4 Description of components used in aerosol industries

Industry	Components	Description
Can Manufacturers	Aluminium cans	These are made from slugs, which are round pieces of aluminium of a very specific quality. The slugs are being put into a press that forms the raw shape of the can by a pressure induced extrusion process. If the quality of the aluminium is bad, e.g. if there is too much iron in the slugs, the extrusion process would produce cans with holes and ruptures. Different additions of metals like Titanium and Manganese can lead to more resistant cans while having even thinner container walls. Other important procedures include beading of the orifice, shaping, coating inside and outside and possibly abrasion technologies. All these procedures can have an impact on the leak-proofness of the can.
	Tin plate cans	These are made from tinned steel plates of defined diameter and defined tin coverage. All plates are being tested on pin holes before manufacturing. Normally tin plates are being coated and imprinted before assembling of the different pieces that make the final can: cylinder (being welded), bottom and cup, which are equipped with a sealing compound and necked together. Quality of the necking and the chemical and physical properties of the sealing compound have a role in the long-term stability of the can.
	Plastic cans	These are made primarily of PET preforms and blow moulding process. The quality of PET the handling of the preform and the blow moulding process can have an impact on the long-term stability of the can.
	Testing - Aerosol Can	Leakage tests have to and are being conducted on all containers either before or after filling. The procedure to test empty cans is very similar to the procedure to test filled cans. See below.

Industry	Components	Description
Valve Manufacturers	Valves	Valves made of metal are being produced with plates that are shaped, beaded and cut to the final form and assembled together with plastic parts and other metal parts, e.g. springs and beads.
	Testing - Aerosol Valves	All valves are tested on function and leakage before they are shipped to the filler, where the components of an Aerosol are put together. Plastic cup valves are made differently. Nevertheless, they need to be checked on function and leakages before filling.
Filling and assembling	Leakage and pressure test of the filled cans	Leakage tests have to and are being conducted on all containers either before or after filling. In most cases, all cans are being immersed into a water bath. Another possibility is to check the pressurized cans in a leak detector. In all cases the cans need to be pressurized during the leakage test. This test checks the mechanical integrity of the can. The test can be conducted at the manufacturer of the containers and performed on the empty cans or the test can be conducted as the final step after filling, crimping of the valves and gassing at the fillers facilities. In the end, it is imperative to have all containers tested on pressure resistance and leaks during the manufacturing process.

Source: Technical experts compiled by Technopolis Group.

3.3.3. Aerosol landscape

This section describes the available business demography data in terms of the number of companies and the characteristics in terms of size and location of the top 5 companies along the value chain.

In total, there are about 330 EU-based companies organised in the European Aerosol Federation (FEA)[4], which are members of their respective national associations. Some more companies are organised in different associations with contacts to national associations and FEA (there is some fluctuation in these numbers). However, and according to the technical experts of this study we can assume that the majority of aerosols companies have a link to Associations.[5] FEA estimates a coverage of 90% based on internal estimations with information from contacts with the industry e.g. at exhibitions.

In the absence of official Eurostat industry data, the database of FEA represents the main source of information for the mapping of the aerosols industry. To further complement the latter, it has been merged with the company repository of Grand View Research, a market research company that provided a market intelligence study on the aerosol industry. Together, the two databases provide an idea not only about the number of companies in a given country, but also the presence of industries along the value chain.

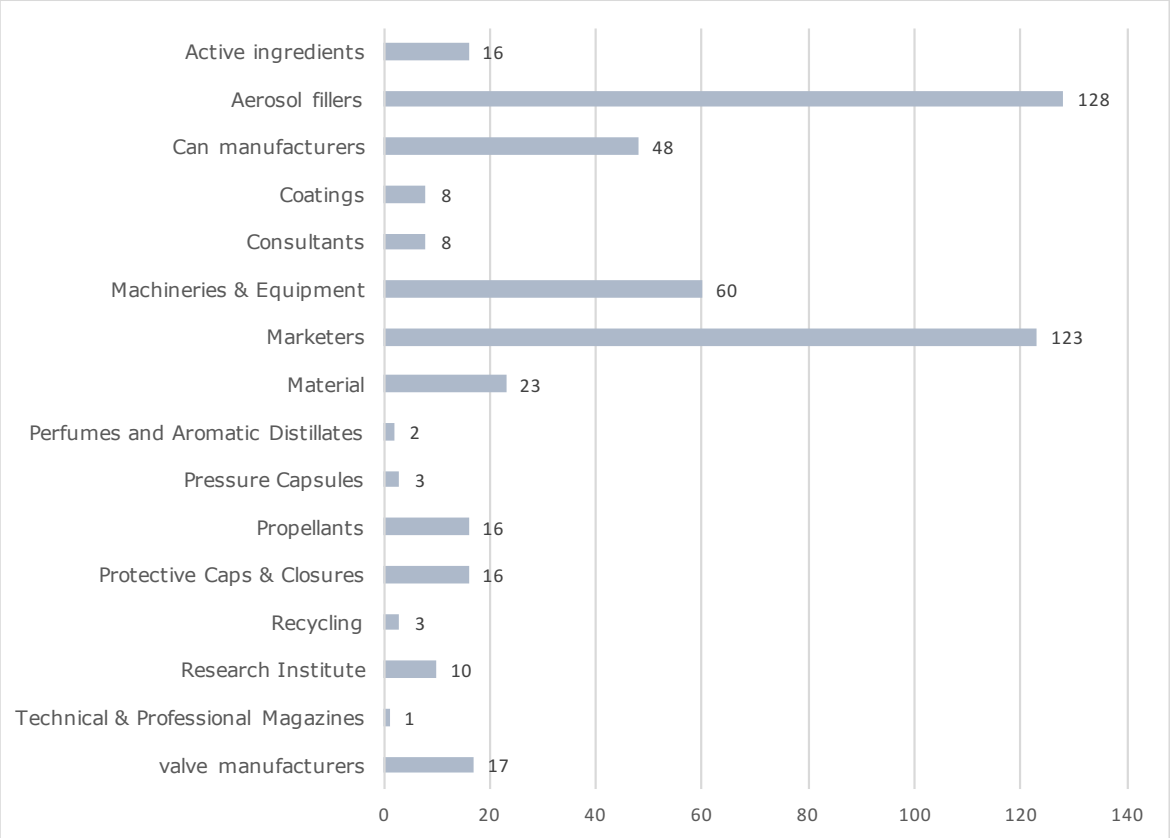
Several are subsidiaries with production plants or other capacities in several EU-MS. Companies are categorised by their main activities and can have more than one activity, thus Figure 5 indicates the number of companies active per activity.

[4] FEA's direct members are the national association of the EU 28 Member States and hence the company repository of FEA corresponds to that of the individual national associations (for more detail on FEA see http://www.aerosol.org)

[5] The consulted experts of the study pointed out that among those companies that are not organised in Associations there are e.g. a company dealing with aerosol can type fire extinguishers, some producers of food aerosols (whipped cream) and some small companies filling pharmaceutical products and technical sprays.

If we first look at the global EU-level (and based on FEA and Grand View Research data), there is a dominance of the last stages of the supply chain with aerosol fillers and marketers (with a strong overlap between the two activities), while companies producing the outer material such as glass or plastic, are rare (there are no glass producers as member companies). This may explain some of the very low production units of glass and plastic containers (see Figure 12) but it also indicates the low importance of these materials for the aerosol market.

Figure 5 Number of companies by main activity



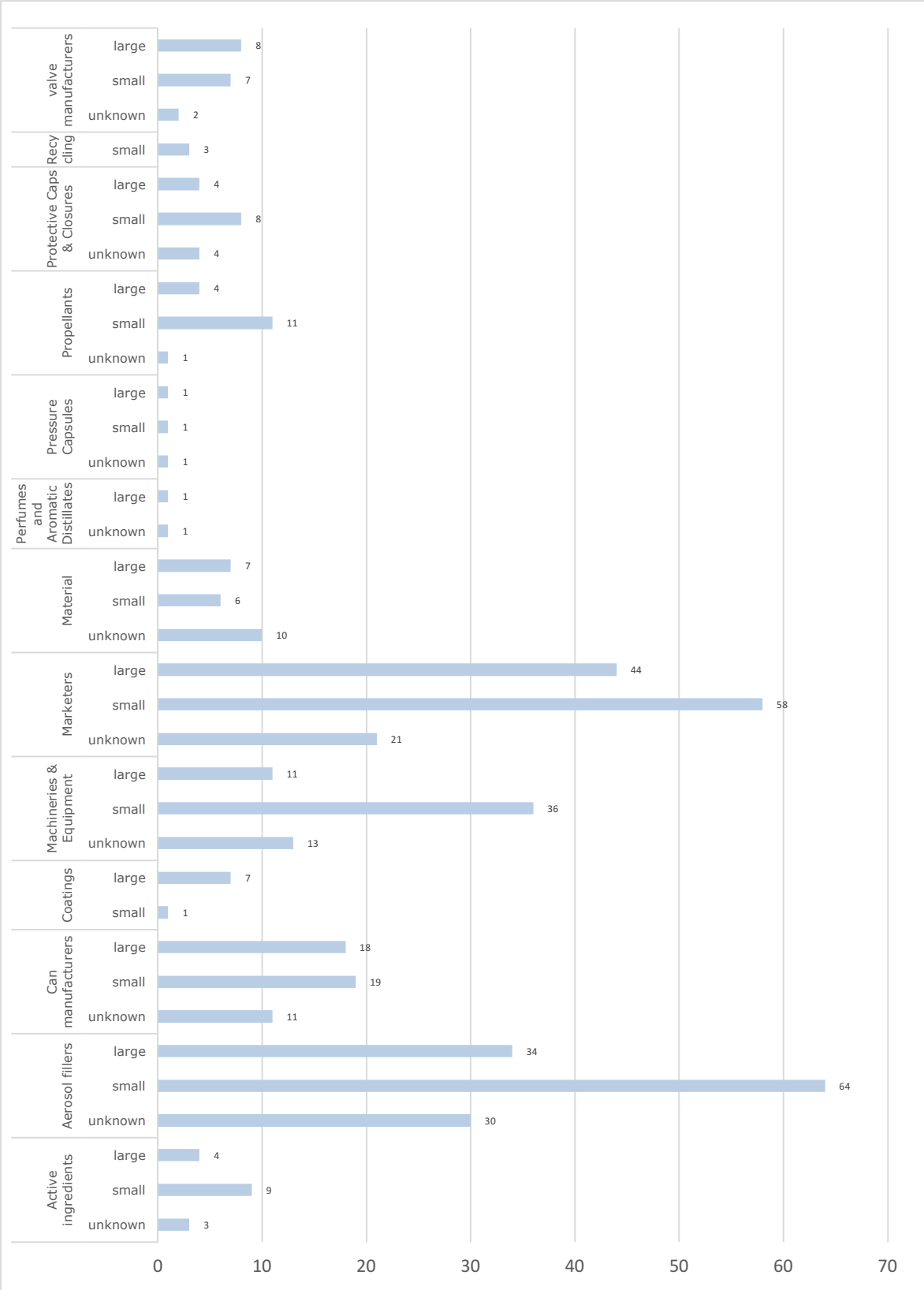
Source: based on data from FEA & Grand View Research, compilation: Technopolis Group. Notes: (1) Includes double counting between activities i.e. companies with multiple activities; (2) subsidiaries with the same activities have been excluded and hence multinationals only have multiple entries if their activities differ.

In terms of composition by size, a categorisation of SMEs versus large companies has been made. As FEA does not collect information on turnover and employment the database had to be manually checked with information available online. It is for this reason that the classification made is not following strictly the European Commission definition and companies are classified as SMEs when meeting one and not both of the criteria (less than 250 persons employed and an annual turnover of up to EUR 50 million, or a balance sheet total of no more than EUR 43 million). The constructed database most often contains information on employment only. Moreover, it was not possible to complete the information for all companies so some gaps remained.

Bearing in mind the latter caveats the composition of the aerosols value chain by size is summarised in Figure 6. What can be observed is that: 1) at least half of the aerosol fillers are SMEs and 27% large companies leaving 23% un-identified companies, 2) at least 40% of aerosol can manufacturers are SMEs and 38% large companies leaving 22% unidentified companies and 3) at least 41% of the valve manufacturers are SMEs and 47% large companies leaving 12% unidentified companies.

Among the rest of the sectors, from the data available, we can observe that companies in aerosol specific active ingredients, machineries and equipment, propellants, protective caps and closures and recycling tend to be 'SMEs' while companies in coatings, perfumes and aromatic distillates tend to be large companies. Companies in pressure capsules and material (which includes slugs and plate producers) appear equally split between SMEs and large companies.

Figure 6 Number of companies by main activity and size



Source: based on data from FEA and Grand View Research, compilation: Technopolis Group. Notes: (1) Includes double counting between activities i.e. companies with multiple activities; (2) subsidiaries with the same activities have been excluded and hence multinationals only have multiple entries if their activities differ.

By analysing the data by country, one can see that Germany, France, Spain, Italy and the UK have a rather complete supply. The majority of fillers are concentrated in Italy and Germany, can manufacturers and valve manufacturers in Germany, machinery and equipment in the UK and Germany while marketers are present in almost all countries with the UK leading followed by Poland.

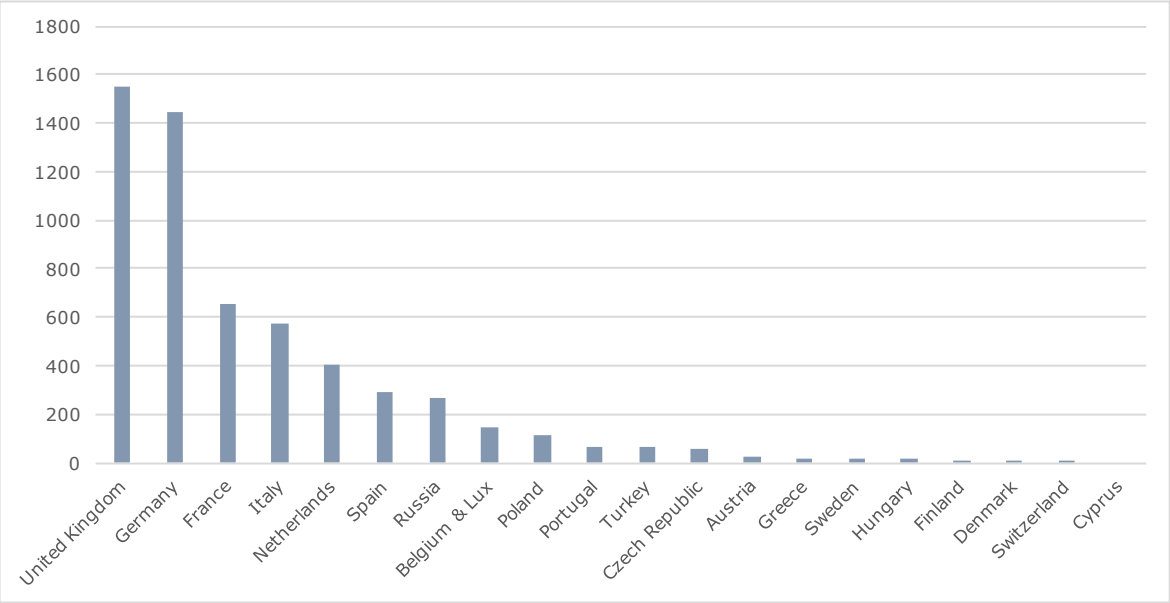
Figure 7 EU member companies by main activity and country (counts)

Row Labels	AT	BE	CH	CZ	DE	DK	EL	ES	FI	FR	HU	IE	IT	LU	NL	PL	PT	SE	SI	UK	Grand Total
Active ingredients		1			1	1		2	1	1			5		1					3	16
Aerosol fillers	6	7		2	22	3	4	18	7	10	7		24		5	3	1	3		13	135
Can manufacturers			2	2	12		1	4	1	5	3	1	6		3	2		4		4	50
Coatings		1			5								2								8
Consultants	1	1						1	1				1							3	8
Machineries & Equipment	1	1	4		15			3	1	4			7		2	3	1	1		20	63
Marketers	8	9		4	7	6	7	11	8	12	1	1	13		5	19		3		24	138
Material	3	2			4		2				2		1	1				1	4	4	24
Perfumes and Aromatic Distillates								1		1											2
Pressure Capsules					1			1		1			2					1			6
Propellants	1				4			1		3			4		2			1		3	19
Protective Caps & Closures				1	6			3	1	2			7		3			2		2	27
Recycling													2							1	3
Research Institute								1		3	2				3					2	11
Technical & Professional Magazines			1		1																2
valve manufacturers		1		1	8			3		6			6		2		1			4	32
Grand Total	20	23	7	10	86	10	14	49	20	48	15	2	80	1	26	27	3	16	4	82	544

Source: based on data from FEA and Grand View Research, compilation: Technopolis Group.

The **market in Europe is dominated by a few countries**, between 2005 - 2012 there were subtle changes on the largest market share; overall the UK is the largest producing country, followed by Germany and with quite a distance, France, the Netherlands, and Italy. Some countries have abandoned container production altogether, such as Denmark, Finland, or Austria, while others have marked decreases (Hungary (-11%), Greece (-9.8%), Belgium & Luxembourg (-6.5%), or the Czech Republic (-2.2%)) or increases such as Germany (2.7%), Italy (2.3%), France (2.3%), Spain (1.9%), or the UK (1.1%).

Figure 8 Container production by EU countries (grand total 2005-2015 in million container units)



Source: FEA; calculations: Technopolis Group.

The dominance of a few countries is reflected in the competitive landscape in terms of the ranking of European companies per industry based on the following parameters: 1) Extensiveness of product portfolio; 2) Sales of aerosol producing division and 3) Global presence. In the case of coatings industries companies headquartered in the US are listed due to the significant presence as well as share within the European market.

Figure 9 Competitive landscape – top 5 companies along the value chain

Industries	Rank	Company	Headquarters	Subsidiaries
Aerosol Dispenser	1	Ardagh Group	Ireland	Czech Republic
				France
				Germany
				Italy
				Netherlands
				Poland
				UK
	2	Crown Holdings Inc.	Switzerland	UK
				Italy
				Netherlands
				France
	3	Tubex GmbH	Germany	-
	4	Nussbaum	Switzerland	Germany
				Switzerland
	5	Colep	Portugal	Poland
				Germany
				Portugal
Slugs	1	The Neuman	Austria	-
	2	ALUMAN S.A.	Greece	-
	3	CCL Containers	U.S.	Germany
				France
	4	Aluminium-Werke	Germany	-
	5	ALUSTOCKACH	Germany	-
Plates	1	ThyssenKrupp	Germany	Germany
				Austria

Industries	Rank	Company	Headquarters	Subsidiaries
		Steel Europe AG.		UK
	2	Emballator Metal Group	Sweden	Sweden
				Germany
	3	TATA Steel Europe Ltd	UK	France
				Germany
				Spain
	4	ArcelorMittal Europe	Luxembourg	France
				Germany
				UK
	5	Magnitogorsk Steel	Russia	-
Welding, extrusion and blow moulding machines manufacturers for aerosol can production in Europe	1	Hochbach GmbH	Germany	-
	2	Zarif Kimya Ltd.	Turkey	-
	3	Sphinx Industrial	UK	-
	4	GAMA J.G.M	Spain	-
	5	James Briggs Ltd	UK	-
Molding Machine	1	Boston Matthews	UK	
	2	Haumiller	U.S.	
	3	Newpla Co. Ltd	Japan	
	4	Wuppermann AG (dip tube)	Germany	France
				Spain
				Italy
	5	Unvented	U.K.	UK
Testing Equipment	1	Specialist Tooling	UK	-
	2	Bautz Engineering	Germany	-
	3	Canneed	Ukraine	-
	4	Geopal System A/S	Denmark	-
	5	Ball Aerocan Europe	U.S.(Global); Switzerland (Europe)	Czech Republic
				France
				UK
Filling Lines	1	Coster Group	Italy	France
				UK
				Spain
				Netherlands
	2	DH Industries	UK	-
	3	HITIT Machine	Turkey	-
	4	Coesia Group	Italy	-
	5	Pamasol Willi	Switzerland	-
Coatings	1	AkzoNobel	Netherlands	Germany
				UK
				France
				Spain
	2	Henkel AG	Germany	Germany
				France
				UK
				Austria
				Belarus
				Bosnia
				Bulgaria
				Croatia
				Cyprus
				Czech Republic
	3	PPG Industries Limited	U.S.	France
				Germany
				Italy
				Poland
				Spain
				Turkey
				UK
				Ukraine
				Russia
	4	BASF Coatings	Germany	UK

Industries	Rank	Company	Headquarters	Subsidiaries
	4	BASF Coatings	Germany	Russia
				Italy
				France
				Spain
	5	Valspar	U.S.	France
				Germany
				Ireland
				Italy

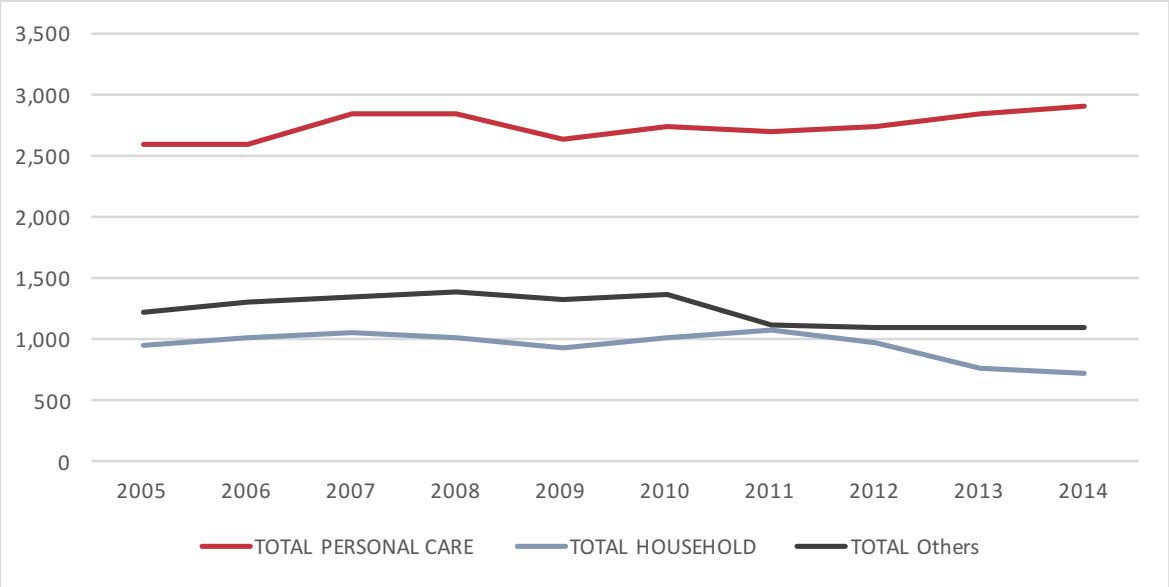
Source: Grand View Research customised report 2016; compilation: Technopolis Group.

3.3.4. Aerosol trends

From 2005-2014 the overall production of aerosol container units in the EU declined. Overall, the production decreased by an annual average rate of -0.58%. The real production increased between 2005-2007, picked up slightly in 2010, decreasing again until 2013 and recovered only in 2014. While is 2005, the real production counted almost 475 million containers, the numbers decreased to 450 million container units in 2014.

In terms of **main product groups, the personal care group is by far dominating**. It is also the only product group realising growth (1.2% average annual), compared to small declines in household (-2.8%), and other (-1.1%). Also within personal care, shifts have taken place: only deodorants and the category 'other' grew by 3.5% and 3.9% respectively, while the rest declined: hair mousse (-6.1%), shaving mousse (-1.2%), and hairsprays (-0.7%).

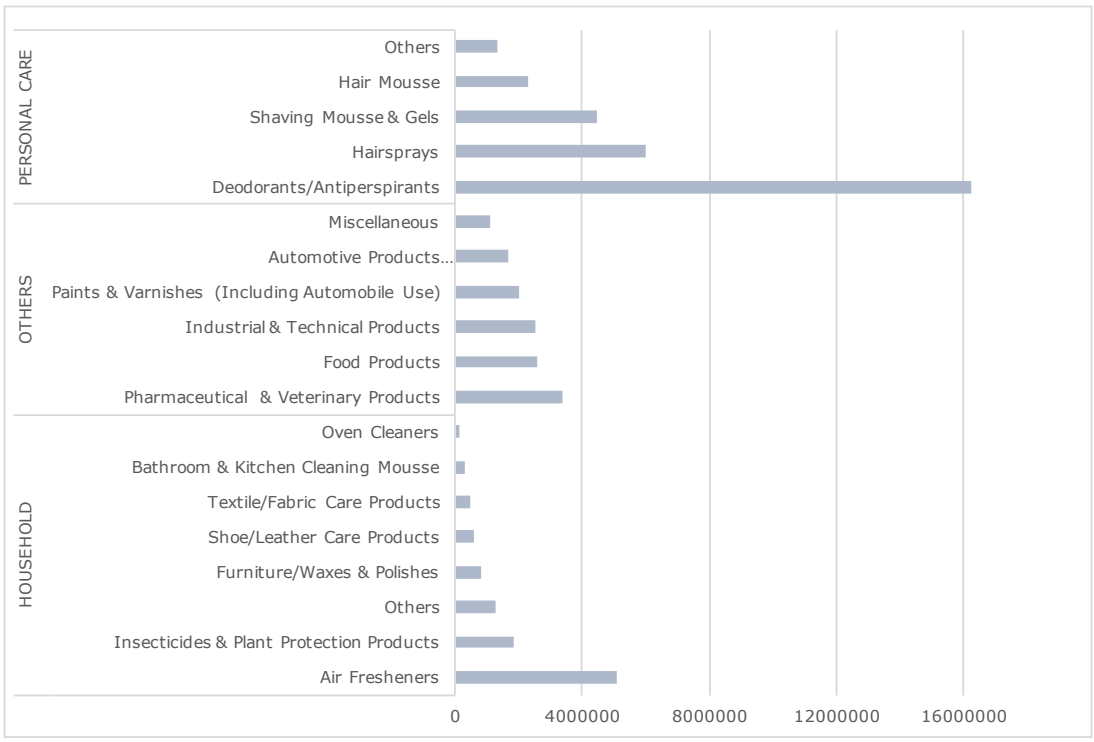
Figure 10 Evolution of demand by product groups (EU, in million container units)



Source: FEA; calculations: Technopolis Group.

Within the three main product categories, there is a leading product as visualised in Figure 11. In personal care, it is deodorants/antiperspirants (with 53% of total EU consumption in personal care products), in household it is air fresheners (with 47% of total EU consumption in household products) and among the remaining aerosol products (the so called 'others' category) pharmaceutical & veterinary followed by Industrial & Technical Products and Food Products (each respectively representing 26%, 20% and 19% of total EU consumption in other aerosol products).

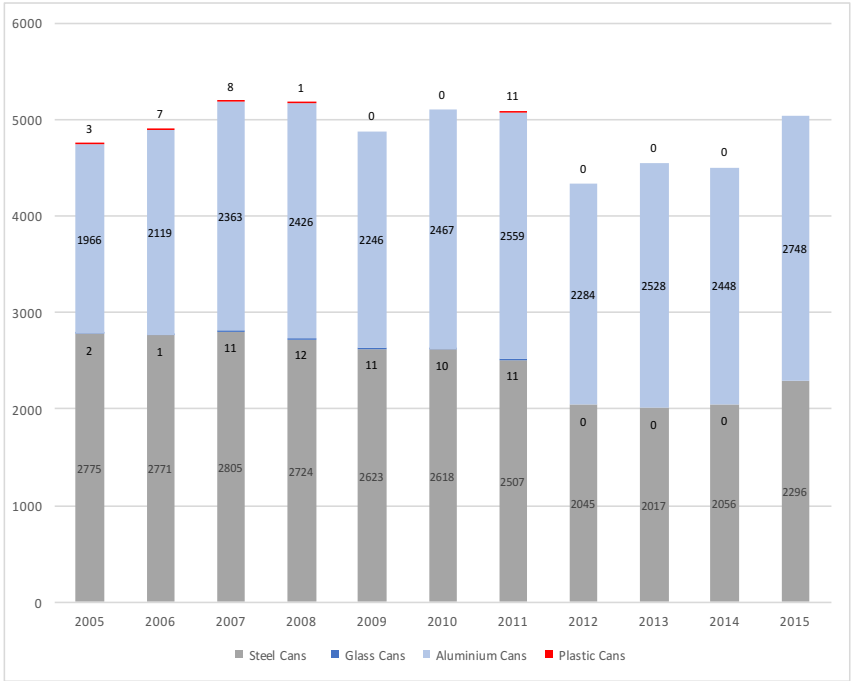
Figure 11 Top products per product group (EU consumption only, in container units grand total 2005-2015)



Source: FEA; calculations: Technopolis Group.

In terms of material, there seems to be a paradigm shift since 2011: the previously dominating material was steel cans, but since 2011, there is a marked decline. Overall production of steel containers fell on average annually by -3.3%, while aluminium containers grew by 2.5% on average. Although the increases are 33% and 24% for glass and plastic respectively the absolute numbers are extremely low.

Figure 12 Development by material (EU countries, in million container units)



Source: FEA; calculations: Technopolis Group Note: no data is available for plastics and glass for 2015; For Italy and Denmark there is no data for 2015.

3.3.5. Aerosol market prospects

Aerosol market prospects are described as inputs for a forward-looking perspective on how the market will evolve world-wide with implications on the competitiveness of the European aerosols industry. Market prospects could for instance inform the work on international competitiveness implications and competitiveness implications from the introduction of plastic aerosols. A summary of the analysis performed by Grand View Research (2016) is provided below:

Increasing awareness for hygiene coupled with growth in the home furnishing market is expected to drive aerosol demand in household applications. Increasing automobile production in China, Mexico, Germany, Brazil, and Indonesia is expected to have a positive impact on market growth. In addition, rising government spending for infrastructure improvement in China, India, and Brazil is expected to fuel aerosol paint demand in construction.

North America and Europe are expected to lose their market share to Asia Pacific and Latin America owing to **stringent environmental regulations** by the European Commission and U.S. Environmental Protection Agency for restricting use of compounds. **Growing personal care products demand coupled with growing household products consumption in emerging markets** of Brazil, China and India is expected to fuel aerosol demand in Latin America and Asia Pacific. The rest of the world aerosol market accounted for 2.1% of global volume and is expected to account for 1.9% by 2020. **Infrastructure development coupled with urbanization in the Middle East** is expected to augment aerosol market growth in architectural and household applications.

Europe was the largest market and is expected to witness significant growth on account of the growing personal care sector mainly in the UK and Germany. Rapid growth in perfume industries in various countries including Germany, Italy, the Netherlands, and Spain will propel market growth over the period until 2020. **Introduction of new product formats, gender-specific products, and technological developments** is expected to drive demand for personal care products. **Urbanization, higher spending power and growing awareness regarding appearance and grooming** is expected to propel perfume industry in the region thereby aerosol demand.

Food was the fastest growing segment for aerosols in Europe owing to the growing food & beverage sector in Germany. The presence of various market giants including Dr. Oetker Group, Südzucker, Arla, Mondelēz Deutschland, Nestlé, and Cargill will further fuel industry expansion.

Paints as another prominent market in Europe is also expected to drive demand for aerosols in the near future. In fact, the European Commission's framing of the Paints Directive 2004/42/EC, intended for limiting Vollatile Organic Compound (VOC) emissions is expected to fuel the demand for eco-friendly products such as waterborne coatings thereby promoting industry growth.

Growth in the construction sector in various countries including the UK, the Netherlands, Germany, Hungary, Poland, Sweden, and Ireland will propel market demand. Growing EU funding coupled with supportive measures taken by governments including subsidies, tax breaks and incentives will augment the construction industry in Europe. Similarly, the commencement of "Construction 2020"

Action Plan will also augment the construction sector in Europe. Efficiency improvements in existing buildings and renovations have the highest potential to stimulate demand. In addition, improving technologies will augment demand for coatings over the forecast period. Moreover, urbanization along with infrastructure development in the Middle East is expected to augment aerosol market over the forecast period.

New product launches including Unilever's deodorant aerosols made using less amount of raw material and low energy use in Europe and North America is expected to stimulate market growth.

Technological advancements such as stahl monoblock aerosol cans and airless dispensers are expected to fuel market growth.

Influencing factors of aerosol market prospects along the value chain are described in Annex 5.

3.3.6. Aerosol demand forecasts

Global aerosol demand was 14,611.8 million units in 2013 and is expected to reach 18,040.5 million units by 2020, growing at a rate of 3.1% (average annual) from 2014 to 2020. In terms of **revenue**, global aerosol market was valued at USD 54,327.9 million in 2013 which is expected to reach USD 70,151.2 million by 2020 growing at a 3.8% (average annual) from 2014 to 2020 (Grand View Research, 2016).

Figure 13 Global aerosol market volume by region, 2012 – 2020 (in million container units)

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020	Average annual (2014-20)
North America	4 217	4 327	4 439	4 558	4 680	4 810	4 944	5 087	5 228	2.8%
Latin America	1 093	1 130	1 167	1 206	1 247	1 291	1 336	1 384	1 432	3.5%
Europe	5 297	5 428	5 563	5 707	5 854	6 011	6 172	6 343	6 513	2.7%
Asia Pacific	3 294	3 424	3 557	3 700	3 847	4 005	4 168	4 341	4 517	4.1%
Rest of the World	298	304	310	316	322	329	336	343	350	2.1%
Total	14 200	14 612	15 036	15 487	15 951	16 446	16 956	17 498	18 041	3.1%

Source: ICIS, FEA, NAA, Aerosol Europe, CMI, Primary Interviews, Grand View Research
Notes: time series dating back from 2005 are not available.

Europe had the largest market share in 2013, owing to high cosmetics demand in countries including UK, France, Italy and Germany. North America followed Europe in terms of volume as well as revenue due to the presence of major fast moving consumer goods companies including Proctor & Gamble in the region. Asia Pacific is expected to be the fastest growing market mainly due to the growing home furnishing market which is expected to augment household aerosol demand (Grand View Research, 2016).

Figure 14 Global aerosol market revenue by region, (EURO million), 2012 - 2020

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020
North America	12 408	12 415	12 813	15 869	16 458	17 003	17 610	18 255	18 905
Latin America	3 200	3 207	3 324	4 124	4 285	4 447	4 614	4 792	4 973
Europe	15 623	15 577	16 102	19 869	20 586	21 301	22 039	22 765	23 490
Asia Pacific	8 718	8 844	9 251	11 613	12 209	12 779	13 413	14 089	14 783
Rest of the world	882	874	899	1 106	1 136	1 169	1 201	1 234	1 266
Total	40 830	40 918	42 388	52 581	54 673	56 698	58 877	61 135	63 417

Source: ICIS, FEA, NAA, Aerosol Europe, CMI, Primary Interviews, Grand View Research
Notes: time series dating back from 2005 are not available.

The **price trends** as calculated by Grand View Research show that Europe and North America have consistently the highest prices compared to other major regions. The lowest prices have been estimated for Asia Pacific. The difference between Europe and the cheapest aerosol producers is on average €0.33 (considering the entire period including the forecasted years). Note that the figures for 2012 and 2013 are based on secondary sources[6] and verified with industry participants located across the aerosol industry value chain.[7]

Figure 15 Global aerosol price trend, by region, 2012-2020, (EURO/container unit)

Region	2012	2013	2014	2015	2016	2017	2018	2019	2020
North America	2.94	2.87	2.89	3.48	3.52	3.53	3.56	3.59	3.62
Latin America	2.93	2.84	2.85	3.42	3.44	3.44	3.45	3.46	3.47
Europe	2.95	2.87	2.89	3.48	3.52	3.54	3.57	3.59	3.61
Asia Pacific	2.65	2.58	2.60	3.14	3.17	3.19	3.22	3.25	3.27
Rest of the world	2.96	2.88	2.90	3.50	3.53	3.55	3.58	3.60	3.62

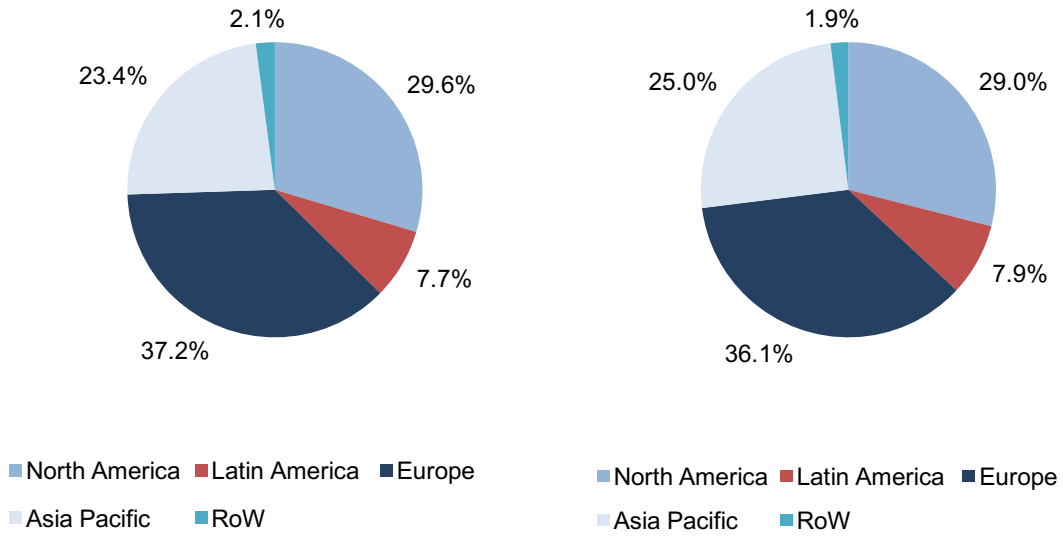
Source: ICIS, FEA, NAA, Aerosol Europe, CMI, Primary Interviews, Grand View Research
Notes: Figures represent proxies of average shelf price for aerosol dispensers; time series dating back from 2005 are not available.

Europe was the largest aerosol market, accounting for 37.2% of global volume in 2013. Growing personal care products demand in Germany, France, UK and Spain is expected to fuel aerosol market growth in the region. North America was the second largest market, with 29.6% of global aerosol market volume in 2013 (Grand View Research, 2016).

[6] Federación Latinoamericana Del Aerosol (FLADA); Consumer Specialty Products Association (CSPA); Southern Aerosol Technical Association (SATA); Fédération Européenne des Aérosols or European Aerosol Federation (FEA); Plastic Aerosols Independent Review (PAIR); Aerosol Association of Australia & New Zealand (AU); Spray Technology Magazine; American Association for Aerosol Research; Aerosol Association of Australia

[7] Raw material suppliers; Container manufacturers; Aerosol manufacturers; Can filling companies; Distributors; Buyers

Figure 16 Market shares (volume) in 2013 and 2020



Source: ICIS, FEA, NAA, Aerosol Europe, CMI, Primary Interviews, Grand View Research.[8]

3.3.7. Aerosol Market Consolidation and value chain insights

According to FEA the numbers of their members through national associations has decreased in the last years while production volumes increased. Also, according to Grand View Research (2016) mergers & acquisitions along with organic growth through expansion of production capacity remain critical success factors for the future growth of the aerosol industry. M&A activity is observed in the aerosol industry both as a strategy for expansion and vertical integration along the value chain in order to augment market shares, increase revenues and provide superior products and service to clients. Expansion includes both European companies expanding operation overseas or companies from Asia Pacific, the US etc. expanding operations in Europe. Moreover, besides expansion of production, expansion in R&D facilities is also observed (see Figure 17 for a listing of M&As and Figure 18 with some examples on production expansion).

[8] RoW stands for Rest of the World.

Figure 17 Consolidation - M&As

Ardagh Group	Can manufacturer	Ireland	Boxal Group	Can manufacturer	France/ Netherlands	2012
Ardagh Group	Can manufacturer	Ireland	Finanziaria di Partecipazioni Industriali S.p.A.	Can manufacturer	Greece	2013
Colep	Can manufacturer	Portugal	Aerosoles y Liquidos	Can manufacturer	Mexico	2013
Sanmex International	Aerosol filler	Scotland	Barony Universal Products	Aerosol manufacturer	Scotland	2015
Massily Group	Aerosol filler	France	Linar	Can manufacturer	Russia	2012
James Briggs Ltd	Can manufacturer	UK	Premier Products	Aerosol fillers	UK	2015
Ball Corporation	Can manufacturer	UK	Envases del Plata S.A. de C.V.	Can manufacturer	Brazil	2012
Ball Corporation	Can manufacturer	UK and U.S.	Rexam PLC	Can manufacturer	UK	2016
Ball Corporation	Can manufacturer	UK and U.S.	Sonoco	Metal ends & closures	U.S.	2015
Exal Corporation & Indicans Holdings	Can manufacturer	U.S. and Netherlands resp.	Casablanca Industries Pvt. Ltd.	Can manufacturer	India	2014
Emballator Metal Group	Can manufacturer	Sweden	Skanem Moss A/S	Can manufacturer	Norway	2015
Tata Steel Europe	Can manufacturer, aerosol plates	UK	SSAB	Aerosol plates	Sweden, Finland, Norway	2015
Milacron LLC	Molding machine	Europe and U.S.	Mold- Masters	Molding machine	India	2013
TASI Group	Testing equipment	U.S.	Bonfiglioli Engineering	Testing equipment	Italy	2012
Bausch + Strobel	Packaging	Germany	Wilco AG	Testing equipment	Switzerland	2013
Coesia Group	Molding equipment	Italy	GF S.p.A	Filling lines	Italy	2016
Coesia Group	Molding equipment	Italy	Emmeci S.p.A	Packaging machinery	Italy	2016
AkzoNobel	Coatings	Germany	BASF Industrial Coatings	Coatings	Germany	2016
Henkel AG	Coatings	Germany	Darex Packaging Technologies	Can manufacturer, can closures & sealants, coatings	U.S.	2017
Valspar	Coatings	U.S. with operations in Europe	Quest Specialty Chemicals	Coatings	US	2015

Figure 18 Examples of production capacity expansions

Exal Corporation a large manufacturer of impact extruded aluminium containers is increasing expenditure to expand the production of aluminium slugs. Also, CCL, a key slug manufacturer is investing in new a R&D plant setup to produce slugs used in the extrusion process for manufacturing tubes, bottles, and aerosol cans for consumer packaged goods.
In May 2015, Lindal Group, a valve, actuator and spray caps manufacturer, announced the establishment of new production facility at Istanbul, Turkey for the production of actuators and valves. This establishment is expected to ensure access of raw material for aerosol spray manufacturers in Turkey over the next six years.
In March 2014, Precision Valve Corporation announced the establishment of a product development centre at Hattersheim, Germany. The centre is meant for the development of new products such as valves and actuators.
In February 2013, Unilever announced that it would invest USD 62 million to establish its first Asian aerosol deodorant manufacturing plant in Maharashtra, India. In May 2013, Unilever announced the opening of a new state-of-the-art deodorant manufacturing facility in Mexico.

Besides consolidation and expansion, collaborations along the value chain are also considered strategic. Collaborations occur at different levels between for instance:

- Fillers-brand owners and contract fillers to strike better deals as a result of high volumes;
- Fillers-brand owners and can manufacturers, similarly due to volume being a critical cost component and also due to exclusive collaborations in the form of partnerships for the development of new dispensing systems for e.g. paints, household and personal care products
- Testing equipment manufacturers and can manufacturers with the testing equipment industry servitising by increasingly providing services benefits including free installation. In addition, testing equipment manufacturers are expected to increase R&D expenditure for the development of new products such as testing equipment without the use of water bath intensifying the collaboration with fillers.

Value chain configurations are thus being reshaped for the aforementioned reasons including augmentation of market share, increase of revenues, provision of superior products and service to clients. Changes in strategies/product portfolios of key stakeholders labelled as such due to their positioning in the aerosol value chain namely the strength of their linkages with all other stakeholders can have an impact on the growth and survival of companies along the value chain. An example could be the interruption of a long-term collaboration between a large aerosol filler and a small valve manufacturer whose survival largely depends on the specific cooperation. Another example could be a change in product portfolio of a number of aerosol fillers, shifting from aluminium to plastic cans with an impact on aluminium can manufacturers. Factors such as competition from new players entering the European market and regulatory changes related to plastic aerosols to name a couple, could eventually depending on scale cause notable shifts in current value chain configurations of the European aerosol industry. A thorough value chain analysis with empirical evidence would however be needed to map current and explore future value chain configurations.

3.4. COMPETITIVENESS – PRELIMINARY INSIGHTS

In line with the guidelines laid out in the Commission's "Competitiveness Proofing" Toolkit competitiveness considerations include three dimensions: Cost competitiveness (cost of production and price of products and/or services), Innovation competitiveness (capacity to innovate) and international competitiveness (impacts on trade flows and cross border investment). The assessment of competitiveness would eventually require a comparison of the differences on the aforementioned dimensions between the EU aerosol industry and non-EU aerosol industry.

In the subsequent paragraphs, we touch upon the three dimensions of cost, innovation and international competitiveness based on the information obtained for the market analysis and in the context of the ADD evaluation. Hence, these inputs should not be read as the result of a fully elaborated competitiveness analysis.

Cost competitiveness: Changes in the production cost per unit (and prices) of aerosol products can change the relative attractiveness of the product or service which can lead to changes in market shares. The production cost and price of products produced by the European aerosol industry is determined by a range of resources as presented in the following section (3.3.7) on costs. One of the major resources is raw material. In particular, for can manufacturers tin plate can manufacturers use tin plate sheets for the production in different sizes, plate thickness, tin layer (g/m2), while aluminium can manufacturers use aluminium slugs.[9] According to our technical experts, material is surely being sourced from non-EU countries. Moreover, according to Grand View Research the European aerosol can manufacturers are relying on imports of plates from metal sheet manufacturers on account of high concentration of sheet manufacturers in Asia Pacific, particularly in China and India. However, there is no public data available on quantities as the trade data available is not appropriately granular to allow the identification of imports for aerosol production. Given, the volatility of raw material prices and the significant impact on the production costs it is a relevant factor to be accounted for in considerations regarding the competitiveness of the European aerosol industry. This is linked to the ability of European Aerosol companies to purchase raw materials at low cost. For instance, implications arise due to increased costs of raw material that may push prices for aerosol cans of European manufacturers upwards which may in turn lead to the filling industry (brand owners) shifting to overseas suppliers.

Production costs are described in the subsequent section more in detail. These costs may differ for non-EU aerosol manufacturers as they do not need to comply with ADD for their internal markets but apply should the latter target the European market. Differences between EU and non-EU aerosol manufacturers would then occur due to namely plant location and employment costs. To make an assessment of those costs one would need to map the location of plants of European Aerosol manufacturers and inquire their intention to move plants to countries with lower costs.

Innovation competitiveness: Trends in products are observed along the value chain. Key market participants are increasingly looking at product innovation for manufacturing environment-friendly components using latest aerosol technologies. Over the past few years, there has been a shift from traditional aerosol manufacturing

[9] Depending on their knowledge and capabilities the slugs contain additions of manganese and other materials to make the final container more pressure resistant with thinner walls.

towards enhanced sustainability, which includes reduced energy and raw material consumption along with sealing materials including valves causing low harm to the ozone in recent aerosol packaging. The industry has witnessed significant advancements in terms of application as well as production and filling methods. An overview of key innovations provided by Grand View Research (see Annex 5) shows that European Aerosol Industries are leading innovators.

With respect to ADD, economic operators have stated during the interviews and survey that it does not hamper innovation and as such their capacity to innovate. Limitations arise with respect to plastic aerosols in which some aerosol fillers have been investing R&D resources and are awaiting future actions taken by the European Commission.

International competitiveness: The ability to export aerosol products is a result of European manufacturers' cost and innovation competitiveness. Other conditions affecting growth as identified by Grand View Research in the section (3.3.4) on Aerosol market prospects point to both positive and negative factors for European Manufacturers with an ultimate forecasted reduction of the European market share in 2020 by 1.1%. The main upcoming and competing region being Asia Pacific raises concerns about the ability of European aerosols manufacturers to penetrate those markets. Moreover, increased competition within European domestic markets as Asia Pacific companies penetrate the European market in another aspect affecting the competitiveness of European aerosol manufacturers. An analysis of trade data allowing the mapping of international flows for aerosol products would have been particularly insightful on the subject but unfortunately such data are not available at the necessary level of granularity in existing product classifications.

With respect to ADD, interviewees have noted that they perceive ADD as having a positive impact on their internationalisation activities as it is globally viewed as a 'model' directive. No empirical evidence is however available to validate or rather investigate the scale at which such effect could be observed when aggregating export flows to non-EU countries.

Finally, another dimension of international competitiveness to account for relates to consumer needs. Consumers increasingly demand products that are packaged appropriately to reduce occurrences of leakage and spilling, along with ease of use. According to Grand View Research rising importance of e-commerce portals in Europe is expected to provide access to buyers looking for aerosol dispensers. Buyers are expected to have high bargaining power in light of increased availability of aerosol dispensers along with easy access of products. As a result, aerosol dispenser manufacturers are expected to offer discounts on their products which may reduce their profitability over the next years.

Costs of containers: The main cost components for the production of aerosols includes the raw material (consumption and price), the sealing materials and quality of seaming, coatings, gaskets, sealings, the pressure level, the size of the cans, the volume of production, the line speed and the aesthetic aspects. Moreover, for a full costing approach, packaging, transport, marketing, and design related costs must be accounted for (see Figure 19).

Figure 19 Cost components and influencers

	Main cost components	Cost influencors
Cans	• Material: Aluminium price per kg is sometimes 2 times the price of tin plate, prices for plastics can be less than tin plate, but also higher than for aluminium. • Pressure level: 10, 15, 18 bar (rating based on test pressures) and above requires more material or even different specifically designed materials (especially the case for aluminium). An important technical note is that it depends also whether the elevated pressure is only expected in unusual conditions (liquefied propellant filling) or ongoing (compressed gases, e.g. nitrogen). • Size of the can: it ranges between 50-1,000 ml. The majority range between 150-400 ml. • Decoration and coating: either on aluminium layer or on stannium. Also, coverage and thickness of the coating such as print, sleeve etc. • Aesthetic aspects: like shaping, embossing and other tactile decorations. • Sealing materials and quality of seaming (especially the case for tin plate). • Line speed i.e. required tools, maintenance and product changes • Order quantity	• Packaging • Transport • Marketing • Design and Construction
Valves	• Material consumption to make the cup • Coatings • Line speed (required tools and maintenance) • Sealings and gaskets • Other components	• Design and construction, determined by the components, primarily the material of the cup • Design and construction themselves have less impact considering standard valves, however tools[10] are recurring costs as well • Sizes of the valve (1 inch, 20 mm) • Different pressure levels might have an impact, primarily for pressures at 50°C > 12 bar • Packaging and Transport are minor costs • Marketing
Manufacturing Process	• Line speed • Filling speed, the bigger the can, the more concentrate,[11] the longer it takes • Gassing speed, the bigger the can, the more gas, the slower the absorption, the longer it takes also depending on valve construction (through the stem or alongside) • Size of the can (range of 50–1000ml) the majority range between 150–400ml • Tests to be conducted (test procedures like leakage tests require 100% of the cans to be tested) • Required tools, maintenance and product changes • Order quantity per variant	• Packaging • Transport • Marketing

According to expert opinion from our interviews with economic operators, using the aluminium can production cost as the basis for comparison, **tin plate is typically said to be 10%-15% cheaper than aluminium, while plastics, particularly of small volumes are more expensive than aluminium by 30%-50%** (see Figure 20 for cost components specifically for plastics). The latter estimates aim at mirroring the current typical aerosol supply, in terms of aerosols per product type i.e. aluminium

[10] For every shape of a product the right set of tools are needed. All these tools are subject to abrasion and changes.

[11] Concentrate is defined as the compound of liquids and solids that will be filled into the can

and plastic cans for luxury products and tin plate for more basic products. It is however very important to point out that tin plate cans can be as costly as aluminium (e.g. the case of labelling requirements, printing directly on the metal) and plastic cans as cheap as tin plate (e.g. the case of standard shaped plastic cans).

Figure 20 Plastic cans cost drivers – high end plastics

Plastic aerosols cost drivers for shaped plastics (beyond standard plastics cans)

More specifically on plastic aerosols the following cost drivers are identified for non-standard shaped plastic cans:

- High costs due to difficulties to shape plastic cans more attractively;
- R&D costs due to the need to find solutions for 1) permeation (for instance UV rays and 2) welding a plastic valve on top of the container;
- Higher environmental costs due to the difficulties in recycling plastic aerosols
- Lower material savings compared to aluminium and tin plate aerosol cans which can achieve a reduction in the material used of up to 30% and possibly more (e.g. Laserdome concept); and
- Multiple plastic layers.

To provide cost estimates by material we focus on the differences in costs between aluminium, tin plate and plastic cans due to differences in the price of raw materials and the manufacturing process. As such we put aside the variability due to the many other factors that influence total production cost such as volume, artwork, other aesthetic aspects etc. (see Figure 19 for the extended list of cost components that can influence the comparison of the costs across cans of different material). That said, note that the cost of raw material and production process are among the core cost drivers.

Cost of raw material: The differences in the prices of raw materials are substantial. Moreover, the prices of raw materials are highly unstable particularly in the recent years and can impact the aerosol manufacturers' profitability significantly. On average, however, the price of aluminium is $1,500 per ton while the price of tin plate is $800 per ton. Plastics suitable for aerosols tend to be high quality and hence the price for e.g. polyethylene ranges between 500-3,000$.

Cost of manufacturing process: The manufacturing process for mass production cans tends to be more costly for tin plate as most commonly three piece cans are produced. Note however that coil to can technology to make production as cheap as aluminium is available but not (yet) widely adopted due to outstanding technical issues subject to further improvements. Aluminium cans can be produced in one piece with neither bottom chime nor side seam which means that the cost of the production process of aluminium is lower than the production process cost of tin plate. These differences however considering mass production cans are not significant. Plastic cans production requires processes (blow moulding or extrusion) that are more complicated than aluminium and tin plate for more complex shapes. Standard shapes of plastic aerosol containers however can be as cheap to produce as tin plate containers (see Figure 20).

In light of the above, Figure 21 summarises estimates for the costs of the can, valve, manufacturing process and transport marketing. It includes a range independent of material (column "Range all aerosols") and an average range by material (columns

"Aluminium", "Tin plate", "Plastics") based on interviews with the industry and consultations with experts. The latter are estimates representing typical costs for mass production aerosols. Further explanations are included within the table and in the notes.

Figure 21 Cost ranges

Costs for:	**Range all aerosols** – per can (material independent)	**Aluminium** - typical	**Tin plate** - typical	**Plastics** - typical
Can	**0.1 – 1 €**	**0.15 €** for standard mass production aerosols (1) (2)	**0.12 €** for standard mass production aerosols (1) (2)	**0.12 €** for simple PET cans that can be as cheap as standard tin plate cans (1) (2); for purpose of shaped cans the average cost would be much higher **0.21 €** (2)
Valve	**0.03 - 0.1 €**	**0.03** for standard mass production aerosols; no notable differences across materials (4)		
Manufacturing process (3)	**0.05 – 1 €**	**0.2-0.25** for standard mass production aerosols - the differences between cans of different material are not significant (5)		Plastic cans need tools and filling lines like you have in the shampoo industry; Valve assembly machines are different from those for metal cans; Weldined valves may be used (not the case for aluminium or tin plate); Gassing stations are different than for metal cans (6)
Transport & Marketing	**… - 1 €** Costs can go beyond the typical 1€ per can due to e.g. advertising, regulatory interventions, consumer research and tests (e.g. a test of an aerosol product with 100 consumers can easily cost 10,000 € – 20,000 €). This cost is hence highly dependent on the product type and consumer segment it is meant for and is independent from the material.			

(1) Assumes a can of 150 ml, 12 bar, standard internal lacquer, order of 100,000 cans.
(2) Excludes artwork cost of on average 2,300 per design.
(3) Includes filling of the liquid phase, the propellant, other ingredients, assembling of valve and can, as well as the actuator. also referring to bag on valve systems, which require assembling of can and valve, pressurizing and sealing the outside chamber, filling of the bag, mounting of the actuator and the protective cap.
(4) The distinction is predominantly in the choice of the valve considering standard versus high end/ special valves.
(5) These estimates exclude the cost of the water bath for aluminium can manufacturers.
(6) This means that shifting from tin plate or aluminium to plastic aerosol cans is a costly affair as it implies investing in a new assembly line. Production volume and size of plastic containers are very important aspects in the decision-making process.

4. EVALUATION QUESTIONS

4.1. EVALUATION CRITERIA AND QUESTIONS

The evaluation assessed five main evaluation criteria, namely effectiveness, efficiency, relevance, coherence, and EU added value. Figure 22 provides an overview of the 12 overarching questions that were addressed during the evaluation.

Figure 22 Overview of evaluation criteria and questions

Criteria	Evaluation questions
Context	1. What was the **origin of ADD** and what were its main objectives? What progress has been made over time?
Relevance	2. To what extent do the initial **objectives** of ADD correspond to the current needs? How well adapted is ADD to **technological/scientific progress** and innovation that took place in the area of aerosol dispensers over time?
Effectiveness	6. Has the Aerosols Dispensers Directive been effective in achieving its **main objectives?** To what extent has ADD contributed to an effectively operating internal market for the products in its scope? To what extent has ADD contributed to the safety of the products in its scope?
	7. What **aspects, means, or actors** render ADD (or certain aspects of ADD) more or less effective?
	8. To what extent has the **procedure to adapt the Annex** of ADD to technical progress been effective?
	9. What **barriers** (if any) exist to the effective application of ADD?
	10. How are **different groups of stakeholders** affected by the Directive? What are the environmental, social, and economic impacts of ADD?
	11. Did ADD generate any **unexpected** or **unintended impacts** (positive or negative)?
Efficiency	4. What are the **costs associated with ADD** on different stakeholder groups (including Member States and economic operators)? Are there significant differences in costs or benefits between MS? If so, what causes these differences? What aspects of ADD are most or least efficient?
	5. Are the administrative and regulatory costs on the stakeholders **proportionate** to the results achieved? How do the costs borne by stakeholders compare to the benefits received?

Criteria	Evaluation questions
Coherence	12. To what extent are there **overlaps** or complementarities between ADD and any other EC or international legislation (e.g. in the area of transport)?
EU added value	3. What is the **added value** of ADD, compared to what could have been achieved at national level? To what extent do the issues addressed by the ADD continue to require action at EU level?

5. METHOD/PROCESS FOLLOWED

The methodology is summarised in the following sub-sections describing what has been done and when relevant highlighting any changes from the original plan and any mitigating measures taken. The ADD was subject to external and independent evaluation based on standard methodology following the requirements set out in the Better Regulation Guidelines[12].

5.1. STUDIES USED

In terms of the literature review, we analysed the documents and reports identified during the inception phase of the evaluation. This included the assessment of all relevant legislative instruments, reading through relevant literature studies and reports, and reviewing the various FEA guidelines. The results of this analysis fed into the evaluation questions. Annex 2 provides an overview of the main documents and data sources that were reviewed.

5.2. SOURCES OF INFORMATION/DATA

An overview of the different information/data and data collection sources that were used for the evaluation of the ADD are presented in Figure 23.

Figure 23 Overview of the data collection tools

Type of consultations	**Data collection source**	**Expected outcomes**	**Targets**	**Number of inputs**
Targeted consultation	In-depth interviews with stakeholders	Interviews with the key stakeholders	EU officials National/regional authorities Industry Consumer organisations	1 interview 21 interviews 29 interviews 1 interview
	Consultations with 'typical' companies	Consultations with the industries directly impacted by ADD/questionnaire designed to collect cost estimates	Typical companies per industry	10 consultations in total
	Targeted online survey	Industry survey	Industry	Responses to Industry survey (97 usable responses)
Public consultation	Public consultation survey	Public survey capturing the views of all interested parties	All stakeholders	Responses to Public consultation (139 in total)

[12] http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

Particular attention was paid to ensure participation of SMEs in the various data collection mechanisms. Unfortunately the response rate was very low. More details can be found in Annex 11.

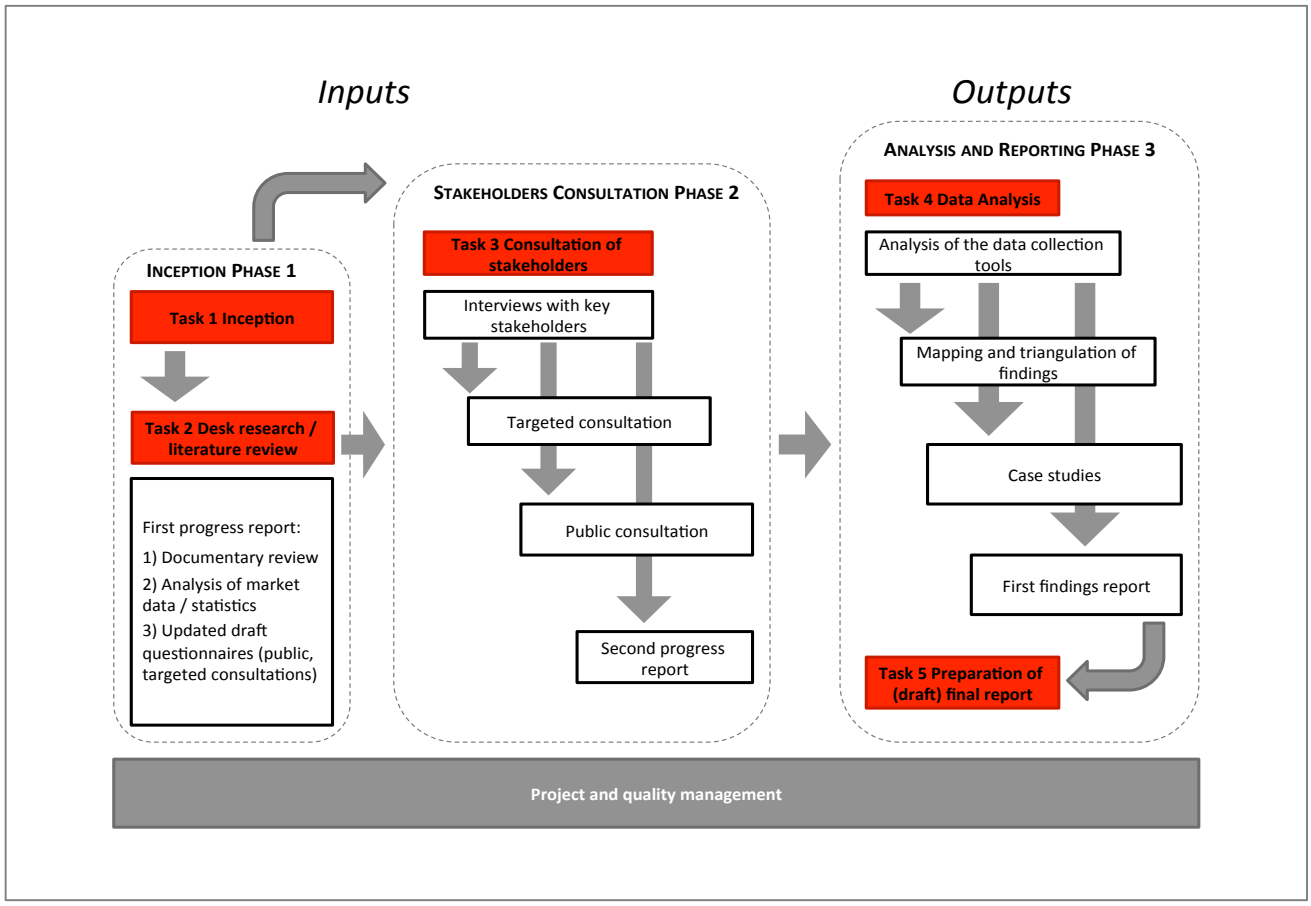
5.3. Steering group

The evaluation study was accompanied by a Steering Group comprised by representatives of the EC services, namely DG Internal Market, Industry and Entrepreneurship, DG Justice and the Secretariat General.

5.4. Overall approach

The evaluation approach aimed at gathering both qualitative and quantitative evidence from a number of complementary data sources, including European and national public authorities, industry associations, economic operators, and consumer organisations and consumers/citizens. An overview of the various tasks conducted as part of the evaluation is provided in Figure 24.

Figure 24 Overall approach and methodology to the evaluation



The tasks are described as follows:

- Task 1 Inception: familiarisation activities were carried out (kick-off meeting, Initial desk research, expert workshop, familiarisation interviews) to ensure that the evaluation team was familiarised with the subject of evaluation and based on that refined and updated the evaluation's methodological approach. This included the validation of the intervention logic, a revision of the evaluation grids, development of data collection tools and the drafting of the inception report.

- Task 2 Desk research / literature review: an extensive desk research exercise was carried out which aimed at analysing all existing relevant data and information related to the ADD. The desk research served as a key input to the evaluation of the Directive's effectiveness, efficiency, relevance, coherence, and EU added value.

- Task 3 Consultation of stakeholders: We performed a total of 52 in-depth interviews with key stakeholders (including European and national authorities, industry, and consumer organisations), in order to gather their views and opinions on the functioning of the Directive. We also launched a targeted online survey for economic operators to collect more qualitative information for the triangulation of findings and collect quantitative information from this key target group. We obtained 97 usable responses. Lastly, we organised a public consultation to offer a broad range of (potentially) interested stakeholders with a platform to voice their opinions on the Directive.

- Task 4 Data analysis: Once all evidence was collected, we employed various data analysis techniques to process and assess the data and information gathered through the various tools. The data analysis task included a qualitative analysis of the desk research, in-depth interviews, and open questions of the surveys and a quantitative (statistical) analysis of the survey responses and where relevant quantitative data available from the desk research. We also conducted an analysis of the costs related to the ADD based on the information collected from the focused consultations and benefits based on the information collected from the interviews. The benefits of ADD were thus captured in a qualitative manner. Upon completion of the data analysis, a mapping and triangulation of the findings from each of the data collection / analysis tools, was performed in order to further develop conclusions for each of the evaluation questions.
- Task 5 Presentation of results: Lastly, all findings and conclusions of the evaluation are written up in the final report. The findings and conclusions to the Commission services and relevant stakeholders will be presented during a final workshop.

5.5. STAKEHOLDERS CONSULTATION

The main objective of this task was to collect the requisite evidence and data through a process of consultations. More details can be found in Annex 11.

Targeted consultation: The targeted consultation consisted of three main data collection tools, namely in-depth interviews to gather qualitative information on the

performance of the Directive according to different groups of stakeholders, consultations with 'typical' companies per industry to collect absolute cost figures, an online survey to gather quantitative data on the views and opinions of economic operators in the industry. The sections below elaborate in more detail on the progress made in relation to each of those two data collection tools.

In-depth interviews with stakeholders: The interview programme provided for 52 interviews conducted involving the main relevant actors at EU, national and regional levels, as well as industry and SMEs representatives. The specific actors covered included all relevant Commission services, national (market surveillance) authorities, representatives from industry (including economic operators and industry associations), and consumer organisations (as shown in Figure 25).

Figure 25 Overview of in-depth interviews

EU officials	National/regional authorities	Industry	Consumer organisations	Total interviews
1	21	29	1	52

During the inception phase, we developed tailored interview guides for each of the three stakeholder groups; (1) one guide for industry, (2) one guide for national authorities, and (3) one guide for consumer organisations.

In addition to the interview guides, we also developed a list of potential interviewees. This list of contacts was based on information received from the European Commission, our thematic experts, and a few people we spoke to as part of the familiarisation interviews.

Consultations with 'typical' companies: Consultations with 'typical companies' per industry based on a questionnaire designed with industry experts were performed to provide cost estimates. A total of 10 consultations with the industries directly impacted by ADD were undertaken to construct company level cost estimates (Manufacturers of cans (3), Filling industry (7)). Note that none of the valve manufacturers agreed to be part of this exercise due to confidentiality concerns (expressed namely due to the small size of the sector in Europe). The information on costs for the valve industry is therefore based on the survey only. Note that by 'typical' companies we refer to company profiles per industry that represent to the extent possible the vast majority of companies in the industry. Elements accounted include: Number of sites in Europe and locations; Company average tonnage (tons per annum); Number of Employees (latest available year); Turnover (Thousand € per annum – average of last three years); Total Production Cost (Thousand € per annum – average of last three years); EBITDA – Earnings Before Interest, Taxes, Depreciation and Amortisation (not all were provided by all companies). The outcome of the company consultations were cost grids with company cost estimates. The tool to collect absolute cost figures was designed in the form of a questionnaire presented in Annex 7.

Targeted online survey: The industry survey was used alongside the interviews to act as a key data source for assessing the extent to which the Directive is "fit for purpose". The survey approach is described in more detail in the following subsections.

- Target population: The target population consisted of private sector enterprises in the aerosols supply chain, who are impacted by the Directive. This includes: Manufacturers of cans; Manufacturers of valves; Filling industry; Marketing/sales/distribution.
- Also, an extended number of products had been identified including a range of products in personal care, household but also automotive products, paints and varnishes, industrial and technical products, pharmaceutical and veterinary products and food products. Geographically, the survey was distributed to all EU Member States.
- Survey design: The survey questionnaire was divided in the following 6 sections: Presentation of company; Extent to which ADD achieved its main objectives; Procedures to adapt ADD to technological progress; Costs associated with ADD; Proportionality of costs associated with ADD; Relevance of ADD.
- Response rate: In order to ensure a high response rate, we designed a survey questionnaire that is simple (i.e. avoiding complex questions), limited suggestive arguments and left open spaces for respondents to express their views.
- Questionnaire Distribution: The industry survey questionnaire was distributed through European and National industry associations in all concerned sectors. the associations distributed the survey questionnaire themselves (online through a survey web-link). The European Commission also engaged the ADD Working Group by asking them to transmit to their respective national economic operators. The Enterprise Europe Network (EEN)[13] was also asked to disseminate the survey web-link. The Enterprise Europe Network helps businesses innovate and grow on an international scale. It is the world's largest support network for small and medium-sized enterprises (SMEs) with international ambitions.

Public online consultation: The public consultation was exclusively survey based. Overall, the objective of the public consultation was to capture the views of all interested parties including consumers and citizens. The inputs were used to inform the evaluation questions.

5.6 Costs and Benefits

An analysis of the costs and benefits, as part of the evaluation question related to the efficiency of the Directive was performed.

To perform the cost assessment, we performed a mapping of costs during the inception phase of the project with the help of technical experts. The mapping informed the questionnaires for the consultations with "typical" companies and the targeted online survey as described in the above paragraphs. Based on the in-depth interviews and online survey, we defined in as much detail as possible the type and degree of costs that are associated to the Directive.

A similar approach was followed for the benefits i.e. a detailed mapping of benefits which informed the questionnaire of the targeted online survey. Since quantified

[13] See: http://een.ec.europa.eu

assessments of the benefits were not possible with the available data, the assessment of benefits was performed in a qualitative way.

The exercise relied on the typology elaborated for the Better Regulation Toolbox (European Commission, 2015) by the Centre of European Policy Study in their report "Assessing the costs and benefits of regulation" (CEPS, 2013). Note, that not all cost and benefit categories were covered in this evaluation as they do not fall under the scope of the Directive (see Annex 12 for the mapping of costs and benefits).

The main methodological aspects emphasized for the analysis are described below (for more details see Annex 12):

Attribution to legislation: To calculate the cost of ADD, costs were attributed to ADD only. To do that interviewees/survey respondents provided answers accounting for ADD only and not for other related legislations in combination with ADD (e.g. Nominal Quantities Directive 2007/45/EC[14]; EC 1272/2008 repealing Council Directive 67/548/EEC, CLP). To avoid over-estimating costs the interview guidelines included auxiliary information for those cost categories where this issue was anticipated. In particular, we referred to difficulties attributing costs to ADD in the case of investments simultaneously addressing requirements of compliance to multiple legislations introduced/enforced in different moments in time. To remedy such occurrences, interviewees were asked to provide estimations of the percentage of total legislative costs dedicated to comply with ADD.

Business as Usual (BAU): The costs of BAU can be understood as the costs that a company would engage any way even in absence of regulation on the sole basis of its commitment to responsible care or social corporate responsibility. The approach followed was to assess per cost category by means of interviews whether in the absence of legislation the expenditures implied by the legislations would have been made. The BAU was hence based on statements by interviewees.

Time span: the period of the analysis for the evaluation was set as being 2005-2015. In order, however to get a full picture of the costs attributable to ADD the period had to be extended to cover the investments made before 2005.

The cost figures are provided in ranges of absolute values per plant or per line in order to provide as accurate and transparent information as possible. Information explaining the variability between the low and high end ranges together with a description by type of costs is provided in Annex 12.

[14] See: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0017:0020:en:PDF

5.7 LIMITATIONS – ROBUSTNESS OF FINDINGS

The limitations and corresponding mitigation actions undertaken are described in Figure 26.

Figure 26 Limitations and mitigation action

Limitations	**Mitigation action**
Involvement of stakeholders / obtaining precise data: Ensuring the direct involvement of stakeholders especially SMEs and obtaining precise quantitative data on the costs and benefits. Also, experience with previous surveys of enterprises and consumer organisations shows that there could have been a realistic risk of survey fatigue. For Member States, it is also important to note that the ADD is not treated as a high priority dossier in all Member States, even though considerable efforts have been made to raise interest in this topic.	During the stakeholder consultation, the study team worked closely together with European and National industry associations that systematically encouraged their members to respond to participate to the cost assessment exercise and the survey. By monitoring responses closely and target sectors/countries with very low responses timely we managed to ensure a satisfactory participation of the industry. For Member States, continuous efforts were made to get in touch with the Member States' representatives provided by the European Commission. Despite all the efforts made 9 out of 28 Member States did not participate to an interview.
Dealing with associations' positioning bias: The economic operators interviewed and surveyed subscribe to a large extent to the associations' positioning. This means that there is a risk of obtaining biased results from the surveys.	The specific actors covered in the consultation strategy included a sample that consisted of different economic operators and their professional associations. As such it is possible to assess how large the bias is and in which specific dimensions (and hence evaluation questions). Possible associations' bias can be addressed by a good understanding of their positioning and a critical assessment of the inputs obtained with the help of the European Commission and the study's sectoral experts. Moreover, according to estimations and the study team's sectoral experts the coverage in number of companies under associations is ca. 90%.
Disentangling the costs of ADD from the other acts: Disentangling the costs incurred by the ADD from the costs incurred by other (related) pieces of legislation. One important relevant piece of legislation is for example the CLP Regulation.	The evaluation only assessed the costs which are directly linked to the ADD. Possible costs stemming from the provisions of other directives were not taken into consideration by the present evaluation. When asking about costs of the ADD, the interviewers made sure stakeholders referred to costs directly related to ADD (through explicit reference within the questionnaire, during the interview and in the follow up discussions).
Establishing causality: Assessing/establishing the causality between the ADD on the one hand, and the internal market and safety of products on the other hand. The main reason for this is that in both cases there are a large number of external factors that influence the internal market and product safety. These external factors are beyond the reach of the Directive. Moreover, the data available is limited (there is no database on the number of accidents caused by ADD, no specific indicators for the functioning of the internal market, etc.).	To the extent possible, the evaluation prompted interviewees and survey respondents to be as specific as possible in relation to the benefits of the ADD and the context in which they take place. Nevertheless, it needs to be acknowledged that it has not been possible for the evaluation to identify concrete causal relations between the ADD and the internal market or product safety beyond what has been obtained from the opinions of the stakeholders.

Limitations	Mitigation action
Lack or limited data provided by companies on the costs imposed by ADD: We anticipated that the main reasons for the lack or limited data could have been: 1) workload implied; 2) lack of trust; 3) lack of engagement, among others.	Consultations with typical companies (10 in total) was made exclusively on cost data to limit the time companies dedicated to this exercise (particularly important for SMEs). Confidentiality agreements were signed between Technopolis and some of those companies willing to share cost figures. The number of companies participating to this exercise though less than originally planned provided good quality data and were considered sufficient to run the analysis.Moreover, the study team extended the questionnaire to 1) cover a longer period (from 1975) and 2) inquire the costs for a single new line. This adaptation to the original plan was done in order obtain a better understanding of the costs of the ADD.
Reliability of cost data: We anticipated bias to result from the sample (FEA's recommended selection on the 10 companies/ type of companies willing to participate to the study).	The companies providing cost data did not appear to follow one single line of thought which has thus been assessed as non-problematic with respect to the robustness of the data. The 2-3 follow up discussions allowed the study team to gain a good understanding behind the figures provided by the companies by encouraging in certain instances companies to reconsider some estimations during the course of the cost assessment in order to guarantee comparability across companies.
Quantification of Benefits	The analysis of benefits was limited to the survey questions on benefits and interviews. A quantification of benefits was not possible due to the absence of data on accidents and trade data (imports/exports)
Defining and quantifying the baseline (Costs)	The approach followed was to assess per cost category by means of interviews whether in the absence of legislation the expenditures implied by the legislations would have been made. This was done during the follow up discussions with the companies i.e. after completing the cost assessment grid.
Survey 'representativeness': the distribution of the survey to members of industry associations was expected to potentially introduce a certain bias in the sample. For instance, if members of the associations tended to be larger companies, then this could have led to under-representation of the smallest businesses.	The study team assessed that industry associations were the best way to elicit the maximum number of industry responses. By closely monitoring responses we have obtained a sample that represents both large and small companies. Moreover, according to the technical experts, the great majority of companies are organised in associations.
Reliance on the views and opinions of stakeholders: Given the lack of secondary sources informing the evaluation criteria.	To increase the robustness of the findings interviews were conducted with selected economic operators and associations, coupled with the responses from the survey of 97 responses. Triangulation of inputs (views and opinions) was thus performed. For National Authorities quality of inputs was assessed through the profiles of the

Limitations	Mitigation action
	interviewees (i.e. their knowledge of ADD) - the contacts were provided directly by the European Commission.
Evaluation of a Directive (rather than a Regulation) and as a result the various transposition processes in Member States etc.	It should be noted that the nature of a Directive (rather than e.g. a Regulation) means that the effectiveness and efficiency of the evaluation subject depends to some extent on the way in which it is transposed in national legislation. The interviews with National Authorities help to collect information with respect to the transposition of ADD in national laws and hence investigate the compliance to the ADD. Conclusions are thus drawn with the country variability accounted for.
Data availability: this is particularly the case for business demography data, accidents and trade data (i.e. exports and imports with the required level of granularity allowing the identification of aerosol products)	Questions regarding safety and the internal market were asked in the survey and interviews. Data on business demography namely company counts and size were constructed by creating a database with both FEA and Grand View Research data and by complementing through desk research the database with information on companies' size.

Overall, the reliability and robustness of the data/approach taken is assessed as satisfactory given the good response rates of the targeted online survey, the good quality inputs and engagement of the companies contributing to the cost assessment and the numbers of interviews conducted with national authorities and economic operators.

6. STATE OF PLAY OF THE IMPLEMENTATION (RESULTS)

6.1. IMPLEMENTATION

At national level, the rules and requirements of the Directive were directly transposed into national legislation. None of them maintained additional rules or requirements related to aspects that are regulated by the ADD. The evaluation found no evidence of any situations in which an aerosol dispenser was refused, prohibited, or restricted from the market despite compliance with the ADD. The Directive appears highly successful in harmonising rules and requirements in EU Member States, and thus facilitating the free movement of aerosol products across the Union.

The evaluation showed that there have not been any barriers in the effective transposition of the ADD into national legislation. There have also been very few (potential) barriers to the application of the Directive in practice. The first issue related to the alternatives to the hot water bath test. The criteria and conditions for these tests were established at national level, which may lead to differences in application. For example, in Germany there is an additional obligation for the alternative test with a requirement to use an additional statistical test in a hot-water bath test with 1 out of 2,000 units. The second potential barrier concerned the derogations between the Nominal Quantities Directive and the ADD. However, this issue was clarified by the European Commission in November 2010.

6.2. STATE OF PLAY

The evidence of this evaluation suggests that a large number of Member State had very few controls and checks on aerosol dispensers in their country. ADD is not treated as a high priority dossier in all Member States because some countries have very little aerosol industries or consider that there are no major safety concerns in the vast number of products and goods.

The aerosol industry has a good safety record. In fact, neither in RAPEX nor elsewhere there has been an incident reported that could be rooted back to bad requirements of aerosol dispensers within the scope of ADD. In all cases the incidents were due to abuse or accidents. Since incidents where aerosols are involved are tracked by national aerosol associations and covered by newspaper-, radio and television reports, including internet, we can assume that the available data is reliable.

While the ADD had a positive influence on the safety of aerosol dispensers, it should be noted that not all incidents are officially reported. Based on the interviews, approximately half of the national authorities did not keep any records of the number and type of consumer complaints and incidents with aerosol dispensers. The other half of national authorities that did keep some records of consumer complaints and incidents, but they did so in quite different way.

6.3. UNEXPECTED RESULTS

The only unexpected impact that was identified by the evaluation is the fact that the rules and requirements of the Directive are used and acknowledged by non-EU countries, such as Brazil, China and India. The global acknowledgement of the rules and requirements have led to even more harmonisation and this benefits for economic operators than it had been anticipated. Two important exceptions to this are the United States and Canada, which both maintain their own standards.

The 220-ml limit for plastic aerosols was also mentioned by a few stakeholders as an unexpected effect. In fact, this limit was imposed on purpose due to the lack of experience with plastics and a potential amendment on this topic is currently being investigated.

7. ANSWERS TO THE EVALUATION QUESTIONS

7.1. CONTEXT

7.1.1. What was the origin of ADD and what were its main objectives? What progress has been made over time? (Evaluation Question 1)

This first evaluation question is intended to establish the general context and background to the evaluation. It requires a description of the main origin and objectives of the Aerosol Dispensers Directive (75/324/EC), as well as the progress that has been made in relation to the Directive over time (in particular any revisions that were made to the Directive between its establishment in 1975 and now).

7.1.1.1. Definition of aerosol dispensers

Before elaborating on the main origin and rationale for the ADD, it is important to delineate the products that are subject to the Directive. **Article 2** of Directive 75/324/EC on the approximation of the laws of the Member States relating to aerosol dispensers defined 'aerosol dispensers' as follows:

"any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

The application of the Directive is limited to aerosol dispensers made of metal, glass, or plastic. However, the ADD does not apply to aerosol dispensers that have a maximum capacity of less than 50 ml or with a maximum capacity greater than:

- For metal aerosol dispensers, the total capacity of the container may not exceed 1000 ml;
- For glass aerosol dispensers that have plastic coated or permanently protected containers, the total capacity of the container may not exceed 220 ml (the same applies to plastic containers that do not splinter when burst); and
- For glass aerosol dispensers that have unprotected containers, the total capacity of the container may not exceed 150 ml (the same applies to plastic containers that can splinter when burst).

7.1.1.2. Main origin and rationale for establishing ADD

The ADD is one of the oldest EU legislations related to product safety. Traditionally, Member States already had regulations in place before 1975 to reduce the safety hazards or dangers related to aerosol dispenser products to consumers. The ADD harmonised certain technical specifications at EU level. These technical specifications related to the manufacturing, filling, and nominal capacities of aerosol dispensers.

The ADD includes specific requirements related to flammability and pressure hazard. It also contains a general obligation to analyse all hazards that could apply to particular

aerosol products. Based on such analysis, aerosol dispensers have to be designed, constructed, and tested accordingly to meet the appropriate safety requirements concerning its use.

By doing so, the ADD aims to achieve the following two overarching objectives:

- **Objective 1:** To guarantee that products within the scope of the Directive will be safe for consumers and other users in respect of hazards related to pressure and where appropriate, flammability and inhalation.

- **Objective 2:** To secure the free movement of aerosol dispensers throughout the EU. As such, Member States must allow the marketing of aerosol dispensers that comply with ADD on their territory.

7.1.1.3. Technical amendments to ADD and progress made over time

The ADD is a so-called 'old-approach' Directive, which means that it includes detailed technical requirements regarding a range of issues. While it should be recognised that this type of legislation has advantages as well as disadvantages, one clear disadvantage is the need to adapt the Directive in line with technical progress (with the risk of hampering innovation). Any modification of the Articles requires a legislative process to be initiated by the European Commission (by way of a legislative proposal), followed up and approved by the co-legislators the Council (the governments of the 28 EU Member States) and the European Parliament. In practice, this never happened in relation to ADD. Instead, in order to avoid the long procedure to amend the Directive, references were included to other relevant pieces of legislation (for example in relation to CLP Regulation, as discussed in more detail below).

From its creation in 1975 onwards, the ADD was developed based on the understanding that the technical specifications listed in the Annex of the Directive would need to be adapted over time in line with the technical progress made in the area of aerosol dispensers.

Articles 5, 6, and 7 of the Directive laid down the procedure to facilitate the necessary adaptations to the Directive. This procedure was based on the close cooperation between the Member States and Commission in the form of a **"Committee on the Adaptation to Technical Progress"** of the Directive on Aerosol Dispensers. In line with these articles, the procedure was designed to allow necessary adaptation measures to amend 'non-essential' elements of the Directive.

There has not been a full revision of the Directive since its establishment in 1975. However, the Directive has been amended a number of times, namely in 1994, 2008, and 2013. These adaptations were all in line with the technical adaptation procedure of the Directive. The amendments aimed to accommodate technological changes or to ensure coherence with other pieces of EU legislation. In addition to these amendments, there has been more recently the Commission Directive EU 2016/2037 introducing further changes to the ADD.

On two occasions an amendment to the Directive followed directly from the fact that one of the Member States had applied the **'safeguard clause'** (Article 10 of the ADD), which allows Member States to prohibit aerosol dispensers that prove to represent a safety or health hazard, despite compliance with the Directive. Both times, the application of this safety clause by Member States led to an amendment to the definition of "flammable contents" (in 1994 and 2008).

Figure 27 summarises the main technical amendments that were made to the ADD in 1994. The changes were made by amending Directive 94/1/EC. This amending Directive entered into force in January 1994. Its provisions became applicable from April 1995 onwards.

Figure 27 Technical amendments made by amending Directive 94/1/EC

Technical amendment on the definition of flammable contents:

The first technical adaptation to the Directive took place in 1994 and was made by the Commission Directive 94/1/EC of 6 January 1994. The amendment was introduced after it was found that the provisions that were in force were not sufficient to prevent certain aerosol dispensers from constituting a safety hazard. Among others, this argument was based on findings that there was an increased use of extremely flammable propellants in aerosol dispensers (substitutes for chlorofluorocarbons, known also as CFCs). This led to a change in the definition of "flammable contents" (point 1.8 of the Annex to the ADD).[15]

Technical amendment on the derogation from labelling requirements:

A second technical amendment in 1994 related to the finding that some aerosol dispensers, while containing flammable substances and/or preparations, did not present any risk of ignition. Therefore, the amending Directive introduced a derogation from the labelling requirements (i.e. the hazard and precautionary statements that were laid down in points 2.2 and 2.3 of the Annex to the ADD) if the person responsible for the marketing of the respective aerosol dispensers had test results that showed that the flammable contents did not represent a risk of ignition under normal or reasonable foreseeable conditions of use. In order to use this derogation, the person would have to provide this documentation to its respective Member States. He/she would also have to label the quantity of the flammable material contained in the aerosol dispenser.[16]

Figure 28 summarises the main technical amendments that were made to the ADD in 2008. The changes were made by amending Directive 2008/47/EC. This amending Directive entered into force in April 2008. It provisions became applicable from April 2010 onwards.

Figure 28 Technical amendments made by amending Directive 2008/47/EC

Technical amendment on hazard analysis:

Amending Directive 2008/47/EC introduced the requirement on the person responsible for the marketing of aerosol dispensers to carry out a hazard analysis, including an assessment of the effects that the aerosols may have on health (i.e. inhalation of the spray under normal and reasonable foreseeable conditions of use). Based on this hazard analysis, the amending Directive also required this person to design, construct, and test special statements concerning the use of the aerosol dispenser. This requirement was inserted after point 2 in the General Provisions of the ADD.[17]

Technical amendment on the definition of flammable contents:

The second important amendment to the Directive in 2008 was related to the definition of 'flammable contents', which was – despite the amendment of this point in 1994 – found not to be sufficient to

15 Source: Amending Directive 94/1/EC of 6 January 1994 adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0001&qid=1493048194045&from=EN

16 Source: Amending Directive 94/1/EC of 6 January 1994 adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0001&qid=1493048194045&from=EN

17 Source: Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0047.

guarantee a high level of safety in all cases. More specifically, some contents were not defined as flammable according to the criteria listed in Annex VI to Council Directive 67/548/EEC, while they may lead to ignition under normal or reasonable foreseeable conditions of the use of the aerosol dispensers. Moreover, it was found that the existing criteria for flammability only addressed chemical substances and did not take sufficiently into account the physical conditions of an aerosol spray or specific conditions of use. As a consequence, the amendment introduced new criteria for the classification of the flammability of aerosol dispensers.[18]

Technical amendment on the alternative test methods:

A third amendment that was introduced in 2008 related to the alternative test methods to the hot water bath test. In order to use such alternative tests, there was a procedure that required a dedicated Committee to approve such alternative tests. Given that this procedure was considered very heavy and was therefore rarely used in practice, amending Directive 2008/47/EC introduced a lighter procedure for the alternative tests. It laid down that alternative test methods would no longer have to be approved by the Committee, but by the relevant competent authorities designated by Member States (under Council Directive 94/55/EC).[19]

Technical amendment on the maximum allowable pressure: A fourth amendment that was adopted in 2008 related to the maximum internal pressure of aerosol dispensers. It was argued that the use of compressed gases as propellants should be encouraged by increasing the maximum internal pressure of aerosol dispensers to the extent that it is safe for consumers. Therefore, amending Directive 2008/47/EC increased the maximum allowable pressure from 12 to 13.2 bar.[20]

Technical amendment on the maximum filling level: The last amendment introduced by amending Directive 2008/47/EC in 2008 related to the maximum filling level of aerosol dispensers. The amendment required that the volume of the liquid phase of all relevant types of aerosol dispensers at 50°C should not exceed 90% of the net capacity of the aerosol dispenser. This amendment was invoked due to safety concerns in relation to the burst and leak of metal aerosol dispensers heated to high temperatures.[21]

Figure 29 summarises the main technical amendments that were made to the ADD in 2013. The changes were made by amending Directive 2013/10/EU. This amending Directive entered into force in April 2013. A transitional period was adopted so as to allow economic operators sufficient time to comply with the amendments. Aerosols containing a single substance e.g. lighter refills and air dusters needed to comply by June 2014. Aerosols containing mixtures need to comply by June 2015. Aerosols marked in accordance with the previous labelling regime and placed on the market before 1 June 2015 did not need to be re-labelled until 1 June 2017.

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18 Source: Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0047.

19 Source: Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0047.

20 Source: Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0047.

21 Source: Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0047.

Figure 29 Technical amendments made by amending Directive 2013/10/EU

Technical amendment on labelling requirements:

The latest amendment in 2013 served to ensure coherence with other EU legislation. Amending Directive 2013/10/EU was invoked by the adoption on Regulation (EC) No 1272/2008 on the classification, labelling, and packaging of substances and mixtures (CLP Regulation). This regulation amended the existing labelling requirements at the time. The ADD included references to these labelling requirements (namely labelling provisions to inform consumers of the hazards in relation to using and storing aerosol dispensers) and thus needed to be aligned with the new Regulation. The changes were made to point 2.2. of the Annex to the ADD.[22]

Most recently, a Commission Directive was published in 2016 to increase the **maximum allowable internal pressure of aerosol dispensers from 13.2 to 15 bar** at 50°C when non-flammable propellants are used. As mentioned previously, in 2008 the maximum allowable pressure for aerosols was already increased from 12 to 13.2 bar at 50°C by amending Directive 2008/47/EC. This was at the time the maximum allowable pressure for which safety could be guaranteed according to the public authorities.

The most recent Directive, however, stated that the current maximum pressure limits the use of non-flammable propellants for some categories of aerosol dispensers. Given that progress and innovation was made over time to further increase the maximum allowable internal pressure for non-flammable aerosol dispensers (which remedied the situation where a drop in the internal pressure during the use of the aerosol dispenser resulted in a deterioration of its performance), it was decided to allow a further increase of the maximum allowable internal pressure to 15 bar.

In other words, the Directive allows to increase the maximum pressure in aerosol containers, thereby improving the performance of the products while at the same time guaranteeing the safety of these products to consumers. Moreover, by increasing the maximum pressure of aerosol dispensers, the draft Directive aims to encourage the industry to change from flammable towards non-flammable propellants, which are more environmental-friendly. Lastly, the increase in the pressure will help to widen the choice for manufacturers as well as consumers. The Commission Directive also intends to **adapt the labelling provisions** of the ADD by referring directly to the corresponding provisions in the Regulation (EC) No 1272/2008 (CLP Regulation). These intended changes would not result in any substantial changes to the content of the definitions of "non-flammable", "flammable", and "extremely flammable".[23] The changes were introduced into the amending Directive 2016/2037 published in

[22] Source: Commission Directive 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Government Response Document to the Department for BIS – UK. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/397791/bis-15-30-european-internal-market-government-response-on-updating-the-labelling-requirements-in-the-aerosol-dispensers-regulations-2009.pdf.

[23] See: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L2037&from=EN

November 2016 (OJ EU L 314/11 of 22/11/2016). Figure 30 summarises the technical amendments that were introduced to the ADD in 2016.

Figure 30 Technical amendments made by Commission Directive (EU) 2016/2037

Technical amendment on maximum allowable pressure and labelling provisions:

The amendment introduced by Commission Directive (EU) 2016/2037 in 2016 related to the maximum allowable pressure of aerosol dispensers and labelling provisions on classification, labelling and packaging of substances and mixtures. The latest adaptation to technical progress allows the increase in pressure to 15 bar for dispensers with non-flammable propellants and adapts its labelling provisions to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Member States shall adopt the laws, regulations and administrative provisions no later than 12 December 2017 and apply the respective provisions from 12 February 2018 onwards.[24]

Another issue that has been under discussion for several years already relates to the definition of the tests and criteria for **plastic aerosol dispensers above 220ml capacity**. Given that plastic has several advantages over other materials (for certain applications it might be cheaper than metal, can be shaped more attractively, and is better corrosion resistant), there has been a request from the European Aerosol Federation (FEA) to permit larger plastic aerosol sizes (up to 1000 ml) under the Directive. This would open opportunities to aerosol manufacturers. While this topic was initially dealt with in the same legislative process with the increase of the internal pressure from 13.2 to 15 bar, the Commission decided to separate the legislative processes so as to collect more evidence on the safe use of plastic material for the containers.

Following this long-standing debate, FEA launched a project called the "Plastic Aerosol Independent Review" (PAIR). This project is a study funded by FEA, executed by an independent third party and supported by a steering group with representative of the European Commission services, volunteering Member States and FEA itself. It aimed at evaluating the available industry data on plastic aerosols, and providing independent expertise in reviewing the FEA proposals on this topic.[25] The PAIR project was completed in June 2016 and the final report was made available on the Interest Group related to the ADD on the CIRCABC[26] platform. The report provided a detailed analysis of the technical aspects and summarised the available test results collected from a group of data providers. Following this study, FEA reconfirmed its request to permit plastic aerosol sizes (up to 800 ml) without changing the current maximum pressure limits. At the moment of drafting this evaluation study, no final decision has been taken and a discussion with the representatives of Member States in the Committee on the adaptation to technical progress of the ADD[27] will be organised.

[24] Source: Commission Directive 2016, amending Council Directive 75/324/EEC as regards the maximum allowable pressure of aerosol dispensers and to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling, and packaging of substances and mixtures. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:314:FULL&from=EN

[25] Source: FEA Annual report 2015.
Weblink: http://www.aerosol.org/uploads/Modules/Publications/fea_annrep2015.pdf

[26] Communication and Information Resource Centre for Administrations, Businesses and Citizens

[27] See article 6 of ADD.

7.1.1.4. Progress made over time by the aerosols industry

In addition to the technical amendments that were made to the ADD, there have also been **developments at industry level through the European Aerosol Federation** (FEA). FEA is the European association for the aerosol industry. In order to help its members to fulfil the obligations imposed by the ADD (and other relevant legislation in the field of aerosols), FEA developed standards and guidance that are available for its members as well as non-members. These standards and guidance provide a standardisation of the dimensions, terminology, and methodology, so as to foster a uniform and safe production, storage and use of aerosols.

More detailed information is presented in Annex 4.

There is a general perception among the consulted stakeholders that the ADD is a specific and unique piece of legislation, setting out common standards in the field of aerosol dispenser products across the EU. It was also mentioned the Directive is **recognised internationally** as a good practice. Although the interviewees pointed that some non-EU markets accept the ADD compliant products or even have sought to introduce the same approach in their own legislations, it was added that this is not the case in all regions of the world. This opinion refers to countries which do not recognise the same level of safety standards as the EU Member States and other countries where the legislation differs from the EU legislation.

The ADD differs in particular from the mandatory legal requirements in the US and Canada. Further differences can be found in other regions, e.g. Japan, Korea, Israel and Argentina. There are also regions in the world which accept the ADD compliant aerosol dispensers (and US standard) like Brazil, China and India.

The main differences between the US/Canada and the EU legislation are outlined below:

- The Test pressure requirement in ADD is stricter than in US DOT[28] and Canada.
- Additionally, minimum wall thickness (see figure above) is required
- Labelling of weight is mandatory, not volume.

In the US and Canada there are several classifications for aerosol packs, based on the filling pressure. These are called Non-classified (2N), 2P and 2Q. For further information see the overview concerning global classifications worldwide compiled by the Ball Corporation.

[28] US DOT (Department of Trade) rules concerning transport legislation.

AEROSOL CONTAINER PRESSURE REQUIREMENTS
PRODUCT/CAN BUCKLE/CAN BURST/THICKNESS

COUNTRY	RATING	PRODUCT MAX PRESS		CAN MIN PERFORMANCE		MIN. PLATE THICKNESS	MARKING
		@ TEMP °C/F	PRESS. bar/psig	BUCKLE bar/psig	BURST bar/psig	mm/inches	
USA & CANADA	Non	54.4/130	9.66/140	9.66/140	14.48/210	NR	None
	DOT 2P		11.03/160	11.03/160	16.55/240	0.18/0.007	DOT-2P + MFG[5]
	DOT 2Q		12.41/180	12.41/180	18.62/270	0.20/0.008	DOT-2Q + MFG[5]
	Max Press.		12.41/180				Exemption Cans Available
Europe	Min Can	50/122	6.7/97	10.0/145	12.0/174	NR	Epsilon to be required in new legislation – some countries already mandate (e.g. France)
	"12 Bar"		8.0/116	12.0/174	14.4/209	NR	
	"15 Bar"		10.0/145	15.0/218	18.0/261	NR	
	"18 Bar"		12.0/174	18.0/261	21.6/313	NR	
	Max Press		12.0/174	See "18 bar"	See "18 bar"	NR	
Australia	Min Can	50/122	6.7/97	10.0/145	12.0/174	NR	NR
	Other (12/15/18 bar)		P= pressure	1.5xP	1.8xP	NR	
	Max Press[4]		12.0/174	See "18 bar"	See "18 bar"	NR	
Japan	None	37/98	7.86/114	12.8/185	14.7/213	NR	NR
		50/122	P= pressure	1.5xP	1.8xP	NR	NR
Argentina	Standard	Unknown		10/145	15/219	NR	Unknown
	2P			11.4/163	17.2/245	NR	Unknown
	2Q			12.8/185	19.4/281	NR	Unknown
Korea	None	Unknown		12.8/185	14.7/213	0.22/0.0085	NR

Notes:

1. Europe ratings are convention, not law. Their law is based on pressure at 50/122 and the can minimum buckle is 1.5 times this pressure and minimum burst is 1.8 times this pressure.
2. Japan pressure listed is maximum allowable. For can performance can use the second line but product pressure cannot exceed 7.86/114 at 37/98.
3. No one seems to know if there is a Korean product pressure or temperature.
4. Australia also has an additional "non-flammable compressed gas" regulation which also 50°C maximum product pressure of 15 bar requiring a 22.5 bar can. Their comment probably will never be used. Australia is adopting the European 12/15/18 bar grouping but confirm that you can make and use a 13 bar can for a "13 bar product" (product with equilibrium pressure of 8.7 bar).
5. Manufacturer's symbol or number must be registered with the U.S. DOT. Ball Aerosol's registration number is M5702.

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Pressure classifications 2N,2P and 2 Q do not match with the ADD e.g. 2Q cans may not buckle up to 180 psig (12.4 bar) and may not burst up to 270 psig (18.6 bar) – in fact a can that matches ADD requirements would easily fulfil these requirements, but not vice versa. Plastic cans are allowed in similar ways as metal cans (e.g. 2S pressure rating similar to 2P) brim-full volume is exactly the same as for metal cans.

Other countries require sometimes specific tests and labelling of weight. For example, Argentina has different flammability classification especially the ignition test is different from ADD and CLP. While Israel requires corrosion tests, especially concerning the seam coating of tin plate cans, Korea and Japan have different test pressures. Comparatively, the transport requirements are very similar, primarily due to harmonisation with global transport rules (e.g. ADR). The ADD compliance is also accepted in China, India and Brazil.

From the competitiveness point of view promoting the **alignment** between the European legislation and other countries could be interesting, however, it is not considered to be a specific policy priority. In the past, FEA has tried to involve the Commission to actively promote the European legislation in ASEAN[29] countries but there was no follow-up on that.

[29] See: Association of Southeast Asian Nations, http://asean.org

7.1.1.5. Conclusion

In conclusion, the ADD is one of the oldest EU legislations related to product safety. Its two main objectives are to guarantee the safety of products within the scope of the directive and secure the free movement of aerosol dispensers across the EU Member States. Although the Directive has not been subject to a full revision since its adoption in 1975, it has been amended a number of times, namely in 1994, 2008, 2013 and more recently in 2016. The modifications were of technical nature to accommodate technological developments or to ensure coherence with other legislation (e.g. those related to the labelling requirements derived from the CLP Regulation). Overall, the industry representatives follow evolutions at the technical level, in order to ensure that the requirements set out in the Directive are up-to-date and reflect developments in relation to the science and technology. In the light that there is no global harmonisation in aerosol legislation, the evaluation of the ADD puts also a spotlight on the fact that from the competitiveness point of view it could be interesting to promote the alignment between the European legislation and other countries.

7.2. RELEVANCE

7.2.1. To what extent do the initial objectives of ADD correspond to the current needs? How well adapted is ADD to technological/scientific progress and innovation that took place in the area of aerosol dispensers over time? (Evaluation Question 2)

This evaluation question is about the extent to which the initial objectives of ADD (still) correspond to the current needs and problems in the field. The answer to this evaluation question also assesses the extent to which the ADD is still relevant in the light of technological progress. Third, the answer to this question assesses whether the ADD is adequate in fostering / supporting innovation.

7.2.1.1. Extent to which the objectives are still relevant to the needs in the field

The ADD has a dual objective. On the one hand, it aims to guarantee the safety of aerosol dispenses for consumers and other users in respect of hazards related to pressure, flammability, and inhalation. On the other hand, it intends to support the EU internal market by ensuring the free movement of aerosol dispensers throughout the EU.

Overall, the findings from this evaluation suggest that these two key objectives of the Directive are still relevant today. The consultations carried out in the framework of this evaluation with the representatives of public authorities and economic operators confirmed that both the objectives correspond to the needs of consumers and economic operators in the field.

In respect to **consumer safety**, the consulted stakeholders unanimously felt that – given that most of the aerosol dispenser products will operated by a large number of users and the potential risk to aerosol dispensers – it is of utmost importance that the Directive guarantees the safety of these products.

With regard to the **internal market,** stakeholders (including economic operators) argued that it is important for those who want to market their products on the EU market, that their products are recognised by other Member States. Moreover, they argued that it is in their favour as well to be able to communicate to consumers that their products adhere to common European standards. This helps them to market their products across the Union.

When asked about whether there was a need of adapt the ADD's objectives or to widen the Directive's scope, most consulted stakeholders felt that the Directive was still in line with the needs in the field, and thus no change was required. However, one interviewee explained that the **'environmental aspect'** to aerosol dispensers had become more important over time, since nowadays it is possible to produce smaller cans and thus to reduce waste. He/she argued that it might be worth to consider whether the environmental aspect could be added to the scope of the Directive in the future. In his/her remark though, the interviewee clearly indicated that this was not to say that the current environmental legislation is not appropriate, but rather that it might be worth investigating.

In this context, it is important to note that environmental aspects concerning the packaging and waste are regulated by the respective directives, e.g.:

- Directive 94/62/EC and 2004/12/EC (on packaging and packaging waste);
- Directive 2007/45/EC (on nominal quantities); and
- Directive 76/211/EEC[30] of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products" further in this report referred to as the "weights and volumes directive 76/211/EEC".

Other relevant pieces of legislation include Regulation (EU) No 517/2014 on fluorinated greenhouse gases, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and Directive 2004/42/EC – Paints Directive) on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products.

Given the fact that this remark was only made by one interviewee and the lack of evidence for added value of integrating the environmental aspects into ADD, it can be concluded that suggestion does not affect the overall conclusion that the objectives of the Directive do not require any change.

7.2.1.2. Relevance of ADD in the light of technological progress

The evidence collected as part of this evaluation shows that there has been a number of **scientific and technological developments** in the field of aerosol dispensers. This include the following:

- Development of new materials (e.g. new alloys allowing to reduce the wall thickness using less raw material, plastic aerosols/PET plastic aerosol technology);

- Alternative propellants, liquefiable but non-flammable and compatible with plastic aerosols;

- New ecological propellants (change from liquefied to compressed gases, considered to be the most important technical evolution for the packaging producers);

- A range of new products based on innovative technologies, in addition to higher control capacity over the production process (e.g. aerosol dispensing textile like protection);

- Material optimisation, shaped and embossed cans;

- Development of new valves and new dispensing systems (relatively more products on the market with a bag on valve);

- Internal coating of cans;

[30] See: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31976L0211

- Development of new leak detectors (X-ray, laser) providing higher accuracy; and

- Increasing the pressure resistance of cans up to 15 bar at same material consumption as today, which might be enabled e.g. by laser dome technology.

The aerosol industry is a conservative market that is characterised by a high degree of cyclicality, meaning that the demand for certain category of products is constantly changing. Economic operators noted there is a lot of interest in the cosmetics, medical and food aerosol new applications. Nonetheless, from the product point of view not many changes can be expected in the future. According to the interviewees, the content of aerosols might change overtime which is driven by the demand for more environmental friendly products.

As explained in more detail in Section 7.1, there have been several amendments to the Directive to ensure that it stayed up to date with these technological and other developments in the field. These amendments were aimed at ensuring coherence with the regulation related to Classification, Labelling and Packaging of substances and mixtures (CLP) and increasing the maximum pressure to 15 bar (in cases of non-flammable propellants).

Overall, based on the evidence collected and the stakeholders consulted as part of this evaluation, it can be confirmed that the ADD is up-to-date and in line with the technological progress that has been made over time, the majority of the stakeholders felt that the various amendments to the Directive ensured that technological developments in the field were taken into account. None of the interviewees identified any provisions or articles in the Directive that were outdated or no longer relevant.

7.2.1.3. Appropriateness of ADD in fostering innovation

There was a general consensus that ADD does not directly stimulate innovation but offers a framework which allows innovating as long as the compliance with the basic safety requirements is respected. Apart from the plastic aerosols and constraints on the capacity, a large majority of stakeholders (including economic operators) were of the opinion that ADD allows sufficient flexibility for innovation. The ADD does not actually provide a guidance how to innovate. However, since there are no precise requirements in ADD about materials, dimensions (except the brim-full capacities), there is a lot space for innovation as being demonstrated in material development, especially for aluminium, shapes and decorations, sizes, etc. In fact, the industry needed to come up with standard size tables to limit the proliferation of can sizes and shapes in the market, and only two diameters of can orifices (1 inch and 20 mm).

7.2.1.4. New legislative framework[31]

When asked whether there was a need to make any changes to the ADD in the future (further to the currently pending increase in the maximum content for plastic aerosol dispensers), the majority of Member State representatives indicated that there was no need for any changes in the future (unless industry would request this, which according to them was not the case). They felt that despite the fact that the Directive was quite old and detailed, it worked and was effective. Moreover, all stakeholders involved knew what the Directive means and how it should be interpreted. They did not see the point of changing a well-functioning Directive.

However, one representative of national authorities mentioned the possibility of aligning ADD to the **New Legislative Framework (NLF).** When we asked what precisely the benefit would be of such an alignment, the interviewee noted that it would help to align the ADD with other (more modern) Directives. Thus, it would contribute to more consistency in EU legislative instruments. Additionally, he/she argued that an NLF-type of Directive would establish a clearer system of technical safety requirements.

7.2.1.5. Conclusion

Overall, the findings of this evaluation suggest that the dual objective of the ADD (ensuring consumer safety and facilitating the internal market) is still highly relevant to the problems and needs in the field. There have been several technological and other developments in the field, including the development of new materials for aerosols (plastics), alternative propellants, new products based on innovative technologies, development of new valves and dispensing systems, etc. Despite the fact that the Directive is relatively old, the vast majority of stakeholders that were consulted for this evaluation were of the opinion that it remains relevant. The amendments to technological progress have played an important role in keeping up with these developments. There was a general consensus that the Directive does not directly stimulate innovation and does not hinder it either. The conditions and requirements of the Directive are sufficiently flexible for this purpose. Lastly, one representative of national authorities argued that the Commission should consider aligning the ADD to NLF.

[31] See: General information about the New Legislative Framework can be found at: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en. The 2016 Blue Guide on the implementation of EU products rules is available at: http://ec.europa.eu/DocsRoom/documents/18027/attachments/1/translations/en/renditions/native

7.3. EFFECTIVENESS

This section assesses the extent to which the ADD has been effective in achieving its two main objectives. In other words, this section discusses the extent to which the Directive has contributed to safety of aerosol products for consumers and the smooth functioning of the internal market for aerosol dispensers. It also assesses the extent to which the procedure to adapt the Annex of the Directive to technical progress has been effective and identifies whether any aspects, means, or actors render the Directive more or less effective, whether there are any barriers to the application of ADD, how different groups of stakeholders are affected, and whether the Directive generated any unexpected or unintended impacts.

7.3.1. To what extent has the ADD been effective in achieving its main objectives? (Evaluation Question 6)

7.3.1.1. Contributions to product safety

The aerosol industry has a good track-record of safety. In fact, neither in RAPEX nor elsewhere there has been an incident reported that could be rooted back to bad requirements of aerosol dispensers within the scope of ADD. Incidents where aerosols are involved are tracked by national aerosol associations and covered by newspaper-, radio and television reports, including internet. Therefore, we can conclude that none of these sources reported problems.

The evidence of this evaluation suggests that the ADD had a positive influence on the safety of aerosol dispensers. Most Member State representatives reported none or very few incidents in their respective countries (one interviewee estimated once every two years, another even once every ten years). Two Member State representatives gave examples of aerosol dispensers that were found to be non-compliant with the Directive. In one case this was discovered through a regular site visit control. Both examples regarded products that were imported from outside Europe. In both cases, corrective actions were taken by the national authorities and the issues were resolved.

In this context, it should be noted that not all incidents are officially reported. Based on the interviews, approximately half of the national authorities did not keep any records of the number and type of consumer complaints and incidents with aerosol dispensers. The other half of national authorities that did keep some records of consumer complaints and incidents, but they did so in quite different way. For example, some only kept records for a certain number of years (e.g. the past five years) or in a way that does not allow differentiation between what Directives the complaints relate to (e.g. ADD, CLP, or other). Some Member State representatives did mention specific examples of incidents that happened with an aerosol dispenser in their country. However, they noted that the few incidents that did happen were in almost all cases due to misuse or abuse by the user, or non-compliance of the aerosol dispenser. In a few cases, the cause of the incident was not known or investigated.

The consumers' organisations feedback (see Annex 11) suggests that there are no problems regarding aerosol dispensers, as those organisations have not received any complaints or due to the low number of incidents do not follow this topic internally.

While the level of safety cannot be directly attributed to the Directive alone – after all the industry itself also takes considerable measures to prevent any safety incidents to avoid reputational damage – it is likely that the Directive did play a role by harmonising adequate safety standards. The industry itself monitors continuously competitive activity, also concerning imports. In all cases, a person responsible for marketing aerosols is responsible for providing information about the design and production of aerosols products if needed. However, documents could be fake. Industry does recognise a risk of counterfeit and fake products. There is no clear proposal how to defend the European Market from this. It could be quite expensive to check all products entering the European market. Large companies follow measures to prevent counterfeit, e.g. by applying hidden marks on products. This is one possible measure to identify counterfeited products. There is also a higher risk that such products will also not be compliant to ADD as well. The issue of counterfeiting is addressed in Intellectual Property Rights Enforcement Directive (IPRED) of the European Commission (2004/48/EC)[32] and not ADD.

The objective related to safety is subject to constant monitoring by the industry. Most of the time, accidents occur due to misuse. Back in 2010, the ADD expert group was asked about the potential safety problems and concluded that there were no such problems. Likewise, a similar finding emerged from the Impact Assessment Study on the Adaptation to Technical Progress of the Aerosol Dispensers Directive (RPA study of 2014)[33]. It was found that there were no issues related to the safety of ADD that would justify a full revision of the Directive.

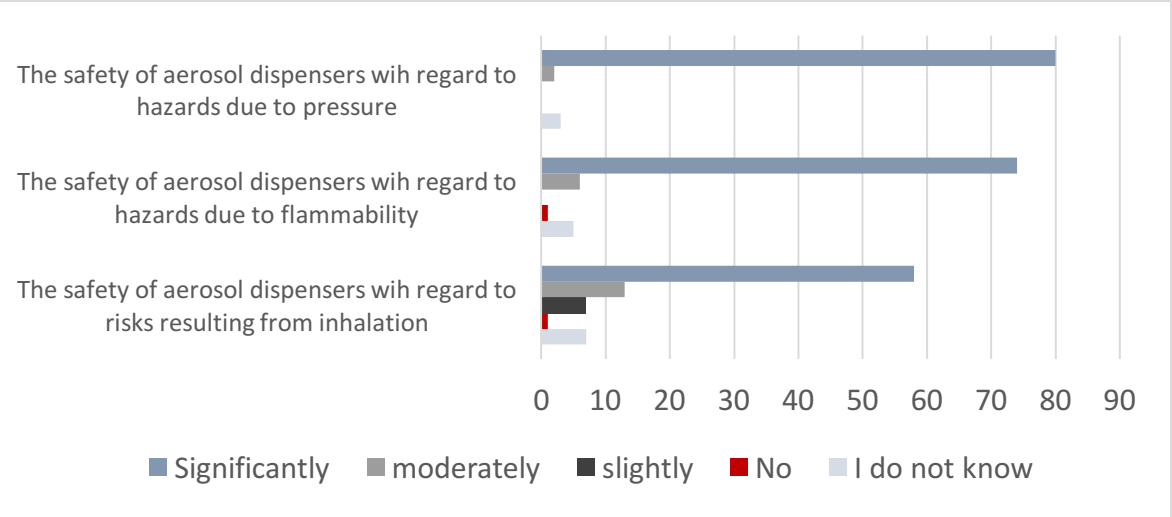
The vast majority of interviewees, survey and public consultation respondents felt that the Directive made a positive contribution to the safety of aerosol dispensers (as shown in the figure below). This was especially the case in Member States where there was not legislation on aerosols in place before the ADD was introduced. For example, one public authority representative mentioned that in his/her country, the ADD helped to get the topic of the 'safety of aerosol dispensers' on the political agenda. Before the ADD, this country had no legislation in this area and the topic was rarely discussed.

No safety issues were reported by any of the survey respondents with the exception of one valve manufacturer pointing out the issue of controls of aerosol dispensers. The suggestion is to conduct audits regularly which in practice means retaining the aerosol dispenser for at least two years (the shelve life of the product). In this way, a standardisation of ageing test (on leakage, corrosion, choice of seals and valves) would be achieved.

[32] See: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0048R%2801%29

[33] See: http://ec.europa.eu/DocsRoom/documents/5361

Figure 31 Contribution of ADD to consumer health and safety



Source: ADD evaluation survey, 2016.

The findings were more mixed in relation to the extent to which the Directive enhanced **clarity on the safe use of aerosol dispensers.** While some stakeholders were not able to comment on this question, others argued that since consumers rarely read labels properly, the ability of the Directive to improve clarity is limited.

According to the results obtained through the public consultation (see Annex 9), 99% of the **consumers/users** considered aerosol dispensers as safe products. With regard to the safety related information placed on the packaging of an aerosol dispenser, 25% of respondents answered that they did not read this information, 40% 'always' read the label, while 35% read it 'most of the time'. It is also found that 60% of the respondents do not know that the symbol of '3' (inverted epsilon) certifies the compliance of an aerosol dispenser product with the ADD. All the respondents identified as the **economic operators/professional associations** state that they have never encountered any problem in relation to aerosol dispenser products. The availability of data on the number and type of consumer complaints and incidents with aerosol dispensers reflects a high degree of limitation we have and for that reason the obtained results should be treated with caution.

The high level of safety of aerosol dispensers is also reflected in the fact that none of the national authorities that we spoke to ever applied the procedure laid down in Article 10 of the ADD (i.e. provisional prohibition of an aerosol dispenser if they represent a hazard to safety or health despite compliance with the Directive). This finding is in line with the information available to the Commission (DG GROW). In other words, it rarely or never happens that products are unsafe despite their compliance with the Directive.

7.3.1.2. Contributions to the internal market

This evaluation also found that the ADD had made a significant positive contribution to the **harmonisation of rules and requirements** in relation to aerosol dispensers.

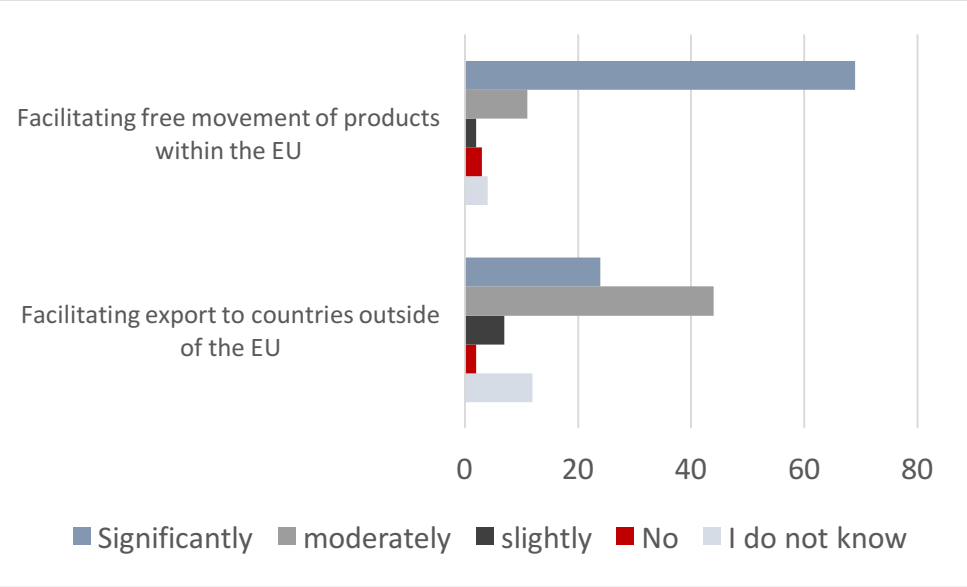
The Directive has clearly led to the adoption of harmonised rules and requirements. None of the stakeholders that we spoke to recalled any situations in which an aerosol dispenser was refused, prohibited, or restricted from the market despite compliance with the ADD. The figure below shows that 78% of the survey respondents felt that

the Directive facilitated to the free movement of products within the EU. Most of the respondents to the public consultation identified as economic operators/professional associations (92%) considered that the ADD has achieved the objective of free movement of goods within the EU Single Market. The same proportion of respondents never encountered any problem when placing aerosol dispenser products on the market (see Annex 5).

However, it was noted during interviews that there is an additional obligation in Germany for the alternative test with a requirement to use an additional statistical test in a hot-water bath test with 1 out of 2,000 units.

As shown in Section 3.3 on market analysis[34], the European aerosol market has a strong position of in the world. Europe had the largest market share in 2013 in terms of volume as well as revenue. While there is not enough evidence to attribute any of these positive findings to the ADD, the industry representatives felt that the Directive probably played a positive (albeit small) role in this. They argued that as a result of the harmonisation of the rules and requirements for aerosol dispensers, the Directive most likely helped to **foster both intra-EU and extra-EU** trade and thus businesses' competitiveness. As regards the facilitation in exports to countries outside of the EU 27% of survey respondents consider ADD's contribution as significant and 57% as either moderate or slight.

Figure 32 Contribution of ADD to the EU internal market



Source: ADD evaluation survey, 2016.

[34] The trade data came from various sources and was not collected by means of the targeted online survey as it had been originally planned.

7.3.1.3. Conclusion

First of all, it should be noted that the objectives of the ADD are not only ambitious but also hard to measure in quantitative terms. There is a multiplicity of external factors that influence the internal market and product safety. Moreover, given the fact that the ADD has been in place for such a long time, it is hard to estimate what would be the safety level or trade flows without the Directive in place. This makes it impossible to attribute the high level of safety and the strong position of the European aerosol market directly to the ADD. It needs to be noted that it has not been possible for the evaluation to identify causal relations between the Directive and the internal market or product safety beyond what has been obtained from the opinions of stakeholders.

Nevertheless, a clear majority of stakeholders felt that it was likely that the Directive made a positive contribution to the achievement of the ADD's objectives. They were of the opinion that the ADD made clear contributions to the health and safety of consumers and other users of aerosol dispensers. Moreover, the Directive was highly successful at harmonising rules and requirements in EU member States, and thus facilitating the free movement of aerosol products across the Union.

7.3.2. What aspects, means, and/or actors render ADD (or certain aspects of ADD) more or less effective (Evaluation Question 7)

This question is intended to gather the necessary evidence with the view to evaluate the effectiveness of provisions, requirements, and methods outlined in the annexes of the Directive, as well as appraise the role of any stakeholders, activities or procedures in applying the ADD.

7.3.2.1. Wording and content of the Directive

In general, the findings on the effectiveness of the Directive from the interviews with Member State representatives are positive. The vast majority of interviewees indicate that the Directive works well, and that there were no issues or concerns in relation to this Directive.

The vast majority of Member State representatives (18 out of 21 interviewees in total) felt that the wording and content of the Directive is sufficiently clear and appropriate. In the opinions of three interviewees, the wording and content of the Directive is not sufficiently clear and appropriate. Additionally, three interviewees mentioned that **annexes** of the Directive were very detailed. While some felt that this was an advantage, others felt that it was too detailed. To place this finding into context, the main reason for this level of detail in the annexes of the Directive is that the tests were derived from UN legislation. The European Commission was not allowed to simply include a reference to this legislation in the Directive, which meant that all details had to be included. However, given the CLP Regulation that is now in place, there may be scope for reducing and/or simplifying the annexes of the ADD.

Only one interviewee made a concrete recommendation for improvement of the content of the ADD. He/she mentioned that the Directive does not require manufacturers or the persons responsible for the marketing of aerosol dispensers to keep **technical files** that can be used by the market surveillance authorities. Such reports should, according to the interviewee, show that the dispensers had been tested in line with the requirements of the Directive. According to the ADD (Article 6.1.4.3, point c) the person responsible for the marketing of aerosol dispensers must,

for surveillance purposes, keep the approval of the competent authority, the technical file describing the test method and, if applicable, control reports readily available at the address specified on the label. In this context, it should be noted that none of the other Member State representatives made reference to this issue.

Moreover, a large number of Member State representatives (10 out of 21 interviewees in total) indicated that there were very few **controls and checks** in their countries either because of a limited production of aerosol dispensers or a relatively good safety performance in comparison with other products. The total number of inspections is relatively low except in the Czech Republic and Bulgaria which accounted for 1,745 and 367 controls in 2013, respectively. For the following group of Member States, no information on enforcement activities carried out in the 2010-2013 period was provided at all: Belgium, Croatia, Estonia, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Slovakia, Spain, and the United Kingdom.[35]

One individual Member State representative mentioned the flammability criteria. He/she argued that there might be an issue with the size of aerosol dispensers and the **labelling requirements** (especially when having to use different national languages and various symbols). There is a requirement for the minimum size of the font. In case of a multilingual product to be sold in several European countries the hazard statements and precautionary warnings need to be in the individual language of the country. Particularly, for smaller cans there is not sufficient area left to include all languages, which leads to fact that one product needs different artwork for different European regions. This consequently makes it more expensive to market products across Europe. There are on-going discussions with industry in this country to discuss how many languages should be obligatory for the labels. Using fold-out labels is an option that could address this issue. The discussion is however taking place in the context of the CLP Regulation. It appears that several Member States would like to restrict the number of languages used on normal or fold-out labels which may lead to increased cost (smaller batches, customised labelling per country).

All provisions were also considered relevant by the economic operators and industry representatives whom we have interviewed in the framework of this evaluation study. Overall, there are no concerns about inconsistencies, out-dated provisions or requirements which would be inherent to ADD itself.

It is found that the wording of the Directive is sufficiently clear and appropriate. It was noted that the language is technical but it was right to be like this. In practice, it has not created any problems. Companies which are new in the sector need assistance to understand the Directive and this kind of support can be provided by the national associations. Also, new employees require special training sessions and it was pointed that these would be needed in case of any other legislation or standards.

For example, the European Aerosol Federation (FEA) has not received any questions for further clarifications from the industry which is an indication that the industry knows and understands the Directive very well. The interviewees noted that they do

[35] See: Review of market surveillance activities 2010 - 2013 - Sector 06 Aerosol dispensers, http://ec.europa.eu/DocsRoom/documents/13906/attachments/1/translations

not recall any intensive discussions with the national authorities concerning the interpretation of ADD. Comparatively, there was an important difference noted by the interviewees with regard to the **CLP Regulation** due to different language translations. This is the main problem for differences between ADD and CLP.

The fact that ADD provides detailed requirements in a single document is considered as an advantage from the industry point of view. It is also positively assessed by the industry representatives that the Directive does not refer too much to other directives/legislations, whilst a possibility of introducing modifications in annexes allows the necessary degree of flexibility. During the interviews carried out in the framework of this evaluation, it was suggested only once that potentially ADD should be transferred into an easy to read and up-to-date document.

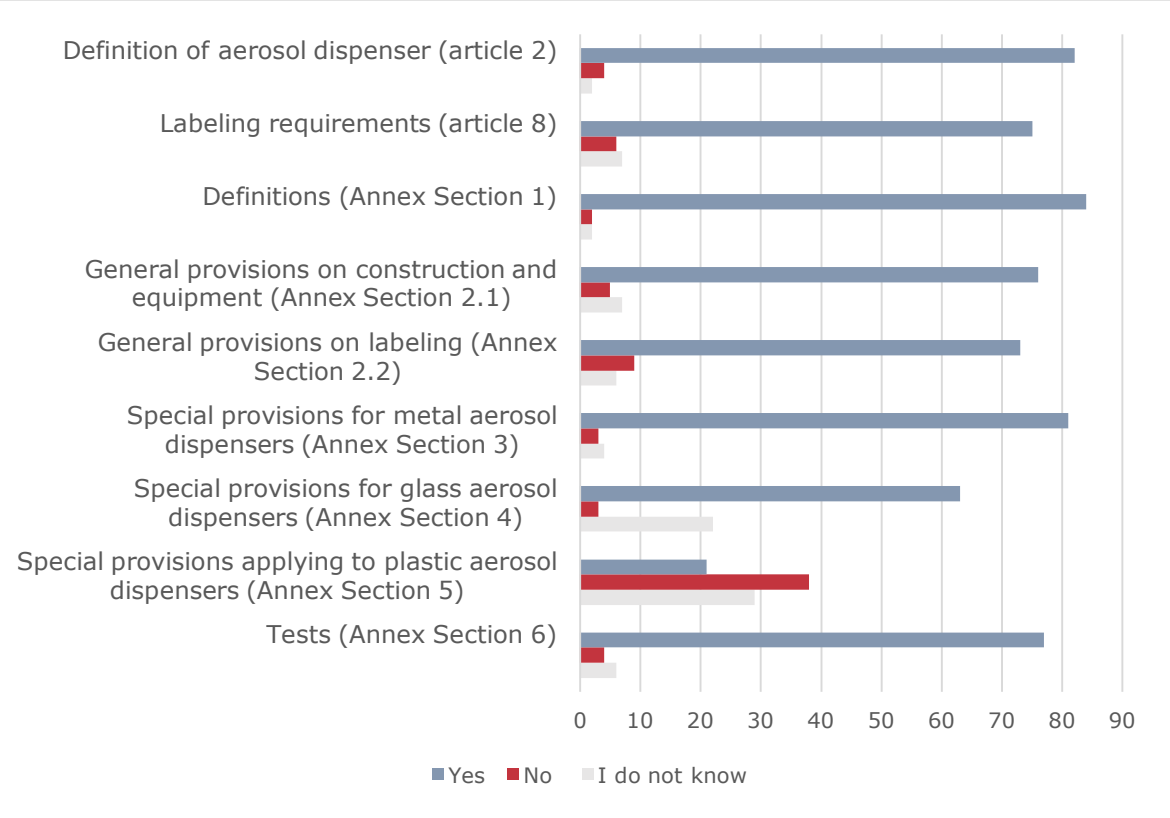
A lot of requirements of aerosols are being regulated in other directives and regulations which are not even mentioned in ADD. This is the difficulty to update the ADD considering all aspects of safety etc. Uneducated users of ADD might be overwhelmed by the multitude of requirements that need to be considered for marketing aerosol products.

In fact, aerosol experts share the opinion that all the necessary aspects are reflected in ADD and related directives, except **the content of plastic containers.** In the course of this evaluation, the issue with 15 bar when using compressed gases as propellant has been resolved by adopting the Directive in November 2016 amending the ADD as regards the maximum allowable pressure of aerosol dispensers using a non-flammable propellant (compressed gases).[36]

According to the targeted online survey, ADD's provisions and technical specifications are viewed as appropriate and still relevant by the great majority of the survey respondents (with a provision average of 80%). The only provision which according to the survey respondents is not predominantly appropriate and still relevant is the special provision applying to plastic aerosol dispensers with 43% of respondent considering it as not required, appropriate and still relevant (while 33% does not know).

[36] See: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L2037&from=EN

Figure 33 ADD's provisions and technical specifications (x axis=response counts)



Source: ADD evaluation survey, 2016.

7.3.2.2. Flammability classification

The interviews with the economic operators pointed also to **a gap concerning the classification between flammable and non-flammable materials**. The percentage of flammable content in % needs to be labelled if the product is being classified as non-flammable. This is a requirement that is sometimes criticised. If the product is classified as non-flammable (as stipulated in Article 8 1a), which requires passing all relevant tests, the information about the percentage of flammable ingredients in the formulation is being seen as not relevant. It appears that the requirement is considered unjustified not from the safety point of view but it is rather driven by commercial interest of not including the required information on the packaging.

Labelling of the percentage of flammable content has several disadvantages. First, concentrations are integral parts of formula and linked to specific substances, in this case all substances which are classified as flammable. This means that parts of the formula are being publicly available. Secondly, if the formula is subject to minor changes in the concentration of flammable substances, the entire artwork definitely needs to be changed. This happens, e.g. if perfume oils are being changed or other adjustments occur. Although these changes do not consequently have an impact on the ingredients declaration that does not require exact percentages, the changes in artwork of printed cans are expensive. To sum up, the evaluation finds no evidence suggesting that this a major issue that would have a negative influence on the effectiveness of ADD. It is also important to note that there are no issues with the

requirement to place a warning of flammability for aerosol dispensers classified as flammable.

7.3.2.3. Safeguard clause

Article 10 of Directive 75/324/EEC lays down a safeguard clause. According to Article 10, if a Member State notes, on the basis of a substantive justification, that one or more aerosol dispensers, although complying with the requirements of the Directive, represent a hazard to safety or health, it may provisionally prohibit the sale of the dispenser or dispensers in its territory or subject it or them to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

The evaluation found that in practice this clause has been very rarely used. In 2003, there was an accident caused by an oil spray that had been sprayed during barbeque. The Olive Oil, which is not flammable being brushed on goods on the grill would not cause a hazard, but the fine droplets are highly flammable. The spray was not labelled as such in the past. Generally, the Member States authorities felt that safeguard measure is justified in view of the risk of flammability raised, under normal or reasonably foreseeable conditions of use, by the substances contained in the aerosol dispenser.

7.3.2.4. Alternative and water bath test method

A so-called **'hot water bath test'** is a water bath that enables to fully immerse the filled aerosol dispensers in water and heat them to 50°C. This test checks whether cans have any leaks or bursts. In terms of the practical implementation of this test, cans have to be transported into a water bath that contains hot water above 50°C. Depending on the temperature of the water, it takes up to several minutes to heat cans from ambient temperature to 50°C.

Depending on line speed there will be several hundreds of cans in a water bath before the check point, which requires space consuming apparatus and machinery. At the check point a leak detection shall take place and a check, whether the can is distorted or even ruptured. After the immersion in the water bath the cans need to be cleaned from the water. This takes place in a hot air dryer at non specified temperature. As a rule, the air is hot as well, above 50°C.

In this context, one concern is that bursting or leaking cans can only be detected at a check point, although the leak could appear before and even afterwards. If the failure happens before the check point, this could mean that all cans that were in the water at the same time might be polluted and need to be verified. Most probably they would need to be cleaned. The water in the bath needs to be replaced and sometimes treated as special waste, due to the polluting compounds and due to additives that enable better detection of bubbles and therefore leakages. If there a leak would occur during drying, it will only be detected during packaging. This might lead to pollution of machinery, other cans, and/or the packaging.

Estimate costs of water bath test

The water bath is an existing installation and only maintenance cost are due. Since there is no data on the actual costs of running a hot water bath (energy consumption, etc.), we can only provide the estimated cost. One bursting or leaking can in the water bath can easily pollute the entire water and all other cans running in the bath. Cleaning the cans, exchanging the water, cleaning the water bath, and refilling hot water is expensive. Each leakage costs some hundreds of Euros for leaking cans and cleansing. This often happens at least once a day. Therefore, a rough estimate is that besides the higher cost to heat the water and dry the cans can be at least about 100 000 Euro per year, if the can quality is not being tested prior to the water bath. If we consider that an exchange of water would take at least 30 minutes to 1 hour, the stand by time itself would be worth thousands of Euros. In this case the costs to run a water bath would cost at least 300 000 Euros per year up to 1,400,000 Euros per year and even more.

Only *preventive* actions can avoid leaking or bursting cans in the water bath and therefore avoid related waste. All leakages in the past could be classified as:

- bad can quality
- bad clinch (due to fatigue of clinching machines)
- overfilling

This evaluation found some indications that water bath tests are not being performed as described in ADD. Based on the expert assessment, there is evidence that for instance only a pressure test[37] for aerosols filled with compressed gasses is carried out. It should be noted that the prescribed test is not being conducted in this case, which is illegal. The justification that compressed gases do not create a significant increase in pressure is insufficient. All cans need to resist temperatures up to 50°C and the respective pressure.

In the past the difficulties with the hot water bath test led to the development of the **cold alternative** to the hot water bath as described in ADD. It comprises a QA-system, pre-testing empty containers concerning pressure resistance and leakage, as well devices that address the causes of failures: clinch checker, check weighter and leak detector for the filled cans. Additionally a 100% test on all empty containers is being conducted (primarily by the can manufacturer, but can be conducted by the filler after reception of empty cans as well). The method requires a lot of documentation for all steps, which is a lot, compared to the minimum documentation to run a hot water bath.

The alternative method is based on the voluntary principle. There is no obligation to use this test method and thus no requirement to make the necessary investments. The interviews underlined that especially for SMEs it is sometimes better not to invest in new technologies but keep the existing ones. It is to be acknowledged that no specific issues were raised during the interviews carried out in the framework of this evaluation by the representatives of SMEs.

[37] This is a pressure test directly after filling the propellants (a compressed gas) and then after a certain time. Since leakage would lead to a significant pressure loss in case of filling only compressed gases, which do not dissolve in the liquid phase of the aerosol, pressure testing before and after would be a leakage test.

Several issues were raised in relation to the cold alternative test during the evaluation:

- **High cost:** It was also stated that the alternative test method requires major investments due to changes in the production line and supply-chain (also from the fillers side). To make an estimate, we need to consider that the alternative test method requires the installation of a leak detector and a check weighter. Both cost some hundreds of thousand Euros. One individual Member State representative for example indicated that in order to be able to use alternative test methods (like the cold final test), a company needs to have in place certain quality systems, which are quite expensive. It was therefore argued that it might be more difficult for smaller companies to use the alternative test method.

- **Lack of harmonisation at EU level:** The alternative test method also requires obtaining the permission from the relevant authorities. One consideration might be whether there are too many aspects left to the Member States. National authorisation should ensure that the alternative is being run under the regime of a QA system. The validation of the alternative test method by national authorisation leaves room for introducing additional test methods, e.g. as seen in Germany. By definition , this part is not harmonised by ADD, so Member States are free to determine the details of the test method.

- **Technical challenges:** There are also technical challenges to overcome to implement successfully the alternative method. Overall, there are few companies using the alternative test method according to one of our interview sources.

In terms of **other alternative tests**, during one of the interviews with the economic operators, it was pointed that the today's **leak detection capability** is more advanced than what is prescribed in the Directive. The hot-water bath test is a traditional method based on visual observations and there are currently other more reliable methods. A minority of interviewees expressed an opinion that the new techniques of production and the rapidity with which production is done today should call for a change of this test. The alternative test method was developed by FEA and subsequently tested at a plant in Germany. The main benefits of using this method lie in reducing the waste and accelerating the production process.

In the past, the FEA had a Working Group on the **alternative test method for aluminium**. Test were conducted with especially prepared cans in which a pin hole of 200 µm diameter has been punctured. These tests showed that there would be no burst confirming the feasibility of testing technologies. The cost factor and the availability of physical space required to install new testing equipment might also play a role but there is no cost comparison to prove this point. As a result, the idea of introducing the alternative test method was abandoned and the fillers who use aerosols with aluminium cans continue to apply the hot-water bath method. The alternative to the hot water bath requires pressure and leakage testing of the empty aerosol containers. The fact that aluminium cans are being filled on the same lines as tin plate cans is the reason why a lot of fillers do not use alternatives to the hot water bath.

In conclusion, there are a number of issues raised in relation to both the hot water bath test and the cold alternative test. The water bath is very simple and does not require the same amount of documentation. However, incidents in the water bath can be costly. It is essential to check the quality of the aerosol products before they enter the water bath. The cold alternative test on the other hand represents costs (especially for smaller companies), as it requires a full QA system (due to changes in the production line, the need for extensive documentation, etc.).

Due to these disadvantages of both testing options, there have been some efforts to develop new and more efficient testing methods. The conclusion of this evaluation is that, despite the disadvantages of the test methods available, none of the industry representatives have asked for specific changes in the Directive.

7.3.2.5. Other aspects, means or actors

During the interviews with Member State representatives, there were no specific aspects, means or actors that were mentioned repetitively as clearly driving or hindering the ADD. However, some interviewees did mention the following actors as being important partners in relation to the implementation of the ADD:

- **Customs authorities:** Several interviewees mentioned the customs authorities as important actors in their country. The coordination with customs authorities was considered quite important, not only in relation to aerosol dispensers but also other potentially dangerous products and goods. Indeed, information retrieved from the official website of DG Taxation and Customs Union (DG TAXUD) indicates that product safety is one of the focus areas of customs controls. Representatives of national authorities argued that in practice the actual controls on aerosol dispensers in particular usually does not have priority in the vast number of products and goods that customs authorities control.

- **Consumer protection authorities:** The way in which the ADD is implemented at national level and numbers and types of organisations involved differs per Member State. A few interviewees mentioned that in their case there was a consumer protection authority, which was considered important in terms of obtaining information on the number and types of incidents.

- **Trade associations**: A few individual interviewees mentioned FEA and the FEA guidelines in relation to the effective implementation of the ADD. They argued that these guidelines contributed to a common understanding and interpretation of the Directive at industry level as well as by national authorities.

Likewise, there has been relatively little information provided by the economic operators and industry representatives in relation to stakeholders, activities and/or procedures viewed to be important in applying the Directive.

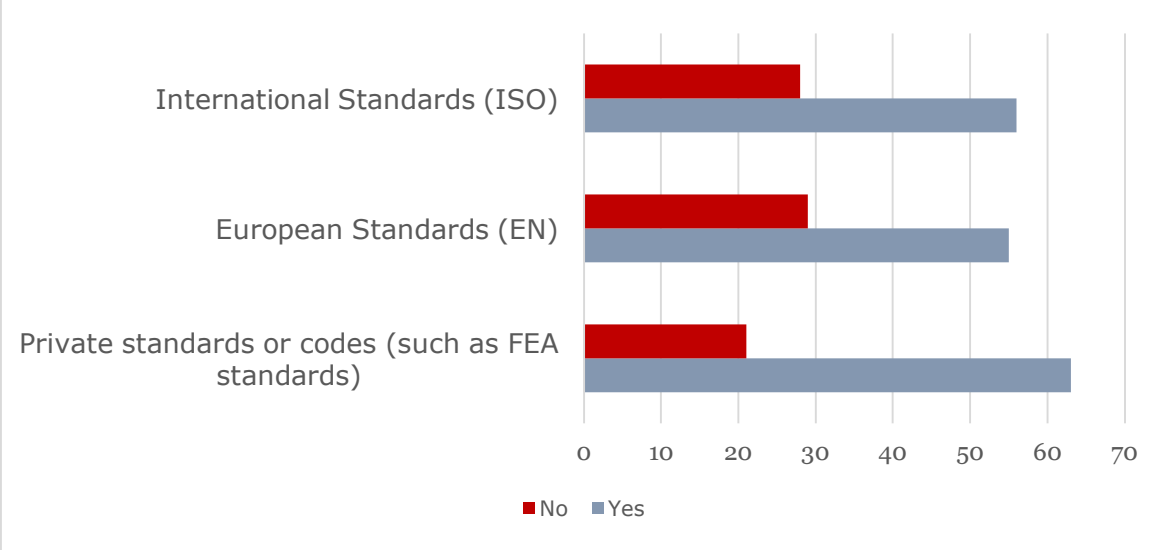
7.3.2.6. Standards

It is important to note that the FEA standards[38] exist since many years based on the requirements set out in the Directive. FEA standards are also European EN standards, however, not in the way of a typical European harmonised standard.

One of the main concerns for industry is the potential introduction of conformity assessment including third parties if the ADD would be converted into a new approach style of legislation, compared to the current self-certification. Other possible consequences of converting the Directive into a full new approach piece of legislation involve the need to define appropriate essential safety requirements, decision on conformity assessment modules, quality assessment systems, testing, and the development of standards which would implement more general essential safety requirements that would be in the Directive.

As shown in the figure below, International, European and Private standards are used by the majority of survey respondents, namely private standards as indicated by 75% of the respondents (predominantly FEA standards), international standards as indicated by 67% of the respondents (namely ISO 9001) and European standards as indicated by 65% of the respondents (namely CEN Standards developed by TC 261/SC5/WG22).

Figure 34 International, European and private standards (x axis=response counts)



Source: ADD evaluation survey, 2016.

7.3.2.7. Conclusion

In conclusion, the majority of Member State representatives considered that both the wording and content of the Directive is sufficiently clear and appropriate. There have been very few specific issues mentioned during the interviews carried out in the framework of this evaluation that have an influence on the effectiveness of the ADD (e.g. too detailed annexes of the Directive, such as Annex 6.3 test on flammability,

[38] See: http://www.aerosol.org/publications-news/publications/standards

lack of obligation for keeping technical files, very few controls and checks, and labelling requirements especially when having to use different national languages).

The interviews with the economic operators confirmed that there are no concerns about inconsistencies, out-dated provisions or requirements. It was also found that the wording of the Directive is sufficiently clear and appropriate. In general, the provisions and technical specifications are viewed by experts as appropriate, except the limit of the maximum pressure to 13,2 bar when using non-flammable propellants and the limitation of the content of plastic containers. These findings are confirmed by the results of the targeted online survey. In relation to the maximum pressure when using non-flammable propellants, the adaptation of the ADD to increase to the maximum to 15 bar was still ongoing at the time of the consultations. It is to be noted that in the meantime the new Commission Directive (EU) 2016/2037[39] was adopted in November 2016 allowing such an increase.

Some specific issues have been mentioned during the interviews with the economic operators and industry representatives (e.g. transposition of the CLP into national law following different translations, the inhalation of spray analysis, and labelling of the flammable content). The issue of transposition of the CLP into national law was considered to be more serious by the economic operators consulted as part of this evaluation.

In order to use the alternative test method a full QA system needs to be in place. Comparatively, the water bath is very simple and does not require the same amount of documentation. However, incidents occurring during the water bath test can be costly, and in practice there are regularly such incidents. There was not any detailed information available on the precise frequency and costs of such incidents.

7.3.3. To what extent has the procedure to adapt the Annex of ADD to technical progress been effective? (Evaluation Question 8)

Article 5 of the ADD lays down the procedure to adapt the Annex of the ADD to technical progress. This procedure only concerns non-essential elements of the Directive. In other words, it cannot be used to adapt the main text of the Directive (i.e. any of the Articles). Article 6 of the ADD establishes a Committee (consisting of representatives of the Member States and an EC representative as Chairman) to coordinate the adaptation procedure. The answer to this evaluation question assesses to what extent Article 5 and 6 have been effective in practice, and whether it helped to keep the Directive up to date with the technological developments in the field.

7.3.3.1. Effectiveness of the procedure for the Adaptation to Technical Progress (ATP)

The majority of Member State representatives was satisfied with the procedure to adapt the ADD to technological progress. They felt that the procedure worked well and they did not have any specific complaints. Only few interviewees (3 out of 21 in total) pointed that they were not satisfied with the procedure. A number of other interviewees (5 out of 21 in total) mentioned that they had not been actively involved in it (for example because it was not their priority as some countries had very little

[39] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L2037&qid=1493211832465&from=EN

aerosol industries). Therefore, they felt unable to discuss this procedure in much detail. The interviews with economic operators and industry representatives confirm that the length of the process is justified by safety considerations. It was appreciated that changes are discussed with experts from different EU Member States. As a consequence, the outcomes are thoughtful and adopted changes are always implemented.

7.3.3.2. General issues related to the procedure

There was a few authorities that highlighted some issues in relation to the procedure. Some interviewees (3 out of 21 in total) felt that the procedure was **quite slow.** They mentioned a number of potential reasons for this: bureaucracy and a lack of human resources on the side of the Commission, Member States that were not always actively engaged, and the fact that it takes time to conduct stakeholder consultations and to gather information from industry (both at EU and national level). The interviewees mentioned that it would be preferable to speed up the process and to reduce uncertainty for industry. One representative specifically referred to the most recent procedure on plastics. He/she felt that due to the EC's decision to gather additional evidence, the process had become quite long. A representative of the European Commission explained that this additional evidence was necessary in order to ensure that the safety of these aerosol dispensers would not be compromised due to legislative amendments. Moreover, he/she explained that reaching an agreement between all Member States (and voting on this agreement) takes considerable time as well.

Another complaint made by 2 interviewees out of 21 in total related to the fact that there had been **(too) many amendments** over the past couple of years. It was pointed out that the EC should aim to reduce the number of amendments for two reasons. First, some felt that it was hard for SMEs to track legislation that is constantly changing. Second, some national authorities were unsatisfied with the administrative burden of having to transpose all individual amendments in national legislation (they noted it took at least several months for each amendment). A representative of the European Commission acknowledged this. However, he/she explained that it had not been possible to group some of the most recent ATPs. In the case of the split between the increase in pressure and the plastics file, the lack of supportive evidence caused disagreements and thus required the collection of additional evidence related to the safety. If the two proposed changes would have remained within the same amendment, this would have meant that the increase in pressure would have also been delayed. The choice was made to make progress for the changes which were agreeable to all in order not to further delay the possibility to use more often compressed gases as propellant.

Another topic related to the number of meetings of the **Committee**. A few interviewees (2 out of 21 in total) felt that there were too few meetings, and that almost all discussions and voting took place in writing. However, another interviewee felt the contrary and was satisfied with the writing voting, which he/she considered to be sufficient and efficient.

One of the issues raised during the interviews with the economic operators and industry representatives was that half of Member States are neither interested in aerosols dispenser products nor dedicate the necessary resources. It was also suggested during one of the interviews that the establishment of the **ADD working group meeting** to take place on the annual basis could introduce a new dynamic.

There would need to be of course sufficient content to justify such meetings, in addition to active participation of the Member States' representatives.

7.3.3.3. Increase of the internal pressure for aerosols using non-flammable compressed or dissolved gas propellants

During the interviews with the economic operators and industry associations, it was noted that the process of increasing the internal pressure for aerosols using non-flammable compressed or dissolved gas propellants was smooth and efficient. The process was viewed to reflect the industry interest to use these types of propellants for environmental reasons. There were no problems observed at the technical level because of a good capacity of verifying the pressure and performing the necessary tests. In transport regulations pressure up to 13.2 bar had been allowed already for decades. Comparatively, it was easier than in the case of other adaptations to the technical progress because there was no major issue affecting the safety.

According to 80% of respondents to the targeted online survey, no new aerosol dispenser applications have resulted from the change in 2008 to increase maximum pressure from 12 to 13,2 bar at 50 °C in case of non-flammable propellant. Among the 20% that replied positively very limited indications were given on the percentage shift in using a non-flammable propellant. The three responses provided ranged from 2% to 20%. It is also important to note that the latest ATP will allow 15 bar but it would only be beneficial for a limited number of products. Moreover, also transport legislation still needs to be modified to allow the transport of such dispensers. Those results raise a question whether the change was worth the effort. Despite that the survey results do not indicate major shifts in using non-flammable propellants, it is important to remember about the potential benefits of increasing the pressure in aerosol containers, such as improving the performance of products while at the same time guaranteeing the safety of these products to consumers, the introduction of more environmental-friendly products and a generally wider choice for manufacturers as well as consumers.

7.3.3.4. Alignment to the CLP Regulation

With regard to the underlying processes of alignment to the CLP Regulation, the industry representatives pointed to the complexity of CLP. It was explained that CLP labelling implied a re-verification for flammability test and re-classification in line with the new requirements of CLP. The interviews carried out in the framework of this evaluation study also highlighted the importance of implementation by local regulators in a consistent way.

It is to be noted that the ADD is a downstream legislation in relation to the CLP Regulation. The CLP implied a number of changes to several pieces of downstream legislation. The ADD used to have labelling requirements included in its core text. In order to avoid duplication and incoherence between the ADD and the CLP, the labelling provisions in ADD were gradually replaced by dynamic references to the CLP. There have been some issues because the CLP had not been initially fully in line with the needs and practices for aerosol dispenser products. The problems have gradually been removed in various steps through adaptations of the CLP.

7.3.3.5. Increase of maximum content for plastic aerosols and modifications of related requirements

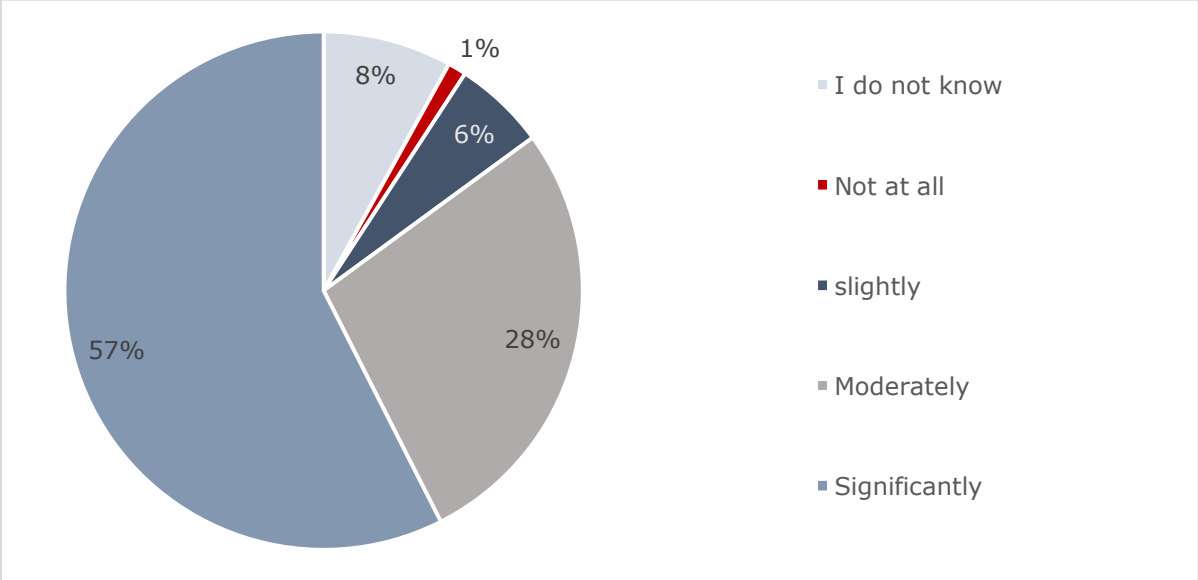
There are differences in the opinions among the economic operators about the increase of maximum content for plastic aerosol dispensers and modifications of related requirements. Some interviews were of the opinion that it was a normal process, while others pointed that it was far too long process. The interviews which provided a more positive assessment also noted that probably at the beginning there was not enough information available to the legislator to proceed with a legislative proposal changing the current content limits.

The PAIR report (see also point 7.1.1.4) assessing potential increase of the maximum content for plastic aerosol dispensers identified which information/test results are available but there is still only limited data for the higher range content (600 up to 1000 ml). From EC point of view, this study was a necessity and further examination will be needed. It appears that due to confidentiality and commercial sensitivity, industry is not so open to share data. For some ranges (800 to 1000 ml), there is no test data or no data could be collected via the PAIR project. Regulators are not agreeing on permitting parameters for products which do not exist or for which no test data is available from test samples. A point of the discussion is still whether virtual samples via computer simulation would be acceptable (e.g. for the higher volume range) The emphasis is in the first place on the safety of aerosol products. This is also in the interest of the industry given potential reputational damage for the whole aerosol dispensers industry in case of failure of plastic dispensers.

A large majority of industry representatives agree that ADD in the current format reflects the technological state-of-the-art. Some interviews (2 out of 29 in total) also pointed that sound integration of new ATPs would be desired. However, it was noted that it is difficult to predict what companies are planning and there are no signs of the next major innovations to come. It is also worthwhile mentioning that the adaptation to technological progress (ATP) can only address technical issues and is based on an exceptional procedure the use of which must be justified and supported by evidence and impact assessment.

The targeted online survey found that the ADD provides a flexible framework according to 57% of the survey’s respondents while 34% is of the opinion that ADD only does so moderately or slightly.

Figure 35 ADD and technological innovation (% share based on response counts)



Source: ADD evaluation survey, 2016.

7.3.3.6. Conclusion

In conclusion, the majority of Member State representatives was satisfied with the procedure to adapt the ADD to technological progress, however, few authorities highlighted some issues in relation to the procedure (i.e. speed of the procedure, number of amendments, and frequency of meetings of the Committee). The interviews with economic operators and industry representatives confirm that the length of the process is justified by safety considerations. With regard to the underlying processes of alignment to the CLP Regulation, interviews with the economic operators and industry representatives pointed to the complexity of CLP. The evaluation also found that the process of increasing the internal pressure for aerosols using non-flammable compressed or dissolved gas propellants was smooth and efficient. However, a limited number of new aerosol dispenser applications have resulted from the change in 2008 to increase maximum pressure from 12 to 13,2 bar at 50 °C in case of non-flammable propellant. Moreover, there were differences in the opinions among the economic operators about the increase of maximum content for plastic aerosols and modifications of related requirements. The existing evidence points that this is the main pending issue. The majority of stakeholders agree that ADD in the current format reflects the technological state-of-the-art and this finding is confirmed by the results of the targeted online survey.

7.3.4. What barriers (if any) exist to the effective application of ADD? (Evaluation Question 9)

This evaluation questions assess if and what barriers that hinder the practical application of the ADD. If so, it also aims to assess to what extent and how these barriers (may) have a negative effect on the achievement of the ADD's objectives.

7.3.4.1. Barriers related to the transposition of the ADD into national legislation

This evaluation concludes that there have not been any significant barriers to the effective transposition of the Directive into national legislation. Almost none of the Member State representatives that we spoke to encountered any problems in transposing the ADD into national legislation. Only one individual interviewee mentioned that there had been some difficulties in translating all the technical terms into the national language. However, this issue was finally resolved and not considered a significant problem. Moreover, the issue was related to linguistic issues rather than the Directive itself.

7.3.4.2. Barriers related to the practical application of the ADD

The evidence available also suggests that there were very few barriers that significantly hindered the effective application of the Directive in practice.

However, one potential issue that was identified via the interviews with economic operators concerned the alternatives to the hot water bath test (Annex 6.1.4.1.c of the ADD). A couple of industry actors explained that the alternative test methods to the hot water bath test have to be agreed and approved at national level by the competent authorities. In other words, the Member States have the freedom to define the exact criteria and conditions for the alternative test methods. This may lead to differences between Member States in terms of the rules and requirements that economic operators have to comply with when using alternative test methods.

Another relatively small potential barrier concerned the derogation from labelling weight (Nominal Quantities Directive 2007/45/EC). This has been a long-standing issue, however, there is no evidence suggested that this is causing any real problem. In the working group meeting of 4 November 2010 the issue was clarified by EC service:

"It was explained that the Commission service accepted the mention of "net contents by volume" in some transpositions but the free circulation in the internal market is also guaranteed if a manufacturer decided to label also with "net contents by weight". It resulted from the exchange of views that: the volume must be indicated and that the weight may be indicated; the legibility of this article could be improved. It will be examined whether this is possible within the context of the ATP of ADD".

Other possible changes include the reversed epsilon "3" and possibly re-editing the paragraphs of the annexes of the Directive to be even easier to read. Concerning the former, it needs to be acknowledged that the ADD does not include a drawing of how the symbol should look like and there are quite varying symbols being used. In 2012, FEA issued a document "Recommendation on reversed epsilon" which contains a layout for the reversed epsilon.[40]

7.3.4.3. Conclusion

In conclusion, this evaluation showed that there have not been any barriers in the effective transposition of the ADD into national legislation. There have also been very few (potential) barriers to the application of the Directive in practice. Moreover, none

[40] See: http://www.aerosol.org/wp-content/uploads/2016/12/20121129-fea-recommendation-on-reversed-epsilon.pdf

of the barriers were considered significant problems, nor was there enough evidence to show that issues actually hinder the effective application of the Directive in practice. The first issue raised by consulted stakeholders related to the alternatives to the hot water bath test. Stakeholders argued that the criteria and conditions for these tests were established at national level, which may lead to differences in application. The second potential barrier concerned the derogations between the Nominal Quantities Directive and the ADD. However, this issue was clarified by the European Commission in November 2010.

7.3.5. How are different stakeholder groups affected by the Directive? If relevant, what are the environmental, social, and economic impacts of ADD? (Evaluation Question 10)

The objective of this evaluation question is to evaluate the extent to which there are any differences in the impact of ADD on different stakeholder groups on the one hand, and gather the evidence on the economic, environmental and social impacts of ADD.

7.3.5.1. Degree of economic impacts

In general, the ADD influences the way companies do business. The Directive lays down clear safety requirements for all aerosol products and secures the free movement of these products on the EU internal market. It establishes clear rules for the responsible person for marketing in the supply and thus facilitates doing the business. Since the ADD does not require a lot of complex systems to be put in place and it is relatively easy to comply with, there are no differences in terms of the impacts on SMEs and large companies. The Directive has been in place for many years and this stability is appreciated by the industry representatives.

The aerosol industry is characterised by solid growth, innovation and evolving market. It was noted that large companies have become more efficient, achieving the speed of production from 200 to 600 cans per minute. Also, small companies are expanding their activities and growing their businesses. During the last decade, there have been a lot of mergers and acquisitions and hence there are relatively less companies carrying out activities in this field.

As presented in Section 7.3.1.2, the ADD does not directly have an impact on the competitiveness of aerosol sector. The Directive is not considered to be the main driver but it contributes to improving the competitiveness of the industry because it harmonises the requirements within the EU and some other jurisdictions around the world also accept ADD compliant aerosol dispensers hence facilitating the export with limited changes to the products. We can conclude that the competitiveness of European aerosol manufacturers compared to other international producers is not hampered by ADD provisions. Some interviewees also pointed to more stringent regulatory requirements in Europe compared to other countries which in their opinions have an influence on the costs of production. Carrying out more strict controls over imported products is seen by some interviewees as a necessity. Based on current practice, the industry itself could play a role in identifying non-compliant products and reporting this to the relevant authorities.

7.3.5.2. Degree of environmental and social impact

According to the feedback received for Evaluation of the Aerosol Dispensers Directive, there is some evidence that the waste sector faces regular problems with aerosols products. As put in one of the received contributions:

"Aerosol waste, except Aerosol Packs for Professional use or waste from Manufacturing sites, is being considered officially as household non-hazardous waste and collected as such. During the transport, sorting, conditioning, these aerosols, often drawing hazard symbols, are managed by installations not licensed for the management of hazardous waste. One of the reasons of these problems is that an 'empty' aerosol, is never empty for 100%. Even some (new) aerosols are now built with an inner flexible bag (e.g. shave gel). The gas is just putting pressure on the flexible bag without coming out of the aerosol. In such situation, the 'empty' aerosol contains exactly the same quantity of gas than a new one. The gas in the outside chamber is normally non-flammable. However, it could be also a flammable liquefied propellant. The entry into force of the CLP-Regulation did also increase the number of aerosols with hazardous pictograms, making the problem of licenses for waste management companies even more acute".

However, this waste management problem only occurs, when aerosols are not being emptied during normal usage, i.e. the problem occurs when partly or entirely filled aerosols with flammable contents are going to the waste stream. Another feedback submitted points to risks for facility workers and impact on the environment, precisely because aerosol waste may be treated in non-authorised facilities.

With regard to the disposal of a used aerosol dispenser, more than three quarters of respondents to the public consultation include it as separate recyclable waste and some 19% include it in the normal household garbage.

Taking into account that environmental aspects concerning the packaging and waste are regulated by different directives (e.g. Directive 94/62/EC and 2004/12/EC on packaging and packaging waste, and the Weights and Volumes Directive 76/211/EEC) the issue outlined above is outside the scope of the ADD.

7.3.5.3. Conclusion

In conclusion, the evaluation found no evidence of any major differences in the impact of ADD on different stakeholder groups. The ADD has been in place for many years and this stability is appreciated by the industry representatives. The existing evidence also points that the Directive contributes to improving the competitiveness of the industry by providing guidelines about the requirements and the fact that ADD framework is applied to other jurisdictions around the world. With regard to waste management, problems mainly occur when the aerosol dispenser is not emptied during normal use. In recent designs, the aerosol dispensers remains under pressure even when it is empty. These developments will require further attention to be dealt with in the appropriate legislation dealing with waste management facilities. There exists also potential risks for facility workers if aerosol waste is treated in facilities where household non-hazardous waste is recycled.

7.3.6. Did ADD generate any unexpected or unintended impacts (positive or negative)? (Evaluation Question 11)

This evaluation question assesses whether the ADD led to any unexpected or unintended impacts, whether they be positive or negative.

7.3.6.1. Unintended or unexpected effects of the ADD

The only unexpected or unintended impact that was identified by the evaluation is the fact that the rules and requirements of the Directive are used and **acknowledged by a large number of non-EU countries.** The ADD had a clear geographical scope, namely the aerosol dispenser products sold in the European Union. The global acknowledgement of the rules and requirements have led to even more harmonisation and this benefits for economic operators than was anticipated. Two important exceptions to this are the United States (US) and Canada, which both maintain their own standards. On the basis of information available, we can conclude that the ADD drives to some extent international legislation.

7.3.6.2. Conclusion

There was only one unexpected/unintended (positive) impact, which is the fact that the rules and requirements of the Directive are used and taken over by a large number of non-EU countries, such as Brazil, China and India (with the exclusion of two important countries, namely the US and Canada).

7.4. EFFICIENCY

7.4.1. What are the costs associated with ADD on different stakeholder groups, including Member States and economic operators? (Evaluation Question 4)

7.4.1.1. Economic Operators – ADD costs

According to the evidence basis (targeted consultations, survey, interviews) economic operators unanimously stated that investments made to produce ADD compliant aerosol products were made before the period under consideration for this evaluation (2005-2015). Some of them even noted that investments were made before ADD. Moreover, all operators pointed out that the investments were made as part of industry and/or company standards and also as a response to the requirements of other legislations (e.g. CLP, cosmetics, general product safety, transport regulation). The attribution hence of the costs to the ADD in the strict sense are minimal as investments necessary to produce safe aerosols would have been made in the absence of ADD as well. It is also important to note that none of the private stakeholders pleaded for a simplification of ADD with as objective to bring down costs.

Subsequently, the cost assessment performed relied on the assumption that the costs provided are independent of their attribution to the ADD and instead the question was formulated as the costs to produce ADD compliant aerosols. Based on this assumption, the cost of ADD in relative terms, as a % share of production cost per unit, for the period 2005-2015 has been estimated as being ca. 5% according to the majority of survey respondents, insights from the targeted consultations and interviews with industry stakeholders. With a total production cost per unit of output ranging between €0.14 to €1 the cost of ADD ranges from €0.007 to €0.05. For SMEs, according to the

survey the majority of respondents estimated costs as being less than 5% of total production cost per unit for the period 2005-2015. However, and while SMEs were invited to participate to the detailed cost assessment exercise none of them accepted to take part in it and thus the latter figure could not be further validated.

The 5% is partly explained by the timeline set for this evaluation which means that since ADD dates back in 1975 companies that made no adaptations due to the ATPs have not experienced any significant investments costs (in terms of Capex) unless they have introduced new lines. Also, companies referred to tests that are not explicitly required by ADD (but may be either required by the client, or performed as Good Manufacturing Practice). The 5% thus reflects the investment costs made as an explicit requirement in the ADD and for the period 2005-2015. As such, the costs associated to ADD for the period 2005-2015 are namely maintenance costs, personnel costs and recurrent costs i.e. training costs.

Capital Expenditures (CAPEX) - Investment Costs: However, to get an idea of the minimum capital cost for setting up an ADD compliant plant, the main cost driver identified for can manufacturers is the burst and pressure tester machinery which today costs about €40,000 and for the fillers the hot water bath which costs € 0.5 million (with a line speed of 300 cans per minute). Alternative test methods for fillers as they are typically customised vary greatly (for fillers providing this information the range is € 250,000 – € 1.3 million in terms of Capex).

Operating Expenses (OPEX) - Operation and Maintenance: More specifically, yearly maintenance costs (in terms of Opex) per line for can manufacturers range between €25,000-€50,000 and for the filling industry between €50,000-€100,000. The final cost is a function of size although economies of scale do play a role depending on how many lines share the same equipment (typically 2-3 lines for can manufacturers). Fillers typically use one hot water bath per line. The maintenance costs are linked to the machinery for testing predominantly driven by the cost of machinery for burst and pressure testing for the can manufacturers and the hot water bath/alternative test method for the fillers. Maintenance costs can be quite volatile depending on the investment cycles of companies and the need to replace machinery.

Operating Expenses (OPEX) Personnel costs: Personnel costs (in terms of Opex) involve management, technical and administrative personnel/R&D personnel (namely for documentation). The quality managers and engineers are typically one per plant while technical personnel can range for can manufacturers ca. 0.5 FTE per line and for fillers from 0.5 to 2 FTE per line. Large companies also have a manager of regulatory affairs.

Recurrent costs – training: Recurrent costs in terms of training are also part of the ADD specific substantive costs. All companies organise trainings yearly which include many more aspects than ADD. The average time employees allocate to ADD specific training ranges for the can manufacturers from 5 to 10 days and for the fillers from ¼ to 2 days.

Administrative costs: The administrative costs associated to ADD are less than 1 FTE although for the filling industry the results are substantially more spread as indicated in the survey and confirmed by the targeted consultations with the industry. One of the reasons for this variability is CLP and the fact that many of the duties are seen as common (i.e. the labelling and artworks) which in practice means that you can have a very high number of above 10 FTE if you allocate the full administrative

personnel to ADD or very low if you allocated it fully to CLP. In the latter case companies note that the costs are insignificant and no incremental costs are born due to ADD.

Note that for none of the aforementioned cost categorisations did economic operators indicate potential for further simplification. What was stated instead was that ADD related processes have been optimised given the longstanding experience of the industry.

The mapping of costs and cost ranges for can manufacturers and fillers are detailed in Annex 12 (Figure 59 and Figure 60 respectively). Note that the valve manufacturers are not represented in the cost assessment given the difficulties in allocating costs to the ADD and the fact that in attempting to provide as accurate figures as possible confidential information would need to be disclosed. This argument was used by the small size of the industry in Europe.

7.4.1.2. Public authorities – ADD costs

The cost imposed by the Directive on national authorities is according to the interviews very low.

None of the Member State representatives were able to estimate the costs imposed by the ADD on national authorities in quantitative (number of FTE's) or monetary (euros) terms. However, they anonymously stated that the cost imposed by the Directive on their national authority was very low. Usually, only a few people were dealing with this Directive. Moreover, these people were also dealing with a number of other EU Directives, and thus ADD was only a small part of their responsibilities.

Given that the Directive was introduced a long time ago (in 1975), the costs in the past years constituted of the following two elements:

- **Transposing the amendments to the Directive:** As mentioned in Section 7.3.3.2, some interviewees mentioned that it would be even more efficient if there were fewer amendments (or bundled amendments) to reduce the burden on Member States.

- **Communication and guidance to industry:** While theoretically communication and guidance to industry could impose a cost on national authorities, the interviews revealed that practice this is hardly necessary and thus there is almost no real cost related to this element. In this respect, a few interviewees explained that the Directive had been in place for a long period, which meant that industry was generally familiar with the Directive. Moreover, the guidelines of FEA also contributed to awareness and understanding of the ADD.

7.4.2. Are the administrative and regulatory costs on the stakeholders proportionate to the results achieved? How do the costs borne by stakeholders compare to the benefits received? (Evaluation Question 5)

7.4.2.1. Benefits

The benefits of ADD are measured according to its contribution on health, safety and market operation as described under effectiveness (see Section 7.3). With respect to

health, aerosol products designed and manufactured, including a sound hazard analysis and respecting the provisions laid down in ADD, are considered as not harmful to health, if used correctly and foreseeable. Moreover, all cans that have been designed and manufactured according to ADD are burst proof up to temperatures of 50°C and not leaking. The latter is supported by economic operators in the interviews and survey who agree that ADD requirements proved to be successful in guaranteeing the safety of aerosol dispenser products and subsequently contributing to ensuring the safety of consumers. In terms of market operation, as a Single Market tool, ADD is said by economic operators to have fulfilled its purpose in facilitating the free movement of products within the EU (considered significant by 78% of survey respondents) and facilitation in exports to countries outside of the EU (considered significant by 27% of survey respondents and moderate or slight by 57% of survey respondents). Finally, as there are no provisions concerning shapes of packaging, material consumption or specific requests for certain materials, innovation in product and packaging design is possible, including also savings in material and therefore cost savings.

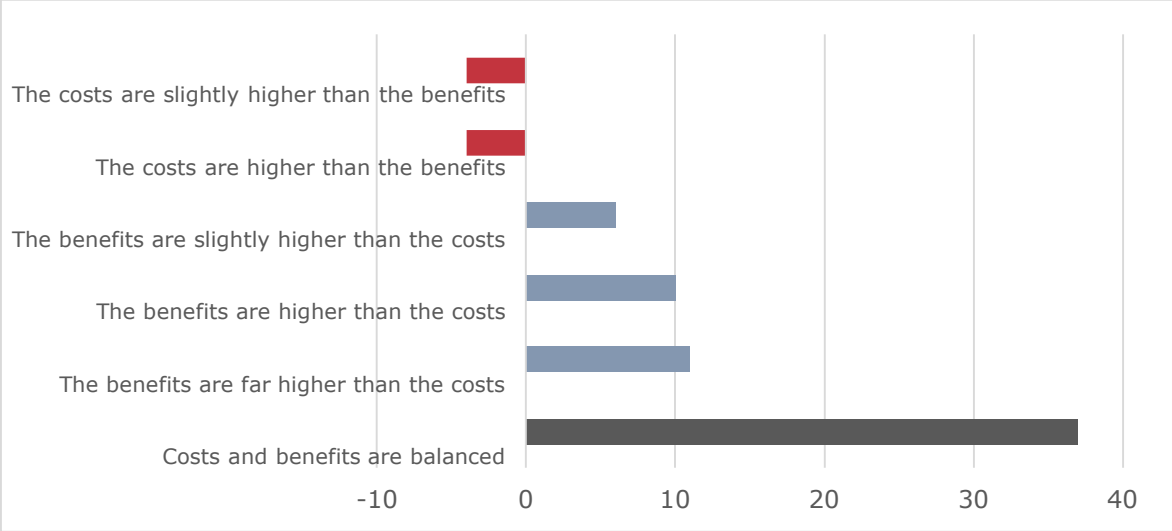
Note that the above is based on the opinions of economic operators. As no hard data on accidents is available nor appropriately granular trade data on exports and imports for aerosol products the validation and further quantification of the aforementioned statements is not possible. Nevertheless, given the consistency in the replies from stakeholders and the lack of any signals indicating the contrary there is no grounds to question the validity of the stakeholders' statements.

7.4.2.2. Economic operators - proportionality

The economic operators consider costs associated to ADD to be proportionate to the benefits. This was confirmed by the interviews and survey responses (Figure 36). According to the survey half of the survey respondents consider that costs and benefits are balanced. The rest of respondents, 15% of them indicate that the benefits are far higher than the costs and 14% indicate benefits as being higher than the costs, followed by 8% of respondents who consider that benefits are slightly higher. Only 12% of the respondents think costs are higher or slightly higher than benefits.

The only issue noted during the interviews related to non-EU competitors who commercialise products which do not comply with the Directive. This highlights the need for market surveillance and/or specific action in cooperation with the customs authorities. It was also stated that costs are always proportional to the benefits when the consumer safety is at stake which is one of the main objectives of ADD. Most of the respondents (14 out of 24) to the public consultation identified as economic operators/professional association consider the costs associated with the ADD to be proportionate to the actual benefits.

Figure 36 Proportionality (responses count)



Source: ADD evaluation survey, 2016.

7.4.2.3. Public authorities - proportionality

The cost related to ADD on **national authorities** was considered to be very low according the interviews with the public authorities. Member State representatives indicated that their national authorities generally spent very little time and effort on this Directive, especially compared to other EU Directives. Based on these low costs and the large benefits in terms of the EU internal market and consumer safety, all interviewees that we spoke to agreed that the costs on national authorities were proportionate to the benefits achieved.

7.4.2.4. Conclusion

Costs are seen as proportionate to the benefits achieved by both economic operators and national authorities. For economic operators, this is the result of on the one hand the industry's positioning regarding the attribution of costs to ADD, namely that the investments were made as part of industry and/or company standards and also as a response to the requirements of other legislations and on the other hand their opinion on the positive contribution of ADD on health, safety and market operation. For public authorities given the very low costs born for ADD, benefits in principle outweigh costs.

7.5. COHERENCE

7.5.1. To what extent are there overlaps or complementarities between ADD and any other EC or international legislation, e.g. in the area of transport? (Evaluation Question 12)

This evaluation question relates to the coherence between the Aerosol Dispensers Directive on the one hand, and any other (national, EC or international) legislation on the other hand. There are a number of additional legislations that may apply to aerosol dispensers. First, additional legislation could include national laws (Member States are allowed to apply provisions that are additional to those specified in the ADD). Second, aerosol dispensers may be subject to European or international legislation in other policy areas, such as chemical, environmental, or transport related legislation.

7.5.1.1. Coherence between ADD and other Community legislation

The ADD forms part of the **EU legislation framework for equipment presenting pressure hazard**. As described below, all Directives under this legislative framework pursue the same dual objective. They aim to guarantee the free movement of pressure equipment while at the same time ensuring a high level of safety.

In addition to the ADD, the legislative instruments of this framework include:

- **Pressure Equipment Directive = Directive 2014/68/EU (Pressure Equipment Directive from which Aerosols following 75/324/EEC are exempted –Article 1.2.(d)) based on 2014/68/EU (PED):** The Pressure Equipment Directive is one of the main EU product harmonisation Directives. It harmonises the national safety protection requirements related to pressure equipment and assemblies. The Directive requires that all pressure equipment and assemblies within the scope of the Directive must be safe when placed on the market and put into service. The Directive covers pressure equipment and assemblies with a maximum allowable pressure (PS[41]) of more than 0.5 bar. Pressure equipment, as defined by the Directive, are vessels, piping, safety accessories, and pressure accessories. Under the Directive, pressure equipment and assemblies below and above specified pressure and/or volume thresholds must satisfy specific 'essential safety requirements'. However, the Directive does not indicate how these requirements must be met (which is left to the responsibility of the manufacturers). Depending on the level of hazard, this conformity assessment may require the involvement of an independent third party (notified body). PED was recently aligned to the New Legislative Framework to simplify and improve the implementation of this Directive.[42]
- **Simple Pressure Vessels Directive 2014/29/EU (SPVD):** Based on this Directive, simple pressure vessels must not endanger the safety of persons, domestic animals, or property, when they are properly installed, maintained,

[41] PS is the maximum allowable pressure for which the equipment is designed, as specified by the manufacturer.

[42] Sources: Pressure equipment website on Europa: https://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/directive_en, PED 2014/68/EU : weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0068

and used. The SPVD applies to simple pressure vessels manufactured in series. The Directive defines a 'simple pressure vessel' as "any welded vessel subjected to an internal gauge pressure greater than 0,5 bar which is intended to contain air or nitrogen and which is not intended to be fired" (Article 1, SPVD). Similar to the PED, the SPVD requires the simple pressure vessels in its scope to comply with specific 'essential safety requirements'. These safety requirements concern in particular the materials that should be used, requirements for design, manufacturing, testing etc. The manufacturer is responsible for the conformity assessment of the products. Depending on the level of hazard, this conformity assessment may require the involvement of an independent third party (notified body).[43]

- **Transportable Pressure Equipment Directive 2010/35/EC (TPED):** This Directive sets out detailed rules on transportable pressure equipment. It comprises obligations for different types of economic operators (e.g. manufacturers, authorised representatives, importers, distributors, owners and operators). Products that are compliant with the Directive shall bear the 'Pi' marking.[44] It should be noted that, based on Article 2 of this Directive, aerosols are not included in the definition of 'transportable pressure equipment'. This means that although rules of this Directive do not apply to aerosols, transport legislation is applicable (see below point 7.5.1.3).

In addition to the framework for equipment presenting pressure hazards, there are **other pieces of European legislation** that are relevant to aerosol dispensers. Non-exhaustively, these include:

- **Seveso III Directive 2012/18/EC:** This Directive aims to prevent major accidents involving dangerous substances and to limit the consequences of such accidents for human health and the environment. The Directive covers establishments where this kind of accidents may happen, and categorises them into lower and upper tier establishments (depending on the amount of dangerous substances present). Filled aerosols are also to be considered under this Directive. Operators are obliged to take necessary measures to prevent accidents and to limit their potential consequences.[45]
- **Chemical Agents Directive 98/24/EC:** This Directive covers all industrial and commercial sectors. It lays down the minimum requirements for the protection of workers. It relates to risks to their safety and health arising from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents[46].

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[43] Source: Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0105&from=EN.

[44] Source: Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Atr0034.

[45] Source: Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC. Weblink: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:197:0001:0037:en:PDF.

- **ATEX Directives 2014/94/EU:** The Directives lay down requirements concerning explosive atmospheres. They aim to improve the safety and health for workers and define minimum technical requirements and conformity assessment procedures for equipment and protection systems intended for use in potentially explosive atmospheres.[46]
- **Nominal Quantities Directive 2007/45/EC:** This Directive on pack sizes deregulates package sizes, by freeing sizes from previous restrictions and precluding Member States from refusing, prohibiting or restricting the placing on the market of pre-packed products, with the exception of still wine, yellow wine, sparkling wine, liqueur wine, aromatised wine, and spirit drinks, for which a range of mandatory nominal quantities/volumes is set out. The Directive also waives the requirement in the Aerosol Dispensers Directive (75/324/EEC) for indicating the weight of contents of aerosol dispensers, requiring only the volume of contents to be indicated.[47]
- **CLP Regulation (EC) No 1272/2008:** This Regulation on classification, labelling, and packaging lays down EU-wide criteria that must be applied to determine whether a substance or mixture has properties that could damage human health or the environment. For products where this is the case, suppliers must communicate the identified hazards to the users (e.g. consumers).[48]

The interviews with Member State representatives and economic operators reveal that in principle, the ADD is coherent with most other Community legislation. However, one issue that was frequently mentioned by the interviewees related to the CLP Regulation (EC) No 1272/2009. They mentioned that the labelling requirements of CLP are not entirely consistent with those in the ADD. These overlaps refer to the hazard statements (CLP, Section 2.11)[49] and classification of flammable aerosols (CLP, Table 2.2.1 in Section 2.2.2. Classification Criteria).[50] None of the interviewees mentioned that it caused any major issues in practice. Although the ADD was inconsistent concerning label texts due to various translations, this problem should be solved now.

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[46] Source: Website European Commission, DG GROW on Equipment for potentially explosive atmospheres (ATEX). Weblink: http://ec.europa.eu/growth/sectors/mechanical-engineering/atex/.

[47] Source: Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC, and amending Council Directive 76/211/EEC. Weblink: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0045&from=EN.

[48] Source: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Weblink: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF.

[49] Aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 in the Annex to Directive 75/324/EEC. There are different translations of H222 which was different from translations known before etc. (e.g. Entzündbar vs Entzündlich) and other H-phrases and P-statements. Differences in relation to ADD ANNEX 1.8., 1.9., 1.10. and 2.2.

[50] Aerosols shall not be classified as flammable gases.

During one of the interviews with the economic operators it was pointed to a reference in ADD to the **inhalation of the spray** which overlaps with other sectoral legislations (i.e. Regulation EC No. 1223/2009 on cosmetic products). Art. 2 of ADD specifies that:

"Without prejudice to specific provisions of the Annex on requirements related to the flammability and pressure hazard, the person responsible for the marketing of aerosol dispensers is under an obligation to analyse the hazards in order to identify those which apply to his aerosol dispensers. Where appropriate, this analysis shall include a consideration of the risks resulting from the inhalation of the spray ejected by the aerosol dispenser under normal and reasonably foreseeable conditions of use, taking into account droplet size distribution in conjunction with physical and chemical properties of the contents. He must then design, construct and test it and, if applicable, draft special statements concerning its use, taking account of his analysis".

Nevertheless, it needs to be acknowledged that there is no practical consequence resulting from the existing provision. There is an expectation of many ADD users that the directive should cover all aspects concerning aerosols. In some ways ADD fulfils this expectation, pointing to the related issues. However, every user of the ADD needs to consult other directives, e.g. cosmetics regulation, CLP etc. to get the appropriate and correct guidance on how to do.

7.5.1.2. New Legislative Framework (NLF)[51]

Overall, a clear distinction should be made between aligning the ADD to certain NLF provisions (and keeping it as an old approach style piece of legislation) and a revision turning ADD into a full New Approach type piece of legislation. Aligning to NLF is related mainly about definitions and obligations. According to the latest version of the Blue Guide 2016[52], a product is placed on the market when it is made available for the first time on the Union market. The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, the operation is always labelled in legal terms as 'placing on the market'. Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.

One national representative argued that the Commission should consider aligning the Directive to the NLF. He/she pointed to the need of having technical requirements for safety (i.e. a list of essential safety requirements depending on the material used) as well as clarifying the involvement of actors and their roles (e.g. an important role for 'notified bodies').

7.5.1.3. Coherence between ADD and international legislation

In addition to the EU legislation described above, there are also a number of international agreements and conventions that are – at least in part – relevant to aerosol dispensers. For example, the United Nations **"Globally Harmonised System**

[51] See: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

[52] See: http://ec.europa.eu/DocsRoom/documents/18027

of Classification and Labelling of Chemicals" (UN GHS) harmonised the criteria for the classification and labelling of physical, environmental, health, and safety information on hazardous chemicals.[53]

There are also **several agreements and UN model regulations on the transport of dangerous goods** (including filled aerosol dispensers) via different modes of transport (road, rail, and air transport).

- The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) was developed by the United Nations Commission for Europe in 1957. It states that (with the exception of some excessively dangerous goods), good may be carried internationally in road vehicles subject to compliance with a set of conditions, among others on packaging and labelling as well as construction, equipment, and operation of the vehicle in carrying the goods.[54]
- Rules and requirements for the transport of dangerous goods by rail are laid down in the Convention concerning International Carriage by Rail (COTIF) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).[55]
- The International Civil Aviation Organisation (ICAO) developed a Convention on the safe transport of dangerous goods by air. Among others, this contains description of extreme conditions in transport. In addition to that the IATA Dangerous Goods Regulation (developed by the International Air Transport Association) contains provisions including a limit on aerosols in aircraft baggage.[56]

As presented above, the ADD is not fully independent. For an aerosol dispenser product to be sold in the EU it must meet the requirements of the ADD, the transport legislation, in addition to the legislation concerning storage in warehouses and possibly other legislation (e.g. related to food, cosmetics, etc.). In case of restrictions in transport legislation they need to be respected or adaptation in the transport legislation has to be made via the appropriate mechanisms at the proposal of a Member State and accepted internationally (beyond the EU competence).

The majority of Member State representatives that we spoke to felt that the ADD is largely coherent with relevant international legislation. The only issue that came up in some interviews related to the European Agreement on International Carriage of Dangerous Goods by Road (ADR). This concerned the definition of an "aerosol". The definition of ADD is stated in Article 2 and reads as follows:

"For the purpose of this Directive, the term 'aerosol dispenser' shall mean any non-reusable container made of metal, glass or plastic and containing a gas compressed,

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53 Source: United Nations "Globally Harmonised System of Classification and Labelling of Chemicals" (UN GHS). Weblink: https://echa.europa.eu/documents/10162/13643/questions_and_answers_clp_20090526_en.pdf

54 Source: Website UNECE. Weblink: http://www.unece.org/trans/danger/publi/adr/adr_e.html.

55 Source: Convention concerning International Carriage by Rail (COTIF). Weblink: http://www.otif.org/fileadmin/user_upload/otif_verlinkte_files/07_veroeff/99_geschuetzt/RID_2013_e/RID_2013_E.pdf.

56 Source: Website ICAO. Weblink: http://www.icao.int/safety/dangerousgoods/pages/technical-instructions.aspx.

liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state."

The definitions of the CLP (Clause 2.3.1) and ADR (in 1.2.1), however, state that an aerosol can eject the contents as gas as well: *"Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state."*

The interviewee argued that it is not clear whether cans ejecting the content as gas (like an air duster) would be considered an aerosol dispenser or not. The EC representative confirmed that within the current definition of ADD, also air dusters are considered to be covered by the ADD. In the context of CLP, there is a guidance document on mono-substance aerosol dispensers which is aiming at this type of product. This point could be addressed in a possible future revision.

During the interviews with the economic operators, it was noted that the ADR foresees 500 ml maximum capacity for plastic and glass. It is considered to be a major issue by the industry which is related to the forthcoming provisions for plastic aerosols. Comparatively, the US and the UK (British standard going into force after Brexit) accept the volumes up to 1,000 ml. In France, the plastic aerosols can be transported up to 500 ml, whilst it is not allowed in the ADD. Consequently, it is possible to transport such goods but not sell them. Overall, general requirements for aerosol dispensers set out in Article 6.2.6 of ADR are not fully in line with the current Annex of ADD (e.g. discrepancies concerning plastics).

The evaluation identifies a number of differences between the ADR and ADD, however, it should be noted that these issues did not represent problems in practice. For example, while the ADR allows lower temperature of tests (30°C) for certain products, the ADD mentions the alternative test. The ADR has also a specific exemption concerning hot-water bath test for aerosol products required to be sterile which does not exist in ADD. This could have a potential influence when selling the products outside the EU market. In this context, it has to be remembered that the alternative test method is costly because of a requirement to have in place the accredited quality system and the infrastructure installed. However, it is possible to produce aerosol products which do not comply with the ADD and transport them to countries outside the EU. While this might be possibly not clear at all, the ADD makes a clear reference to products to be placed in the EU markets.

None of the Member State representatives felt that the ADD contradicted with any of the other national legislation in place. Moreover, what existed before the transposition of the ADD was in most cases already very similar to the Directive.[57] None of the

[57] In some other cases, countries had barely any rules in place before the ADD.

Member State representatives indicated that their country had any rules or requirements on aerosols in place that went beyond what was required in the ADD.[58]

7.5.1.4. Conclusion

Overall, there is a general good degree of coherence achieved between the ADD and the other national, European and international legislations. The issues related to inconsistencies between the ADD and the CLP regulation have been resolved by now and no specific action is required in this regard. Overall, a clear distinction should be made between aligning the ADD to certain NLF provisions and a revision turning ADD into a full New Approach type piece of legislation. One of the arguments in support of the alignment to NLF is to better define the involvement of actors and their roles and have in place a list of safety requirements depending on the material used. Another argument is to modernise the format of the Directive which currently follows the old approach. On the other hand, the interviewees pointed that aligning to NLF would impose significant cost on economic operators as well as Member States.

With regard to the transport of dangerous goods, the existing differences do not represent any major problems in practice because the ADR accepts aerosol products which comply with the ADD provisions. In contrast, an aerosol which only complies with the ADR but not with the ADD could not be marketed in the EU.

[58] It should be noted that we were not able to check this for those Member States that did not take part in an interview, or only provided limited written responses.

7.6. EU ADDED VALUE

7.6.1. What is the added value resulting from ADD, compared to what could have been achieved at national level? To what extent do the issues addressed by the ADD continue to require action at EU level? (Evaluation Question 3)

The evaluation criterion EU Added Value is about the additional value of this Directive compared to what could be achieved at national level. It also assesses the extent to which the issues addressed by the ADD continue to require action at EU level (in other words, what would happen if the Directive was withdrawn?).

7.6.1.1. Additional value of ADD in relation to the EU internal market

Based on the evidence collected as part of this evaluation, we can conclude that the Directive has a clear additional value compared to policies or legislation at the national level. The consulted public authorities and industry representatives felt that the Directive added value in various different ways, which could not be achieved by individual countries or private actors alone:

- **Better functioning of the EU internal market:** The Directive helps the EU internal market to function more smoothly. Without the common rules and requirements at EU level, it would be much harder for companies to export their aerosol products to other countries. Some stakeholders mentioned that for large multinationals it would be costly to adapt their products and labels to the various national requirements. Others referred to SMEs, and the fact that it would be harder for them to even enter other (new) markets. None of the Member States for which we were able to conduct interviews had additional (stricter) rules or requirements than the ADD.

- **Broad recognition of safety requirements:** The ADD has consistent and broadly recognised safety requirements that allow for the free marketing of aerosol dispensers in the whole of the EU. Moreover, compliance to the Directive is also recognised and accepted by a number of non-EU countries.

The industry representatives highlighted an aspect of **legal certainty for companies**. It was noted that since 1975 the ADD has been a relatively stable Directive for economic operators. By harmonising the rules and requirements related to aerosol dispensers, the Directive provides a degree of legal certainty across all Member States that is important to help stimulate competitiveness and innovation in the sector.

The industry stakeholders consulted for this evaluation also suggested that non-harmonised national legislation and differences in enforcement would hinder the free movement of aerosol dispenser products and drive the costs and increase the administrative burden for the industry. For example, an economic operator would face significant costs from changed requirements (from the current status quo), having to adopt its procedures, adjust to various national legislations across the Union, etc.

Moreover, a repeal of ADD would have detrimental effects on the competitiveness of European aerosol industry. The cost of aerosol products would increase because of compliance to varying national requirements. For example, if one country applied the US standard which requires a minimum wall thickness and the same pressure test requirements as described in ADD the costs of aerosol cans will increase.

Administration would be significantly more complex and costly. In conclusion, the large majority of stakeholders (including public authorities and economic operators) felt that if there is a framework in place which works well there is no need of changing it and taking unnecessary risks.

7.6.1.2. Additional value of ADD in relation to consumer safety

The evidence of this evaluation also points to a clear added value of the ADD in relation to consumer safety. The Directive provides safety requirements that are generally considered adequate by all national authorities and industry representatives we spoke to. These requirements ensure a **high level of consumer safety across the Union.**

As pointed out by a number of stakeholders, the safety of aerosol dispensers is of paramount importance to the whole sector. A failure or incident of one product of a specific brand could jeopardise the reputation of the entire industry. The requirements guarantee the safety of products in the market and the observed failure rate is extremely low. It was pointed that without ADD safety incidents would be more likely to occur.

It should be noted that while the aerosol industry in Europe would most likely not take any risks when it comes to the safety of their aerosol dispensers (due to the reputational risks involved), there is more concern among economic operators when it comes to aerosol dispensers that are imported from countries outside the Union.

7.6.1.3. Conclusion

This evaluation concludes that the ADD has clear additional value compared to what could be achieved at national level, in respect of facilitating the internal market and ensuring consumer safety. Non-harmonised national legislation and differences in enforcement would hinder the free movement of aerosol dispenser products and drive the costs and increase the administrative burden for the industry. Moreover, a repeal of ADD would have detrimental effects on the competitiveness of European aerosol industry. The cost of aerosol products would increase because of compliance to varying national requirements. Also, the likelihood of incidents with users would be significantly larger, according to the majority of consulted stakeholders.

8. CONCLUSIONS

8.1. BACKGROUND

This evaluation assesses the relevance, effectiveness, efficiency, coherence, and EU Added Value of the Aerosols Dispensers Directive (75/324/EC). More specifically, it examines the extent to which the Directive contributed to the free movement of aerosol dispensers in the internal market and the safety of consumers in respect of hazards related to pressure, flammability, and inhalation. While the Directive exists since 1975, the present study represents the first formal evaluation of the ADD.

The conclusions of this evaluation are based on a broad range of qualitative and quantitative sources of information. We conducted extensive desk research, in total 52 interviews with various stakeholder groups (including national authorities, economic operators, professional associations, consumers and their associations), an online survey with economic operators, a cost-assessment of specific companies in the sector, and a broad EC stakeholder consultation to which all potentially interested stakeholders could respond. The combination of these sources provided useful insights into the functioning of the Directive in practice, and allowed us to provide comprehensive answers to all evaluation questions.

Nevertheless, there are some issues and caveats that need to be kept in mind when interpreting these results. First of all, the findings are mostly qualitative in nature (consistent data on the number of aerosol dispensers stopped at EU borders, number of aerosol dispensers banned from the EU market or complete reports of aerosol incidents at EU level do not exist). Moreover, attributing the results directly to the ADD (e.g. in case of identifying causal relations between the Directive and performance of relevant industries in the aerosol value chain) is problematic given the large number of external factors that play a role. Due to the lack of independent and comparable data, the evaluation had to rely to a large extent on stakeholder views and opinions. It has been clear from the start that many of these stakeholders did not necessarily have an interest in making any substantial changes to the Directive, not the least because of the cost that could result from making such changes. Having said this, the high degree of consistency of the findings from all stakeholder groups (even national authorities and consumer organisations) indicates that the overall positive conclusions of this evaluation can be considered well-founded and reliable.

8.2. RELEVANCE

The findings of this evaluation confirm that the dual objective of the ADD is still highly relevant to the problems and needs in the field. Product safety of aerosol dispensers and a smooth functioning of the EU internal market are still seen as important objectives to be pursued and safeguarded at EU level.

There have been several policy developments and technological advancements in the field, including the development of new materials for aerosols (plastics), alternative propellants, new products based on innovative technologies, development of new valves and dispensing systems, etc. Despite the fact that the Directive is relatively old, the vast majority of stakeholders were of the opinion that it remains relevant. The amendments to technological progress have played an important role in keeping up with these developments. Article 5 of the ADD lays down the procedure to adapt the

Annexes of the ADD to technical progress. While this procedure was considered lengthy, in general national authorities felt that this was justified by the safety aspects in question.

While not a direct objective of the Directive, this evaluation also assessed whether the objectives of the ADD helped to stimulate innovation. In this respect, there was a consensus that the Directive does not directly stimulate innovation but does not hinder it either. The conditions and requirements of the Directive are sufficiently flexible for this purpose.

8.3. EFFECTIVENESS

Overall, the evaluation found the ADD to be effective. While the achievement of the Directive's objectives is hard to measure and subject to a multitude of external factors (beyond the control of the ADD), a vast majority of the stakeholders believed that it had made significant contributions to the safety of users and the smooth functioning of the EU internal market. The Directive has been successful in harmonising rules and requirements in relation to aerosol dispensers between EU Member States, thereby facilitating intra-Union trade and guaranteeing a strict safety level for users/consumers. There had been rarely any cases in which compliant aerosols were refused in Member States on the basis of reasons related to the Directive. Moreover, there had been very few reported incidents with aerosol dispensers. The incidents that did take place were often due to misuse of products. Stakeholders felt that the Directive, despite its age, had managed to keep up with technological developments in the field.

In terms of the wording and content of the Directive, the vast majority of the stakeholders (public authorities and industry representatives) indicated that the provisions, requirements, and methods outlined in the annexes of the Directive are effective. Very few stakeholders identified any inconsistencies, out-dated provisions or requirements. Moreover, the vast majority of Member State representatives felt that the wording and content of the Directive is sufficiently clear and appropriate. While the Directive in itself is very technical in nature (especially the annexes were considered to be very detailed), generally industry knows and understands the Directive very well.

While the overall content of the Directive was considered to be clear and appropriate, there were some issues that did come up during the evaluation. Issues that were mentioned by more than one industry stakeholder are discussed below:

- Special provisions on plastic aerosol dispensers: There was a disagreement between stakeholders in relation to the appropriateness and relevance of Annex Section 5 – the special provisions applying to plastic aerosol dispensers. In total, 43% (38 responses out of 97) of the survey respondents felt that provisions related to volume limit were no longer appropriate or relevant, while 24% (21 responses out of 97) did feel these provisions were still appropriate and relevant and 33% (29 responses of 97) of respondents did not know. This is likely related to the on-going discussions to adapt these provisions. The inappropriateness of the provisions applying to plastics was predominantly raised by aerosol fillers.
- Alternatives to the hot water bath test: The alternative test methods to the hot water bath test were a frequently discussed topic, especially among economic operators. There are a number of issues related to the alternative tests. They

were considered to be very expensive (due to the large investments due to changes in the production line and supply chain), there was a need to obtain permission from the relevant national authorities.

- Labelling on flammability: Some economic operators criticised the requirement that the percentage of flammable content needed to be labelled on products even if those products were classified as being non-flammable (Article 8 1a of the ADD). At the same time though, they all indicated that this did not constitute a significant problem in practice.

It should be noted that while these issues were mentioned by some stakeholders, this did not lead them to doubt the overall effectiveness and clarity of the Directive. The overall conclusion emerging from this evaluation is that the identified issues did not cause any serious problems to the ADD's effectiveness in practice. The issue of plastics though was considered to be more serious by the economic operators consulted as part of this evaluation.

The evaluation did not identify any significant barriers in the effective transposition of the ADD into national legislation. There have also been very few (potential) barriers to the application of the Directive due to differences between Member States in terms of the rules and requirements that economic operators have to comply with when using alternative test methods, the derogation from labelling weight (2007/45/EC Nominal Quantities Directive), and the clarity of paragraphs of the annexes of the Directive which could be even easier to read. However, none of the barriers were considered significant problems, nor was there enough evidence to show that issues actually hinder the effective application of the Directive. The evaluation did not find any evidence of any major differences in the impact of ADD on different stakeholder groups.

Lastly, the evaluation found one positive unexpected/unintended impact, which is the fact that the rules and requirements of the Directive are used and taken over by a large number of non-EU countries, such as Brazil, China and India (with the exclusion of two important countries, namely the US and Canada).

8.4. EFFICIENCY

Aerosol companies (namely can manufacturers and fillers) unanimously pointed out that the investments were made as part of industry and company standards and not exclusively in response to the ADD. Moreover, all stakeholders participating to the more detailed consultation on costs stated that investments made to produce ADD compliant aerosol products were made before the period under consideration for this evaluation (2005-2015) unless new investments in new lines/plants were made. Also, no issues aroused with respect to affordability nor the necessity for simplification.

Irrespective of the attribution of costs to ADD, the costs for aerosol can manufacturing companies and fillers are predominantly CAPEX (Capital expenditures), OPEX (Personnel, Operation and Maintenance), and Recurrent costs namely training and Administrative costs.

Aerosol can manufacturers

To set up a new aerosol can plant the main ADD related capital investment is the **burst and pressure tester machinery** which today costs about €40,000 in terms of

Capex. The burst and pressure machinery can be shared by more than one production line as it is an offline test (i.e. lab testing during which a sample of cans is removed from the line and tested e.g. 2-3 cans per hour). In terms of personnel costs the test is performed by the quality control team managing a rotation (to accommodate for the multiple production lines). The cost is estimated at approximately €1 per hour of production per production line. The annual cost of maintenance accounts for roughly about €1,000 per machine. More tests are performed by companies either as a result of Good Manufacturing Practice or upon request from their clients.

Aerosol fillers

To set up a new aerosol plant the main ADD related capital investment is for the equipment for the final inspection (the **hot water bath test or its alternative test methods).** Today the investment cost for a hot water bath with a line speed of 300 cans per minute is € 0.5 million. Typically, there is one hot water bath per line of production. In terms of personnel the test requires supervision from the technical staff per line. The maintenance includes the cost for heating and maintaining the water bath which is about € 50,000 per line per year.

In terms of administration the activities undertaken include the qualification of aerosols[59], verification in production, administration of artworks, printing of labels and traceability. The administrative costs implied however cannot be solely attributed to ADD and companies explain that no incremental costs are made due to ADD given the need to perform the activities as part of GMP and CLP. Irrespective of this the total cost could be on average 0.5 FTE per plant but can go as high as 10 FTE per plant for large companies.

Differences between companies and the investments made can vary substantially. This is because:

- The testing machinery of today varies substantially in price depending on its different functionalities, for instance can testers can vary from 200,000-700,000.
- The speed of each production line (i.e. the number of cans/aerosols per minute) influences its cost i.e. the higher the speed the higher the investment. Economies of scale however play an important role for the large producers of aerosols. Thus, the higher the production the more sensible it becomes to aim for a fast line with higher investment costs.
- The equipment per aerosol line varies for some product categories. This is particularly the case for food aerosols and some pharmaceuticals/cosmetics. More specifically in some cases, the hot water bath test is destructive for the content of the aerosol can and cannot hence be applied on all cans. For these product categories, alternative test methods are necessary and the use of statistical sampling is not an ADD compliant test method.
- The use of an alternative to the hot water bath testing. Among the companies participating to the cost assessment only two are using alternative leak testing

[59] Qualification means testing potential cans concerning mechanical integrity, conduction of stability tests with filled and pressurized cans etc. respecting the requirements laid down in ADD.

equipment. Among the main advantages brought forward by the company which is using both systems, is the fact that the alternative testing method does not reduce the production speed as it is an automated inline test. It also requires less technical personnel.

It was not possible to validate the costs for SMEs with the detailed cost assessment as none of the invited SMEs accepted to be part of the evaluation. The assessment from the survey with economic operators indicated costs as being less than 5% of total production costs. Nevertheless, the costs identified for large companies as listed in Annex 12 correspond to the costs borne by SMEs bearing in mind the aforementioned reasons for the variability in costs borne by different companies. One main difference is that SMEs typically do not have a dedicated employee dealing exclusively with regulatory issues as indicated by the companies participating to the detailed cost assessment.

Benefits were accounted for as ADD's contribution on health, safety and market operation as described under effectiveness. The great majority of economic operators considered ADD's contribution to be significant.

Finally, according to economic operators and national authorities costs were proportionate to the benefits achieved.

8.5. COHERENCE

At national level, the public authorities that we spoke to explained that the rules and requirements of the Directive were directly transposed into national legislation. None of them maintained additional rules or requirements related to aspects that are regulated by the ADD. Therefore, we can conclude that the Directive was fully coherent with national legislation in Member States.

At EU level, the ADD forms part of the EU legislative framework for equipment presenting pressure hazard. All Directives that fall under this framework pursue the same objective, namely guarantee safety and to facilitate the internal market. Other relevant EU legislation includes the Pressure Equipment Directive (2014/68/EU), the Simple Pressure Vessels Directive (2014/29/EU), and the Transportable Pressure Equipment Directive (2010/35/EC). The evaluation found that the ADD is coherent with these other Directives.

In addition, there are also a number of other pieces of legislation that are relevant at EU level (including the Seveso III Directive (2012/18/EC), the Chemical Agents Directive (98/24/EC), the ATEX Directive (2014/34/EU), the Nominal Quantities Directive (2007/45/EC), and the CLP Regulation (EC No 1272/2008). The ADD was found to be coherent with these pieces of legislation. In other words, we did not identify any overlaps or contradictions between the ADD and these other pieces of legislation. One exception to this, however, was the CLP Regulation. With the introduction of this Regulation on the classification, labelling, and packaging of products in 2008, some overlaps and inconsistencies were created with the labelling criteria that were laid down in the ADD. These inconsistencies mainly related to the hazard statements and classification of flammable aerosols. While some stakeholders felt that these inconsistencies should be addressed, a majority of stakeholders indicated that so far they had not caused any major problems as most economic operators were aware of the fact that more specific Community law always takes

precedence. In other words, while legally speaking there would not necessarily be a problem, it could be argued that such inconsistencies would ideally be resolved in order to avoid any confusion. It should be noted that adaptations to technical progress of the CLP Regulation and the ADD have in the meantime resolved these issues.

During one of the interviews with the economic operators it was pointed to a reference in ADD to the inhalation of the spray which overlaps with other sectoral legislations (i.e. Regulation EC No. 1223/2009 on cosmetic products). Nevertheless, it needs to be acknowledged that there is no practical consequence resulting from the existing provision.

Recently, some of the discussions around the ADD have revolved around the question whether the ADD should be aligned with the New Legislative Framework (NLF). One national representative argued that the Commission should consider aligning the Directive to the NLF. However, the evaluation also found that such an exercise could be very expensive for economic operators (who would face potential changes in their production and labelling processes and legal uncertainty if the Directive were to be fundamentally changed) and for national authorities (who would have to transpose the new Directive into their national legislation). An impact assessment of a potential NLF alignment was beyond the scope of this evaluation.

At international level, the ADD was found to be largely coherent with the existing agreements and conventions (e.g. the Globally Harmonised System of Classification and labelling of Chemicals). One issue that did come up related to the European Agreement on International Carriage of Dangerous Goods by Road (ADR). This agreement maintains a somewhat different definition of what constitutes an 'aerosol'. While the ADR (and CLP) definitions include dispensers that eject content as gas (like air duster), the definition of the ADD does not mention this. In practice, it was argued that this did not constitute a real problem since countries using ADR also accept products that comply with the ADD.

8.6. EU ADDED VALUE

Lastly, the evaluation assessed the additional value of the ADD compared to what could have been achieved at national or even regional level. It shed light on the question of why action should be taken at the European level and what would happen if the Directive were to be discontinued.

The fact that the Directive aims to facilitate trade between Member States already demonstrates the potential additional value that harmonisation at EU level could bring. Indeed, the better functioning of the internal market was seen by most of the consulted public authorities and industry representatives as one of the most obvious and most important added values of the Directive. They considered that there was a clear added value of harmonisation of safety, testing and labelling requirements. In essence, companies complying with the Directive do not have to worry about varying safety requirements in different Member States, delays due to additional checks or controls when exporting aerosols to other Member States, or different labelling requirements. This was different from the situation before 1975, when each Member State had their own rules and requirements in these respects. The fact that the Directive eliminated these barriers provides legal certainty and thus helped to stimulate growth and competitiveness of the aerosol industry.

The industry representatives felt that non-harmonised national legislation and differences in enforcement would hinder the free movement of aerosol dispenser products, hamper innovation, drive the costs and increase the administrative burden for the industry. Moreover, a repeal of ADD would have detrimental effects on the competitiveness of European aerosol industry. The cost of aerosol products would increase because of compliance to requirements which may diverge from one Member State to another. In addition to the benefits in relation of intra-EU trade, the evaluation found that the Directive helped to facilitate trade with non-EU countries. The fact that the rules and requirements are broadly used and acknowledged by a number of non-EU countries helps EU companies to export their products even outside the Union.

The evaluation found that there is also a clear EU added value in relation to consumer protection. The Directive provides minimal safety requirements that are generally considered to be solid according to all public authorities and industry representatives we spoke to. These minimal requirements help to ensure a high level of consumer safety in relation to aerosol dispenses across the Union. As pointed out by a number of stakeholders, the safety of aerosol dispensers is not only of interest to consumers of aerosol dispensers, but also of paramount importance to the whole sector. A failure or incident of one product of one brand could jeopardise the reputation of the entire industry. It should be noted that while the aerosol industry in Europe would most likely not take any risks when it comes to the safety of their aerosol dispensers (due to the reputational risks involved), there is more concern among economic operators when it comes to aerosol dispensers that are imported from countries outside the Union.

8.7. OTHER

Other relevant information from this evaluation include the following topics:

- Plastics: aluminium and tin plate can manufacturers are following closely the legislative developments for plastic aerosols. The attractiveness of plastic aerosols in terms of the variety in shapes (e.g. for purely aesthetic reasons but also ergonomic designs for the disabled or elderly), the possible economies of scale for the larger containers and the ongoing R&D efforts to address safety aspects explored by the filling industry justify concerns from aluminium and tin plate can manufacturers. Note that fillers' main driver for the selection of material of aerosol products is consumer needs and even if costs to shift to plastic aerosol dispenser production lines are high, they are not prohibitive given the expected demand (assuming that the current limit of the maximum content for plastic aerosol dispensers would be increased). A revision hence of ADD on the current restrictions on plastic aerosols related to size, filling volume and pressure range is expected to impact can manufacturers.
- R&D and Innovation is a critical factor for future growth given environmental concerns, prices of raw materials and increased competition from overseas. EU companies are among the market leaders and lead on major innovations that shape the future of the aerosol industry. Overall, ADD has not been found to hinder innovation activity and is not impacting the cost of innovation.
- The EU market is an attractive growing market which means that aerosol industries from other continents have an interest in penetrating the EU market introducing more competition to local providers. On the other hand, European industries face difficulties competing with local providers overseas due to the high prevalence of local aerosol dispenser manufacturers in China and India in light of easy access to raw materials and consumables along with low production costs in Asia Pacific. The ADD although it has no impact on the latter factors of competitiveness due to it being globally recognised it is seen as a competitive advantage of European companies in their expansion overseas.
- Importation of counterfeited aerosol products, or aerosol products non-compliant to ADD is at the moment not highly ranked on the priority list of the customs services. Rising importance of e-commerce portals in Europe may however create additional challenges in the future. The issue of counterfeiting is addressed in IPRED the enforcement of intellectual property rights directive of the European Commission (2004/48/EC)[60] and not ADD.

[60] See: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0048R%2801%29

9. ANNEXES

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ANNEX 1 – STUDY CONTRACT - TERMS OF REFERENCE

Task specifications for the assignment:

Evaluation of the Aerosol Dispersers Directive 75/324/EC

- Background

- Description and objectives of the Aerosol Dispensers Directive 75/324/EC

The Aerosol Dispensers Directive (ADD) (75/324/EEC) [61] is one of the oldest EU legislations related to product safety. The directive defines aerosol dispensers as: "any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

An aerosol dispenser is composed of a container, an actuator (button), a valve, a propellant and the actual active product. The container is made from metal, plastic or glass and holds the propellant and the product. Within the container, the propellant exerts pressure on the product. When the actuator is pressed by the user, the pressure will force the product out of the container.

The ADD includes specific requirements related to flammability and pressure hazard as well as a general obligation to analyse all hazards which could apply to a particular aerosol product. Based on such an analysis, the aerosol dispenser is designed, constructed and tested accordingly and meets the appropriate safety requirements concerning its use.

Europe is a world leader in the sector of aerosol dispensers which concerns mainly consumer products (large volumes of products in various sectors: cosmetic, healthcare, food, etc.) although there are also a substantial number of products for professional use on the market (e.g. construction products, paints, lubricants, etc.).

The ADD has two objectives which are fulfilled by technical harmonisation at the European level:

- Guaranteeing that products within the scope of the directive will be safe for consumers and other users in respect of hazards related to pressure and where appropriate, flammability and inhalation.

- Securing the free movement of aerosol dispensers throughout the EU. As such, Member States must allow the marketing on their territory of aerosol dispensers that comply with ADD.

ADD is a so-called "old approach" directive including very detailed technical requirements regarding labelling, manufacturing, testing, etc. Whereas such legislative style may facilitate the application, it has the drawback that a change to the legislation itself is

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[61] COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) (OJ L 147, 9.6.1975, p. 40) Consolidated version on EURLEX: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01975L0324-20130409&rid=1

needed to keep pace with technical progress. Such changes require a substantial administrative/legislative process and may hamper innovation.

It should be noted that additional national, European and/or international legislation may apply (chemical, environmental, transport, etc.) possibly in combination with sector specific legislation (cosmetics, pharmaceutical, foodstuff, etc.).

The ADD has been a forerunner for regulation in this field and some third countries adopted legislation which is equivalent or similar to the ADD. This has been to the advantage of European industry and facilitated export. The European Aerosol Federation also developed a vast collection of standards some of which are de facto standards in this industry in Europe but are also widely used and accepted in third countries.

Within DG GROWTH Unit C3 is responsible for the management of the ADD in cooperation with the Working Group on Aerosol Dispensers composed of representatives of the Member States. The industry association FEA[62] is represented as observer and acts as the main interface with the various industrial stakeholders. Other sector specific associations such as for example Aerobal[63] are also invited to meetings of the Working Group.

- Rationale for and purpose of the evaluation

- Rationale for the evaluation

Since its adoption in 1975, the ADD has not been subject to a formal evaluation. The overall perception of the performance of the Directive is positive. There are hardly any reported safety issues over the last ten years and there are no cases of barriers to trade reported to the European Commission. The sector seems to operate smoothly within the current legal framework. A rigorous evaluation involving all interested parties should assess whether this perception corresponds to the real situation.

Although there has not been a full revision since its adoption in 1975, the ADD has been modified three times for adaptations to technical progress in accordance with Article 5 of the Directive (in 1994, 2008 and more recently in 2013). These modifications were of technical nature to accommodate changes in technology (e.g. safely increasing the pressure in the containers resulting in better performance of the products) or to ensure coherence with other legislation (e.g. related to the labelling requirements derived from the CLP Regulation[64]).

Recently and in the context of further requests to adapt the ADD to technical progress, the question was raised by national authorities whether the ADD is still adequate in its current format and whether it should not be modernised to bring it in line with the New Legislative Framework which is also applied for other product safety legislation. It should be assessed whether the ADD provides the mechanisms to deal with the changing business environment (need to better identify responsibilities of economic operators,

[62] FEA Fédération Européenne des Aérosols / European Aerosol Federation (http://www.aerosol.org/)

[63] AEROBAL is the international organisation representing manufacturers of aluminium aerosol cans (http://www.aerobal.org/)

[64] REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures

procedures to deal with non-compliant products, enforcement and market surveillance, etc.).

- Purpose of the evaluation

The main objectives of the evaluation are to assess: effectiveness, efficiency, coherence, relevance and EU added-value of the Aerosol Dispensers Directive. Analysis of environmental, social and economic impacts should also be covered, if relevant. The evaluation shall also assess the competitiveness of the European aerosol dispensers' industry on a global scale.

- Scope of the evaluation

The scope of the evaluation will be an overall evaluation of the Aerosol Dispensers Directive. As this is the first formal evaluation of the directive since its adoption, all aspects related to the implementation should be examined systematically.

Although the perception of the functioning of the Directive is positive, the evaluation shall include an assessment of the implementation identifying possible weaknesses and identify areas which could be improved to cope with the current and future challenges. The results of the evaluation shall be used in future policy decisions.

The evaluation should cover all Member States, for the period 2005 to 2015 and identify potential issues due to differences in implementation at national level.

The study should focus on aspects regulated by the ADD itself. The ADD only addresses some of the aspects related to the safety of an aerosol dispenser (pressure hazard and to a lesser extent and if applicable flammability and inhalation). It will be important to keep this in mind to avoid that the evaluation loses focus and enters into areas covered by other specific legislation. During the whole evaluation process (for example literature review, data collection, survey, public consultation, interviews and analysis), a clear distinction should be made between aspects in the scope of the ADD and those governed by other legislation which are outside the scope of this evaluation.

Some requirements in ADD directly relate to requirements or restrictions defined in other legislation, this is in particular the case for transport and testing requirements defined at international level in transport legislation or in chemical legislation (e.g. with regard to labelling). It should be verified when testing for the coherence criterion whether the relationship between ADD and other legislation is sufficiently clear and whether there is scope for simplification in ADD. Also as a result of the evaluation, potential gaps in the legislation could be identified.

Although aerosol dispensers are rather simple products, a high number of different and specialised economic operators, including SMEs, are involved in the development, manufacturing and distribution of the final aerosol product. There is a large variety of products, both for consumer and professional/industrial applications. The economic operators in the value chain may have different or competing interests:

1. manufacturers of components (containers in tin plate, aluminium, glass or plastic, valves and caps);
2. the manufacturers of specialised machinery (for filling, labelling, testing);
3. a wide variety of companies developing the contents of the aerosol dispensers (pharmaceutical, cosmetics, food, paint, etc.);
4. producers of propellants;

5. professional fillers;
6. companies active in the branding, distribution and sales along the different distribution channels to consumers and professional users;
7. test laboratories;
8. operators involved in storage, transport and recycling.

Primary stakeholders are the economic operators and their professional associations, the public authorities and the users of these products (consumers or industrial users and their professional associations). Particular attention should be paid to SMEs.

- Commissioning body and user(s) of the evaluation

This evaluation is commissioned by Directorate Industrial Transformation and Advanced Value Chains, Unit C3 Advanced Engineering and Manufacturing Systems of DG Internal Market, Industry, Entrepreneurship and SMEs (DG Growth). Other Commission services involved with these activities will participate in the study: DG Transport and Mobility, DG Environment, DG Justice, Secretariat General and the evaluation unit in DG Growth.

Other parties involved in the exercise are the national authorities in charge of implementation and enforcement of the Directive, representatives of the industry (the European Aerosol Federation and European associations representing specific stakeholder groups) and user/consumer organisations.

The results may be shared with other interested bodies inside and outside the European Commission.

The evaluation report and its quality assessment performed by the Steering Group will be published on the DG Internal Market, Industry, Entrepreneurship and SMEs evaluation internet site and the sector website related to the ADD (http://ec.europa.eu/growth/sectors/pressure-gas/index_en.htm). The final report will also be communicated to the Commission's central evaluation services and published on their web site.

- Relevant documentation and information

The following documentation is available for the contractor:

1. ADD website (http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/add/index_en.htm) including a consolidated version of the ADD (link on ADD website/ link to EURLEX) and the impact assessment study on the Adaptation to Technical Progress of the Aerosol Dispensers Directive;
2. CIRCABC interest group related to ADD including minutes / documents / Powerpoint presentations of meetings of the Working Group Aerosol Dispensers Directive;
3. RAPEX database (information on non-compliant products);
4. Website of European Aerosol Federation FEA (www.aerosol.org) includes valuable information on the sector including basic market data;
5. In the context of the evaluation, it is also necessary to have a good understanding of the New Legislative Framework. More information can be found on: http://ec.europa.eu/growth/single-market/goods/index_en.htm .

- Objectives and tasks of the assignment

- Evaluation objectives

The overarching objective of the study will be to evaluate the **effectiveness, efficiency, coherence, relevance and EU added-value** of the Aerosol Dispensers Directive. Analysis of environmental, social and economic impacts should also be covered, if relevant.

- Evaluation tasks

The specific tasks of the evaluator are to identify, test and apply methodologies to collect, analyse, judge and present primary and secondary data that address the main evaluation objectives and answer the evaluation questions.

It shall at minimum include:

1) An assessment of the implementation of the directive in all Member States, identifying possible weaknesses.
2) An analysis of the European aerosol dispensers market, how it has evolved in terms production, intra and extra community trade and with regard to its competitiveness.
3) To propose a comprehensive, robust and clear methodology to collect and analyse data aiming at assessing the **effectiveness, efficiency, coherence, relevance and EU added-value** of the Aerosol Dispensers Directive and, if relevant, the environment, social and economic impacts. The methodology shall identify the means to answer the evaluation questions set out below. The evaluators shall be free to elaborate further evaluation questions if they deem it necessary. The final approach will be submitted for the approval of the steering group at the inception phase.
4) To collect pertinent data in accordance with the methodology agreed. Data collection should cover secondary as well as primary data gathered during the fieldwork. Purchase of commercial datasets to satisfy the information needs to address evaluation questions might also be required (appropriate budget should be allocated in the financial proposal).
5) To analyse the data collected in accordance with the methodology agreed. Data analysis will include the selection of a set of appropriate indicators to assess the selected evaluation criteria.
6) To answer the evaluation questions and present the evaluator's conclusions regarding the selected evaluation criteria on the basis of the evaluation findings in relation with the purpose of the exercise.
7) To present findings and conclusions in a final evaluation report according to the requirements listed below.
8) To present the findings and conclusions to the Commission services and/or stakeholders in a final workshop.

- Evaluation questions

The questions below are **examples** which could be adapted following the initial research and discussion with the steering group.

- what is the origin of the intervention and what were its objectives?

- what progress has been made over time?

- what is the current situation for different stakeholders and how are they affected by the directive? If relevant, what are the environment, social and economic impacts of the Directive?

Effectiveness

- To what extent has ADD contributed to an effectively operating internal market for the products in its scope?
- To what extent has ADD contributed to the safety of the products in its scope?
- To what extent has the procedure allowing to adapt the annex of the Directive to technical progress been useful for effective implementation?
- What are the barriers to effective application of the ADD if any?
- Are there any aspects/means/actors that render certain aspects of ADD more or less effective than others, and – if there are – what lessons can be drawn from this?

Efficiency

The evaluation shall include a deep analysis of the costs and benefits. The Commission is placing an increasing focus on the quantification of costs and benefits, as reported in the Better Regulation package[65]. The contractor is expected to include in the efficiency section a quantitative analysis of the administrative and regulatory costs and benefits triggered by the directive and to this end is expected to present an appropriate methodology (including the preliminary typology of costs and benefits incurred by the directive on stakeholders) on how to obtain those data.

- To what extent are the regulatory costs proportionate to benefits achieved? What factors are influencing any particular discrepancies? How affordable are the costs borne by different stakeholder groups, given the benefits received?
- To what extent are there any administrative and reporting burdens on stakeholders and/or other actors? If yes, what is the level of the burdens on stakeholders?
- To what extent are there significant differences in costs or benefits between MS? If so, what is causing them?
- What aspects of ADD are the most efficient or inefficient?

Coherence

- To what extent are there overlaps or complementarities between the ADD and any other Community or international legislation? (e.g. in the area of transport) To what extent are they coherent?

Relevance

- To what extent do the initial objectives correspond to (current) needs?
- How well adapted is the intervention to subsequent technological or scientific advances/progress?

[65] http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm

- Which innovation has taken place in the area of aerosol dispensers and what are the prospects? Is the scope of the ADD appropriate considering product and technological innovation?

EU added value

- What is the additional value resulting from ADD, compared to what could be achieved at national level? To what extent do the issues addressed by the ADD continue to require action at EU level?

- Approach and methodology

The proposal shall include a methodological approach for the achievement of each of the following tasks, which may include the use of such tools as:

- Data collection

a) Desk research / literature review

a) Specify the existing documents and reporting to be reviewed at national level, European and international level.
b) Other

b) Collection of market data/statistics

c) Specify the method for collecting market data/statistics. In case purchase of data is envisaged, the proposal should describe the nature of this data, a deep analysis of the quality of the data and the allocated budget.

d)Market data/statistics should allow a breakdown in product categories, intra community trade flows, export/import figures, information on the size/volume of dispensers (50ml, 220ml, 500 ml, 1 L or more) and materials (metal, plastic, glass) used.

c) It is very important to get an insight in the cost structure of an aerosol dispenser (the individual components / value added by the various operators involved in the production and distribution etc.). Such information will be necessary to understand the position / views expressed by certain stakeholders. It should allow a good understanding and identify any commercially or other driven bias in the replies. Such data will also be crucial to be able to analyse the efficiency criterion.

- Consultation strategy

The contractor shall present a detailed consultation strategy that will overall allow all stakeholders to be duly consulted. Particular attention should be paid to SMEs. The Commission guidelines on stakeholder consultation shall be followed.

For each proposed consultation tool and for each category of stakeholder the contractor shall detail the potential gaps and propose a mitigation strategy. Such strategy will be completed after finalisation of each step of consultation process. Analysis of possible overlapping between the different tools shall also be put forward.

The consultation strategy shall at least include the following:

- Interviews with key stakeholders

The contractor shall carry out a number of structured/semi-structured interviews. Whereas most interviews could be done via the phone or video conferencing (e.g. skype), face to face interviews will be needed at an early stage to get a good understanding of the sector. Further interviews may be needed when analysing the information received via the targeted and public consultation.

Interviews should be conducted with:

- EU officials in relevant services: desk officers in DG Growth, Mobility and Transport, Justice and Environment;
- Relevant National and Regional Administration officials: members of the Working Group ADD and national market surveillance authorities; [at least 28 authorities, the report shall list the Member States / national authority which participated in the interview];
- Selected representatives from Industry and SMEs: European (FEA) and national aerosol associations, manufacturers of components (e.g. container in various material (tin plate, aluminium, plastic, glass), equipment/machinery manufacturers, fillers and distributors (of both consumer and industrial products); [at least 50 entities, the report shall list the entities which participated in the interview];
- consumer organisations.
- Targeted consultation

A targeted consultation should be used to collect the specialist view of stakeholders.

The contractor shall prepare a questionnaire which has to be agreed with the Steering Group. It should be possible for the respondents to provide open answers allowing them to explain more in detail their views.

The questionnaires will be translated by the Commission services into the 6 EU languages (EN, FR, DE, ES, IT, PL). Other languages can be added if considered particularly relevant for this study. The survey shall be conducted for a period of at least two months but shall not exceed three months.

The survey will be conducted by the contractor with an appropriate internet based tool to be agreed upon by the Steering Group. The operational work related to the survey itself (setting up the tool, managing the data, etc.…) will be the responsibility of the contractor.

The contractor remains the sole responsible for the analysis. The contractor shall respect the European Commission standards for data protection when analysing responses.

> All replies should be properly registered and made available to the Commission service upon simple request.

It should be described what methods will be used to reach a high number and wide range of stakeholders. The survey will target:

- Public authorities in charge of the implementation of the ADD in the MS and EEA countries, including market surveillance authorities;
- Economic operators active in the field of developing, manufacturing, and distribution of aerosol dispensers and their professional associations at European and national level.
- Public consultation

The contractor shall prepare a questionnaire for Public Consultation which has to be agreed with the Steering Group. The survey shall run on the Commission infrastructure (EU Survey tool[66]). The survey shall be uploaded in Your-Voice on the Europa website (http://ec.europa.eu/yourvoice/consultations/index_en.htm).

The questionnaires will be translated by the Commission services into the 6 EU languages (EN, FR, DE, ES, IT, PL). Other languages can be added if considered particularly relevant for this study. The Commission service will manage the EU Survey tool (uploading questionnaires, collecting replies, …). The contractor will be closely involved during this process and may be asked to assist the Commission services to handle requests from stakeholders. The answers received by the Commission services will be forwarded to the contractor who remains the sole responsible for the analysis.

The minimum time period for the public consultation is 12 weeks. Additional time should be given in case it runs during major holiday periods.

The contractor shall respect the European Commission standards for data protection when analysing responses.

- OTHER TOOLS

Any other tools deemed appropriate for the purpose of the evaluation e.g. Focus groups/ Expert panels.

- DATA ANALYSIS

a) Intervention logic analysis
b) Indicators
c) Triangulation of information
d) Statistics
e) Counterfactual analysis
f) Benchmarking/comparative analysis
g) Cost-effectiveness, cost- benefit analysis
h) Case studies, in order to assess the results achieved so far as well as the perception by stakeholders undertaken in several member states or on specific issues. Please be as specific as possible regarding your expectations: illustrative cases/examples, or success stories/failures, or specific issues worth additional research and analysis.

[66] https://ec.europa.eu/eusurvey/home/welcome/runner

ANNEX 2 – BIBLIOGRAPHY

Documents and data sources to be reviewed as part of Task 2	Main Eqs
ADD Council Directive 75/324/EEC of 20 May 1975 (Aerosol Dispensers Directive)	All EQS
Amending Directives: 94/1/EC, 2008/47/EC, 2013/10/EU, and 2016/2037	All EQS
PED Directive 2014/68/EU (Pressure Equipment Directive)	EQ11
SPVD Directive 2009/105/EC relating to Simple Pressure Vessels.	EQ11
TPED Directive 2010/35/EU on transportable pressure equipment	EQ11
Seveso Council Directive 2012/18/EC (Seveso III)	EQ11
CAD Council Directive 98/24/EC (Chemical Agents directive)	EQ11
ATEX Council Directives 1999/92/EC and 94/9/EC (ATEX directives).	EQ11
Council Directive 2007/45/EC repealing 80/232/EEC	EQ11
Globally Harmonized System of classification and labelling of chemicals	EQ11
Regulation EC 1272/2008 repealing Council Directive 67/548/EEC (CLP)	EQ11
ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) - Dir 94/55	EQ11
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail	EQ11
ICAO code - International Civil Aviation Organisation	EQ11
IATA Dangerous Goods Regulations - International Air Transport Association	EQ11
British Aerosol Manufacturers' Association - BAMA (2014) Annual Report and Accounts 2013-2014	All EQS
CIRCABC Working Group meeting minutes of 4.11.2010.	EQ5
Centre for Strategy & Evaluation Services (2012) Evaluation of the Pressure Equipment Directive	All EQS
Dutch Aerosol Association – NAV (2005-2014) Annual Reports 2005-2014	All EQS
European Aerosol Federation – FEA, Annual Reports 2009-2015	EQ4
European Aerosol Federation – FEA, European Aerosol Production data 2005-2014.	EQ2
European Commission, Aerosol Dispensers Directive 75/324/EEC (ADD) Adaptation to technical progress, Impact Assessment	EQ4
European Commission (2014) Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008	EQ2, EQ8, and EQ9
European Commission (2016) SG Input Roadmap Feedback on the Evaluation of the Aerosol Dispensers Directive.	EQ6

Documents and data sources to be reviewed as part of Task 2	Main Eqs
French Committee of Aerosols – CFA (2014) Code de Bonnes Pratiques de L'Industrie des Aérosols	All EQS
Montfort A. Johansen (1982) The Aerosol Handbook, 2nd Edition	All EQS
Paul A. Sanders (1987) Handbook of Aerosol Technology, 2nd Edition	All EQS
Rapid Alert System database (RAPEX)	EQ2
RPA (2014) Impact Assessment Study on the Adaptation to Technical Progress of the Aerosol Dispensers Directive	EQ10
RPA (2013) Impact Assessment Study on the Alignment of the Pressure Equipment Directive to the CLP Regulation	EQ10
TÜV Austria (2004) Comparative Study on Pressure Equipment Standards	All EQS
United Nations (2011) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Fourth revised edition.	EQ10
UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification and Labelling of Chemicals (2003) the Alternatives to the Waterbath Test for Aerosol Dispensers	All EQS
European Aerosol Federation - FEA (2013) Guide on Inhalation Safety Assessment for Spray Products	EQ2
European Aerosol Federation - FEA (2013) Transport of Dangerous Goods – FAQs, Briefing paper	EQ2
European Aerosol Federation - FEA (2013) Guidelines on Basic Safety Requirements in Aerosol Manufacturing	EQ2
European Aerosol Federation - FEA (2009) Guide on Hot Water Bath Testing and Its Alternatives	EQ2
European Aerosol Federation - FEA (2009) Guide on Particle Size Measurement from Aerosol Products	EQ2
European Aerosol Federation - FEA (2008) Guidelines on Basic Safety Requirements in Laboratories dealing with Aerosols	EQ2
European Aerosol Federation - FEA (2005) Guidelines on Basic Safety Requirements in Aerosol Storage	EQ2

ANNEX 3 – CHALLENGES RELATED TO THE QUALITY OF SPRAY AND THE PERFORMANCE OF THE DISPENSER DURING ITS USE

Aim of the industry has always been to make the product as attractive as possible for consumers at the lowest possible cost. Additionally, environmental aspects became more and more important over the years.

Flammable and liquefied propellants had been introduced to replace Fluorocarbons (FCs) in the 80s due to the fact that FCs were components that contributed to the destruction of the ozone layer above the atmosphere which protects the earth from excessive UV radiation. This happened at a time when industry already had sufficient experience in guaranteeing virtual leak-proofness of aerosol dispensers. However, flammability of aerosols became one item that had not been covered by the directive and led to an ATP in the 90s.

Already before and especially in the progress of the Volatile organic compounds (VOCs) discussion where flammable propellants are being discussed as a VOC, there was a push to increase the pressure level of aerosol dispensers, which enables in limits the formulation of products with compressed nitrogen or air. These compressed gases are being used in various applications already, e.g. air fresheners, technical sprays, but only rarely in those areas where the majority of aerosol applications are being marketed, e.g. deodorants/antiperspirants and hair sprays.

The established product performance of these products has been enabled by formulations with liquefied propellants, which provide two effects, thermodynamical and mechanical break up, and therefore deliver fine sprays, which are appreciated in the market.

Compressed gases only provide mechanical break up, which can only be improved by decreasing the viscosity of the aerosol concentrate (liquefied propellants, which are compatible and soluble in the concentrate do that even better than any other ingredient), and by increasing the pressure in the aerosol container. Furthermore, the pressure decrease over the time of use is much more for compressed gases than for liquefied propellants, which leads to the problem that the product performance of products containing compressed gases becomes unacceptable to consumers even before the aerosol container is almost empty (in most cases even before it is half empty).

ANNEX 4 – FEA STANDARDS AND GUIDANCE DOCUMENTS

FEA issues standards and guidance documents developed by and within the European aerosol industry.

The FEA **standards** can be classified into four broad categories:

- Communication standards that comprise terms, definitions, and classifications in general (FEA 100 to 199);
- Dimensional standards that contain dimensions and associated tolerances (FEA 200 to 399);

- Standards relating to measuring techniques and measuring devices for determination of mechanical properties (FEA 400 – 499); and

- Standard test methods and test devices for the determination of other properties of aerosol products or their components (FEA 600 – 699).[67]

The FEA standards are in line with the standards of the European Committee for Standardisation (CEN).

The FEA **guidance documents** aim to provide industry with guidance in relation to specific topics. FEA published a number of guides to date, including a guide on inhalation safety assessments for spray products, a guide on hot water bath testing and its alternatives, a guide on particle size measurement from aerosol products, guidelines on basic safety requirements in aerosol manufacturing, guidelines on basic safety requirements in aerosol storage, and guidelines on basic safety requirements in laboratories dealing with aerosols.

While the FEA standards and guidance documents are not mandatory, in practice they are applied by a large part of the aerosol industry in Europe.

[67] Source: FEA document "Standardisation Basic terms, principles, procedure and layout". FEA 100E, November 2013.

ANNEX 5 – MARKET ANALYSIS COMPLEMENTARY INFORMATION

5.1. PRODUCT DEVELOPMENTS

5.1.1. Upcoming technological advancements for aerosols

Key market participants are increasingly looking at product innovation for manufacturing environment-friendly components using latest aerosol technologies. Over the past few years, there has been a shift from traditional aerosol manufacturing towards enhanced sustainability, which includes reduced energy and raw material consumption along with sealing materials including valves causing low harm to the ozone in recent aerosol packaging.[68]

5.1.2. Recent/key innovations in application segments by key users

Over the past few years, the industry has witnessed significant advancements in terms of application as well as production and filling methods. Rising consumer needs for products that are packed appropriately to reduce occurrences of leakage and spilling, along with ease of use.

Figure 37 Key innovations

Key Innovation by key users
Unilever has reduced aerosol deodorants spray sizes with an aim to introduce an innovation in actuator technology that delivers fine sprays, thereby reducing consumption as well as wastage. This initiative is not in relation to other FMCG products reducing sizes to maintain price margins. The innovation enables longer use of small size containers (75 ml) similar to that of standard size containers (150 ml). This is a huge environmental impact initiative which claims 25% less aluminium usage for containers and 25% lower carbon footprint. In February 2013, Unilever announced that it would invest USD 62 million to establish its first Asian aerosol deodorant manufacturing plant in Maharashtra, India In May 2013, Unilever announced the opening of a new state-of-the-art deodorant manufacturing facility in Mexico
In September 2013, Rexona/Sure, a brand of Unilever, relaunched its deodorant range for men with new look-packaging along with its MotionSense antiperspirant technology
Yves Rocher has launched a perfumed deodorant spray with pure air propellants which has botanical ingredients including rose, jasmine, petitgrain essential oil, bergamot, patchouli and contains no aluminium salts or animal ingredients. Muller M-lady shaving foam is a new product claiming lower consumption of energy while manufacturing. Manufacturers are also shifting from steel packaging to plastic bottles owing to reduced weight, easy mouldability, expanded packaging options and customer friendliness (anti-rust).
GreenSpense's Eco-Sleeve enables gas-free continuous dispensing that eliminates the need for pressurized canisters and maintains the desired convenient user experience. The Eco-Sleeve generates high pressure (that

68 Honeywell has introduced a next generation propellant known as 1234 ze. Solstice propellant falls into a new class of propellants and solvents based on an unsaturated fluorinated base molecule, thus HydroFluoro-Olefin (HFO) name. This new propellant has zero Volatile Organic Compounds (VOC), low Global Warming Potential (GWP), and is considered non-flammable under Department of Transportation (DOT) definitions; 2) Introduction of ethane as propellants; which is a saturated hydrocarbon will contribute to the increasing demand for hydrocarbon aerosol propellants. Ethane has a pressure of 543 psig at 70°F. In addition, it is soluble in most solvents to the extent that 4% to10% can be used in an aerosol formulation. Ethane possesses various advantages which includes zero VOC or ozone depleator, low GWP, and good Threshold Limit Value (TLV). Ethane offers better spray pattern than a comparable carbon dioxide product and its higher propellant volume will give greater protection from propellant exhaustion.

Key Innovation by key users
is directed to the centre of the package only) and enables innovative packaging designs at low costs with recyclable materials such as plastic or cardboard. Easy to implement in production lines, the patent-pending technology works with dual-compartment dispensers, exerting consistent pressure throughout the entire dispensing process. The technology is expected to hinder aerosol propellants demand.
Salvalco Eco-Valves utilizes patented "Bubbly Flow" technology for providing a fine and consistent spray to the content in the aerosol container. In addition, the company is one of its kinds to pioneer commercialization of the replacement aerosol valve technology, developed by the University of Salford, UK. The company's product, Eco-Valves, offers a range of benefits to manufacturers as well as buyers. Salvalco has developed the product, Eco-Valve, using compressed nitrogen aerosol propellants, which is capable of reducing the use of volatile organic compounds (VOC's). It reduces reliance on potentially dangerous flammable propellants, cutting the cost of storage, transportation, and insurance as Salvalco aerosols are categorized as non-hazardous (Seveso III Directive 2012/18/EU classification).
In September 2015, Lindal established a strategic agreement with Russian healthcare company, Nativa, for the development of metered dose inhalers for respiratory diseases. The prime motive of this agreement is to ensure effective drug release for active pharmaceutical ingredients (API) for patients diagnosed with respiratory syndrome, particularly asthma. These solutions use engineered valves made to handle active ingredients and optimize delivery of low doses of medication directly inside the bronchial system of the human body In April 2015, Lindal Group launched a new ball valve with actuation of 360°. The product is approved by the Food and Drug Administration (FDA) for use in cosmetics, toiletries, household, automotive, and pharmaceutical industries. In July 2013, Lindal Group announced launch of a new product, Twist-Lock Actuator, for the packaging of deodorants & antiperspirants and sun care products Lindal offers aerosol technology to have applications in the food sector The Double-Piston Can utilizes a standard actuator such as the LINDAL Group's Cozy model, and a special insert for oil, which breaks up the oil into a fine spray, along with a double-piston can. An appealing alternative is the Bag-On-Valve system, which keeps the oil inside a bag within the canister. Compressed air or a standard propellant surrounds the bag. Both systems maintain 100% separation of the oil and propellant, and keep the oil safe from oxygen and UV exposure permitting a 360o application for enhanced ease of use.
In April 2015, Colep launched a new bag-on valve-based product, NATRUE certified, organic aerosol cream, which has foaming properties as a result of incorporation of CO2
In April 2015, Crown aerosol packaging entered into a partnership with Unilever to introduce TRESemmé Expert Selection premium hair spray line in cans manufactured by Crown
In February 2015, APPE launched Spray PET Reveal, which is a combination of a polyethylene container with Power Container Corporation's power pouch dispensing system. The pouch is developed with bag-on valve system, which is made up of laminated aluminium bags along with layers of nylon and polyethylene.
In April 2014, Ball Corporation and Henkel AG collaborated to launch lightweight aluminium aerosol cans. These aerosol cans will be used for the packaging of Henkel's beauty care Fa Brand products
In September 2013, Airolux AG, a joint venture between I.P.S. Innovative Packaging Solutions AG and Resilux NV, signed a five-year supply contract with Procter & Gamble for delivery of Airopack system. The system is a plastic pressurized dispenser which is environment friendly and provides clean and safer alternative to the conventional aerosol dispensing systems. It consumes 42% less energy and emits 74% less CO2.
Crown developed the EarthSafe Dispensing System which replaces hydrocarbons with compressed air as the propellant. Developed with Ultramotive Corporation, the system's unique valve technology allows total aerosol product evacuation at consistent flow rates from beginning to the end. In addition, a patented multi-layer barrier piston eliminates gas permeation, extending shelf life and increasing evacuation of package contents. Available in North America, the EarthSafe Dispensing System is suitable for gels, personal care products and other viscous aerosol applications.

Source: Grand View Research customised report 2016; compilation: Technopolis Group.

5.1.3. Key trends across the value chain

The list includes new product developments, establishment of strategic partnerships and production capacity expansion in the coatings, cans, slugs and propellant industries.

Figure 38 Product developments aerosols value chain

Industry	Product development
Coatings	In February 2016, Michelman launched a new waterborne polyimide binder, ProHere I 13002, which is used for manufacturing metal coatings with high levels of thermal resistance, excellent adhesion and mechanical strength. This VOC-free formulation provides metal coatings that can withstand temperatures up to 370°C.
	In January 2016, Dow Coating Materials launched a new polyolefin dispersion formulation, under the brand name, "CANVERA" for packaging coatings manufacturers. The polyolefin dispersions offer a safety profile for coating manufacturers to produce sustainable and non-BPA products catering to the packaging industries particularly, aerosol products.
Cans	In April 2014, Germany-based Henkel AG, and the NYSE-listed Ball Corporation launched a new, lighter industrial aluminium aerosol can for beauty care brand, Fa. Henkel AG will use lightweight aluminium plate to manufacture the finished product.
Slugs	In December 2014, CCL Industries Inc. announced the establishment of a new manufacturing unit to produce aluminium slugs used in the impact extrusion process to make aerosol cans, tubes, and bottles for consumer packaged goods companies.
Alternatives to cans	In September 2013, Airolux AG, a joint venture between I.P.S. Innovative Packaging Solutions AG and Resilux NV, signed a five-year supply contract with Procter & Gamble for delivery of Airopack systems. The system is a plastic pressurized dispenser which is environment-friendly and provides clean and safer alternative to the conventional aerosol dispensing systems. It consumes 42% less energy and emits 74% less CO2.
Propellants	In October 2014, DuPont launched a new product for AC fresh and AC Pharmacair shipments named as Tyvek Coveralls. Other business products include propellants, refrigerants, lubricants, solvents, fire extinguishers, electronic gasses, and fluoroelastomers.
Propellants	Honeywell International Inc. produces a low-global-warming material which is used in insulation and aerosols. HFO-1234ze has been accepted for utilization and sale in foam and aerosols by the U.S. Environmental Protection Agency. It is currently used in Europe and Japan, with the majority of demand coming from Europe. In July 2012, Honeywell launched a new product range, "Solstice" propellants, which is non-flammable, non-ozone-depleting, and has low global warming potential (GWP) In October 2014, Honeywell announced launch of its low-global-warming propellant, "Solstice", which is used for treatment of diaper rash in toddlers, infants, and adults In December 2014, the company launched Hydro Fluoro Olefin (HFO) product range for safer work environment with no harmful impact
Coating and foam	In September 2014, Lapolla Industries Inc. announced its partnership with Honeywell and Purdue University to add to Lapolla's new 4th generation wall foam insulation to the Purdue's ReNEWW Net-Zero Home Project In July 2014, Lapolla Industries Inc. incorporated Honeywell's new Solstice Liquid Blowing Agent (LBA) in spray foam insulation wall system mainly in the U.S. to expand its environment-friendly offerings with Solstice LBA
Propellants	Since 1991, AkzoNobel N.V. offers Demeon D propellant, which is used as a stand-alone product or in combination with other propellants. The propellant also functions as a co-blowing agent for foam, refrigerant, solvent, extraction agent, chemical reaction medium, or multi-purpose clean fuel, for use in deodorants, fragrances, sunscreens, insect repellents,

Industry	Product development
	air fresheners and cleaning products. The unique propellant offers exceptional benefits when used in hairspray formulations. Demeon D propellant is an excellent solvent which is miscible with both ethanol and water and allows broad formulation latitude across a wide VOC spectrum.
Slugs	CCL (key slug manufacturer) is investing in new a R&D plant setup to produce slugs used in the extrusion process for manufacturing tubes, bottles, and aerosol cans for consumer packaged goods. BALL is introducing metal technology breakthrough that enables the use of recycled aluminium in the manufacture of extruded packaging for aerosol. The resulting new metal alloy exhibits increased strength and retains the light weight property of the container without affecting package integrity. Extruded aluminium aerosol is manufactured from virgin aluminium slugs. These metals are used to produce packaging for aerosol products including body spray, sunscreen and air freshener.
Cans	Henkel AG & Co., KGaA was founded in 1876, and is headquartered at Düsseldorf, Germany. The company operates in three business segments including laundry & home care, beauty care and adhesives technologies. As of 2014, Henkel had over 14,000 employees operating in more than 160 subsidiaries with regional offices and distribution centres located in the U.S., Canada, Argentina, Mexico, Brazil, France, Spain, Italy, Japan, China and India. The company markets its products under several brands including Persil, Purex, Pril, Schwarzkopf, Syoss, Loctite and Technomelt
	Pokon Naturado was established in 1975 and is headquartered at Veenendaal, Netherlands. The company is engaged in the business of manufacturing agricultural products which are used in soil potting, fertilizers, grass seeds and crop protection. As of 2014, Pokon exported products to Czech Republic, Poland, Germany, France and Russia. In April 2013, the company launched a new trigger sprays under the brand name, Flairosol-Pokon Powerspray for Europe market. The product is a two-in-one leaf fertilizer and life shine indoor plant care product. Aforementioned strategic move is expected to play a crucial role in increasing the application growth of spray products in agriculture industry of Europe over the next six years.
Coating	As of 2014, Dow Coating Materials was headquartered at Midland, U.S. and had subsidiaries located in Brazil, China, Malaysia and Netherlands. The company is engaged in the business of manufacturing paints, coatings, and additives for manufacturing, packaging, automotive and paper industries. Dow Coating Materials operates its business in Europe through strategic business unit located at Hoek – Terneuzen, Netherland under the name, Dow Customer Information Group. As of 2014, the company operated as a subsidiary of Dow Chemical Company and had 24 production units located across six continents. In January 2016, Dow Coating Materials launched a new polyolefin dispersion formulation, under the brand name, "CANVERA" for packaging coatings manufacturers on a global level. The polyolefin dispersions offer a safety profile for coating manufacturers to produce sustainable and non-BPA products catering to the packaging industries particularly, aerosol manufacturers located in Europe. Unilever N.V. is a multinational company, headquartered in Rotterdam (Netherlands) and London (UK). The company was established in 1929 by the merger of Margarine Unie, a Dutch margarine manufacturer, and Lever Brothers, a British soap maker. The company has its operations in more than 190 nations, with major regional offices in India, Australia, Philippines, UK, Netherlands and Germany. In September 2014, Unilever chose Lindal aerosol packaging technology for the manufacturing of Axe's Chilled Shaving Gel. In May 2014, the company introduced compressed deodorant cans for most of its brands including Sure, Dove, Axe/Lynx in Europe and Asia. The new product design is anticipated to cut the carbon footprint of an aerosol spray by almost 25% per can. In September 2013, Rexona/Sure, a brand of Unilever, re-launched its deodorant range for men with new look-packaging along with its MotionSense antiperspirant technology in

Industry	Product development
	Europe. In February 2013, Unilever launched new female aerosol deodorants under the brands, Sure Women, Dove and Vaseline for UK market. These products are available in the preposition of 5ml compressed SKU with 16 variants
	Reckitt Benckiser (RB) is a consumer goods company established in 1823 and headquartered at Berkshire, United Kingdom. The company's product portfolio includes cleaning products, health care products, personal care and condiments. RB's brand portfolio includes Dettol, Strepsils, Veet, Air Wick, Lysol, Calgon and Vanish. RB's operations unit is headquartered in Slough, Berkshire. The company has business operation units in around 60 countries and has market presence in about 200 countries. In July 2014, UK based RB announced an investment of USD 125 million to establish R&D centre in Northern England focusing on consumer health segment. This strategic move is expected to increase the expenditure for the development of new products. In April 2011, RB launched a new 100% natural air freshener in household applications targeting the UK market. Rising awareness towards eco-friendly products in household industry of Europe in light of increasing concerns over greenhouse emissions is expected to augment the market reach for aforementioned product.
Alternatives to cans	Proctor and Gamble (P&G) was established in 1837 and is headquartered at Ohio, U.S. The company has a wide range of products for skin care, house care, hair care, health care, food products and oral care. P&G owns over 300 brands across its product portfolio. As of 2014, the company has an employee base of about 118,000 people operating in over 80 countries. In September 2013, Airolux AG, a joint venture between I.P.S. Innovative Packaging Solutions AG and Belgium-based Resilux NV signed a five-year supply contract with Procter & Gamble for delivery of Airopack system. The system is a plastic pressurized dispenser which is environment friendly and provides clean and safer alternative to the conventional aerosol dispensing systems. It consumes 42% less energy and emits 74% less CO2.

Source: Grand View Research customised report 2016; compilation: Technopolis Group.

5.2 VALUE CHAIN INSIGHTS

The list includes industry insights across the aerosol value chain.

Figure 39 Value chain insights

Industry	Industry insights
Slugs	Growing aerosol production in major markets of the U.S., China and Brazil in light of increasing domestic consumption is expected to increase the incorporation of usage of slugs over the forecast period. However, rising importance of lightweight material in the automotive industry of developed markets including the U.S. and Germany is expected to upscale the requirement of aluminium slugs. In addition, positive outlook towards electronics industry in Japan, China and South Korea in light of exponential increase in launch of advanced electronics gadgets is expected to further promote the usage of slugs. Aforementioned factors pertaining to the usage of aluminium slugs in automotive and electronics industries is expected to challenge the supply of raw material for the production of aerosol cans over the forecast period. Key slug manufacturers include CCL Containers, Rondal and Neuman. Canada-based CCL Containers has strategic business units located in Germany, UK and France.
Plates – Aerosol Can	Majority of aerosol can manufacturers procure plates from metal sheet manufacturers. The European aerosol can market participants are relying on imports on account of high concentration of sheet manufacturers in Asia Pacific, particularly in China and India. As a result, sheet manufacturers are expected to provide the raw material to aerosol can manufactures at high prices which may induce increased cost for the finished product. Moreover, decreasing profitability in the metal manufacturing sector of developed economies including UK, Germany and France on account of increasing utility expenditure and declining

Industry	Industry insights
	demand from automotive and construction sector is expected to have a negative impact on the mineral industry. This trend is expected to result in the shifting focus of metal processing companies to establish their production units in emerging economies including China and India which in turn is likely to reduce the availability of metal plates to aerosol can manufacturers. Key vendor suppliers for plates in aerosol industry were leading mineral processing companies including ThyssenKrupp, Emballator Metal Group and Tata Steel.
Plates – Aerosol Valve	Rising consumption of carbonated soft drinks in emerging markets of China, India and Brazil in light of new product launches by the Coca Cola Company and PepsiCo is expected to increase the usage of tin plates. This trend may result in reducing supply of tin plate as a raw material for aerosol valve manufacturers over the forecast period. In addition, stringent regulations by the European Commission towards restricting environmental pollution in the metal processing sector is expected to reduce the output for metal sheets including tin plate. As a result, aerosol valve manufacturers are expected to rely on imports of metal sheets from leading manufacturing countries including China.
Welding, extrusion and blow moulding machines in aerosol can production	Aerosol can manufacturers are expected to procure moulding and welding equipment from Europe on account of getting benefits including online condition monitoring (or predictive maintenance) and automation control services. Moulding manufacturers are expected to increase expenditure for the incorporation of new lubrication systems with a small capacity of tanks. These companies are expected to focus on the sale of electrically operated moulding and welding machines which require low level of maintenance expenditure. Technological advancement pertaining to the development of welding machines with reduced idle time may force aerosol can manufacturers to increase the R&D expenditure among welder companies over the next seven years. Employment of costly labour in developed countries increases manufacturing costs, owing to which companies are adopting industrial robotics, further stimulating market development. Surging shortage of skilled labour, especially in developed countries is impelling manufacturers to take new strides to automate processes. The advent of welding robot for manufacturing processes reduces dependency on manual labour and thus drives demand for welding machinery. In addition, the advent of laser systems, Computer Aided Design (CAD) and manufacturing systems is expected to increase expenditure among welding manufacturers. Escalating demand across various application segments such as shipbuilding, automotive, offshore exploration, aerospace, oil & gas, energy, and construction is anticipated to be the key force driving the global welding machinery market growth over the coming years (until 2020). Shifting focus towards automatic welding from manual operations is a major trend witnessed by welding machinery market.
Moulding machines used in aerosol valves production	The metal moulding market witnessed strong growth over the past decade on account of expansion of the manufacturing sector in various regions. Metal moulding is employed in manufacturing processes to reduce cycle time and improve efficiency in size and shape of metal products. Increasing demand for extrusion moulding from healthcare and medical industries is likely to boost its market over the forecast period. However, limitations of product size and weight are anticipated to hamper market growth in the near future. End-user industries of extrusion and blow moulding market include automotive, aerospace, medical & healthcare, industrial machinery and niche applications include defence, electronics and consumer products. Companies including Boston Mathews, Haumiller and Newpla Co. Ltd are engaged in the business of supplying moulding machines to dip tube and aerosol valve manufacturers.
Testing equipment – Filling lines	The majority of suppliers operating in the business of supplying testing equipment to filling line manufacturers are expected to focus more on valves and cans. Key testing equipment manufacturers include Bautz Engineering, Specialist Tooling Technologies Ltd., Canneed Instrument Limited, and Aero-Tech Laboratory Equipment Company. Establishment of strategic partnership with aerosol can manufacturers along with providing services benefits including free installation are expected to remain a critical success factor for the market players.

Industry	Industry insights
	Atek Leak Testing (U.S.), Raupack and Labthink are key suppliers of testing equipment to aerosol valve manufacturers. U.S, based Atek Leak Testing was the largest manufacturer which operates through its strategic business units located in France, Germany and UK. R&R Midlands Ltd, ALPS and Wilco AG supply testing equipment to aerosol can filling manufacturers.
Coating	Rising concern regarding durability, thermal stability, corrosion and fire protection in construction, oil & gas, power and automotive industry is expected to drive the protective coatings market in the near future. Development of eco-friendly products such as powder coatings is expected to play a key role in driving market growth. European Commission and the U.S. EPA have framed regulations intended for reducing volatile organic compounds (VOC) emission. These regulations are widely adopted by automobile manufacturers such as Volkswagen and the company has begun using protective coatings in automobile production. Automobile production growth in China, Mexico, Indonesia, Malaysia and Germany is expected to augment protective coatings market demand in the near future. Increased government spending towards improving infrastructure in BRICS and Middle East countries is expected to fuel protective coatings market demand. Increased accidents and surging expenditure in the oil & gas sector on account of corrosion and fire is expected to boost protective coatings demand over the next six years. European Commission has framed REACH regulations, intended for restricting the use of certain chemicals in industrial applications and is likely to hamper the protective coatings market growth over the forecast period. Growing consumption of coatings in automotive and construction industries as a protective medium against corrosion and thermal protection is expected to reduce the product supply to aerosol can manufacturers over the next seven years.
Filling lines	Technological advancement pertaining to the programmable logic control (PLC) systems in automation control industry is expected to force aerosol filling machinery manufacturers to increase expenditure. In addition, filling lines manufacturers are expected to increase their budget intended for providing service benefits including free installation and automation control support. High concentration of aerosol filling equipment manufacturers in European countries including Germany and UK on account of easy access of consumables along with availability of technical experts in industrial automation is expected to ensure the product supply over the next seven years. However, high manufacturing cost in developed markets of Europe on account of increasing utility expenditure in terms of electricity and water supply is expected to remain a concerning factor for aerosol filling manufacturers. Filling equipment vendors are likely to establish strategic business units in emerging markets of Asia Pacific including China and India on account of high gains in aerosol packaging in personal care and household segments. In addition, the European Commission has framed stringent regulations aimed at reducing the usage of HFC compounds which is expected to cause a change in the installations of filling equipment. All aforementioned factors are expected to have a negative impact on the market for aerosol filling equipment in Europe over the period until 2020.

Source: Grand View Research customised report 2016; compilation: Technopolis Group.

ANNEX 6 – EVALUATION GRIDS

Context criteria

What was the origin of ADD and what were its main objectives? What progress has been made over time? (Evaluation Question 1)		
Sub-question	Judgment criteria	Indicators
N.A.	Main origin and rationale for establishing ADD	Description of the situation at the time before ADD and main rationale for maintaining a separate Directive for aerosols (as opposed to e.g. including it in the Pressure Equipment Directive)
		Main needs identified to establish ADD
		Specific objectives of ADD
N.A.	Progress made over time in relation to ADD	Any changes or developments in relation the science and technology driving the manufacturing of aerosol dispensers
		Adaptations of ADD over time (in response to the changing environment)

Relevance criteria

To what extent do the initial objectives of ADD correspond to the current needs? How well adapted is ADD to technological/scientific progress and innovation that took place in the area of aerosol dispensers over time? (Evaluation Question 2)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which the objectives of ADD correspond with the needs of various stakeholders	Level of alignment between the objectives of ADD and the needs it is intended to address
		% of economic operators, national authorities and consumer organisations that support the relevance of the objectives of ADD
N.A.	Extent to which ADD is still relevant today in the light of technological progress made over the years	Nr and types of adaptations of ADD since its establishment in 1975 (cf. also EQ4) and main reasons / actors pushing for these adaptations
		% of stakeholders that believe that ADD is still relevant today
		% of stakeholders of the opinion that ADD contains any inconsistencies or out-dated provisions or requirements
N.A.	Extent to which the ADD is appropriate for fostering product and technological innovation	Nr and types of innovation that has taken place in the area of aerosol dispensers
		% of stakeholders of the opinion that the ADD is appropriate for developing product and technological innovation

EU added value criteria

What is the added value resulting from ADD, compared to what could have been achieved at national level? To what extent do the issues addressed by the ADD continue to require action at EU level? (Evaluation Question 3)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which ADD brings additional value compared to what would be achieved at national level	% of stakeholders of the opinions that the application of national legislation (instead of ADD) would hinder the internal market
N.A.		% of stakeholders of the opinions that the application of national legislation (instead of ADD) would represent a higher degree of safety risk

Efficiency criteria

What are the costs associated with ADD on different stakeholder groups, including Member States and economic operators (Evaluation Question 4)?

Sub-question	Judgment criteria	Indicators
What are the costs imposed on (different types and sizes) economic operators	Extent to which ADD incurred an administrative burden on economic operators?	Stakeholder descriptions on the types and amount of administrative burden associated with ADD
		Typical administrative cost of economic operators Note: considers specific administrative personnel dedicated to handling any information obligations to comply with ADD (e.g. test records, traceability, etc.)
	Extent to which ADD incurred substantive compliance costs on companies	Stakeholder descriptions on the types and amount of substantive compliance costs associated with ADD
		Typical compliance cost of economic operators (assessment of the annual average level of capital expenditure of their investment) Note: considers investment in testing, equipment, systems, procedures or intangibles to comply with ADD e.g. testing, labelling, flammability classification, etc.
		Distribution of costs across (1) capital expenditures (testing), (2) personnel, (3) training, and (4) maintenance.
	Extent to which ADD incurred hassle costs on companies ('annoyance' and 'waiting time')	Economic operators' description of costs due to delays related to the late transposition of additional amendments of the Aerosols Dispensers Directive (Qualitative assessment)
What are the costs imposed on public authorities?	Extent to which ADD incurred enforcement costs on national authorities	Nr of MS that report a cost due to the enforcement and monitoring of the Aerosols Dispensers Directive? (e.g. monitoring, carrying out on-site controls). These costs will depend on the implementation at national level.
		Value of costs reported by Member States due to the enforcement and monitoring of the

What are the costs associated with ADD on different stakeholder groups, including Member States and economic operators (Evaluation Question 4)?

		Aerosols Dispensers Directive
	Extent to which ADD incurred enforcement costs on the Commission	Nr, type, and value of costs identified by Commission officials (e.g. due to facilitating the Committee on technological progress, monitoring the implementation at national level, etc.)

Are the administrative and regulatory costs on the stakeholders proportionate to the results achieved? How do the costs borne by stakeholders compare to the benefits received, affordability? (Evaluation Question 5)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which the costs incurred by ADD are proportionate to the benefits achieved	Economic operators' description of benefits associated with ADD (Qualitative assessment)
		% of economic operators of the opinion that the costs associated with ADD are proportionate to the benefits received
		Nr of public officials (EC and national authorities) of the opinion that the costs associated with ADD are proportionate to the benefits received

Effectiveness criteria

Has the Aerosols Dispensers Directive been effective in achieving its main objectives? (Evaluation Question 6)

Sub-question	Judgment criteria	Indicators
Objective 1: To what extent has ADD contributed to an effectively operating internal market for the products in its scope?	Extent to which ADD led to a harmonisation of aerosol legislation (i.e. common standards and criteria) in Member States	Adoption of the same specifications by Member States as laid down in the ADD (i.e. the absence of additional requirements, access of norms, guidelines and procedures which could interfere the trade within the EU)
		% of relevant stakeholders of the opinion that rules and legislation has been harmonised across EU Member States in the field of aerosol dispensers since 1975[69]
		Member State compliance with the provisions set out in the ADD (i.e. not leading to a refusal, prohibition or restriction of any aerosol dispenser which complies with the requirements of the Directive, except of cases representing a hazard to safety or health)
	Extent to which ADD fostered trade (both intra-EU and extra-EU trade) and helped strengthen businesses' competitiveness	Imports and exports of aerosol dispensers between EU Member States between 2005 and 2015
		Market concentration of aerosol dispensers and degree of competition in this product area
		% of economic operators indicating that ADD has a positive (or negative) effect on their competitiveness
Objective 2: To what extent has ADD contributed to the safety of the products in its scope?	Extent to which ADD enhanced the consumer safety of aerosol dispensers marketed in the EU	Nr of complaints filed by consumers and other users of aerosol dispensers (as per Rapex or national records where available) – related to the objectives of ADD
		Perceptions on ADD contributions to product safety
	Extent to which ADD enhanced clarity on the safe use of aerosol dispensers	(Estimated) number or proportion of identified dispensers not compliant with labelling provisions
		Perceptions of consumer organisations on the effectiveness of the ADD labelling provisions and its effects in practice

[69] Qualitative assessments will be also taken into account for this type of indicators.

What aspects, means, and/or actors render ADD (or certain aspects of ADD) more or less effective? (Evaluation Question 7)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which specific aspects inherent to the ADD itself render it more or less effective	Provisions of ADD that render certain aspects of the directive more effective
		Provisions of ADD that render certain aspects of the directive less effective
N.A.	Extent to which any means or actors render ADD more or less effective	Nr and types of stakeholders in the field of aerosols that play a major role in the application of ADD and their (positive or negative) effect on the Directive's effectiveness
		Nr and types of means that facilitate the effective application of ADD (e.g. means employed by national authorities to implement the Directive)
		Measures/actions taken by stakeholders at EU or national level to address any hindering factors

To what extent has the procedure to adapt the Annex of ADD to technical progress been effective? (Evaluation Question 8) (Evaluation Question 8)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which the procedure allowed for effective adaptation of the Directive	Nr and types of adaptations of ADD since its establishment in 1975, and main reasons / actors pushing for these adaptations
		% of EC and MS representatives indicating that the appropriate regulatory and management procedures (Articles 5a(1) and 4 of Decision 1999/468/EC) were followed when adapting the Annex of ADD
		% of stakeholders indicating that the Committee on technological progress performs its tasks
N.A.	Extent to which the adaptation procedure helped to keep the Directive in line with technological developments in the field	% of stakeholders that feel that ADD is adequate in its current format in light of the technological state-of-the-art in the field of aerosols

What barriers (if any) exist to the effective application of ADD? (Evaluation Question 9)

Sub-question	Judgment criteria	Indicators
N.A.	Existence of any barriers to the practical application of ADD	% of relevant stakeholders (EC, MS, Economic Operators) that claim to have experienced barriers when applying the Directive
N.A.	Extent to which these barriers negatively affect the achievement of ADD's objectives	Stakeholder opinions on the severity of the barriers identified, and the types of negative consequences resulting from them
		Nr and types of solutions and practices used by the different stakeholders to overcome the barriers or to mitigate their effects

How are different groups of stakeholders affected by the Directive? If relevant, what are the environmental, social, and economic impacts of ADD? (Evaluation Question 10)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which there are any differences in the way in which ADD affected different stakeholder groups	Differences in the impact of ADD on large versus small and medium sized companies (if any)
		Differences in the impact of ADD on different types of economic operators (e.g. manufacturers, fillers, distributors, importers, etc.) (if any)
		Differences in the impact of ADD on stakeholders (consumers/economic operators) based in different EU Member States (if any) Such differences could be due to different ways of transposition into national legislation or any other external factors at national or regional level.
N.A.	Degree of environmental, social, and/or economic the impact of ADD	Existence of any secondary data and stakeholder opinions on of the environmental impact of ADD

Did ADD generate any unexpected or unintended impacts, positive or negative? (Evaluation Question 11)

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which ADD generated any effects that were not originally planned or expected	Nr and types of direct unplanned effects (if any), for example on stakeholders (positive or negative)
		Nr and types of indirect/wider unplanned effects (if any), for example on the economy, environment, or societal effects

Coherence criteria

To what extent are there overlaps or complementarities between ADD and any other EC or international legislation, e.g. in the area of transport (Evaluation Question 12)?

Sub-question	Judgment criteria	Indicators
N.A.	Extent to which there are any overlaps/complementarities between ADD and any other Community legislation	Nr and types of overlaps between ADD and other EU legislation (if any) Complementarity with other acts
		Where overlaps exist: stakeholder opinions on the clarity in terms of which piece of legislation takes precedence (e.g. provision on labelling and potentially other provisions of ADD)
		% of national authorities that think that the transposition of ADD into their national legislation allows for a coherent implementation of various related Directives (e.g. on transport)
N.A.	Extent to which there are any overlaps/complementarities between ADD and any international legislation	Nr and types of overlaps between ADD and other international legislation (if any)
		Where overlaps exist: stakeholder opinions on the clarity in terms of which piece of legislation takes precedence

ANNEX 7 – INTERVIEW GUIDELINES

Interview guide for Economic Operators and Industry Associations

Evaluation of the Aerosol Dispenser Directive

Introduction

(N.B. Notes to interviewers in italics)

Information to the interviewee at the start of the interview: reference is to be made to the letter of intent that the interviewee has received when the contact for the interview was established.

The European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) has recently commissioned Technopolis Consulting Group to conduct an evaluation of the Aerosol Dispensers Directive (ADD) 75/324/EC. The objective of the evaluation is to assess whether the Directive is meeting its objectives of guaranteeing free circulation of aerosol dispensers within the EU while ensuring a high degree of safety. The evaluation will assess the effectiveness, efficiency, relevance, coherence, and EU added value of the Directive. It covers the period from 2005 to 2015.

The evaluation will apply the standard principles for evaluation as established by the European Commission. These provide a consistent framework for assessing the extent to which a Directive or policy has reached its set policy objectives. Information will be collected from all stakeholders (economic operators and their associations, public authorities and consumers/users and their associations). The information collected via the interviews will be complemented with information obtained via other data collection techniques such as an online targeted consultation and an online public consultation.

The evaluation project is scheduled to run from December 2015 to March 2017. The evaluation report will be presented and discussed in the Commission's working group related to the ADD and discussed with all relevant stakeholders. The final report of this study will also be made publicly available.

This interview constitutes an important input into this study. We will use the information from the interview in our reports to the European Commission.

Please be reassured that all data or opinions shared with the evaluation team will be analysed in all confidentiality and results will only be presented in an aggregated manner thus no commercially sensitive information will be disclosed in the evaluation report.

We will not quote you directly, nor will we attribute any statements to you as an individual. The name of your organisation may be included in the report as part of a list of stakeholders consulted during the study.

Background information to the interviewer. It is not needed to explain this to the interviewee. The ADD is one of the oldest EU legislations related to product safety. The directive defines aerosol dispensers as: "any non-reusable container made of metal,

glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".[70]

COMPANY /ASSOCIATION ACTIVITY

Company Information / Association information
Interviewee name & job title
Company name /association name
Size of the company & Where is the organisation located? *Note to interviewer:* *In case of an association, find out who this association is representing. Can you please elaborate on the number and types of economic operators that you represent?*
What economic sector is the organisation in? *Note to interviewer:* *The interviewer should fill in the information prior to the interview based on desk research and only ask the interviewee, if necessary.* *We have also categorised the economic operators according to the following main types:* *1. Manufacturers of cans* *Subgroups: slug producers, plate producers, manufacturers of machines for welding, extrusion, blow moulding and equipment for testing, manufacturers of coatings.* *2. Manufacturers of valves* *Subgroups: plate producers, manufacturers of machines for moulding etc. and test equipment, manufacturers of coatings.* *3. Filling industry* *Subgroups: manufacturers of filling lines (liquid filling, crimping/clinching, gas filling), test equipment (water bath, leak detector etc.), users/manufacturers of aerosol packs, product development.* *4. Marketing/sales/distribution - the persons responsible for marketing* *Subgroups: as above - often part of the filling industry, product development* *5. Indirect suppliers of actives, propellants and solvents – primary in product*

[70] COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) (OJ L 147, 9.6.1975, p. 40) Consolidated version on EURLEX:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01975L0324-20130409&rid=1

development

We have also categorised the associations according to the following main types:

1) European Aerosol Association (FEA)

2) National Aerosol Association

3) Specific EU level associations such as Aerobal for Aluminium applications

4) Other associations e.g. for the production of machinery, filling lines, testing equipment (ORGALIME or associations from testing labs could have an interest)

In case of an association the questions may need to be adapted "by your company" change to "within the sector" / "by the companies your organisation represents" etc.

Q1 What is the balance between aerosol dispenser and non-aerosol dispenser activities in your organisation?

Q2 To what extent you are familiar with the provisions set out in ADD?

Q3 Note to interviewer: (Question is only for economic operator, not for an association). Does your company's products have to comply with any additional aerosols-related rules or requirements in specific EU national markets in which your company is operating? If so, please explain what rules and in which countries.

Q4 Which are the recent changes and developments in relation to the science and technology driving the design, manufacturing and testing of aerosol dispensers? Are there new applications for aerosol dispensers to be expected in the near future?

RELEVANCE

RELEVANCE AND APPROPRIATENESS OF ADD

Q5 The objectives of the ADD are to guarantee that products within the scope of the Directive will be safe and to secure the free movement of aerosol dispensers across the EU: To what extent do you think are the ADD objectives relevant? Please explain.

Note to interviewer:

The answer could be a scale: very relevant, relevant, not so relevant, irrelevant, in addition to elaborate information on why.

Q6 Do you agree with the following statement that ADD is still relevant today?

Note to interviewer: here you would expect an answer Yes/No, in addition to elaborate information on why.

Q7 Does ADD in your opinion contain any inconsistencies, out-dated provisions or requirements? If so, please briefly explain.

Q8 What innovation relevant to aerosol dispensers have been implemented by your

company? What are the effects on other companies in the area of aerosol dispensers?

Q9 Overall, do you think that the Aerosol Dispensers Directive allows sufficient flexibility to develop new and innovative products?

EFFECTIVENESS

Aspects, means, and actors that render ADD more or less effective

Q10 In your opinion, are the wording and the content of the Directive sufficiently clear and appropriate? What about the methods outlined in the annexes of the Directive? For example, methods for hot water bath testing, testing of flammability, etc.

Q11 Can you name any stakeholders, activities, and/or procedures that you think are particularly important in successfully applying the Directive in your country? Note to interviewer: Information about the number and types of stakeholders, means and/or procedures to be collected.

PROCEDURES TO ADAPT ADD TO TECHNICAL PROGRESS

Recently, there have been three requests to adapt the Directive to technological progress:

- Alignment to the CLP Regulation (completed)
- Increase of the internal pressure from 13.2 to 15 bar for aerosols using non-flammable compressed or dissolved gas propellants; (ongoing)
- Increase of max volume to 1000 ml for plastic aerosols and modification of related requirements. (under discussion)

Q12 To what extent do you feel that these processes were smooth and efficient? To what extent and how did you as an association communicate an industry position on these matters to the Commission?

Note to interviewer: For interviews with professional associations.

Q13 Overall, do you feel that ADD is adequate in its current format to reflect the technological state-of-the-art in the field of aerosols?

Extent to which ADD achieved its main objectives

Q14 In your opinion have you observed that rules and legislation in the field of aerosol dispensers have been successfully harmonised across EU Member States? If not, please explain the consequences.

Q15 Have any of your aerosol products ever been subject to a refusal, prohibition or restriction by a Member State? Note to the interviewer: In case of associations use 'product within your sector' instead 'your product'

1. Did the product not comply with the Directive? What was the problem? Were the measures taken by the authorities justified?
2. Did the product formally comply with the requirements of the Directive? What was the problem? Were the measures taken by the authorities justified?
3. Do you know of any such cases outside your company / within the sector?

Q16 Have you received any complaints in relation to the safety of aerosol dispensers (e.g. by consumers or consumer organisations)? What was the problem? Was it linked to the ADD itself or was it another issue?

BARRIERS TO THE APPLICATION OF ADD

Q17 Has your company ever encountered any barriers in complying with the Directive? If so, can you explain which provisions were problematic and why?

Q18 To what extent the identified barriers have had a negative influence on the company's activities and performance? Please explain briefly the consequences resulting from them. What types of solutions and practices has your company adopted to overcome the barriers or to mitigate their effects?

Note to interviewer: For interviews with professional associations use the word "sector" instead "company".

IMPACTS OF ADD

Q19 What are the impacts on activities of your company "ways you do business"/ activities of economic operators as a whole (large companies or SMEs, different types of economic operators, e.g. manufacturers, fillers, distributors importers, etc.)?

Note to interviewer: relevant for economic operators and industry associations.

COMPETITIVE POSITION

Q20 How do you assess the company ability to mobilise and employ the productive resources required to successfully offer aerosol dispenser products and services in global economic environment? Has the situation evolved since 2005?

Q21 What is the company ability to drive and adapt to change through innovation? Likewise, has the situation changed since 2005?

Q22 Do you think that the Aerosol Dispenser Directive contributes to improving your company's ability to drive and adapt to change/competitiveness?

Note to interviewer: For interviews with professional associations use the word "sector" instead "company".

EXISTENCE OF ANY UNEXPECTED OR UNINTENDED IMPACTS

Q23 What unexpected or intended impacts (if any) has the ADD had on your company?

Note to interviewer: For interviews with professional associations refer to "sector" instead "company".

COST AND PROPORTIONALITY OF COSTS ASSOCIATED WITH ADD

Q24 What is the percentage of ADD related costs in total production costs per unit?

Note to interviewer: Unit to be defined per stakeholder (e.g. can for can manufacture, valve for valve manufacturers, etc.). Please also ask the company representative whether he/she would be willing to be part of the consultation with "typical companies".

Q25 Overall, were the costs associated with ADD proportionate to the benefits received?

If not, can you explain what/why the costs were too high?

What could be done to reduce these costs?

COHERENCE

Complementarity

Q26 Are there any overlaps or inconsistencies between ADD and any other Community or international legislation?

VALUE-ADDED

Q27 Describe the main benefits ADD has secured (and will secure for your organisation). Would the benefits be any different without the ADD? In what way and to what extent they would be different?

Note to interviewer: Relevant for interviews with economic operators.

Here you check in fact also what is the difference of applying one harmonised legislation in all MS compared to 28 national legislations each of them with similar but possibly and likely small differences.

Q28 in case the ADD would be repealed, do you consider that the application of 28 possibly different national legislation would hinder the internal market or represent a higher safety risk? What would it mean for your business

Q29. Any other issue you would like to raise in relation to ADD?

Interview guide for Public Authorities

Introduction

(N.B. Notes to interviewers in italics)

Interviewer to introduce the evaluation and purpose of the interview:

Information to the interviewee at the start of the interview: reference is to be made to the letter of intent that the interviewee has received when the contact for the interview was established.

The European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) has recently commissioned Technopolis Consulting Group to conduct an evaluation of the Aerosol Dispensers Directive (ADD) 75/324/EC. The objective of the evaluation is to assess whether the Directive is meeting its objectives of guaranteeing free circulation of aerosol dispensers within the EU while ensuring a high degree of safety. The evaluation will assess the effectiveness, efficiency, relevance, coherence, and EU added value of the Directive. It covers the period from 2005 to 2015.

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The evaluation project is scheduled to run from December 2015 to March 2017. The evaluation report will be presented and discussed in the Commission's working group related to the ADD and discussed with all relevant stakeholders. The final report of this study will also be made publicly available.

This interview constitutes an important input into this study. We will use the information from the interview in our reports to the European Commission.

Please be reassured that all data or opinions shared with the evaluation team will be analysed in all confidentiality and results will only be presented in an aggregated manner thus no commercially sensitive information will be disclosed in the evaluation report.

We will not quote you directly, nor will we attribute any statements to you as an individual. The name of your organisation may be included in the report as part of a list of stakeholders consulted during the study.

Background information to the interviewer. It is not needed to explain this to the interviewee. The ADD is one of the oldest EU legislations related to product safety. The directive defines aerosol dispensers as: "any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to

be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".[71]

Background information

Q1 Could you introduce yourself and your role within the national, regional or local authority?

Q2 Could you describe you authority's responsibilities with regard to ADD?

Note to interviewer: the answer would typically be: policy development / legal transposition in national law or enforcement (market surveillance consumer protection / economic inspection departments. In some countries, some responsibility is delegated to agencies (sometimes semi public-private bodies). Please note that market surveillance is often decentralised to the regional level.

Q3 How was the Directive transposed into the national legislation of your country? What is the name and reference of the relevant national law? How is it implemented and enforced in practice (main institutions and procedures involved)? Does the national law include requirements that are not included in ADD?

Note to interviewer: the last question could hint on gold-plating, but it could also be something quite normal to be specified at national level such as penalties and sanctions that apply when economic operators place non-compliant products on the market (pure penalties but also costs for testing, withdrawal from the market, destruction, etc.)

RELEVANCE

Q4 The Objectives of ADD are:

Guaranteeing that aerosol dispenser products are safe in respect of hazards related to pressure, flammability, and inhalation.

Securing free movement of aerosol dispenses on the EU common market.

Are those two main objectives relevant to the needs in the aerosol dispensers market? Can you explain why/why not?

Q5 In your opinion, is the Directive (including its articles and technical annexes) still relevant in the light of the technological progress made over the years/any potential newly emerging market trends?

Are any of the provisions out-dated or no longer relevant?

Are there any developments that have not been taken into account yet by the Directive?

[71] COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) (OJ L 147, 9.6.1975, p. 40) Consolidated version on EURLEX:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01975L0324-20130409&rid=1

IMPACT

Q11 Do you feel that the Directive led to a harmonisation of aerosol dispensers legislation across the EU? Can you explain why/why not?

Q12 Do you know of any cases where aerosol dispensers were prohibited from the market despite compliance with the ADD (either in your or another EU Member States)? If so, how was this resolved/addressed?

Q13 Does your national authority keep track of the number and types of consumer complaints in relation to aerosol dispensers? Can you explain how often you receive complaints related to the ADD and how severe these complaints are in your opinion?

Q14 Does your national authority keep track of the number of aerosol dispensers that were not compliant with the Directive between 2005 and 2015? When such cases are identified, what measures are taken to ensure compliance in the future?

EFFICIENCY

Q15 What are the costs and burdens associated with the implementation of the Directive (and the enforcement mechanisms) in your country? Have these costs changed over time?

Q16 What are the challenges with regard to market surveillance and enforcement? If any, how are these challenges addressed? Are there any specific market surveillance actions for products imported from third countries (e.g. at the level of customs control)?

Q17 Do you feel that the costs and burdens associated with ADD on your organisation are proportionate to the benefits of the Directive? Can you explain why/why not? Can you indicate how many Full time Equivalent (FTE) all allocated for the management and enforcement of ADD at national level?

COHERENCE

Q18 Does the Directive overlap or conflict with other European or national provisions? If so, do you think it is clear to economic operators which legislation takes precedence?

EU ADDED VALUE

Q19 In your opinion, what is the added value of Directive compared to regulation at national level? What would be different if each Member State had its own national aerosol dispensers legislation?

For the interviewer: before 1975 (start of ADD), there was national legislation. ADD harmonised that legislation with common provisions applicable across EU. Please note that ADD was an "optional" directive. A MS could allow an aerosol still locally on its market but could no longer refuse ADD compliant dispensers manufactured in another Member State and placed on its local market. Nowadays this is no longer applied and we have full harmonisation. It may happen that someone still refers to the optional aspect of ADD.

CONCLUSION

Q20 Did the Directive have any other positive or negative (unexpected or unintended) effects in practice? If so, can you explain?

Q21 Do you think that there are any necessary changes that should be made to the ADD in

the future?

If so, can you explain what changes and what would be the legislative procedure?

If so, can you explain why you consider such change is needed and what would be the most significant impacts of such change?

For the interviewer: the procedure is either a normal legislative proposal or a comitology procedure (adaptation to technical progress).

Q22 Can you think of any data sources or documents that would be useful for this evaluation (e.g. in terms of the impact of ADD on the environment or the EU internal market)? These could include studies at national level, statistical data on trade, data on accidents, etc.

Q23 Do you have any other final comments or remarks?

Interview guide for Consumer Organisations

Interviewer to introduce the evaluation and purpose of the interview:

Information to the interviewee at the start of the interview: reference is to be made to the letter of intent that the interviewee has received when the contact for the interview was established.

The European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) has recently commissioned Technopolis Consulting Group to conduct an evaluation of the Aerosol Dispensers Directive (ADD) 75/324/EC.

The objective of the evaluation is to assess whether the Directive is meeting its objectives of guaranteeing free circulation of aerosol dispensers within the EU while ensuring a high degree of safety. The evaluation will assess the effectiveness, efficiency, relevance, coherence, and EU added value of the Directive. It covers the period from 2005 to 2015.

The evaluation will apply the standard principles for evaluation as established by the European Commission. These provide a consistent framework for assessing the extent to which a Directive or policy has reached its set policy objectives. Information will be collected from all stakeholders (economic operators and their associations, public authorities and consumers/users and their associations). The information collected via the interviews will be complemented with information obtained via other data collection techniques such as an online targeted consultation and an online public consultation.

The evaluation project is scheduled to run from December 2015 to March 2017. The evaluation report will be presented and discussed in the Commission's working group related to the ADD and discussed with all relevant stakeholders. The final report of this study will also be made publicly available.

This interview constitutes an important input into this study. We will use the information from the interview in our reports to the European Commission.

Please be reassured that all data or opinions shared with the evaluation team will be analysed in all confidentiality and results will only be presented in an aggregated manner thus no commercially sensitive information will be disclosed in the evaluation report.

We will not quote you directly, nor will we attribute any statements to you as an individual. The name of your organisation may be included in the report as part of a list of stakeholders consulted during the study.

Background information to the interviewer. It is not needed to explain this to the interviewee. The ADD is one of the oldest EU legislations related to product safety. The directive defines aerosol dispensers as: "any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".[72]

BACKGROUND INFORMATION

Q1 Could you introduce yourself and your role within your organisation? Where is the organisation based and how many consumers does it represent approximately?

Q2 Do you know about this specific legislation related to the safety of aerosol dispensers?

- How familiar are you with the ADD?
- Are you familiar with the labels (and symbols like the inverted epsilon, hazard pictograms) on aerosol dispenser products and the meaning?

Q3 Do you know how to reach the national market surveillance authority. If you received a complaint from a consumer/user (citizen, worker), what do you do with it (e.g. contacting the authorities, the manufacturer)?

Note to interviewer: If the interviewee does not know well ADD (which is likely) this question is not giving any result. There could be a general question about what do you know about the information on the label of an aerosol dispenser? Do you know this information is obligatory by law (e.g. ADD)

RELEVANCE

Q4 One of the main objectives of the Directive is "To guarantee that aerosol dispenser products are safe in respect of hazards related to pressure, flammability, and inhalation" To what extent do you think that this objective is still relevant today? If not, can you explain why?

Q5 In your opinion, are the provisions of the Directive relevant to ensure the safety of aerosol products? Can you explain why/why not?

[72] COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) (OJ L 147, 9.6.1975, p. 40) Consolidated version on EURLEX:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01975L0324-20130409&rid=1

EFFECTIVENESS

Q6 To what extent do you think that the Directive contributed to enhancing the safety of aerosol dispensers in the EU? Please explain.

Q7 How many complaints does your organisation receive approximately in relation to aerosol dispensers? If any, can you elaborate on what types of complaints you receive and how often? Has the type and frequency of complaints changed over time? Are the complaints related to the requirements governed by the ADD or to other Directives?

Q8 Do you feel that the labelling provisions as laid down in ADD are sufficient and adequate to inform consumers/user (citizen, worker) of the safety hazards in relation to aerosol dispensers? If not, can you explain why?

Q9 Are there any differences in the extent to which ADD protects consumers/user (citizen, worker) in different EU Member States? If so, please explain. Note: Question only to be asked to EU level consumer organisations

Q10 Can you think of any institutions, means and/or procedures that you think are particularly important in successfully applying the Directive in your country?

CONCLUSION

Q11 Did the Directive have any other positive or negative (unexpected or unintended) effects in practice? If so, can you explain?

Q12 Do you think that there are any necessary changes that should be made in the future to the Aerosol Dispensers Directive? If so, can you explain how?

Q13 Can you think of any data sources or documents that would be useful for the evaluation (e.g. in terms of safety, accidents, the impact of ADD on the environment or the EU internal market)?

Note for interviewer: ADD as such has no provision on environment. From consumer organisations, you may get remarks related to greenhouse gases etc. or waste recycling.

Q14 Do you have any other final comments or remarks?

ANNEX 8 - TARGETED ONLINE SURVEY

Please select language /Bitte wählen Sie Ihre Sprache / Veuillez sélectionner votre langue/ Por favor, seleccione su idioma / Si prega di selezionare la vostra lingua / Proszę wybrać język

- English
- Français
- Deutsch
- Español
- Italiano
- Polski

Introduction to the survey

Background information on the Aerosol Dispensers Directive 75/324/EC

The Aerosol Dispensers Directive (ADD) (75/324/EEC) is one of the oldest EU legislations related to product safety.

The text of the directive can be found on EURLEX: link. This document is the consolidated version based on the original directive and includes all changes until now.

The directive defines aerosol dispensers as: "any non-reusable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".[73]

Technopolis Group, has been commissioned by the European Commission to conduct an evaluation of the ADD. The objective of the evaluation is to assess whether the Directive is meeting its objectives of guaranteeing free circulation of aerosol dispensers within the EU while ensuring a high degree of safety. To achieve this purpose the study evaluates the effectiveness, efficiency, coherence, relevance and EU added value of the Directive.

The evaluation will cover the period 2005 to 2015, although in specific cases it will be inevitable to take into account the situation before this period in order to be able to evaluate some aspects which are related to the ADD.

The evaluation project is scheduled to run until March 2017. The evaluation report will be presented and discussed in the Commission's working group related to the ADD and with all relevant stakeholders. The final report of this study will also be made publicly available.

We are conducting this survey in order to gather information on the influence of the Directive on different type of stakeholders. We would greatly appreciate if you could complete the following questionnaire. It is made up mostly of multiple-choice questions and it should take no more than 15 minutes to complete.

---

[73] COUNCIL DIRECTIVE of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) (OJ L 147, 9.6.1975, p. 40) Consolidated version on EURLEX:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01975L0324-20130409&rid=1

Your response will be treated confidentially and care will be taken to ensure specific responses cannot be linked to individual companies.

If you have any questions regarding this survey or if you encounter any technical difficulties, please contact: Paresa Markianidou, Technopolis Group, paresa.markianidou@technopolis-group.com +32 2 737 74 42

How familiar are you with the Aerosol Dispensers Directive (75/324/EC)?

- I do not know ADD
- I partially know ADD
- I know ADD very well

Thank you for your willingness to participate to this survey. The survey is targeted to the Aerosol industry and concerns the Aerosols Dispenser Directive. Should you know other relevant stakeholders we would appreciate if you could forward the survey to them.

Presentation of company

Q1 Is your company one of the following (please select one or several options from a single column):

- Manufacturers of cans
- Manufacturers of valves
- Filling industry
- Other, please specify (e.g. marketing/sales/distribution, test laboratories, R&D, storage, transport, waste and recycling, etc.)

Q2 If yes, please specify the types of goods you work with (if more than three, please select the three most important in terms of volume):

PERSONAL CARE	
Deodorants/Antiperspirants	
Hair Mousse	
Hairsprays	
Shaving Mousse & Gels	
Others	
HOUSEHOLD	
Insecticides & Plant Protection Products	
Textile/Fabric Care Products	
Air Fresheners	
Furniture/Waxes & Polishes	
Oven Cleaners	
Bathroom & Kitchen Cleaning Mousse	
Shoe/Leather Care Products	
Others	
OTHERS	
Automotive Products (excluding paints)	
Paints & Varnishes (including automobile use)	

Industrial & Technical Products	
Pharmaceutical & Veterinary Products	
Food Products	

Q3 If yes, please insert the name of company and contact information (Optional – Please only provide this information if you agree to being contacted by the evaluation team for a qualitative telephone interview)

Q4 In which country are the headquarters of your company located?

Q5 Please state the number of personnel currently working in your company (<250, >=250)

Note to designer of online survey (no translation required): use drop down menu.

Q6 Please specify the turnover of your company for the last year of operation (<=50M€, >50M€)

Q7 Please indicate what share of your turnover comes from each of the following markets: domestic, European, international (0%-100%)

Domestic

European (drop down list with European countries)

Note to translator: list of European countries to be translated (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, Other please specify)

International

ADD in practise within your industry

Q8 Is your company subject to different rules and requirements for aerosol dispensers in different EU Member States in which you operate?

No the EU markets I operate in apply the rules and requirements set out in ADD in the same way

Yes the EU markets I operate in apply the rules and requirements set out in ADD differently

Not Applicable

[IF yes]

- Explain the rules and/or requirements that differ

- Indicate the country(ies)

Q9 Were your aerosol dispenser products ever refused, prohibited, or restricted in another Member State, despite compliance with the ADD?

Yes

No

Not Applicable

[IF Yes]

- Explain why

- In which country?

- Were the reasons for refusal, prohibition, or restriction on the basis of ADD provisions?

Contribution of ADD on Health, Safety and Market Operation

Q10 In your opinion has ADD contributed to

	No	Yes			I Don't Know
		Slightly	Moderately	Significantly	
The safety of aerosol dispensers with regard to hazards due to pressure					
The safety of aerosol dispensers with regard to hazards due to flammability					
The safety of aerosol dispensers with regard to risks resulting from inhalation					
Facilitating free movement of products within the EU					
Facilitating export to countries outside of the EU					

Please describe any other variables that also influence the health, safety, environmental impact, market operation and innovation of aerosol dispensers and their importance.

ADD's provisions and technical specifications

Q11. In your opinion, are the following provisions or technical specifications in the Directive required, appropriate and still relevant?

Provision and requirements of the Directive	Yes	No	I don't know	Please explain why or comment if changes would be required
Definition of aerosol dispenser (article 2)				
Labelling requirements (article 8)				
Definitions (Annex Section 1)				
General provisions on construction and equipment (Annex Section 2.1)				
General provisions on labelling (Annex Section 2.2)				
Special provisions for metal aerosol dispensers (Annex Section 3)				
Special provisions for glass aerosol dispensers (Annex Section 4)				
Special provisions applying to plastic aerosol dispensers (Annex Section 5)				
Tests (Annex Section 6)				
Other (please specify)				

Q12 Are you aware of any safety gap in the current requirements of ADD?

- Yes
- No
- Not Applicable

IF [Yes], could you please explain

Q13 According to your opinion, to what extent does ADD provide a flexible framework that allows technological innovation and the development of new products?

- Significantly
- Moderately
- Slightly
- Not at all
- I don't know

Q14 In the past, the directive has been changed in order to adapt to technical progress. In this context, do you know about the alternative test methods for final inspection of filled aerosol dispensers introduced in the ADD in 2008?

- Yes
- No

Have you used any such method?

IF [Yes], what are the experiences and possible gaps (if any)?

Q15 Has the change to the ADD in 2008 to increase maximum pressure from 12 to 13,2 bar at 50 °C in case of non-flammable propellant led to new aerosol dispensers' applications?

- Yes
- No

IF [Yes], can it be quantified, i.e. percentage shift in using non-flammable propellant due to the change in maximum allowable pressure limit in ADD (13,2 bar)?

Q16: In order to ensure compliance of the aerosol dispensers with the requirements of the Directive, do you use:

Private standards or codes (such as FEA standards)?

IF [Yes], could you specify which standards?

European Standards (EN)

IF [Yes], could you specify which standards?

International Standards (ISO)?

IF [Yes], could you specify which standards?

Costs imposed on your company associated with ADD

Q17 What is the cost of ADD in relative terms (% share of production cost per unit) on average (consider the period 2005-2015)?

Example: ADD represents on average 0.2 % of total production cost per unit during the period 2005-2015

Notes: consider total production cost as all costs incurred to the production of the good in itself, such as raw materials, direct labour costs (staff directly linked to a production unit), energy, buildings, machinery and equipment, production overheads.

- 0 %
- below 5 %
- between 5 %-10 %
- between 10 % - 30 %
- between 30 % - 50 %
- Above 50 %, please specify

Comment:

Q18 How many resources has your company dedicated on average (consider the period 2005-2015) to fulfil the administrative tasks resulting from ADD?

Example: to comply to ADD 0.2 Full Time Equivalent are required annually to handle the administrative burden (an FTE of 0.2 signals a fifth of a full work)

Notes: consider labelling and artworks, traceability i.e. the legal entity responsible for marketing of the product appears on the label, test records.

- Less than 0.5 FTE, please specify
- 0.5 – 1.0 FTE
- – 2.0 FTE
- – 5.0 FTE
- 10.0 FTE
- Above 10.0 FTE, please specify

Comment:

Q19 How much has your company spent to invest in equipment, testing, human resources, training costs resulting from ADD (consider the period 2005-2015)? Please indicate the years during which the majority of the investments were made.

Example: to comply to ADD an investment of 2,000,000 euros was made during the period 2005-2015; the investments were made predominantly in the years 2005, 2006 and 2007.

Notes: consider capital expenditures (CAPEX), operating expenditures including personnel, operation and maintenance (OPEX)

- less than € 200,000, please specify
- € 200,000 - € 500,000
- € 500,000 - € 1,000,000

- € 1,000,000 - € 2,000,000
- € 2,000,000 - € 5,000,000
- above €5,000,000, please specify

Comment:

Q20 To comply with the legislation did you get a loan (i.e. to finance the aforementioned investments)?

- Yes
- No

IF [Yes]

- Indicate the year you received the financial support

- Provide an estimate of the percentage of ADD related costs that are financed through this loan

Q21 In implementing the legislation have you experienced delays in operations with financial implications or losses in business?

- Yes
- No
- Not Applicable

Comment:

Q22 As a consequence of the introduction of ADD did you experience increased costs due to the need to substitute inputs e.g. propellants and solvents for aerosol products?

- Yes
- No
- Not Applicable

IF [Yes]

What is the % increase of production cost

Comment:

Q23 Overall, to what extent do you think that costs outweigh benefits (Health, Safety and Market Operation) of the Directive?

3 The benefits are far higher than the costs	2 The benefits are higher than the costs	1 The benefits are slightly higher than the costs	0 Costs and benefits are balanced	-1 The costs are slightly higher than the benefits	-2 The costs are higher than the benefits	-3 The costs are far higher than the benefits

Comment:

Q24 Any other issue you would like to raise in relation to the Aerosol Dispensers Directive?

IF [Yes], could you please explain.

Thank you for your participation in this survey.

ANNEX 9 – PUBLIC CONSULTATION

This annex presents the results of an Open Public Consultation (OPC) on the Aerosol Dispensers Directive (ADD) 75/324/EEC. The consultation consisted of an online questionnaire available in English, French, German, Spanish, Italian and Polish. It ran from the 30th of September 2016 to the 15th of January 2017 (15 weeks).

The aim was to collect feedback from the public on their use of aerosol dispensers and their views on the Directive. DG GROW advertised on the consultation via its website. The questionnaire was available on EUsurvey and accessible on the 'single access point'.

The OPC was launched prior to the analysis phase and the inputs were used to inform the evaluation questions. The OPC was part of the stakeholder consultation task, which also included three targeted consultations (in-depth interviews, consultations with 'typical' companies and a targeted online survey). The questionnaire complied with the general principles of stakeholder consultation and the five minimum standards set out in the guidelines, namely: Clarity, Targeting, Publication, Consultation period and Feedback[74]. All the opinions expressed by the 139 respondents have been taken into account and are presented below.

IDENTIFICATION

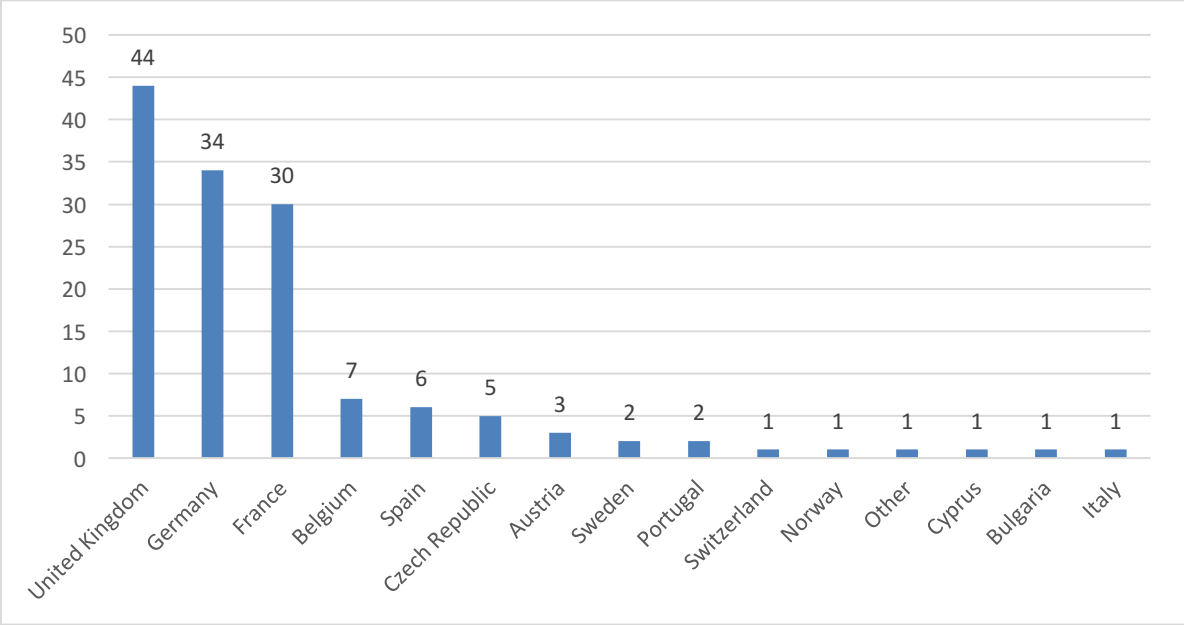
BACKGROUND

A large majority of the respondents identified as **consumers/users or members of an association of consumers/users**: 111 out of 139 (**80%**). **Economic operators or members of professional associations** were 24 (17%) to answer. The four remaining respondents participated as **public authority** (3%).

COUNTRY

More than three quarters (78%) of the respondents come **from three countries**: The United Kingdom (32%), Germany (24%) and France (22%). The remaining respondents come from 11 countries (including non-EU members Norway and Switzerland) (Figure 40).

FIGURE 40 – COUNTRY OF ORIGIN OF THE RESPONDENTS



Source: Technopolis Group 2017.

[74] Box 2: General principles and minimum standards for consultation: http://ec.europa.eu/smart-regulation/guidelines/ug_chap7_en.htm

REGISTRATION

Most respondents answered the consultation **as individuals** (76%). The rest answered as **organisations**. Of the 33 respondents answering on behalf of organisations, 22 of them **were not registered** in the Transparency Register of the European Commission and the European Parliament; hence, 11 were registered (they represent 33% of the organisations and 8% of all the respondents).

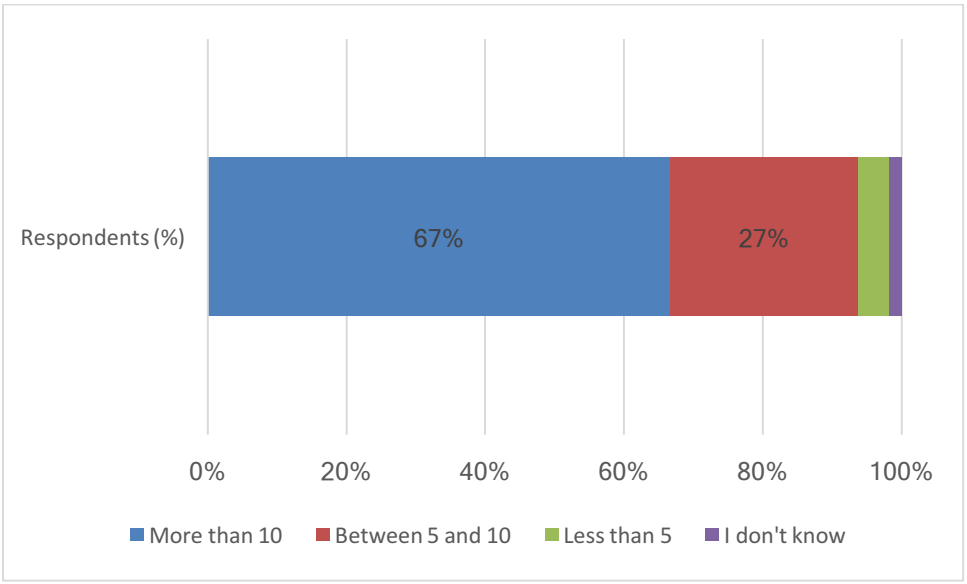
QUESTIONS FOR CONSUMERS/USERS

As mentioned above, 111 respondents identified as (association of) consumers/users. The following questions were asked to those respondents only and thus they will be described accordingly (n=111).

PRODUCTS PURCHASE

Overall, 94% of the consumers/users buy, in average **at least five aerosol products a year**. While 27% buy between 5 and 10 products a year, 67% buy more than 10. The remaining 6% either buy less than five products per year (4%) or do not know (2%) (Figure 41).

FIGURE 41 – AMOUNT OF AEROSOL PRODUCTS BOUGHT BY THE CONSUMERS/USERS

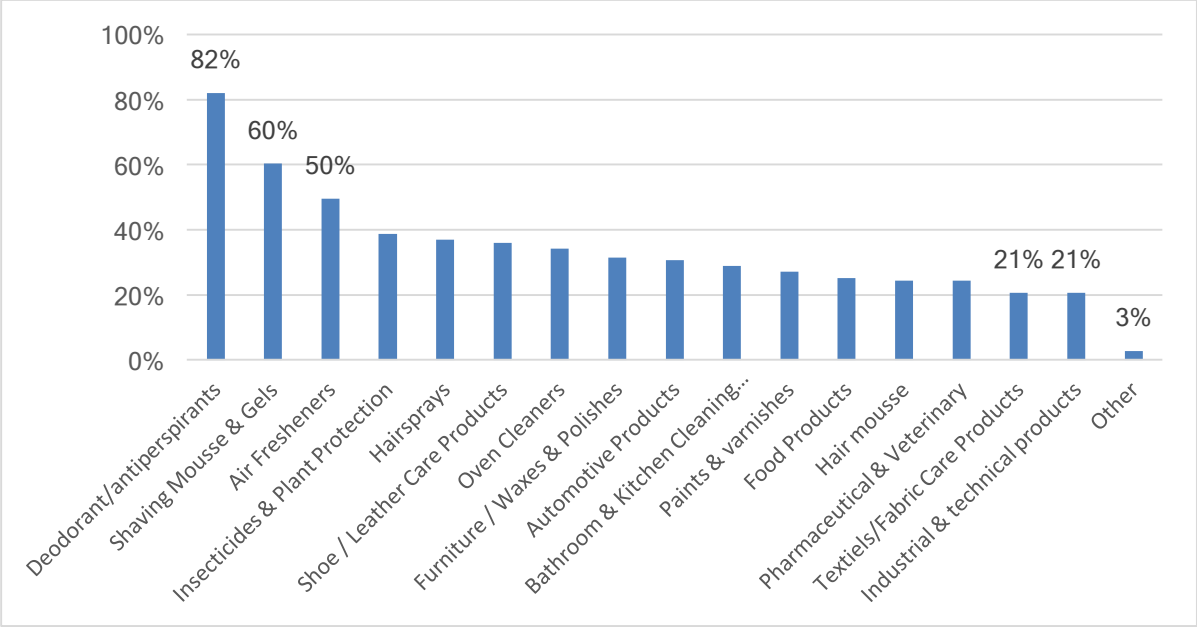


Source: Technopolis Group 2017.

CATEGORIES OF PRODUCT

The respondents were asked to answer a multiple-choice question concerning **the categories of aerosol dispenser products they use regularly**. Except for the "Other products" (3%), each type is used by **at least 20%** of the users/consumers. Textiles/Fabric care products and Industrial/technical products are the less used (21% each). On the other hand, Deodorant/antiperspirants are the most used product (82% of the respondents), followed by Shaving mousse/gels (60%) and Air fresheners (50%) (Figure 42).

FIGURE 42 – CATEGORIES OF THE AEROSOL PRODUCTS REGULARLY USED BY THE CONSUMERS/USERS

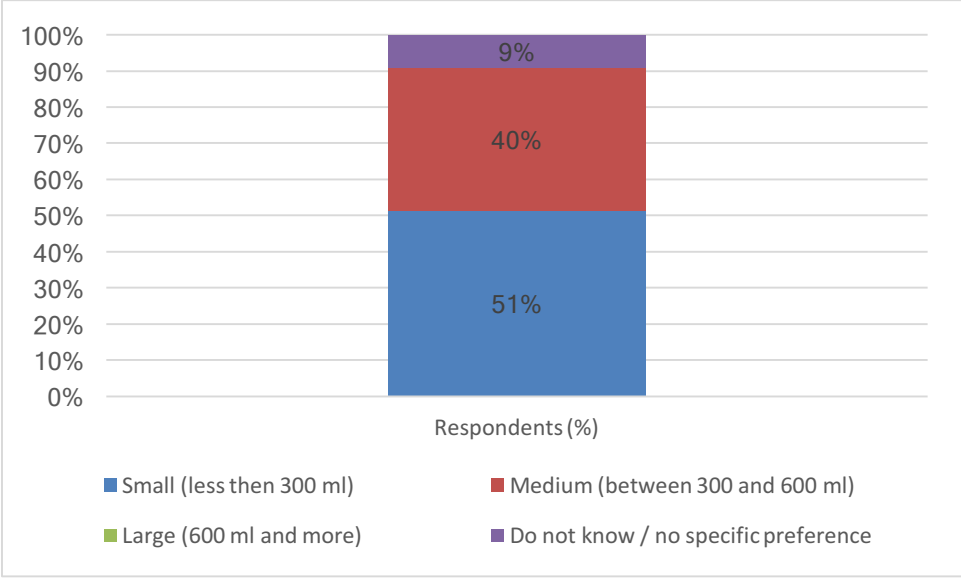


Source: Technopolis Group 2017.

SIZE OF THE AEROSOL DISPENSERS AND APPROPRIATENESS

Half of the respondents mostly buy **Small dispensers** (less than 300 ml, 51%). The rest either buy Medium size dispensers (300/600 ml, 40%) or have no specific preference (9%). Consequently, none of the 111 respondents buy Large size dispensers (600+ ml) (Figure 43).

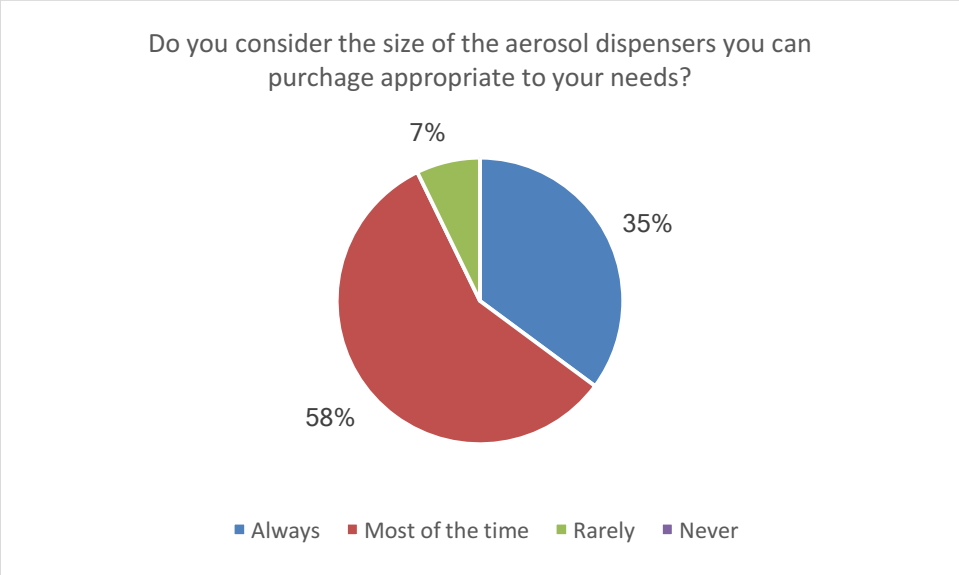
FIGURE 43 – SHARE, BY TYPE, OF THE SIZE OF THE DISPENSERS PURCHASED BY THE USERS/CONSUMERS



Source: Technopolis Group 2017.

93% of the respondents find **the size of the dispensers purchased appropriate to their needs**: while 35% are 'always satisfied', a majority (58%) is satisfied 'most of the time' with the size of the dispensers. If a small share of the respondents (7%) is 'rarely' satisfied, none are 'never' happy with their purchase (Figure 44).

FIGURE 44 – SHARE, BY TYPE, OF THE ANSWERS TO THE QUESTION ON THE APPROPRIATENESS OF THE SIZE OF THE DISPENSERS PURCHASED



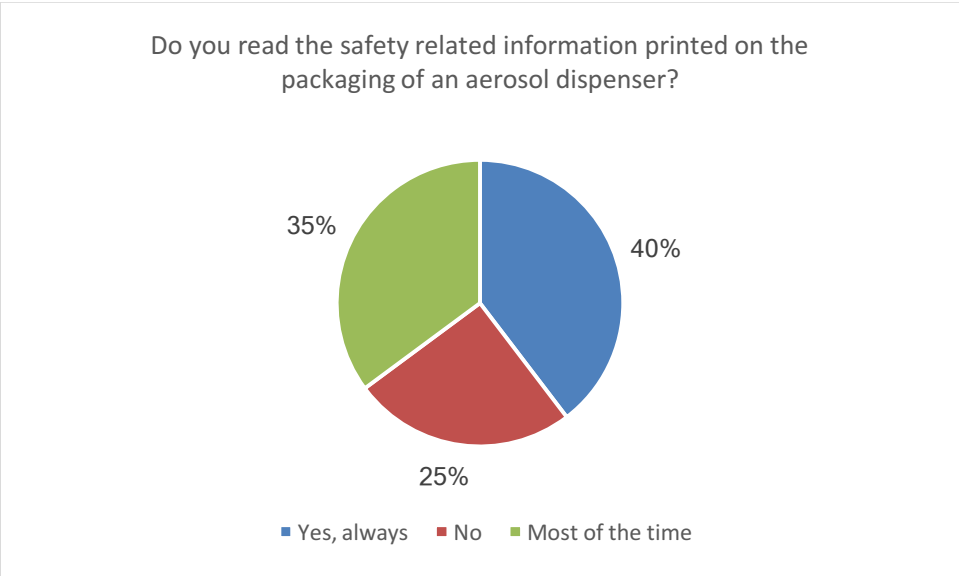
Source: Technopolis Group 2017.

Note that the share of 'always' satisfied is higher among Small-size buyers (43% of them) than among Medium-size buyers (27% of them).

LABEL AND RELATED INFORMATION

To the question '*Do you read the safety related information printed on the packaging of an aerosol dispenser?*', 25% of the respondents answered that they 'did not'. On the other hand, **a majority (40%) 'always' read the labe**l, while 35% read it 'most of the time' (Figure 45).

FIGURE 45 – SHARE, BY TYPE, OF THE ANSWERS TO THE QUESTION ON THE READING OF SAFETY RELATED INFORMATION

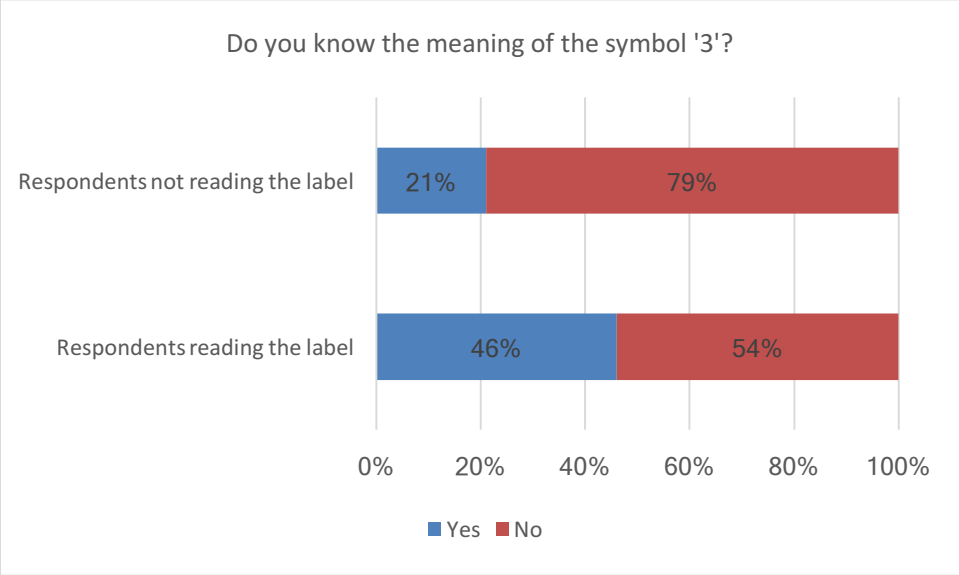


Source: Technopolis Group 2017.

Of the 111 respondents, **60% did not know** that the symbol '3' (*inverted epsilon*) on the label of an aerosol dispenser certifies the compliance of the product with the Aerosol Dispensers Directive. We crossed the answers to this question with the answers to the question above. It appears that among the respondents who

read the label (both Always and Most of the time), 46% of them knew the meaning of the symbol '3'. This rate drops to 21% among the respondents who do not read the label (Figure 46).

FIGURE 46 – SHARE OF THE ANSWERS TO THE QUESTION ON THE MEANING OF THE SYMBOL '3' BY TYPES OF RESPONDENTS



Source: Technopolis Group 2017.

SAFETY OF AEROSOLS

99% of the respondents consider aerosol dispensers as safe products. Only one respondent considers aerosol dispensers not to be safe. However, he/she did not explain his/her answer.

Similarly, 97% of the respondents have never encountered any safety problem when using an aerosol dispenser. Of the three respondents who faced a safety problem, one described it as follows: "actuator stopped working".

QUESTIONS TO THE ECONOMIC OPERATORS/PROFESSIONAL ASSOCIATIONS

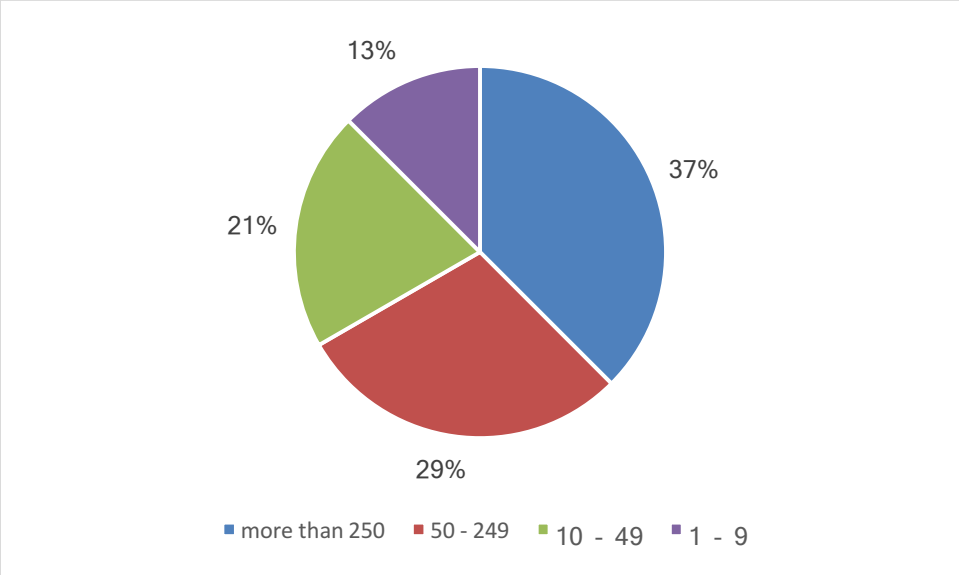
Twenty-four respondents identified as economic operators or professional associations. The following questions were asked to them only. The results will be described accordingly (n=24).

PROFILE

Respondents mostly come from filling industry (9 of them, or 38%), marketing/sales/distribution (6, 25%) and professional associations of economic operators (5, 21%). Three respondents are manufacturers (cans and household products) and one is a consultant.

More than a third (37%) of the respondents come from large companies (250+ staff). The share of the other groups decrease with the size of the company (see below). Overall, smaller size companies (less than 50 staff) represent a third of the total respondents (8 out of 24, 34%) (Figure 47).

FIGURE 47 – SHARE, BY SIZE, OF THE ANSWERS TO THE QUESTION ON THE SIZE OF THE RESPONDENTS' COMPANY



Source: Technopolis Group 2017.

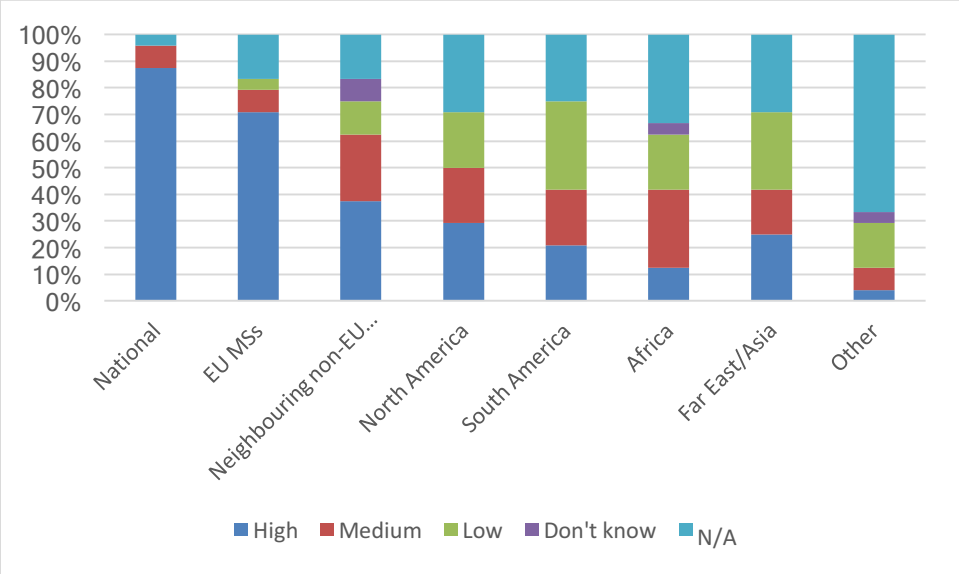
IMPORTANCE OF GEOGRAPHICAL AREAS

Among the respondents, the **national level is the most important geographical area** with 96% of respondents flagging it as of either 'high' (88%) or 'medium' (8%) importance (the remaining 4% are 'non-applicable' answers). EU level comes second with 71% of the respondents flagging it as of 'high' importance. Neighbouring non-EU countries are in third position in terms of importance, with 38% of the respondents flagging them as of 'high' importance and 25% as of 'medium' importance.

Other continents are of less importance to the respondents, as half or less of them consider North America, South America, Africa and Far East/Asia to be of 'high' or 'medium' importance. South America (33%) and Far East/Asia (29%) are the geographical areas mostly flagged with 'low' importance (Figure 48).

Note that if respondents did not tick any option, we included it as 'non-applicable', in order to maintain a constant n=24.

FIGURE 48 – SHARE, BY GEOGRAPHICAL AREAS, OF THEIR LEVEL OF IMPORTANCE



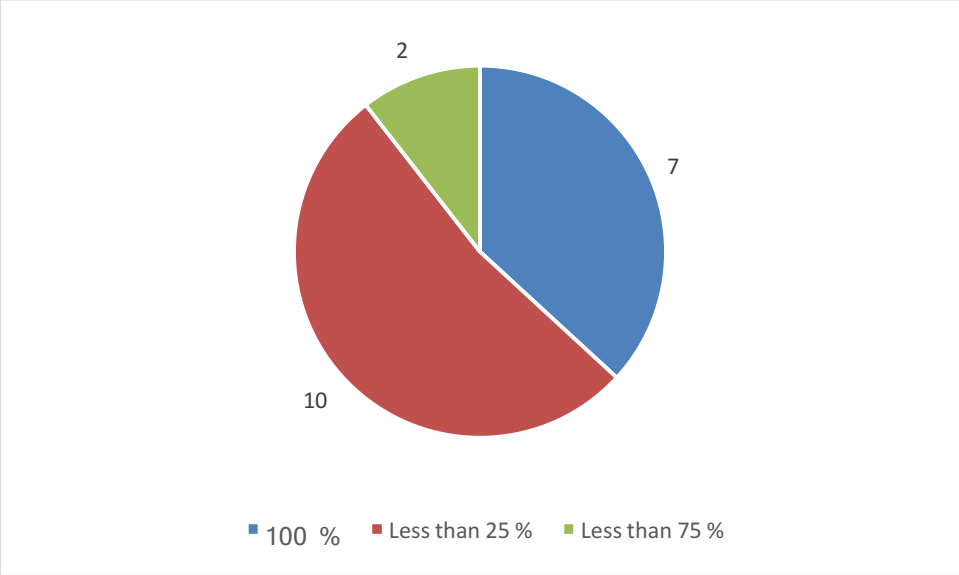
Source: Technopolis Group 2017.

RATIO AEROSOL DISPENSER ACTIVITIES/OVERALL REVENUE

Concerning the share of aerosol dispenser activities compared to the respondents' company's overall revenue, it appears that the question was not applicable to five (21%) of them (e.g. because they are professional associations). They were deduced of the total for this calculation.

Henceforth, for more than half (10, 53%) of the remaining 19 respondents, the share of aerosol dispenser activities represents less than 25% of their company's overall revenue. It represents less than 75% for 2 respondents (11%). 7 respondents (37%) have their company's overall revenue coming 100% from aerosol dispenser activities (Figure 49).

FIGURE 49 – SHARE, BY CATEGORY, OF THE RATIO AEROSOL DISPENSER ACTIVITIES/OVERALL REVENUE (NB: N=19)



Source: Technopolis Group 2017.

ADD'S SAFETY OBJECTIVES

21 of the 24 (88%) respondents believed that the ADD achieved its safety objectives (aerosol dispenser products are to be safe in respect of hazards related to pressure, flammability and inhalation) 'to a large extent'. Two believed the ADD achieved its objective to a 'moderate extent' and one did not know.

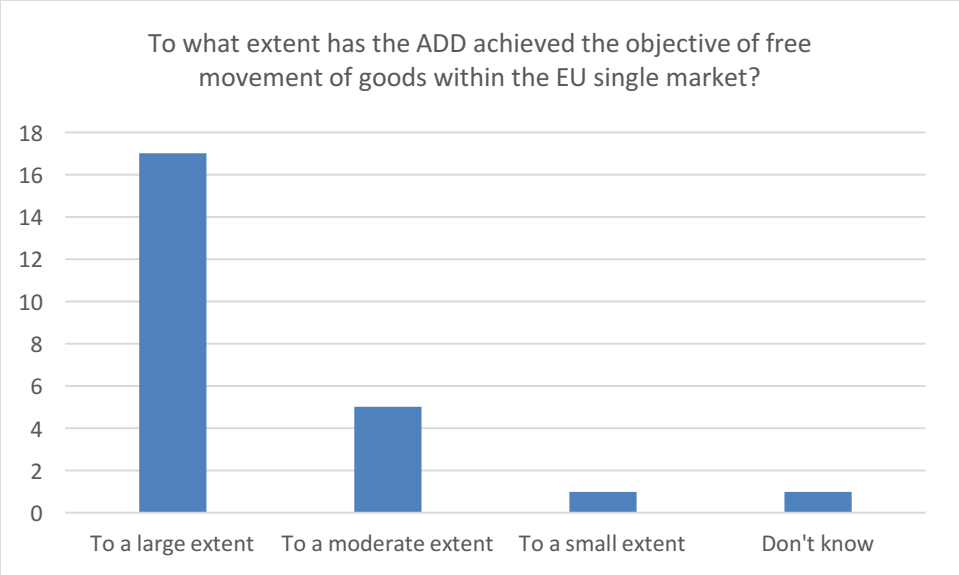
SAFETY PROBLEMS

All 24 respondents have never encountered any problem in relation to unsafe aerosol dispensers.

ADD AND FREE MOVEMENT OF GOODS

Most of the respondents (92%) considered that ADD has achieved free movement of goods within the EU single market. 71% considered the objective was achieved "to a large extent" while 21% considered it was achieved 'to a moderate extent. The remaining 8% represents two respondents: one considered it was achieved 'to a small extent'; the other one did not know (Figure 50).

FIGURE 50 – EXTENT TO WHICH THE RESPONDENTS CONSIDER THE FREE MOVEMENT OF GOODS OBJECTIVE HAS BEEN ACHIEVED BY THE ADD



Source: Technopolis Group 2017.

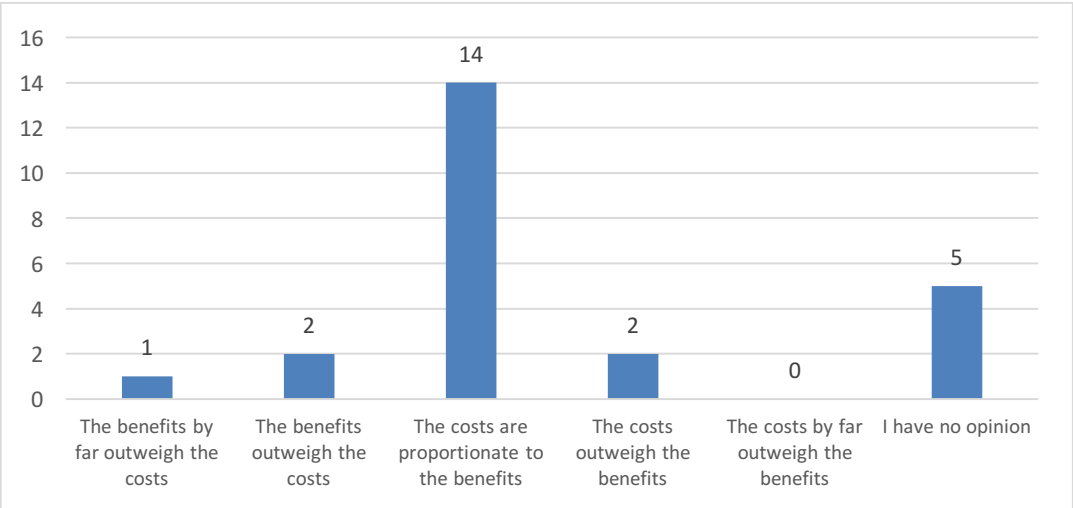
AEROSOL DISPENSERS ON THE MARKET

Most of the respondents (92%) never encountered any problem to place aerosol dispensers on the market. However, two of them faced difficulties. A respondent said difficulties emerge when one wants to commercialise a specific size. The other one said that ADD, because of regulations ("*technologies made of plastics are limited in size and have to fulfil a legislation which is not taking into account all the technological progress made by the industry*"), prevented new technologies to be placed on the market.

HARMONISATION'S COSTS AT EU LEVEL

The respondents were asked to balance the costs due to the Aerosol Dispensers Directive and the benefits obtained via this harmonisation at EU level. Though a fifth (21%) of the respondents did not have an opinion, it appears that the answers are slightly bending towards the benefits outweighing the costs. 14 respondents, out of 24 (58%), think **the costs are proportionate to the benefits**; two (8%) believe that the costs outweigh the benefits while three (12%) consider the opposite (Figure 51).

FIGURE 51 – EXTENT TO WHICH THE RESPONDENTS COMPARED THE COSTS AND BENEFITS BROUGHT ABOUT BY THE ADD

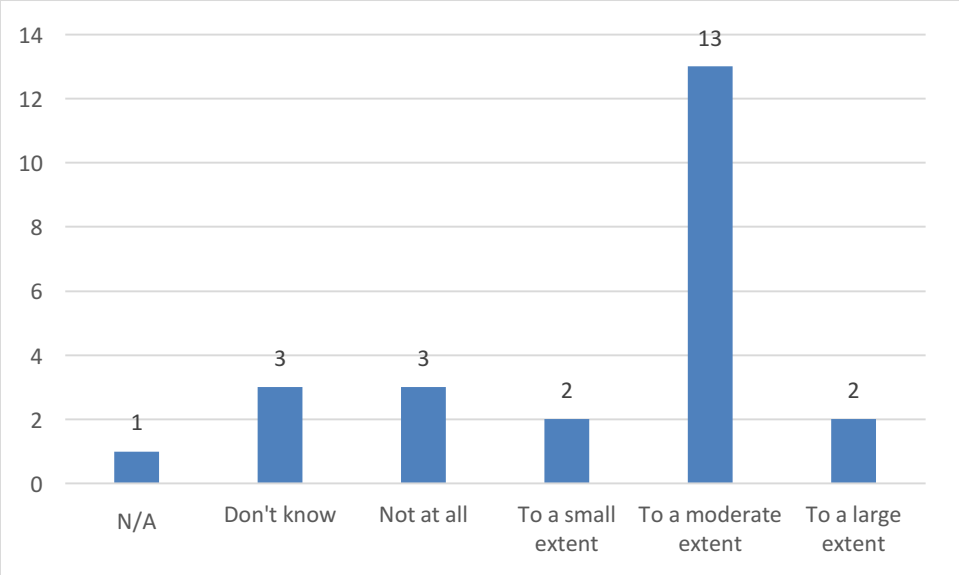


Source: Technopolis Group 2017.

COST SAVINGS IN INNOVATION

When it comes to innovation in product development and packaging design, half (54%) of the respondents considered that the ADD brought cost savings 'to a moderate extent'. Two of them (8%) considered the ADD enabled cost savings 'to a large extent'. The rest considered the ADD had either a 'small' impact (8%) or 'no' impact (13%) on cost savings. Three respondents (13%) did not know and one did not answer the question (Figure 52).

FIGURE 52 – EXTENT TO WHICH THE ADD HAS LED TO COST SAVINGS IN RELATION WITH INNOVATION IN PRODUCT DEVELOPMENT AND PACKAGING DESIGN



Source: Technopolis Group 2017.

QUESTIONS TO PUBLIC AUTHORITIES

Four respondents identified as public authorities. Three have replied to the questionnaire on behalf of national authorities (only one specified: the Norwegian Directorate for Civil Protection) and one on behalf of another entity (namely, an eco-agency certified by public authorities).

MARKET SURVEILLANCE

One respondent works for an authority in charge of market surveillance and/or inspection of aerosol dispensers. The three others are not.

SAFETY OBJECTIVE

The ADD aims at securing the free movement of aerosol dispensers while guaranteeing safety objectives. One respondent considers it has managed to guarantee this objective "to a large extent", two "to a moderate extent" and one "to a small extent".

SAFETY PROBLEMS

Two respondents are aware of safety problems with aerosol dispensers, while two are not. When asked to specify, the respondents answered as follows:

- Some aerosol dispensers used as fire extinguishers are filled with Nitrogen, a compressed gas as a propellant. The provided response had suggested butane in the first instance, however, there is no evidence of its use as propellant.
- The presence of inflammable gas is a source of ignition in sorting centres (both for aluminium and PET dispensers). For conditioning purposes, the dispensers are pressed. During the operation, the simultaneous outburst of gas residual, active substance and solvents can provoke fires.

BAN OF UNSAFE PRODUCTS

None of the respondents are aware of unsafe aerosol dispensers banned from the market by the market surveillance authority.

FREE MOVEMENT OF GOODS

Two respondents considered that the ADD has achieved the objective of free movement of goods within the EU single market "to a large extent" and one "to a moderate extent". The fourth respondents did not know.

CHANGES TO THE ADD

While two of the respondents have answered that their authority considers that no changes to the ADD are needed, two said their authority considers changes are needed. Both are mentioning safety issues.

- Establishing safety requirements for aerosol dispensers and technical procedures to verify their compliance to the requirements
- Total absence of the recycling / "end of life" part in the Directive. It should be included, especially when it comes to safety issues related to inflammable gas contained in this type of packaging.

OTHER QUESTIONS AND FURTHER COMMENTS

DISPOSAL

The respondents were asked on the way they dispose a used aerosol dispenser. More than three quarters of them (77%) include it as separate recyclable waste. 19% include it in the normal household garbage. Two respondents follow another procedure: one disposes his/her used aerosol dispenser in a *gelber sack* (yellow bag in German)[75] while the other one uses the "destruction chain for aerosols". Six (4%) respondents did not answer the question.

FURTHER COMMENTS

The respondents were offered the opportunity to submit any additional comments to their answers.

Twenty users did so. Overall, they all commented on their satisfaction with the ADD and its impact. The ADD is regarded as properly enforced and effective. It set clear and harmonised standards and became an international reference. The users/consumers feel well informed and safe. They believe no improvement is needed.

However, a respondent emphasises the absence of a recycling / "end of life" part. Though he acknowledges that safety is achieved for the users, he believes it is not the case for sorting centre's agents. Another respondent believes that it is difficult to understand how to dispose of the dispensers as disposal is not harmonised among the regions.

When it comes to the economic operators, 11 have added a comment. Overall, they are also satisfied with the ADD. They believe it has brought about an effective market with harmonised standards and allowed the free circulation of goods and safety for users. The fact that it is a single piece of legislation is a plus. It is clear and easy to understand.

However, a respondent mentioned that the legislation deals with existing technology only. Therefore, new propellant-free technology cannot access the market. Another respondent emphasised on the fact that health risks should be included in an updated version of the ADD. He mentions the issue of the inhalation of aerosols droplets/particles and the lung deposition it creates to the professionals who frequently use this kind of product.

[75] Gelben sack (in Germany and Austria) are plastic bags in which light packaging waste can be dispensed.

ANNEX 10 – COSTS GRIDS

COMPANY PROFILE

Company profile	
Company name	
Address of headquarters	
Address of European headquarters if different	
Countries in which the company has operations (plants, distribution, etc.)	
Contact person (name)	
Contact person (position in company)	
Contact person (e-mail)	
Contact person (telephone number including country code, e.g. +32 for Belgium)	
Industry	Manufacturer of cans Manufacturer of valves Filling industry
Product	Deodorants/Antiperspirants Hair Mousse Hairsprays Shaving Mousse & Gels Insecticides & Plant Protection Products Textile/Fabric Care Products Air Fresheners Furniture/Waxes & Polishes Oven Cleaners Bathroom & Kitchen Cleaning Mousse Shoe/Leather Care Products Automotive Products (excluding paints) Paints & Varnishes (including automobile use)

	Industrial & Technical Products Pharmaceutical & Veterinary Products Food Products
Number of Employees (latest available year)	
Turnover (Thousand € per annum – average of last three years)	
Number of sites in Europe and locations	
EBITDA	
Company average output (number of units: Number of cans for can manufacturers; Number of valves for valve manufacturers; tons for solvents and propellants)	
Total Production Cost (€ per annum – average of last three years)	
Total Production Cost (€ per unit of output – aerosol dispense, aerosol can, aerosol valve)	

DATA REQUIREMENTS IMPLIED BY ADD DURING THE PERIOD 2005-2015

QUESTIONS			EXPLANATORY NOTES	COSTS ESTIMATIONS
SUBSTANTIVE OBLIGATIONS **Capital Expenditures (CAPEX)** **Investment Costs**				
Q1	**To comply to the legislation did you have to invest in tangibles (e.g. testing equipment in Research & Development and in production)**	YES/NO	Add explanatory notes	Yes/No
Q1.1	If [YES]: What was the level of capital expenditure of your investment?	Insert total capital cost and expected lifetime. Provide as much detail as possible on the type of investments (e.g. equipment for test pressure and bursting pressure, for flammability testing, for compatibility testing, hot water bath testing etc.)	Add explanatory notes	Total capital cost Expected lifetime
Q1.1.3	When did you initiate the investment to comply with regulation?	Insert the start year	Add explanatory notes	Year
Q1.1.3.1	Over which years where investments made and what was the % made per year	Insert year and % share of investment	Add explanatory notes	Year & % share
Q1.1.4	What is the share (%) of this investment dedicated to comply with this legislation	Provide estimates of the % share attributable to ADD	Add explanatory notes	% share
Q1.2	If [NO]: What was the reason for not making investments to comply with legislation	Examples include equipment's, systems, procedures already in place with adequate performance, outsourcing some testing requirements etc.	Add explanatory notes	Text
Q1.2.1	IF (NO): What was the additional capital expenditure invested in anticipation of the upcoming	Equipment or standards already in place and sufficient to comply with	Add explanatory	Total capital cost

QUESTIONS			EXPLANATORY NOTES	COSTS ESTIMATIONS
	legislation or the additional cost of such investments made as business as usual	legislation or investments made as business as usual	notes	
SUBSTANTIVE OBLIGATIONS **Operating Expenses (OPEX)** **Personnel Costs**				
Q2.1	To comply with this legislation did you allocate specific existing personnel or hire additional human resources or outsourced services with the necessary skills?	YES/NO (examples include personnel costs for engineers, operators, researchers, technicians, project managers, administrative staff etc.)	Add explanatory notes	Yes/No
Q2.1.1	If [YES]: How many people do you allocate annually to ensure compliance with the legislation in each of the following qualifications	Technical staff	Add explanatory notes	Numbers in full time equivalent
Q2.1.1.1	insert average annual salary (12 month)	Technical staff	Add explanatory notes	Average annual salary
Q2.1.2	If [YES]: How many people do you allocate annually to ensure compliance with the legislation in each of the following qualifications	Management staff	Add explanatory notes	Numbers in full time equivalent
Q2.1.2.1	insert average annual salary (12 month)	Management staff	Add explanatory notes	Average annual salary
Q2.1.3	If [YES]: How many people do you allocate annually to ensure compliance with the legislation in each of the following qualifications	Administrative support	Add explanatory notes	Numbers in full time equivalent
Q2.1.3.1	insert average annual salary (12 month)	Administrative support	Add explanatory notes	Average annual salary
Q2.1.4	Are external resources contracted to comply with obligations?	YES/NO	Add explanatory notes	Yes/No
Q2.1.4.1	If [YES]: what is the annual cost of this service?	External resources	Add explanatory notes	Average annual cost

QUESTIONS			EXPLANATORY NOTES	COSTS ESTIMATIONS
Q2.1.4.2	If [YES]: provide a description of the service	External resources	Add explanatory notes	Text
SUBSTANTIVE OBLIGATIONS **Operating Expenses (OPEX)** **Operation and Maintenance**				
Q2.2	**What is the annual cost of operation and maintenance for systems/procedures/equipment installed in order to comply with the legislation?**		Add explanatory notes	Average annual cost
Q2.2.1	Provide starting year	According to entry into force	Add explanatory notes	Year
Q2.2.2	What was the annual cost of operation and maintenance for systems/procedures/equipment which was sufficient to comply with legislation or investments made as business as usual	According to entry into force	Add explanatory notes	Average annual cost
SUBSTANTIVE OBLIGATIONS **Financial costs**				
Q3	**To comply with the legislation did you ask for financial support?**	YES/NO	Add explanatory notes	Yes/no
Q3.1	If [YES]: Did you get a loan?	YES/NO	Add explanatory notes	Yes/no
Q3.1.1	Please provide the following information	Loan amount	Add explanatory notes	Thousands €
Q3.1.2	Please provide the following information	Duration of loan	Add explanatory notes	Months
Q3.1.3	Please provide the following information	Year of loan	Add explanatory notes	Year

QUESTIONS			EXPLANATORY NOTES	COSTS ESTIMATIONS
SUBSTANTIVE OBLIGATIONS **Recurrent costs**				
Q4	**In order to comply with the legislation and as a consequence of the investments in either, new equipment or new personnel, did you encounter recurrent training costs?**	YES/NO	Add explanatory notes	Yes/no
Q4.1	If [YES]: What is the cost of training provided annually with regards to this legislation?	People participating per day	Add explanatory notes	People
Q4.2	If [YES]: What is the cost of training provided annually with regards to this legislation?	Number of days of training	Add explanatory notes	Days
Q4.3	If [YES]: What is the cost of training provided annually with regards to this legislation?	Average Annual salary of people following the training	Add explanatory notes	Average annual salary
Q4.4	If [YES]: What is the cost of training provided annually with regards to this legislation?	Annual cost of trainer or external training service	Add explanatory notes	Thousands €
ADMINISTRATIVE BURDEN				
Q5	**To comply with the legislation did you dedicate specific administrative personnel to handle documentation requirements for e.g. 1) labelling and artworks, 2) traceability (the legal entity responsible for marketing of the product appears on the label) and 3) test records (all cans need to pass certain tests)?**	YES/NO	Add explanatory notes	Yes/No
Q5.1	If [YES]: How many FTE are allocated to handle the administrative burden necessary to comply with the legislation?	Average number of persons allocated annually to information obligations	Add explanatory notes	Numbers in full time equivalent
Q5.2	Are external resources contracted to comply with the administrative burden?	YES/NO	Add explanatory notes	Yes/No
Q5.2.1	If [YES]: what is the annual cost of this service?		Add explanatory	Thousands €

QUESTIONS			EXPLANATORY NOTES	COSTS ESTIMATIONS
			notes	
Q5.2.2	If [YES]: provide a description of the service		Add explanatory notes	text
HASSLE COSTS				
Q6	**In implementing the legislation have you experienced delays in operations with financial implications or losses in business?**	YES/NO	Add explanatory notes	Yes/No
Q6.1	If [YES]: How many days of business have you missed?		Add explanatory notes	Days
Q6.2	If [YES]: During which year(s)	Insert years during which delays occurred	Add explanatory notes	Year
Q6.3	What is the equivalent % of turnover lost		Add explanatory notes	% turnover
SUBSTITUTION COSTS				
Q7	As a consequence of the introduction of ADD did you experience increased costs due to the need to substitute inputs e.g. propellants and solvents for aerosol products?	YES/NO	Add explanatory notes	Yes/No
Q7.1	if [YES]: what is the % increase of production cost		Add explanatory notes	Average annual % share
Q7.2	If [YES]: During which year(s)		Add explanatory notes	year

ANNEX 11 – OVERVIEW OF CONSULTATION WITH STAKEHOLDERS

Interviews with the public authorities

The table below provides an overview of the total number of interviews conducted and the type of responses (oral or written) received.

Figure 53 Overview of interviews with the national authorities conducted to date

Responses	Number of interviews
Total number of interviews conducted	21 interviews
Total number of Member States interviewed	19 Member States
Total number of written responses	8 written responses
Total number of telephone interviews	13 telephone interviews

As shown in the table below, we conducted one interview per Member State, with the exception of Germany. We held three interviews with German officials, one with a representative at federal level, one at state level, and one interview with a representative of the market surveillance authority. Despite several invitations and reminders, we were not able to conduct interviews with representatives of Bulgaria Croatia, Denmark, Hungary, Italy, Luxembourg, Malta, Portugal, Romania, Slovakia, and Slovenia.

Figure 54 Number and type of interviews conducted with the national authorities

Ref. no.	Country	Organisation	Type of consultation
1	AT	Federal Ministry of Science, Research and Economics	Written response
2	BE	Federal Public Service Economy	Telephone interview
3	CY	Ministry of transport, Communications and Works	Telephone interview
4	CZ	Czech Office for Standards, Metrology and Testing	Written response
5	EE	Ministry of Economic Affairs and Communications	Written response
6	ES	Ministry of Energy, Tourism and the Digital Economy, Sub-Directorate General of Quality and Safety of Industry	Telephone interview
7	FI	Finnish Safety and Chemicals Agency (market surveillance authority)	Telephone interview
8	FR	DG Competition, Consumption and Fraud	Telephone interview
9	DE	Federal Ministry of Labour and Social Affairs	Telephone interview

Ref. no.	Country	Organisation	Type of consultation
10	DE	State authority Thüringen	Telephone interview
11	DE	Market surveillance authority	Telephone interview
12	EL	Ministry of Economy, Development and Tourism	Written response
13	IE	Department of Jobs, Enterprise & Innovation	Telephone interview
14	LV	Ministry of economy	Telephone interview
15	LT	State Consumer Rights Protection Authority (market surveillance authority)	Written response
16	NL	Ministry of Health, Welfare, and Sport	Telephone interview
17	PL	Ministry for Economic Development	Written response
18	RO	Ministry of Economy Commerce and Relations with the Business Environment, State Inspection Body for Control of Boilers, Pressure Vessels, Hoisting Equipment	Written response
19	SK	Slovak Trade Inspection	Written response
20	SE	The Swedish Civil Contingencies Agency	Telephone interview
21	UK	Department for Business, Innovation & Skills	Telephone interview

Interviews with the economic operators and industry associations

The interviews with the economic operators and industry representatives were conducted during the period from 13 June to 25 October 2016.

The results of these interviews present the opinions of 29 interviewees on the relevance, the effectiveness, the efficiency, the coherence and the EU added value associated with ADD. The table below gives a breakdown of the number of sent out invitations to participate in the regular interviews and the actual number of conducted interviews per type of stakeholder.

Figure 55 Overview of interviews with the economic operators and industry representatives conducted to date

Type of stakeholder	Invited to participate in the interview	Number of conducted interviews
Fillers and marketing	24	10
Packaging	10	7
European associations	8	3
National associations	11	6
Institutes	2	1
SMEs – fillers	10	1
SMEs – packaging	4	1
Sub-total	69	29

Consumer associations' consultations

Despite several attempts, consumer's associations mobilisation for the evaluation of the ADD Directive has resulted in only one interview, out of two set as a target. The attempts to get in touch with consumer's associations from EU28 Member States can be summarised as follows:

- 30 consumer's associations in total have been contacted, most of them both by email and phone.
- 25 countries of the EU28 were covered.
- The 11 biggest EU28 countries were followed-up more intensively, with an average of three attempts per country, in order to ensure coverage of the biggest markets.
- The European Consumer Organisation (BEUC) has also been contacted with a request to participate in the interview.

We have encountered difficulties in being redirected to the most appropriate person within the respective association in the majority of cases. The European Organisation, had to decline our invitation to participate in an interview because this topic is not followed internally, and thus it was not possible for them to identify a relevant contact person.

On the same token, the evaluation study team received three negative replies from the associations in Denmark, the Netherlands, and Greece. The reason behind declining the request for interview was two-fold. First, the associations do not cover this topic. Second, they had received no complaint on this matter.

As an outcome of the consultation, it was possible to carry out one interview with the national consumer associations, namely from the Italian association "Federconsumatori". The representative of the association noted that the association never faced problems regarding aerosols nor received any complaint.

Targeted online survey for industry

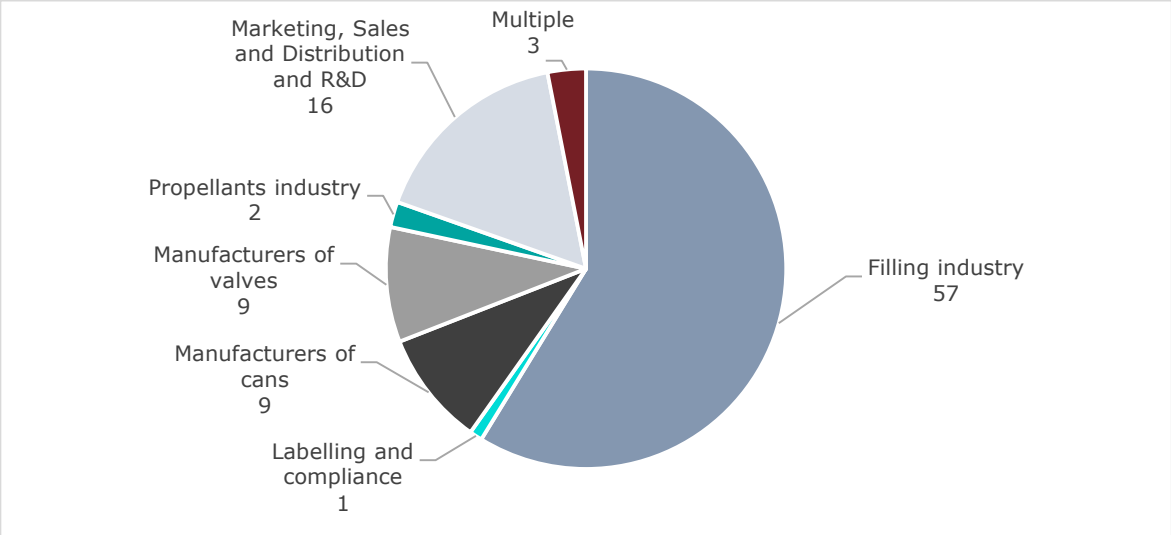
The online survey was launched the 3rd of August 2016 and was closed the 15th of October 2016. Three reminders were sent out via FEA to all National Associations. Additional reminders were sent to National Associations due to the unexpected low responses from some countries during the monitoring of the survey's progress.

The survey has in total 97 responses of good quality among the 199 total responses (which contains responses with viewings of the first page only or responses "I do not know ADD").

The aerosol industry value chain was represented in the survey as follows: 59% from the filling industry, 9% from the can manufacturing industry, 9% from the valve manufacturing industry, 16% from Marketing and/or Sales and/or Distribution and/or R&D, 2% from the propellants industry and finally 3% from companies integrated along the value chain, including multiple of the aforementioned industries (labelled as "Multiple").

As a check for the representation of the industry by the survey the directorate of FEA has been consulted for three stakeholders, filling industry, can manufacturing industry and valve manufacturing industry. According to the directorate there are in total 373 aerosol related companies (note however that the number includes duplicates due to multinationals being members in multiple countries) represented largely by the filling industry (at 80%), followed by the can manufacturing industry (at 12%) and finally the valve manufacturing industry (at 9%). In the survey conducted in this study the responses obtained from the latter industries are split as follows: 76% coming from the filling industry, 12% from the can manufacturing industry and 12% from the valve manufacturing industry. Thus, the survey mirrors the industry's composition very well.

Figure 56 Aerosol industry value chain representation in the survey (numbers represent response counts)



Source: ADD evaluation survey, 2016.

Other dimensions of the coverage include geography, size and turnover market shares which are briefly presented below.

Geography: The geographical coverage of the survey is as follows:

Country	Count of responses
Belgium	5
Bulgaria	1
France	26
Germany	15
Greece	1
Ireland	1
Italy	9
missing	1
Netherlands	5
Other	7
Poland	3
Portugal	1
Switzerland	2
United Kingdom	20
Total	97

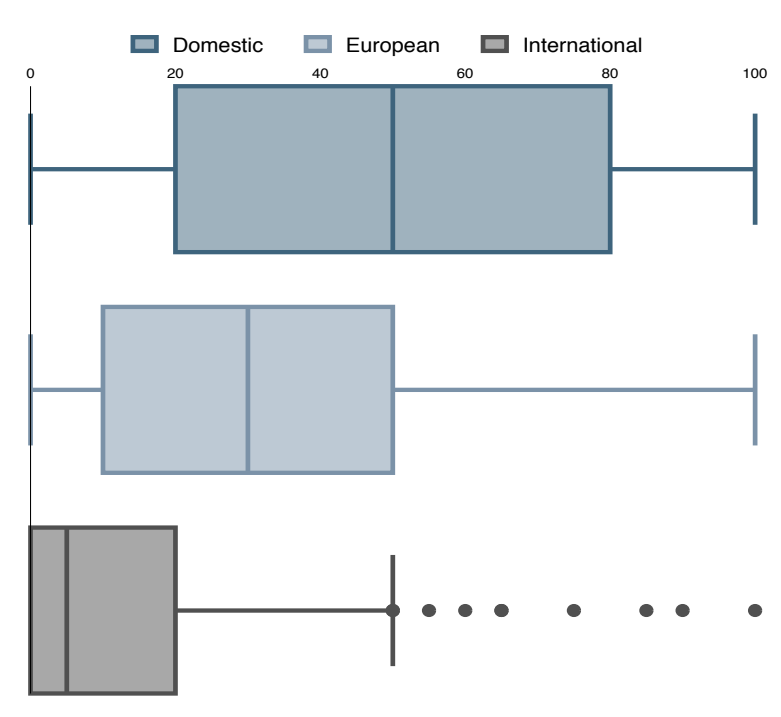
Size: The respondents are equally split between SMEs (ca. 50% below 250 employees and turnover below or equal to 50M€) and Large companies (50% above 250 employees and above 50M€ turnover):

Please state the number of personnel currently working in your company (<250, >=250) – counts of responses	< 250	>= 250	Grand Total
	52	45	97
Please specify the turnover of your company for the last year of operation (<=50M€,>50M€) – counts of responses	<= 50M€	> 50M€	Grand Total
	48	49	97

Market share expressed by turnover: The median turnover share coming from the domestic market is 50%, while from the European market it is 30% and from the international market it is 5% (shown by the marked mid-point in the box). Moreover, the turnover from the domestic market differs between respondents more, compared to the

European and International markets (shown by the differences in sizes of the box). Also, among the companies active internationally there are several positive outliers (shown by the points outside of the box plot) demonstrating that there are companies that differ substantially from the rest.

Figure 57 Domestic, European and International markets of the European aerosol industry



Source: ADD evaluation survey, 2016.

ANNEX 12 – COST ASSESSMENT

Cost Mapping

The theoretical framework used as guideline is the typology elaborated for the Better Regulation Toolbox (European Commission, 2015) by the Centre of European Policy Study in their report "Assessing the costs and benefits of regulation" (CEPS, 2013). Not all cost (sub)categories are covered in this evaluation as some do not fall under the scope of the Directive. The mapping of relevant cost categories presented in Figure 58 as included in the inception report is the result of consultations with industry experts. We provide below a short description of each cost category.

Figure 58 Overview of regulatory costs

REGULATORY COSTS				National authorities	Economic Operators
DIRECT	Compliance costs	Regulatory Charges		NA	NA
		Administrative burdens	internal or external personnel handling administrative tasks (verification, management, reporting etc.)	✓	✓
		Substantive obligations as a result of 'obligations' included in the directive	capital expenditures		✓
			personnel costs		✓
			operation and maintenance		✓
			financial costs		✓
	Hassle costs	Administrative delays and/or overlaps inconsistencies between legislative provisions	waiting time and delays, redundant legal provisions etc. resulting from the implementation of legislation and preventing normal execution of operations; complexity of administrative procedures, lack of clarity in guidance, gaps in legal provisions etc.	NA	✓
INDIRECT	Indirect compliance costs	Costs incurred in related markets, governments, consumers	indirect costs transmitted through changes in the prices of the goods or services produced	NA	NA
	Other indirect costs	Transaction costs	delays to identify suppliers or customers etc.	NA	NA
		Reduced Competition	some regulations can reduce the amount of competition in markets, thus affecting the efficiency of resource allocation	NA	NA
		Market Access	concern regulation as a barrier to entry to the market due to standards, national labelling or certification systems, trade tariffs, lack of harmonization across Member States etc.	NA	NA
		Substitution costs	concern costs arising as a result of reliance on alternative sources of supply	NA	NA
		Innovation	concern opportunity costs caused by the fact that certain activities or investments are no longer undertaken due to regulations imposing restrictions or reduced investment or innovation capacity	NA	NA

REGULATORY COSTS				National authorities	Economic Operators
	Enforcement costs	Costs related to monitoring that do not fall under administrative burdens [76] and litigation	concern one-off adaptation costs, information costs and administrative burdens related to monitoring, monitoring costs, pure enforcement costs, adjudication/litigation costs	✓	NA

Notes: National Authorities will be asked to provide information on costs during the interviews while economic operators will need to complete more detailed cost grids. Based on our experience national authorities are not able to provide detailed information which results in the outcome being unreliable. For this reason, the final outcome on the costs borne by national authorities will be predominantly qualitative.

Direct Compliance Costs

Charges: Based on ADD no direct charges have been introduced neither for producers, designers, traders nor for users, customers and consumers. Being compliant to ADD means to respect the requirements laid down in the articles and the annex, to respect labelling principles and tests.

Administrative Burdens: Administrative costs result from information obligations regarding 1) labelling and artworks, 2) traceability (the legal entity responsible for marketing of the product appears on the label) and 3) test records (all cans need to pass certain tests).

Substantive obligations: Substantive obligations arising from ADD include the following:

<u>Intangibles</u>

- cost for packaging design, especially labelling. While in fact logos, H & P statements are taken from CLP there are specific requirements in ADD (e.g. Art. 8 and Annex 2.2. as well as the reversed epsilon) that have an impact on the labelling cost.
- cost for cans meeting the provisions of ADD, based on formulation/product;
- cost for valves meeting the provisions of ADD, based on formulation/product;
- cost to achieve the principle provisions concerning all aerosol dispensers: burst proof - no leak - up to 50°C;

<u>Testing</u>

- (fixed) cost for testing equipment in design of products (hazard analysis required in Annex 2, Packaging design in Annex 2,3,4 and 5, 5) classification as flammable Aerosol in Annex 1.8,1.9 and Annex 6.3);
- recurrent cost for the conduction of tests as mentioned above;

[76] Depending on the information collected during the interviews it may be best to consolidate monitoring with administrative burden and keep only litigation costs under Enforcement.

- cost for testing equipment in production, either hot water bath or alternative (link to another directive);
- Cost to provide safety in use of aerosols to consumers (ergonomic aspects of the design);
- Cost of the design of the product to enable in full the benefits of a convenient, hygienic and economic application (minimum and precise dosage without losses to the intended destination);

Other

- Cost for the communication of correct use – education about risks and how to avoid;
- Cost of Quality Assurance in all steps of the process. Management of Quality Systems to maintain and improve the high level of safety.

Direct Compliance Costs - Hassle costs: Hassle costs occur due to waiting time and delays, redundant legal provisions resulting from the implementation of legislation and preventing normal execution of operations, complexity of administrative procedures, lack of clarity in guidance, gaps in legal provisions etc. In the case of ADD the basic frame work is a summary of what worked well in more than 20 years of development of the European Aerosol Industry. Only minor adaptations to technical progress have been requested by the Aerosol Industry until 2008, mainly driven by missing definitions (flammable Aerosols) or environmental aspects (alternatives to the hot water bath). Later the link to CLP brought another adaptation to technical progress. Adaptations to technical progress require time but do not paralyze the entire industry. Waiting time is only an issue for some interest groups (who invested in R&D) concerning the most recent topics i.e. flammable aerosols and alternatives to the hot water bath.

Enforcement Costs

One-off adaptation costs: National authorities incur costs for cascading ADD's provisions over national regulations (not all countries in Europe have a mechanism that all EC-directives automatically become national law).

Monitoring: Monitoring costs are relevant primarily for public authorities that monitor the industry on provisions and tests from ADD and/or suggested by national authorities and authorized test institutes/trade supervisory authorities. Companies and manufacturing sites are being controlled in spot checks.

Adjudication: Adjudication costs arise in case needed by local/national trade supervisory authorities. However, cases concerning an aerosol product that are known in public do not exist. Costs are similar as known in other industries. Moreover, adjudication costs vary on a case by case basis. It is for all the aforementioned reasons that adjudication costs will not be included in the analysis.

Indirect Costs

It is anticipated that indirect costs are not very significant (cf. below a description of the reasons why this is the case):

- Substitution costs: ADD did not require substitution of materials etc. so far. This might only be due, if existing equipment or packaging materials would be prohibited
- Transaction costs: ADD does not impose additional costs beyond the normal transaction cost level in an established European Market.
- Reduced efficiency, competition, innovation: Competition between different companies helped automatically improving the quality of the aerosol products. This already happened during the time in the past without ADD in place before 1975. This led to the establishment and the maintenance of aerosol laboratories focusing on research and development of aerosol products, which were quite costly compared to application labs known in other industries, due to the necessary safety level of such a laboratory.
- Innovation: Innovation had been seen primarily with metal cans (can materials, can sizes, pressure levels. The discussion is driven by the packaging industry, divided into specialized manufacturers of tin plate, aluminium and plastic cans (glass is of minor importance). There are no indications of innovation activity slowing down due to ADD provisions. Moreover, the cost of ADD does not justify cuts in innovation investment.
- Market Access: Market access is primarily limited due to national labelling requirements. All texts, hazard- and precautionary statements need to be in national language, which is not harmonized across Europe. Trade tariff codes may vary but are in general easy to adapt. There are no specific certificates related to aerosol products.

Findings of targeted consultations with stakeholder

General remarks – what has been feasible: The companies providing detailed estimates of ADD related costs via the targeted consultations unanimously stated that investments made to produce ADD compliant aerosol products were made before the period under consideration for this evaluation (2005-2015). Moreover, all stakeholders pointed out that the investments were made as part of their corporate responsibility and not exclusively in response to the ADD.

In the context of this evaluation question there are hence two different levels of analysis that are relevant and feasible:

1. Firstly, the estimations of costs broken down by main category (CAPEX, OPEX, Substantive obligations and Administrative costs) as provided by the can manufacturers and fillers for the period 2005-2015. This analysis implies that not all costs are accounted for as part of CAPEX and that OPEX costs are more informative as regards the costs borne by the aerosol industry.
2. Secondly the estimations of CAPEX for a new ADD compliant production line today. Given the aforementioned specificities of ADD we believe it is relevant information to provide cost estimates for a typical aerosol ADD compliant line should it have been an investment today.

Variability - beyond the 'typical' ADD costs: In interpreting the figures it should be noted that differences between companies and the investments made can vary substantially. This is because:

- The testing machinery of today varies substantially in price depending on its different functionalities, for instance can testers can vary from 200,000-700,000.
- The speed of each production line (i.e. the number of cans/aerosols per minute) influences its cost i.e. the lower the speed the higher the investment. Economies of scale however play an important role for the large producers of aerosols. Thus, the higher the production the more sensible it becomes to aim for a fast line with higher investment costs.
- The equipment per aerosol line varies for some product categories. This is particularly the case for food aerosols. More specifically for food aerosols the hot water bath is destructive for the content of the aerosol can and cannot hence be applied on all cans. For this product category, there are two ways: 1) use alternative test methods or 2) and/or use of the hot water bath on a sample of cans.

Alternative test method – food aerosols
To test food cans for leakages using an alternative test method includes three key aspects: 1) to start with a pressure test is typically applied by the can manufactures (at least 10 bars), 2) then an exchange gassing is performed (cans are filled with the product, then the valve is placed and then the gassing starts, and gassing is done on time and pressure, which means that the aerosol is gassed for a certain amount of time and no overgassing is hence possible (note that a propellant and not liquefied gas is used); 3) at the end of the line there is a pressure tester and the can is excluded if there is a leakage (a leakage is found by a pressure drop). Note that a leakage, since the gas used for food is non-flammable, does not lead to fire or explosion and the impact is that the can will not function properly.

- The use of an alternative to the hot water bath testing. Among the companies participating to the cost assessment only two are using alternative leak testing equipment. Among the main advantages brought forward by the company which is using both systems, is the fact that the alternative testing method does not reduce the production speed as it is an automated inline test. It also requires less technical personnel.
- The attribution of costs to ADD is unknown and inconclusive. As mentioned earlier all companies stated that independently of ADD investments to assure safety of aerosol products would have been made. While some claimed to have the necessary processes before ADD some mentioned that they may not have invested as much as they do today in the absence of ADD.

Cost estimates – cost drivers of a new ADD compliant plant: To set up a new aerosol can plant the main ADD related capital investment is the burst and pressure tester machinery which today costs about €40,000 in terms of Capex and possibly a water bath test for the adhesion of coatings. The burst and pressure machinery can be shared by more than one production line as it is an offline test (i.e. lab testing during which a sample of cans is removed from the line and tested e.g. 2-3 cans per hour). In terms of personnel costs the test is performed by the quality control team managing a rotation (to accommodate for the multiple production lines). The cost is ca. €1 per hour of production per production line. The yearly cost of maintenance is ca. €1,000 per machine. More tests are performed by companies as described either as a result of GMP or upon request from their clients.

To set up a new aerosol plant the main ADD related capital investment is the hot water bath or its alternatives. Today the investment cost for a hot water bath with a line speed of 300 cans per minute is € 0.5 million. Typically, there is one hot water bath per line of production. In terms of personnel the test requires supervision from the technical staff per line. The maintenance includes the cost for heating and maintaining the water bath which is about € 50,000 per line per year. In terms of administration the activities undertaken include the qualification of aerosols, verification in production, administration of artworks, printing of labels and traceability. The administrative costs implied however cannot be solely attributed to ADD and companies explain that no incremental costs are made due to ADD given the need to perform the activities as part of GMP and CLP. Irrespective of this the total cost could be on average 0.5 FTE per plant but can go as high as 10 FTE per plant for large companies.

Cost estimates – the typical aerosol producer: costs for aerosol can manufacturing companies and fillers are predominantly CAPEX (Capital expenditures), OPEX (Personnel, Operation and Maintenance), Recurrent costs namely training and Administrative costs.

For can manufacturers the typical costs encountered are summarised in table xxx, showing per cost category its composition in terms of detailed cost items, an estimate range per line or per plant and comments that aim to put the estimates in context.

Figure 59 Can manufacturers (based on three consultations. The table has been quality reviewed by the project's technical experts)

Cost Category	Composition	Estimate (range)	Comments/Assumptions
Capital Expenditures (CAPEX) Investment Costs	Typical investments attributed to ADD include inline and offline tests: • Welding monitors • Leak detector • Bursting test (random sample) • Pressure test (all cans go through the tester; any pressure loss and the can gets rejected; 10 bar system) • Calibration of all aerosol instruments • Water bath test for adhesion of the coating • Water bath test for leak detection (random sample is taken e.g. 125 per 10,000) • Compressor (typical for tin plate) online test – full system of testing the can (pressure, leakages)	€500,000-€900,000 (per line)	Note that the estimates correspond to a hypothetical cost for a new line today. This figure is significantly lower if strictly accounting for the period in focus since companies have made ADD related investments before 2005 and some even before ADD. Also, the figures would vary substantially between companies due to the different investment cycles. The main costs arise due to the testing processes and corresponding machinery. However not all companies are aligned in terms of which tests strictly fall under ADD (for instance some consider the leak detector to be part of ADD some do not). Moreover, some companies go beyond what ADD makes compulsory and for instance include a water bath in their testing process as an offline test to test for leakages. Note that some tests are different depending on the material (tin plate versus aluminium e.g. compressor is typical for tin plate)
Operating Expenses (OPEX) Personnel Costs	A typical mix of profiles and time allocation includes the following profiles and time allocation: • Quality Manager: 1 FTE (20%-70%) per plant • Senior Manager: 1 FTE on regulatory affairs (20-30%) for all plants (typically only for large companies) • Mechanical engineer: 1 FTE (20%-30%) - all plants • Technical staff per plant: Between 0.5-1 FTE per line	Quality manager: €20,000-€70,000 Senior Manager: €20,000-€30,000 Mechanical engineer: €20,000-€30,000 Technical staff: €50,000-€150,000	The estimates assume a yearly gross salary of Management/ Mechanical engineers: €100,000 and Technical staff: €50,000
Operating Expenses (OPEX) Operation and Maintenance	May include the following: • Calibration • Repair • Replacement	€25,000 - €50,000 (per line)	
Recurrent costs - Training	Each worker follows training every year that contains ADD specific training and most importantly training on the burst and pressure test.	Between 5-10 days of training	The estimate would assume 40% of the cost of training
Administrative costs	Includes administrative staff typically experts from R&D centres (e.g. engineers that are following up on legislations)	€50,000-€100,000	The estimate corresponds to the range of 0.5 to 1 FTE

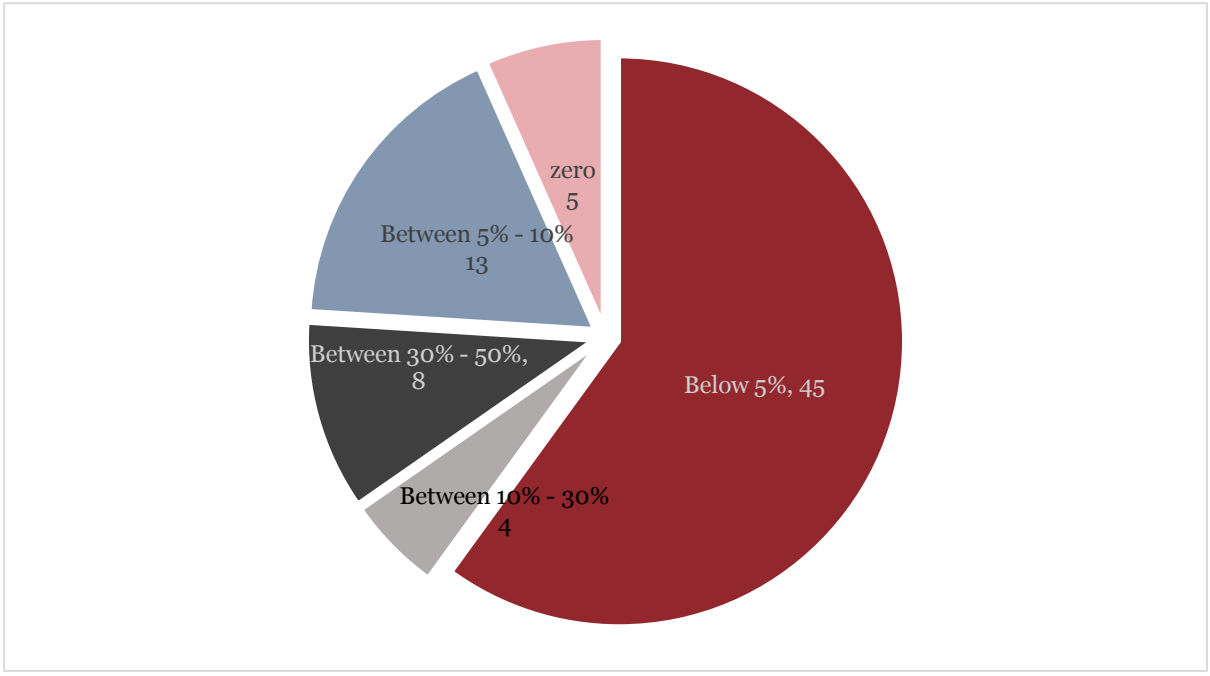
Figure 60 Fillers (based on seven consultations. The table has been quality reviewed by the project's technical experts)

Cost Category	Cost Composition	Estimate range	Comments
Capital Expenditures (CAPEX) Investment Costs	The main ADD investment cost is the hot water bath or its alternatives. The investment cost for a water bath with a line speed of 300 cans per minute is € 0.5 million	€250,000 - €500,000 per line	The variability in the investment cost can result from the volume of production per line. For instance, low speed lines and hence also low production volumes may share one hot water bath while high speed lines require a hot water bath each. Moreover, the costs for an alternative test methods can be very high depending on the aerosol product. For instance, food products that require customised machinery can be considerably higher. The attribution to ADD is not always straightforward to companies as there are overlapping requirements with other legislations (e.g. cosmetics, general product safety, transport regulation) and also industry and/or company standards.
Operating Expenses (OPEX) Personnel Costs	The following profiles undertake ADD specific activities: • Technical staff (Surveillance of running production; Preparation of documentation): from 0.1 to 2 per line • Management staff (Documentation; Communication): from no incremental additional manager for the purpose of the ADD to 1 FTE per plant • Administrative (Monitoring and Artwork processes): from 0.5 to 1 FTE per plant • R&D staff: 0.5 per plant (this has only been mentioned by one company and is not combined with other technical, management or administrative staff)	Technical: €250,000-€500,000 per plant Management: €0-€100,000 per plant Administrative: €25,000-€50,000 per plant	The staff attributed to ADD specific activities varies between companies. One reason is the difference between the hot water bath and the use of the alternative equipment for leak detection which has the lowest personnel costs. On the other hand, a reason for increased personnel costs is the use of staff to supervise the water bath without technical detection system. The estimates assume a yearly gross salary of Technical staff: €35,000 – €50,000; Management staff: €100,000; Administrative staff: €25,000
Operating Expenses (OPEX) Operation and Maintenance	The following maintenance is typically performed: • Cost for heating of water bath • Water bath maintenance	€50,000-€100,000	
Recurrent costs - Training	All companies provide internal training sessions besides the aerosol association training course. The internal training makes use of either internal or external trainers.	ADD specific training time: from 2 hours to 2 days per employee Cost of internal/external trainer: €1,000-2,000 per year	The time dedicated to ADD specific activities varies between companies from 2 hours to 2 days.
Administrative costs	The following tasks are typically undertaken: • Qualification of aerosols • Verification in production • Administration of artworks • Printing of labels • Traceability	From 0 to 10 FTE per company (€0-€500,000)	The administrative personnel has many duties, and without the ADD the great majority of the work would happen anyhow. More specifically this is because of work attributable to GMP according to which aerosol products are produced and Labelling and artworks anyhow under CLP.

Findings of targeted online survey

Cost of ADD in relative terms (% share of production cost per unit) on average (period 2005-2015): The cost of ADD in terms of the share it represents in production cost[77] per unit has been estimated by 65% of survey correspondents to be on average below 5%. This is followed by 19% of respondents that estimate costs at 5%-10% of production cost, 11% at 30%-50% and 6% at 10%-30%. No differences are observed between the three stakeholders, valve manufacturing industry, can manufacturing industry and the filling industry. The five respondents indicating zero costs (including can manufacturers, fillers and valve manufacturers) is because they cannot provide this information or they attribute all cost outside of the period in focus i.e. before 2005.

Figure 61 ADD share in production cost



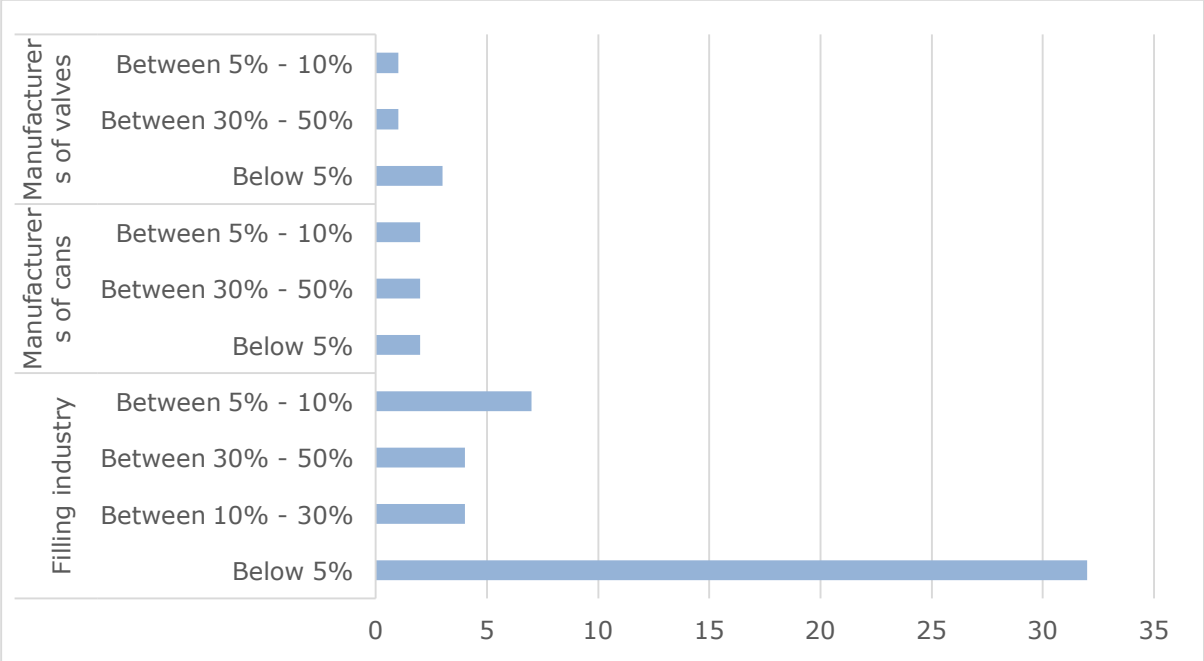
Source: ADD evaluation survey, 2016.

Notes: includes all survey respondents from all sectors along the value chain

Looking at the three stakeholders, it is the can manufactures that show more mixed outcomes, although numbers are low (2 respondents for each of the cost categories which means that answers need to be assessed individually when information is available). In the cost category 30%-50% one respondent made reference to the material cost as the cost driver so it explains why the cost attribution to ADD is higher.

[77] Total production cost is accounted for as all costs incurred to the production of the good in itself, such as raw materials, direct labour costs (staff directly linked to a production unit), energy, buildings, machinery and equipment, production overheads.

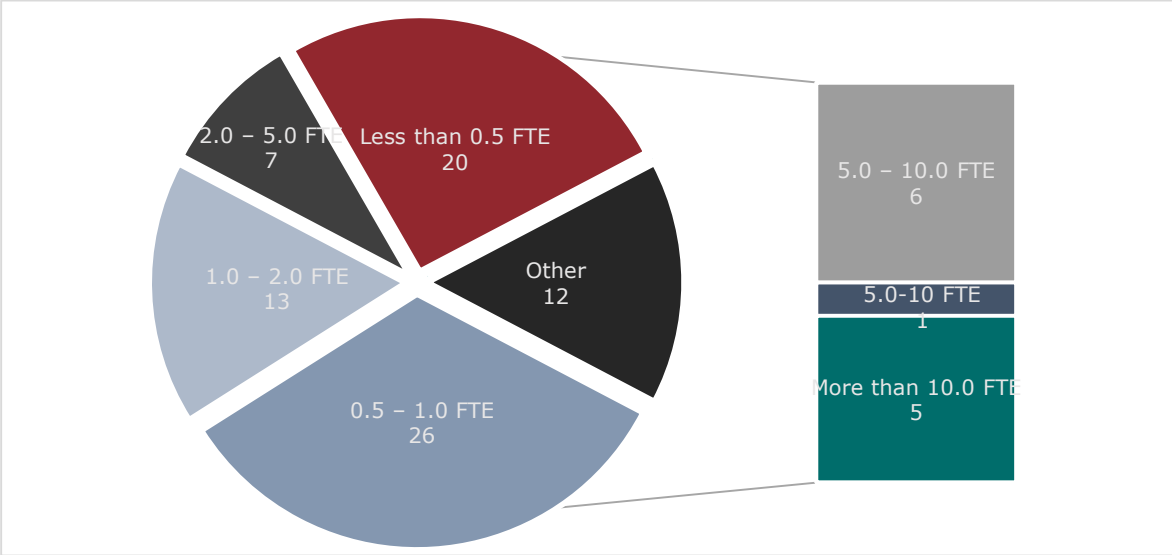
Figure 62 ADD share in production cost by stakeholder



Source: ADD evaluation survey, 2016.

Resources dedicated on average to fulfil the administrative tasks resulting from ADD (period 2005-2015): To comply with ADD 76% of the respondents indicate that they dedicate less than two Full Time Equivalent (FTE). In particular, 33% of the respondents indicated that they dedicate between 0.5 and 1.0 FTE, 26% less than 0.5 FTE and 17% between 1.0 and 2.0 FTE.

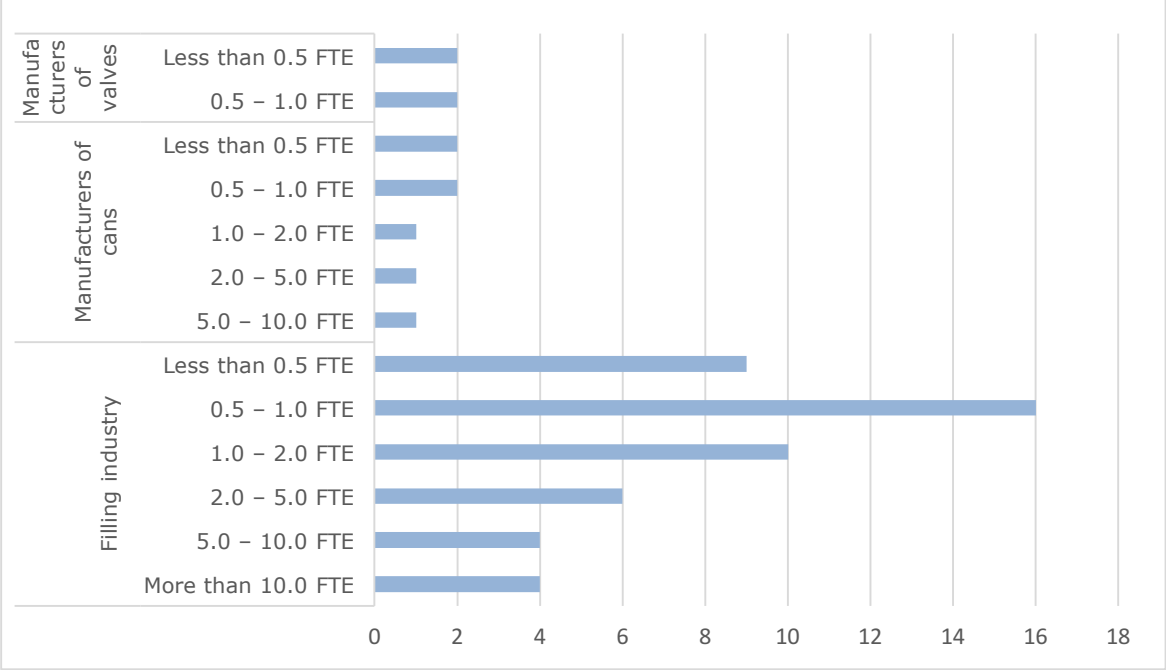
Figure 63 Administrative resources dedicated to ADD



Source: ADD evaluation survey, 2016.

The results split by stakeholder show that manufacturers of valves dedicate less than 1 FTE, 57% of the manufacturers of cans dedicate less than 1 FTE and 55% of the filling industry dedicates less than 1 FTE. For the fillers, however, for which more responses are available, although there is one dominant answer for between 0.5-1.0 FTE results are more spread.

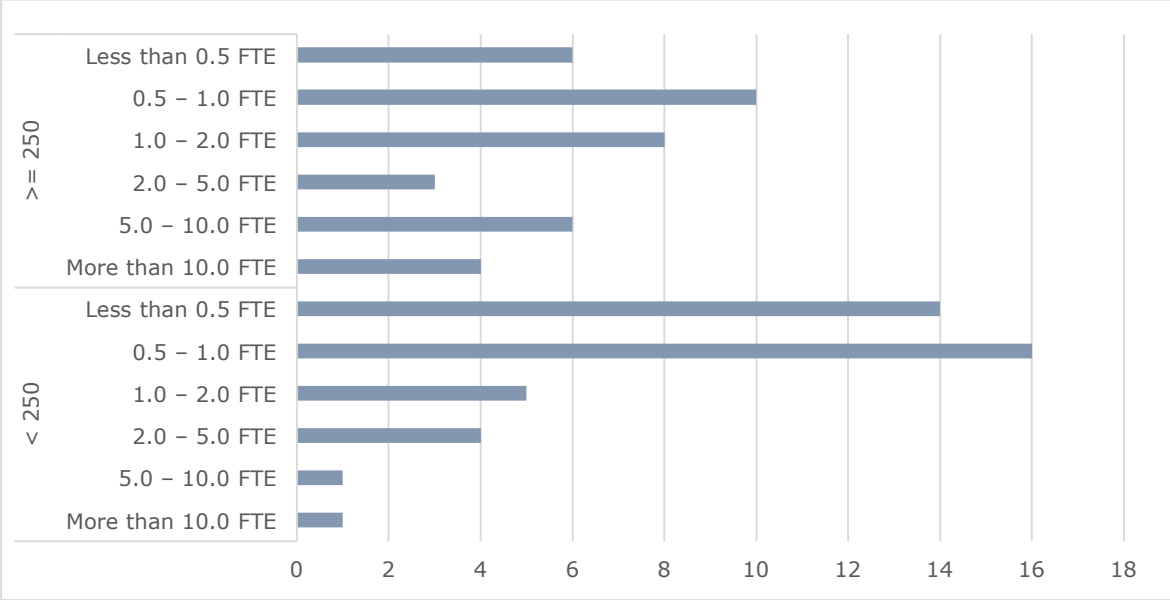
Figure 64 Administrative resources dedicated to ADD by stakeholder



Source: ADD evaluation survey, 2016.

Looking at the differences by company size, the ADD dedicated FTE is estimated as being less than one FTE by 73% of SMEs versus 43% of Large companies. The spread between the different ranges is more notable for large rather than small fillers.

Figure 65 ADD investments by size



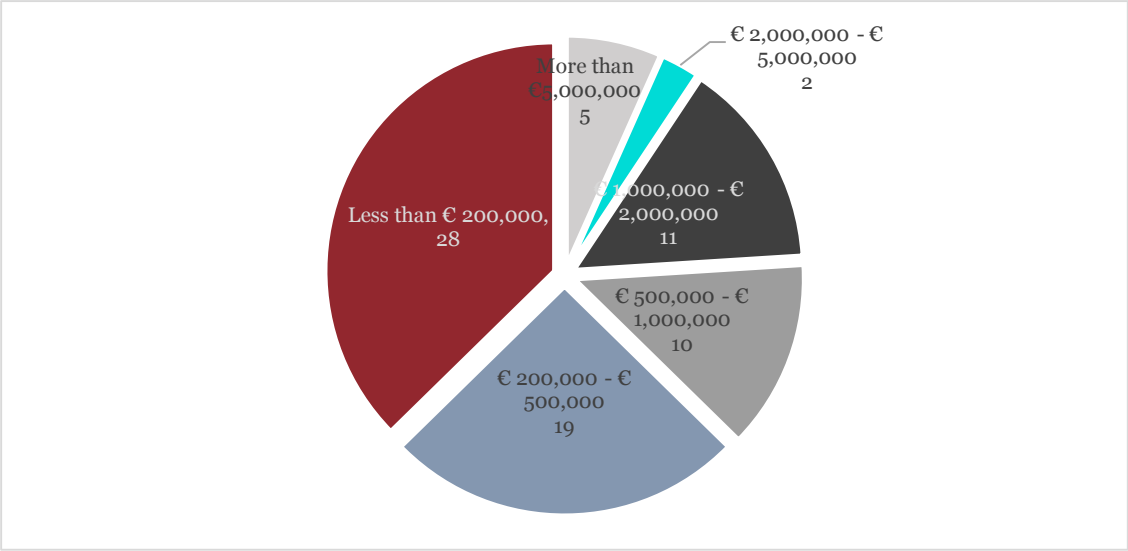
Source: ADD evaluation survey, 2016.

Investments in equipment, testing, human resources, training costs resulting from ADD (period 2005-2015): To comply to ADD more than half of the respondents invested less than €500,000 during the period 2005-2015. In particular, 37% of respondents invested less than €200,000 and 25% between €200,000 and €500,000.[78] The estimates are influenced by the following parameters (based on the qualitative comments within the survey).

The inclusion of costs required for artwork re-labelling and re-approval to align labelling of aerosols with the CLP (not included).

Includes costs for water baths, leak testing, alternative test methods, testing of plastic aerosols (included).

Figure 66 ADD investments

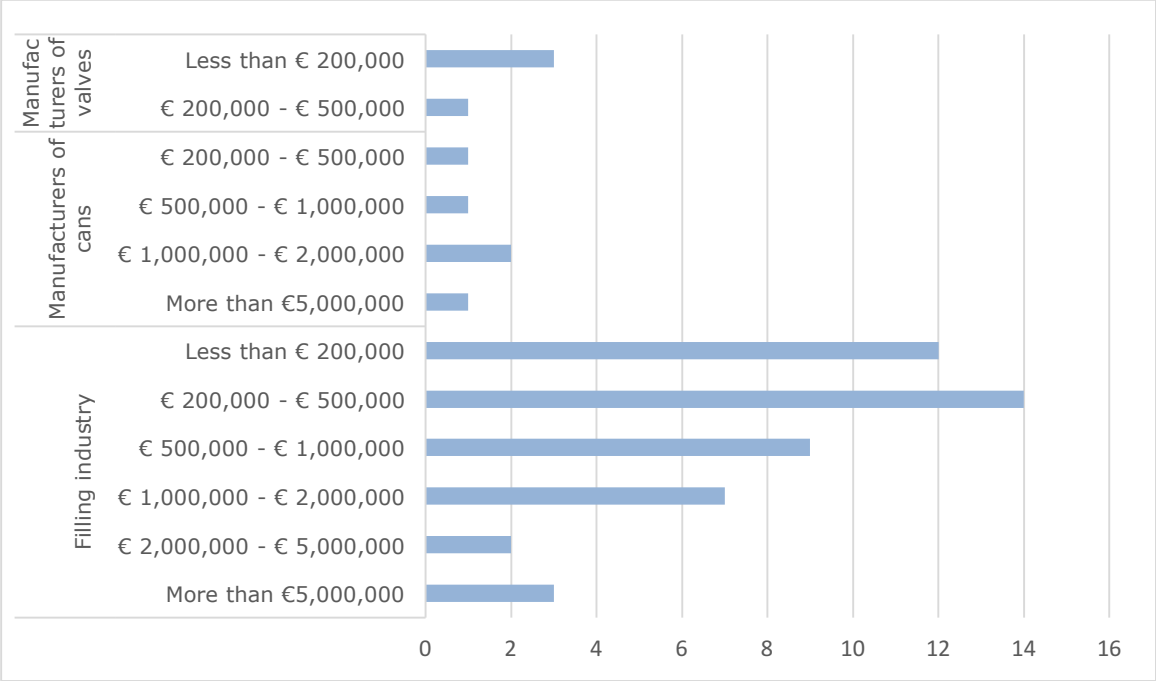


Source: ADD evaluation survey, 2016.

The results split by stakeholder show that manufacturers of valves invested less than €500,000 according to all four respondents, while the investments for can manufacturers vary substantially ranging from €200,000 to more than €5,00,000, as is the case for the filling industry ranging from less than €200 to more than €5,000,000 although 55% of respondents indicated an investment of less than €500,000.

[78] The question requested respondents to consider capital expenditures (CAPEX), operating expenditures including personnel, operation and maintenance (OPEX)

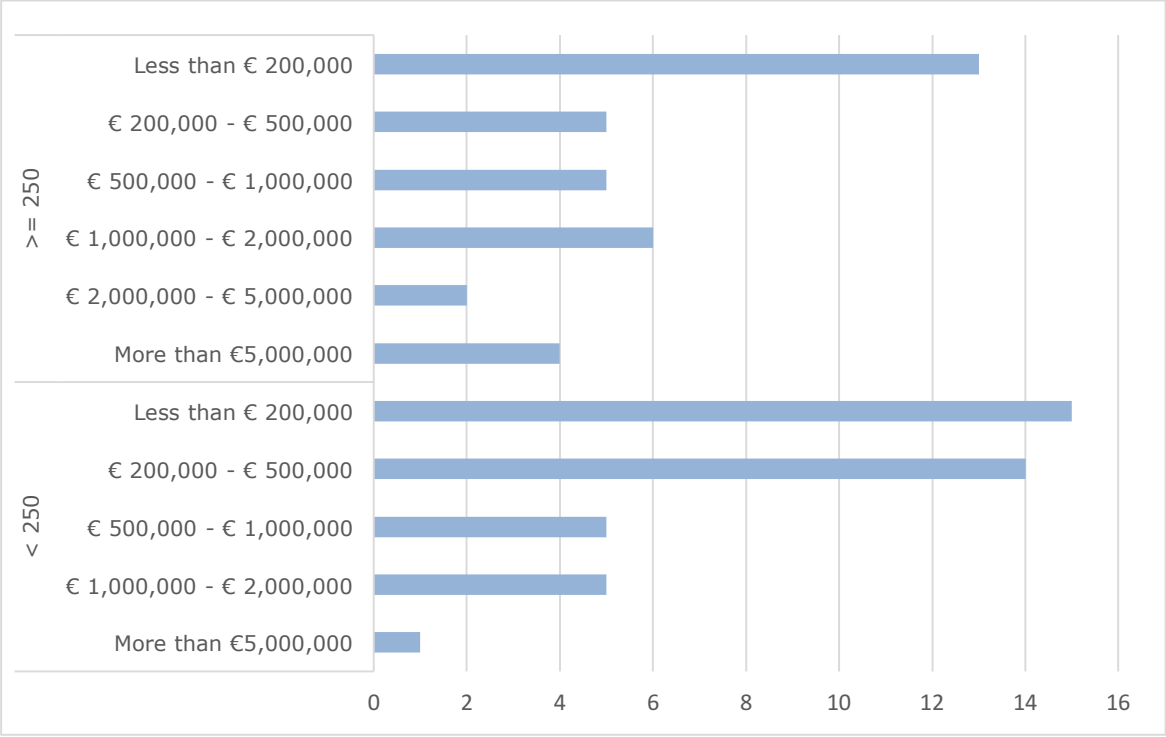
Figure 67 ADD investments by stakeholder



Source: ADD evaluation survey, 2016.

Looking at the differences by company size, the ADD related investment is estimated as being less than €500,000 by 73% of SMEs versus 51% of Large companies.

Figure 68 ADD investments by size



Source: ADD evaluation survey, 2016.

Loan for the financing of ADD related investments: To finance the investments the great majority of companies did not require a loan. Only four companies did request a loan one from each stakeholder group (can manufacturing industry, valve manufacturing industry, filling industry and the broader category of Marketing, Sales and Distribution and R&D). Among those two companies provided an estimate of 30% ADD related costs being financed through a loan.

Delays in operations with financial implications or losses in business: The great majority of companies did not experience delays in operations with financial implications or losses in business. Only four companies recorded that they did, namely due to labelling and production equipment.

Increased costs due to the need to substitute inputs e.g. propellants and solvents for aerosol products: The great majority of survey respondents did not experience increased costs due to the need to substitute inputs. There were however 11 companies stating the contrary and among those six provided an estimate of the percentage increase of production cost ranging from 2% to 20%.

Findings of interviews with the economic operators and industry associations

According to the interviews with economic operators, ADD related costs in total production costs per unit could range from €0.2 cents to €0.3 cents per unit. Some interviews pointed that ADD related costs in total production costs per unit are estimated to be less than 2%.

Particularly, the hot-water bath test was found to be expensive as it requires important initial investments that last on average some 20-30 years. The costs associated with setting up technologies to install alternatives to the water bath test account for approximately €15 thous. for each type of can, in addition to €350 thous. in new equipment for one production line only.

The costs related to CLP were considered as one of the most important costs due to the different translations required and labelling. It is estimated that the translation costs are approximately €2,000 multiplied by the number of countries in which the company operates.

To comply with ADD requirements, the costs related to human resources are estimated at 4 full-time equivalents which represents on average between €100 thous. and €150 thous. There are also some administrative costs involved because ADD is an overarching piece of legislation for different products. According to the interviewees, these costs were not considered to be significant.

The consulted stakeholders considered the costs as proportionate to the benefits received and not excessive; however, the majority of them was not in the position to give the exact indication of costs associated with the Directive. Comparatively, the interviews pointed that costs associated with tests required in other sectoral legislations are much higher than in ADD.

There is a difference in opinions whether the costs savings could be further achieved. Some interviewees pointed that the costs could decrease further if editorial changes in hazard communication and labelling would be allowed without changing the meaning of the existing rules. If the official texts were modified at the country level, this would allow less changes in labelling. Other stakeholders noted that in Europe there are companies with more than 30 years of experience in the field. Taking into account that they have

enough knowledge and expertise in manufacturing efficiently aerosol dispenser products, further costs savings are not possible any more. In conclusion, it was found that the Directive does not create additional costs and costs associated with ADD are necessary and well placed.