

EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Evaluation of the Aerosol Dispensers Directive		
LEAD DG RESPONSIBLE UNIT	GROW / C3	DATE OF THIS ROADMAP	10 / 2015
TYPE OF EVALUATION	Mixed Evaluation	PLANNED START DATE	Q4 / 2015
		PLANNED COMPLETION DATE	Q1 / 2017
		PLANNING CALENDAR	<a href="http://ec.europa.eu/smart-regulation/evaluation/index_en.htm">http://ec.europa.eu/smart-regulation/evaluation/index_en.htm</a>
<b>This indicative roadmap is provided for information purposes only and is subject to change.</b>			

A. Purpose
(A.1) Purpose
The purpose of the evaluation is to assess the functioning of the Aerosol Dispensers Directive (ADD) and to what extent the directive met its objectives of guaranteeing free circulation of aerosol dispensers in its scope and ensuring a high degree of safety.
(A.2) Justification
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. However, some questions were recently raised as to whether the Directive was still relevant in its current format and whether it should be modernized to be brought in line with the New Legislative Framework, which is also applied for other product safety legislation. The evaluation will assess the performance of the Directive and whether there are issues to be addressed to improve the implementation.

B. Content and subject of the evaluation
(B.1) Subject area
The Aerosol Dispensers Directive (ADD) (75/324/EEC) <sup>1</sup> is one of the oldest EU legislations related to product safety. 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 to ensure that it meets the requirements for safe 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.).

<sup>1</sup> 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>

## (B.2) Original objectives of the intervention

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

- (1) Guaranteeing that aerosol dispensers 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.
- (2) Ensuring the free movement of aerosol dispensers throughout the EU, so as to enhance competitiveness and innovation.

## (B.3) How the objectives were to be achieved.

General objectives: see point( B.2)

Specific objectives: not applicable

### Resources and mechanisms

- ADD is a so-called "old approach" directive based on technical harmonisation at European level. The directive includes detailed requirements regarding construction, labelling, testing, etc... to ensure the safety of filled aerosol dispensers. It concerns technical parameters (such as maximum volume and pressure) and labelling and testing requirements. Special provisions apply depending on the material of the container (metal, plastic, glass).
- The person responsible for the marketing of aerosol dispensers is under the obligation to conduct a hazard analysis and take into account this analysis when designing, constructing and testing the dispenser.
- The directive prescribes a series of tests including a final inspection of filled aerosol dispensers.
- The ADD directive was adapted to technical progress in 2013 to ensure coherence with European and international legislation related to the classification, labelling and packaging of chemicals (CLP Regulation).

### Results

- High level of safety of aerosol dispensers placed on the EU market with regard to the hazards covered by the directive (hazards related to pressure and where appropriate, flammability and inhalation)
- harmonised rules for construction and testing of aerosol dispensers placed on the EU market

### Impacts

- high level of safety resulting in very low accident rates
- consumer/user trust in aerosol dispensers products
- better functioning of the internal market while preserving growth and competitiveness

### External factors

- Market surveillance and enforcement at the level of the Member States

- European and international regulatory instruments applicable to Aerosol Dispensers with regard to labelling and transport.

## C. Scope of the evaluation/FC

### (C.1) Topics covered

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 shall be examined systematically.

It will cover all Member States and focus on the period between 2005 and 2015.

### (C.2) Questions/issues to be examined

#### **Effectiveness**

- (a) To what extent has ADD contributed to an effectively operating internal market for the products in its scope?
- (b) To what extent has ADD contributed to the safety of the products in its scope?
- (c) To what extent has the procedure allowing to adapt the annex of the Directive to technical progress been useful for effective implementation?
- (d) What are the barriers to effective application of the ADD if any?
- (e) 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**

- (f) 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?
- (g) 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?
- (h) To what extent are there significant differences in costs or benefits between MS? If so, what is causing them?
- (i) What aspects of ADD are the most efficient or inefficient?

#### **Coherence**

- (j) 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**

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

- (m) 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**

- (n) 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?

(C.3) Other tasks

The evaluation will be performed by an external contractor.

**D. Evidence base**

(D.1) Evidence from monitoring

Not applicable

(D.2) Previous evaluations and other reports

This is the first evaluation of the ADD directive since its adoption in 1975.

An impact assessment study<sup>2</sup> related to some technical aspects was conducted in 2014. The final report of this study is publicly available on the ADD website on Europa and provides detailed information in particular about plastic aerosol dispensers ([http://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/index\\_en.htm](http://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/index_en.htm)).

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

Despite the very wide-spread use of aerosol dispensers in the EU, there is hardly any safety problem reported related to the hazards covered by the Directive. There have been very few complaints or infringement procedures.

(D.4) Consultation

The stakeholders are the following:

1. economic operators and the professional associations representing them
  - a. manufacturers of components (containers in tinplate, aluminium, glass or plastic, valves and caps);
  - b. the manufacturers of specialised machinery (for filling, labelling, testing);
  - c. a wide variety of companies developing the contents of the aerosol dispensers (pharmaceutical, cosmetics, food, paint, etc.);
  - d. producers of propellants;
  - e. professional fillers;
  - f. companies active in the branding, distribution and sales along the different distribution channels to consumers and professional users;
  - g. test laboratories;
  - h. operators involved in storage, transport and recycling.
2. the public authorities
3. the users of these products (consumers or industrial users and their associations).

The following tools will be used to reach these stakeholders:

- online targeted consultation (survey) in 6 languages (EN, FR, DE, ES, IT, PL) with all stakeholder categories

<sup>2</sup> Impact Assessment Study on the Adaptation to Technical Progress of the Aerosol Dispensers Directive (March 2014)

- online public consultation of 12 weeks in 6 languages (EN, FR, DE, ES, IT, PL)
- this roadmap will be available at [http://ec.europa.eu/smart-regulation/roadmaps/index\\_en.htm](http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm) during 4 weeks to collect feedback from stakeholders
- face to face interviews with key stakeholders from the three main groups: economic operators, public authorities and users.

Other tools might be proposed where deemed appropriate, in the course of the evaluation study, depending on the level of information needed.

More details about the consultation strategy will be made available of the webpage dedicated to this evaluation on the Europa DG GROW website ([http://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/index\\_en.htm](http://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/index_en.htm)).

(D.5) Further evidence to be gathered

Not applicable

#### **E. Other relevant information/ remarks**