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MEASUREMENT OF ADMINISTRATIVE BURDENS GENERATED BY THE EUROPEAN LEGISLATION

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SECOND INTERIM REPORT
FIRST PART: AB QUANTIFICATIONS

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ABBREVIATIONS AND DEFINITIONS

The following terms are defined on the basis of Annex 10 of the Impact Assessment Guidelines, published by the European Commission; and of the International Standard Cost Model manual, published by the SCM Network.

SCM: Standard Cost Model. The Standard Cost Model is designed to measure the administrative consequences of legislation for businesses. The SCM has been developed to provide a simplified, consistent method to estimate the administrative costs imposed on business by central governments. The SCM method is a way of breaking down regulation into a range of manageable components that can be measured. The SCM does not focus on the policy objectives of each regulation. As such, the measurement only focuses on the administrative activities that must be undertaken to comply with regulation and not on whether the regulation itself is reasonable or not.

IO: Information Obligation. Information obligations are obligations arising from regulation to provide information and data to the public sector or third parties. IOs are the unit of analysis of the present report. A piece of legislation may include one or more IOs. A single IO may refer to a single provision, a single article, or to a group of related articles. The EU Standard Cost Model guidelines provides 12 categories to classify an IO.

DR: Data Requirement. Each information obligation consists of one or more data requirements. A data requirement is each element of information that must be provided when complying with an IO. Our analysis usually does not focus on DRs, but only on single IOs. DRs can be used to assess the impact of a new legislative provision changing only part of an existing IOs (for instance, a new proposal on food labelling may impose 5 DRs instead of 6).

AC: Administrative Cost. Administrative costs are defined as the costs incurred by a normally efficient enterprise in meeting legal obligations to provide information on its action or production, either to public authorities or to private parties. Information is to be construed in a broad sense, i.e. including labeling, reporting, registration, monitoring and assessment needed to provide the information. In some cases, information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or supply on request. Recurring administrative

costs and, where significant, one-off administrative costs must be taken into account. Administrative costs are measured over a one-year period.

BAU: Business-As-Usual. BAU costs (or BAU factor, in percentage terms) correspond to the costs resulting from collecting and processing information which would be collected or processed by an undertaking even in the absence of the legislation. For instance, firms would keep annual accounts even if they were not required by law.

AB: Administrative Burdens. Administrative burdens are the part of the administrative costs resulting from collecting and processing information which would not be collected or processed by an undertaking in the absence of legislation. Formally:

ACs = BAU costs + ABs.

Finding that a legislative provision generates many burdens does not imply any judgment on its usefulness and benefits. Our analysis is not a net analysis of costs and benefits created by an act, but only a partial analysis of part of its costs. For instance, highly beneficial acts may be burdensome, and burdens may arise also from provisions whose content has been agreed on by the industry.

P: Price; Q: Quantity. Price and quantity are the key variables of the "core" equation of the Standard Cost Model. Price of an IO is its cost per occurrence, calculated multiplying the time spent on complying with an IO by the appropriate tariff. A price of an IO may also include external and one-off costs. Quantity of an IO is calculated multiplying the number of entities concerned by the frequency of the IO. Administrative costs are calculated through the following formula:

$$\sum P \times Q$$

QUANTIFICATION OF ACTS INCLUDED IN THE EXTENSION LIST

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EXECUTIVE SUMMARY

This report contains a measurement of a number of baseline acts that have been included in the Original List and in Extension List annexed to the Action Programme on Administrative Burdens, or in the Sectoral Reduction Plans. It also includes and a measurement of the related amending acts / amending proposals. The main goal of this report is to extend the baseline measurement of administrative burdens generated by the EU legislation, enlarging the original group of 42 acts measured by the Consortium. Furthermore, we also provide an assessment of whether some of the policy initiatives of the first Barroso Commission have generated a significant change in the baseline since 1 January 2005.

In particular, we analyse 13 baseline acts / bundles of two acts,[1] namely 1 from the Original List, and 12 from the Extension Lists. For 1o of them, we also analyse the related amending acts/proposals. Subsequently, we also assess the impact of 5 reduction measures included in the Sectoral Reduction Plans. 4 of them amend baseline acts included in the Original List, whilst 1 amends an act which had not been previously included in the measurement programme.[2]

Measured acts and their impact[3] on Administrative Burdens are shown in the table below. Please note that for baseline acts the total impact is shown, whilst for amending acts / proposals (in italic) we show the expected reduction (if any).

[1] For four couples of acts, the analysis has been carried out jointly.

[2] In this case, we have also to create a baseline measurement of the existing act to measure the impact of the amending proposal. Cf. paragraph 4.2.1.

[3] We measure the annual impact of a legislative act, i.e. the number of ACs/ABs imposed on firms over a period of one year.

Acts covered by this report and impact on ABs

Priority Area	Act	Administrative Burdens
ACTS INCLUDED IN THE ORIGINAL LIST		
Transport	Council Regulation (EEC) No 3820/85 of 20 December 1985 on the harmonization of certain social legislation relating to road transport	€3,024,159,000
	Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport	
	Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85	-€ 286,597,309
ACTS INCLUDED IN THE EXTENSION LIST		
Agriculture	Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector	€ 2,198,287,890
	Commission Regulation (EC) No 1221/2008 of 5 December 2008 amending Regulation (EC) No 1580/2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector as regards marketing standards	-€ 973,715,878
	Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)	€ 28,044,620
	Council Regulation (EC) No 72/2009 of 19 January 2009 on modifications to the Common Agricultural Policy by amending Regulations (EC) No 247/2006, (EC) No 320/2006, (EC) No 1405/2006, (EC) No 1234/2007, (EC) No 3/2008 and (EC) No 479/2008 and repealing Regulations (EEC) No 1883/78, (EEC) No 1254/89, (EEC) No 2247/89, (EEC) No 2055/93, (EC) No 1868/94, (EC) No 2596/97, (EC) No 1182/2005 and (EC) No 315/2007	-€ 28,044,620
	Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)	n.a.
	Council Regulation (EC) No 74/2009 amending Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)	n.a.

Food Safety	Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption	€ 135,065,143
	COM(2008)345 Proposal for a regulation of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption	-€ 21,752,645
	Council Directive 96/25 on the circulation of feed materials	€ 6,225,135
	Council Directive 82/471/EEC concerning certain products used in animal nutrition	€ 1,172,438
	COM(2008)124 Proposal for a Regulation of the European Parliament and of the Council on the placing on the market and use of feed	- € 2,000,756
	of which: Reduction of ABs attributed to dir. 96/25 Reduction of ABs attributed to dir. 82/471	-€828,318 -€1,172,438
	Council Directive 89/107/EEC on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption;	€ 1,645,626
	Regulation (EC) No 2232/96 of the European Parliament and of the Council laying down a Community procedure for flavouring substances used or intended for use in foodstuffs	€45,216
	Regulation (EC) No 1331/2008 of the European Parliament and of the Council of establishing a common authorisation procedure for food additives, food enzymes and food flavourings.	-€ 1,399
	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of on food additives;	-€ 81,743
	Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market;	€ 3,501,338
	Council Directive 90/425/EC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animal and products with a view to the completion of the internal market	
Statistics	Council Regulation 1172/98 on statistical returns in respect of the carriage of goods by road.	€ 4,077,000
	Council directive 95/64/EC on statistical returns in respect of carriage of goods and passengers by sea.	€ 6,700,000
Transport	Council Directive 96/35/EC on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway	€ 60,348,580
	Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods;	-€ 2,172,221

	Council Directive 94/57/EC on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administration	€ 452,812
	Directive 2009/15/EC of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations; Regulation no. 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations (Recast)	€ 0
	Directive 2002/6/EC of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing from ports of the Member States of the Community	€ 558,525,000
	COM(2009)11 Proposal for a Directive of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing from ports of the Member States of the Community and repealing Directive 2002/6/EC	-€ 75,000,000
ACTS INCLUDED IN THE EXTENSION LIST		
Cohesion Policy	Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999	€ 922,634,000
	Regulation (EC) No 396/2009 of 6 May 2009 amending Regulation (EC) No 1081/2006 on the European Social Fund to extend the types of costs eligible for a contribution from the ESF;	-€ 22,386,374
	Regulation (EC) No 397/2009 of 6 May 2009 amending Regulation (EC) No 1080/2006 on the European Regional Development Fund as regards the eligibility of of energy efficiency and renewable energy investments in housing	-€ 23,474,764
	Commission Regulation 846/2009 amending Regulation (EC) No 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund	-€33,383,677

Pharmaceutical Legislation	Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.	€205,700
	Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC and Regulation (EC) No 726/2004	-€ 66,011
Transport	Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85	€ 2,737,561.391
	Commission Regulation (EU) No 1266/2009 adapting for the tenth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport	-€ 234,515,552

The identification of Information Obligations (IOs) in the various pieces of legislation (so-called "Mapping of IOs") has been carried either by the relevant DG, or by us. All the mapping results have nevertheless either been validated by the relevant DG, or the relevant DG had the opportunity to provide comments.

We have quantified the impact of legislative acts on administrative burdens based on a number of sources, including information provided by the relevant DGs, or retrieved from Consortium's baseline measurements, national databases, or other public sources, or on the basis of our expert assessment. Our tasks did not include direct surveys of economic operators.

QUANTIFICATION OF ACTS INCLUDED IN THE EXTENSION LIST

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1 METHODOLOGY

The present report aims at:

1) extending the baseline measurement of ACs/ABs due to European legislation;
2) measuring the reduction of ACs/ABs achieved by the first Barroso Commission.

This goal will be achieved measuring the impact due to acts included in the original List and the Extension List attached to the Action Programme on Administrative Burdens, and of other acts included in the Sectoral Reduction Plans.

The list of acts is shown in Table 1. For acts which have either been amended, or for which an amending proposal has been issued, the amending act / proposal is shown in the right column. We will also measure the reduction of ACs/ABs, if any, due to the amending acts / proposals therein listed.

Table 1 – Acts covered by the present report

Existing Act	Amending Act / Proposal
ACTS INCLUDED IN THE ORIGINAL LIST	
TRANSPORT	
a) Council Regulation (EEC) No 3820/85 of 20 December 1985 on the harmonization of certain social legislation relating to road transport b) Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport	QUANTIFIED BY CONSORTIUM - Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85

ACTS INCLUDED IN THE EXTENSION LIST (JANUARY COMMUNICATION)

AGRICULTURE (PARTIAL MAPPING AND QUANTIFICATIONS)

Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector	Commission Regulation (EC) No 1221/2008 of 5 December 2008 amending Regulation (EC) No 1580/2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector as regards marketing standards
Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)	Council Regulation (EC) No 72/2009 of 19 January 2009 on modifications to the Common Agricultural Policy by amending Regulations (EC) No 247/2006, (EC) No 320/2006, (EC) No 1405/2006, (EC) No 1234/2007, (EC) No 3/2008 and (EC) No 479/2008 and repealing Regulations (EEC) No 1883/78, (EEC) No 1254/89, (EEC) No 2247/89, (EEC) No 2055/93, (EC) No 1868/94, (EC) No 2596/97, (EC) No 1182/2005 and (EC) No 315/2007
Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD).	Council Regulation (EC) No 74/2009 amending Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

FOOD SAFETY

Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption	COM(2008)345 Proposal for a regulation of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption
a) Council Directive 96/25 on the circulation of feed materials; b) Council Directive 82/471/EEC concerning certain products used in animal nutrition	COM(2008)124 Proposal for a Regulation of the European Parliament and of the Council on the placing on the market and use of feed

a) Council Directive 89/107/EEC on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption; b) Regulation (EC) No 2232/96 of the European Parliament and of the Council laying down a Community procedure for flavouring substances used or intended for use in foodstuffs	a) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives; b) Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.
a) Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market; b) Council Directive 90/425/EC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animal and products with a view to the completion of the internal market	
STATISTICS	
Council Regulation 1172/98 on statistical returns in respect of the carriage of goods by road. Council directive 95/64/EC on statistical returns in respect of carriage of goods and passengers by sea.	
TRANSPORT	
Council Directive 96/35/EC on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway	Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods;

Council Directive 94/57/EC on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administration	Directive 2009/15/EC of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations; Regulation no. 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations (Recast).
Directive 2002/6/EC of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing form ports of the Member States of the Community	COM(2009)11 Proposal for a Directive of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing from ports of the Member States of the Community and repealing Directive 2002/6/EC

OTHER ACTS INCLUDED IN THE SECTORAL REDUCTION PLANS (OCTOBER COMMUNICATION)

COHESION POLICY

MEASURED BY CEPS – PREVIOUS REPORTS – Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999	a) Regulation (EC) No 396/2009 of 6 May 2009 amending Regulation (EC) No 1081/2006 on the European Social Fund to extend the types of costs eligible for a contribution from the ESF; b) Regulation (EC) No 397/2009 of 6 May 2009 amending Regulation (EC) No 1080/2006 on the European Regional Development Fund as regards the eligibility of energy efficiency and renewable energy investments in housing c) Commission Regulation 846/2009 amending Regulation (EC) No 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund

PHARMACEUTICAL LEGISLATION	
Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin	Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC and Regulation (EC) No 726/2004
TRANSPORT	
MEASURED BY CEPS – PRESENT REPORT – Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85	Commission Regulation (EU) No 1266/2009 adapting for the tenth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport

1.1 Sources

Throughout the present report, the individual IOs included in these acts are the unit of analysis. IOs had been identified (mapped) before proceeding with the quantification. The mapping process is carried out usually by the relevant DGs, which helped in the identification of the IOs as well as in providing comments on the likely effect of legal changes on ACs/ABs. In the following cases, we have carried out the assessment and the DGs have then had the opportunity to comment on the results:

1. Council Directive 94/57/EC on common rules and standards for sip inspection and survey organisations and for the relevant activities of maritime administrations, and related amending acts (Transport Priority Area);

2. Council Directives 89/662/EEC and 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade with a view to the completion of the internal market (Food Safety / Transport Priority Area);

3. for the other baseline acts and related amending acts / proposals in the Food Safety Priority Area, the assessment has been jointly carried out with DG SANCO, which has then validated the results.

4. acts included in the Cohesion Policy Sectoral Reduction Plan:

    i. Regulation (EC) No 396/2009 of 6 May 2009 amending Regulation (EC) No 1081/2006 on the European Social Fund to extend the types of costs eligible for a contribution from the ESF;

    ii. Regulation (EC) No 397/2009 of 6 May 2009 amending Regulation (EC) No 1080/2006 on the European Regional Development Fund as regards the eligibility of energy efficiency and renewable energy investments in housing;

    iii. Commission Regulation 846/2009 amending Regulation (EC) No 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund

5. an act included in the Pharmaceutical Legislation Sectoral Reduction Plan: Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, and the related amending act;

6. an act included in the Transport Sectoral Reduction Plan: Commission Regulation (EU) No 1266/2009 adapting for the tenth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport.

For acts included in the Sectoral Reduction Plans, you may find the mapping sheets in Annex II to the present report. For the other acts, mapping sheets have already been submitted annexed to previous reports.

Mapping of baseline and amending acts was complete, that is we have identified and tried to measure every IO included in these acts, regardless of the expected burdensomeness. Because of the complexity of certain legislative areas, and because of time constraints, for the Priority Area “Agriculture” our focus is more limited. In this PA, the mapping process and the quantifications are focused on the IOs which have undergone relevant changes. Therefore, we estimate only the ACs/ABs due to the baseline IOs which have undergone changes, regardless of their burdensomeness. Total estimates in this area are only partial and cannot be considered as a proxy of total ACs/ABs attributable to baseline and amending acts.

The availability of data on population, costs and time needed to comply with an IO is of paramount importance for the quantification process. The availability of different data

typologies explains to a large extent the need to adopt different approaches. Relevant data have been retrieved from a number of different sources, such as:

1. The relevant DGs of the European Commission. They have directly provided quantification-related data alongside the information on IOs, or after being specifically contacted by us. Cooperation and retrieval of information with the relevant DG has been of paramount importance and had a very positive impact on the quality of many quantifications;

2. Impact Assessments of the amending acts/proposals or other studies / internal documents made available by the relevant DGs. These documents sometimes contained comprehensive ACs/ABs quantification of some IOs, which have been adapted and included in this report. In other cases, they have provided us with relevant data. Importantly, we are asked in most cases to avoid re-calculating what the European Commission has already calculated in its official documents. If no explicit calculation of ABs was included in Commission's documents or external studies, it has nevertheless been possible to retrieve from them a large amount of data to perform our own calculations;

3. EU database on AB and other material produced by the Consortium when measuring the acts included in the Action Programme on Administrative Burdens. Thanks to the features included in the latest version,[4] the AB calculator included in the EU database has been used to find possible analogies with IOs already measured by the Consortium, and to perform calculation on the basis of Consortium's data;

4. National documents and databases on ABs. National databases, national impact assessments, explanatory memoranda attached to national proposals implementing a European act and studies at national level on the impact of ACs/ABs have been consulted. Most of the documents originate from the UK, the Netherlands, Germany and Denmark;

5. Position papers and other information material prepared by the industry.

6. Direct contact with experts or economic operators.

[4] The latest release used for this study is 1.2.7

1.2 Outcome and scope of the measurement

The quantifications carried out in this report are based upon the EU Standard Cost Model methodology. ACs/ABs attributable to each IO have been quantified, followed by the total ACs/ABs attributable to a whole baseline piece of legislation. In case there is sufficient ground to believe that most of ACs/ABs due to a legal act arise from few IOs, it is possible to limit quantification to these IOs, disregarding other IOs whose impact is likely to be negligible / minor.

In some cases, because of lack of data, a joint estimate of ACs/ABs due to a group of two (or more) IOs has been produced. When there was not sufficient or complete data for a negligible/minor IO, we have preferred not to provide a tentative quantification, and stated that it is unlikely to have a relevant effect on the results for the whole act. Where the lack of data concerned an important IO, we have gone further and tried to provide a tentative quantification based on several assumptions. Only in very few cases a measurement for IOs which are considered as non-marginal could not be provided.[5]

For each IO that could be measured, the total of ACs/ABs due to it (and consequently the BAU factor applied) is provided. The figures that we provide measure the amount of ACs/ABs imposed on firms over a period of one year. For almost every IO the population subject to it and the cost per occurrence are also provided. When possible, i.e. when disaggregated data on the population could be retrieved, data concerning ACs/ABs per country and national costs per occurrence are also provided.

When an amending act / proposal exists, the impact of the new legal texts on the baseline measurement previously carried out is assessed. E.g., we look at whether a new piece of legislation adds/removes an IO, modifies the time needed to comply with an IO, its frequency, or the subject population. Then, the total amount of ACs/ABs, and their variation, attributable to the amending act / proposal is calculated. An estimate of the reduction (or increase) of ACs/ABs due to the legislative amendment is provided, both in absolute and relative terms.

1.3 Methods of estimation

The quantification methodology varies on a case-by-case basis, according to the single act to be assessed and to the available data. The methodology applied and the data sources used are detailed infra for each quantification. However, the following general principles can be highlighted.

[5] Cf. paragraph 3.2.4.1.

1.3.1 Baseline acts

Three main methods have been used to estimate ACs/ABs due to the IOs included in the baseline acts:

1. Direct application of SCM. If sufficient data on population and costs are available, or if population figures can be extrapolated or cost data can be estimated on the basis of an expert's assessment, ACs/ABs due to the IO have been quantified by applying the SCM formula (Cost X Frequency X Population). Since it is the most direct, this method is likely to be the most reliable and has been used as much as possible. However, its use is affected to a large extent by the availability of sufficient data, especially on population;[6]

2. Extrapolation from national databases / other national measurements. In case national databases or documents on ABs contain sufficiently homogeneous data related on an IO, total ACs/ABs for the EU can be extrapolated. Further details on the parameters used for extrapolation are given in paragraph 1.5 below. If possible, that is if sufficient data on population are available, we retrieve only the cost per occurrence from national databases or other measurements, and carry out an extrapolation to calculate only the EU average cost per occurrence, and not total ACs/ABs;

3. Analogy with another IO. In case there is ground for establishing a sound analogy between the IO under analysis and another IO included in the EU database on AB, or already measured by us, it is possible that the latter is used to estimate the total ACs/ABs of the former. For example, part of results of the measurement of dir. 2000/13 on food labelling has been used to estimate ACs/ABs due to dir. 96/25 on feed labelling.[7]

   The latest version of the AB calculator allows for an automatic application of the analogical method, both facilitating the individuation of the IO upon which the analogy should be based, and performing the calculation. It is now possible to find the most appropriate existing IO for the analogy searching the database according to three criteria: Priority Area, Target Group, and Obligation Type. The user can therefore decide which of these search criteria is the fittest, and obtain from the AB calculator a list of all the possibly relevant IOs. Further scrutiny can subsequently be conducted on the basis of the information included in the EU database, Consortium's report, and legislative texts. The AB calculator also provides the opportunity of considering an IO as a "typical obligation". E.g., the

[6] Costs can be more easily estimated on a basis of an experts' assessment, or contacting economic operators.

[7] See paragraph 3.2.2.2

user may consider that a certain obligation to apply for an authorisation represents a "typical application for an authorisation", and use it as the basis to quantify analogous IOs. Using the "typical IO" tool can be useful to standardise calculations and results for certain IOs which are quite similar across different acts and/or priority areas, reducing the risk of having inconsistent or aberrant results.

Once the proper IO has been individuated for the analogy, the user may type the new estimated values for population, costs, frequency and BAU factor in the AB calculator, which will calculate costs and burdens due to the IO in the scope of the quantification.

1.3.2 Amending acts / proposals

To measure variation of ACs/ABs due to amending acts / proposals, three scenarios are frequent:

1. Change in the population coverage. In this case, the total amount of ACs/ABs generated by the IO is increased/decreased by the same percentage variation of the population. When only a particular group of firms is affected (i.e. small firms), quantification is based on data referred to that group;

2. Change in (part of) the business process needed to comply with the IO. In this case, the variation has been estimated in the cost per occurrence due to the legal changes and applied uniformly to the (part of the) population concerned;

3. Change in the DRs. In this case, we have usually assumed that ACs/ABs generated by the IO are equally spread across the DRs and carry out the quantification accordingly. If any data or evidence shows that DRs should not be assigned equal weight, this has been expressly stated and duly justified in the report.

In the following sections, a summary table[8] provides an overview of ACs/ABs due to each baseline act, and to the IOs therein included. Then, each IO is analysed, providing a short description and then highlighting data sources, assumptions and steps used to perform the quantifications. Finally, the quantification of ACs/ABs due to each IO is delivered. When an amending act / proposal exists, changes due it are analysed, both on the general legal framework and on single IOs. Quantification is provided for new,

[8] Please note that the quantification tables for whole acts or single IOs are colour tables, while other tables inserted in the report are black and white.

changed, or deleted IOs. Finally, a final summary table quantifies the variation of ACs/ABs, if any, due to the amending act / proposal.

In any case this report does not contain quantification obtained through empirical methods such as interviews or other forms of direct data collection from the affected businesses, which were out of the scope of the task.

Importantly, sometimes the amending act / proposal establishes a new IO or modifies an existing IO, but leaves the specification of details to future implementing measures. In this case, the quantification can be particularly difficult. Generally:

1. If the framework act specifies the DRs but not the means of implementation, we explicitly make assumptions on how the provision could be implemented and provide quantification of the related ACs/ABs.

2. If the framework act establishes only some general principles, leaving the specification of the DRs and of the means of implementation to subsequent measures, sound quantification cannot usually be provided. In this case, we only a qualitative analysis is provided.

1.4 The "ceteris paribus" assumption

We try to estimate the effects of the legal changes under a condition of ceteris paribus. It means that, for the purposes of this report, changes in ACs/ABs are not considered if due to:

1. variation of salary rates;

2. variation of prices of equipment or outsourced services;

3. changes in the population figures. With regard to population, in general figures are kept constant, unless the variation of population is a direct consequence of the amending act (see for example paragraph 3.2.1.7). In this case, the variation of population is taken in due account and its effect is quantified.

Our choice not to consider external factors (the ceteris paribus assumption) is justified by the need to reflect the impact of amending acts as precisely as possible. Furthermore, this choice is to a certain extent necessary because data concerning population, costs and salaries do not refer to the same time period – e.g. data on

population usually refer to previous and not homogeneous periods; information about costs retrieved from firms refers to their latest experience with complying with the IO.

As a corollary, if the text of the amending act does not differ from that of the baseline, the same amount of ACs/ABs is attributed to both acts. This methodology is necessary since we want to track the impact of legal reforms on the baseline. Similarly, if the text of an IO has not changed, or has changed in a way that does not affect ABs, we consider that ACs/ABs have not varied. When an IO is eliminated, the amount of ACs/ABs due to it is entirely subtracted from the total.

1.5 Extrapolation Parameters

The extrapolation methodology is as simple and sound as possible.

Differently from the Consortium's work, the extrapolation is usually carried out on the basis of a single data point, not on the basis of a series of data; and only EU-totals of ACs and ABs, not national figures, must be delivered. Therefore, we have not resorted to particularly complex econometric or statistical techniques. We consider that for our work, which must be much less detailed than Consortium's, the higher quality of most sophisticated estimates does not compensate for the lack of clarity and for the need of many more assumptions.

Several variables have been used to draw an estimation of the EU-totals on the basis of figures from a single Member State. Below, a list of the relevant variables and of the parameters used to estimate these variables is provided:

1. Dimension of the economy. The biggest is the economy, the greatest is the number of undertakings, and the highest ACs/ABs can be expected to be in absolute terms. To evaluate the dimension of national economies, data on Gross Domestic Product (GDP), both in Purchase Power Parity (PPP) and in nominal prices, have been retrieved from Eurostat. Since our report covers the legislative activity of the Barroso's Commission, we have retrieved data concerning the GDP of the EU Member States over the period 2005-2008. According to our goal to reduce as much as possible variance due to other factor, such as GDP annual variations, annual GDP data over this period have been averaged and the so-obtained value is used to carry out the extrapolation;

2. Number of firms. Where possible, extrapolations have been carried out on the basis of the number of firms belonging to a specific sector and consequently subject to an IO. In this case, the dimension of the economy, proxied by the GDP, is not used for the extrapolations. Numbers of firms are retrieved from the Structural Business Statistics published by Eurostat;

3. Salary rate. For sake of comparability with the measurement carried out by the Consortium, the national hourly salary rates used by it have been retrieved from the EU database on AB. Salary rates are available for the following categories of workers: (i) Legislators, senior officials and managers; (ii) Professionals; (iii) Technicians and associate professionals; (iv) Clerks; (v) Service workers and shop and market sales workers; (vi) Craft and related trades workers; (vii) Plant and machine operators and assemblers; (viii) Manual workers (agricultural and fisheries); and (ix) Elementary occupations;

4. Working force. In some cases, an EU average salary rate for a certain category of workers must be calculated. In this case, an average of national salary rates, weighted for the dimension of the national workforce, has been calculated. As for GDP, we have retrieved annual data on the dimension of the workforce in the EU Member States for the period 2005-2008 from Eurostat, and calculated the average over this period, to reduce variance due to transient variations;

5. ABs – GDP ratio. An economic study[9] has shown that the EU Member States impose different levels of ACs/ABs on firms. This can be due both to the different number of IOs and DRs imposed by the national legislations and to the different features of the national legal and administrative frameworks. As a consequence, the same IOs of EU origin may impose different burdens in two Member States with a different legal and administrative background. This phenomenon can be proxied by the ratio of ABs on GDP calculated in the paper, providing data for the EU-25 only.[10] To estimate the AB-GDP ratio of Bulgaria and Romania, the ratios of the 10 new Member States acceded in 2004 has been averaged out;

6. Exchange rate. When we had to use values expressed in currencies other than Euros, official exchange rate have been retrieved from the European Central Bank. To reduce the variance of the exchange rates, we have tried to use data referred to a time span as large as possible. For extrapolation purposes, the currency rate of the British Pound is particularly important. Annual €/£ exchange rates for the period 2005-2008 have been retrieved and averaged. The resulting average €/£ exchange rate is of 1.4116. Data from the British database on ABs are reported directly in Euro, for sake of comparability.

[9] Kox 2005: intra-EU differences in regulation-caused administrative burden for companies. CPB Memorandum 136, the Hague.

[10] Belgium and Luxembourg; and the Baltic States, Malta and Cyprus are grouped in single entities.

2 ESTIMATING THE REDUCTION OF ABS: THE ORIGINAL LIST

2.1 Priority Areas: Transport

Within this area, we have to measure the reduction of administrative burdens brought about by an act: Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85.

2.1.1 Regulation 561/2006: introduction of the digital tachograph to record time spent by drivers for the carriage by road of goods or passengers

Regulation 561/2006 is one of the acts measured by the Consortium. It amends or repeals several directives concerning road carriage of goods and passengers. The ACs due to it amount to €3,101,843,000, of which €3,024,159,000 are considered ABs. Two IOs are responsible for this burden:

1) recording time spent driving a vehicle and recording working time, as provided by art. 6 par. 5. This provision causes ACs equal to €3,062,234,000 and ABs equal to €2,984,544,000;

2) notification of exception situation in which driving times cannot be met, as provided by art. 12. This provision causes ACs equal to €39,615,000, all of which are considered ABs.

These IOs were previously regulated by Council Regulations (EEC) 3820/85 and 3821/85. To assess the ABs reduction due to reg. 561/2006, we have to analyze the situation when the previous legislation was in force:

1) recording time spent driving a vehicle and recording working time was regulated by art. 15 par. 2 and 3 of reg. 3281/85;

2) notification of exception situation in which driving times cannot be met was regulated by art. 12 of reg. 3280/85.

The wording of the IOs has been left almost unchanged by reg. 561/2006. The changes brought about by the latter piece of legislation are due to art. 27, stating that every vehicle put into service for the first time shall be fitted with a digital tachograph. Before reg. 561/2006, carriage operators could choose whether to install either an analogue or

a digital tachograph.[11] Thus, the evaluation of the change in ABs has to be focused on the switch from analogue to digital tachographs.

The Consortium has calculated the total ABs by considering the current road carriage fleet as composed of vehicles equipped partly with analogue tachographs and partly with digital tachographs. They assume that the vehicles sold in 2006 and 2007 have digital tachographs installed, while the others have not. Throughout the EU, 26% of vehicles are assumed to be equipped with digital tachographs[12].

Reg. 561/2006 is going to deliver its effects over the long run, when the vehicles equipped with analogue tachographs will be substituted by new vehicles equipped with digital ones. Even though this process has not yet been completed, we try to compute the whole future consequence of adopting reg. 561/2006. To do this, we evaluate whether the use of a digital tachographs to record drivers' working times reduces or increases the ABs on carriage operators (both drivers and administrative staff).

The Consortium measurement shows that fulfilling IO 1) through a digital tachograph is slightly more costly than through an analogue one. The average AB per driver[13] per month measured by the consortium amounts to €22.37 for vehicles equipped with analogue tachographs and to €22.96 for vehicles equipped with digital tachographs. The difference is due to the fact that the time needed to comply with the IO through a digital tachograph is slightly lower, but the equipment costs are considerably higher. However, another study carried out by the Department for Transport of the British Government[14] finds that the adoption of digital tachographs is very likely to reduce ABs for carriage firms, regardless of their size, and that savings increase with the firm dimension.

We cannot support Consortium's view for two reasons:

1) Downloading time. Data has to be extracted from each digital tachograph at least once every 90 days and from each driver card[15] at least once every 28 days. Downloading time is reported to be substantial, amounting to about 20-30 minutes per month. However, contacting carriage operators and consulting card reader producers' websites, we have found evidence that the downloading time can be much lower. Card reader advertisements state that downloads may take less than 30 seconds, and several operators have confirmed this statement. However, even if the downloading time amounted to about 20-30 minutes, the fact that drivers and administrative operators may perform other tasks while data are being downloaded should be discounted. The consortium has decided not to

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[11] An obligation to install digital tachographs in new vehicles was included in Art. 2 of Council Regulation (EC) No 2135/98 of 24 September 1998, but had never been made effective before reg. 561/2006 was enacted.

[12] EU SCM Final Report PA Transport, Annex 5.

[13] The number of drivers and vehicle population are assumed to be equal.

[14] Department for Transport: Tachographs – Data downloading and record retention, available at: http://www.dft.gov.uk/consultations/archive/2007/consultachogrhs/multitachogrphs

[15] Whenever a driver drives a vehicle equipped with a digital tachograph, it must insert its personal driver card, where his/her working time is recorded.

take into account of this remark and has not provided a justification for this methodological decision. For these two reasons we consider that a part of the estimated 20-30 minutes needed for downloading tasks should be deducted by the time needed to comply with IO 1).

2) Equipment costs. To estimate the equipment costs, the Consortium has retrieved data about the cost of buying either a digital or an analogue tachograph "off the shelf". This approach is not correct, since the directive does not prescribe to upgrade analogue tachograph installed on existing vehicles, but only to have new vehicles equipped with a digital one. If a company buys a new vehicle, it is already equipped with a digital tachograph; in every other situation carriage companies are never compelled by reg. 561/2006 to directly buy a digital tachograph on the market. The approach of the Department for Transport seems much more realistic. It takes account of the fact that vehicles manufacturers must equip new vehicles with a digital tachograph and it leads to no difference in price, therefore asking a vehicle manufacturer to install an analogue tachograph on a new vehicle would cost more even though analogue tachographs cost less "off the shelf". Therefore, there is no relevant difference between the equipment costs of a digital or analogue tachograph.

To take these assumptions into consideration, we reduce the time needed to comply with IO 1) through a digital tachograph by 12.5 minutes (half the average time needed to download data).

As for equipment costs, we take into consideration that when buying a new vehicle it makes no price difference to ask for a digital or analogue tachograph. Therefore, we assume that the same equipment costs can be applied both to analogue and digital tachograph. We consider the Consortium estimate of €5 per driver per month as accurate to measure the equipment costs for both analogue and digital tachograph users. The difference in cost per occurrence between the Consortium's and our approach are detailed in Table 2.

Table 2 Estimates of ABs due to IO recording time spent driving a vehicle and recording working time when it is fulfilled through analogue or digital tachographs

	Analogue tachograph		Digital tachograph	
	Consortium (Measured)	CEPS	Consortium (Measured)	CEPS
Average internal time per driver per month	138,7	*138,7*	123,0	*110,5*
Average Cost per time per month due to time requirements	€ 17,4	*€ 17,4*	€ 16,0	*€ 14,3*
Equipment Cost per driver per month	€ 5,0	*€ 5,0*	€ 7,0	*€ 5,0*
Average Total Administrative Cost per driver per month	€ 22,4	*€ 22,4*	€ 23,0	*€ 19,3*
Average Total Administrative Burden per driver per month	**€ 22,4**	***€ 22,4***	**€ 23,0**	***€ 19,3***

According to this calculation, switching from analogue to digital tachographs leads to a reduction of administrative burdens. This saving will actually take place when the whole EU fleet for carriage of goods and passengers switches to digital tachographs as prescribed by reg. 561/2006.

To calculate the total reduction of ACs/ABs, we have to consider that the Consortium's population figures include 74% of drivers still using the analogue tachographs. According to our estimation, when they switch to digital tacographs, the cost per equipment will remain the same, but the other internal unit costs will decline from €17.4 to €14.3, therefore by 17.4%. According to EU database, internal (non-equipment) costs amount to €2,279,216,543. The saving will therefore amount to 12,9% of total internal costs (i.e. the savings, 17.4%, times the population concerned, 74%), i.e. to €294,057,634.

At the same time, we have to "go back in time", that is to try to figure out how was the situation when no digital tachograph was installed. Since the original cost per occurrence in the Consortium figure is approximately the same for both digital and analogue tachographs, we assume that the amount of ACs/ABs measured in the EU database is a good proxy of the situation under reg. 3281/85.

The quantification is summarized in Table 3. Savings of ABs are estimated by applying the same BAU factor applied by the Consortium for this IO.

Table 3 Reg 561/2006 – Changed IO: Recording time spent driving a vehicle and recording working time

CHANGED IOs			
Priority Area	*Trasnport*		
Existing EU legislation	**Reg. 3281/85**	Amending Act	**Reg. 561/2006**
EU Info obligation	Recording time spent driving a vehicle and recording working time (art. 6 par. 5)		
Obligation Type	10. Cooperation with audits and inspection by public authorities, including maintenance of appropriate records		
	QUANTIFICATION		
	Reg. 3281/85		**Reg. 561/2006**
Frequency (per year)	each working day		each working day
Population	5,900,424		5,900,424
Administrative Costs	€ 3,062,233,725		*€ 2,768,176,091*
Administrative Burdens	**€ 2,984,543,991**		*€ 2,697,946,682*
AC Difference	**-€ 294,057,634**		**-9.6%**
AB Difference	**-€ 286,597,309**		**-9.6%**

As far as IO 2) is concerned (notification of exception situation in which driving times cannot be met), there is no relevant change. The wording of the IO remains the same and the introduction of the digital tachograph is not likely to modify the way of complying with this IO or the time needed to do it. Therefore, reg. 561/2006 neither reduces nor increases the ABs arising from IO 2), that is from reg. 3280/85.

Results for reg. 561/2006 are summarized in Table 4.

Table 4 Summary table for Reg. 561/2006

SUMMARY			
Priority Area	Transport		
Existing EU legislation	Reg. 3820/85 Reg. 3821/85	Amending Act	Reg. 561/2006
	QUANTIFICATION		
	Reg. 3820/85	Reg. 561/2006	
Administrative Costs Administrative Burdens	€ 3,101,843,000 € 3,024,159,000	*€ 2,807,785,366* *€ 2,737,561,691*	
AC Difference	-€ 294,057,634	-9.5%	
AB Difference	-€ 286,597,309	-9.5%	

3 ESTIMATING THE REDUCTION OF ABS: THE EXTENSION LIST INCLUDED IN ANNEX 9 TO THE "JANUARY COMMUNICATION" (COM(2009)16)

3.1 Priority area: Agriculture

Within the present area, we have to analyse the ACs/ABs due to the following baseline acts and the reduction brought about by the related amending acts/amending proposals. As explained in the methodological chapter, differently from the other priority areas, we do not have to provide a total mapping and quantification quantification of the baseline and the amending acts, but only to focus on main legal changes expected to have an impact on burdens. The acts analysed are:

1. Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector. It has been amended by Commission Regulation (EC) No 1221/2008 of 5 December 2008 amending Regulation (EC) No 1580/2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector as regards marketing standards;

2. Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation). It has been amended by Council Regulation (EC) No 72/2009 of 19 January 2009 on modifications to the Common Agricultural Policy by amending Regulations (EC) No 247/2006, (EC) No 320/2006, (EC) No 1405/2006, (EC) No 1234/2007, (EC) No 3/2008 and (EC) No 479/2008 and repealing Regulations (EEC) No 1883/78, (EEC) No 1254/89, (EEC) No 2247/89, (EEC) No 2055/93, (EC) No 1868/94, (EC) No 2596/97, (EC) No 1182/2005 and (EC) No 315/2007;

3. Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD). It has been amended by Council Regulation (EC) No 74/2009 amending Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD).

3.1.1 Marketing standards in the fruit and vegetable sector

In the area of marketing standards for fruits and vegetables, several Community regulations have been enacted over the past years. Council Regulation (EC) No 1234/2007 established a common organisation of agricultural markets which includes specific rules as regards the fruit and vegetable sector, including marketing standards. Commission Regulation (EC) No 1580/2007 lays down the implementing rules in the fruit and vegetable sector, which again covers marketing standards.

Commission Regulation 1221/2008 repealed 34 previous regulations which covered 36 products[16]. The only products for which a separate marketing standard still remains are now sweet peppers, table grapes, tomatoes, lettuces and curled-leaved and broad-leaved (Batavian) endives, citrus fruit, strawberries, apples, pears, kiwifruit, peaches and nectarines. Arguments in favour of the repealing of 26 specific marketing standards are the following: specific costs entailed by complying with marketing standards such as extra grading costs due to compliance with legislation may be reduced diminishing the number of specific marketing standards.

The General Marketing Standard for Fresh Fruit and Vegetables implies:

1. Minimum quality requirements. Subject to the tolerances allowed, the products shall be: intact, sound, clean, practically free from pests, practically free from damage caused by pests affecting the flesh, free of abnormal external moisture, free of any foreign smell and/or taste; the condition of the products

[16] Content-wise, 10 of the regulations are included in the 1221/2008. Below the list of the repealed regulations, in bold the regulations corresponding to the products which are still covered by a specific marketing standard in the Reg 1221/2008. (EEC) No 1292/81 of 12 May 1981 laying down quality standards for leeks, aubergines and courgettes [5]; (EEC) No 2213/83 of 28 July 1983 laying down quality standards for onions and witloof chicory [6]; (EEC) No 1591/87 of 5 June 1987 laying down quality standards for cabbages, Brussels sprouts, ribbed celery, spinach and plums [7]; (EEC) No 1677/88 of 15 June 1988 laying down quality standards for cucumbers [8]; (EC) No 831/97 of 7 May 1997 laying down marketing standards applicable to avocados [9]; (EC) No 2288/97 of 18 November 1997 laying down marketing standards for garlic [10]; (EC) No 963/98 of 7 May 1998 laying down marketing standards for cauliflowers and artichokes [11]; (EC) No 730/1999 of 7 April 1999 laying down the marketing standard for carrots [12]; (EC) No 1168/1999 of 3 June 1999 laying down marketing standards for plums [13]; (EC) No 1455/1999 of 1 July 1999 laying down the marketing standard for sweet peppers [14]; (EC) No 2377/1999 of 9 November 1999 laying down the marketing standard for asparagus [15]; (EC) No 2561/1999 of 3 December 1999 laying down the marketing standard for peas [16]; (EC) No 2789/1999 of 22 December 1999 laying down the marketing standard for table grapes [17]; (EC) No 790/2000 of 14 April 2000 laying down the marketing standard for tomatoes [18]; (EC) No 851/2000 of 27 April 2000 laying down the marketing standard for apricots [19]; (EC) No 175/2001 of 26 January 2001 laying down the marketing standard for walnuts in shell [20]; (EC) No 912/2001 of 10 May 2001 laying down the marketing standard for beans [21]; (EC) No 1508/2001 of 24 July 2001 laying down the marketing standard for onions and amending Regulation (EEC) No 2213/83 [22]; (EC) No 1543/2001 of 27 July 2001 laying down the marketing standard for lettuces and curled-leaved and broad-leaved (Batavian) endives [23]; (EC) No 1615/2001 of 7 August 2001 laying down the marketing standard for melons and amending Regulation (EC) No 1093/97 [24]; (EC) No 1799/2001 of 12 September 2001 laying down the marketing standard for citrus fruit [25]; (EC) No 2396/2001 of 7 December 2001 laying down the marketing standard applicable to leeks [26]; (EC) No 843/2002 of 21 May 2002 laying down the marketing standard for strawberries and amending Regulation (EEC) No 899/87 [27]; (EC) No 1284/2002 of 15 July 2002 laying down the marketing standard for hazelnuts in shell [28]; (EC) No 1466/2003 of 19 August 2003 laying down the marketing standard for artichokes and amending Regulation (EC) No 963/98 [29]; (EC) No 1757/2003 of 3 October 2003 laying down the marketing standard for courgettes and amending Regulation (EEC) No 1292/81 [30]; (EC) No 85/2004 of 15 January 2004 laying down the marketing standard for apples [31]; (EC) No 86/2004 of 15 January 2004 laying down the marketing standard for pears [32]; (EC) No 214/2004 of 6 February 2004 laying down the marketing standard for cherries [33]; (EC) No 1673/2004 of 24 September 2004 laying down the marketing standard applicable to kiwifruit [34]; (EC) No 1861/2004 of 26 October 2004 laying down the marketing standard applicable to peaches and nectarines [35]; (EC) No 1862/2004 of 26 October 2004 laying down the marketing standard applicable to watermelons [36]; (EC) No 1863/2004 of 26 October 2004 laying down the marketing standard applicable to cultivated mushrooms [37]; (EC) No 634/2006 of 25 April 2006 laying down the marketing standard applicable to headed cabbages and amending Regulation (EEC) No 1591/87 [38].

must be such as to enable them: to withstand transport and handling, to arrive in satisfactory condition at the place of destination;

2. Minimum maturity requirements. The products must be sufficiently developed and display satisfactory ripeness; the development and state of maturity of the products must be such as to enable them to continue their ripening process and to reach a satisfactory degree of ripeness;

3. Tolerance. A tolerance of 10% by number or weight of product not satisfying the minimum quality requirements shall be permitted in each lot, but this tolerance shall not however cover product affected by rotting or any other deterioration rendering it unfit for consumption;

4. Marking of origin of produce. Full name of the country of origin. For products originating in a Member State this shall be in the language of the country of origin or any other language understandable by the consumers of the country of destination. For other products, this shall be in any language understandable by the consumers of the country of destination.

Regulation 1221/2008 also merged three previous articles in Regulation 1580/2007 into one article, by establishing a single conformity check procedure. More in detail, articles 10, 11 and 12 of Reg 1580/2007 established different provisions for conformity checks carried out according to the destination of the product (export, import, the internal market). With Article 10 of Regulation 1221/2008, conformity checks are the same whatever the destination of the product.

3.1.1.1 Changes in the regulatory regime

For the purposes of our report, we refer to two different regulatory regimes in order to establish the reduction in administrative burdens achieved during the Barroso presidency: the situation with Regulation 1580/2007; and changes achieved with Reg. 1221/2008.

The difference between the two regimes can be summarised as follows:

1. The role of risk analysis in selecting products for checks has been strengthened;

2. A reduction from 36 to 10 Specific Marketing Standards (SMS) which are to be enforced as at present at all stages of the marketing chain (i.e. import, grower, wholesale, distribution and retail);

3. A General Marketing Standard (GMS) which will apply to all fresh produce except 8 products (paragraph 3b of Article 3 of Regulation (EC) No 1580/2007) and produce not covered by a Specific Marketing Standard. See Annex D for a list of products. This will be legally binding on all traders in these products. Member States may opt to adjust the frequency of selective checks on low risk products based on risk analysis;

4. The database of traders is to be maintained (RPAI will update and extend to cover all products);

5. Data on the conformity of all products is required to ensure conformity checks can be carried out with appropriate risk-based frequency;

6. Mixed packages of a net weight of 5kgs or less are allowed, providing the products are of uniform quality and comply with the relevant Specific Marketing Standard or, where none applies, with the General Marketing Standard. In addition, if the fruit and vegetables in a mix originate in more than one Member State or third country, the full names of the countries of origin may be replaced with one of several phrases e.g. 'mix of EC fruit and vegetables or 'mix of non-EC fruit and vegetables';

7. Mixed packages of a net weight of 5kgs or less are allowed, providing the products are of uniform quality and comply with the relevant Specific Marketing Standard or, where none applies, with the General Marketing Standard. In addition, if the fruit and vegetables in a mix originate in more than one Member State or third country, the full names of the countries of origin may be replaced with one of several phrases e.g. 'mix of EC fruit and vegetables';

8. Approved Inspection Services (AIS) for selected approved Third Countries shall remain;

9. Approved Trader Scheme (ATS) may be extended to allow traders to self certify consignments at import;

10. Requirement to notify and certify consignments for processing is removed;

11. Regulatory powers are extended to distance selling, such as via the internet, for example on-line shopping and other internet trading;

12. An option is granted for derogation from the Specific Marketing Standards for products presented for retail sale to consumers for their personal use and labelled as 'intended for processing' (or similar wording). To be able to use this derogation the produce would still have to meet the General Marketing Standard.

Thanks to Reg. 1221/2008 the following requirements have been eliminated:

1. 26 products will no longer have Specific Marketing Standards relating to classification, size, shape, development, variety and labelling details;[17]

2. Notification and certificates for all imported produce for processing (2,250 certificates were issued in 2007);

[17] Apricots, Artichokes, Asparagus, Aubergines, Avocados, Beans, Brussel sprouts, Carrots, Cauliflowers, Cherries, Courgettes, Cucumbers, Cultivated mushrooms, Garlic, Hazelnuts in shell, Headed cabbages, Leeks, Melons, Onions, Peas, Plums, Ribbed celery, Spinach, Walnuts in shell, Watermelons, Witloof chicory.

3. References to minimum quality criteria for products intended for industrial processing deleted, as they were related to aid schemes abolished in the 2007 reform.

The following elements are retained in the new Regulation:

1. 10 Specific Marketing Standards, chosen as they are the top 10 traded produce in the EU by value - both imported and intra-EU trade.[18] For these, there is no change in the regulatory regime;
2. Significant core of official controls;
3. Inspection and enforcement required at all stages of the marketing chain;
4. Import notification;
5. Approved Inspection Services (AIS) for selected Third Countries;
6. Risk based approach to enforcement;
7. Removal of rotten/soiled/pest affected produce.

The new requirements brought in by this Regulation are the following:

1. A General Marketing Standard for all produce covered by the regime (see Annex D), apart from those covered by the 10 Specific Marketing Standards, legally binding on all traders, to deliver the 'sound, fair and of marketable quality' requirement;
2. Country of origin labelling for all products covered by the Marketing Standards for transparency;
3. Member States are allowed to decide whether to implement a derogation to the 10 Specific Marketing Standards for produce sold to consumers for personal use at retail level if it meets specific labelling criteria i.e. labelled as "intended for processing" (or similar wording). This produce would still need to meet the General Marketing Standard;
4. Allows for mixed packages of a net weight of 5kgs or less providing the products are of uniform quality and comply with the relevant Specific Marketing Standard or where none applies then the General Marketing Standard. In addition if the fruit and vegetables in a mix originate in more than one Member State or third country, the full names of the countries of origin may be replaced with one of several phrases e.g. 'mix of EC fruit and vegetables';
5. Member States allowed to decide whether to extend the Approved Trader Scheme to importers and exporters;

[18] Apples, citrus fruit, kiwi fruit, lettuces, curled leaved and broad-leaved endives, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes.

6. Distance contracts (i.e. via internet, for example on-line shopping and other internet trading) brought into scope of the Regulation i.e. requirements now apply to these sales;
7. Definition of 'trader' widened to ensure all in the marketing chain are covered by the Regulation;
8. Exemption from the Marketing Standard for certain products not intact when sold i.e. products having undergone a trimming or cutting making them 'ready to eat' or kitchen ready';
9. Products subject to the General Marketing Standard will be considered as conforming where the holder is able to show they are in conformity with any such applicable United Nations Economic Commission for Europe (UNECE) standards;

3.1.1.2 Identifying the IOs

DG AGRI has identified the following potential IOs that have changed in Reg. 1580/2007 as amended by Reg. 1221/2008:

1. Article 2a of Reg. 1580/2007 (as amended) replaces 26 marketing standards with a General Marketing Standard (GMS). It affects mostly compliance costs, rather than administrative burdens, but it covers also labelling details (indicating packer/dispatcher ID, size, class, etc), and this should be taken into account in assessing the impact of the new regime on admin burdens;
2. Article 3 of Reg. 1580/2007 (as amended) introduces derogations (intended for processing, personal use, local production), and exemptions for 8 products from the GMS. Also this article affects mostly compliance costs, rather than administrative burdens: however, also labelling details are covered by this article, and should be taken into account in assessing the impact of the new regime on admin burdens;
3. Article 4 of the same regulation describes the labelling of these products by imposing a specific format and presentation of the label, by mandating that the information particulars be shown "legibly and obviously on one side of the packaging, either indelibly printed directly onto the package or on a label which is an integral part of the package or affixed to it". In addition, Reg. 1221/2008 added a requirement for the case of distance contracts, requiring sellers to make the information particulars available before the purchase is concluded. The content of this IO is further specified as regards invoices and accompanying documents (excluding receipts for the consumer), which shall indicate "the name and the country of origin of the products and, where appropriate, the class, the variety or commercial type if required in a specific marketing standard, or the fact that it is intended for processing";

4. Article 5 (as amended) requires that "the information particulars ... be legible and conspicuous". Products may be presented for sale provided the retailer displays prominently, adjacent to and legibly the information particulars relating to country of origin and, where appropriate, class and variety or commercial type in such a way as not to mislead the consumer. In addition, for pre-packaged products "the net weight shall be indicated, in addition to all the information provided for in the marketing standards;[19]

5. Article 6 (as amended) i.a. extends the labelling requirement to mixes of fruits and vegetables, and allows – in case of products originating from different countries – replacing the country of origin with alternative indications ("mix of EC fruit and vegetables", "mix of non-EC fruit and vegetables", "mix of EC and non-EC fruit and vegetables").

6. Article 8 (already in Reg. 1580/2007) deals with the designation of inspection bodies. The IO contained in this article is implicit, and refers to the information that traders must provide to inspection bodies and records than have to be kept for inspections. Other than that, the SCM does not cover admin burdens borne by public coordinating authorities and inspection bodies;

7. Article 9 (already in Reg. 1580/2007) provides for the setup of a database of traders. In this respect, the IO is the information that must be periodically provided to the public authority that runs the database – this includes the trader's "registration number, name, address, information needed for its classification in one of the categories mentioned in Article 10, in particular, position in the marketing chain, information concerning the importance of the firm, information concerning findings made during previous checks of each trader, as well as any other information considered necessary for checks";

8. As regards conformity checks, the issue is more complex. As a matter of fact, in Reg. 1580/2007:

    i. Article 10 contains several IOs: (i) Article 10.2 of Reg 1580/2007 requires traders to provide the inspection bodies with all information those bodies judge necessary for organising and carrying out checks; (ii) Article 10.3 of Reg. 1580/2007 allow traders that have achieved a high and consistent conformity rate to use the specimen provided at Annex II of Reg 1580/2007. This qualifies as an application for an authorisation, but is subject to the fact that the traders (i) have inspection staff who have received training approved by the Member State; (ii) have suitable equipment for preparing and packing produce; and (iii) commit themselves to proceed to a conformity check of the goods they dispatch and have a register recording all operations of checks carried out. Authorisation shall be for three years, renewable.

[19] However, in the case of products sold by number, the requirement to indicate the net weight shall not apply if the number of items may be clearly seen and easily counted from the outside or, if the number is indicated on the label.

ii. Articles 11 and 12 introduce separate procedures for conformity checks at the point of export and import, respectively. These procedures entailed the provision of information and the application for simplified procedures and self-assessment in case of consistent and high rate of conformity. For imports, there is a possibility of derogation in case the inspection body consider that the imported product is low-risk.

However, Reg. 1221/2008 merged these three procedures into a single conformity check procedure: this may reduce the administrative burden. The new rule implies that member states introduce risk analysis criteria to make sure that inspections and conformity checks are performed in line with the perceived riskiness of the activity at hand. Traders may apply for becoming "approved traders", which may use the specimen provided by the Regulation subject to the fact that they (i) have inspection staff who have received training approved by the Member State; (ii) have suitable equipment for preparing and packing produce; and (iii) commit themselves to proceed to a conformity check of the goods they dispatch and have a register recording all operations of checks carried out. The authorisation must be for at least one year (as opposed to 3 years in Reg. 1580/2007) – this may under some circumstances increase the frequency of this voluntary IO.

9. Article 12a provides that Member States may issue they certificates of conformity. This possibility is not an Information Obligation under the SCM, although it may have an impact on administrative burdens in case traders can avail of a simplified procedure.

10. Article 15 deals with case of suspension of approval. As this case deals with enforcement activities, no additional IO is found compared to the regular inspection activities.

All other provisions in Reg. 1580/2007 (in original and as amended) do not imply additional information obligations on businesses, though they impose IOs on public authorities. Accordingly, we do not consider them in our calculations below.

In conclusion, the most important IOs for the purposes of our analysis are the following:

1. The exoneration from labelling details for 26 products out of 36. the reduction of SMS to 10 accounts for 75% of the trade in fresh fruit and vegetables in Europe (UNECE, 2008) and so has the potential to reduce administrative burdens and also inspection costs;[20]

2. The elimination of separate import certificates. For example, 2,250 certificates were issued in 2007 in the UK and Wales, according to DEFRA;

3. The labelling requirements under Article 4, 5 and 6 of Reg. 1580/2007;

[20] ECE/TRADE/C/WP.7/2008/25, 10 November 2008, at page 3.

4. The implicit IOs in Articles 8 and 9 of Reg. 1580/2007. These are mostly related to collaboration with inspection bodies and other public authorities;
5. The IOs related to conformity checks at Articles 10, 11 and 12 – merged into article 10 in Reg. 1221/2008;
6. The IOs related to the Approved trader scheme.

3.1.1.3 Calculation of administrative burdens

The calculation of administrative burdens generated by Reg. 1580/2007 was carried out based on a number of assumptions. The IOs we measure are the following:

1. Cost of labeling and grading is estimated (based on UK calculations) at around 2 hours per ton;[21]
2. Indicating on all invoices and accompanying documents the quality class, country of origin and that it is intended for processing (if applicable) for products for which marketing standards have been adopted - ensuring that all accompanying documents indicate quality class, country of origin and that it is intended for processing (if applicable) takes 14 hours per year.
3. The cost of securing import certificates under Reg. 1580/2007 are estimated based on the UK database and then extrapolated to the EU27 based on EUROSTAT data on the population of traders/wholesalers and number of occurrences. Based on the calculations performed by PwC with DEFRA in the UK, we estimate that providing an import certificate takes 20 minutes per occurrence, of which 5 for collection of data and calculation, 5 minutes for preparation, and 10 for familiarization with the IO. The BAU factor for this IO is 6%;
4. Securing export certificates. Providing inspection bodies with all the information those bodies judge necessary for organising and carrying out marketing standards conformity checks on fruit and vegetables intended for export to third countries takes 3 hours, with a BAU factor of 30%;
5. Providing export certificates. Providing or holding a certificate of conformity with marketing standards, to allow an export declaration for products to be accepted by custom authorities. A single certificate can certify a consignment of several lots. This takes 30 minutes with a BAU factor of 5%;
6. Completing a processing certificate for products that are intended to be exported to third countries (non EU) and also for products that are imported into the community which are intended for processing, in order to ensure conformity to marketing standards of products held by traders at all stages of marketing, takes 4 hours and 30 minutes per year per business, BAU factor is 0%;

[21] DEFRA data.

7. Providing information to inspection bodies takes 1 hour and 30 minutes, of which 10 minutes for familiarization, 10 for gathering and preparing information, 10 for calculations and 1 hour for receiving the inspection. The BAU factor is approximately 30%;

8. Assisting inspectors in the inspection of fresh fruit and vegetables in order to issue a certificate of conformity takes 1 hour and 30 minutes, of which 10 minutes for familiarization, 20 for gathering and preparing information and 1 hour for receiving the inspection. The BAU factor is approximately 30%;

9. Demonstrating a consistent high level of conformity requires 17.5 hours due to familiarization (4 hrs, 22.5 minutes), calculation (4 hrs, 22.5 minutes), gathering/preparing (1 hour and 45 minutes), inspections (4 hours, 22.5 minutes) and meetings (2 hours, 37.5 minutes). The BAU factor is 6%;

10. Providing information as part of the training of inspection staff - where traders are authorised by Member States to label fruit and vegetables (with an EC stamp) as having a guaranteed uniform and high conformity rate at the stage of dispatch takes 20 minutes, with a BAU factor of 20%;

11. Applying for approval to use a specific label on each package of fruit and vegetable. Specific criteria which need to met: - must have trained inspection staff - must have suitable equipment for preparing /packing - must be committed to a checking procedure and keep a record of the checking. This IO takes 1 hour 20 minutes with a BAU factor of 34%;

12. Obtaining authorisation at the stage of dispatch to use the specimen label (in annex 3) in the labelling of each package (guranteeing uniform and high conformity rate of the fruit and vegetables subject to marketing standards) takes 1 hour and 45 minutes yearly, but BAU factor is 90%;

13. Keeping records of all checks carried out in order to use the specimen label in the regulation, to ensure conformity to marketing standards of products held by traders at all stages of marketing takes 45 minutes yearly, with a BAU factor of 33%;

14. Having a conformity check of the goods you dispatch where you use the labelling specimen takes 45 minutes, with a BAU factor of 29%;

15. Marking clearly the packaging of products intended for processing with the words "intended for processing" or other equivalent wording, and - for bulk shipments – placing the indication in an accompanying document or notice placed in an obvious position in the means of transport take 2 hours and 5 minutes per year per affected business, with a BAU factor of 37%;

16. Carrying out conformity checks to ensure conformity to marketing standards of products held by traders at all stages of marketing takes 35 minutes for familiarizing, gathering information, calculating necessary information. The BAU factor is 56%;

17. Complying with conformity checks at the point of retail sale to the end consumer, in order to ensure conformity to marketing standards of products held by traders at all stages of marketing, takes 55 minutes, of which 10 minutes for familiarization, 15 for gathering and preparing information, and 30 minutes for receiving the inspection. The BAU factor is approximately 30%.

18. Providing information to set up and update the database of traders in fruit and vegetables (i.e. those holding fruit and vegetables with a view to their displaying or offering for sale their sale or their marketing in any manner for itself or on behalf of a third party) means providing the registration number, business information, position in the marketing chain, importance of the firm, and any further information that the member state requires that is necessary for checks. It takes in total 1 hour and 15 minutes for familiarizing, gathering information, calculating necessary information. The BAU factor is 41%.

In addition, we assume the following:

1. Price: we apply the salary level used by the Consortium for the Agriculture priority area (agricultural workers), averaging €12.5 (hourly tariff).

2. Population and frequency: we rely where possible on EUROSTAT data, or data from other studies from DG AGRI (for data on the costs of specific activities, such as labelling)[22]. For labelling requirements, we have the availability of data per volume traded, and will use this to estimate total administrative burdens. However, in most cases available statistics are insufficient to determine the population affected by a given IO: this is also due to the fact that even if the overall population of processors, traders, wholesalers and retailers is known, (i) the share of these operators that engage in import/export; and most importantly (ii) the frequency of occurrences (how many consignments, how many applications for import certificates, how many inspections) is not known. Accordingly, we have used in most cases an extrapolation of the population calculated in the UK by PwC, weighted with the average share of UK operators on total EU27 operators (drawn from EUROSTAT data for traders, wholesalers and retailers).

Table 5 below shows our results for both Reg. 1580/2007 and Reg. 1221/2008. As can be seen in the table:

1. Our estimate of the total administrative cost generated by the selected IOs in Reg. 1580/2007 is approximately €3.5 billion, whereas ABs are approximately €2.2 billion;

2. Of these burdens, the lion's share is represented by "labelling and grading" (74%), and providing and carrying import certificates (25%);

[22] Directorate-General for Agriculture and Rural Development (DG AGRI): Study to assess the administrative burden on farms arising from the CAP. Available at: http://ec.europa.eu/agriculture/analysis/external/burden/fulltext.pdf.

3. The impact of Reg. 1221/2008 is mostly referred to the elimination of separate conformity checks for import and export;

4. Changes introduced with Reg. 1221/2008 amount to a saving of almost €1 billion in administrative burdens, or 44.3% of the total burden of Reg. 1580/2007;.

Please note that this are only indicative results. First, the impact of Reg. 1221/2008 should be assessed also in light of the expected increase in administrative burdens generated by the extension of the scope to distance and online contracts. Secondly, data on the population are extrapolated, and would of course be way more precise if detailed figures on population and frequency of occurrence were available.

Table 5 – Impact of Reg. 1221/2008

N.	IO	Time (min)	Population	Price (€/hr)	BAU factor	1580/2007		1221/2008		Change with reg. 1221		
						Admin cost	Admin burden	Admin cost	Admin burden	Admin cost	Admin burden	% change
1	Indicating on all invoices and accompanying documents the quality class, country of origin and that it is intended for processing (if applicable) for products for which marketing standards have been adopted - ensuring that all accompanying documents indicate quality class, country of origin and that it is intended for processing (if applicable)	2 hours per ton	108000000	12.5	40%	€ 2,700,000,000	€ 1,620,000,000	€ 2,025,000,000	€ 1,215,000,000	-€ 675,000,000	-€ 405,000,000	-25%
2	Providing or holding an appropriate import certificate of conformity with marketing standards (issued by the official inspection body at the point of import) to allow custom authorities to authorise the release of produce for free circulation.	840	4539599	12.5	30%	€ 794,429,866	€ 556,100,906	€ 0	€ 0	-€ 794,429,866	-€ 556,100,906	-100%
3	Applying for import certificates	20	3166738	12.5	6%	€ 13,194,740	€ 12,403,056	€ 0	€ 0	-€ 13,194,740	-€ 12,403,056	-100%
4	Complying with conformity checks at the point of retail sale to the end consumer, in order to ensure conformity to marketing standards of products held by traders at all stages of marketing	55	689184	12.5	30%	€ 7,896,905	€ 5,527,833	€ 7,896,905	€ 5,527,833	€ 0	€ 0	0%
5	Providing information to inspection bodies	90	131667	12.5	30%	€ 2,468,750	€ 1,728,125	€ 2,468,750	€ 1,728,125	€ 0	€ 0	0%
6	Demonstrating a consistent high level of conformity .	1050	3865	12.5	6%	€ 845,523	€ 794,792	€ 845,523	€ 794,792	€ 0	€ 0	0%
7	Assisting inspectors in the inspection of fresh fruit and vegetables in order to issue a certificate of conformity	90	48546	12.5	30%	€ 910,239	€ 637,168	€ 910,239	€ 637,168	€ 0	€ 0	0%
8	Carrying out conformity checks to ensure conformity to marketing standards of products held by traders at all stages of marketing	35	131525	12.5	56%	€ 959,035	€ 421,975	€ 959,035	€ 421,975	€ 0	€ 0	0%
9	Providing information to set up and update the database of traders	75	38688	12.5	41%	€ 604,499	€ 356,654	€ 604,499	€ 356,654	€ 0	€ 0	0%
10	Securing export certificates. Providing inspection bodies with all the information those bodies judge necessary for organising and carrying out marketing standards conformity checks on fruit and vegetables intended for export to third countries	180	3475	12.5	30%	€ 130,319	€ 91,223	€ 0	€ 0	-€ 130,319	-€ 91,223	-100%
11	Marking clearly the packaging of products intended for processing with the words "intended for processing"	125	4645	12.5	37%	€ 120,974	€ 76,213	€ 0	€ 0	-€ 120,974	-€ 76,213	-100%
12	Providing information as part of the training of inspection staff - where traders are authorised by Member States to label fruit and vegetables (with an EC stamp) as having a guaranteed uniform and high conformity rate at the stage of dispatch	20	15071	12.5	20%	€ 62,796	€ 50,236	€ 62,796	€ 50,236	€ 0	€ 0	0%
13	Applying for approval to use a specific label on each package of fruit and vegetable. Specific criteria which need to met: - must have trained inspection staff - must have suitable equipment for preparing /packing - must be committed to a checking procedure and keep a record of the checking.	80	3865	12.5	34%	€ 64,421	€ 42,518	€ 64,421	€ 42,518	€ 0	€ 0	0%
14	Completing a processing certificate for products that are intended to be exported to third countries (non EU) and also for products that are imported into the community which are intended for processing, in order to ensure conformity to marketing standards of products held by traders at all stages of marketing	270	426	12.5	0	€ 23,936	€ 23,936	€ 0	€ 0	-€ 23,936	-€ 23,936	-100%
15	Providing export certificates. Providing or holding a certificate of conformity with marketing standards, to allow an export declaration for products to be accepted by custom authorities. A single certificate can certify a consignment of several lots.	30	3475	12.5	5%	€ 21,720	€ 20,634	€ 0	€ 0	-€ 21,720	-€ 20,634	-100%
16	Obtaining authorisation at the stage of dispatch to use the specimen label in the labelling of each package (guranteeing uniform and high conformity rate of the fruit and vegetables subject to marketing standards)	105	3865	12.5	90%	€ 84,552	€ 8,455	€ 84,552	€ 8,455	€ 0	€ 0	0%
17	Keeping records of all checks carried out in order to use the specimen label in the regulation, to ensure conformity to marketing standards of products held by traders at all stages of marketing	45	355	12.5	33%	€ 3,324	€ 2,227	€ 3,324	€ 2,227	€ 0	€ 0	0%
18	Having a conformity check of the goods you dispatch where you use the labelling specimen	45	355	12.5	39%	€ 3,324	€ 2,028	€ 3,324	€ 2,028	€ 0	€ 0	0%
Total						**€ 3,521,824,923**	**€ 2,198,287,980**	**€ 2,038,903,369**	**€ 1,224,572,012**	**-€ 1,482,921,554**	**-€ 973,715,968**	**-44.29%**

Table 6 summarizes the results for this couple of baseline/amending acts. Please take into account that this is a partial quantification, focused on the main changes due to reg. 1221/208.

Table 6 – Summary table for Regulation 1580/2007 and Regulation 1221/2008

SUMMARY			
Priority Area	*Agriculture*		
Existing EU legislation	**Reg. 1580/2007**	Amending Act	**Reg.1221/2008**
	QUANTIFICATION*		
	Reg. 1580/2007	**Reg.1221/2008**	
Administrative Costs	€ 3,521,824,923	*€ 2,038,903,369*	
Administrative Burdens	**€ 2,198,287,890**	***€ 1,224,572,012***	
AC Difference	**-€ 1,482,921,554**	**-42.1%**	
AB Difference	**-€ 973,715,878**	**-44.3%**	

* Partial quantification

3.1.2 Single CMO Regulation – Health Check

The reforms of the Common Agricultural Policy (CAP) agreed in 2003 and 2004 included provisions for reports to gauge their effectiveness, and in particular to appraise their impact with respect to their objectives and to analyse their effects on the relevant markets. In this context, the Commission presented a Communication to the European Parliament and Council entitled 'Preparing for the "Health Check" of the CAP reform' on 20 November 2007. That Communication and the subsequent discussions of its main elements by the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, as well as numerous contributions arising from public consultation should be taken into account. The provisions of the CAP concerning public intervention should be simplified and aligned by extending tendering in order to achieve a harmonised approach insofar as possible. In particular, the respect of maximum quantities and quantitative limits for cereals, butter and skimmed milk powder may require rapid action. In order to provide for this, and since closing buying-in at a fixed price, adopting allocation coefficients and, for common wheat, switching to the tendering procedure, do not involve the exercise of discretion, the Commission should be permitted to do so without the assistance of the Committee.

Regulation 72/2009, in particular, significantly modified the provisions for public intervention to support the competitiveness of certain agricultural products, such as common and durum wheat, barley, maize, sorghum and paddy rice, beef and veal, starch etc. Most of the provisions in Reg. 72/2009 are not relevant for our calculation of administrative burdens, as they do not include the modification, addition or repeal of any information obligation. However, the discontinuation of certain aid schemes may

eliminate also the voluntary IO of applying for the Community aid. This is the case for the following products:

1. The abolition of the aid scheme for dried fodder, at Article 86 of Reg. 1234/2007 (the implementing rules of which were found in Commission Regulation 382/2005);
2. The abolition of the production refund for starch as provided for at Article 96 of Reg 1234/2007 and implemented by Commission Regulation 491/2008;
3. The abolition of the aid for the purchase of cream, butter and concentrated butter at reduced prices (article 101); the implementing rules of that aid scheme are laid down in Commission Regulation 1898/2005;
4. Changes introduced in the rules on use of casein and caseinate in the manufacture of cheese. Following the amendment of Article 119 of Regulation (EC) No 1234/2007 by Regulation (EC) No 72/2009, prior authorisation for using casein and caseinates in cheese manufacture is no longer required unless aid is paid under Article 100 of Regulation (EC) No 1234/2007 and the Commission decides to make the use of casein and caseinates in the manufacture of cheese subject to that authorisation[23].

3.1.2.1 Aid scheme for dried fodder

We already estimated the impact of the dried fodder scheme in a previous report. This proposal was related to Commission Regulation (EC) No 382/2005, and consisted in an amendment of Article 27 of the above regulation to allow only an ancillary control of farmers and the downstream sector instead of a full, systematic control of farmers, processors and the downstream sector as is currently the case. This aims at easing the control obligations concerning farmers that grow the material to be processed into dried fodder and the downstream sector handling dried fodder.

In the UK, the references found are mostly related to Commission Regulation (EC) No 785/95 of 6 April 1995 laying down detailed rules for the application of Council Regulation (EC) No 603/95 on the common organization of the market in dried fodder. Related regulations are Commission Regulation (EC) No 1362/95; Commission Regulation (EC) No 620/96; Commission Regulation (EC) No 629/97; Commission Regulation (EC) No 1794/97; Commission Regulation (EC) 676/1999; Commission Regulation (EC) No 1413/2001.

Main IOs related to Regulation 785/95 are:

[23] See also http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:162:0003:0004:EN:PDF.

- Display certain information when the fodder leaves the processing undertaking or other storage facility mentioned in 3(1)(a)
- Inform the competent authority when bringing onto its premises products other than fodder to be dried and/or ground for the manufacture of mixtures within the meaning of article 2(5).
- Enter products in the undertaking's stock accounts when products enter or re-enter the premises of processing undertakings
- Lodge applications for aid within 45 days of the end of the month
- notify the competent authority at least two working days in advance each time dried fodder leaves the undertaking or is mixed, if required
- Make an application for an advanced payment
- Submit to the competent authority copies of contracts referred to in 8(1) and a copy of the delivery declarations referred to in paragraphs 2 and 3 with a list of the parcels concerned not later than 15 September following the beginning of the marketing year in question. These documents may be submitted electronically if the parties mutually agree.
- Provide a file to the competent authority in order to obtain approval for the processing undertaking comprising the documents listed in the corresponding DRs
- Lodge with the competent authority the contracts concluded with producers together with a list of all the agricultural parcels concerned when seeking approval for status as "a purchaser of fodder for drying and for grinding"
- Draw up a delivery undertaking providing certain information
- Keep financial accounts (which shall be available for inspection by the competent authority).
- notify the competent authority within days of any change or changes to the details contained within the files
- notify the competent authority in the first ten working days of each quarter of the average moisture content recorded during the previous quarter in respect of fodder they have dehydrated
- Make documentary evidence available to the competent authority at its request
- Inform the competent authority of certain information when the products consist of fodder dried and/or ground by another processing undertaking
- Draw up a delivery declaration where an undertaking obtains supplies from an approval purchaser
- Keep separate stock accounts for dehydrated fodder, sun dried fodder, protein concentrates and dehydrated products. This applies to processing undertakings only

- Apply to the competent authority for approval of a storage location where the premises of the processing undertaking are unsuitable.

These obligations involve up to 300 firms in the UK, for a total cost of £402,831. In the DEFRA Final Report, the UK dehydrated fodder scheme is said to impose £700,000 in administrative burdens. We then decided to adopt this figure as the most updated one, as Commission Regulation (EC) No 382/2005 repealed Regulation 785/95.

We then converted this figure to Euros (€1,061,900), averaged it to account for the percentage of administrative burdens on GDP at EU level (€2,477,767) and extrapolated it to the EU25 level, reaching a final figure €16,237,501 of ABs. We apply a BAU rate similar to that applied in paragraphs 3.1.2.3 and 3.1.2.4 below, that is 30%. ACs therefore amount to €23,196,430.

3.1.2.2 Production refund for starch

Table 7 below shows our calculation to estimate the administrative burden generated by the production refund for starch, showing an overall burden in the range between €156,224 and €378,880. We adopt, for the purposes of our report, the intermediate value of €267,552. We apply a BAU rate similar to that applied in paragraphs 3.1.2.3 and 3.1.2.4 below, that is 30%. ACs therefore amount to €382,217.

Table 7 – Estimates on administrative burdens created by Reg. 1722/93, EU27

	No. of starch producers				Administrative burdens (based on DK data)			Admin burden
Country	2003	2004	2005	Weight	Control part	Written Request	Total	UK data
EU27		**256**		100.00%	**€ 189,440**	**€ 189,440**	**€ 378,880**	**€ 156,224**
EU25		221		86.33%	€ 163,540	€ 163,540	€ 327,080	€ 134,865
Austria	4	4	3	1.56%	€ 2,960	€ 2,960	€ 5,920	€ 2,441
Belgium					€ 0	€ 0	€ 0	€ 0
Bulgaria			3	1.17%	€ 2,220	€ 2,220	€ 4,440	€ 1,831
Cyprus	0	0	0	0.00%	€ 0	€ 0	€ 0	€ 0
Czech Republic					€ 0	€ 0	€ 0	€ 0
Denmark	7	7	8	2.73%	€ 5,180	€ 5,180	€ 10,360	€ 4,272
Estonia	1	2	1	0.78%	€ 1,480	€ 1,480	€ 2,960	€ 1,221
Finland	8	7	6	2.73%	€ 5,180	€ 5,180	€ 10,360	€ 4,272
France	11	9	12	3.52%	€ 6,660	€ 6,660	€ 13,320	€ 5,492
Germany	27	25	24	9.77%	€ 18,500	€ 18,500	€ 37,000	€ 15,256
Greece		11		4.30%	€ 8,140	€ 8,140	€ 16,280	€ 6,713
Hungary	3	3	4	1.17%	€ 2,220	€ 2,220	€ 4,440	€ 1,831
Ireland					€ 0	€ 0	€ 0	€ 0
Italy	34	32	32	12.50%	€ 23,680	€ 23,680	€ 47,360	€ 19,528
Latvia	1	1	1	0.39%	€ 740	€ 740	€ 1,480	€ 610
Lithuania					€ 0	€ 0	€ 0	€ 0
Luxembourg	0	0	0	0.00%	€ 0	€ 0	€ 0	€ 0
Malta					€ 0	€ 0	€ 0	€ 0
Netherlands	15	10	10	3.91%	€ 7,400	€ 7,400	€ 14,800	€ 6,103
Poland	14	15	17	5.86%	€ 11,100	€ 11,100	€ 22,200	€ 9,154
Portugal			4	1.56%	€ 2,960	€ 2,960	€ 5,920	€ 2,441
Romania	28	30	26	11.72%	€ 22,200	€ 22,200	€ 44,400	€ 18,308
Slovakia	7	10	10	3.91%	€ 7,400	€ 7,400	€ 14,800	€ 6,103
Slovenia	2	2	2	0.78%	€ 1,480	€ 1,480	€ 2,960	€ 1,221
Spain	23	22	21	8.59%	€ 16,280	€ 16,280	€ 32,560	€ 13,426
Sweden	13	12	12	4.69%	€ 8,880	€ 8,880	€ 17,760	€ 7,323
United Kingdom			4	1.56%	€ 2,960	€ 2,960	€ 5,920	€ 2,441

Source: Wifo-CEPS Third progress report.

3.1.2.3 Aid for the purchase of cream, butter and concentrated butter

Information on administrative burdens generated by the aid scheme for the purchase of cream, butter and concentrated butter can be found in the UK database on administrative burdens. Table 8 below shows our estimate for the UK based on data retrieved from the database.

Table 8 – Admin burdens generated by the aid to cream, butter and concentrated butter in the UK (pounds and Euros)

	UK Pounds			Euros		
Type of IO	Admin Cost	BAU factor	Admin burden	Admin Cost	BAU factor	Admin burden
Applications for authorisation	£552,600	34%	£412,388	€ 780,050	34%	€ 582,127
Returns and reports	£9,206	41%	£6,529	€ 12,995	41%	€ 9,216
Keeping records	£7,323	32%	£5,548	€ 10,338	32%	€ 7,832
Keeping records	£5,572	40%	£3,980	€ 7,865	40%	€ 5,618
Applications for authorisation	£2,694	0%	£2,694	€ 3,803	0%	€ 3,803
Returns and reports	£3,495	41%	£2,479	€ 4,934	41%	€ 3,499
Applications for subsidies or grants for…	£1,766	15%	£1,536	€ 2,493	15%	€ 2,168
Keeping records	£1,885	32%	£1,428	€ 2,661	32%	€ 2,016
Returns and reports	£1,967	41%	£1,395	€ 2,777	41%	€ 1,969
Returns and reports	£1,376	41%	£976	€ 1,943	41%	€ 1,378
Keeping records	£870	32%	£659	€ 1,228	32%	€ 930
Applications for subsidies or grants for…	£282	15%	£245	€ 398	15%	€ 346
Notification of activities	£224	18%	£190	€ 316	18%	€ 268
Statutory labelling for the third parties	£90	37%	£66	€ 128	37%	€ 93
Applications for authorisation	£38	34%	£28	€ 53	34%	€ 40
Applications for authorisation	£14	0%	£14	€ 20	0%	€ 20
Applications for authorisation	£0	34%	£0	€ 0	34%	€ 0
Statutory labelling for the third parties	£0	37%	£0	€ 0	37%	€ 0
Statutory labelling for the third parties	£0	37%	£0	€ 0	37%	€ 0
Total	**£589,403**		**£440,155**	**€ 832,001**		**€ 621,323**

Source: AB Calculator, UK Note: exchange rate applied is the 2005-2009 average, 1.4116

This figure can be extrapolated to the EU27 based on weights such as the production of butter in the Member States (EUROSTAT data). Based on these figures, the UK holds a share of 5.50% in the production of butter in the EU27. As such, extrapolating the figure at EU level would yield an administrative cost of €15.1 million and a corresponding burden of €11.3 million. This, at the same time, is also the saving that would be obtained by removing this aid scheme.

3.1.2.4 Changes introduced in the rules on use of casein and caseinate in the manufacture of cheese

The same methodology as in the previous section can help us quantify the ABs associated with the rules on casein and caseinates in the manufacture of cheese.

According to the UK database on administrative burdens, the rules at hand generate a total burden in the UK of £6,500. An extrapolation to the EU27 leads to a finding of a total administrative cost of €308,619, and an administrative burden of €239,567.

Table 9 – Admin burdens generated by the rules on the use of casein and caseinates in the manufacture of cheese

	UK Pounds			Euros		
Type of IO	**Admin Cost**	**BAU factor**	**Admin burden**	**Admin Cost**	**BAU factor**	**Admin burden**
cooperating with inspections and checks during the year. (Note; if a cheese producer produces 300 tons of cheese a year, it will receive checks twice a year.)	£8,271	29%	£6,412	€ 11,676	29%	€ 9,051
making an application for a period of 12 months on the provision of the use of casein and caseinate which states in writing the commitment to accept and comply with the provision of the regulations, including keeping with stock accounts information as to the origin, composition and quantity of the raw materials used in the manufacture of the cheeses and complying with checks	£102	16%	£88	€ 144	16%	€ 124
Total	**£8,374**		**£6,500**	**€ 11,820**		**€ 9,175**
EU27 (UK weight: 3.83%)				**€ 308,619**		**€ 239,567**

3.1.2.5 Conclusion

We could measure the impact of the elimination of schemes related to dried fodder, starch, cream, butter and concentrated butter and the use of casein and caseinates in the manufacture of cheese. As these schemes are being eliminated (with the exception of rules on casein and caseinates, the scope of which is anyway drastically narrowed), we estimate the initial value of the ABs at approximately €28 million. The reduction achieved is equal to 100% in this case. Results are summarized in Table 10.

Table 10 – Summary table for Regulation 1580/2007 and Regulation 72/2009

SUMMARY			
Priority Area	*Agriculture*		
Existing EU legislation	**Reg. 1580/2007**	Amending Act	**Reg. 72/2009**
	QUANTIFICATION*		
	Reg. 1580/2007		**Reg. 72/2009**
Administrative Costs	€ 38,987,266		-
Administrative Burdens	**€ 28,044,620**		**-**
AC Difference	**-€ 38,987,266**		**-100.0%**
AB Difference	**-€ 28,044,620**		**-100.0%**

* Partial quantification

3.1.3 Council Regulation on the European Agricultural Fund for Rural Development (EAFRD)

Regulation (EC) No 1698/2005 sets the legal framework for support of rural development, creating the European Agricultural Fund for Rural Development (EAFRD) and defining the targets to be achieved through this tool and the criteria to be

met to have access to its resources. The act has been amended by Council Regulation on support for rural development by the European Agricultural Fund for Rural Development

(EAFRD) (EC) No. 74/2009. Upon agreement with DG ENTR and DG AGRI, for this act we have to focus only on main amendments to IOs and to other provisions having a direct effect on ABs.

The main goals of reg. 74/2009 are:

1. harmonization of the existing first Pillar provisions and the second Pillar;

2. introduction of new priorities to be financed through EAFRD, namely: (i) climate change; (ii) renewable energies; (iii) water management; (iv) biodiversity; and (v) restructuring of the dairy sector;

3. amendment of the procedures in case of non-compliance of the beneficiary of the fund with the mandatory requirements listed in the regulation.

The latter point is going to reduce administrative work for firms. Namely, art. 1.(11) introduces a de minimis threshold for reduction or exclusion of payments. When reductions or exclusions would result in an amount lower than €100 per calendar year per beneficiary, Member States may refrain from executing it. Furthermore art. 1.(13) gives Member States the opportunity not to apply any reduction in case of minor non–compliance. Limits for the definition of a minor non-compliance are stated therein.

Generally speaking, since fewer procedures for exclusion or reduction of payments are undertaken by the Fund Managing Authorities, these simplifying provisions reduce burdens on firms using the EAFRD and address irritation caused by the lack of flexibility in the old system in case of non-compliance. In practice, in case of a minor irregularity, farmers can now remedy to them “on the spot”, without any follow-.up inspection or visit on behalf of the managing authorities. However, the SCM methodology assumes full compliance with the measured law and excludes costs due to litigation. In a nutshell, we measure burdens imposed on firms fully compliant with the regulation and not subject to extra burdens because of any voluntary or involuntary error. Therefore, through the methodology adopted in this report we cannot quantify the impact of these provisions on ABs.

3.2 Priority Area: Food Safety

Within this area, CEPS has to quantify ACs/ABs due to the following groups of baseline acts and the reduction brought about by the respective amending acts/amending proposals, if any:

1. Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption. The act is going to be amended by proposal COM(2008)345 of 10 June 2008 for a regulation of the European Parliament and of the Council laying down health rules as regards animal by-products not intended for human consumption;

2. Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials (including the amendment due to Commission Directive 98/67/EC) and Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[24]. The acts are going to be amended by proposal COM(2008)124 for a Regulation of the European Parliament and of the Council on the placing on the market and use of feed;

3. Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption and Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs. The acts have been amended by regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives and (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

4. Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market and Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market.

[24] The latter directive has been added to the list of acts to be measured after consultation with DG SANCO experts and validation by DG ENTR.

3.2.1 Regulation 1774/2002 on animal by-products (ABPs)

Regulation 1774/2002[25] lays down rules concerning animal by-products (ABPs) not intended for human consumption. According to our analysis, it includes six IOs, and imposes ACs for €903mln, of which 135mln (15%) are ABs.

Table 11 Summary table Regulation 1774/2002

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Regulation 1774/2002 laying down health rules concerning animal byproducts not intended for human consumption		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Accompanying documents for ABPs	€ 29,706,897	**€ 29,706,897**
IO 2	Authorization for ABPs to be dispatched to another Member State	€ 7,769,384	**€ 7,769,384**
IO 3	Keeping record of ABP consignment	€ 843,462,692	**€ 84,346,269**
IO 4	Approval of plants for ABP purposes	€ 22,027,460	**€ 13,216,476**
IO 5	Keeping record of plants' own checks*	€ 4,360	**€ 2,965**
IO 6	Notification of non-compliant own-checks	€ 23,152	**€ 23,152**
* Partial quantification	**TOTAL**	€ 902,993,945	**€ 135,065,143**

ABPs are defined in art. 2 of the regulation as entire animal bodies, or parts of animals, or products of animal origin not intended for human consumption, including ova, embryos and semen. An ABP can belong to one of three different categories, according to the level of risk (category 1 being the most dangerous and 3 the least). E.g. by-products of non-farmed animals or of animals suspected of being infected by TSE[26] fall within category 1. According to DG SANCO services' estimates, 10% of ABPs fall within category 1, 20% within category 2, and 70% within category 3.

As stated in the Impact Assessment to the proposal for a new regulation on ABPs,[27] it is very difficult to estimate ABs imposed by reg. 1774/2002. The main difficulty lays in the identification of the population subject to the various IOs. Unlike most of the other acts analyzed in this report, reg. 1774/2002 does not apply to a specific industry, but to every economic operator using ABPs. The range of possible users is very wide, going from photographic film producers to the petfood industry. The following industries are potentially touched upon by this act: gelatine manufacturers, fat processors, slaughterhouses, oleochemical plants, pharmaceutical companies, veterinary product companies, diagnostic material producers, tanners, and cosmetic producers. Besides, it cannot be assumed that all companies belonging to these sectors use ABPs.

For this reason, we will quantify IOs due to reg. 1774/2002 basing mainly on data retrieved from the UK database, where the Animal By-Products Regulation 2005 is measured. The act makes provisions for the administration and enforcement of reg. 1774/2002 in England. Since figures on the population could not be retrieved, the extrapolation of total ABs will be carried out on the basis of the following parameters:

[25] As amended by Commission Regulations 808/2003, 668/2004. 92/2005, and 93/2005.

[26] Transmissible Spongiform Encephalopathy

[27] SEC(2008)1994

1. salary rate, where appropriate;

2. GDP in PPP;

3. AB-GDP ratio.

Where data from the UK database are not available, quantification will be carried out in analogy with Council Regulation 1/2005 on the protection of animals during transport and related operations. Differently from other quantifications, we could not find a properly comparable analogical act in the EU database. We would like to stress that similarities between these two acts are quite loose; therefore several assumptions will be necessary to allow for a comparison of costs.

3.2.1.1 IO 1: Accompanying documents for ABPs

Art. 7 of reg. 1774/2002 requires ABPs to be collected, transported and identified in accordance with Annex II to the directive. Par. 2 of the present article imposes an IO, stating that during transportation, a commercial document or, if required, a health certificate, shall accompany ABPs and processed products. Documents shall be drawn in accordance with Annex II and shall be kept for the period therein specified.

Category 1 and 2 materials need to be accompanied with specific documents, whilst for category 3 materials commercial documents drawn for other purposes are sufficient. According to DG SANCO estimates, category 1 material represent 10% of total ABPs, whilst category 2 material represents 20%.

This IO is not measured in the UK database. Therefore, data for the quantification are retrieved from the EU database, namely from the measurement of Council Regulation 1/2005 on transport of live animals. There is no identical IO, but an analogy can be drawn with IO “drawing up and keeping available transport and planning information”, concerning accompanying documents for the transportation of live animals.

Two assumptions are made:

1. documentation for ABPs. According to a qualitative assessment provided by DG SANCO, we assume that documents for ABPs are less burdensome than for live animals. Therefore, we consider that the cost per occurrence is 75% of the cost of the IO “drawing up and keeping available transport and planning information”.

2. the relative number of occurrence, i.e. number of journeys. Contacting veterinary experts, we have been told that, on average, 40% of the weight of a live animal becomes ABP at slaughterhouses, and 15% more during further processing or distributing phases. Therefore, we assume that for every kilo of a live animal, 500g become animal products and 500g ABPs. However, it is not correct to

assume a 1:2 ratio between an IO concerning transport of ABP and an IO concerning transport of live animals, since transporting live animals requires much more volume, therefore many more journeys and much more related documentation. We assume that a plausible ratio for volume is 1:5, that is one kg of live animal needs the same load volume of 5 kg of ABPs. Applying both ratios, the number of occurrence for ABPs is estimated to be one tenth of that for live animals (1:2 X 1:5 = 1:10). DG SANCO experts did not discard this assumption, even though it is quite approximate.

On the basis of these assumptions ACs arising from IO "Accompanying documents for ABPs" would amount to 7.5% (75% X 10%) of those caused by the IO "Drawing up and keeping available transport and planning information". We have also to take into consideration that only for 30% of ABPs specific documents must be drawn, therefore ACs eventually amount to 2.5% of those arising from IO "Drawing up and keeping available transport and planning information". The BAU level used by Consortium is of 0% and we consider it appropriate. Hence, ACs/ABs arising from the present IO amount to €29,706,897.

3.2.1.2 IO 2: Authorization for ABPs to be dispatched to another Member State

Art. 8 of reg. 1774/2002 deals with dispatches of ABPs to another Member State. Dispatch of materials belonging to categories 1 or 2 must be authorized in advance by the receiving Member State and ABPs must be accompanied by the documents prescribed by the present regulation. These requirements fall on the economic operator dispatching ABPs. Furthermore, plants receiving ABPs from abroad shall keep full records to demonstrate compliance with this regulation.

The cost of producing documents has already been measured in IO 1, since no difference is made between dispatches within or between Member States. The same is true for the cost of keeping records, which is measured below in IO 3. Consequently, this IO measures only the cost of requesting an authorization for dispatching ABPs to another Member State.

The IO is not measured in the UK database. Data for the quantification are retrieved from the EU database, namely from the measurement of Council Regulation 1/2005 on animal transports. An analogy can be drawn with IO "Submission of a journey log" in case of live animal transports. The analogy is quite loose, based only on the similar duties to submit in advance a request for transport authorization to the competent veterinary authority. Again, we would like to warn about the level of approximation of this analogy. The ratio between the costs per occurrence is to be considered higher than for IO 1, since authorizations have to be requested to other Member States, making the

process more time-consuming and usually requiring translations. We conservatively assume that the cost per occurrence in case of dispatches of ABPs is 1.5 times higher compared to the submission of a journey log for live animals. As for the number of occurrence, it is to be considered that only material falling into categories 1 and 2 have to be authorized. According to DG SANCO experts' estimates, they represent 30% of total ABPs. Therefore, the ratio between dispatches of ABPs and of live animals should be of 3:100, instead of 1:10 Hence, ACs of the present IO amount to 4.5% of ACs arising from IO "Submission of a journey log" (3% X 1.5), that is €7,769,384. The BAU level used by Consortium is 0% and we consider it appropriate.

3.2.1.3 IO 3: Keeping record of ABP consignments

Art. 9 of reg. 1774/2002 provides that any person consigning, transporting or receiving ABPs shall keep a record of consignments. An exception is granted for manure transported between two points located in the same Member State.

ABs due to this IO are extrapolated on the basis of the corresponding IO in the UK legislation, "Keeping a record of consigning, transporting or receiving animal by-products in accordance with annex II of Commission Regulation 1774/2002", imposing ACs amounting to €88,360,401, of which €8,836,040 (10%) are considered ABs.

The cost per occurrence amounts to €1,234.64. From this amount, we have to subtract costs related to submission of records and settlements, not required by the EU legislation. They represent 19.1% of the costs, therefore we discount total costs for this value.

On the basis of the extrapolation, we can assume that throughout the EU this IO would impose ACs amounting to €1,042,599,125, of which €104,259,912 (10%) are considered ABs. There is no explicit explanation for such a high BAU ratio, but it is reasonable to assume that the undertakings would keep a register of consignments for their own commercial reasons. Applying the correction to the cost per occurrence, ACs amount to €843,462,692, of which €84,346,269 (10%) are considered ABs. The extrapolation is based on following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a clerk.

3.2.1.4 IO 4: Approval of plants for ABP purposes

Plants dealing with ABPs are subject to prior approval by the competent authority. Art. 10-18 of reg. 1774/2002 specifies the categories of plants concerned: (i) category 1, 2 and 3 intermediate plants; (ii) ABP storage plants; (iii) incineration and co-incineration

plants; (iv) category 1 and 2 processing plants; (v) category 2 and 3 oleochemical plants; (v) biogas and composting plants; (vii) category 3 processing plants; and (viii) petfood and technical plants.

As stated above, data about total population cannot be retrieved. Therefore, ACs/ABs are extrapolated from the results of the UK measurement exercise. The UK database contains an IO explicitly measuring the cost of authorizing these categories of plants. ACs amount to €5,653, of which €3,731 (66%) are considered ABs. The very low amount of ACs is due to the relatively low number of new plants authorized per year. We consider appropriate to fix the BAU threshold at 0%.

Furthermore, one data required by the authorization scheme is measured separately in the UK database: keeping a record in relation to laboratory tests carried out, as required e.g. by items (iii) and (iv) of lett. a of art. 18.2. As measured in the UK database, ACs due to this IO amount to €1,936,989, of which €1,162,193 (60%) are considered ABs.

On the basis of the extrapolation, we estimate that throughout the EU this IO imposes ACs amounting to €22,091,744, of which €13,280,760 (60.1%) are considered ABs. The extrapolation is based on the following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a professional worker.

3.2.1.5 IO 5: Keeping records of plants' own-checks

Ex art. 25.1, operators and owners of intermediate and processing plants shall take representative samples to check compliance with the standards established by reg. 1774/2002 and record the results of own checks and tests.

The UK database contains an IO measuring the costs related to keeping a record of all actions taken as a result of own checks on the plant, imposing ACs amounting to €370, of which €251 (68%) are considered ABs. These are only part of the information to be recorded, which should include also results of the tests. However, the remaining burdens of the EU IO are not measured and we have not been able to retrieve other data about it. Hence, the following quantification is only partial. However, the impact of this IO is likely to be limited compared to total ACs; therefore final quantification results should not be affected.

Partial quantification shows that the present IO imposes ACs amounting to €4,360, of which €2,965 (68%) are considered as ABs. The extrapolation is based on the following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a clerk.

3.2.1.6 IO 6: Notification of non-compliant own-checks

Par. 2 of art. 25 requires operators of intermediate and processing plants to immediately notify the competent authority in case the results of a test do not comply with the provision of this regulation.

The UK database contains an IO measuring exactly the same requirement: "notifying the Secretary of State in the event of any test results from the tests required in the regulation showing that the material does not comply with the limits set out". It imposes ACs for €1,962, all of which are considered ABs. The number of occurrence is six, explaining the low burdensomeness.

On the basis of the extrapolation, we estimate that throughout the EU this IO imposes ACs amounting to €23,152, all of which are considered ABs. The extrapolation is based on the following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a clerk.

3.2.1.7 COM(2008)345: proposal for a new regulation on ABPs.

COM(2008)345 is a proposal for a regulation updating the legislative framework on ABPs. It mainly aims at better defining the regulatory framework and reducing ABs. They are lessened through changes both to the regulatory approach and to single IOs.

The following general changes are going to have an impact on ACs/ABs due to reg. 1774/2002:

1. Better definition of ABPs. For certain material, under reg. 1774/2002 it is not clear when ABPs become "safe" processed products and fall outside of the scope of the regulation. Under the new proposal, this definition is left to implementing measures, ex art. 10.2. The actual reduction of ABs will depend on the content of the implementing act and it cannot be estimated at present. If only marginal products will be exempted from the scope of the regulation, reduction will be negligible. If implementing provisions benefit large sectors of the ABPs value chain, its impact can be relevant. The reduction due to this change will concern all IOs, reducing the number of occurrence subject to them;

2. New product categorization. The Impact Assessment calls for a more accurate categorization of products, adjusting the level of attention to the actual level of risk. However, the only change that we have found consulting the IA text and comparing art. 4, 5, and 6 of reg. 1774/2002 to art. 11, 12, and 13 of COM(2008)345 concerns blood from ruminants not tested for BSE. Therefore, the change is too marginal to have a relevant impact on ACs/ABs. A further

reduction may come from implementing measures dealing with product categorization, to be adopted ex art. 14 of COM(2008)345.

3. Exclusion of some industries from the scope of ABPs legislation. Art. 2.3 defines the negative scope of the regulation, introducing new exemptions for several industries, such as: (i) cosmetic industry; (ii) pharmaceutical industry (veterinary medicinal products included); and (iii) producers of medical devices, active implantable medical devices, or in vitro diagnostic medical devices. Processing of derived products from these industries is excluded from the application of provisions of COM(2008)345 concerning obligations for operators and operation of plants, disposal and use of ABPs, and official controls. However, they would still be subject to the sector-specific Community acts listed in art. 2.3. The impact of this exclusion is likely to be very relevant. Unfortunately, it is not possible to know the number of operators / establishments which will be exempted from the application of COM(2008)345. However, it is fair to conservatively assume that art. 2.3 will reduce subject population, and consequently ACs/ABs, by 10%.

COM(2008)345 also has a relevant impact on the IO "Approval of plants for ABP purposes". Art. 7 states that prior approval of plants shall not be required for establishments already authorized in accordance with other EU legislation. The goal of this provision is to eliminate AB duplication, due to double authorization. Art. 7 concerns: (i) plants for processing of food or feed of animal origin; (ii) incineration and co-incineration plants; (iii) biogas and composting plants; and (iv) plants for manufacturing certain derived products. Under the new ABP regulation, these plants shall be subject only to prior registration. The extent of the reduction depends on the detail of the implementing measures: if the amount of information to be provided for registration is very close to that necessary for claiming an authorization, ABs reduction will be very limited. Differently, this provision could eliminate most ABs on plants falling under art. 7 of COM(2008)345.[28] In our opinion, registering a plant is likely to be much less burdensome than applying for a prior approval. Therefore the impact of this "simplification by eliminating duplication" is going to be relevant. Again, we do not possess figures about the number of plants likely to be exempted from prior approval. However, given that derogation is provided for a lot of categories of plants, we conservatively estimate that art. 7 of COM(2008)345 will cut ACs/ABs due to IO "Approval of plants for ABP purposes" by one third. Quantification for this IO is summarized in Table 12. Estimates also include the variation of ACs/ABs due to the general provisions analyzed above.

[28] Cf. Impact Assessment of a EC proposal in respect of animal-by-products not intended for human consumption carried out by the Department for Food, Environment and Rural Affairs of the UK government.

Table 12 COM(345)2008 – Changed IO: Approval of plants for ABP purposes

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	**Reg. 1774/2002**	Amending Acts	**COM(2008)345**
EU Info obligation	Approval of plants for ABP purposes (art. 10-18)		
Obligation Type	6. Application for general authorization or exemption		
	QUANTIFICATION		
	Reg. 1774/2002	**COM(2008)345**	
Frequency (per year)	on occasion	on occasion	
Population	n.a.	*reduced by art. 7*	
Administrative Costs	€ 22,027,460	*€ 12,555,652*	
Administrative Burdens	**€ 13,216,476**	***€ 7,533,391***	
AC Difference	**-€ 9,471,808**	**-43.0%**	
AB Difference	**-€ 5,683,085**	**-43.0%**	

ACs/ABs due to the IO "Authorization for ABPs to be dispatched to another Member State" are going to be reduced by COM(2008)345. Par. 2 of art. 33 requires requests for authorization to be submitted to the competent authority of the place of destination via TRACES system. TRACES system is an integrated veterinary computer system used for exchanging documents and information. According to DG SANCO experts' evaluation, the use of TRACES will simplify submission of documents and exempt operators from the obligation to translate documents and requests. We estimate that the use of this database will relieve 50% of burdens caused by the present IO. Quantification for this IO is summarized in Table 13. Estimates also include the variation of ACs/ABs due to the general provisions analyzed above.

Table 13 COM(345)2008 – Changed IO: Authorization for ABPs to be dispatched to another Member State

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	**Reg. 1774/2002**	Amending Acts	**COM(2008)345**
EU Info obligation	Authorization for ABPs to be dispatched to another Member State (art.		
Obligation Type	5. Application for individual authorization or exemption		
	QUANTIFICATION		
	Reg. 1774/2002	**COM(2008)345**	
Frequency (per year)	on occasion	on occasion	
Population	n.a.	unchanged	
Administrative Costs	€ 7,769,384	*€ 3,107,754*	
Administrative Burdens	**€ 7,769,384**	***€ 3,107,754***	
AC Difference	**-€ 4,661,630**	**-60.0%**	
AB Difference	**-€ 4,661,630**	**-60.0%**	

Quantification of the reduction due to COM(2008)345 is summarized below in Table 14.

Table 14 Summary table for Regulation 1774/2002 and COM(2008)345

SUMMARY			
Priority Area	*Food safety*		
Existing EU legislation	**Reg. 1774/2002**	Amending Act	**COM(2008)345**
	QUANTIFICATION		
	Reg. 1774/2002	**COM(2008)345**	
Administrative Costs	€ 902,993,945	*€ 801,540,795*	
Administrative Burdens	**€ 135,065,143**	***€ 113,312,498***	
AC Difference	**-€ 101,453,149**	**-11.2%**	
AB Difference	**-€ 21,752,645**	**-16.1%**	

3.2.2 Feed marketing

3.2.2.1 The authorizations of bio-proteins: directive 82/471/EEC

Directive 82/471/EEC[29] concerns certain products used for animal nutrition. A new regulation, currently at the stage of proposal approved by the European Parliament (COM(2008)124), is going to repeal and replace it. According to our analysis, dir. 82/471 includes two IOs, and imposes ACs amounting to €1.5mln, of which €1.2mln (75%) are considered ABs. The quantification related to this baseline act is summarized in Table 15.

Table 15 Summary table for Directive 82/471

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Council Directive 82/471/EEC concerning certain products used in animal nutrition		
INFORMATION OBLIGATION		**AC**	**AB**
IO 1	Authorization for bio-proteins	€ 1,563,250	**€ 1,172,438**
IO 2	Labelling of bio-proteins	*SEE PARAGRAPH BELOW*	
	TOTAL	€ 1,563,250	**€ 1,172,438**

Art. 3 of dir. 82/471 provides that products acting as direct or indirect protein sources and marketed as feeding stuff (so-called bio-proteins) may be marketed only if authorized by the Commission, and consequently included in the Annex to the directive. Furthermore, all conditions laid down therein are to be fulfilled. A bio-

[29] As amended by Commission Directives 84/443/EEC, 85/509/EEC, 86/530/EEC. 88/485/EEC, 89/520/EEC, 90/439/EEC, 93/26/EEC, 93/56/EEC, 95/33/EC, 2003/104/EC, 2004/116/EC; by Council Regulation (EEC) No. 3768/85; by Council Directives 90/654/EEC, 93/74/EEC, 95/69/EC, 96/25/EC, 1999/20/EC; by Directive 2001/16/EC of the European Parliament and of the Council; by Regulations of the European Parliament and of the Council (EC) No. 1829/2003, 1831/2003, and 1882/2003; and by the Act of Accession of Austria, Sweden and Finland.

protein can be authorized and lawfully marketed if it does not cause any detrimental effect on human or animal health, or on the environment. Art. 6 provides that the list of authorized bio-proteins can be updated according to the Comitology procedure referred to in art. 13.

The joint provisions of art. 3 and 6 create an IO: "Marketing authorization of new bio-proteins". To calculate the impact of the IO on firms, we have retrieved data from the Impact Assessments of COM(2008)124.[30] The cost per authorization has been estimated at €481,000. The population figure so far has been very low: from 1990 to date (i.e. over 20 years), only four bio-proteins have been authorized. Therefore, the number of occurrence, i.e. the number of authorizations granted per year, would amount to 0.2. However, this figure seems completely unrealistic given the importance of the market for bio-proteins. According to information given to DG SANCO by the industry, we have been told that the ABs were so high that market entry of new bio-proteins was completely discouraged. According to the number of products currently "in the pipelinea", i.e. waiting for the new legal framework to request the authorization for marketing, it would be more correct to consider a "potential" population of 30-35 requests over the last decade. Therefore, we assume that, on average, 3.25 requests would have been submitted per year.[31] BAU level is fixed at 25%, since part of the safety-related data would be collected by firms also if an authorization were not requested, to comply with the general legal principle of product liability.

Given the burdensomeness of the IO and the fact that it is disproportionate compared to the health and safety concerns it is supposed to prevent, COM(2008)124 deletes it. Results of the quantification related to this IO are detailed in Table 16.

Table 16 Dir. 82/471 – Deleted IO: Marketing authorization of new bio-proteins

DELETED IOs			
Priority Area	*Food safety*		
Baseline Act	**Dir 82/471**	Amending Acts	**COM(2008)124**
EU Info obligation	Authorization for bio-proteins (Art. 3, 6)		
Obligation Type	5. Application for individual authorisation or exemption		
	QUANTIFICATION		
	Dir 82/471	**COM(2008)124**	
Frequency (per year)	on occasion	*never*	
Population	3.25 (30-35 over 10 years)	-	
Administrative Costs	€ 1,563,250	*€ 0*	
Administrative Burdens	**€ 1,172,438**	***€ 0***	
AC Difference	**-€ 1,563,250**	**-100%**	
AB Difference	**-€ 1,172,438**	**-100%**	

[30] SEC(2008)275

[31] This the only exception we make to the principle of "ceteris paribus" and of not considering the market uptake due to the elimination of ABs, since otherwise measuring the burdens on such a small population would not make any sense.

3.2.2.2 Feed labelling provisions: Directive 96/25/EC, Directive 82/471/EEC, et al.

Regulation 96/25/EC[32] contains the general provisions on feed labelling. The act has a horizontal nature, whilst several other acts provide specific obligations for specific categories of feedstuff products. Regulation 96/25/EC is going to be repealed, alongside with several other acts, by COM(2008)124, which will be the new horizontal regulation on feed labelling. According to our analysis, it includes 1 IO, imposing ACs amounting to €25mln, of which €6.3mln (25%) are considered ABs. Quantification is summarized in Table 17.

Table 17 Summary table for Directive 96/25

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Council Directive 96/25 on the circulation of feed materials		
INFORMATION OBLIGATION		**AC**	**AB**
IO 1	Labelling of feedstuff	€ 25,100,557	**€ 6,275,139**
	TOTAL	€ 25,100,557	**€ 6,275,139**

According to the approach used by the Consortium concerning food labelling legislation, we have decided to measure a single IO called “Labelling of feedstuff”, including all the obligations laid down by the horizontal legislation.

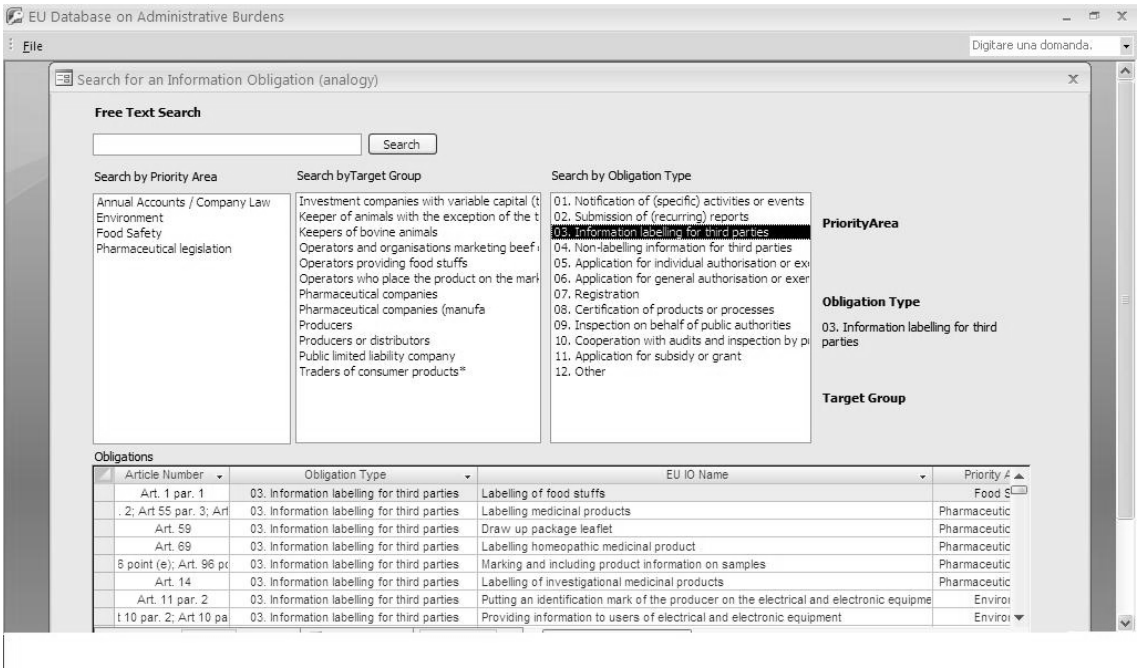
Art. 5 of dir. 96/25 provides that feed materials may be put into circulation only if labelled according to this directive, and lists the mandatory elements to be included. Further details concerning the labelling requirements and the exact wordings for different typology of feeding stuff are given in the annexes to the directive. Small quantities intended for the final users may be relieved from labelling requirements if an appropriate notice is displayed at the point of sale, ex art. 5 par. 3. Furthermore, art. 8 provides for specific labelling requirements for feed materials containing a level of undesiderable substances exceeding the legal threshold provided by directive 74/63/EEC.

Horizontal provisions on feed labelling are complemented by several vertical provisions which are scattered among many European legislative acts. One of them, analysed supra, is dir. 82/471 concerning bio-proteins. Ex art. 5, the feeding products listed in the annex to the directive, i.e. bio-proteins, cannot be marketed unless the required information appears in the package or containers.

[32] As amended by Commission Directives 98/67/EC and 99/61/EC; by Council Directive 99/29/EC; by Directives of the European Parliament and of the Council 2000/16/EC and 2001/46/EC; and by Council Regulation (EC) No 806/2003.

ACs/ABs attributed to the IO "Labelling of feedstuff" are quantified through the AB calculator via analogy. Through the mask "Search for an information obligation (analogy)" of the AB calculator, it has been possible to have a comprehensive list of similar obligations measured by the Consortium. In this case, we have chosen to look for all IOs belonging to the category "Information labelling for third parties", and then refine the research by considering the priority area "Food Safety" (cf. Figure 1).

Figure 1 Selecting the IO for the analogy – Labelling of feedstuff



Once the choice has been restricted to few IOs, the most efficient method to identify the fittest is to consult the Consortium's report, and subsequently the legislative texts themselves. In this case, we have deemed that the best choice was to analyse the IO "Labelling of foodstuff" arising from dir. 2000/13. According to the EU database on AB, this IO imposes ACs of €726,604,631, of which €181,651,158 (25%) are ABs.

DRs required by dir. 2000/13 and dir. 96/25 are similar. On the one hand, food labels must be more detailed and food legislation allows for less exception than feed legislation.[33] However, especially for feedstuff not intended for pets, the AC of labelling feeding stuff is much lower than in the case of foodstuff, because there is a much lower

[33] Cf. e.g. the possibility of providing information on the responsible packer/importer/seller/distributor also on accompanying document (ex art. 5 par. 1) or the exception for small quantities of feed materials intended for the final consumer ex art. 5 par. 3.

number and variety of labels, which last more time. This is due to the fact that marketing strategies, brand characterization, and product variety are much less important in the feed market. On the other hand, feed legislation on labelling contains more specific requirements for compulsory declarations, detailed in the Annex to dir. 96/25. On the basis of our expert assessment, validated after consultation with DG SANCO experts, we consider that this simplification leads to a reduction of the cost per occurrence, i.e. the "P" factor, equal to 55% for non-petfood, and by 16% for petfood.[34] According to the Prodcom data analyzed below, petfood represents 19.11% of total market for feedstuff. Accordingly, total "P discount" amounts to 47.5% (55% X 80.89% + 16% X 19.11%).

We also believe that the BAU factor used by the Consortium for food labelling, that is 75%, is appropriate also for the IO "Labelling of feedstuff". The high BAU ratio can be explained by considering that firms would label their products even if there were no legal obligation, and that most of the information required by law would be included in the label in any case.

The main difference between the two IOs is the different size of the subject markets. We consider that the market size is a more accurate cost-driver than the number of companies covered by the IOs, because labelling obligations are more related to the quantity of products sold than to the number of market participants. Label requirements may have a hugely different impact on different firms depending on sold quantity and on the number of products. As a proxy for market sizes, we use data retrieved from the Prodcom database by Eurostat.[35] The value of the feedingstuff market is estimated summing up the value of the products identified by the following codes: 157010Z3 (Preparations for animal feeds (excluding dog or cat food, p.r.s.)), 15721030 (Dog or cat food, p.r.s.), and 1572106 (Preparations used for feeding pets (excluding preparations for cats or dogs, p.r.s.)). According to these data, feedingstuff market value amounts to €43bln. The value of the foodstuff market is estimated summing up the value of the products identified by the following codes: from 15111140 to 15622300 and from 15811100 to 15981270. According to these data, the foodstuff market value amounts to €652bln.

As expected, the market for foodstuff is much larger than the market for feedingstuff. The latter represents 6.58% of the former. The correctness of these data is roughly confirmed by the IA of COM(2008)124, where it is estimated that the turnover of the feedingstuff industry (compound feed and pet foods) amounted to €46mln in 2005.

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[34] We have assumed that in general cost per occurrence of labelling is higher in case of foodstuff than in case of feedstuff. More specifically, we have assumed that labelling of non-petfood is much simpler, and less expensive, than labelling of foodstuff. On the contrary, petfood labels have much more in common with food labels, therefore the cost per occurrence can be assumed to be closer. No precise figures about cost per occurrence in the feedstuff sector could be retrieved, therefore we have proposed our expert assessment to DG SANCO. The P discount factors reported in the text have been obtained by adjusting our assessment according to Commission officers' evaluation.

[35] Data refers to 2007.

We have used the AB calculator to quantify the ACs/ABs attributable to the IO "Labelling of foodstuff" on the basis of the partial estimates illustrated above.

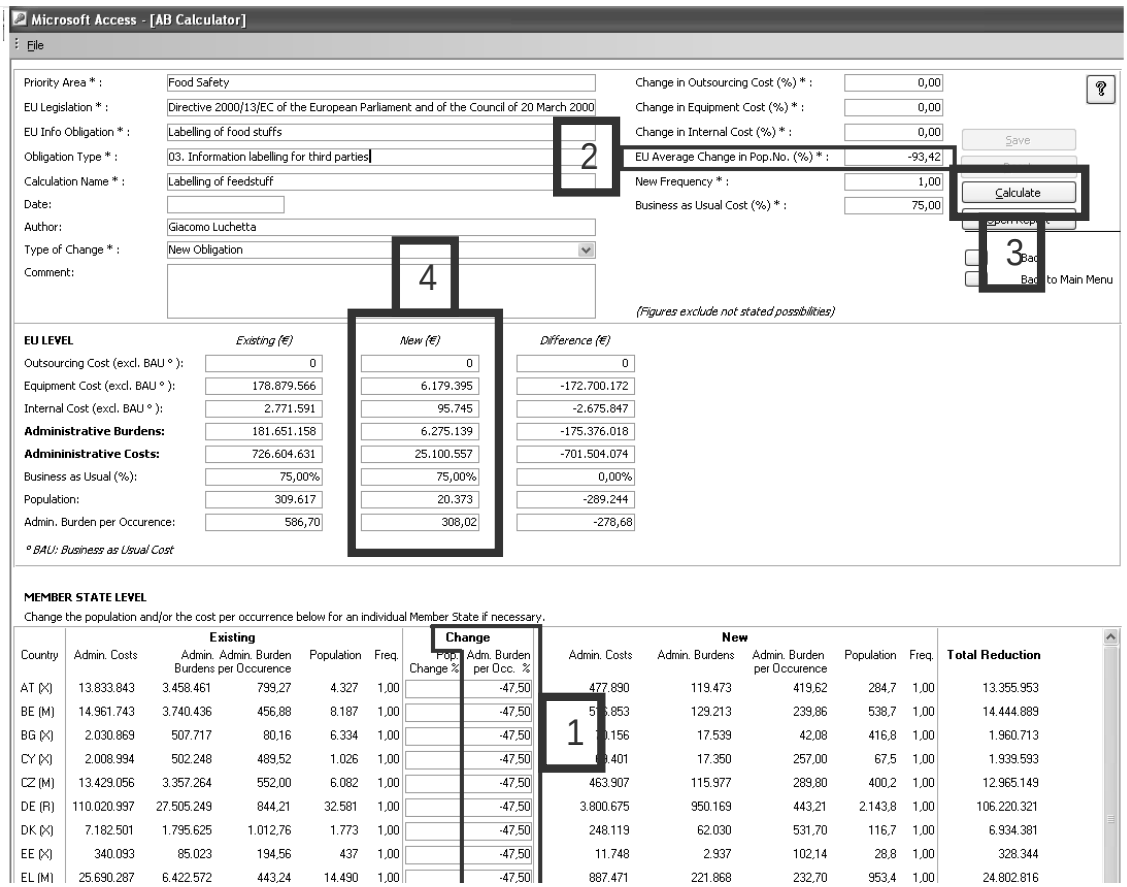
In Figure 2, we show how we have performed the calculation. In the AB calculator, you can change several variables, related mainly to costs, population, frequency and business as usual factor.

Costs can be changed at aggregate level or at member state level. At aggregate level an user may change "outsourcing costs", "equipment costs" or "internal costs" by a certain % factor. At member state level, the user may change the burden per occurrence by a certain % factor, regardless of whether internal, outsourcing or equipment costs are concerned. Since in this quantification our estimate for cost variation (the P discount factor) does not differentiate among neither cost types nor member state, the same value (-47.5%) has been typed in cells "Adm. Burden per Occ. %" for each Member State (see [1] in Figure 2).

Population can be changed at both member state and aggregate level. Our estimates do not discriminate among member states' populations, therefore the expected change in population (-93.42%) has been inserted in the cell "EU average Change in Pop. No. (%)" (see [2] in Figure 2). As for frequency and business as usual factor, no changes are brought about by COM(2008)124, therefore no other data should be typed into the AB calculator mask for this quantification.

By clicking on the button "Calculate" (see [3] in Figure 2), the AB calculator computes costs and burdens according to our input. The values of costs and burdens due to the new act in scope of the quantification are shown in the column "New" (see [4] in Figure 2).

Figure 2 Calculating ACs/ABs via the AB calculator – Labelling of feedstuff



According to this estimate, the IO "Labelling of feedstuff" is estimated to impose ACs/ABs amounting to €25,100,557, of which €6,275,139 (25%) are considered ABs.

COM(2008)124 amends and redefines the current framework on feed labelling, consolidating the existing provisions in one act. According to the IA, there are 4 main Council Directives on feed labelling and about 50 implementing or amending acts. Consolidating these provisions in a single text is going to reduce the time that undertakings spend to become familiar with the legal framework. Analogously to the estimation carried out for COM(2008)40, we consider that the mere fact that several legal texts on feed labelling are consolidated in a single regulation relieves firms from part of the ABs. Also in this case, we estimate that savings amount to 1.7%-3.3% of total ACs/Abs, implying that in this respect COM(2008)124 reduces ACs due to the IO "Labelling of foodstuff" by €828,318 - €426,709, and ABs by €207,080 - €106,677. The average value of the range is taken into account in Table 18 for quantification.

The main new provision dealing with feed labelling included in COM(2008)124 concerns the list of ingredients in compound feed: the duty to declare the percentage of ingredients used in compound feed on labels has been eliminated.[36] The main benefit of this new provision is to better protect the intellectual property rights, and to avoid disclosure of commercial information. As a side effect, this provision also allows producers to change less frequently their labels. Recipes of compound feed are quite sensitive to variation of the price of raw materials, and may change accordingly. According to our and DG SANCO's assessment, the impact is relevant, but it is difficult to provide a precise estimate. We tentatively assume that ACs/ABs on compound feed producers are relieved by a third. Since compound feed represents 32% of the total quantity of feedingstuff,[37] we estimate that this provision will reduce total ACs/ABs by 10.7% (32% * 0.33), i.e. respectively by €2,685,760, and by €671,440.

ACs/ABs may increase because of art. 19 of COM(2008)124, where it is stated that producers of petfood shall indicate on the label a free telephone number to allow the customers to obtain additional information on feed additives and certain categories of feed materials. We estimate that this article is going to increase ACs on petfood producers by 20%. The percentage of ABs related to this article can be fixed at 67% (i.e. BAU costs amount to 33%), since it is likely that petfood producers would anyway put in place systems to provide additional information to consumers. However, the mandatory provision for a free telephone number and the mandatory indication of this opportunity on the label are likely to increase costs for firms, therefore creating additional ABs. Since the market size of petfood amounts to 19.11% of the total market for feedingstuff, art. 19 increases ACs by 3.82%, or by €958,841. According to the fixed BAU level, ABs increase by €639,228. However, this article has been modified during the co-decision procedure. The amended legislative proposal does not require anymore petfood producers to provide information trough a free telephone number. They are free to choose the most appropriate (and least expensive) means, e.g. through their websites. Therefore, the impact of this provision on ACs/ABs can be estimated to be negligible. Accordingly, the ACs/ABs increase due to "original" art. 19 will not be included in the quantification.

The total amount of ACs/ABs due to the IO "Labelling of feedingstuff" arising from dir. 96/26 and the impact of COM(2008)124 are detailed in Table 18. Table 18 summarizes the results of the quantification carried out on the baseline acts dir. 82/471 and dir. 96/25, and on the amending the proposal COM(2008)124.

[36] According to art. 17.1.(e), it is up to the producers to show percentage of ingredients on the label. It must however list ingredients in descending order by weight.

[37] As reported in the Impact Assessment of COM(2008)124

Table 18 Reg. 96/25 – Changed IO: Labelling of Feedstuff

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	Dir 96/25	Amending Acts	COM(2008)124
EU Info obligation	Labelling of feedstuff (art. 5)		
Obligation Type	3. Information labelling for third parties		
	QUANTIFICATION		
	Dir 96/25	COM(2008)124	
Frequency (per year)	ongoing	ongoing	
Population	20373*	20373*	
Administrative Costs	€ 25,100,557	*€ 21,787,283*	
AdministrativeBurdens	**€ 6,275,139**	***€ 5,446,821***	
AC Difference	**-€ 3,313,274**	**-13.2%**	
AB Difference	**-€ 828,318**	**-13.2%**	

* population is estimated considering that the market for feedstuff is 6.58% of the market for foodstuff

Table 19 Summary table for Directives 82/471 and 96/25, and COM(2008)124

SUMMARY			
Priority Area	*Food safety*		
Existing EU legislation	**Dir 82/471**	Amending Act	**COM(2008)124**
	QUANTIFICATION		
	Dir 82/471	**COM(2008)124**	
Administrative Costs	€ 1,563,250	*€ 0*	
Administrative Burdens	**€ 1,172,438**	***€ 0***	
AC Difference	**-€ 1,563,250**	**-100.0%**	
AB Difference	**-€ 1,172,438**	**-100.0%**	

SUMMARY			
Priority Area	*Food safety*		
Existing EU legislation	Dir. 96/25	Amending Act	COM(2008)124
	QUANTIFICATION		
	Dir. 96/25	COM(2008)124	
Administrative Costs	€ 25,100,557	*€ 21,787,283*	
Administrative Burdens	**€ 6,275,139**	***€ 5,446,821***	
AC Difference	**-€ 3,313,274**	**-13.2%**	
AB Difference	**-€ 828,318**	**-13.2%**	

3.2.3 Food additives and food flavouring substances

Several Community acts regulate the use of substances added to food for certain goals during the manufacturing process. These substances are food additives, such as colourings or sweeteners, flavouring substances, and, recently, food enzymes. Generally speaking, the European legislation provides a list of authorized substances, a procedure

to update the list, i.e. for authorizing new substances, and labelling requirements. Therefore, it creates IOs to be complied with by the manufacturing undertakings.

These substances were regulated by several vertical directives and regulations. However, not all IOs of this legislative area are going to be measured, but only the IOs arising from two acts among the baseline acts included in the extension list:

1. Directive 89/107/EEC on the approximation of laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption. The act provides that food additives are to be authorized before being placed in the market and lists the labelling requirements, which are different in case of sale to the ultimate consumer or to other subjects.

2. Regulation 2232/96/EC laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs. The act regulates the authorization to market new flavouring substances.

This legislative area has been recently reformed by four regulations:

1. Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes, and food flavourings;

2. Regulation 1332/2008 on food enzymes;

3. Regulation 1333/2008 on food additives;

4. Regulation 1334/2008 on flavourings.

However, given the scope of the baseline acts, only the impact of the provisions amending the IOs included in dir. 89/107 and reg. 2232/96 will be measured.

3.2.3.1 Directive 89/107 on food additives

Directive 89/107/EEC[38] sets the general framework for the harmonization of national laws on food additives. Food additives are defined in art. 1 as substances not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, the intentional addition of which to food may be expected to result in it or its by-products becoming a component of such foods. Processing aids, substances used for the protection of plants, flavourings and nutrients are excluded from the application of this directive. According to our analysis, the directive includes 2 IOs, imposing ACs

[38] As amended by European Parliament and Council Directive 94/34, and by Regulation 1882/2003.

amounting to €6.6mln, of which €1.6mln (25.1%) are considered ABs. Information on the quantification of this baseline act is summarized in Table 20.

Table 20 Summary table for Directive 89/107

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Council Directive 89/107/EEC on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption		
INFORMATION OBLIGATION		**AC**	**AB**
IO 1	Authorization for food additives	€ 17,943	**€ 10,766**
IO 2	Labelling of food additives	€ 6,539,441	**€ 1,634,860**
	TOTAL	€ 6,557,384	**€ 1,645,626**

Art. 2 states that only food additives included in the list drawn up pursuant art. 3.3 can be used in the manufacture or preparation of foodstuffs. Therefore, new food additives must be authorized according to the procedures laid down in other acts.[39] We consider that the joint provisions of art. 2 and 3.3 of dir. 89/107 create the IO "Authorisation for food additives".

DG SANCO services have reported to us the number of requests for authorization of new food additives received by the Commission, that is 27 from the second semester of 2006 to the first semester of 2009, thus an average of about 10 per year. Consequently, we consider that this IO has a population of 1o occurrences per year.

No data about the cost of an authorization for additives could be retrieved. However, a similar IO has been found in the UK database, that is the request for authorization for new vitamins, minerals and other substances, ex Regulation (EC) 1925/2006. According to the British database on ABs, the cost per occurrence amounts to €1,794.29. Therefore, total ACs caused by this IO amount to €17,943 per year. The UK database fixes the BAU threshold at 40% and we consider it appropriate because the undertaking would produce evidence about the safety of its additive even if not required by the authorization process. Accordingly, ABs due to this IO are estimated at €10,766.

Art. 7 lays down the labelling requirements for food additives not intended for sale to the ultimate consumer, while art. 8 lays down the same requirements in case of sale to the ultimate consumer. DRs required by art. 7 and 8 are slightly different, but can be expected to impose the same burden on undertakings.

According to the approach already adopted by us and by the Consortium for other provisions on labelling, we consider that these articles create a single IO: "Labelling of

[39] European Parliament and Council Directives 94/35/EC on sweeteners; 94/36/EC on colours; and 95/2/EC on other additives.

food additives" and measure its impact on the basis of an analogy with the IO "Labelling of foodstuff" arising from dir. 2000/13. In general, DRs of art. 7 and 8 of dir. 89/107 are similar to those due to dir. 2000/13. This can be explained considering that both acts concern products for human consumption. Therefore, the P factor, i.e. the cost per occurrence, is estimated to remain the same. The impact of the IO "Labelling of food additives" is estimated taking into account the much smaller population subject to it.

As stated in the introduction to the impact assessment to the proposal for a regulation on food additives,[40] an estimate of the dimension of the food additive industry is very difficult. Only a data on the value of the global market of food additives could be retrieved, which was estimated at $22bln in 2004, that is €17.7bln.[41] Considering that, according to the Prodcom data, the European food market value amounts to €652,338,963,613, the global market of food additives corresponds to 2.7%. We assume that the EU market for food additives is one third of the global market, therefore its value is equal to 0.9% of the EU food market. According to this estimation, we consider that the IO "Labelling of food additives" imposes ACs equal to 0.9% of the IO "Labelling of foodstuff", i.e. €6,539,441.[42] The BAU factor already used for the IOs "Labelling of foodstuff" and "Labelling of feedstuff", that is 25%, is considered appropriate also for this IO. Therefore, we estimate that it imposes ABs amounting to €1,634,860.

3.2.3.2 Regulation (EC) 2232/96 on the authorization for flavouring substances

Regulation 2232/96 lays down the Community procedure to create the list of flavouring substances authorized within the Community and for its update. It is complementary to directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuff, the general directive for food flavourings. According to our estimates, reg. 2232/96 includes 1 IO and imposes ACs amounting to €75,360, of which €45,216 (60%) are considered ABs. Results of the quantification are summarized in Table 21.

[40] SEC(2006)1041

[41] Cf. Food Additives Market - Global Trends and Developments (3rd Edition), summary available at http://www.researchandmarkets.com/reportinfo.asp?report_id=302099&t=e&cat_id=. The exchange rate is the annual USD/EUR rate for 2004 reported by the ECB.

[42] The accuracy of this estimate is roughly confirmed by the data of the UK database, where two IOs related to labelling of food additives imposes ACs for about £400,000, i.e. €560,000. This value is consistent with the order of magnitude of the EU-wide ACs estimated by us.

Table 21 Summary table Regulation 2232/96

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Regulation 2232/96 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs		
INFORMATION OBLIGATION		**AC**	**AB**
IO 1	Authorization for flavouring substances	€ 75,360	**€ 45,216**
	TOTAL	€ 75,360	**€ 45,216**

The use of a food flavouring substance in the EU is allowed only if it is included in a register of authorized substances. Art 5.2. of reg. 2232/96 provides that the use of a new flavouring substance not included in the register may be authorized in accordance with the procedure laid down in art. 7. Accordingly, we consider that this article creates the IO "Authorization for flavouring substances".

DG SANCO services have reported to us the number of requests for authorization received by the Commission, that is 127 over the period 2004-2006, or 42 per year. In 2007 and 2008, only 4 requests per year were submitted. However, this may be due to the fact that in these years the reform of the authorization process was being discussed, therefore undertakings may have decided to wait for the new legal framework. Consequently, we consider that this IO has a population of 42 occurrences per year.

No data about the cost of an authorization for flavourings could be retrieved. However, a similar IO has been found in the UK database, that is the request for authorization for new vitamins, minerals and other substances, ex Regulation (EC) 1925/2006. According to the British database on ABs, the cost per occurrence amounts to £1271.11, i.e. €1,794.29. Therefore, total ACs due to this IO amount to €75,360 per year. The UK database fixes the BAU threshold at 40% and we consider it appropriate because the undertaking would produce evidence about the safety of its flavouring substances even if not required by the authorization process. Accordingly, ABs due to this IO are estimated at €45,216.

3.2.3.3 Regulation (EC) 1331/2008 on the authorization for food additives, flavourings and enzymes

Reg. 1331/2008 establishes a new approach to the authorization for food additives and flavourings. Under the previous legal regime they had to undergo specific authorization procedures, while the present legislation establishes a single process regardless of the nature of the substance. Furthermore, an authorization is now required also for food enzymes.

The new authorization procedure is much more detailed and includes limits and deadlines to ensure a timely handling of the file. Furthermore, authorizing a new substance, i.e. updating the Community list of authorized substances, no longer

requires to undergo the co-decision procedure. Consequently, the time needed to grant an authorization, and thus the time-to-market of new products, is drastically reduced, since co-decision procedures usually take two years. However, time savings cannot be measured via SCM. Therefore, the provision does not relieve firms of ABs in a strict sense. Differently, we have been told by DG SANCO experts that the main steps of the authorization procedure for both additives and flavourings and the data to be submitted have not been changed by the new legislation. Therefore, the impact of reg. 1331/2008 on the existing ABs/ACs is negligible in this respect.

Establishing a common procedure for different food improving substances, by merging different specific regulations into reg. 1331/2008, is likely to cause a reduction of ABs/ACs. According to the quantification performed in another sector of food legislation priority area,[43] we estimate that merging different horizontal acts into a single piece of legislation reduces ACs/ABs by 1.7-3.3%. The medium value of the range is used to perform the quantification.

Food enzymes were out of the scope of the European food legislation. For this reason, they were unevenly regulated at national level. Therefore, undertakings had to bear ABs to market food enzymes in countries where an authorization scheme was provided and to overcome barriers due to different national schemes and laws. Including food enzymes in the European food legislation is going to remove these barriers and to switch the AB origin from "national" to "EU" but is not going to impose new ABs.[44] In any case, given the baseline acts included in the extension lists, measuring burdens on food enzyme producers is out of the scope of this measurement exercise.

The quantification of the impact of reg. 1331/2008 on ACs/ABs due to the IOs “Authorization for flavouring substances” and “Authorization for food additives” is summarized in Table 22.

[43] Cf. paragraph 3.2.2.2

[44] To the extent that the EU legislation is not more burdensome than the existing national ones.

Table 22 Reg. 1331/2008 – Changed IOs: Authorization for food additives and Authorization for Flavouring Substances

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	**Dir 89/107**	Amending Acts	**Reg. 1331/2008**
EU Info obligation	Authorization for food additives (art. 2, 3.3)		
Obligation Type	5. Application for individual authorisation or exemption		
	QUANTIFICATION		
	Dir 89/107	**Reg. 1331/2008**	
Frequency (per year)	on occasion	on occasion	
Population	6	6	
Administrative Costs	€ 17,943	*€ 17,494*	
Administrative Burdens	**€ 10,766**	***€ 10,497***	
AC Difference	**-€ 449**	**-2.5%**	
AB Difference	**-€ 269**	**-2.5%**	

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	**Reg. 2232/96**	Amending Acts	**Reg. 1331/2008**
EU Info obligation	Authorization for flavouring substances (art. 5.2)		
Obligation Type	5. Application for individual authorisation or exemption		
	QUANTIFICATION		
	Reg. 2232/96	**Reg. 1331/2008**	
Frequency (per year)	on occasion	on occasion	
Population	42	42	
Administrative Costs	€ 75,360	*€ 73,476*	
Administrative Burdens	**€ 45,216**	***€ 44,086***	
AC Difference	**-€ 1,884**	**-2.5%**	
AB Difference	**-€ 1,130**	**-2.5%**	

3.2.3.4 Regulation (EC) 1333/08 on food additives

Regulation 1333/2008 recasts existing EU acts on food additives, repealing 11 existing acts, including one of the baseline acts measured by us, that is dir. 89/107. Namely, it modifies the IO "Labelling of food additives".

The reduction due to the simplification and merger of several acts concerning food labelling has been estimated for other acts at 1.7%-3.3%. However, in this case the impact is likely to be higher, because reg. 1333/2008 also eliminates previous differentiations, that is legislation on specific additives, such as colourings and sweeteners. Therefore, it reduces burdens due to both horizontal and vertical acts.

Accordingly, we estimate that the simplification of the legislative framework on food additives due to reg. 1333/2008 has a larger than usual impact on ACs/ABs, reducing them by 3.4%-6.6%. The medium value of the range is used to perform the quantification.

In other respects, the new legislation does not dramatically alter the existing obligations for labelling of food additives, mainly aiming at bringing it into line with the existing legislation on food labelling and labelling of genetically modified organisms in foodstuff. In case of sale to the ultimate consumer, art. 8 makes an explicit reference to dir. 2000/13 on food labelling, whose provision are made binding also on food additives. Other limited changes are located at:

1. art. 22.1.(i), stating that the date of minimum durability is to be indicated also for food additives not intended for sale to the final consumer. However, DG SANCO experts have told us that the date of minimum durability was already included in labels, even though it was not required by law. As a consequence, ABs do not change;

2. art. 22.5. In case additives are transported via tankers, information can be displayed on accompanying documents and on a label;

3. art. 23.4. Manufacturers of table-top sweeteners shall make available by appropriate means the necessary information to allow their safe use by consumers. However, DG SANCO experts have reported to us that this DR was already required by several national legislations.

According to the assessment by DG SANCO services, the impact of the changes to labelling requirements for food additives is going to be minimal, because the main goal of the new regulation is not to tackle ABs. Changes in the labelling requirements are likely to impose one-off costs because of re-designing of existing labels. However, since changes are minimal and new requirements, such as art. 23.4, come into force at a later stage, one-off costs ca be expected to be negligible. Therefore, we agree with DG SANCO and do not expect any change in ACs/ABs due to the new provisions. Quantification of changes to IO “Labelling of food additives” in summarized in Table 23.

Table 23 Reg. 1333/2008 – Changed IO: Labelling of food additives

CHANGED IOs			
Priority Area	*Food safety*		
Baseline Act	**Dir 89/107**	Amending Acts	**Reg. 1333/2008**
EU Info obligation	Labelling of food additives (art. 7, 8)		
Obligation Type	3. Information labelling for third parties		
	QUANTIFICATION		
	Dir 89/107		**Reg. 1333/2008**
Frequency (per year)	ongoing		*ongoing*
Population*	2,787		2,787
Administrative Costs	€ 6,539,441		*€ 6,212,469*
Administrative Burdens	**€ 1,634,860**		***€ 1,553,117***
AC Difference	**-€ 326,972**		**-5.0%**
AB Difference	**-€ 81,743**		**-5.0%**

* population is estimated considering that the market for food additives is 0.9% of the market for foodstuff

The quantification of the impact of the new food improvement regulations, that is reg. 1331/2008 and 1333/2008, on dir. 89/107 on food additives and reg. 2232/96 on the authorization procedure for flavouring substances is summarized in Table 24.

Table 24 Summary table for Directive 89/107, Regulation 2232/96, and the amending Regulations 1331/2008 and 1333/2008

SUMMARY			
Priority Area	*Food safety*		
Existing EU legislation	**Dir 89/107**	Amending Act	**Reg. 1331/2008** **Reg. 1333/2008**
	QUANTIFICATION		
	Dir 89/107		**Reg. 1331/2008 & Reg. 1333/2008**
Administrative Costs	€ 6,557,384		*€ 6,229,964*
Administrative Burdens	**€ 1,645,626**		***€ 1,563,614***
AC Difference	**-€ 327,421**		**-5.0%**
AB Difference	**-€ 82,012**		**-5.0%**

Reduction by act	Administrative Costs	Administrative Burdens
Reg. 1331/2008	-€ 449	-€ 269
Reg. 1333/2008	-€ 326,972	-€ 81,743

SUMMARY			
Priority Area	*Food safety*		
Existing EU legislation	**Reg. 2232/96**	Amending Act	**Reg. 1333/2008**
	QUANTIFICATION		
	Reg. 2232/96		**Reg. 1333/2008**
Administrative Costs	€ 75,360		*€ 73,476*
Administrative Burdens	**€ 45,216**		***€ 44,086***
AC Difference	**-€ 1,884**		**-2.5%**
AB Difference	**-€ 1,130**		**-2.5%**

3.2.4 Council Directives on veterinary checks on intra-community trade of animal products and live animals

Council Directives 89/662[45] and 90/425[46] set the rules for veterinary checks on animal products and live animals traded within the Community. They aim at completing the internal market providing that veterinary checks shall no longer be carried out at the internal borders. Checks may be carried out at origin or at destination in a non-discriminatory way and regardless whether goods originate from, or are destined to, the same or another Member State. Further obligations are imposed on operators receiving animal products or live animals from another Member State, such as the duty to keep records.

The two directives are very similar, imposing almost the same IOs, but they deal with different goods. Roughly, dir. 89/662 concerns animal products, whilst dir. 90/425 deals with live animals and a small sub-group of other animal products. Therefore, we carry out a joint analysis of both acts.

According to our analysis, validated by DG SANCO, dir. 89/662 would contain two IOs, and dir. 90/425 three. For methodological and technical reasons, as explained below, we have carried out quantification 0f three of them. This partial quantification shows that the two directives impose ACs for €4.8mln, of which €3.5 (72.3%) are considered ABs. Details are shown in Table 25. It is to be kept in mind that if one included also IOs 1 and 2, total ACs and ABs would be much higher.

[45] As amended by Council Directives 90/675, 91/67, 91/492, 91/493, 91/494, 91/495, 91/496, 92/45, 92/46, 92/67, and 92/118; by Council Regulation 806/2003; and by Directive 2004/41/EC of the European Parliament and of thee Council.

[46] As amended by Council Directives 90/539, 90/667, 90/675, 91/68, 91/174, 91/496, 91/628, 92/60, 92/65, and 92/118; and by Directive 2002/33/EC of the European Parliament and of the Council

Table 25 Summary table for Directives 89/662 and 90/425

SUMMARY OF BASELINE ACTS			
Priority Area:	Food Safety		
Act:	Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market; Council directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Cooperation with veterinary checks (89/662)	-	**-**
IO 2	Cooperation with veterinary checks (90/425)	-	**-**
IO 3	Keeping record of deliveries and related documents (89/662)	€ 1,385,317	**€ 1,049,483**
IO 4	Keeping record of deliveries and related documents (90/425)		
IO 5	Report in advance the arrival of animals and products from another Member State (90/425)	€ 3,457,116	**€ 2,451,855**
	TOTAL	€ 4,842,433	**€ 3,501,338**

Data for the quantification of these directives are retrieved from the UK database on ABs, namely from the measurement of the Animals and Animal Products (Import and Export) (England) Regulations 2006, updating Community trade requirements and implementing and enforcing EU controls on animals and animals product. The extrapolation of total ABs is carried out on the basis of the following parameters:

1. Appropriate salary rate;

2. GDP in PPP;

3. AB-GDP ratio.

3.2.4.1 IO 1 and IO 2: Veterinary checks on live animals and animal products

Art. 1 of dir. 89/662 requires Member States to ensure that veterinary checks on products of animal origin covered by Annex A and intended for trade are no longer carried out at frontiers, but in accordance to the directive. Art. 1 of dir. 90/425 imposes the same obligation on Member States for live animals and animal products covered by this act.

The criteria to be met by the veterinary authorities when checking animal products and live animals intended for trade are listed in the following articles of the directives:

1. they must verify that products intended for trade are checked, marked and labeled in accordance with the EU acquis, and that the required accompanying document and certificate are attached to the dispatch (art. 3 of dir. 89/662,

explicit list of requirements in art. 3 of dir. 90/425). These checks shall be carried out on establishments, holdings, approved markets and assembly centres (art. 3.1 of dir. 89/662 and art. 3.3 of dir 90/425);

2. they shall check products in the same way, whether they are intended for intra-Community trade or for the national market (art. 4 of dir. 89/662 and of dir. 90/425);

3. when competent authorities on the place of destination carry out veterinary spot-checks, they shall not discriminate whether animal products and live animals are of national or intra-EU origin (art. 5 of dir. 89/662 and of dir. 90/425). The same is true for checks carried out during transport in case there is any suspect of infringement of Community rules;

4. in case of veterinary checks carried out at external border inspection posts, veterinary authorities shall comply with the rules laid out in this directive for animal products or products of animal originating from within the Community territory.[47]

The above-mentioned IOs are a borderline case. Directives 89/662 and 90/425 do not require Member States to carry out veterinary checks. This obligation arises from other legislative Community acts, or from national measures and programmes. Since both directives provide rules to ensure that animal products and live animals intended for trade are checked in same way whether they are of national origin or originate form another EU Member States, they impose obligations on veterinary authorities rather than on economic operators. The modality to carry out veterinary and zootechnical checks is then spelled out in Regulation 882/2004.

In any case, if one opted for attributing ACs/ABs due to veterinary checks on live animals and animal products to these acts, the quantification of ACs/ABs would be hindered because there are no data concerning the number of occurrence, that is the number of veterinary checks carried out in accordance with the directives. Whilst it would not be difficult to retrieve information and consequently estimate an "average" time needed to comply with physical or documentary checks on animal products and live animals,[48] it is not possible to carry out any sound quantification without a thorough assessment of the number of occurrence.

Contacting DG SANCO, we have been told that data concerning veterinary inspections carried out at external border inspection posts would have been available or quickly retrievable. However, we have agreed with DG SANCO that it is fair to assume that the

[47] Otherwise, dir. 90/675 applies.

[48] As we have done when quantifying Commission Decision 2008/807/EC, concerning veterinary checks at the EU-CH borders. Cf the previous CEPS report "Measurement of administrative burdens generated by the acts included in the "Extension List" attached to the Action Programme on Administrative Burdebs".

number of checks carried out at places of origin and destination would be greater than those carried out at the external borders. Consequently, these would not be a sound-enough basis for quantification.

We would recommend to survey national (or local where appropriate) veterinary authorities to know the number of veterinary checks on live animals and animal products intended for trade yearly carried out in accordance with the present directives. On this basis, it would be possible to provide a rather sound quantification.

We have also tried to retrieve data from national databases on ABs. They measure other IOs due to these directives, as reported below, but they contain no indication about IOs to carry out veterinary checks. It may be the case that the criteria spelled out in these directives are not implemented in any single act, but are included in several national sectoral acts concerning checks on economic operators dealing with animal products or live animals.

We have also searched for other public documents or studies measuring the costs or the number of veterinary checks, both in English and in other Community languages. However, no data or analysis could be retrieved concerning these directives. This could also be due to the fact that these acts are quite old and that no revision of them is foreseen.

3.2.4.2 IO 3 and IO 4: Keep records of deliveries and related documents

Art. 5.3 of dir. 89/662 imposes several obligations on operators who have animal products delivered to them from another Member State, or who completely divide up a batch of such products. First of all, they shall register deliveries and keep the health certificates and documents required by the directive for not less than six months. Furthermore, they may be subject to prior registration at competent authorities' discretion. The first two DRs are made mandatory by the EU legislation, therefore we measure their impact under the IO 3 "Keep records of deliveries and related documents".

Art. 5.2 of dir. 90/425 also requires keeping for a period of not less than six months the health certificates and documents required by the directive. Furthermore, art. 12 requires dealers engaging in intra-Community trade in the animals and products covered by the directive to keep a record of deliveries. Therefore, the same IO "Keep records of deliveries and related documents" arises from these articles of dir. 90/425.

The impact of these IOs will be measured jointly, because the English database does not make any difference between traders of live animals and animal products. Data to estimate these IOs are retrieved from the following British IOs:

"keeping any certificates received with a consignment of animals for 12 months". imposing ACs amounting to €45,235, of which €34,269 (68%) are considered ABs. Since both directives require to keep certificates for a minimum of six months, total ACs are discounted by half for extrapolation purposes;

"keeping records of all cattle, pigs, sheep and goats they import or export and preserve the records for at least 3 years", imposing ACs amounting to €94,788, of which €71,089 (68%) are considered ABs. Since both directives require to keep records only of animals delivered to the dealers, total ACs are discounted by half for extrapolation purposes to exclude exports. Furthermore, since the British IO does not concern animal products, total ACs are doubled to take account of them. Therefore, we use the amount of ACs reported in the UK database as basis for the extrapolation.

On the basis of the extrapolation, we estimate that throughout the EU these IOs impose ACs amounting to €1,385,317, of which €1,049,483 (68%) are considered ABs. The extrapolation is based on the following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a clerk.

3.2.4.3 IO 5: Report in advance the arrival of animals and products from another Member State

Art. 5.2 of dir. 90/425 requires consignees to report in advance the arrival of live animals or of products covered by the act (such as animal by-products, semen and embryos). The communication is to be made to the competent authority, to the extent necessary to carry out the checks at destination provided by par. 1 of art. 5 of the directive.

An analogue IO is measured in the UK database: "informing an authorized inspector of the arrival of a consignment of animals or animal products (except registered horses)"[49], imposing in the UK ACs amounting to €292,991, of which €207,795 (59%) are considered ABs.

On the basis of the extrapolation, we estimate that throughout the EU these IOs impose ACs amounting to €3,457,116, of which €2,451,855 (59%) are considered ABs. The extrapolation is based on the following parameters: (i) AB-GDP ratio; (ii) GDP in PPP; (iii) salary rate of a clerk.

[49] The same exception is granted by lett. (a) of art. 5.2.

3.3 Priority Area: Statistics

Within this area, we have to quantify ACs/ABs due to the following baseline acts and the reduction brought about by the related amending acts/amending proposals, if any:

1. Council Regulation 1172/98 on statistical returns in respect of the carriage of goods by road. No amending proposal has been tabled concerning this act;

2. Council directive 95/64/EC of 8 December 1995 on statistical returns in respect of carriage of goods and passengers by sea. No amending proposal has been tabled concerning this act.

3.3.1 Council Regulation 1172/98 on statistical returns in respect of the carriage of goods by road

A similar rationale applies to Reg. 1172/98 on statistical returns in respect of the carriage of goods by road. Here, we were asked to estimate the cost of the original act only, as the amending act has not been fully defined yet. According to the mapping process carried out by DG ESTAT, reg. 1172/98 includes 1 IO: "Collection of statistics concerning carriage of goods by road". According to our analysis, it imposes an AC of €8.2mln, of which €4.1mln (50%) are considered ABs. The quantification of this baseline act is summarized in Table 26.

Table 26 – Summary table for Regulation 1172/98

SUMMARY OF BASELINE ACTS			
Priority Area:	Statistics		
Act:	Council Regulation 1172/98 on statistical returns in respect of carriage of goods by road		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Collection of statistics concerning carriage of goods by road	€ 8,154,000	**€ 4,077,000**
	TOTAL	€ 8,154,000	**€ 4,077,000**

Council Regulation (EC) 1172/98 on the carriage of goods by road permits the exclusion from the survey, if the reporting country so wishes, of goods road vehicles with a load capacity (LC) of less than 3.5 tonnes or with a maximum permissible weight (MPLW) below 6 tonnes. Several reporting countries opt for this exclusion. Consequently, small goods vehicles fall outside the coverage of EU road freight statistics. Because the lower thresholds are not fixed and reporting countries are free to select them, the lower boundary of vehicles included in road freight surveys varies according to the reporting countries[50]. In what follows, we consider all national practices including vehicles below

[50] Four reporting countries - Germany, France, the United Kingdom and Norway - have carried out special surveys of small vehicles. Finland made a specific survey on lorries outside the survey frame. Poland estimates the road freight

6 tonnes to be “B” or “national” burdens, i.e. under the sphere of control of national legislators, and outside the control of EU policymakers.

The only IO affects approximately 300000-500000 businesses owning half a million of vehicles and for approximately one week a year.[51] Businesses owning more than one vehicle can be surveyed more than once a year. However, we have opted for including this information in the cost per occurrence and not in the frequency value, which is fixed at 1.

“Cutting red tape: comparing administrative costs across countries” (2007), the estimated time for a business to comply with the IO is described as follows: “[businesses] in Belgium, Denmark, Norway and Sweden, businesses spend less than 90 minutes providing the authorities with statistical information. In France and Germany, businesses spend between 90 minutes and three hours complying with the common obligation, whereas in Turkey and the Netherlands more than three hours are needed”[52]. On the basis of the information provided by Member States to DG ESTAT, I many member states the time spent per survey per vehicle is 60 minutes or less. However, when estimating the cost per occurrence, we also have to take into account that a firm can be surveyed more than once per year.

In our search for the “normally efficient firm”, we have adopted 90 minutes as the reference time for our calculation in Table 27 below. The BAU factor is 50%, as the activities performed would not be undertaken at all absent the legislation, but most of the information would be retrieved in any case due to the need to control the movement of individual vehicles. The salary level applied is the weighted average for elementary occupations in the EU27 (€13.59).

Table 27 – ABs created by Reg. 1172/98

Art. no.	Description of the Information Obligation (mainly juridical)	Type of obligation	Main action(s) required	Target group(s) / segments	Total nbr of entities concerned	Time (minutes)	Frequency per year	BAU	Price	Adiminstrative cost	Adiminstrative burden
Art 1. to 4.	Each Member State shall compile Community statistics on the carriage of goods by road by means of goods road transport vehicles which are registered in that Member State, and on the journeys made by such vehicles. The data relate to the vehicles, the journeys and the goods carried.	12 Other. (Filling in questionnaires or providing data in electronic format for a statistical sample survey on heavy road freight vehicles.)	3, 4, 5, 7, 11	Heavy (>6 tonnes total weight) goods road transport vehicles registered in the EEA Member States or (international) road freight transport companies.	400,000	90	1	50%	13.59	**€ 8,154,000**	**€ 4,077,000**

Accordingly, we conclude that Reg. 1172/98 creates administrative costs of €8.2 million, of which approximately €4.1 million are administrative burdens.

transport performed by small vehicles for national statistics. The coverage of small goods vehicles in all reporting countries in 2007 under Council Regulation (EC) 1172/98 is summarised in a methodological report 's Table 1, p.90: http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-RA-08-009.

[51] Surveys are usually based on vehicles. The population of surveyed firms has been estimated internally by DG ESTAT, taking into account that it is very common that in the road freight sector there is a 1:1 ratio between vehicles and undertakings. However, the surveys concern also vehicles used in other economic sectors. We use the average value of the range, that is 400,000, as the basis for our quantification.

[52] See http://www.unece.org/trans/doc/2009/wp6/ECE-TRANS-WP6-2009-INF09e.pdf.

3.3.2 Council Directive 95/64/EC of 8 December 1995 on statistical returns in respect of carriage of goods and passengers by sea

Council Directive 95/64 is another act concerning statistics on transport. In particular, it deals with goods and passengers travelling by sea. Analogously to the previous Directive on transport of goods by road, it includes 1 IO: "Collection of statistics concerning carriage of goods and passenger by sea". According to our analysis, it imposes ACs amounting t €11.3mln, of which €6.7mln (59%) are considered ABs. Results of the quantification are summarized in Table 28.

Table 28 – Summary table for Directive 95/64

SUMMARY OF BASELINE ACTS			
Priority Area:	Statistics		
Act:	Council Directive 95/64/EC on statistical returns in respect of carriage of goods and passengers by sea		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Collection of statistics concerning carriage of goods and passengers by sea	€ 11,300,000	**€ 6,700,000**
	TOTAL	€ 11,300,000	**€ 6,700,000**

Council Directive 95/64/EC of 8 December 1995 on statistical returns in respect of carriage of goods and passengers by sea accounts for the smallest user requirements among the statistics on transport, and from a Danish point of view the compilation of the statistics could be discontinued. In the Netherlands, the estimated reduction potential was smaller than €1,000,000. In the UK, the estimated net cost was approximately €408,000 (£289,193), although this figure was corrected from a higher figure in an earlier version of the database (£666,000). The UK Main IO (DRID 1482 in the UK AB calculator) reads as follows (with BAU Factor = 41%):

"reporting in writing to the secretary of state information on the movement of cargo, passenger and vessels. This includes:

- gross weight of goods in tonnes loaded onto or unloaded from a vessel or vessels;
- type of cargo, according to the nomenclature shown in Annex II to the Directive;
- reporting port;
- direction of movement of vessel, whether inwards or outwards;
- number of movements of vessels;
- for inward cargo: the port of loading (i.e. the port in which the cargo was loaded on to the ship in which it arrived in the reporting port);
- for outward cargo: the port of unloading (i.e. the port in which the cargo is to be unloaded from the ship in which it left the reporting port);
- number of containers with cargo;

- number of containers without cargo; and
- the number of passengers embarking on and disembarking from a voyage."

In the Wifo-CEPS Third Progress Report, we already measured this act and reached an estimate in the range between €11.1 million (NL data, but very tentative) and €15.4 million (UK data) of administrative burdens. This is both an assessment of the overall cost generated by the regulation, and an assessment of the reduction potential, as the proposal was to discontinue this data collection. Given the change in the figure provided in the UK database, we have to update the calculation on the basis of the official result. This leaves us with an estimated administrative cost (based on the UK figures) of €11.3 million, of which €6.7 million are administrative burdens (BAU factor = 41%).

3.4 Priority Area: Transport

Within this area, we have to quantify ACs/ABs due to the following baseline acts and the reduction brought about by the related amending acts/amending proposals, if any:

1. Council Directive 96/35/EC on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway. The act has been repealed by Directive 2008/68/EC of the European Parliament and of the Council on the inland transport of dangerous goods;

2. Council Directive 94/57/EC on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administration. The act has been amended by:

    i. Directive 2009/15/EC of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations;

    ii. Regulation no. 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations (Recast);

3. Directive 2002/6/EC of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing form ports of the Member States of the Community. It is going to be repealed by COM(2009)11 Proposal for a Directive of the European Parliament and of the Council on reporting formalities for ships arriving in and/or departing from ports of the Member States of the Community and repealing Directive 2002/6/EC.

3.4.1 The legislative framework for transport of dangerous goods

Several European acts are devoted to the regulation of transport of dangerous goods, by either road, rail, or inland waterways. Directive 96/35 on safety advisers for the transport of dangerous goods is part of this acquis and is one of the baseline acts included in the Extension List to the Action Programme on Administrative Burdens.

According to the mapping by DG TREN, it includes one IO. An additional IO has been found by our analysis and is going to be measured as well. Globally, dir. 96/35 imposes ACs of €80mln, of which €60mln (75%) are considered ABs. Quantification of this baseline act is summarized in Table 29. Importantly, burdens partly arise from international agreements to which EU Member States adhere. Therefore, they are not entirely of EU origin. However, as we will show, the EU has a say about them through

the acts extending the applicability of the international conventions to the intra-Community shipments of dangerous goods.

Table 29 Summary table for Directive 96/35

SUMMARY OF BASELINE ACTS			
Priority Area:	Transport		
Act:	Council Directive 96/35/EC on the appointment and vocational qualifications of safety advisers for the transport of dangerous goods by road, rail, and inland waterway		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Annual report on the undertaking's activities in the transport of dangerous goods	€ 80,428,370	**€ 60,321,277**
IO 2	Reporting accidents	€ 109,210	**€ 27,302**
	TOTAL	€ 80,537,580	**€ 60,348,580**

The international transport of dangerous goods is regulated by international agreements, based on a common model regulation issued by the United Nations. In Europe, two of these agreements, ADR for transport via road and RID for transport via rail, are currently into force, while an agreement on transport by inland waterways (called AND) is undergoing the ratification process.

Transport within the Community was regulated by two framework directives, one for road transport and one for rail transport, and several other pieces of legislation, such as dir. 96/35. Through these acts, the provisions of ADR and RID were made binding also on internal shipments, with some differences and derogations.

In particular, dir. 96/35 requires undertakings carrying out the activity of transporting dangerous goods to have at their disposal one or more security advisers. He/she shall be in charge of helping to prevent the risks inherent in such activities. This provision is valid regardless whether the undertaking transports dangerous goods by road, rail, or inland waterways.

3.4.1.1 IO 1: Annual report on the undertaking's activities in the transport of dangerous goods

Two IOs are imposed on the safety advisers. One, as identified by DG TREN, arises from Annex I to the directive, stating that the safety adviser shall prepare an annual report to the management of the undertaking or a local public authority, on the undertaking's activities in the transport of dangerous goods. The report shall be preserved for five years and made available to the competent authorities at their request. According to DG TREN estimates, between 200,000 and 300,000 organizations are concerned by this provision. We use the medium value of the range, i.e. 250,000, as population figure for the quantification. As for cost per occurrence,

data are retrieved from the British database on AB. There, ADR is measured and the IO "Preparing an annual report on the carriage of dangerous goods which shall be kept for five years and made available to the national authorities at their request" is relevant for our quantification. According to data retrieved, in the UK this IO has a cost per occurrence equal to €426.68.[53] To extrapolate the EU average cost per occurrence, we have multiplied this data for the ratio between the EU average salary rate for a professional (€37.7) and the UK salary rate for a professional (€50). Therefore, the EU average cost per occurrence is estimated at €321.71. Since an estimated population of 250,000 organizations have to provide this report once a year, the estimated ACs amount to €80,428,370. As for the BAU factor, we apply a factor of 25%, since it is fair to assume that part of the data to be retrieved for the report would be recorded and kept anyway by the transport undertaking. Therefore, ABs are estimated at €60,321,277.

3.4.1.2 IO 2: Reporting accidents

As noticed through our analysis of the legal text, another IO is due to art. 7 of dir. 96/35, requiring that whenever an accident occurs during transport, loading or unloading carried out by the undertaking, and affects, or results in, damage to persons, property or the environment, the safety adviser shall prepare an accident report to the management of the undertaking or to a public authority, where appropriate.

A similar IO is measured in the UK database, under the name "Preparing an accident report to management or the public authority as appropriate regarding the following: - an accident affecting persons, property or the environment - or results in damage to property or the environment during carriage, loading or unloading". The cost per occurrence is €76.85. To extrapolate the EU average cost per occurrence, we have multiplied this data for the ratio between the EU average salary rate for a professional (€37.7) and the UK salary rate for a professional (€50). Therefore, the EU average cost per occurrence is estimated at €57.95. The population includes 49 undertakings, out of a total population of 6500 undertakings (retrieved from the previous British IO). Thus, it is assumed that there is, on average, 0.0075 accidents to be reported per undertaking per year, i.e. 0.75% of undertakings have an accident per year. We consider this ratio as reasonable, and apply it to the total European population. Accordingly, the number of occurrence is fixed at 1,885. Hence, total ACs amount to €109,210. The BAU factor is fixed at 75%, since it is reasonable to assume that the safety adviser would report to its management in any case. Therefore, ABs amount to €27,302.

[53] Since only ADR is measured, the cost per occurence concerns only transport of dangerous goods by road. However, there is no reason to believe that the costs of the annual reports are different for other transport modes.

3.4.1.3 The new directive on transport of dangerous goods: Directive 2008/68/EC

Directive 2008/68/EC on the inland transport of dangerous goods sets the new legislative framework for transport of dangerous goods, extending the scope of applicability of ADR, RID, and AND to intra-Community shipments. This is relevant to ensure consistency between national and international transport of dangerous goods. Furthermore, directive 2006/68/EC covers every transport mode. Differently, in the past transport of goods by road or by rail was regulated by two different legal texts and transport of goods by inland waterways was out of the scope of EU legislation. Another legislative simplification is due the repeal of dir. 96/35. The obligations therein included are now directly spelled out in the text of the international agreements.

The provisions concerning both IO 1 and 2 do not undergo any change, since the text of the international agreements imposes the same duties on safety advisers.[54] However, a reduction of ABs is due to the simplification of the legislative framework. As stated above, it is driven by two factors:

1. all duties for undertakings are now detailed only in the international agreements and not in different EU legal acts;

2. all the modes of transport of international goods are now consistently regulated.

The UK database provides us with data concerning the time spent with familiarizing with the legal rules, which is the step of the business process affected by a simplification of the legislative framework. As for IO 1, time spent for familiarization is 5.4% of total time spent to comply with it. As for IO 2, time spent for familiarization is 3.6% of total time spent to comply with it. Neither external nor equipment costs are relevant for both IOs, therefore these percentages also represent the percentage of internal costs spent by undertakings to comply with the IOs. We estimate that the new legislative framework will allow firms to save two thirds of ABs due to familiarizing with the legal requirements, that it 3.6% of ABs due to IO 1, and 2.4% of ABs due to IO 2. The reduction of ABs is summarized in Table 30.

[54] IO 1 can be found at section 1.8.3.3 and IO 2 at section 1.8.3.6 of ADR.

Table 30 Summary table for Directive 96/35 and Directive 2008/68

CHANGED IOs			
Priority Area	*Transport*		
Baseline Act	**Dir. 96/35**	Amending Acts	**Dir. 2008/68**
EU Info obligation	Annual report on the undertaking's activities in the transport of dangerous goods (Annex I)		
Obligation Type	2. Submission of (recurring) reports		
	QUANTIFICATION		
	Dir. 96/35		**Dir. 2008/68**
Frequency (per year)	1		1
Population	200,000 - 300,000		200,000 - 300,000
Administrative Costs	€ 80,428,370		*€ 78,256,804*
AdministrativeBurdens	**€ 60,321,277**		***€ 58,149,711***
AC Difference	**-€ 2,171,566**		**-2.7%**
AB Difference	**-€ 2,171,566**		**-3.6%**

CHANGED IOs			
Priority Area	*Transport*		
Baseline Act	**Dir. 96/35**	Amending Acts	**Dir. 2008/68**
EU Info obligation	Reporting accidens		
Obligation Type	2. Submission of (recurring) reports		
	QUANTIFICATION		
	Dir. 96/35		**Dir. 2008/68**
Frequency (per year)	on occasion		on occasion
Population*	1,885		1,885
Administrative Costs	€ 109,210		***€ 108,555***
AdministrativeBurdens	**€ 27,302**		***€ 26,647***
AC Difference	**-€ 655**		**-0.6%**
AB Difference	**-€ 655**		**-2.4%**

SUMMARY			
Priority Area	*Transport*		
Existing EU legislation	**Dir. 96/35**	Amending Act	**Dir. 2008/68**
	QUANTIFICATION		
	Dir. 96/35		**Dir. 2008/68**
Administrative Costs	€ 80,537,580		*€ 78,365,358*
Administrative Burdens	**€ 60,348,580**		***€ 58,176,358***
AC Difference	**-€ 2,172,221**		**-2.7%**
AB Difference	**-€ 2,172,221**		**-3.6%**

3.4.2 Council Directive 94/57 on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administrations

The Community legislator has long been convinced of the need for appropriate action to deal with the organisations, generally known as "classification societies", which

inspect ships and issue ships' certificates. Dir. 94/57 is the EU legislative act covering this area.

In terms of population, Directive 94/57 affects the 13 recognised classification societies in the EU[55]. According to the mapping process carried out by us and validated by DG TREN, which also provided useful comments on the draft version of this report[56], dir. 94/57 includes six IOs. It creates total administrative costs of €546,795 and administrative burdens of €452,812 (82.8%). IOs are listed in Table 31, and results of the quantification are summarized therein.

Table 31 – Summary Table for Dir. 94/57

SUMMARY OF BASELINE ACTS			
Priority Area:	Transport		
Act:	Council Directive 94/57/EC on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administrations		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Provision of periodical reports with essential information about their classed fleet, changes of	€ 220,184	**€ 154,129**
IO 2	Periodical audit by the administration or by an impartial external body appointed by the administration into the duties the organizations are undertaking on its behalf	€ 211,514	**€ 211,514**
IO 3	Cooperation in case of inspections	€ 98,175	**€ 73,631**
IO 4	Provision of periodic reports on fundamental progress in standards to the Commission	€ 16,923	**€ 13,538**
IO 5	Provision of information in case of class transfer	-	**-**
IO 6	Provision of information to obtain recognition	-	**-**
	TOTAL	€ 546,796	**€ 452,812**

We estimate the administrative burden related to the first four IOs, as IO n. 5 is likely to lead to a very low estimate, also due to a very high BAU factor; and IO n. 6 includes only one-off costs and affects a very limited population (it is unlikely that the list of recognised associations will be expanded significantly in the next years, and currently includes only 13 classification societies).

We assume that:

1) The average salary is the same as the average salary in the EU27 for "technicians and associate professionals" (€18.41);

2) The time needed to cooperate with administrations in case of inspections is 990 minutes;

[55] See http://www.emsa.europa.eu/end185d007d001d001.html. American Bureau of Shipping (ABS), Bureau Veritas (BV), China Classification Society (CCS), Det Norske Veritas (DNV), Germanisher Lloyd (GL), Hellenic Register of Shipping (HRS), Korean Register of Shipping (KR), Lloyd's Register of Shipping (LR), Nippon Kaiji Kyokai (NK), Polish Register of Shipping (PRS), Registro Italiano Navale (Rina), Registro Internacional Naval SA (Rinave), Russian Maritime Registry of Shipping (RS).

[56] DG TREN's comments focus especially on art. 10 of the new directive on survey organisations. Cf. paragraph 3.4.2.1.

3) The number of inspections per year to recognised organisations is 13 (EMSA organised 20, 13 and 10 inspections in 2006, 2007 and 2008 respectively)[57], times 23 (the 22 member states that have ports, plus EMSA), i.e. 299.

4) The time needed to issue a periodical report is 2400 minutes (one week of work), for retrieval of information, preparation, drafting and delivery;

5) The time needed to issue a periodical report with fundamental progress in standards is 600 minutes (10 hours) for retrieval of information, preparation, drafting and delivery;

6) The BAU factor is 25% for inspections, 20% for reports on standards and 30% for standard periodical reports.

7) An average audit costs €15,000.

8) Periodicity is yearly, and quarterly for reports on standards.

9) The population includes the 13 recognised organisations;

Detailed results are shown in Table 32.

Table 32 – Classification societies

IO No.	Total nbr of entities concerned	Population	Frequency	Time	Price	Ext cost	BAU	Administrative cost	Administrative burden
1	need to provide periodical reports with essential information about their classed fleet, changes of class or declassing of vessels;	13	23	2400	€18.41	€ 0	30%	€220,184	€154,129
2	provisions for a periodical audit by the administration or by an impartial external body appointed by the administration into the duties the organizations are undertaking on its behalf.	13	23	180	€18.41	€ 15,000	0%	€211,514	€211,514
3	need to cooperate with the administration in case of random inspections;	13	23	990	€18.41	€ 565	25%	€98,175	€73,631
4	obligation to provide the Commission with periodic reports on fundamental progress in standards.	13	4	600	€18.41	€ 565	20%	€16,923	€13,538
Total old								**€ 546,795**	**€ 452,812**

A different issue would be if the burdens to be measured were related to the information that ship owners and manufacturers have to provide to the classification societies, for them to report to national administrations. But these IOs cannot be directly attributed to Directive 94/57, and would be at best indirect IOs. In order to estimate them, we would need to have more data on the frequency of inspections, on the periodicity of reports according to national agreements, etc.

[57] https://extranet.emsa.europa.eu/index.php?option=com_docman&Itemid=113&task=doc_download&gid=525.

3.4.2.1 The new legal framework for ship inspections and survey organisations

Dir. 94/57 has been repealed and recasted by two acts recently approved: (i) directive 2009/15/EC of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations; and (ii) Regulation no. 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations (Recast).

In its Erika I Communication, the Commission seriously asked whether the classification system as a whole made sufficient effort to attain the standards required. The existing system no longer suffices and was to be further improved in order to separate the good operators from the bad, to remedy the shortcomings in a proportionate but effective manner, and to exclude from the system those who do not comply with it.

As a response to these concerns, these acts are intended to reform the present system for the recognition of classification societies by the Community established by Directive 94/57/EC (OJ L 319, 12.12.1994, p. 20), and especially to:

1. strengthen the control systems of recognized organizations;
2. harmonise the current dual system of ordinary and limited recognition;
3. simplify and improve the structure of the Community recognition criteria;
4. reform the system of penalties;
5. clarify the scope and facilitate the application of certain provisions of the Directive.

These acts modify only one of the IOs included in dir. 94/57, that is IO n. 6. Under the new legal framework, IO 6 includes the need to provide an independent audit certificate. Since it has not been possible to measure IO 6, we could not even provide an estimate of this new DR. Therefore, according to our analysis the amending acts have no measurable effects on ACs/ABs. Results are summarized in Table 33.

However, the main advantage for maritime undertakings due to the new legal framework could not be taken into consideration in this measurement exercise. When validating the comparative mapping, DG TREN pointed out, in particular, that art. 10.1 of reg. 391/2009 provides for mutual recognition of class certificates and of certificates on marine equipment bearing the wheel mark. According to the information provided to us by DG TREN as a feedback to our mapping analysis, the maritime industry has estimated that this new provision will lead to a saving of €500mln-€1bln. However, as explained above, we focus only on IOs directly imposed by dir. 94/57 on classification societies, and not on ship owners or manufacturers. For this reason, it is not possible to directly attribute this saving to reg. 391/2009, although this is a very relevant simplification measures. We agree with DG TREN's opinion that a study of this indirect

benefits should be done via a dedicated and larger study and that it is out of the scope of this burden measurement exercise.

Table 33 – Summary table for Directive 94/57, Directive 2009/15, and Regulation 391/2009

SUMMARY			
Priority Area	*Transport*		
Existing EU legislation	**Dir. 94/57**	Amending Act	**Dir. 2009/15** **Reg. 391/2009**
	QUANTIFICATION		
	Dir. 94/57	**Dir. 2009/15 & Reg. 391/2009**	
Administrative Costs* **Administrative Burdens***	€ 546,796 **€ 452,812**	*€ 546,796* ***€ 452,812***	
AC Difference	**€ 0**	**0.0%**	
AB Difference	**€ 0**	**0.0%**	

* Not including variation due to IO 6

3.4.3 Directive 2002/6/EC on maritime transport: formalities for ships arriving in and departing from Community ports

Dir. 2002/6 deals with the formalities required to ships entering into or leaving from Community ports. In this context, we have been asked to quantify the burden generated by two IOs:

1) IO 1: "Reporting formalities for ships arriving in or departing from ports of the European Community". For this reporting formalities, Member States have to use a series of forms standardised by the IMO (International Maritime Organisation)'s FAL, and in particular

   i. IMO FAL form 1, general declaration - The general declaration shall be the basic document on arrival and departure providing information required by the authorities of a Member State relating to the ship.

   ii. IMO FAL form 3, ship's stores declaration – The ship's stores declaration shall be the basic document on arrival and departure providing information required by the authorities of a Member State relating to a ship's stores.

   iii. IMO FAL form 4, crew's effects declaration – The crew's effects declaration shall be the basic document providing information required by the authorities of a Member State relating to the crew's effects. It shall not be required on departure.

   iv. IMO FAL form 5, crew list – The crew list shall be the basic document providing the authorities of a Member State with the information relating to the number and composition of the crew on the arrival and departure of a ship. Where the authorities require information about the crew of a ship on its departure, a copy of the crew list, presented on arrival, shall be accepted

on departure if signed again and endorsed to indicate any change in the number or composition of the crew or to indicate that no such change has occurred.

v. IMO FAL form 6, passenger list – For ships certified to carry 12 passengers or fewer, the passenger list shall be the basic document providing the authorities of a Member State with information relating to passengers on the arrival and departure of a ship.

2) "Collection of security information prior to a ship's arrival into the port". The burden is imposed by the fact that Member States impose different rules on ships concerning security information collected prior to their entry into the port of another EU Member State.

According to our analysis, ACs imposed by these two IOs (which have been measured jointly) amount to €745mln, of which €559mln (75%) are considered ABs. Results are summarized in Table 34.

Table 34 – Summary table for Directive 2002/6

SUMMARY OF BASELINE ACTS			
Priority Area:	Transport		
Act:	Directive 2002/6/EC of the European Parliament and of the Council of 18 February 2002 on reporting formalities for ships arriving in and/or departing from ports of the Member States of the Community		
INFORMATION OBLIGATION		**AC**	**AB**
IO 1	Reporting formalities for ships arriving in or departing from ports of the European Community	€ 744,700,000	**€ 558,525,000**
IO 2	Collection of security information prior to a ship's arrival into the port		
	TOTAL	€ 744,700,000	**€ 558,525,000**

Formalities applicable to intra-EU maritime transport depend on each port. In general, the main Authorities collecting information from the ships are: (i) harbor-masters in ports; (ii) customs in port; and (iii) vessel traffic services controlling ships traffic along the coasts. The Commission reported that three main representatives of the ships are involved in the procedures, reporting activities and possible checks on crew and passengers: (i) shipmasters; (ii) ship agents; and (iii) ship operators (owners or carriers). All the procedures could be divided into three main areas: (i) ship reporting documents (usually related to port authority); (ii) declaration and clearance of cargo (usually related to customs); and (iii) routine checks or inspection.

Costs for administrative formalities depend on the time spent preparing and carrying out specific procedures in port: document related and full-time-equivalent related procedures ("vessel side" and "port side") and the possible delays of vessels or goods due to specific inspections and/or procedures. The following table summarises the total

man-hours (considering an average, best-case and worst-case scenario) required to carry out the various procedures for all entities/counterparts[58].

Time involved for procedures on standard goods (man-hours per call) Source PwC Enquiry 2007

	Proc. related to goods	Proc. related to vessels	Total
Average time for the document preparation	2.5-3.0	3-3.5	6-6.5
Average time carrying out the procedures in port	2.0-2.5	4.5-5.0	6.5-7.0
Average time for carrying out the procedures	5.0-5.5	7.5-8.0	13.0-13.5

According to the assumption on personnel costs, the average personnel cost related to all the administrative procedures could be fixed at around € 288 per port call. The number of vessel calling to the main EU27 ports (excluding Italian posts) reported by Eurostat for 2007 was 1,659,110[59]. A quick calculation would thus indicate that the personnel cost for performing these formalities amounts to €643.7 million, which become €744.7 million by extrapolating to the whole Eu27, including Italy[60]. On the basis of the IOs measured in the UK database on AB reported below, we apply a BAU factor of 25%, therefore the ABs originating form these formalities amount to €558.5 million.

3.4.3.1 COM(2009)11 reforming ship formalities

In the proposed reform of the European Maritime Transport Space without Barriers, the Commission services have assessed the main administrative and documentary procedures in Short Sea Shipping with a view to simplifying, reducing or, when possible, eliminating them for transport operations between two EU ports. The repeal of Directive 2002/6 and the proposed Directive on the formalities of ships arriving in and departing from MS ports aim at reducing delays in maritime transport and reduce the burden for businesses.

Current proposals to simplify shipping formalities are:

1) the possibility of exempting ships falling within the scope of Dir 2002/59 and moving between ports situated within the European Community's customs

[58] See Commission Impact Assessment and external PwC study.

[59] http://bookshop.europa.eu/eubookshop/download.action?fileName=KSSF09006ENC_002.pdf&eubphfUid=10053436&catalogNbr=KS-SF-09-006-EN-C.

[60] Extrapolation based on the Italy's share in 2006 on gross weight of seaborne goods handled in all ports (in million tonnes), ibidem, Table 1.

territory from the obligation to send the FAL forms referred to in Directive 2002/6, provided that the goods are presumed to have Community status[61].

2) The possibility of sending the information electronically to a single competent authority nominated by the Member States, via the SafeSeaNet system, as soon as possible and by 15 February 2013 at the latest[62].

The Commission's impact assessment, based on a PwC study, estimated that the amending proposal would lead to a total decrease of €2.4bln in administrative burdens (including also burdens due to sanitary and phytosanitary measures and others not directly attributable to dir. 2002/6). As regards the specific IOs at hand, the Commission estimates a reduction of approximately €75 million.

An estimate of the time needed to comply with the IOs at hand, i.e. to deal with the IMO FAL forms, could be derived from the UK database. There, especially in the Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended), the following IOs can be found:

- General declaration: Notifying the port of departure takes 15 minutes per occurrence (notifying the port authorities of the port of departure. With the following information: - ship identification (name, call sign, IMO identification number or MMSI number); - port of destination; - for a ship leaving a port in a Member State: estimated time of departure from the port of departure or pilot station, as required by the competent authority, and estimated time of arrival at the port of destination; - for a ship coming from a port located outside the Community and bound for a port in a Member State: estimated time of arrival at the port of destination or pilot station, as required by the competent authority; total number of persons on board. - and additional Cargo information, such as: the correct technical names of the dangerous or polluting goods, the United Nations (UN) numbers where they exist etc.); The same time is attached to notifying the port of arrival. The IDs in the UK database are 6041 and 6115. The BAU factor for both is 18%. However, notifying local authorities when the ship is coming from (or bound to) a non-EEA port takes 22 minutes, i.e. 7 minutes more.
- Crew and passenger list: Producing a list of all persons on board ship and taking copies of official log-books or other such documents (UK ID 37174, corresponding to Section 257(2)(b) of the Merchant Shipping Act 1995) takes 5 hours per occurrence and has a BAU factor of 32.4%.

Table 35 below shows our calculation from the UK database, based on Eurostat data on the number of ships calling at ports in the Eu27.

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[61] Remark: Directive 2002/59/E mandates that all vessels carrying freight above 300 gross tonnage are equipped with AIS. "Ships falling within the scope of Directive 2002/59/EC and moving between ports situated in the European Community's customs territory, but which do not come from, call in or are headed towards a port situated outside that territory or a free zone subject to type I controls under customs legislation shall be exempt from the obligation to send the information referred to in the FAL forms, without prejudice to the applicable Community legislation."

[62] Date on which the provisions of Decision No 70/2008/EC on a paperless environment for customs and trade are to enter into force.

Table 35 – Extrapolation from UK database on Ship formalities

Dept	Regulation	Activity	Description	AB
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the port authorities of the port of departure. With the following information: - ship ide...	£104,014
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the competent authority of an EEA State with the information where a UK ship is coming fro...	£28,144
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the 'competent authority' of a port located in an European Economic Area State (...	£28,144
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Cooperating with audits/inspections	providing, upon request, specified voyage information in an electronic format for the Maritime and C...	£2,259
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the port of destination with information: Including; - ship identification (name, call sig...	£88,619
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the Maritime and Coastguard Authority before a ship departs. Including the following; - s...	£80,922
DfT	Merchant Shipping (Vessel Traffic Monitoring and Reporting Regulations) Regulations 2004 (as amended)	Notification of activities	notifying the UK authorities of the following information relating to a ship which is not coming fro...	£46,907
DfT	Merchant Shipping Act 1995	Keeping records	maintaining an official log book in a form approved by the Secretary of State on every UK ship	£138,823
Total				**£517,832**
Extrapolation to EU27 (pounds)				**£9,415,127**
Extrapolation to EU27 (Euros)				**€ 13,290,394**

Overall, these IOs generate a total administrative of €13.3 million. No information could be retrieved from the other three FAL forms, that is those on ship's stores and crew effects. This partial calculation, being of the same order of magnitude of the Commission's estimates, suggests that the expected €75 million of ABs saved by eliminating the requirement to file the FAL forms is reasonable. We therefore consider it as the probable AB reduction due to COM(2009)11.

Results of the quantification of the amending proposal is summarized in Table 36.

Table 36 – Summary Table for dir. 2002/6 and COM(2009)11

SUMMARY			
Priority Area	*Transport*		
Existing EU legislation	**Dir. 2002/6**	Amending Acts	**COM(2009)11**
	QUANTIFICATION		
	Dir. 2002/6		**0**
Administrative Costs	€ 744,700,000		*€ 644,700,000*
Administrative Burdens	**€ 558,525,000**		***€ 483,525,000***
AC Difference	**-€ 100,000,000**		**-13.4%**
AB Difference	**-€ 75,000,000**		**-13.4%**

4 ESTIMATING THE REDUCTION OF ABS: OTHER ACTS INCLUDED IN THE SECTORAL REDUCTION PLANS

4.1 Priority Area: Cohesion Policy

Within this area, we have to quantify the reduction of ACs/ABs due to the following amending acts:

1. Regulation (EC) No 396/2009 of the European Parliament and of the Council amending Regulation (EC) No 1081/2006 on the European Social Fund to extend the types of costs eligible for a contribution from the ESF;
2. Regulation (EC) No 397/2009 of the European Parliament and of the Council amending Regulation (EC) No 1080/2006 on the European Regional Development Fund as regards the eligibility of energy efficiency and renewable energy investments in housing;
3. Commission Regulation (EC) No 846/2009 of 1 September 2009 amending Regulation (EC) No 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund.

All these acts are going to affect, directly or indirectly, burdens generated by Council Regulation 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) 1260/1999. This act has already been measured by us in our previous reports, Council Regulation (EC) No 1260/1999 laying down general provisions on the Structural Funds is one of the baseline act measured by the Consortium.

In Table 37 below, ACs/ABs measured by the Consortium for reg. 1260/1999 are reported. On the basis of our analysis, we have estimated that reg. 1083/2006, which is currently in force, creates the same IOs and impose the same ACs/ABs as reg. 1260/1999. This has been confirmed by the opinion of DG REGIO, stating that most of the reforms included in reg. 1083/2006 aims at improving the relationship between the Commission and national/local authorities in charge of managing the European funds. The effects on ACs/ABs imposed on beneficiaries would therefore be indirect and not very relevant.

The problem of "indirectness" is a common feature of all the measures in the the Priority Area "Cohesion Policy". The great part of the European legislation has a direct impact on national/local authorities managing the programmes, rather than on beneficiaries. Estimating the impact on beneficiaries on the basis of norms which regulate the relationship between the Commission and national/local authorities is

quite hard. This exercise is even harder because the present is based only on EU legal texts, and not on direct measurement.

In addition, other hindrances make quantifications in this Priority Area particularly difficult. The Consortium reports and database provide information about the programming period "2000-2006", but we are going to measure amendments applicable to the programming period "2007-2013". Even though we have assumed, that costs and burdens remain more or less the same, and DG REGIO has agreed on it, this assumption adds a further layer of uncertainty. Importantly, data collected by the Consortium concerned not only burdens on undertakings, but also on NGOs and (semi)public authorities. Nevertheless, it is not possible to disentangle the effects on the different groups. Furthermore, in this priority area data are not always easily retrievable, since in most cases they are scattered among more than 400 national/local authorities.

For these reasons, we would like to stress that quantifications in this Priority Area are likely to enjoy a higher degree of approximation than in others. We would recommend further research, based on direct contacts with and survey of the beneficiaries, possibly better focusing on burdens imposed over undertakings.

Table 37 – Summary Table for reg. 1260/1999 and 1083/2006

SUMMARY OF BASELINE ACTS			
Priority Area:	Cohesion Policy		
Baseline Act:	Council Regulation (EC) No 1260/1999 laying down general provisions on the Structural Funds		
(analoguesly):	Council Regulation 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) 1260/1999		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Financial Control on Final Beneficiaries by the Member States	€ 132,136,261	€ 132,136,261
IO 2	Financial Control on Final Beneficiaries by the European Commission	€ 5,421,659	€ 5,421,659
IO 3	Intermediate Payment Request	€ 98,198,997	€ 98,198,997
IO 4	Final Payment Request	€ 34,892,057	€ 34,892,057
IO 5	Submitting Information needed by Management Authorities to draft Annual Implementation/Final Report	€ 585,991,709	€ 585,991,709
IO 6	Information and Publicity	€ 65,993,328	€ 65,993,328
	TOTAL	€ 922,634,011	**€ 922,634,011**

During our meetings with DG REGIO, we have received several comments about the amount of ACs/ABs measured by the Consortium, namely about IO 5. Several officers were concerned by its excessive high burdensomeness relatively to other IOs. In particular, it has been suggested that its burdensomeness could be justified only assuming that IO 5 covers the whole flux of information submitted on a continuous basis by beneficiaries to managing authorities, not only related to annual/final reports.

In any case, correcting drastically the Consortium's approach is out of the scope of this report, therefore we have to work on the basis of the present baseline measurement.

4.1.1 Regulations 396/2009 and 397/2009

Regulations 396/2009 and 397/2009 are part of the "recovery plan" adopted by the Commission in November 2008 and aimed at encouraging the effective, efficient and fast uptake of available European resources.

Regulation 396/2009 focuses on projects funded under the European Social Fund (ESF). Regulation 397/2009 focuses on projects funded under the European Regional Development Fund (ERDF). Both regulations add new methods, or extend the application of existing methods, to calculate eligible costs in case of grants.[63] These methods are:

1) Flat-rate basis to calculate indirect costs. If this option is chosen, indirect costs are calculated on the basis of a flat-rate up to 20%. Consequently, beneficiaries must keep and/or submit supporting accounting documents only for direct costs, while this is no longer required for indirect costs;

2) Standard scale of unit costs. If this option is chosen, payments are based on quantified activities, outputs or outcomes multiplied by standard scale of unit costs. Consequently, beneficiaries must not keep and/or submit supporting accounting documents, but only have to show proof of the activities/outputs/outcomes;

3) Lump sums. Lump sums may cover all or parts of the costs of an operation, up to a cap of €50,000. In this case, beneficiaries must only proof that they have fulfilled the condition stated in the grant, without having to explicitly certify eligible expenditures. Activities/outputs/outcomes are verified through a "yes/no" approach.

These options are going to reduce ABs/ACs due to the IOs concerning final controls and requests for payments, therefore to IOs 1, 2, 3 and 4 reported in Table 37. Their application is retroactive, that both regulations have effect from 1st of August 2006.

Significantly, the implementation of these new provisions is up to the national/local management authorities. However, when a Community act gives the Member States the opportunity to alleviate burdens, these burdens are considered as eliminated from an EU point of view. If Member States do not fully implement Community acts, burdens can no longer be considered of EU origin, but of national, thus reducing total EU burdens.[64]

[63] The main aim of reg. 397/2007 is to make certain expenditures on energy efficiency improvements eligible also in old EU Member States, but this provision has no effect on ACs/ABs.

[64] Only burdens of EU origin fall within the scope of this measurement exercise.

To estimate the impact of these regulations, both the number of projects potentially subject to them, and the reduction in terms of cost per occurrence compared to the old population must be estimated.

Unfortunately, detailed data on the number of projects funded by either the ESF or by the ERDF are not available. Furthermore, information concerning the average amount of a project would also be necessary, since, as clearly stated in the Consortium's report, the amount of ACs/ABs is linked also to the dimension of the projects.

As a proxy, the amount of financial resources allocated through the ESF and ERDF is used. As for the former, DG REGIO has reported to us that the total amount of resources allocated through the ESF is €75,593mln for the period 2007-2013. As for the latter, resources allocated through the ERDF amount to €198,775mln. Total resources allocated for the programming period 2007-2013 amount to 344,349mln, including also the Cohesion Fund. Amounts are detailed in Table 38.

Table 38 – Amount of expenditures related to reg. 396/2009 and reg. 397/2009

Act	Eligible Expenditure	Amount (€ mln)	% on total resources
Reg. 396/2009	European Social Fund	€ 75,953	22.1%
Reg. 397/2009	European Regional Development Fund	€ 198,775	57.7%

In total, reg. 396 and 397 potentially touch upon 79.8% of funds allocated by the European Union via structural funds. It has to be taken into account that the present regulations affect only projects funded via grants. According to DG REGIO's assessment, roughly 90% of resources are distributed via grants. However, not all grant-funded projects may be eligible for the simplifying options included in regulations 396 and 397, and the impact of these regulations may vary on the basis of the features of the projects.[65]

On the basis of consultation with DG REGIO and DG EMPL, it has been estimated that about 75% of operations funded by the ESF and 30% of operations funded by ERDF may benefit from regulations 396 and 397. Different reasons underline the difference between ESF and ERDF:

[65] Importantly, if a project has already been approved, it will have to stick to the previous rules. Although regulations 396 and 397 are retroactive, costs eligible under the three simplifying options shall be established in advance. Furthermore, not all beneficiaries may resort to the new options for several reasons: they expect to receive more funds under the old regime; the reduction of ACs/ABs is so low as to be negligible; or they are used to the old regime. However, if a managing authority decides to apply one or more simplifying options, beneficiaries have to adopt the new methods.

1) the simplifications were created specifically for ESF, which would have benefited most, and then extended also to ERDF. ESF grants are fitter than ERDF grants to benefit from this simplification;

2) in ESF grants, the bulk of expenditures is linked to human resources and operating costs, whilst in ERDF grants the amount of expenditures linked to capital and investment costs is prevailing. Benefits due to the present regulations are much higher in the former case, therefore it is likely that more ESF managing authorities and beneficiaries will opt for one or more of the simplifying options.

On the basis of this assessment, we estimate that 33.8% of resources allocated under reg. 1083/2006 may benefit from simplifications due to the present regulations, of which 16.5% under ESF grants (22.1% X 75%), and 17.3% under ERDF grants (57.7% X 30%).

As for the cost per occurrence, the impact of regulations 396/2009 and 397/2009 is estimated on the basis of our expert assessment. Very few data could be retrieved. E.g., the ESF management department of the Czech Ministry of Labour and Social Affairs has reported that 73% of invoices attached to payment claims concerned indirect costs.

On the basis of this hint, and of the opinion of several DG REGIO and DG EMPL officers, we expect the reduction of burdens to be very significant. If beneficiaries apply for one or more of the three options introduced by the new regulations, they shall produce and keep a considerably lower number of accounting documents, both to comply with periodical audits, and to show proofs of expenditures when requesting payments.

The real impact on beneficiaries may vary significantly on a case-to-case basis. Furthermore, the different options will not lead to the same level of savings. Employing options 2 or 3 is going to reduce burdens more than employing option 1. On average, we tentatively estimate that the cost per occurrence of IOs 1, 2, 3 and 4 is reduced by half for projects falling within the scope of regulations 396 and 397.

On the basis of these data and assumptions, we estimate that regulations 396/2009 and 397/2009 reduce ACs/ABs due to the 4 IOs concerned by 16.9% (33.8% X 50%). Consistently with the methodology adopted, these savings are to be attributed to the two regulations proportionally to the amounts of resources concerned by the amending regulations. Total results, summarized in Table 39, can be low compared to the extent of the simplification described above. However, as already highlighted, most of ACs/ABs due to reg. 1083/2006 have been attributed by Consortium to the IO 5 "Submitting Information needed by Management Authorities to draft Annual Implementation/Final Report". After consultation with DG REGIO's experts, we expect regulations 396 and 397 not to significantly affect ACs/ABs due to it,[66] although they

[66] This is not exactly true. Since audits will concern activities/outputs/outcomes, the data necessary to draft annual and final implementation reports are likely not to have to be submitted to the managing authorities again. However, this is not going to further reduce burdens, but to switch them from IO 5 to IOs 1 and 2.

will improve the quality of the information provided, and consequently the quality of the reports prepared by the managing authorities.

Table 39 – Summary table for reg. 396/2009 and reg. 397/2009

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 396/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the Member States		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 396/2009**
Frequency (per year)	on occasion		on occasion
Population	82,504		82,504
Administrative Costs	€ 132,136,261		*€ 121,206,784*
Administrative Burdens	**€ 132,136,261**		***€ 121,206,784***
AC Difference	**-€ 10,929,477**		**-8.3%**
AB Difference	**-€ 10,929,477**		**-8.3%**

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 396/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the European Commission		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 396/2009**
Frequency (per year)	on occasion		on occasion
Population	6,168		6,168
Administrative Costs	€ 5,421,659		*€ 4,973,214*
Administrative Burdens	**€ 5,421,659**		***€ 4,973,214***
AC Difference	**-€ 448,445**		**-8.3%**
AB Difference	**-€ 448,445**		**-8.3%**

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 396/2009**
EU Info obligation	Intermediate Payment Request		
Obligation Type	11. Application for subsidy or grant		
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 396/2009**
Frequency (per year)	on occasion (depending on the project schedule)		on occasion (depending on the project schedule)
Population	116,660		116,660
Administrative Costs	€ 98,198,997		*€ 90,076,596*
Administrative Burdens	**€ 98,198,997**		***€ 90,076,596***
AC Difference	**-€ 8,122,401**		**-8.3%**
AB Difference	**-€ 8,122,401**		**-8.3%**

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 396/2009**
EU Info obligation	Final Payment Request		
Obligation Type	11. Application for subsidy or grant		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 396/2009**	
Frequency (per year)	on occasion (depending on the	on occasion (depending on the	
Population	111,473	111,473	
Administrative Costs	€ 34,892,057	*€ 32,006,006*	
Administrative Burdens	**€ 34,892,057**	***€ 32,006,006***	
AC Difference	**-€ 2,886,051**	**-8.3%**	
AB Difference	**-€ 2,886,051**	**-8.3%**	

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 397/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the Member States		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 397/2009**	
Frequency (per year)	on occasion	on occasion	
Population	82,504	82,504	
Administrative Costs	€ 132,136,261	*€ 120,694,939*	
Administrative Burdens	**€ 132,136,261**	***€ 120,694,939***	
AC Difference	**-€ 11,441,322**	**-8.7%**	
AB Difference	**-€ 11,441,322**	**-8.7%**	

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 397/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the European Commission		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 397/2009**	
Frequency (per year)	on occasion	on occasion	
Population	6,168	6,168	
Administrative Costs	€ 5,421,659	*€ 4,952,212*	
Administrative Burdens	**€ 5,421,659**	***€ 4,952,212***	
AC Difference	**-€ 469,447**	**-8.7%**	
AB Difference	**-€ 469,447**	**-8.7%**	

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 397/2009**
EU Info obligation	Intermediate Payment Request		
Obligation Type	11. Application for subsidy or grant		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 397/2009**	
Frequency (per year)	on occasion (depending on the	on occasion (depending on the	
Population	116,660	116,660	
Administrative Costs	€ 98,198,997	*€ 89,696,211*	
Administrative Burdens	**€ 98,198,997**	***€ 89,696,211***	
AC Difference	**-€ 8,502,786**	**-8.7%**	
AB Difference	**-€ 8,502,786**	**-8.7%**	

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 397/2009**
EU Info obligation	Final Payment Request		
Obligation Type	11. Application for subsidy or grant		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 397/2009**	
Frequency (per year)	on occasion (depending on the	on occasion (depending on the	
Population	111,473	111,473	
Administrative Costs	€ 34,892,057	*€ 31,870,848*	
Administrative Burdens	**€ 34,892,057**	***€ 31,870,848***	
AC Difference	**-€ 3,021,209**	**-8.7%**	
AB Difference	**-€ 3,021,209**	**-8.7%**	

SUMMARY			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 396/2009** **Reg. 397/2009**
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 396/2009 and 397/2009**	
Administrative Costs	€ 922,634,000	€ 876,812,862	
Administrative Burdens	**€ 922,634,000**	**€ 876,812,862**	
AC Difference	**-€ 45,821,138**	**-5.0%**	
AB Difference	**-€ 45,821,138**	**-5.0%**	

Reduction by act	Administrative Costs	Administrative Burdens
Reg. 396/2009	-€ 22,386,374	-€ 22,386,374
Reg. 397/2009	-€ 23,434,764	-€ 23,434,764

4.1.2 Commission Regulation 846/2009

The Commission has just adopted a Regulation to amend the implementing act of regulations 1083/2006 and 1080/2006, i.e. Commission Regulation 1828/2006. As reported in the accompanying communication attached to the proposal, reg. 846/2009 deals with many different aspects of the implementation of Cohesion Policies, namely: i) information and publicity; ii) management and audit issues; iii) financial engineering instruments; iv) eligibility issues; v) financial issues; vi) information in annual and final reports; vii) information on major projects.

Issues i) and iii) have a direct impact on beneficiaries. Other issues focus on the relationship between managing and audit authorities and the Commission, therefore have no direct impact on ACs/ABs. However, on the basis of the information provided by DG REGIO, issue vi) is supposed to have a reduction effect on ACs/ABs as well. These three issues are analysed in depth in the paragraphs below.[67]

4.1.2.1 Information and Publicity

The burdens arising from the duties concerning information and publicity have been measured by the Consortium under the IO "Information and Publicity". It is estimated to impose ACs/ABs of €66mln. The Consortium report includes very few information on this IO, and focuses specifically on managing authorities' duties to inform possible beneficiaries, and the public opinion, about European Funds.

Reg. 1828/2006 states clearly what the obligations on beneficiaries are as far as information and publicity are concerned. Art. 8 makes the beneficiary responsible for informing the public about the assistance obtained from the Funds, and specifies the detailed criteria to be complied with. Namely, the beneficiary shall put up a permanent explanatory plaque when i) the total public contribution exceeds €500,000; and ii) the operation consists in the purchase of a physical object, and/or in the financing of infrastructures or construction operations. As for funding of infrastructures or construction operations over the threshold of €500,000, a billboard shall be displayed on site during the implementation of the operation. Finally, the contribution of each EU fund must be clearly distinguished. Art. 8 and 9 provide for the mandatory elements of plaques and billboards: type and name of the operation; the emblem of the European Union; reference to the Fund(s) concerned; and a motto.

Reg. 846/2009 aims at making the duties of information and publicity more flexible. Two main changes have been introduced:

1) if it is not possible to place a permanent plaque on physical objects, other appropriate measures shall be taken for publicity purposes;

[67] Actually, the new provisions for major projects may have a beneficial impact on ACs/ABs as well. However, the number of major projects is 900, that is a very tiny minority of the total number of projects. Therefore, this simplification is estimated to have a neglibile effect on ACs/ABs.

2) if an operation is financed by more than one Fund, no reference to each Fund concerned must be included in the plaques or billboards.

Item 2 is likely to exert a rather marginal effect, whilst item 1 a more relevant. To precisely estimate the latter, we should take into account that permanent plaques are used only in case of projects where physical objects are bought, or infrastructure or other constructions operations are financed. These projects represent only a part, though quite large at least for ERDF, of the total number of EU-funded projects. Then, the simplification measure concerns only a sub-group of projects, i.e. those including only purchases of physical objects (and not infrastructures or construction operations) on which it is not possible to place a permanent plaque. For these projects, simplification is quite relevant, but reg. 846/2009 does not provide benefits for the rest. We expect that the number of projects effectively concerned by this simplifying measure is quite low compared to the total number of projects.

Missing more precise data, we carry out a rather tentative assessment. Combining a rather low number of projects benefitting from reg. 846/2009, and a quite high reduction in their cost per occurrence, we expect that reg. 846/2009 reduces the ACs/ABs due to IO "Information and Publicity" by few percentage points. We consider appropriate to approximately fix the amount of ACs/ABs reduced at 4%, i.e. €2,639,733. Results are summarized in Table 40.

Table 40 – Summary Table for Reg. 846/2009 – Information and Publicity

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 846/2009**
EU Info obligation	Information and Publicity		
Obligation Type	04. Non-labelling information for third parties		
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 846/2009**
Frequency (per year)	on occasion		on occasion
Population	170,763		170,763
Administrative Costs	€ 65,993,328		*€ 63,353,595*
Administrative Burdens	**€ 65,993,328**		***€ 63,353,595***
AC Difference	**-€ 2,639,733**		**-4.0%**
AB Difference	**-€ 2,639,733**		**-4.0%**

4.1.2.2 Financial engineering

The term "financial engineering" refers to the instruments regulated by art. 44 of reg. 1083/2006, aimed at enabling an efficient and sustainable use of Structural Funds in the 2007-13 period. Reg. 1083/2006 aims at making these financial instruments available also for subjects and/or projects which usually do not have access to them,

namely medium and small enterprises and projects linked to sustainable urban development.[68]

More specifically, art.44 of reg. 1083/2006 states that

> the Structural Funds may finance expenditure in respect of an operation comprising contributions to support financial engineering instruments for enterprises, primarily small and medium-sized ones, such as venture capital funds, guarantee funds and loan funds, and for urban development funds, that is, funds investing in public-private partnerships and other projects included in an integrated plan for sustainable urban development.

The Commission has launched four initiatives to help enterprises and other subjects to have access to financial engineering tools. These initiatives are:

1) JEREMIE (Joint European Resources for Micro to Medium Enterprises), enhancing the access of small and medium-sized enterprises (SMEs) to finance. Products include equity, venture capital, guarantees, loans and technical assistance, allowing a multiplier effect of the EU funds by using revolving financial products instead of grants;

2) JESSICA (Joint European Support for Sustainable Investment in City Areas), aiming at promoting sustainable investment in urban projects and programmes;

3) JASPERS (Joint Assistance in Supporting Projects in European Regions), a technical assistance facility to prepare major projects in the new Member States;

4) JASMINE (Joint Action to Support Micro-finance Institutions in Europe), seeking to improve access to finance for small businesses and for socially excluded people, also ethnic minorities, who want to become self-employed. The action aims at making small loans, or micro-credit, more widely available in Europe to satisfy unmet demand.

DG REGIO has provided information concerning the amount of financial resources employed by some of these initiatives. Under JEREMIE initiative, €2,900mln have been allocated to holding funds in 13 Member States. Under JESSICA initiative, 7 agreements in 6 Member States have been signed; and resources allocated to holding funds amount to about €614mln.[69] Resources allocated to holding funds are multiplied because of the leverage effect. The European Investment Fund allows for a leverage effect of 10, but DG REGIO has reported to us that the average leverage is 5. Therefore, total resources distributed through financial engineering instruments amount to €17,570mln.

Financial engineering instruments are regulated in details by articles 43-46 of reg. 1828/2006. As for administrative burdens, attention is focused on art. 43.2, stating that a business plan shall be submitted by the co-financing partners or shareholders of a financial engineering instrument and listing the mandatory elements to be included

[68] Cf. recital (41) of reg. 1083/2006. Application to the urban development is a new feature of reg. 1083/2006. Furthermore, the use of this instrument has been extended to the renewable energy and energy efficiency area.

[69] The European Investment Bank expects 4 o 5 more agreements to be finalized before the end of 2009.

in the business plan. This IO falls upon the financial intermediaries creating the financial engineering instrument, i.e. usually private financial institutions. The business plan shall be assessed and its implementation monitored by the Member State or a managing authority.

Art. 1.(12) of reg. 846/2009 changes this data requirement, allowing the submission of either a business plan or any other appropriate document. Consequently, a business plan is no longer mandatory as long as the required information can be retrieved from other sources.

This paragraph of art. 1 of reg. 846/2009 reduces ACs/ABs on co-financing partners or shareholders of financial engineering instruments, although its impact is limited both in terms of cost per occurrence and in terms of population subject to these provisions. Namely, both ACs/ABs imposed when submitting the proposal and during monitoring are reduced. Unfortunately, no IO measured by the Consortium refers to submission of projects to be financed by the Structural Funds, therefore attention must be focused on the subsequent phase of implementation monitoring. We deem that ACs/ABs related to controls, i.e. to IOs 1 and 2, are going to be reduced.

As already done in this priority area, subject population is estimated taking into account the amount of financial resources allocated via the above-mentioned initiatives, that is €17,570mln, out of the total resources allocated via structural funds, i.e. €344,349mln. As a consequence, the estimated population is equal to 5.1% of the number of beneficiaries of Structural Funds. On the basis of the information provided by DG REGIO, it is likely that the average size of projects financed through financial engineering instrument is lower compared to other areas, since the bulk of these resources are allocated to small and medium enterprises.[70] In particular, we have been told that in this area the average size is about €250,000 per project, compared to €350,000 for the ESF, and to €50,000-€500,000 for the different categories of ERDF. Therefore, since ACs/ABs are proportional not only to the size of the projects (i.e. to the total amount of resources), but also to the number of projects, we raise the estimated population benefiting from this provision of reg. 846/2009 to 7% of total population subject to reg. 1083/2006, estimating that on average projects are about 40% smaller than in other areas.

The business plan is considered to be among the most burdensome tasks when setting up a financial engineering instrument. However, reg. 846/2009 is not going to completely eliminate this data requirement. On the basis of our assessment, the cost per occurrence is going to be reduced by 15%.

In conclusion, we estimate that art.1.(12) of reg. 846/2009 reduces ACs/ABs due to the IOs “financial control of final beneficiaries by the Member State” and “financial control of final beneficiaries by the European Commission” by 1.05% (7% X 15%). Results are summarized in Table 41.

[70] In the programming period 2000-2006, about 15 projects financed by financial engineering tools have targeted large enterprises (information provided by DG REGIO).

Table 41 Summary Table for reg. 846/2009 – Financial Instruments

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 846/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the Member States		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 846/2009**	
Frequency (per year)	on occasion	on occasion	
Population	82,504	82,504	
Administrative Costs	€ 132,136,261	*€ 130,748,830*	
Administrative Burdens	**€ 132,136,261**	***€ 130,748,830***	
AC Difference	**-€ 1,387,431**	**-1.05%**	
AB Difference	**-€ 1,387,431**	**-1.05%**	

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 846/2009**
EU Info obligation	Financial Control on Final Beneficiaries by the European Commission		
Obligation Type	09. Inspection on behalf of public authorities		
	QUANTIFICATION		
	Reg. 1083/2006	**Reg. 846/2009**	
Frequency (per year)	on occasion	on occasion	
Population	6,168	6,168	
Administrative Costs	€ 5,421,659	*€ 5,364,732*	
Administrative Burdens	**€ 5,421,659**	***€ 5,364,732***	
AC Difference	**-€ 56,927**	**-1.05%**	
AB Difference	**-€ 56,927**	**-1.05%**	

4.1.2.3 Information in annual and final reports

Managing authorities must provide information on the implementation of the measures and priorities of the programmes, and on their financial implementation to the Commissionm through recurring (annual) reports. These reports contain information on an aggregated basis, but are based on individual information submitted by the beneficiaries. The process of submitting information by the beneficiaries is regulated by specific national and/or local provisions, and thus may vary considerably. The burdens imposed by submission of information needed to draft annual and final reports are measured by the Consortium under the IO "Submitting Information needed by Management Authorities to Draft Annual Implementation/Final Report", which is the most burdensome of this Priority Area.

The content of the annual and final reports is detailed in Annex XVIII of reg. 1828/2006. It is going to be amended by Annex IV of reg. 846/2009. The aim of the amendments is to fine-tune the content of the reports, making them less burdensome and clearer for managing authorities. It is likely that this provision has an indirect effect on beneficiaries as well.

The legal text of the two annexes is quite similar. Few modifications have been introduced by reg. 846/2009. The following data requirements have been deleted: i) point 2.7: less information needed as for monitoring and evaluation; ii) point 3.1.1: less details on programmes receiving a contribution from the ERDF under the specific allocation for outermost regions; iii) point 5: differentiation between ongoing and completed major projects; and iv) point 7: less information concerning information and publicity (namely, indicators are no longer required for this issue).

As in other cases, it is difficult to estimate the likely impact of these provisions on ACs/ABs imposed on beneficiaries. According to the assessment of DG REGIO officers, the new regulation may approximately reduce about 5% of burdens due to submission of information for annual/final reports. Our assessment is consistent with DG REGIO's, as we deem that annex IV to reg. 846/2009 is likely to have an impact on beneficiaries, and that the magnitude of this impact is likely to amount to few percentage points. Therefore, we adopt DG REGIO's assessment as the basis for our quantification. Results are summarized in Table 42.

Table 42 Summary Table for reg. 846/2009 – Annual / Final reports

CHANGED IOs			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 846/2009**
EU Info obligation	Submitting Information needed by Management Authorities to Draft Annual Implementation/Final Report		
Obligation Type	02. Submission of (recurring) reports		
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 846/2009**
Frequency (per year)	on occasion		on occasion
Population	102,794		102,794
Administrative Costs	€ 585,991,709		*€ 556,692,124*
Administrative Burdens	**€ 585,991,709**		***€ 556,692,124***
AC Difference	**-€ 29,299,585**		**-5.0%**
AB Difference	**-€ 29,299,585**		**-5.0%**

Table 43 summarizes the impact of reg. 846/2009 on ACs/ABs attributed to reg. 1083/2006.

Table 43 Summary Table for reg. 846/2009 – Annual / Final reports

SUMMARY			
Priority Area	*Cohesion Policy*		
Existing EU legislation	**Reg. 1083/2006**	Amending Act	**Reg. 846/2009**
	QUANTIFICATION		
	Reg. 1083/2006		**Reg. 846/2009**
Administrative Costs	€ 922,634,000		*€ 889,250,323*
Administrative Burdens	**€ 922,634,000**		***€ 889,250,323***
AC Difference	**-€ 33,383,677**		**-3.6%**
AB Difference	**-€ 33,383,677**		**-3.6%**

4.2 Priority Area: Pharmaceutical Legislation

Within this area, we have to measure the amount of administrative burdens brought about by an act: Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.[71] Subsequently, we aim at measuring the reduction of ACs/ABs due to Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council.

4.2.1 Regulation 2377/90 on the establishment of Maximum Residue Limits and the new legislative framework

The use of veterinary medicinal products in food-producing animals may result in the presence of residues in food derived from these animals that can be toxic to humans. Therefore, veterinary medicinal products intended for food producing animals must undergo additional safety requirements. To address these concerns, Maximum Residue Limits (MRLs) are established. They represent the level below which the residues arising from a pharmacologically active substance that might be present in foodstuffs do not represent a risk to the consumer. MRLs are used to determine withdrawals period of veterinary medicinal products intended for food-producing species.[72]

The European Medicines Agency (EMEA) may establish the MRLs for a pharmacologically active substance. When it does, the substance is included in Annex I to reg. 2377/90, together with the indication of the MRLs, possibly for different species or tissues. If no MRL is needed, the substance is included in Annex II. Annex III includes substances for which transitional MRLs have been established. Annex IV includes substances for which any residue constitutes a hazard to the consumer, whose use in food-producing species is consequently banned.

[71] We base our quantification on the consolidated version of reg. 2377/90 valid on 01/01/2005. Therein, amendments due to 115 acts are included. Please be aware that the vast majority of the amendments concern the Annexes, i.e. the list of substances, and not the main legal text of the regulation.

[72] MRLs are also used to establish point of reference for control of food of animal origin: food non-compliant with the limits established in reg. 2377/90 is unfit for human consumption. However, these kinds of controls are not mandated by reg. 2377/90, therefore fall outside the scope of the present measurement.

For this reason, establishing MRLs is a pre-condition for applying for marketing authorizations of veterinary medicinal products intended for food-producing species. According to art. 12 of dir. 2001/83:[73]

> In the case of veterinary medicinal products which are intended for one or more food-producing species but whose pharmacologically active substances have not yet been included, for the species in question, in Annexes I, II or III to Regulation (EEC) No 2377/90, a marketing authorisation may not be applied for until after a valid application has been made for the establishment of maximum residue limits in accordance with that Regulation. At least six months shall elapse between a valid application for the establishment of maximum residue limits and an application for a marketing authorisation.

Even though it is a pre-condition for requesting a marketing authorization for veterinary medicinal products, the application to establish MRLs is clearly distinguished from the application for a marketing authorization. The former was regulated by reg. 2377/90, and not by dir. 2001/82. For this reason, it has not been measured during our quantification of ABs/ACs due to dir. 2001/82.

According to our analysis, based on a mapping process carried out by ourselves,[74] reg. 2377/90 includes 1 IO, imposing ABs of about €205,000. Results are summarized in Table 44.

Table 44 Summary table for Regulation 2377/90

SUMMARY OF BASELINE ACTS			
Priority Area:	Pharmaceutical Legislation		
Baseline Act:	Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin		
	INFORMATION OBLIGATION	**AC**	**AB**
IO 1	Application for establishing MRLs	€ 242,000	**€ 205,700**
	TOTAL	€ 242,000	**€ 205,700**

Art. 6 of reg. 2377/90 creates the Information Obligation (IO) "Application for establishing MRLs". The content of the application is detailed in Annex V to the regulation. An application must include information concerning both the pharmacologically active substance for which MRLs are to be established, and the residues themselves. As for the latter, studies on the residues of the active substance and on the techniques used for their detection have to be submitted.

The Impact Assessment of reg. 470/2009[75] reports the number of requests for MRLs submitted to the EMA from 1992 to January 2005, that is 145.[76] Consequently, about 11 requests per year are submitted on average. Compared to the number of requests for

[73] Furthermore, if MRLs for a substance are not established, veterinaries cannot administer it to food-producing species even under the exceptional procedure envisaged in art. 11 of dir. 2001/82.

[74] The mapping results can be found in Annex I to the present report.

[75] SEC(2008)484

[76] 58 applications concern new substances, 87 extensions and modifications.

marketing, this amount is very low. However, it is to be taken into account that requests for MRLs concern a pharmacologically active substance, whilst marketing authorizations are to be submitted for every medicinal product.

As for costs, there are no specific data related to this IO. According to the IA, residue studies represent 7% of total costs for developing a new medicinal product. However, this estimation concern total costs, and not specifically administrative costs.

The content of the application for MRLs is similar to the content of the application for marketing a medicinal product. A lot of information needed for marketing authorization (such as identification of the substance and of its formula; physical description; pharmacological, toxicological studies; studies on other effects) must also be submitted along with a request to establish MRLs. On the contrary, other information specifically concerning the medicinal product and not the active substance, such as dosage, or information about leaflet, label and package, are not needed in case of MRLs. Notwithstanding the differences, we assume that the cost per occurrence of submitting an authorization for marketing is of a similar magnitude compared to the cost per occurrence of submitting a request for establishing a MRLs. Namely, we assume that the latter is 66% of the former, considering that in case of marketing authorizations more information must be submitted.

The Consortium has measured in the EU database on AB the cost of the IO "Application needed for marketing authorization of a medicinal product", arising from dir. 2001/83 on human medicinal product. In our previous report, cost per occurrence of this IO has been estimated not to be relevantly different for human and veterinary medicinal products. Since requests for MRLs concern pharmacologically active substances and not medicinal products, we consider that it is better to use the cost per occurrence measured for innovative firms, rather than that for generic.[77]

According to data collected by the Consortium in six EU countries,[78] an innovative firm spends on average 29,385 minutes to comply with the IO "Application needed for marketing authorization of a medicinal product", i.e. 489.75 hours. Applying the discount factor illustrated above, we estimate that to comply with the IO "Application for establishing MRLs" 323.24 hours are spent on average. To estimate internal costs, time is multiplied by the average European salary of a Professional, that is €35.70 per hour.[79] Accordingly, internal costs per occurrence for the present IO are estimated at €11,540. According to the Consortium estimates on dir. 2001/82, an amount of costs slightly lower than internal costs is incurred because of consultancy costs. Therefore,

[77] Please take into account that the Consortium has measured only the cost of "submitting" the application, i.e. gathering data, dealing with the authorities and following-up the process. The costs of carrying out pharmacological studies have not been considered as Administrative Costs. This is the main reasons why costs can be considered comparable, otherwise the best approximation would be that reported in the IA (7%).

[78] Belgium, Czech Republic, Estonia, Italia, Poland, and Portugal.

[79] The European average is the weighted average of national salary rate for a Professional weighted by the relative dimension of the workforce. Data on salaries are retrieved from the EU database on AB. Data on the workforce are retrieved from Eurostat.

we estimate that total cost per occurrence for the IO "Application for establishing MRLs" amounts to €22,000.

Therefore, total ACs amount to €242,000. The BAU factor is fixed at 15%. For similar provisions concerning the authorisation of a veterinary medicinal product, we have applied a BAU factor of 25%. However, we consider that in case of MRLs the percentage should be lower. Consequently, ABs are expected to amount to €205,700.

4.2.1.1 The new legislative framework on MRLs

Reg. 2377/90 has been replaced by Regulation 470/2009 of the European Parliament and of the Council, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC and Regulation (EC) No 726/2004.

As reported in the Impact Assessment accompanying the legislative proposal,[80] the new regulation has four main aims:

1) improving the availability of veterinary medicinal products for food producing animals. This benefit is not quantifiable via the Standard Cost Model;
2) simplifying the existing legislation as for end-users of veterinary medicinal products. This simplification is going to reduce burdens on veterinaries and users of veterinary medicinal products, making consultation of the list of existing pharmacologically substances subject to MRLs easier. However, these burdens can not be attributed to reg. 2377/90, spelling out the procedure to establish MRLs, but to the food safety acts dealing with the rules to be complied with to market foodstuff of animal origin. Consequently, they fall outside of the scope of this measurement exercise;
3) providing clear references for the control of residues of pharmacologically active substances. This simplification can be expected to reduce burdens imposed on marketers of foodstuff of animal origin. However, as stated above, these ACs/ABs should be attributed to the food safety legislation, and not to reg. 2377/90, therefore falling outside of the scope of this measurement exercise;
4) clarifying the Community procedure establishing MRLs. The new provisions concerning the Community procedure establishing MRLs are expected to reduce ABs measured under IO1 of reg. 2377/90, and are consequently within the scope of this measurement exercise. These provisions are analysed in depth underneath.

[80] SEC(2007)484. The number of the proposal is COM(2007)194

Three factors are likely to reduce burdens imposed because of the request to establish MRLs:

1) a general simplification of the legislative text. In the new regulation, the sequence of articles has been rearranged, better differentiating between risk assessment and risk managemen; and provisions have been made clearer. Furthermore, the four existing annexes are going to be integrated in a single separate Commission Regulation, making easier to retrieve data about existing MRLs. According to the Consortium no time is spent on familiarizing with the legal provision of IO "Application needed for marketing authorization of a medicinal product". We consider it to be unrealistic and approximately assume that a simplification of the legislative framework reduces ACs/ABs by 3%, in line with similar simplification in other Priority Areas;

2) the automatic recognition of MRLs approved by the Codex Alimentarius Commission and endorsed by the EU (lett. (b) of art. 14.3). The Codex Alimentarius Commission is a body established by the Food and Agricultural Organisation, and the World Health Organisation. The Codex Alimentarius is, inter alia, a collection of internationally recognised standards, some of them concerning MRLs. The new regulation makes MRLs of Codex Alimentarius endorsed by the EU without any reservation automatically applicable within the Community. Under the old framework, firms have to apply to establish a MRL even for active substances covered by the Codex Alimentarius. This provision is going to reduce the number of applications. According to data reported in the IA, 800 MRLs exist in the EU, whilst only 50 MRLs, i.e. 6.3%, have been established in the Codex Alimentarius. We estimate that the new provision will reduce the number of requests by a similar percentage factor, that is from 11 to 10 requests per year.[81]

3) the extension of the principle of the extrapolation (art. 5). Extrapolation aims at establishing MRLs for a certain tissue on the basis of MRLs established for another tissue of the same species; or for a certain species on the basis of MRL established for another species. The possible use of extrapolation by EMEA reduces the cost per occurrence of IO1, since studies on MRLs may concern only one tissue or only one species. Reg. 470/2009 states that the EMEA has to mandatorily consider extrapolation, and consequently may be expected to increase the use of this technique. Consulting with Commission's officers, we have been told that the cost reduction can be expected to be significant, since this provision deals with a "core" Data Requirement of IO1. Nevertheless, a numeric

[81] There are other provisions potentially concerning the number of requests per authorisation submitted per year. E.g. art. 9 allows the Commission or the Member Sates to submit a request to establish MRLs in certain cases, mainly to avoid lack of veterinary medicinal products for food-producing species, or the extension of MRL legislation to biocidal products. However, on the basis of the evaluation of Commission officers, the variation of the number of occurences, if any, can be expected to be slight.

estimate could not be provided. We tentatively assume that the cost per occurrence is reduced by 20% on the basis of our expert assessment and of our previous experience in the Priority Area "Pharmaceutical Legislation".

In conclusion, we estimate that the new regulation reduces the cost per occurrence by 23%, and the frequency by 1 request per year. Total impact on ACs/ABs is shown in Table 45.

Table 45 Summary table for Regulation 470/2009 and Regulation 2377/90

CHANGED IOs			
Priority Area	*Pharmaceutical Legislation*		
Existing EU legislation	**Reg. 2377/90**	Amending Act	**Reg. 470/2009**
EU Info obligation	Application for establishing MRLs		
Obligation Type	05. Application for individual authorisation or exemption		
	QUANTIFICATION		
	Reg. 2377/90		**Reg. 470/2009**
Frequency (per year)	on occasion		on occasion
Population	13		*12*
Administrative Costs	€ 242,000		*€ 164,340*
Administrative Burdens	**€ 205,700**		***€ 139,689***
AC Difference	**-€ 77,660**		**-32.1%**
AB Difference	**-€ 66,011**		**-32.1%**

SUMMARY			
Priority Area	*Pharmaceutical Legislation*		
Existing EU legislation	**Reg. 2377/90**	Amending Act	**Reg. 470/2009**
	QUANTIFICATION		
	Reg. 2377/90		**Reg. 470/2009**
Administrative Costs	€ 242,000		*€ 164,340*
Administrative Burdens	**€ 205,700**		***€ 139,689***
AC Difference	**-€ 77,660**		**-32.1%**
AB Difference	**-€ 66,011**		**-32.1%**

4.3 Priority Area: Transport

Within this area, we have to measure the reduction of administrative burdens brought about by an act: Commission Regulation (EU) No 1266/2009 adapting for the tenth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport. It has an effect on the ACs/ABs generated by Regulation 561/2006 of the European Parliament and of the Council on the harmonization of certain social legislation relating to road transport, which is one of the acts measured by the Consortium.

4.3.1 Regulation on digital tachographs

Commission Regulation (EU) No 1266/2009 adapting for the tenth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport is going to amend Annex IB to reg. 3821/85, regulating the construction, installation, use and testing of equipments used to record time spent by drivers for the carriage by road of goods and passengers. More specifically, annex IB deals with the characteristics of digital tachographs, whose installation on new vehicles has been made mandatory by Regulation 561/2006 of the European Parliament and of the Council on the harmonization of certain social legislation relating to road transport.

According to the EU database on AB, reg. 561/2006 includes two IOs, one of which is going to be affected by the regulation: "Recording time spent driving a vehicle and recording working time". This IO causes ACs equal to €3,062,234,000, of which €2,984,544,000 are ABs.[82]

Reg. 3821/85 and reg. 561/2006 have already been analysed by us.[83] We have underlined that data included in the EU database provide a good estimation of the amount of ACs/ABs in 2007.[84] Indeed, our measurement has focused on the full reduction potential of reg. 561/2006, i.e. we have measured the future scenario in which all drivers are using digital tachographs. Differently from the Consortium's data, we have calculated that the use of digital tachographs envisaged in reg. 561/2006 can be estimated to reduce time spent to comply with this IO by 17.4%.[85] On the basis of our estimates, when the full potential reduction of reg. 561/2006 is exploited ABs are reduced to €2,738mln. Results of that quantification are quoted in Table 46.

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[82] Formally, the regulation amends reg. 3821/85, and not reg. 561/2006. However, the Consortium has attributed ACs/ABs to reg. 561/2006, since the Information Obligations are provided therein. Nevertheless, the technical requirements with which tachographs have to comply are still included in reg. 3821/85, and these requirements do have an effect on the ACs/ABs attributed to reg. 561/2006.

[83] See paragraph 2.1.1.

[84] According to the Consortium, 74% of drivers use analogue tachographs, and 26% of drivers use digital tachographs.

[85] Other costs, such as equipment costs, are estimated to be the same both for analogue and digital tachographs. Our estimates try to take into account that the time needed for downloading is lower than that reported in the EU database on AB.

Table 46 Summary table for reg. 3280/85, reg. 3281/85 and reg. 561/2006

SUMMARY			
Priority Area	Transport		
Existing EU legislation	**Reg. 3820/85** **Reg. 3821/85**	Amending Act	**Reg. 561/2006**
	QUANTIFICATION		
	Reg. 3820/85	**Reg. 561/2006**	
Administrative Costs	€ 3,101,843,000	*€ 2,807,785,366*	
Administrative Burdens	**€ 3,024,159,000**	*€ 2,737,561,691*	
AC Difference	**-€ 294,057,634**	**-9.5%**	
AB Difference	**-€ 286,597,309**	**-9.5%**	

To measure the full reduction attributable to the reg. 1266/2009, we need to measure the effect produced over a population of drivers already equipped with digital tachographs, given that the present amending measure has no effect on users of analogue tachographs. In practical terms, we will consider that all drivers have switched to digital tachographs, and measure the consequent ACs/ABs reduction attributable to reg. 1266/2009.[86] Thus, we will use our measurement of reg. 561/2006 as the baseline for the effect of reg. 1266/2009.

Reg. 1266/2009 contains new technical requirements with which digital tachographs have to comply. It is aimed not only at adapting the legal text to technical progress, but also at reducing administrative burdens on operators.[87] Reduction of administrative burdens is achieved mainly through three changes to the technical requirements:

1) changes concerning manual entries. When a driver is away from the vehicle and takes out his/her driver card, the activities carried out during his absence have to be introduced manually in the digital tachograph. Up to now, manual introduction of these entries was complicated and time-consuming. By amending the technical requirements for digital tachographs, reg. 1266/2009 simplifies manual entries and reduces the time spent for it;[88]

2) changes concerning downloading. Downloading is no longer necessary for certain data.[89] This change reduces the time necessary for downloading, and was requested by the industry;

[86] Please note that savings due to reg. 1266/2009 are additional to savings estimated for reg. 561/2006, and that within this quantification we do not deal with savings related to switching from analogue to digital tachographs, but only to the higher level of efficiency of new technical requirements for digital tachographs.

[87] As expressly stated in the recitals.

[88] Cf. Chapter III, Section 3, requirements 028 and 029, and Section 6, Requirements 050, 050a and 050b.

[89] Cf. Chapter I, definition "s"

3) changes in the way of recording driving activities. Recording driving activities has been made more precise, and this would lead to reduced burdens for drivers engaged in frequent stop deliveries.[90] This so-called "one-minute" issue was requested by the industry.

According to DG TREN, these new features allow drivers using digital tachographs to save time both for using the device and for downloading data. We agree on this statement and try to estimate, based on our and DG TREN's expert assessment and on data provided by the Consortium, the magnitude of this reduction.

The population subject to the IO “Recording time spent driving a vehicle and recording working time” is estimated in the EU database at 5,901,421 drivers. Since we are trying to measure the full impact of reg. 1266/2009, we will consider all these drivers as using digital tachographs.

According to our estimates[91], a driver spends on average 110’ 30’’ per month, i.e. about 5’31” per day (assuming that each month consists of 20 working days) to deal with the digital tachograph, both for using it, and for downloading data once every 28 calendar days.

DG TREN suggested that the reg. 1266/2009 would lead to a saving of 5 minutes per day, i.e. 100 minutes over an average month. This estimate is almost equal to total time spent for this IO, as estimated by us. Therefore, we could not fully rely on it without discarding our previous (and also Consortium’s) estimates.

It is difficult to deliver a precise estimate of the savings in term of minutes per day per driver, since no tachographs have been marketed according to the new requirements. We propose a scenario analysis based on possible impacts on ACs/ABs measured by the Consortium. We assume that reg. 1266/2009 may save 10%, 25%, or 33% of total time needed to comply with the present IO, and then show what is the consequent expected reduction of ACs/ABs. Time savings are transformed in Administrative Cost saving through an average of the national salary rates used by Consortium for “Plant and machine operators and assemblers”, weighted by the number of digital tachograph users in each country, that is €18.45 per hour. Administrative burdens savings are calculated applying the BAU ratio used by the Consortium (2.54%). Results are shown in Table 47.

[90] Cf. Chapter III, Section 4, requirement 038, 040, 041, 042

[91] Based on data retrieved by the Consortium in the countries where it has carried out the measurement, corrected for our assumptions. These estimates have been validated by DG TREN.

Table 47 Scenario-Analysis of possible savings due to reg. 1266/2009

Scenario	Time Saving per month (minutes)	Time saving per year (minutes)	Monetary saving per year per driver (€)	Total AC saving (€)	Total AB saving (€)
-10%	-11.1	-132.6	-€ 40.77	-€ 240,627,491	-€ 234,515,552
-25%	-27.6	-331.5	-€ 101.94	-€ 601,568,726	-€ 586,288,881
-33%	-36.5	-437.58	-€ 134.56	-€ 794,070,719	-€ 773,901,323

On the basis of feedbacks provided by DG TREN, the most likely scenario is the 10% burden reduction. Final results of the quantification and the impact of reg. 1266/2009 on the baseline measurement under this scenario are summarized in Table 48.

Table 48 Summary table for the Reg. 3821/85 and Reg. 1266/2009

SUMMARY			
Priority Area	Transport		
Existing EU legislation	**Reg. 561/2006**	Amending Act	**Reg. 1266/2009**
	QUANTIFICATION		
	Reg. 561/2006		**Reg. 1266/2009**
Administrative Costs	€ 2.807.785.366		*€ 2.567.157.875*
Administrative Burdens	**€ 2.737.561.691**		***€ 2.503.046.139***
AC Difference	**-€ 240.627.491**		**-8,6%**
AB Difference	**-€ 234.515.552**		**-8,6%**