



Council of the
European Union

Brussels, 7 June 2018
(OR. en)

9867/18

COMPET 422
MI 437
ENT 105
CHIMIE 29
ENV 414

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	30 May 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2018) 266 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Evaluation of the Aerosol Dispensers Directive

Delegations will find attached document SWD(2018) 266 final.

Encl.: SWD(2018) 266 final



Brussels, 30.5.2018
SWD(2018) 266 final

COMMISSION STAFF WORKING DOCUMENT

Evaluation of the Aerosol Dispensers Directive

{SWD(2018) 267 final}

Commission Staff Working Document

Evaluation of the Aerosol Dispensers Directive (75/324/EEC)

Table of contents

1.	INTRODUCTION	4
	1.1 Purpose of the evaluation	4
	1.2 Scope of the evaluation	4
2.	BACKGROUND TO THE INTERVENTION	5
	2.1 Description of the intervention.....	5
	2.2 Baseline scenario and point of comparison.....	7
3.	IMPLEMENTATION / STATE OF PLAY	8
	3.1 Description of the market.....	8
	3.2 Implementation of the legislation.....	8
4.	METHOD	10
	4.1 Short description of methodology	10
	4.2 Limitations and robustness of findings	11
5.	ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS	14
	5.1 Relevance	14
	5.1.1 <i>Relevance in the light of current needs</i>	14
	5.1.2 <i>Relevance in the light of technological developments</i>	15
	5.1.3 <i>Ability to foster or support innovation</i>	15
	5.1.4 <i>Alignment with the New Legislative Framework</i>	16
	5.2 Effectiveness	17
	5.2.1 <i>Contribution to product safety</i>	17
	5.2.2 <i>Contribution to the internal market</i>	18
	5.2.4 <i>Role of the provisions and requirements set out in the Directive on its effectiveness</i>	19
	5.2.5 <i>Barriers to the effective application</i>	20
	5.3 Efficiency	21
	5.4 Coherence.....	22
	5.5 EU Added value	24
6.	CONCLUSIONS.....	24
	ANNEX 1: PROCEDURAL INFORMATION.....	27
	ANNEX 2: SYNOPSIS REPORT OF THE STAKEHOLDER CONSULTATION.....	29

ANNEX 3. EVALUATION QUESTIONS	38
ANNEX 4. OVERVIEW OF COSTS- BENEFITS IDENTIFIED IN THE EVALUATION	40

Glossary

<i>Term or acronym</i>	<i>Meaning or definition</i>
ADD	Aerosol Dispensers Directive
CLP (Regulation)	Regulation on Classification, Labelling and Packaging of substances and mixtures
FEA	European Aerosol Federation
EEN	Enterprise Europe Network
LPG	Liquefied Petroleum Gas
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
TFEU	Treaty on the Functioning of the European Union

1. INTRODUCTION

1.1 Purpose of the evaluation

The Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, commonly known as the Aerosol Dispensers Directive or ADD (Directive [75/324/EEC](#)), is one of the oldest product safety directives still in force in the EU. It aims to ensure the safety of aerosol dispensers in the EU and secure their free movement on the internal market.

Since its entry into force in 1975, the Directive has not been subject to a formal evaluation. It has been amended several times to keep up with the technical developments on the market, but the essence and structure have stayed the same. Stakeholders (industry, consumers, Member States and the Commission) have not encountered major problems related to the functioning of the Directive. In the context of further requests to adapt the Directive to technical progress in 2014, the question was raised by national authorities whether the Directive was still adequate in its current format and whether it should not be modernised to bring it in line with the New Legislative Framework, like other EU product safety legislation. Therefore, this opportunity was taken to evaluate the performance of the Directive.

1.2 Scope of the evaluation

The evaluation assesses the extent to which the Directive meets its objectives by examining each of the following five criteria: *effectiveness, efficiency, relevance, coherence and EU added value*.

The evaluation analyses the overall performance of the Directive in the period 2005 to 2015 and covers all Member States. Going back further in the past would not provide much information about the current state of implementation of the Directive. Nevertheless comparison with the market situation prior to the harmonisation of the legislation in 1975 was taken into consideration in the analysis.

The results of the evaluation will provide, where appropriate, input for further policy decisions with regard to aerosol dispensers in the EU, e.g. in particular the need for a revision or a partial adaptation to technical progress of the Directive.

The evaluation does not cover aspects governed by other legislation applying to aerosol dispensers (such as for example legislation related to chemicals, transport, packaging, cosmetics, pharmaceuticals, foodstuff or environmental aspects).

2. BACKGROUND TO THE INTERVENTION

2.1 Description of the intervention

The Aerosol Dispensers Directive has two objectives:

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

Prior to the harmonisation of the legislation in 1975, Member States applied diverging national requirements resulting in varying levels of safety of aerosol dispensers and barriers to trade between the different Member States.

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

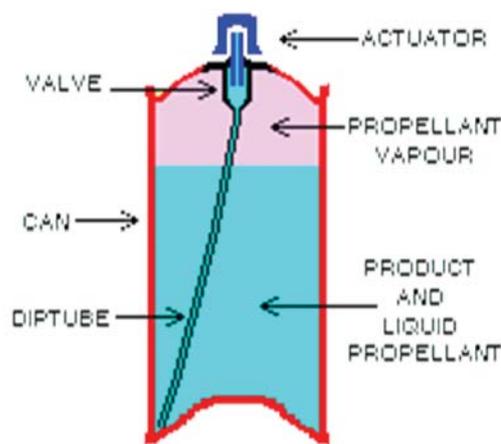
The key characteristics of an aerosol dispenser can be summarised as follows:

- they operate under pressure which creates a hazard which must be addressed in the design, manufacturing and testing of the product;
- they use a propellant which can be flammable or not flammable (adding a safety hazard which must be properly addressed);
- they have an active component (deodorants/antiperspirants, food, paint, etc.); and
- they have a release device (valve/actuator).

A typical aerosol dispenser is based on a dispensing system, typically a container filled with an active component and a propellant. Propellants are chemicals that generate pressure and push the content out of the container where it is suspended as very fine particles, droplets or foam.

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

Figure 1 - Aerosol dispensing system



To ensure the safety of the product, the Aerosol Dispensers Directive includes specific requirements related to the pressure hazard and the flammability as well as a general obligation for the manufacturer to analyse all hazards, which could apply to an aerosol dispenser product. Based on such analysis, the aerosol is designed, manufactured and tested accordingly to fulfil all the appropriate safety requirements. To ensure an appropriate level of safety, the Annex of the Directive sets maximum operating parameters such as volume and pressure and defines detailed requirements related to manufacturing, labelling and testing.

The Directive has not been fundamentally revised since its adoption but several amendments were made over time. These modifications were of a technical nature to accommodate changes in technology (e.g. increasing the pressure resulting in better performance of the aerosol dispensers) or to ensure coherence with other legislation (e.g. related to the labelling requirements of the Regulation on classification, labelling and packaging of substances and mixtures, known also as the CLP Regulation¹). The Directive includes specific provisions² for a procedure to facilitate these adaptations to technical progress. The procedure was designed to allow amendments of ‘non-essential’ elements of the Directive and requires approval by the “Committee on the Adaptation to Technical Progress”. This Committee is composed of representatives of the Member States and the European Commission. The Directive has been amended a number of times based on the adaptation to technical progress procedure, namely in 1994, 2008, 2013 and 2016.

The starting point for the evaluation is the intervention logic³ for the Directive which is a model of causality that presents the links between the needs and objectives on the one hand, and the intended activities, outputs, results and impacts of the Directive on the other.

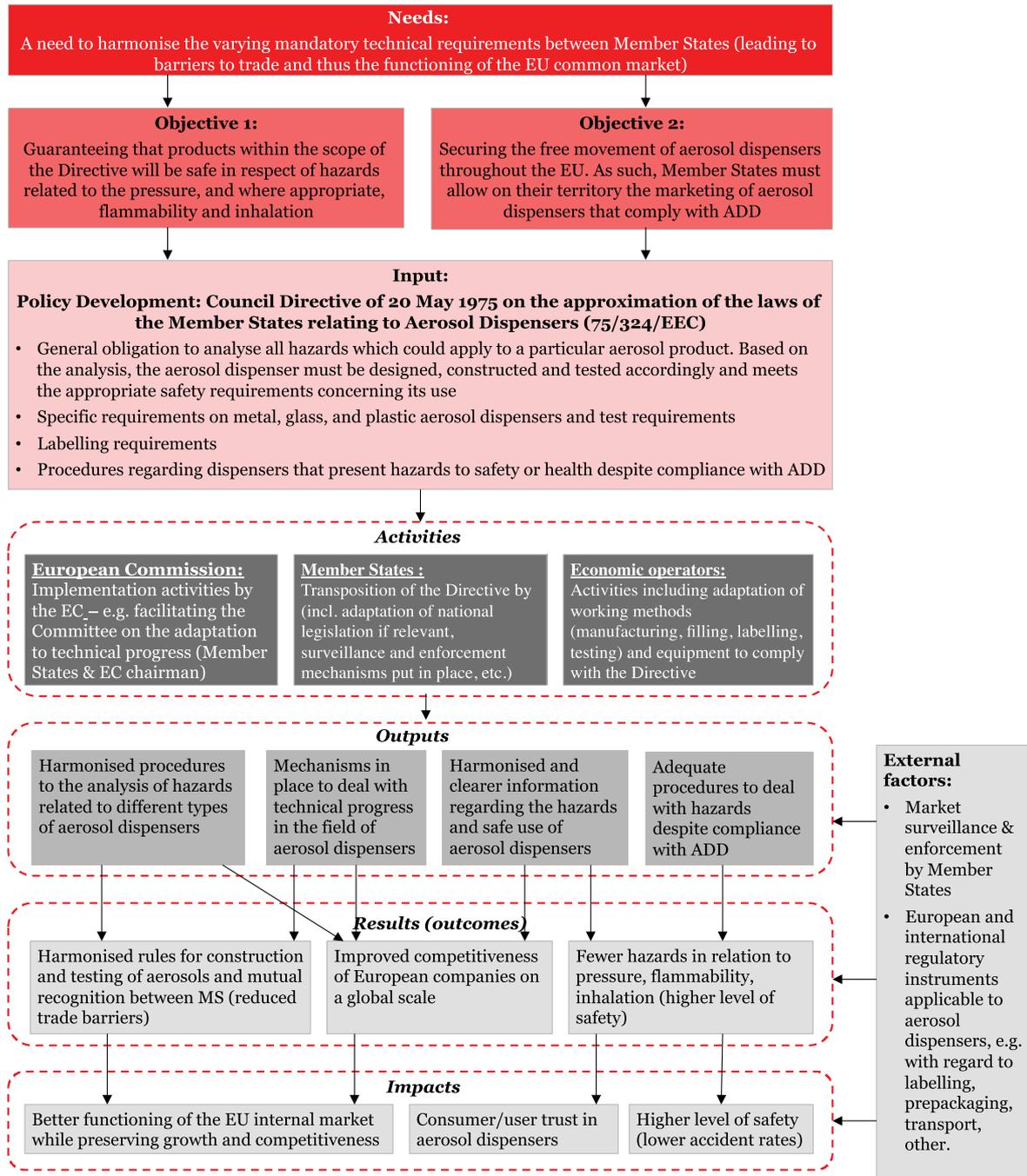
¹ REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures

² Aerosol Dispensers Directive Articles 5, 6, and 7

³ Based on the Commission Guidelines on Better Regulation (May 2015) : http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

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

Figure 2 – Intervention logic of the Aerosol Dispensers Directive



2.2 Baseline scenario and point of comparison

Prior to 1975, Member States had their own national legislations in relation to the safety of aerosol dispensers. Economic operators selling their products across the European Community had to comply with varying requirements in the national legislations which lead to increased costs and were hindering trade within the Community. Based on article 100 EEC (now article 114 TFEU) the Directive was adopted to remove the barriers to the establishment and the functioning of the internal market for aerosol dispensers.

There is no quantitative data available about the situation on the European markets for aerosol dispensers before the adoption of the Directive. It is therefore not possible to

predict how the market would have developed without the Directive. The trade of aerosol dispensers within the Community would have been subject to the general principles of free movement and mutual recognition meaning that products legally marketed in one Member State can be marketed in any other Member State. However, every Member State could have imposed country specific requirements in particular with regard to testing and labelling.

3. IMPLEMENTATION / STATE OF PLAY

3.1 Description of the market

The EU is the largest manufacturer of aerosol dispensers. Each year, more than 5 billion units are produced in Europe compared to the estimated worldwide production of 15 billion units. European production has grown from 5 billion units in 2006 to 5,7 billion in 2016⁴.

The production in Europe is dominated by a few countries. The main manufacturers of aerosol dispensers are based in the United Kingdom, Germany and France. Together they account for more than 60% of the total EU production.

The main industries in the aerosol value chain include the manufacturers of the containers (cans), the manufacturers of the valves, the filling industry with indirect suppliers of active components, propellants and solvents and economic operators active in marketing/sales/distribution.

Production facilities are more and more integrated ensuring economies of scale. There are no intra-community trade figures specific for aerosol dispensers in the official statistics. These are considered under the category of packaged goods which contains much more products than just aerosol dispensers. The main producing countries are exporting their products over the whole EU territory. Some countries have only very limited production capacity and rely mainly on import.

Import / export data related to trade with third countries is not available but consultation of industry experts indicates that less than 10% of the EU production is exported to third countries. In practice, EU companies are setting up local production facilities in third countries to supply the local markets.

In terms of main product groups, the personal care group is by far dominating (56 %) followed by household applications (21 %). Other products such as pharmaceuticals, paints, technical products, food ... account for the remaining 23 %.

3.2 Implementation of the legislation

The Directive was transposed into national legislation of the Member States and is part of the *acquis* to be implemented by the new Member States. Following the subsequent enlargements of the European Union, the Aerosol Dispensers Directive became applicable in more and more countries. Member States did not maintain additional rules or requirements related to aspects that are regulated by the Directive. Over the past ten years,

⁴ Please see also Chapter 3.3 page 16 of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3) <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/> and statistics available on the FEA website: <http://www.aerosol.org/publications-news/publications/statistics/>

the evaluation study found no evidence of any situation in which an aerosol dispenser was refused, prohibited or restricted from the market despite compliance with the Directive⁵.

The Directive appears highly successful in harmonising rules and requirements in the Member States and thus facilitating the free movement of aerosol products across the Union. There are no reports from economic operators or trade associations about national requirements, which would result in a barrier to trade.

The industry itself has facilitated the implementation of the Directive by developing a set of industry (FEA) standards covering in detail the technical requirements to ensure compliance with the Directive. The most important industry standards⁶ have been converted into harmonised standards at European (EN standards) or international level (ISO standards). The content of some standards has been included in the legislation itself via amendments adapting the Directive to technical progress.

Based on the information in the RAPEX⁷ database, only 15 cases are referring to aerosol dispenser products for the period covered by the evaluation (2005-2015). Out of these 15 cases:

- five cases refer to non-compliance with the ADD [pressure hazard (1), risk assessment – inhalation (4)];
- nine cases refer to non-compliance with other European legislation (Reach⁸ (7), F-gas Regulation⁹ (1), Toys Directive¹⁰ (1) because of the active component or the propellant being prohibited);
- one case refers to non-compliance with national legislation (extinguishing capacity of an aerosol type of fire extinguisher).

There have not been any reported incidents that could be rooted back to the failure of aerosol dispensers meeting the requirements of the Directive. In all cases the incidents were due to abuse or non-compliance with the requirements of the Directive.

The national competent authorities in charge of market surveillance conduct very few controls and checks on aerosol dispensers. Given the very low rate of accidents or faulty products, aerosol products are not treated as a priority area. Based on the results of the interviews, approximately half of the national authorities do not keep any records of the number and type of consumer complaints and incidents with aerosol dispensers.

⁵ A safeguard clause issued in 2004 by the Belgian authorities with regard to the flammability of the active component (olive oil spray) and the risk of fire resulted in an adaptation of the ADD in 2008 to address the problem.

⁶ FEA website: <http://www.aerosol.org/publications-news/publications/standards/>

⁷ Rapid Alert System for dangerous non-food products
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

⁸ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

⁹ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006

¹⁰ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys

An unexpected impact that was identified by the evaluation is the fact that the rules and requirements of the Aerosol Dispensers Directive are used by some third countries, such as Brazil, China and India. This has led to even more harmonisation and positively contributes to enhancing the competitiveness of European manufacturers, by facilitating the export. This has also a positive impact for the European manufacturers of machinery and test equipment used in aerosol production facilities worldwide. It should be noted however that there is no global harmonisation: some major aerosol markets have diverging rules and standards (e.g. United States and Canada).

4. METHOD

4.1 Short description of methodology

The evaluation of the Directive was supported by a study¹¹ conducted by an independent consultant.

The methodology comprises major phases of data collection (desk research, stakeholder consultation), analysis and reporting. Analysis is conducted on data collected through review of existing documents and reports, interviews and consultation of all potential stakeholders. The whole process and the findings are included in the publicly available final report on the evaluation of the Aerosol Dispensers Directive.

The evaluation project was monitored by a Steering Group comprised of representatives of the European Commission services, namely DG Internal Market, Industry and Entrepreneurship, DG Justice and the Secretariat General.

The evaluation aimed at gathering both qualitative and quantitative evidence from a number of complementary data sources, including European and national public authorities, industry associations, economic operators, consumer organisations and consumers/citizens.

Concerning the stakeholder consultation, data was collected with various tools aiming to reach out to all stakeholders in the most efficient way. The following techniques were used:

- in-depth interviews were conducted with key stakeholders, like European, national and regional authorities including those responsible for market surveillance, industry and consumer organisations;
- typical companies directly affected by the Directive were approached with a detailed questionnaire to collect cost estimates and market information;
- industry was specifically targeted with an online survey including more in-depth technical questions related to the application and implementation of the directive;
- a public consultation aimed to capture the views of all interested parties with a particular focus on consumers.

Particular attention was paid to ensure participation of SMEs in the various data collection mechanisms.

¹¹ Evaluation of the Aerosol Dispensers Directive, final report of 24 March 2017
<https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

The table below gives an overview of the data collection

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

More details on the consultation are included in the synopsis report in Annex 2.

4.2 Limitations and robustness of findings

The limitations and corresponding mitigation actions undertaken are described in detail in the final report on the Evaluation of the Aerosol Dispensers Directive¹².

The most important points are the following:

- 1) The evaluation consultation depends very much on a sufficiently high participation level by the stakeholders. During the stakeholder consultation, the study team worked closely together with European and national industry associations that systematically encouraged their members to participate to the cost assessment exercise and the survey. By monitoring responses closely and target sectors/countries with very low responses timely, the contractor managed to ensure a satisfactory participation of the industry. For Member States, continuous efforts were made to get in touch with the Member States' representatives based on contact details provided by the EC services. Despite all the efforts made, 9 out of 28 Member States did not participate to an interview. Consumer associations

¹² The Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 5.7) , <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

unfortunately showed no interest despite repetitive invitation and direct involvement of the EC services.

- 2) The economic operators interviewed and surveyed subscribe to a large extent to the position of their professional association (FEA). This means that there is a risk of obtaining biased results from the surveys. The result of the consultation have been critically assessed with the help of the EC services and the study team's sectoral experts. It results from the analysis of the results that a large majority of the economic operators shares the same view. Only minor and isolated issues were raised by individual companies. These issues were carefully assessed and are documented in the final report of the evaluation.
- 3) As already anticipated by the EC services before starting the study, it has proven to be very difficult to collect quantitative data and in particular data about costs directly linked to the ADD. Official statistics do not allow to identify aerosol dispensers from the wider group of pre-packaged goods. No information on costs of an aerosol dispenser is publicly available. It should be noted that such information can only be obtained with the good-will of the concerned economic operators. A specific consultation with a limited number of economic operators (10 in total) allowed to collect some key data. Confidentiality agreements were signed between the contractor performing the evaluation study which enabled some of those companies to share cost figures. The number of companies participating to this exercise, though less than originally planned, provided good quality data. Follow-up discussions between the participating companies and the evaluation team ensured a good understanding and led some companies to reconsider some estimations during the course of the cost assessment in order to guarantee comparability across companies.

With regard to the robustness of the findings, the EC services take the following view:

- The robustness of the consultations that targeted industry and economic operators is possibly influenced by the fact that economic operators generally favour the status quo as they consider that changes in legislation generally lead to additional costs for industry. Responses were therefore assessed bearing in mind that the situation could be pictured as too positive. The high number of replies covering all operators in the value chain allowed to draw reliable conclusions.
- For some Member States, aerosol dispensers are not a priority and 9 out of 28 Member States have not participated in the consultation. This could be explained by the fact that most Member States do not have a large industry for aerosol dispensers, and that there are not many known or reported safety issues. The countries participating in the survey do however cover more than 90 % of the total production in Europe¹³. The top three countries (United Kingdom, Germany and France) provide more than 60 % of the annual aerosol production in Europe and have a market share of respectively 26,8 %, 22,7 % and 13,1 %. It is therefore considered that the view of national authorities is well reflected.
- Overall, the reliability and robustness of the evaluation report is assessed by the EC services as satisfactory given the extensive desk research and the good response rates of the targeted online survey, the good quality inputs and engagement of the companies contributing to the cost assessment and the number of interviews

¹³ From the top 10 ranking based on market share in production, replies were received from United Kingdom, Germany, France, the Netherlands, Spain, Belgium, Poland and Czech Republic. Italy and Portugal did not reply.

conducted with national authorities and economic operators. The consultant has been creative and effective in reaching as many stakeholders as possible with the resources allocated to the project. Right from the start of the evaluation attention was given to identify limitations and addressing these by taking mitigating measures all along the project.

- A Steering Group which closely monitored the study and the interim deliverables did not identify particular shortcomings, which were not identified and/or addressed during the study contract. The final results and conclusions of the study report are therefore considered sufficiently reliable to use as a basis for this document.
- After the publication of the final report of the evaluation, comments were received from FEA supporting the overall conclusions of the study. The final report of study was also presented in a meeting of the Working Group Aerosol Dispensers Directive in October 2017. This Working Group is composed of representatives of the national authorities in charge of the implementation of the legislation and the market surveillance. Also at this level, the quality of the report and its conclusions are well received and supported.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

The core of the evaluation is the analysis of the relevance, effectiveness, efficiency, coherence and EU added-value of the Aerosol Dispensers Directive. Detailed evaluation questions (see Annex 3) were developed to ensure that the evaluation criteria could be properly assessed.

5.1 Relevance

The relevance¹⁴ of the Directive is assessed by (i) checking to what extent the initial objectives correspond to current needs and problems, (ii) identifying the extent to which the Directive is still relevant in the light of technological developments and scientific progress, and (iii) checking whether the Directive is adequate in fostering or supporting innovation. The possible alignment of the Directive to the New Legislative Framework (NLF) was also considered in the light of these questions.

5.1.1 Relevance in the light of current needs

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

The consultations carried out in the framework of this evaluation confirmed that both objectives correspond to the needs of consumers and economic operators in the field and are still particularly relevant today.

In respect to consumer safety, the consulted stakeholders unanimously felt that it is of utmost importance that the Directive guarantees the safety of the products.

With regard to the free movement, economic operators underlined the importance of harmonised European rules which remove barriers to trade significantly, reduce the costs and improve the competitiveness of the sector.

When asked about whether there was a need to adapt the Directive's objectives, both the economic operators and the public authorities considered that the Directive was still in line with the needs in the field and that no change would be needed.

It should be noted that the content of aerosol dispensers may be subject to other legislation depending on the application (e.g. foodstuff, medical devices, pharmaceuticals...). Moreover other EU or national legislation applies with regard to packaging, transport and environmental aspects such as storage, recycling and waste management. These aspects are not within the scope of the Aerosol Dispensers Directive and are not part of this evaluation.

¹⁴ See also point 7.2 Relevance page 59 of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

5.1.2 Relevance in the light of technological developments

The evidence collected as part of the evaluation shows that there have been a number of scientific and technological developments in the field of aerosol dispensers such as for example advances in container materials and coatings, introduction of environmental friendly propellants, optimisation of the spray quality through advanced valve design. The aerosol industry is characterised by a high degree of cyclicality, meaning that the demand for certain category of products is constantly changing. Economic operators noted there is a lot of interest for new applications in the cosmetics, medical and food aerosols. Nonetheless, from the product point of view not many changes can be expected in the future. According to the interviewees, the composition of the content of aerosols might change over time driven by the demand for more environmental friendly products. The interplay between the active component, the solvent and a specific propellant is tuned for each aerosol application to guarantee the performance of the dispenser.

There have been several amendments to the Directive to ensure that it stayed up to date with technological and other developments in the field. For example the more generalised application of LPG as propellant resulted in specific requirements concerning flammability and testing of aerosol dispensers¹⁵. Another amendment¹⁶ was necessary to ensure coherence with the Regulation related to Classification, Labelling and Packaging of substances and mixtures¹⁷. The most recent amendment¹⁸ in 2016 provides for an increase of the maximum pressure to 15 bar at 50 degrees Celsius when using non-flammable propellants resulting in better performance of the dispensers while using less dangerous and more environmental friendly compressed gases as propellants.

Based on the evidence collected and the consultations carried out as part of the evaluation¹⁹, it can be confirmed that the Directive is up-to-date and in line with the technological developments. Both the interviews and the targeted consultation with economic operators covering the full value chain (container manufacturers, valve and actuator manufacturers, aerosol fillers, marketers (brand owners)) confirmed that the changes already applied to the legislation were necessary and appropriate.

5.1.3 Ability to foster or support innovation

There was a general consensus amongst the economic operators that the Directive does not directly stimulate innovation but offers a flexible framework which allows innovating as long as the compliance with the basic safety requirements is respected.

However a specific issue was raised by plastic container manufacturers and some marketers (brand owners) with respect to the limit on the maximum capacity of plastic aerosols dispensers. Since the adoption of the Aerosol Dispensers Directive in 1975, the

¹⁵ Commission Directive [2008/47/EC](#) of 8 April 2008

¹⁶ Commission Directive [2013/10/EU](#) of 19 March 2013

¹⁷ Regulation (EC) No [1272/2008](#) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

¹⁸ Commission Directive [2016/2037/EU](#) of 21 November 2016

¹⁹ Please see point 7.2.1.5 Conclusion page 62 of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3)

maximum capacity is limited to 1000 ml for metallic containers (tinplate and aluminium) and to 220 ml for plastic aerosol dispensers. This limit was imposed to reduce the risks of dispensers using plastic as base material for the containers. As plastic material may be subject to a certain level of degradation of its mechanical properties over time, it was considered appropriate at that time to limit the maximum capacity to 220 ml. Apart from technical issues and the cost of raw material, the limited capacity of 220 ml was a disadvantage for developing and marketing product lines which are typically in the range up to 650 ml for many consumer products. Economic operators preferred in many cases metallic containers which allowed to cover a wider range of packaging. The limited capacity of 220 ml for plastics turned out to be a commercial disadvantage and resulted in a situation that production of plastic aerosol dispensers has been extremely low.

In the meantime, plastic material properties and production technologies have evolved and some economic operators, having a commercial interest in the development of plastic aerosol dispensers, argue that this limit is no longer justifiable on safety grounds. This limit constitutes a significant disadvantage compared to the other materials and prevents the introduction of new plastic aerosol dispenser applications on the European market.

The concerned industries developed materials and containers in plastic material that are suitable for applications in aerosol dispensers and provided test data demonstrating the safety of such products for higher capacities. Based on the information received from several companies, various products are in the final phase of development and laboratory testing. Plastic aerosol dispensers exceeding the capacity of 220 ml are already on the market in third countries.

Plastic aerosol dispensers are however only competitive compared to metallic dispensers if a more complete range of capacities can be placed on the market. For the plastic aerosol dispensers, the current limitation of capacity to 220 ml in the Aerosol Dispensers Directive is actually blocking innovation and further development of a competitive aerosol dispensers market in the EU.

This issue is currently under examination by the European and national authorities responsible for the implementation of the Aerosol Dispensers Directive.

5.1.4 Alignment with the New Legislative Framework

To improve the Internal Market for goods and strengthen the conditions for placing a wide range of products on the EU Market, the New Legislative Framework²⁰ was adopted in 2008. It is a package of measures that aim to improve market surveillance and boost the quality of conformity assessments. It also clarifies the use of CE marking and creates a toolbox of measures for use in product legislation. The question is whether the Aerosol Dispensers Directive should be re-written by using the proposed toolbox including standard definitions and procedures also found in other product safety legislation.

One Member State asked whether an alignment of the Directive to the New Legislative Framework for the marketing of goods should be envisaged²¹. The other national

²⁰ https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_fr

²¹ See point 7.2.1. New Legislative Framework page 62 of the Evaluation of the Aerosol Dispensers Directive, final report of 24 March 2017 (chapter 3.3)

authorities consider that the industry has a good understanding of the Directive and how it should be applied and interpreted. They did not see the need for changing a well-functioning Directive even though such alignment could provide some improvements in the application (e.g. clarifying the responsibilities of the various economic operators). The effort and cost for adaptation to the new legislation would outweigh by far the benefits in particular because there are no particular issues with the implementation of the Directive. The current legislation already provides sufficient mechanisms to hold the economic operators responsible for the products they place on the market and if needed, to take appropriate measures by the market surveillance authorities to ban or order the withdrawal of unsafe products.

5.2 Effectiveness

To assess its effectiveness²², the contribution of the Directive to the safety of aerosol dispensers and to the establishment and functioning of the internal market for aerosol dispensers have been analysed. It has also been assessed to what extent the procedure to adapt the Annex of the Directive to technical progress has been effective; whether there are any barriers to the application of the Directive; how different groups of stakeholders are affected and whether the Directive generated any unexpected or unintended impacts.

5.2.1 Contribution to product safety

Aerosol dispensers have a good track-record of safety. The technical provisions in the Directive are detailed and the test requirements are comprehensive and accepted by the industry as being necessary and proportionate. It provides the best guarantee that no faulty products reach the consumers which is of utmost importance for the economic operators. Considering the very high total number of aerosol dispensers placed on the EU market (more than 5 billion/year), the number of faulty products reaching the market appears to be extremely low²³.

The safety of aerosol dispensers is considered to be very high mainly because of the maturity of the production technology, the rigorous testing requirements mandatory by law (ADD) and the quality control by the economic operators which are very sensitive to reputational damage in case faulty products would reach the consumer.

The evidence found during the evaluation demonstrates that the Directive has a positive influence on the safety of aerosol dispensers:

- During the interviews, the national authorities reported none or very few incidents in their respective countries and no accidents could be rooted back to poor or missing requirements of the Aerosol Dispenser Directive. The high level of safety of aerosol dispensers is also reflected in the fact that none of the national authorities applied the procedure laid down in Article 10 of the Directive in the last ten years (i.e. provisional prohibition of an aerosol dispenser if it represents a hazard to safety or health despite compliance with the Directive). This finding is in line with the information available to the Commission. It should be noted that not all incidents are officially reported. Approximately half of the national

²² See also point 7.3 Effectiveness page 63 of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

²³ See point 3.2 Implementation of the legislation.

authorities did not keep any records of the number and type of consumer complaints and incidents with aerosol dispensers.

- The feedback of consumers organisations also suggests that there are no known problems regarding aerosol dispensers. Those organisations have not received any complaints or, due to the low number of incidents, do not follow this topic specifically.
- This is also confirmed in the public consultation where 80 % of the respondents are consumers, 17 % are economic operators and 3 % are national authorities. In the public consultation, 99 % of the respondents consider aerosol dispensers to be safe products.

It should be noted that the quality control and market monitoring by the economic operators also strongly contributes to the product safety. In case of a problem with a particular product or batch of products, these are often withdrawn from the market spontaneously by the entity which places the product on the market. FEA recently released a "Guide on Faulty Aerosol Recall / Withdrawal"²⁴. The purpose of this guide is to provide practical safety recommendations to operators on how to handle identified or potentially faulty aerosols along the supply chain and to the final users. There is no evidence on the frequency of such recalls but the guide aims to optimise the process based on best practices. Companies marketing aerosols (brand owners) are very sensitive to reputational damage and will also report problems to distributors or national authorities when a competitor's product is unsafe regardless of whether this is caused because of non compliance with the Aerosol Dispensers Directive or any other legislation that may apply. An example appearing occasionally on the market are party horns containing a highly flammable propellant which is prohibited in chemicals legislation²⁵ for aerosol dispensers intended for supply to the general public for entertainment and decorative purposes (see also point 3.2 above on RAPEX notifications). For these cases, the economic operators intervened towards the distributor, retailers and the national authorities to inform that an unsafe consumer product appeared in the distribution channel. It resulted in immediate action by retailers and distributors sometimes even without an intervention of the public authorities.

5.2.2 Contribution to the internal market

The evaluation confirmed that the Directive made a significant positive contribution to the internal market by the harmonisation of rules and requirements within the EU.

The vast majority of respondents of the targeted consultation of the industrial stakeholders consider that the Directive facilitated the free movement of products. During the interviews, national authorities were asked about the level of harmonisation of the legislation and whether they were aware of specific national provisions that could result in barriers to trade. All national authorities confirmed that harmonisation was to their understanding complete and there are no indications that economic operators experience problems to export their products to other Member States.

Most (92%) of the respondents to the public consultation identified as economic operators/professional associations considered that the Directive has achieved the

²⁴ <http://www.aerosol.org/mediaroom/fea-releases-the-first-edition-of-its-fea-guide-on-faulty-aerosol-recall-withdrawal/>

²⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

objective of ensuring the free movement of goods within the EU. The same proportion of respondents never encountered any problem when placing aerosol dispenser products on the market.

Even though there is no statistical data related to import / export of aerosol dispensers between the Member States, the absence of complaints or reported barriers to trade both from the national authorities and the economic operators allows to conclude that the objective of free movement is fully achieved. The production data shows that the main production is now concentrated in a limited number of Member States. The fact that products are exported from those countries to the other Member States also demonstrates that there are no barriers to trade within the EU.

The European aerosol products have a strong position in the global market. Europe had the largest market share in 2016 in terms of volume as well as revenue. The annual worldwide production is estimated at 15 billion units, of which 5,7 billion are produced in Europe, followed by the USA with 3,8 billion units and China which tripled its production from 900 million to 2 billion over the past 10 years. While there is no hard evidence to directly attribute this leading global position to the Directive, the industry representatives felt that it probably played a positive (albeit small) role in this. They argued that as a result of the harmonisation of the rules and requirements for aerosol dispensers, the Directive created a large internal market which most likely helped to foster not only intra-EU but also extra-EU trade and thus businesses' competitiveness.

5.2.4 Role of the provisions and requirements set out in the Directive on its effectiveness

The wording and content of the Directive's provisions and annexes were assessed on how they impact the effectiveness of the Directive. No major concerns were identified during the consultation processes.

The majority of Member States felt that the wording and content of the Directive is sufficiently clear and appropriate; no major issues and concerns exist in relation to it. The annexes were found to be very detailed, however this was not considered problematic²⁶.

Based on the results of the consultation, it is confirmed that economic operators and industry representatives don't have major concerns about the provisions and content of the Directive. They generally consider all provisions relevant. Overall, there are no concerns about inconsistencies or out-dated provisions. It is found that the wording of the Directive is sufficiently clear and appropriate. The fact that the Directive provides detailed requirements in a single document is considered as an advantage from the industry point of view.

The only provision that some part of industry considered not appropriate or relevant anymore is the limit of the maximum capacity of plastic aerosol dispensers to 220 ml as already explained under point 5.1.3 (Ability to foster or support innovation). A modification of the Directive via an adaptation to technical progress which would allow

²⁶ See also point 7.3 Relevance of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

an increase of the maximum capacity of plastic aerosol dispensers is currently under examination by the Commission services.

The Directive has a procedure²⁷ to adapt the Annex of the Directive to technical progress. Those measures are limited to non-essential elements of the Directive. As described in section 2.1 (Description of the intervention) the procedure has been used four times and is considered effective even though some stakeholders consider that the process should be faster. The duration of these adaptations is mainly determined by the preparatory work to examine the problem to be addressed and to define appropriate technical solutions and requirements to be included in the Annex of the Directive. The preparatory phase including the provision of test results and scientific evidence and the consultation of technical experts from the national authorities takes quickly up to 3 or 4 years. Once all information is available, the actual legislative procedure including consultation and vote by the Committee²⁸ on Aerosol Dispensers Directive can be completed in less than one year.

5.2.5 Barriers to the effective application

The national authorities confirmed in interviews that there have not been any barriers in the effective transposition of the Directive into national legislation.

There have also been very few barriers to the application of the Directive in practice. Considering that the directive is applicable since 1975, industry is fully adapted to the requirements in the Directive. Standards have been developed to facilitate the implementation, production methods and infrastructure are fully optimised to produce in the most cost effective way in compliance with the Directive. It is therefore not a surprise to the EC services that currently no barriers or problems with the implementation of the Aerosol Dispensers Directive are reported through the consultation by any of the stakeholders.

One stakeholder (filler/marketer) referred in this context to the alternative test methods for filled aerosol dispensers. These tests can replace the traditional hot water bath test which is perceived by some stakeholders as too costly both with regard to initial investment and operation. The complaint related to the fact that the criteria and conditions for the alternative tests were defined by the national authorities but this is exactly what is required in the Directive as agreed by the co-legislator. The requirements are not defined in the Aerosol Dispensers Directive itself but must be defined at national level. This may lead to differences in application between the Member States but does not constitute a barrier to trade for the final product. It might however lead to diverging requirements (and costs) for the tests from one Member State to another and could potentially lead to distortion of competition. So far, there is however no indication for the Commission services that the alternative test method and the requirement established at national level is actually causing any problem.

²⁷ ADD Article 5 “*The Commission shall adopt the amendments required to adapt the Annex to this Directive to technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(2)*”.

²⁸ ADD Article 6 “*A committee on the adaptation to technical progress of the Directive on aerosol dispensers, hereinafter called the ‘Committee’, is hereby set up and shall consist of representatives of the Member States with a Commission representative as Chairman.*”

Even though the alternative test method is available as an option in the Directive, it is not often applied mainly because of the technical complexity and the associated capital investment for the test equipment and the capacity to test high production speed and volumes. Currently and based on information from the specific consultation on cost assessment, it appears that the hot water bath test is still the preferred solution for the vast majority for the aerosol dispensers produced in the EU. So far, the Commission services are only aware of the application of the alternative test method in a production environment in one Member State.

It appears that the stakeholder is rather expressing dissatisfaction with the required level of tests imposed by the Member State where the production takes place. The fact that the rules should be defined at national level does not appear to be the blocking factor for the wider use of this technology. Other Member States are considering to give authorisation for using the alternative test method.

5.3 Efficiency

To assess the efficiency²⁹ of the Directive, stakeholders were asked about the costs and benefits related to the Directive and about the proportionality of those costs.

Information on costs for the production of aerosol dispensers is not publicly available. Even less available is any data that would demonstrate the costs due to compliance with the requirements of the Directive. Companies are reluctant to share this information either for commercial reasons or simply because the information cannot be easily retrieved from the financial management systems. Therefore, a specific consultation based on in-depth interviews with a representative sample of 'typical' companies who agreed to provide basic estimates of the costs of an aerosol dispenser was organised. Valuable information was obtained from container manufacturers and the filling industry. Data was collected via interviews and using cost grids³⁰ aiming to identify capital expenditure investment costs, operating expenses (personnel costs, operation and maintenance costs), financial costs and administrative burden.

The main cost components for the production of aerosol dispensers includes the raw material for the container, the sealing materials, coatings, the propellant, the active content, the pressure level, the size of the cans, the volume of production, the line speed of production, the labelling on the final product, ...

The final cost of a product is therefore depending on a wide range of parameters. For example for the container itself and based on expert view, a tin plate container is typically 10% - 15% cheaper than aluminium while plastics, particularly of small volumes are more expensive than aluminium³¹. Depending on the application and the content, there will be specific requirements on the coatings, the propellants etc.

²⁹ See also point 7.4 Efficiency page of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

³⁰ More details can be found in the Final report on the evaluation of the Aerosol Dispensers Directive, Annex 10 (Costs Grids)

³¹ Based on the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.4,page 35)

It should be underlined that most of the costs are intrinsically linked to the production of a functional and safe product regardless of the legislation that may apply.

Based on the collected information through the interviews with the 'typical' companies, it can be concluded that the costs associated with the Directive on economic operators are low. Investments and operating costs for production and testing would have also been made in absence of regulation being part of general good manufacturing practices and needed in order to meet acceptable safety and quality levels (business as usual). Information obtained from the other consultations (targeted consultation and interviews with economic operators) also indicate that the costs are low. The majority of stakeholders estimated the costs of compliance with the Directive as 5% of the production costs per unit³².

The production costs of aerosols range between 0.14 € to 1.00 € per unit, so based on the 5% estimation, the costs related to the Directive range from 0.007 € to 0.05 € per unit. The majority of the economic operators (88%) consider these costs proportionate to the benefits. Only 12% think the costs are higher or slightly higher than the benefits.

The costs due to administrative burden is very low. There is no reporting obligation for the manufacturer in the Aerosol Dispensers Directive. Logging and tracing information to identify the production batches is part of the regular production process and is not due to specific legislative requirements in the Directive.

The costs related to the Directive are also considered low for national authorities. The transposition of amendments in national law takes time and resources but in general Member States have indicated that very little time and effort is spent on the Directive. As there are hardly any problems on the market for these products, there are only very limited resources allocated to market surveillance and no Member State has a dedicated resource for the surveillance of the aerosol market. Specific market surveillance actions are absorbed by the teams in charge of the wider range of consumer products. The national authorities therefore consider that the Directive is efficient given the low cost for the administration and the high benefits in terms of the EU internal market and consumer safety. The full harmonisation of the technical requirements lead to substantial economies of scale reducing the overall production cost of the aerosol dispensers.

An overview of costs-benefits as identified in the evaluation can be found in Annex 4.

It can be concluded that the costs related to the Directive are low for both economic operators and national authorities. The costs that do occur are considered as proportionate to the benefits of establishing a well-functioning internal market for safe aerosol dispenser products. Administrative burden is low and no potential for simplification has been detected.

5.4 Coherence

The Aerosol Dispensers Directive is addressing the safety hazards due to pressure and, where appropriate, flammability and inhalation. Other EU or national legislation also applies to aerosol dispensers: for example legislation related to transport of dangerous

³² Based on the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 7.4 section 7.4.1.1 Economic Operators – ADD costs page 84-85), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

goods³³, storage, pre-packaging³⁴ and labelling (CLP Regulation³⁵). Specific legislation may apply to the content of an aerosol dispenser for example for food or pharmaceutical applications.

To assess the coherence³⁶ of the Directive with other legislation was analysed. In the interviews Member State representatives and economic operators were asked about any (potential) inconsistencies. The replies indicate that the Directive is coherent with other EU legislation.

The environmental and social impact of aerosol dispensers relates mostly to propellants, waste management and packaging. The aerosol dispensers industry has adapted its products to meet the environmental requirements for the propellants. The adaptation to technical progress of the ADD adopted in 2016 is supporting this transition by facilitating the use of environmental friendly compressed gases in stead of liquefied gases as propellant. The waste treatment of partly emptied aerosol dispensers and new types of aerosol dispensers that remain under constant pressure was pointed out as an area of concern in the consultation by the professional associations representing companies dealing with waste treatment. These aspects are covered by legislation related to waste and recycling and protection of workers and will require further attention of the Commission services under the applicable EU legislation.

The question was raised whether the ADD should not be aligned to the NLF (New Legislative Framework) similar to other product safety directives (see also point 5.1.4). Such change would not result in a simplification nor would it provide substantial benefits. An aerosol dispenser is not subject to other New Approach product safety directives hence there is not a potential problem of contradicting or overlapping requirements with those directives.

An alignment to the NLF would only provide for an explicit definition of the roles of the different economic operators (manufacturers, distributors and importers). Such changes would however imply a full legislative procedure as it requires a modification of the articles of the Directive. Both the economic operators and the national authorities consider that the costs would be much higher than the benefits in particular because the Directive in its current format does not show significant shortcomings.

In general, the Directive is coherent with other legislation on EU, international and national levels. no inconsistencies or overlaps have been detected that would lead to problems in practice.

³³ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods

³⁴ Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products

³⁵ REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures

³⁶ See also point 7.5 Coherence p. 89 of the Evaluation of the Aerosol Dispensers Directive , final report of 24 March 2017 (chapter 3.3), <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

5.5 EU Added value

To assess the EU added value of the Aerosol Dispensers Directive, a comparison was made between what could be done on a national level (without the Directive) and what has been achieved at EU level by the Directive.

The added value of the Directive is acknowledged by all stakeholders. Based on the results of the consultations³⁷, it can be concluded that the establishment and the functioning of the internal market for aerosol dispensers is best achieved at EU level. Without the Directive, economic operators would have to comply with a multitude of national possibly diverging requirements, which would hamper intra-EU trade and increase the cost of compliance. The Directive provides legal certainty at an EU wide level.

The fact that the rules and requirements of the Aerosol Dispensers Directive are also used by some third countries enhances the competitiveness of European manufacturers by facilitating the export.

6. CONCLUSIONS

The evaluation covers the performance of the Aerosol Dispensers Directive in the period 2005 to 2015 in all Member States. It assesses the relevance, effectiveness, efficiency, coherence and EU added-value in order to verify whether it meets its objectives and provides the mechanisms to deal with future changes in the business environment.

The main conclusion of the evaluation is that the Directive is functioning properly and is contributing positively to its main objectives of guaranteeing the safety of aerosol dispensers while ensuring the free movement on the EU market.

The evaluation is mainly based on desk research and qualitative data received from the main stakeholders, e.g. industry, national authorities and consumers. Aerosol dispensers are not specifically covered in the official statistics. Quantitative information related to the market of the products is also not readily available. Some cost related information was retrieved through focussed consultation of a limited number of companies that agreed to cooperate on this commercially sensitive matter. It allowed to draw some conclusions on the cost-efficiency of the Directive. A full quantitative analysis e.g. on the contribution of the Directive to the internal market was however not possible in absence of market data or official statistics. In the EU, there is no systematic recording and reporting on safety problems of these products but throughout the consultation specific attention was paid to collect such information directly from the economic operators, the national authorities and the consumers.

Overall, the reliability and robustness of the data collected and used in the analysis for the evaluation is assessed as satisfactory by the EC services.

The Directive's objectives are still considered **relevant**: they correspond to the needs of consumers and economic operators and require no change. Although the Directive does not directly stimulate innovation, it provides a flexible framework that allows innovation as long as safety requirements are respected.

³⁷ Full details on the consultation can be found in the Synopsis report in Annex 3.

The Directive has been **effective** in ensuring its objectives:

- The safety of aerosol dispensers is considered to be very high. This result is achieved because of the maturity of the production technology, the rigorous requirements in the Directive and the quality control by the economic operators which are very sensitive to reputational damage in case faulty products would reach the consumer. The Directive is setting strict criteria to ascertain that products on the market, including imported ones, are safe. It results in a very high level of safety and few accidents with aerosol dispensers. This good performance is also reflected in the limited allocation of resources for market surveillance by the national authorities. Consumer organisations' feedback also allow to conclude that there are no significant safety problems with aerosol dispensers on the EU market.
- The Directive has made a significant contribution to the internal market by harmonising rules and requirements in the EU. The vast majority of stakeholders agrees that the Directive has achieved the objective of free movement within the EU and have not encountered problems when placing aerosol dispensers on the market. Economic operators confirmed that they can easily do business in different Member States because their aerosol dispensers only have to comply with one harmonised set of rules across the whole EU market.

Some remarks should be made concerning the analysis of the effectiveness and relevance.

- Some economic operators consider that the current limit for the capacity of plastic aerosol dispensers is no longer justified because the safety of plastic aerosol dispensers with higher capacity can also be guaranteed. The concerned industries have provided test resulting supporting these statements. This particular issue is already under review by the Commission services.
- Although the alignment of the Directive to the New Legislative Framework (NLF) could improve the clarity and consistency, all stakeholders agree that the current situation does not justify a long and costly procedure to revise the entire Directive. The current provisions of the Directive, including the procedure for adaptation to technical progress are adequate. They are considered clear and well understood by stakeholders and cover all relevant aspects.

The Directive is considered **efficient**. Based on the result of the stakeholder consultation, it can be concluded that the costs related to the Directive are proportionate to the benefits.

- Although quantitative data was limited, stakeholders provided basic estimations which allow to conclude that the costs for economic operators directly attributable to the Directive are very low. Many investments (manufacturing, safety and quality checks) would have also been made in absence of the Directive.
- The costs for national authorities are also very low. Aside from the transposition of amendments into national law, little time and effort is spent on it. Given the very low level of problems with aerosol, dispensers, there are no dedicated resources for market surveillance in the Member States. Compared to the high perceived benefits of product safety and free movement, the costs are proportionate.
- administrative burden is low and no potential for simplifctaion has been detected

The Directive is **coherent** with other legislation applicable to aerosol dispensers, for example related to transport of dangerous goods, storage, pre-packaging and labelling, waste and recycling. No overlap or inconsistency have been detected.

Lastly, the **EU added value** was acknowledged by all stakeholders. Intra-EU trade would not be as easy with diverging national requirements in place. In addition, the requirements of the Aerosol Dispensers Directive have also been adopted in the legal framework of several large third countries which facilitates the export and increases the competitiveness of the European industry on the global market.

The overall conclusion is that the Aerosol Dispensers Directive is functioning well. No substantial problems that require changes to the legislation were identified. The large majority of stakeholders (national authorities, economic operators and consumers) are satisfied with the current situation. The provisions and requirements of the Directive are clear to all and sufficiently flexible to allow innovation and technological development.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, PLANNING AND COMMISSION WORK PROGRAMME REFERENCE

Lead DG: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW); Unit C3 Advanced Engineering and Manufacturing Systems.

Agenda planning/work programme reference: 2017/GROW/001

2. ORGANISATION AND TIMING

The inter-service Steering Group was composed of representatives of several Commission departments (Secretariat General, DG JUST and DG GROW).

After the kick-off meeting in July 2015, it met 4 times in 2016; 3 times in 2017 and once in 2018.

3. EXCEPTIONS TO THE BETTER REGULATION GUIDELINES

Not applicable.

4. CONSULTATION OF THE RSB (IF APPLICABLE)

Not applicable.

5. EVIDENCE, SOURCES AND QUALITY

The evaluation study was outsourced to an independent consultant applying the standardised methodology for external evaluations as defined in the Better Regulation framework.

Literature, open on-line sources and publicly available reports have been used. The main source of information was the stakeholder consultation. Information was collected via interviews (economic operators and national authorities in charge of policy or market surveillance), targeted consultations of economic operators and an online public consultation reaching out to a wider audience in particular SMEs and consumers.

Market data about the aerosol dispensers sector is not readily available and there is no specific coverage in the statistical databases of Eurostat or other sources. General market information was collected from the European and national industry associations' publications such as annual reports. More detailed cost related information was collected via a specific consultation of a limited number of economic operators which agreed on a voluntary basis to provide elementary data. Selective global market data including forecasts was obtained via a multi-client study of a market research company³⁸.

The robustness of the consultations:

³⁸ Grand View Research (<http://www.grandviewresearch.com/industry-analysis/aerosol-market/toc>)

- During the preparatory phase, the external consultant used existing studies and documents of the Aerosol Dispensers Directive Working Group to prepare the next steps in the study. The work resulted in the questionnaires for the interviews, targeted and public consultation. It also provides an insight to the adaptations to technical progress of the ADD during the period covered by the evaluation.
- The Steering Group monitored the development of the consultation both with regard the process and the analysis of the information collected by the contractor. The Steering Group paid particular attention to the independence of the evaluation team considering that information sources were limited and replies were potentially driven by commercial interests of the economic operators.
- The external consultant team included also highly qualified technical experts to assist the evaluation team in analysing the more technical and/or safety related issues. This approach resulted in good quality analysis of the replies and reduced the risk of errors in the interpretation of the results.
- The public consultation was announced on the Europa site but also widely publicised via indirect channels (DG GROW Enterprise Europe Network³⁹ to reach also SMEs and consumer associations) to unlock the potential of stakeholders who initially did not engage in the evaluation process.
- Contributions by industry appear to be coherent and representative for the sector. Through targeted interviews of national authorities information could be collected from the majority of the Member States. The online public consultation resulted in 139 replies, providing also the view of consumers and confirmed conclusions that could be drawn from the information already obtained from economic operators and national authorities.
- Triangulation of data from the surveys, the interviews and the online public consultation, allowed to identify divergences between the data collected through the different tools. The answers were largely converging and reinforcing conclusions drawn from the different stakeholder groups.
- Compliance cost appears to be limited but it was difficult to obtain this kind of information as economic operators do not have a record of the break-down of costs for this purpose. Most of the investment, operation and maintenance costs are inherent to the production process anyhow and the specific costs to meet the requirements of the directive appear to be marginal.

Whereas the number of replies and the level of coherence are high, the qualitative assessment can be considered as reliable. However, information related to market size and compliance costs need to be interpreted with care and should be seen as indications of an order of magnitude rather than as precise estimates.

Given the very high number of products placed on the EU market annually (more than 5 billion per year); the number of reported accidents is extremely low. There is no systematic collection of information about faulty aerosol dispensers or accidents with these products, neither at national nor at European level. None of the reported cases revealed any shortcomings in the Directive itself. Whereas this situation is confirming the excellent safety record of aerosol dispensers, caution is needed on the interpretation of this finding and national authorities are encouraged to collect data related to problems they may identify with these products.

³⁹ <http://een.ec.europa.eu/>

ANNEX 2: SYNOPSIS REPORT OF THE STAKEHOLDER CONSULTATION

1. Introduction

The evaluation approach aimed at gathering both qualitative and quantitative evidence from a number of complementary data sources, including European and national. The following groups of stakeholders were consulted:

- Private companies/economic operators covering the whole value chain (container and valve manufacturers, propellant suppliers, aerosol fillers, marketers (brand owners), ...)
- EU and national industry associations
- National authorities including market surveillance authorities
- Consumers (individuals)
- Consumer organisations

Data was collected by the external consultant via desk research / literature review and a targeted consultation of stakeholders. In parallel, the European Commission service ran an online public consultation. All stakeholders were consulted through targeted and online public consultations, with the exception of consumers (individuals), whose views were gathered only through the European Commission's online public consultation.

All Commission minimum standards for public consultations were met.

Targeted consultation: The targeted consultation consisted of three main data collection tools, namely:

- in-depth interviews to gather qualitative information on the performance of the Directive according to different groups of stakeholders,
- consultations with ‘typical’ companies per industry to collect absolute cost figures,
- A targeted online survey to gather quantitative data on the views and opinions of economic operators in the industry.

The paragraphs below elaborate in more detail on each of these data collection tools and the results achieved.

2. Stakeholder groups covered by the consultation activities

In-depth interviews with stakeholders: The interview programme resulted in 52 interviews involving the main actors at EU, national and regional levels, as well as industry and SMEs representatives. The specific actors include all relevant Commission services, national (market surveillance) authorities, representatives from industry (economic operators active in the whole value chain and industry associations) and consumer organisations.

Consultations with ‘typical’ companies: Consultations with ‘typical companies’⁴⁰ per industry based on a questionnaire designed with industry experts were performed to

⁴⁰ ‘typical’ companies refers to company profiles per industry that represent to the extent possible the vast majority of companies in the industry

provide cost estimates. A total of 10 consultations with the industries directly impacted by ADD were undertaken to construct company level cost estimates (Manufacturers of cans (3), Filling industry (7)). Note that none of the valve manufacturers agreed to be part of this exercise due to confidentiality concerns (expressed namely due to the small size of the sector in Europe). The information on costs for the valve industry is therefore based on the survey only.

Targeted online survey: An industry survey was conducted. The target population consisted of private sector enterprises in the aerosols supply chain including: manufacturers of cans; manufacturers of valves; filling industry; marketing/sales/distribution. The industry survey questionnaire was distributed through European and national industry associations in all concerned sectors. The associations distributed the survey questionnaire to their members (through a survey web-link). In total, the survey resulted in 97 responses of good quality.

The European Commission services conducted the **online public consultation** from 30 September 2017 to 15 January 2018. It was available in 6 official EU languages (EN, FR, DE, ES, IT, PL). Information was disseminated via the Working Group Aerosol Dispensers and the Europa site. The DG GROW Enterprise Europe Network⁴¹ (EEN) was also asked to disseminate the survey via a web-link. There were 139 respondents: 111 consumers and consumer organisations, 24 companies or industry associations and 4 public authorities.

2. Stakeholder Consultation: profile of respondents

This section shows the targeted groups and respondents of the consultation activities.

2.1 Interviews

The table below summarises the total number of interviews per category of stakeholders:

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

2.1.1 Interviews with the public authorities

The table below provides an overview of the total number of interviews conducted and the type of responses (oral or written) received.

Responses	Number of interviews
Total number of interviews conducted	21 interviews
Total number of Member States interviewed	19 Member States
Total number of written responses	8 written responses
Total number of telephone interviews	13 telephone interviews

As shown in the table below, one interview per Member State was conducted with the exception of Germany where there were three interviews: one with a representative at federal level, one at state level and one interview with a representative of the market surveillance authority. Despite several invitations and reminders, it has not been possible

⁴¹ <http://een.ec.europa.eu/>

to conduct interviews with representatives of Bulgaria, Croatia, Denmark, Hungary, Italy, Luxembourg, Malta, Portugal, Romania, Slovakia, and Slovenia.

Number and type of interviews conducted with the national authorities

Ref. no.	Country	Organisation	Type of consultation
1	AT	Federal Ministry of Science, Research and Economics	Written response
2	BE	Federal Public Service Economy	Telephone interview
3	CY	Ministry of transport, Communications and Works	Telephone interview
4	CZ	Czech Office for Standards, Metrology and Testing	Written response
5	EE	Ministry of Economic Affairs and Communications	Written response
6	ES	Ministry of Energy, Tourism and the Digital Economy, Sub-Directorate General of Quality and Safety of Industry	Telephone interview
7	FI	Finnish Safety and Chemicals Agency (market surveillance authority)	Telephone interview
8	FR	DG Competition, Consumption and Fraud	Telephone interview
9	DE	Federal Ministry of Labour and Social Affairs	Telephone interview
10	DE	State authority Thüringen	Telephone interview
11	DE	Market surveillance authority	Telephone interview
12	EL	Ministry of Economy, Development and Tourism	Written response
13	IE	Department of Jobs, Enterprise & Innovation	Telephone interview
14	LV	Ministry of economy	Telephone interview
15	LT	State Consumer Rights Protection Authority (market surveillance authority)	Written response
16	NL	Ministry of Health, Welfare, and Sport	Telephone interview
17	PL	Ministry for Economic Development	Written response
18	RO	Ministry of Economy Commerce and Relations with the Business Environment, State Inspection Body for Control of Boilers, Pressure Vessels, Hoisting Equipment	Written response
19	SK	Slovak Trade Inspection	Written response
20	SE	The Swedish Civil Contingencies Agency	Telephone interview
21	UK	Department for Business, Innovation & Skills	Telephone interview

2.1.2 Interviews with the economic operators and industry associations

The interviews with the economic operators and industry representatives were conducted during the period from 13 June to 25 October 2016.

The results of these interviews present the opinions of 29 interviewees on the relevance, the effectiveness, the efficiency, the coherence and the EU added value of the Aerosol Dispensers Directive. The table below gives a breakdown of the number of invitations to participate in the regular interviews and the actual number of interviews per type of stakeholder.

Overview of interviews with the economic operators and industry representatives

Type of stakeholder	Invited to participate in the interview	Number of conducted interviews
Fillers and marketing	24	10
Packaging	10	7

European associations	8	3
National associations	11	6
Institutes	2	1
SMEs – fillers	10	1
SMEs – packaging	4	1
<i>Sub-total</i>	<i>69</i>	<i>29</i>

2.1.3 Consumer associations' interviews

Despite several attempts, consumer association's mobilisation for the evaluation of the Aerosol Dispensers Directive has resulted in only one interview, out of two set as a target. The attempts to get in touch with consumer associations from EU28 Member States can be summarised as follows:

- 30 consumer's associations in total have been contacted, most of them both by email and phone.
- 25 countries of the EU28 were covered.
- The 11 biggest EU28 countries were followed-up more intensively, with an average of three attempts per country, in order to ensure coverage of the biggest markets.
- The European Consumer Organisation (BEUC) has also been contacted with a request to participate in the interview.

The evaluation team has encountered difficulties in being redirected to the most appropriate person within the respective association in the majority of cases. The European Consumer Organisation (BEUC) had to decline the invitation to participate in an interview because this topic is not followed internally and it was therefore not possible for them to identify a relevant contact person.

On the same token, the evaluation study team received three negative replies from the associations in Denmark, the Netherlands, and Greece. The reason behind declining the request for interview was two-fold. First, the associations do not cover this topic. Second, they had received no complaint on this matter.

As an outcome of the consultation, it was possible to carry out one interview with the national consumer associations, namely from the Italian association "Federconsumatori". The representative of the association noted that the association never faced problems regarding aerosols nor received any complaint.

2.2 Targeted online survey for industry

The targeted online survey was launched the 3rd of August 2016 and was closed the 15th of October 2016. Three reminders were sent out via FEA to all national associations. Additional reminders were sent to national associations due to the unexpected low responses from some countries during the monitoring of the survey's progress.

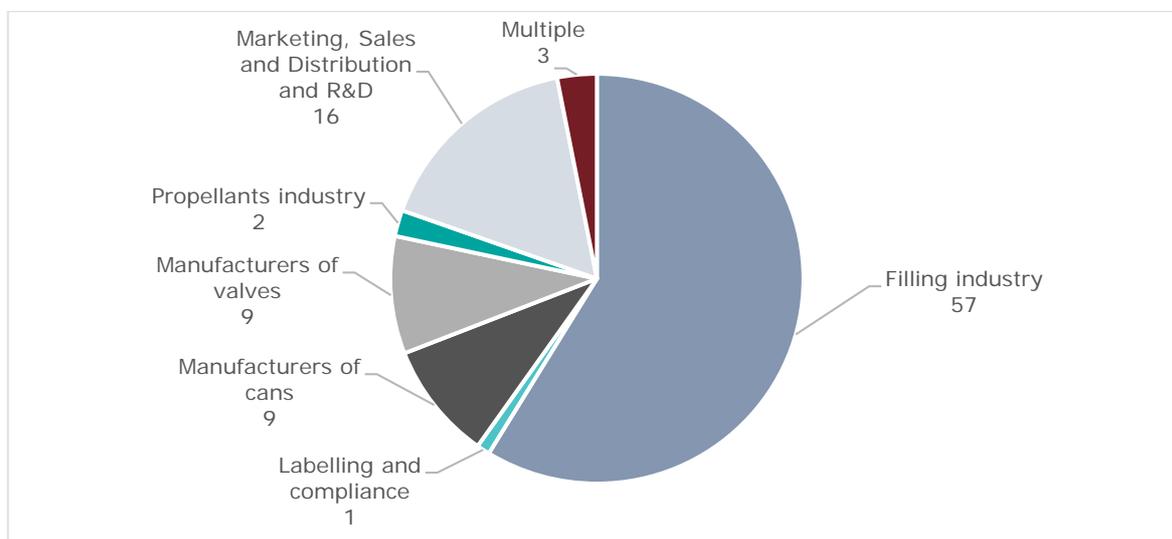
The survey has in total 97 responses of good quality among the total number of 199 responses.

The aerosol industry value chain was represented in the survey as follows: 59% from the filling industry, 9% from the can (container) manufacturing industry, 9% from the valve manufacturing industry, 16% from Marketing and/or Sales and/or Distribution and/or

R&D, 2% from the propellants industry and finally 3% from companies integrated along the value chain, including multiple of the aforementioned industries (labelled as “Multiple”).

As a check for the representation of the industry by the survey, FEA has been consulted for three types of stakeholders: filling industry, can manufacturing industry and valve manufacturing industry. According to FEA data there are in total 373 aerosol related companies (note however that the number includes duplicates due to multinationals being members in multiple countries) represented largely by the filling industry (at 80%), followed by the can manufacturing industry (at 12%) and finally the valve manufacturing industry (at 9%). In the survey conducted in this study the responses obtained from the latter industries are split as follows: 76% coming from the filling industry, 12% from the can manufacturing industry and 12% from the valve manufacturing industry. Thus, the survey mirrors the industry’s composition very well.

Aerosol industry value chain representation in the survey (numbers represent response counts)



Other dimensions of the coverage include geography, size and turnover market shares which are briefly presented below.

Geography: The geographical coverage of the survey is as follows:

Country	Count of responses
Belgium	5
Bulgaria	1
France	26
Germany	15
Greece	1
Ireland	1
Italy	9
Missing	1
Netherlands	5
Other	7
Poland	3
Portugal	1

Switzerland	2
United Kingdom	20
<i>Total</i>	<i>97</i>

Company Size: The respondents are equally split between SMEs (ca. 50% below 250 employees and turnover below or equal to 50M€) and Large companies (50% above 250 employees and above 50M€turnover):

Please state the number of personnel currently working in your company (<250, >=250) – counts of responses	< 250	>= 250	Grand Total
	52	45	97
Please specify the turnover of your company for the last year of operation (<=50M€, >50M€) – counts of responses	<=50M€	>50M€	Grand Total
	48	49	97

2.3 Online public consultation addressed to all stakeholders

The **online public consultation** was open to all stakeholders. There were 139 respondents: 111 consumers and consumer organisations, 24 companies or industry associations and 4 public authorities.

The most important group were the consumers and their replies were crucial in obtaining information straight from the users of the products on the market. Information from this group has proven very useful to compare with findings based on consultation of the economic operators and the national authorities.

The replies received from companies were very much in line with the information of the interviews and the targeted consultation.

The public authorities which replied were new to the consultation process but confirmed the information obtained earlier through interviews with the national authorities.

3. Stakeholder Consultation: Results

The stakeholder consultation was comprehensive and combined various techniques such interviews, targeted consultation and online public consultation each with a particular focus and dedicated questionnaires (see Annexes 7, 8 and 9 of the Final report on the Evaluation study of the Aerosol Dispensers Directive).

Information obtained via the various mechanisms systematically confirmed the good performance of the directive with regard to its objectives.

3.1 Results of the interviews with economic operators and industry associations and public authorities

The interviews were conducted mainly in the beginning of the evaluation process. A detailed interview guide addressing all evaluation questions was developed with specific

questions tailored for each stakeholder group (see Annex 7 – Interview Guidelines of the Final report on the Evaluation of the Aerosol Dispensers Directive).

Industry stakeholders and the professional associations consider that the Aerosol Dispensers Directive is still relevant. Otherwise, they would be confronted with possibly diverging national requirements resulting in high costs.

The Aerosol Dispensers Directive is considered to be effective even though some manufacturers argue that the FEA standards also contribute significantly to the safety of the products.

No barriers to trade in the EU are reported by the manufacturers or the professional associations.

When asked about the efficiency of the Directive, the costs and the proportionality of the costs associated to the Aerosol Dispensers Directive, the interviewees stated that such information was not readily available. As such information could not be obtained via the interviews, a specific consultation of a limited number of companies (10) was setup by the contractor to get a better insight.

Public authorities informed that the Aerosol Dispensers Directive is functioning well in their view. There are hardly any accidents and effort for market surveillance is very limited. All products seem to meet the requirements and no barriers to trade are identified. When asked about the resources allocated to market surveillance, Public authorities explained that no resources are specifically dedicated to the aerosol dispensers given the low accident rate.

With regard to the process to adapt the Aerosol Dispensers Directive to technical progress, several Member States considered that the process was slow while recognising that such modifications needed to be prepared very well and should always be subject to wide consultations not only of the authorities but also of the economic operators. It was recognised that such processes are time consuming but in general Member States consider that part of the process could be faster.

3.2 Results of the online targeted consultation of industry

The online targeted survey of industry included detailed questions addressing all five evaluation criteria (see Annex 8 – Targeted online survey of the Final report on the Evaluation of the Aerosol Dispensers Directive).

Industry considers that ADD has contributed to the health and safety of aerosol dispensers. Where originally, ADD was addressing only the hazard due to pressure, flammability and risks related to inhalation were added to the requirements through adaptations to technical progress. It was stated that ADD includes quite stringent test requirements but this has contributed to the high safety standard according to most of the economic operators. Some economic operators and the professional associations also underlined the benefits of the very widely used FEA standards. Economic operators and the professional associations also consider that there are no safety gaps in the current technical requirements. Some economic operators, mainly marketers and plastic container manufacturers, expressed a strong interest to change the technical limitation of the capacity for plastic aerosol dispensers.

The replies from industry and professional associations confirm that the internal market is functioning well: aerosol dispensers can be easily placed on the market in any Member State and no barriers are reported.

Concerning the costs due to the Aerosol Dispensers Directive, participants to the targeted online survey could not provide much information. There is a consensus that the costs are inherent to the production of a safe product independent of the requirements of the Aerosol Dispensers Directive. The main advantage however is that the Directive lays down specific requirements which ensure the safety of the product hereby creating similar requirements for all market operators. Both the professional associations as well as the individual manufacturers underlined the importance to guarantee the safety of the product because of the high risk for reputational damage in case faulty aerosols would reach the consumer. It was repeatedly stated that the good safety record of aerosol dispensers is not only due to the Directive but also the result of quality control by the manufacturers and monitoring of the market by the distributors and marketers.

3.3 Results of the online public consultation

More than 80 % of the replies were from consumers. Replies were received from 11 countries and more than three quarters of the replies were from the United Kingdom, Germany and France.

Nearly all correspondents (99 %) consider aerosol dispensers as safe products. Aerosol dispensers are a commodity product and consumers expressed a high level of trust.

Most of the correspondents identified as economic operators or professional associations (92 %) consider that the Aerosol Dispensers Directive achieved its objective of free movement of goods within the EU. Also for the other questions, the answers from the economic operators or professional associations to the public consultation were quite similar to the replies also received via the interviews and the targeted consultation. Most likely it were the same entities which participated also in the public consultation.

The number of replies (only 4) from public authorities was too low to draw conclusion. The information obtained via interviews with the national authorities provided a better input for the evaluation.

4. Post information cycle and feedback

The final report of the study is publicly available on the Europa server (ADD website) since June 2017. The study was widely publicised via the national authorities, European and national associations and through that channel to their member companies.

The study results were well perceived by the stakeholders. From the side of industry, FEA welcomed the findings of the study reminding still about the necessity to proceed with the pending request to increase the maximum capacity for plastic aerosol dispensers. This opinion is based on consultation of the national associations and their members. It is therefore considered as a position representative for the sector.

The study was also presented and discussed in the meeting of the Aerosol Dispensers Directive Working Group on 17 October 2017. Members of this group are the representatives from the national authorities; European industry associations participate as observers. The main conclusion of the meeting was that the ADD performs very well

and is fully meeting its objective of ensuring safety and guaranteeing free movement of aerosol dispensers on the EU market.

With regard to the evolution of the internal market product safety legislation, the EC services explained that the alignment to NLF promotes consistency and coherence in particular when a product is subject to various pieces of legislation in parallel (such as Machinery Directive and Radio Equipment Directive). For the Aerosol Dispensers Directive, there are however no overlaps with other product safety legislation and hence the EC services consider that there is no need for such alignment taking into account also the costs of such change for the economic operators and the national regulators.

The EC services continue the examination of the impacts of the request to increase the maximum capacity of plastic aerosol dispensers.

ANNEX 3. EVALUATION QUESTIONS

The evaluation assesses the relevance, effectiveness, efficiency, coherence, and EU added value of the Aerosols Dispensers Directive. To this end, a set of questions was defined to guide the data collection and analysis (see table below).

Criteria	Evaluation questions
Context	1. What was the origin of ADD and what were its main objectives? What progress has been made over time?
Relevance	2. To what extent do the initial objectives of ADD correspond to the current needs? How well adapted is ADD to technological/scientific progress and innovation that took place in the area of aerosol dispensers over time?
Effectiveness	6. Has the Aerosols Dispensers Directive been effective in achieving its main objectives ? To what extent has ADD contributed to an effectively operating internal market for the products in its scope? To what extent has ADD contributed to the safety of the products in its scope?
	7. What aspects, means, or actors render ADD (or certain aspects of ADD) more or less effective?
	8. To what extent has the procedure to adapt the Annex of ADD to technical progress been effective?
	9. What barriers (if any) exist to the effective application of ADD?
	10. How are different groups of stakeholders affected by the Directive? What are the environmental, social, and economic impacts of ADD?
	11. Did ADD generate any unexpected or unintended impacts (positive or negative)?
Efficiency	4. What are the costs associated with ADD on different stakeholder groups (including Member States and economic operators)? Are there significant differences in costs or benefits between MS? If so, what causes these differences? What aspects of ADD are most or least efficient? 5. Are the administrative and regulatory costs on the stakeholders proportionate to the results achieved? How do the costs borne by stakeholders compare to the benefits received?
Coherence	12. To what extent are there overlaps or complementarities between ADD and any other EC or international legislation (e.g. in the area of transport)?

Criteria	Evaluation questions
EU Added Value	3. What is the added value of ADD, compared to what could have been achieved at national level? To what extent do the issues addressed by the ADD continue to require action at EU level?

Before the start of the study, a number of questions was presented in the Roadmap on the Evaluation of the Aerosol Dispensers Directive⁴². Some of the original questions have been improved following feedback from the stakeholders and the members of the steering group.

⁴² http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_001_evaluation_aerosol_en.pdf

The initial questions of the roadmap are listed below for reference:

Effectiveness

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

Efficiency

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

Coherence

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

Relevance

- (k) To what extent do the initial objectives correspond to (current) needs?
- (l) How well adapted is the intervention to subsequent technological or scientific advances/progress?
- (m) Which innovation has taken place in the area of aerosol dispensers and what are the prospects? Is the scope of the ADD appropriate considering product and technological innovation?

EU added value

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

ANNEX 4. OVERVIEW OF COSTS- BENEFITS IDENTIFIED IN THE EVALUATION

Overview of the costs and benefits of the Directive (source: stakeholder consultations and Final report on the Evaluation of the Aerosol Dispensers Directive⁴³), in particular:

- section 5.6 Costs and benefits, page 44,
- section 7.4.1. (What are the costs associated with ADD on different stakeholder groups, including Member States and economic operators?), page 84
- Annex 10 Cost grids, pages 169-175
- Annex 12 Cost assessment, pages 182-196

		Citizens/Consumers		Businesses		Administrations	
		Qualitative [high / medium / low / negligible / unknown]	Quantitative / monetary [e.g. i. full-time equivalents, or €]	Qualitative [high / medium / low / negligible / unknown]	Quantitative / monetary [e.g. i. full-time equivalents, or €]	Qualitative [high / medium / low / negligible / unknown]	Quantitative / monetary [e.g. i. full-time equivalents, or €]
Cost / Benefit]	[Description:]						
Compliance costs	Investments in production line	NA	NA	High	EUR 15.000 for each type of can	NA	NA
	Human resources (training, administrative)	NA	NA	Medium/Low	Unknown	NA	NA
	Costs per unit	NA	NA	Low	5% of total production costs	NA	NA
Enforcement costs	Administrative costs	NA	NA	NA	NA	Low/Negligible	<1 FTEs
	Monitoring costs	NA	NA	NA	NA	Low/Negligible	<1 FTEs; low number of inspections
	Providing guidance	NA	NA	Negligible	None (FEA)	Negligible	<1 FTEs
Implementation costs)	Implementation costs	NA	NA	NA	Unknown	Medium/Low	Depends on national procedure
	Adaptation costs	NA	NA	Low	Unknown	?	?
Benefits	Increased product safety	ADD guarantees high level of safety , 99% of consumers consider the product safe	No reported accidents due to ADD	Guaranteed by application of ADD to all market operators	Unknown	High	No reported accidents due to ADD
	Increased intra-EU trade	NA	Lower prices? Increased choice?	Trade figures show increasing intra EU trade. ADD facilitates trade by removing national barriers	Unknown	NA	NA
	EU competitiveness	NA	NA	Economies of scale in	Unknown	NA	NA

⁴³ <https://publications.europa.eu/en/publication-detail/-/publication/80d193de-e085-11e7-9749-01aa75ed71a1/>

				production			
--	--	--	--	------------	--	--	--