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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION STAFF WORKING DOCUMENT EVALUATION OF THE OUTDOOR NOISE DIRECTIVE 2000/14/EC accompanying the document Report from the Commission to the European Parliament and the Council on the implementation and administration of Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors

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Delegations will find attached Part 1 of 3 of the document SWD(2020) 266 final.

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Brussels, 16.11.2020  
SWD(2020) 266 final

PART 1/3

**COMMISSION STAFF WORKING DOCUMENT**

**EVALUATION**

**OF THE OUTDOOR NOISE DIRECTIVE 2000/14/EC**

*Accompanying the document*

**Report from the Commission to the European Parliament and the Council**

**on the implementation and administration of Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors**

{COM(2020) 715 final} - {SWD(2020) 267 final}

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## Glossary

<i>Term or acronym</i>	<i>Meaning or definition</i>
AdCo	Administrative Co-operation
CATI	Computer-Assisted Telephone Interviewing
CEN	European Committee for Standardization
CU	Custom Union
DG ENV	Directorate-General for Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DoC	(EC) Declaration of conformity
EC	European Commission
EEA	European Economic Area
EFTA	European Free Trade Association
EN	European standard
END	Environmental Noise Directive 2002/49/EC
EU	European Union
ISO	International Organisation for Standardization
MD	Machinery Directive 2006/42/EC
MRA	Mutual Recognition Agreement
MS	Member State
MSA	Market Surveillance Authority
NA / NLF	New Approach / New Legislative Framework
NACE	Statistical classification of economic activities in the European Union
NANDO	New Approach Notified and Designated Organisations information system
NB	Notified body
NOMAD	Noise Machinery Directive project / task force
NRMMR	Non-Road Mobile Machinery Regulation (EU) 2016/1628
OND	Outdoor Noise Directive 2000/14/EC
OPC	Open public consultation
RAPEX	Rapid alert system for dangerous non-food products
RfUs	Recommendation for Use sheet
TFEU	Treaty on the Functioning of the European Union
WG	Working Group

## 1. INTRODUCTION

### *Purpose and scope of the evaluation*

The purpose of this evaluation is to analyse the performance of the **Outdoor Noise Directive 2000/14/EC** during its almost 20 years of its application. The results of the evaluation are intended to be used in view of a possible enactment of the empowerments for delegated acts foreseen in the Directive or the need for a revision of the sectorial legislation on noise emission by outdoor equipment, within the application of the EU strategy to reduce noise at source.

The geographical coverage of the evaluation refers to the 28 Member States of the European Union (including for the period of reference the UK), the EEA countries – Iceland, Liechtenstein and Norway – as well as Switzerland and Turkey. It covers the period from the implementation of the Directive in 2002 – in particular after the last assessment of the Directive, carried out through the “NOMEVAL” study in 2007 –, to 2018 (when the “Supporting study for an evaluation and impact assessment of Directive 2000/14/EC on noise emission by outdoor equipment” was completed and released), seeking to understand trends over this period wherever possible.

The evaluation covers the functioning of the Directive, including the processes involved in the transposition, implementation and enforcement. The evaluation assesses the performance of the Directive according to five criteria: **effectiveness**, **efficiency**, **relevance**, **coherence** and **EU added value** for outdoor equipment in the scope as referred to in Article 2, listed in Articles 12 and 13 and defined in Annex I to the Directive, and taking into consideration the responses and feedback received from sectoral stakeholders and interested parties, in particular from economic operators (manufacturers of outdoor equipment, importers, distributors and others), users (workers and consumers) and citizens exposed to noise emission.

## 2. BACKGROUND TO THE INTERVENTION

### 2.1. Description of the Outdoor Noise Directive and its objectives

Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the law of the Member States relating to the noise emissions in the environment by equipment for use outdoors<sup>1</sup> (in short, the “Outdoor Noise Directive”, OND) is applicable since 3 January 2002. It is part of the EU strategy to reduce noise at source: the Fifth Environmental Action Programme<sup>2</sup> and the Green Paper on Future Noise Policy<sup>3</sup> identified noise in the environment as one of the main local and more pressing environmental problems in Europe especially in urban areas, and the source of an increasing number of public complaints. In line with this strategy, the Directive sets a framework to control noise emission by equipment for use outdoors.

The OND refers to Article 95 of the EC Treaty (now replaced by Article 114 of the TFEU) that enables the EU to adopt measures to harmonise the legislation of the Member States in order to ensure the establishment and functioning of the internal market. Such measures must take as a base a high level of protection of the health and safety of people and of the environment.

Concerning the policy context, the OND is a piece of a wider environmental noise legislative framework, which includes Directive 2003/10/EC on health and safety requirements of workers exposed to noise, the Environmental Noise Directive 2002/49/EC (END), the Machinery Directive 2006/42/EC (MD) and the Non-Road Mobile Machinery Regulation (EU) 2016/1628 (NRMM). **Annex 4** provides for additional information on these legislative acts and their relationship with the OND.

The Outdoor Noise Directive 2000/14/EC, based partially on the principles of the “New Approach” policy, was developed with the specific objective of ensuring harmonisation of rules and procedures across the European Union with respect to noise emissions by outdoor equipment, to avoid fragmentation on the EU internal market and to simplify the existing EU legislation by merging seven specific product directives and two directives on test procedures (see **Section 2.2.**). It provides for detailed noise measurement methods and test codes (also by referring to European and international standards, including the “basic noise emission standards”, their “general supplements” and the operating parameters and conditions to be used); harmonised noise limits for a definite list of outdoor equipment; conformity assessment procedures, with or without intervention of a

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<sup>1</sup> OJ L 162, 3.7.2000, p. 1. Amended by Directive 2005/88/EC (OJ L 344, 27.12.2005, p. 44), by Regulation (EC) No 219/2009 (OJ L 87, 31.3.2009, p. 109) and by Regulation (EU) 2019/1243 (OJ L 198, 25.7.2019, p. 241); corrected by Corrigendum (OJ L 165, 17.6.2006, p. 35 (2005/88/EC)) Regulation (EU) 2019/1243 (OJ L 198, 25.7.2019). Original text: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32005L0088>; consolidated text: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0014-20190726>. Commission’s sectoral webpage on Noise Emission by Outdoor Equipment: [https://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions\\_en](https://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions_en). Commission’s sectoral webpage on Noise Emission by Outdoor Equipment: <http://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions/>.

<sup>2</sup> OJ C 138, 17.5.1993, p. 1: <http://ec.europa.eu/environment/archives/action-programme/5th.htm>

<sup>3</sup> COM(96) 540 final: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=URISERV%3A121224>.

third party (the “notified bodies”); and marking requirements (CE marking of conformity and the specific noise marking, with the indication of the guaranteed sound power level). This is addressed to enable the free movement of outdoor equipment within the EU internal market, whilst reducing permissible noise levels for such equipment in order to protect the health and well-being of citizens and the environment. In parallel, the Directive has also the objective of providing information to the public on the noise emitted by such equipment, thereby promoting less noisy equipment and improving customer choice.

A representation of the intervention logic of the Outdoor Noise Directive 2000/14/EC is provided in **Figure 1** (next page). It shows the logical sequence and causal relationships between the different internal and external aspects to be considered, including the strategic and specific objectives; the EU inputs; and the expected outputs, outcomes and results.

The OND covers 57 types of equipment used outdoors defined in its Annex I, out of which it establishes noise limits for 22 types (Article 12), while another 35 types are subject to noise marking only (Article 13). Such a classification of equipment with different grades of requirements is based on the existence of sufficient knowledge concerning the state of the art, appropriate definition and noise measurement and test methods, and of correlation between test methods and noise limits, for the products in the scope at the time when the Directive was drafted.

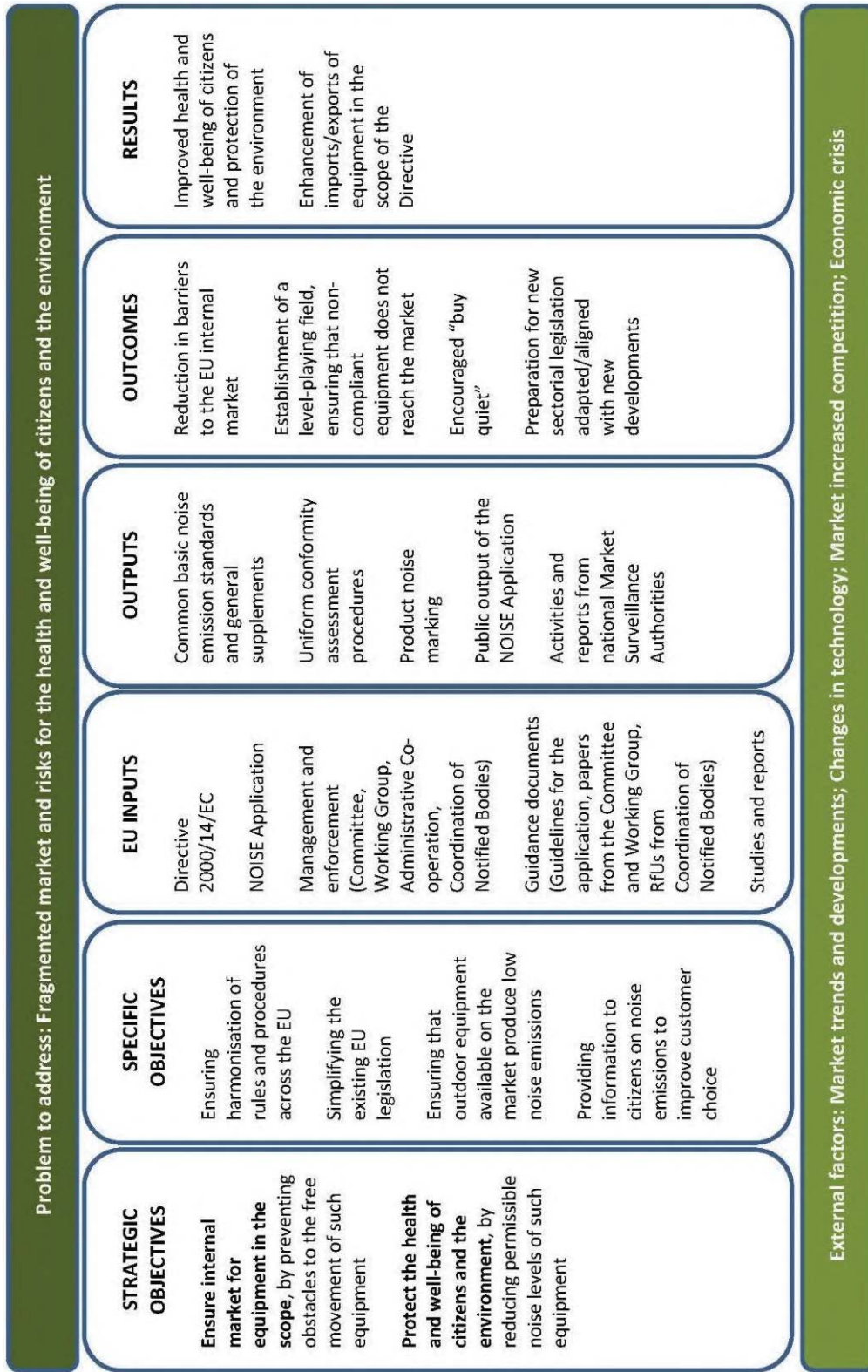
Outdoor equipment in the scope of OND can be grouped into eight clusters:

- I. Cleaning equipment
- II. Construction equipment
- III. Gardening equipment
- IV. Loading and lifting equipment
- V. Power generators and cooling equipment
- VI. Pumping and suction equipment
- VII. Snowmobiles and snow groomers
- VIII. Waste collection, processing and recycling

Together, these types of equipment represent more than 26,000 different models. Around 10,000 models are subject to both noise limits and marking, while nearly 16,000 are subject to noise marking only.

The Directive covers equipment used by both professional and private users, workers and consumers. In the cleaning, construction, loading and lifting equipment, power generators and cooling equipment, and waste collection, processing and recycling categories, the majority of equipment is used by professional users. In gardening and pumping and suction equipment categories all types are used by both professional and private users. Typically, larger and more expensive equipment is used by professionals.

Figure 1: Intervention logic of the Outdoor Noise Directive 2000/14/EC



Source: "Supporting study" and further elaboration



## 2.2. Baseline and points of comparison

The baseline scenario which can be taken into account in the evaluation is referred to the situation before Directive 2000/14/EC on noise emission by outdoor equipment was drafted, adopted and implemented.

At that moment, as mentioned in **Section 2.1.**, in the sector there were nine specific European Community directives (seven on products and two on test procedures), issued between 1979 and 1986. They established requirements on noise emission limits (in terms of permissible sound power levels), noise test codes, marking and conformity assessment procedures, for some types of outdoor equipment (construction machinery and lawnmowers) separately:

- Council Directive 79/113/EEC of 19 December 1978 on the approximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment (OJ L 33, 8.2.1979, p. 15);
- Council Directive 84/532/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for construction plant and equipment (OJ L 300, 19.11.1984, p. 111);
- Council Directive 84/533/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of compressors (OJ L 300, 19.11.1984, p. 123);
- Council Directive 84/534/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes (OJ L 300, 19.11.1984, p. 130);
- Council Directive 84/535/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of welding generators (OJ L 300, 19.11.1984, p. 142);
- Council Directive 84/536/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of power generators (OJ L 300, 19.11.1984, p. 149);
- Council Directive 84/537/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of powered hand-held concrete-breakers and picks (OJ L 300, 19.11.1984, p. 156);
- Council Directive 84/538/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers (OJ L 300, 19.11.1984, p. 171);
- Council Directive 86/662/EEC of 22 December 1986 on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders (OJ L 384, 31.12.1986, p. 1).

The noise emission limits established by this set of legislation have been evolving towards a progressive reduction and can be considered as points of comparison with respect to those introduced by Directive 2000/14/EC for outdoor equipment in Article 12: see **Section 5.1.** on the effectiveness of the OND and the related **Table 1.**

No specific benchmark study is available to analyse the situation before the adoption of Directive 2000/14/EC. This is an objective constraint in the reconstruction of the baseline scenario, also for the limited quality of available and collected data (see **Section 4.2.**). Thus, there are no specific or quantified estimates available about the effective performances of equipment on the market before the OND, in particular on equipment that was later included in Article 13.

Nevertheless, based on feedback from sectoral stakeholders, users and consumers it was recognised that the existence of several different European and national legislative acts concerning noise emission by equipment for use outdoors caused a fragmentation of the market and an insufficient answer to the related risks for the health and well-being of citizens, as well as for the environment. As explained in the Commission Proposal for a Directive on noise emission of equipment used outdoors<sup>4</sup> and then in the recitals of the Directive itself as adopted on 8 May 2000, the rationale behind the legislative intervention was the need to simplify the referred legislation and to create a common framework for the reduction of such noise emissions.

For outdoor equipment, the Directive 2000/14/EC introduced the requirement of noise marking for 57 types of equipment used outdoors, and additionally, set noise limits for 22 of these which had available statistical data to set the noise limits. These limits were set to eliminate the noisiest equipment in the market allowing only equipment that was 3dB (estimate between 30% and 50% on logarithmic base) quieter than the average on the market at the time of the adoption of the Directive<sup>5</sup>.

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<sup>4</sup> COM/98/0046 final (OJ 124, 22.4.1998, p. 1): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:1998:0046:FIN>.

<sup>5</sup> Source: the “NOMEVAL” study (2007), pp. 18-19.

### 3. IMPLEMENTATION / STATE OF PLAY

#### 3.1. Legal provisions, interactions and contributions

In order to achieve its objectives, the Outdoor Noise Directive 2000/14/EC harmonised certain aspects of Member States' laws, regulations and administrative provisions relating to noise emissions by outdoor equipment. Thus, the provisions of the OND, after the adoption on 8 May 2000, must be transposed and implemented by Member States: the necessary national legal provisions were due on 3 July 2001, and to be applied from 3 January 2002<sup>6</sup>.

Afterwards, the noise emission limits as laid down in the Directive continued to be progressively reduced. For permissible sound power levels for equipment subject to noise limits, Article 12 defines "Stage I" limits applicable as from 3 January 2002, followed by "Stage II" limits applicable as from 3 January 2006; later on, the OND was amended by Directive 2005/88/EC<sup>7</sup>, to modify the table in Article 12 to take into account the effective technical feasibility of noise limits for some equipment, and to give more time to fulfil the provisions under Articles 16 ("Collection of noise data") and 20 ("Reports")<sup>8</sup>.

The implementation of the OND requires a wide set of interactions and contributions by the different key actors, within their roles and responsibilities:

- *Manufacturers* design and produce quieter outdoor equipment in line with the requirements of the Directive, carrying out the relevant conformity assessment procedure, according to the requirement for each type of equipment. On that basis, they draw up and sign the EC declaration of conformity and affix the required markings (CE marking and the specific noise marking) to place equipment on the EU market.
- *Notified bodies* assess the conformity of equipment subject to noise limits, through the relevant conformity assessment procedures, ensuring a first and reliable third-party level of control for those products.
- *Member States* and their market surveillance authorities ensure that products on the market are in conformity with the applicable rules, and take appropriate action when necessary.
- *Customers/users* should be able to make an informed purchasing decision, towards less noisy products and therefore stimulating manufacturers to compete also on this specific product feature. For that, the Commission services collect, process and make

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<sup>6</sup> See the national transposition measures communicated by the Member States concerning Directive 2000/14/EC on the EUR-Lex service: <https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32000L0014>.

<sup>7</sup> Directive 2005/88/EC of the European Parliament and of the Council of 14 December 2005 amending Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 344, 27.12.2005, p. 44): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0088>.

<sup>8</sup> See Recitals 2-4 of Directive 2005/88/EC.

public the relevant data through the “NOISE Application” database from the EC declarations of conformity transmitted by the manufacturers.

- Finally, on the basis of sound data from the operation of the whole system, the *Commission* provides reports and, on the base of these, legislation can be opportunely revised and updated.

The listed interactions and contributions are made possible through the appropriate instruments provided by the Directive to effectively implement it since its adoption and applicability. In the following paragraphs, such instruments are briefly presented. More in detail, the related qualitative and quantitative evidences on their implementation and the operational state of play, collected through the studies carried out, are presented in **Section 5** through the analysis and answers to the evaluation questions.

#### ***a) Standards in support of the Directive***

The OND defines, in Annex III, the technical standards to be used by manufacturers to determine the guaranteed sound power levels of outdoor equipment in specific conditions, as noise measurement methods and test codes, in order to obtain coherent and comparable measures of noise emissions. Such standards are developed by the European Committee for Standardization (CEN)<sup>9</sup> (European standards, mostly of them referred to the Machinery Directive 2006/42/EC too) and by the International Organization for Standardization (ISO)<sup>10</sup> (international standards): see **Annex 5** for the complete list of standards referred to in the OND and their current status.

The use of the referred standards as noise measurement methods and test codes has been widely and soundly implemented by manufacturers and notified bodies. Some of these standards have been already replaced by new versions to reflect the evolution of the state of the art. These updates, however, are not reflected in the text of the Directive. Hence, there is a common request from stakeholders to update the legal references of standards in the OND accordingly.

#### ***b) Conformity assessment procedures and notified bodies***

The Directive prescribes, in Article 14 and Annexes V, VI, VII and VIII, different conformity assessment procedures for outdoor equipment subject to noise limits, and for those subject to noise marking only. In the first case, the intervention of a third party (“notified bodies”) is required; in the second case, an internal procedure (“self-assessment”) is allowed.

Conformity assessment bodies, or “notified bodies” (NBs), are appointed by the relevant authorities of the Member States and notified to the Commission, as well as to the other Member States. The NANDO (New Approach Notified and Designated Organisations)<sup>11</sup>

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<sup>9</sup> <https://www.cen.eu/>.

<sup>10</sup> <https://www.iso.org/>.

<sup>11</sup> <http://ec.europa.eu/growth/tools-databases/nando/>.

information system lists all active notified bodies for the OND in the EU Member States, EEA-EFTA countries and others. To date, around 50 notified bodies from 20 countries are available in NANDO for the OND: this has ensured an adequate coverage.

*c) Collection of noise data: the “NOISE Application” database*

In order to assess the “state of the art” of equipment subject to the OND and to provide information to consumers and users while promoting their choices for “quieter equipment”, the manufacturer or his authorised representative is required to send copies of the EC declarations of conformity to both the Commission and the Member State where he resides or where he places such equipment on the market or puts it into service, according to Article 16 of the Directive. Then, the Commission has to collect and publish such data.

Such information can be transmitted by different means, also via an on-line database called “NOISE Application”<sup>12</sup>. At this point in time, the database contains about 31,000 copies and notifications of EC declarations of conformity for equipment in the scope of the OND (more than 12,000 under Article 12 and almost 19,000 under Article 13) placed on the EU market, from around 350 EU and non-EU manufacturers and 70 authorised representatives. The tool allows to produce a public output, making available the key data (in particular the guaranteed sound level and the measured sound power level) extracted from the EC declarations of conformity for the different types and models of equipment covered by Article 12 (subject to noise limits) and by Article 13 (subject to noise marking only). See **Annex 6** for the statistics of the database and **Annex 7** for the analysis of entries of the database for some equipment.

*d) Market surveillance*

Member States provide the Commission with specific market surveillance reports on the most typical irregularities found in inspections, concerning in particular the guaranteed sound power level, the EC declaration of conformity, definitions of equipment, etc.<sup>13</sup>

A supporting tool for market surveillance is the “Information and Communication System on Market Surveillance (ICSMS)” database<sup>14</sup>. It is currently used to exchange information between the relevant Member States authorities about market surveillance activities they carry out and the related outcomes. No cases of non-compliance of equipment, according to the procedures laid down in Article 9 of the OND, have been reported by the Member States.

*e) Working parties under the Directive*

The “Noise Committee”, established by Article 18 of the Directive, is chaired by the Commission and composed of representatives of EU Member States, with EEA-EFTA-

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<sup>12</sup> <https://webgate.ec.europa.eu/growth-portal/index.cfm?fuseaction=noise.main>.

<sup>13</sup> Review of market surveillance activities 2010-2013 - Sector 12 Noise emissions for outdoor equipment: <http://ec.europa.eu/DocsRoom/documents/13912/attachments/1/translations>.

<sup>14</sup> <https://webgate.ec.europa.eu/icsms/>.

MRA-CU countries as observers, to assist and provide advice to the Commission in specific tasks related to the implementation and practical application of the legislation. Within the Noise Committee, the “Outdoor Noise Working Group” includes also representatives from EU-wide stakeholders and interested parties, as manufacturers’ organisations, trade unions, consumers and users’ associations, as well as from the European coordination of notified bodies and the relevant standardisation experts. The common approaches and agreements reached in the OND Committee and Working Group are reflected in the “Guidelines for the application of Directive 2000/14/EC”, drafted and made available by the Commission as guidance on the practical implementation of the Directive. A specific Interest Group “Noise Emissions” is established in the CIRCABC system<sup>15</sup>, for information, communication and exchange of documents.

The Outdoor Noise Administrative Cooperation (AdCo) Group is integrated by representatives of the national market surveillance authorities in the field, with the participation of the Commission as observer. A specific Interest Group “Noise emissions - AdCo” is established in CIRCABC<sup>16</sup>, to support the activities of the group.

The Outdoor Noise Notified Bodies Group has been established in order to ensure that harmonized practices for conformity assessment of equipment subject to noise limits are applied by all the notified bodies concerned by Directive 2000/14/EC. The work group produces the “Recommendation for Use (RfU) sheets” to be applied by the notified bodies in their activities; when endorsed by the OND Working Group, the RfUs are made available on the Commission’s sectoral website as general guidance. A specific Interest Group “Noise Emission NB” is established on CIRCABC<sup>17</sup>.

### **3.2. Studies and follow-up activities**

The Commission has undertaken several studies to assess the implementation of the Directive, to collect as much as possible updated information on the performance of equipment in the scope, and to explore the a possible enactment of the empowerments for delegated acts foreseen in the Directive or the need for a revision of the different aspects of the legislation, as well as to comply with the reporting obligations established in Article 20 of the OND:

- the “Study on the experience in the implementation and administration of Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors” (the “NOMEVAL” study)<sup>18</sup> in 2007;
- the “Impact assessment on possible policy options for reviewing the Outdoor Equipment Noise Directive” (the “ARCADIS” study)<sup>19</sup> in 2009;

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<sup>15</sup> <https://circabc.europa.eu/ui/group/073fa6a8-b0c5-461a-9c17-4e35ebed694d>.

<sup>16</sup> <https://circabc.europa.eu/ui/group/661eebbc-18de-4b80-872f-3cb40efbc853>.

<sup>17</sup> <https://circabc.europa.eu/ui/group/c00d2e19-20dc-4ea1-ade6-e85f3ad30415>.

<sup>18</sup> <http://ec.europa.eu/DocsRoom/documents/1639/attachments/1/translations/en/renditions/pdf>.

- the “Study on the merger of the Directive on noise from outdoor equipment, 2000/14/EC, with the Machinery Directive, 2006/42/EC” (the “CEPS” study)<sup>20</sup> in 2013;
- the “Study on the suitability of the current scope and limit values of Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors” (the “ODELIA” study)<sup>21</sup> in 2015-2016;
- the “Supporting study for an evaluation and impact assessment of Directive 2000/14/EC on noise emission by outdoor equipment”, structured in an “Evaluation Report”<sup>22</sup> and an “Impact Assessment Report”<sup>23</sup> (the “VVA” study), in 2017-2018.

The referred set of studies and their results found that the Directive overall complied with the main objectives of the intervention, by improving the situation in terms of harmonisation of legislation, free circulation of products in the internal market, and reduction of noise emission by outdoor equipment. This represented significant progress in terms of health and well-being of citizens and protection of the environment.

Based on such studies, especially on the most recent ones, the evaluation showed that the Directive has been fully and consistently transposed and implemented across the EU Member States and the other countries where it is applicable.

After a short description in Section 4 of the methodology used to carry out the evaluation, **Section 5** presents the analysis and answers to the evaluation questions, in terms of effectiveness, efficiency, relevance, coherence, complementarity and EU added value of the Directive, as well as the costs and benefits identified in the evaluation.

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<sup>19</sup> <https://ec.europa.eu/docsroom/documents/1635/attachments/1/translations/en/renditions/pdf>.

<sup>20</sup> <http://ec.europa.eu/DocsRoom/documents/4985/attachments/1/translations/>.

<sup>21</sup> <http://ec.europa.eu/DocsRoom/documents/18281/attachments/1/translations/>.

<sup>22</sup> <https://publications.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/90f4d795-e192-11e8-b690-01aa75ed71a1>.

<sup>23</sup> <https://publications.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/69de2e48-e17d-11e8-b690-01aa75ed71a1>.

## 4. METHOD

### 4.1. Short description of methodology

This Staff working document relies on the findings of the “Supporting study for an evaluation and impact assessment of Directive 2000/14/EC on noise emission by outdoor equipment” as the most recent study to be taken into consideration for this evaluation. This study has built its results on the previous assessments, verifying some of their assumptions with the stakeholders and via a public consultation. All these assessments were carried out on the basis of Article 20 of the OND.

The findings of the referred supporting study have been further assessed for the equipment in scope via desk research based on the EC declarations of conformity coming from the “NOISE Application” database. This work proved to be extremely challenging due to the limitations of the data extracted from the NOISE database. The database reports only the declaration of the equipment type but does not provide for the number of equipment placed on the EU market for each type. Hence it is not possible to carry out a balanced assessment of the equipment per type (for further explanations, please refer to Annex 7).

Previous assessment and studies of the Directive which focused on a specific aspect were also taken into account for this purpose.

### 4.2. Sources of information/Literature

Within the “Supporting study for an evaluation and impact assessment of Directive 2000/14/EC on noise emission by outdoor equipment”, the evaluation part was developed on the basis of a methodology for the data collection organised around four main tasks to ensure the most appropriate sources of information:

- a) *Review of the literature*: by using several search tools, the most relevant scientific articles and policy papers on technical, environmental, health, economic and social aspects related to outdoor equipment noise were identified, selected and analysed, in order to include the main outcomes into the report.
- b) *Interviews and surveys*: targeted consultations have been conducted with several EU and national stakeholders and interested parties directly affected by the Directive at EU and national level. This included a balanced geographic representation of market surveillance authorities, standardisers, notified bodies, associations of manufacturers, rental and distribution companies, users, consumers, environmental protection etc.
- c) *Case study*: carried out in the Netherlands about two relief schemes that have been active since 2001, as fiscal incentives that offer entrepreneurs the opportunity to make investments in environmentally friendly techniques in a fiscally attractive way.
- d) *Open public consultation*: running between January and April 2018, it collected 232 contributions from all interested parties (stakeholders, organisations and citizens, in



general) who are affected by the Directive, its current functioning or any potential future modifications.

More detailed information on the above mentioned activities is provided in Annex 2 “Synopsis report of the stakeholders’ consultations” and in Annex 3 “Methods and analytical models for data collection”.

The studies carried out in the past (see **Section 2.2.**) also used a similar methodology to collect and analyse data and contributions from the different sectoral actors. In this sense, the latest study is in full continuity with them, providing a quite coherent basis for the evaluation of the OND as outlined in this document.

### **4.3. Limitations and robustness of findings**

As in the previous studies, there were a number of limitations with the data that were available or could be collected during the “Supporting study”, and used as a basis for the evaluation.

- a) *Noise emission data*: as mentioned in **Section 2.2.** about the baseline, at the time the OND came into force, little information was available on noise emissions of the covered equipment and the state of the art of it. The noise limits aimed at eliminating the noisiest equipment on the market (estimated at about 30% of the equipment in scope according to the information available before the adoption and the implementation of the Directive). For equipment without noise limits, an average reduction of 1 dB due to technical progress and some market demand is estimated since the OND came into force, according to the most recent studies carried out. For some equipment with higher demand for quieter products, more progress has been made than others, with an average estimated reduction of 2-3 dB, although it may not apply to the whole fleet <sup>24</sup>(see Section 5.1. on the effectiveness of the Directive).
- b) *Number of companies and equipment fleet data*: estimating the number of EU manufacturing companies in the market is particularly complex. No official data are available and NACE codes used by Eurostat statistics are too broad to provide a precise picture. Similarly, equipment fleet data could not be assessed using available statistics as the available code systems cover broad categories which, in several cases, do not match with specific equipment. A combination of desk research, data from the “NOISE Application” database and expert opinion was used to produce an estimate which was then validated by sector organisations.
- c) *Data on non-compliant equipment on the market*: no data was found on the existence of non-compliant equipment on the market. Also, stakeholder views on the matter are patchy and mostly rely on anecdotal knowledge. Studies that assessed the compliance

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<sup>24</sup> ODELIA <https://ec.europa.eu/docsroom/documents/18281/attachments/1/translations>, pages 11 and 13

with other Directives and related requirements were used to provide an indication of the extent and potential impacts of the issue.

- d) *Consumers' participation*: participation of consumers in the activities carried out within the "Supporting study" has been low. In general terms, few consumer associations are actively engaged in this specific topic which indicates that other issues are higher on their agenda. This is a finding per se, although it made it difficult to capture the views of consumers on the issue of outdoor noise. On the other hand, more than 100 citizens participated in the open public consultation, mostly persons exposed to noise by outdoor equipment.

Despite these limitations, the reliability and robustness of the data gathered within the framework of the "Supporting study" can be overall considered as satisfactory, taking into account the objective situation of the specific sector of outdoor equipment in the scope of the OND, as well as the quality of the methodology developed by the consultants, with the support and participation of the Commission services and of the Inter-Service Steering Group closely monitoring the study. The study managed to collect and analyse the available information with a sufficient level of coverage and of precision, therefore the final results and conclusions are sufficiently reliable to use as a basis for the present document on the evaluation of Directive 2000/14/EC.

## 5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

The evaluation assesses the **effectiveness, efficiency, relevance, coherence** and **EU added value** of the Outdoor Noise Directive [2000/14/EC](#). To this end, a set of questions was defined for each evaluation criterion, to guide the data collection and analysis. The following sections are based on the information collected through the different sources for the referred “Supporting study”: literature reviews, interviews, surveys and the open public consultation.

### 5.1. Effectiveness of the Directive

#### **Did Member States implement the Directive in a coherent and effective way, ensuring common standards across the EU?**

As mentioned in **Section 3**, the evaluation showed that the Directive has been fully and consistently implemented across the Member States, with no significant issues detected in the national implementing processes through the relevant mechanisms of the OND itself. No infringement cases have been raised, and none of the stakeholders consulted in the “Supporting study” reported any concerns about a lack of implementation; stakeholder consultation and desk research also did not highlight the existence of national rules that could represent a challenge in this sense. About 67% of respondents to the open public consultation who expressed an opinion on this subject agreed that the transposition of the OND into national legislation was adequate and timely; among them, the same opinion was expressed by about the 70% of representatives of private enterprises and trade, business or professional associations.

The majority of stakeholders recognise that the Directive has prevented the potential proliferation of different national standards and regulations, therefore allowing companies to sell their products across Europe. This was also confirmed by the results of the open public consultation, where about 80% of respondents indicated that the OND has ensured harmonisation of rules and procedures across the EU for the covered outdoor equipment. This rate is even higher, at about 94%, among professional respondents.

Notified bodies responsible for carrying out conformity assessment procedures exist in the majority of the Member States, especially in those countries where there is a sufficient number of companies producing equipment covered by the OND. This is an objectively positive element, but, even if it is not an obligation for Member States to appoint notified bodies, the lack of such bodies in several Member States represents a challenge for manufacturers who need to seek the required expertise in other countries, which could imply additional costs.

#### **Were noise levels of outdoor equipment under Article 12 (subject to noise limits) reduced thanks to the Directive? Were noise levels of outdoor equipment under Article 13 (subject to noise marking only) also reduced thanks to the Directive?**

The OND came into force in a period when noise emissions and noise pollution by outdoor equipment were only starting to appear on national agendas and it had the effect of raising awareness of this issue. Over the years there have been more initiatives at

national and local levels targeting noise emissions, indicating a renewed interest in this issue.

According to the data available from different sources (in particular, the Commission’s “NOISE Application” database<sup>25</sup> – see **Annex 7** with the analysis of some entries) – and the studies carried out during the operation of the Directive – see **Section 3.2.**), noise emission levels of outdoor equipment have dropped over the last 20 years. As detected already in the “NOMEVAL” evaluation study (2007) and confirmed by subsequent studies, in particular the “ODELIA” study (2016), several types of equipment in the scope of the OND made significant progress in terms of reduction of noise emissions, especially when there is a market request for operation in sensitive areas (urban environment) or at night, or occupational or public procurement noise requirement. This is the case for example of compressors, excavators and loaders, all of them subject to both noise limits and marking (Article 12) and produced and placed on the market in large numbers, with significant evolution in technological solutions to increase their performances.

At the same time, the majority of the consulted stakeholders recognised the positive role and effect of the OND on noise performance of outdoor equipment in the scope, attributing the reduction of noise levels to the Directive, especially in relation to noise emitted by equipment subject to the noise limits of Article 12. This is indicated by almost 75% of the respondents to the open public consultation, and among them, around 90% of professional respondents and representatives of private enterprises and trade, business or professional associations.

Reliable information on noise emission levels before the OND was introduced is not available for the equipment covered, in particular for equipment subject to noise marking only. Nevertheless, the noise limits established by pre-OND legislation for a set of equipment allows a comparison with the noise limits established in the OND in its two stages of implementation (including indicative figures for stage II): **Table 1** shows the evolution of noise limits expressed as permissible sound power levels (in dB/1 pW<sup>26</sup>) for some outdoor equipment covered by Article 12 of the Directive.

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<sup>25</sup> The “public output” of the “NOISE Application” database is available on [https://ec.europa.eu/growth/tools-databases/noise-emissions-outdoor-equipment\\_en](https://ec.europa.eu/growth/tools-databases/noise-emissions-outdoor-equipment_en). See examples in **Annex 6**.

<sup>26</sup> According to Article 3(d) of the OND, “‘sound power level  $L_{WA}$ ’ means the A-weighted sound power level in dB in relation to 1 pW as defined in EN ISO 3744:1995 and EN ISO 3746:1995”. These “basic noise emission standards” on acoustics, providing for the methods to determine the sound power levels of noise sources using sound pressure, define the sound power level as “ten times the logarithm to the base 10 of the ratio of the sound power of a source,  $P$ , to a reference value,  $P_0$ , expressed in decibels:

$$L_W = 10 \lg \frac{P}{P_0} \text{ dB}$$

where the reference value,  $P_0$ , is 1 pW”.

The “decibel” (dB), tenth part of the “bel”, is a unit of measurement that expresses the logarithmic (to base 10) ratio of two physical quantities of the same dimensions, in this case sound powers. Being the decibel scale logarithmic and not linear, a reduction of 1 dB of sound power level corresponds to a reduction of about 21% of the noise emission, and a reduction of 3 dB corresponds to a reduction of about 50% of the noise emission.

**Table 1: Evolution of noise limits for equipment in pre-OND legislation and in the OND (Source: “NOMEVAL” study and further elaboration)**

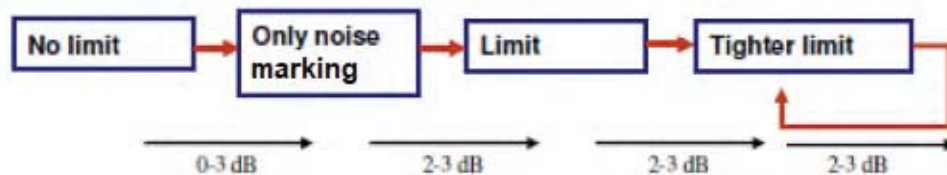
Type of equipment	Net installed power (P) [kW] Electric power (P <sub>el</sub> ) [kW] Mass of appliance (m) [kg] Cutting width (L) [cm]	Directive	Permissible sound power level [dB/1 pW]				
			Pre-Directive	Pre-Directive	Pre-Directive	Implementation of Directive	
			1986-1989	1989-1996	1997-2001	2002-2006 (stage I)	
Compressors (P ≥ 350) (Q: air flow)	Q ≤ 5 m <sup>3</sup> /min	84/533/EEC	101	100	100	97+2lgP	95+2lgP
	5 < Q ≤ 10 m <sup>3</sup> /min	2000/14/EC	102				
	10 < Q ≤ 30 m <sup>3</sup> /min		104	102			
	Q > 30 m <sup>3</sup> /min		106	104			
Concrete-breakers and picks, hand-held	m < 20	84/537/EEC	110	108	108	107	105
	20 ≤ m ≤ 35	2000/14/EC	113	111	111		92+11lgm
	m > 35		116	114	114		94+11lgm
Excavators, hydraulic/rope-operated (P < 500)	P ≤ 70	86/662/EEC		106	96		80+11lgP
	70 < P ≤ 160	89/514/EEC		108			
	160 < P ≤ 350	94/27/EC		112			
	P > 350	2000/14/EC		118			
Excavators-loaders (P < 500)	P ≤ 70	86/662/EEC		106	104		82+11lgP
	70 < P ≤ 160	89/514/EEC		108			
	160 < P ≤ 350	95/27/EC		113			
	P > 350	2000/14/EC		118			
Lawnmowers	L ≤ 50	84/538/EEC	96	96		96	94
	50 < L ≤ 120	2000/14/EC	100	100		100	98
	L > 120		105	105		105	103
Loaders, tracked (P < 500)	P ≤ 70	86/662/EEC		106	106		84+11lgP
	70 < P ≤ 160	89/514/EEC		108			
	160 < P ≤ 350	95/27/EC		113			
	P > 350	2000/14/EC		118			
Loaders, wheeled (P < 500)	P ≤ 70	86/662/EEC		106	104		82+11lgP
	70 < P ≤ 160	89/514/EEC		108			
	160 < P ≤ 350	95/27/EC		113			
	P > 350	2000/14/EC		118			
Power generators (P <sub>el</sub> < 400)	P <sub>el</sub> ≤ 2	84/536/EEC	104	102	102	97+lgP <sub>el</sub>	95+lgP <sub>el</sub>
	2 < P <sub>el</sub> ≤ 8	2000/14/EC		100	100	98+lgP <sub>el</sub>	96+lgP <sub>el</sub>
	8 < P <sub>el</sub> ≤ 240		103			97+lgP <sub>el</sub>	95+lgP <sub>el</sub>
	P <sub>el</sub> > 240		105				
Tower cranes		84/534/EEC		100		98+lgP	96+lgP
		2000/14/EC					

The Outdoor Noise Directive 2000/14/EC led to enhanced noise control and reduction for the different types of equipment in scope, especially for those in Article 12 which have to comply with the noise limits established in the legislation. On the contrary, there are not enough data to quantify to what extent this is the case also for equipment in Article 13 subject to noise marking only. However, the most recent studies carried out, in particular the CATI interviews performed within the “Supporting study”, suggested that noise marking, with the declaration of the guaranteed sound power level, contributed to some extent to promote purchasing of less noisy equipment by public authorities for being the noise level a more relevant feature for this type of consumers<sup>27</sup>.

The limit reduction for several types of equipment already in previous Directives, introduced by the OND, was effectively around 1-3 dB, except for lawnmowers, for which reductions were 0 dB. In the last amendment to the OND (Directive 2005/88/EC), subsequent reductions were made in noise limits, between 2-3 dB.

A representation of the typical evolution of average noise emission of equipment following introduction of noise marking, first stage and subsequent stage noise limits, is shown in **Figure 2**.

**Figure 2: Typical evolution of average noise emission of equipment following introduction of noise marking, first stage and subsequent stage noise limits in Directive 2000/14/EC**



Sources: “NOMEVAL” and “ODELIA” studies

For equipment not covered by any previous legislation, it is more difficult to provide an indication of how noise emissions have changed. New equipment introduced into the OND with noise limits was mainly construction equipment, mobile cranes, and lawn-edge trimmers. For some of this equipment, while pre-OND data is not available, new lower limits were established in the 2005 amendment. On the basis of the indications of the above mentioned studies and the output of the “NOISE Application” database, a noise reduction of at least 3 dB is estimated for equipment subject to noise limits (Article 12) not covered by previous legislation.

On the other hand, for equipment subject to noise marking only (Article 13), it is not easy to establish whether this provision helped to reduce noise levels of the equipment

<sup>27</sup> Pages 90-91, : <https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/90f4d795-e192-11e8-b690-01aa75ed71a1>

covered, due to a lack of relevant and comparable data. Using data from the “NOISE Application” database, the average declared values for the period 2000-2007 were compared with those for the period 2007-2015. This exercise was conducted tentatively on three types of equipment covered by Article 13. It found that the values increased for both chainsaws (by 1 dB) and leaf blowers (by 3 dB), while they decreased for shredders (by 1 dB). These results may be due to different factors. For example, an increase in power of this equipment may have led to an increase in noise emissions. However, also the sample selection and the number of declarations received in specific years may affect the result.

The general opinion expressed by stakeholders is that the inclusion of equipment under Article 13 was not sufficient to encourage manufacturers to develop less noisy products to the extent of those under Article 12. At the same time, the results of the open public consultation evidenced a lack of awareness and knowledge among consumers about the meaning of the noise marking and how to correctly interpret it. Such a situation did not allow these provisions of the OND to achieve its intended objective.

Some examples of the average trends towards a progressive reduction of noise emission limits for outdoor equipment covered by the Directive are analysed in **Annex 7**, on the basis of the data available in the “NOISE Application” database, from the EC declarations of conformity of equipment placed on the EU market.

### **Were noise levels of outdoor equipment reduced by the extent to have an impact on the health and well-being of citizens?**

The OND played an important role in protecting the health and well-being of citizens and the environment by reducing permissible noise levels of outdoor equipment. As mentioned above, noise emission levels of outdoor equipment have dropped over the last years, as evidenced in particular from the data extracted by the “NOISE Application” database from the EC declaration of conformity of equipment placed on the market; the majority of the respondents to the open public consultation supported this view. However, whether noise levels have reduced to the extent to be safe for the health and well-being of citizens, is difficult to evaluate.

Several studies<sup>28</sup> assessed the impact of noise emissions on health, and when exposure to noise is inevitable, it can have detrimental effects on human health, amenity, productivity and natural environment, in particular for a longer duration. Learning and memory start to be affected at 50 dB, sleep at 42 dB (self-reported) or 32 dB (detected in polysomnography). Blood pressure increases at 50 dB. Noise can already be disturbing or annoying at 42 dB, affecting wellbeing. Talking in a noisy environment stresses vocal cords and causes hoarseness.

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<sup>28</sup> Among others: NCTC (2010). Activities of the CAETS Noise Control Technology Committee, available at: <http://www.aph.gov.au/DocumentStore.ashx?id=c174eb07-244e-4bd1-8bef-364efdd1776d>; UK Department for Environment, Food & Rural Affairs (DEFRA) (2014). Environmental Noise: Valuing impacts on: sleep disturbance, annoyance, hypertension, productivity and quiet, available at: [http://www.programmeofficers.co.uk/Cuadrilla/Inquiry/CUA/CUA\\_INQ14.pdf](http://www.programmeofficers.co.uk/Cuadrilla/Inquiry/CUA/CUA_INQ14.pdf). See also the “Supporting study” (2018) for more references.

Several evidence suggests that at an equivalent continuous sound level ( $LA_{eq}$ ) of 24 h of less than 70 dB does not lead to any permanent hearing loss. However, the  $LA_{eq}$  value of more than 80 dB(A) is the limit above which preventive noise reduction measures should be taken in the workplace. Hearing damage may occur when exposed to  $LA_{eq}$  noise levels between 90 and 130 dB (A), or at lower levels but with prolonged exposure. In addition to hearing loss, it can generate extensive collateral damages, such as stress, increased heart rate, blood pressure, respiratory rate, vascular tone, gastric secretion, sweating, muscle tone, and pupil size. Therefore, while sounds higher than 90 dB sound pressure level are considered dangerous to hearing and general health, already noise above 50 dB sound pressure level can have impacts on the wellbeing of people exposed (e.g. sleep disturbance), and over the longer term potentially lead to more serious health effects.

Lower noises from machines used for a shorter period of time (e.g. gardening equipment) can still have an impact on wellbeing, annoyance and stress effects.

The OND establishes sound power limits and the resulting sound pressure level depends on the distance. Also, the equivalent sound level  $LA_{eq}$  over a longer period may be lower if operating conditions are considered. The sound pressure to which a bystander or observer could be exposed is calculated as follows depending on the distance from the noise source:

- sound power level minus 26 dB for 7.5 m distance
- sound power level minus 37 dB for 25 m distance

With this in mind, several types of equipment covered by the OND are above 92 dB sound power level, ranging up to 120 dB for the noisiest. Considering the distance, an observer could be exposed to sound pressure levels ranging between 66 dB and 94 dB at 7.5 metres and 55 dB and 83 dB at 25 metres. Both ranges exceed the guard levels mentioned above indicating that the noise emissions of the equipment covered by the Directive still have the potential to have long-term negative effects on health.

The key source of data with regards to the evolution of noise emission would be the “NOISE Application” database (see also **Annexes 6 and 7**). The “ODELIA” study analysed data contained in this and other databases: it identified types of outdoor equipment for which current noise limits are still adequate and suggested a revision for a number of them. While the recommendations contained in that study were based on several factors (e.g. the assumed exposure to certain noise emissions), it also took into account the technological development of the equipment covered. Out of the 22 types of equipment covered by Article 12, it was found possible to propose new limits for eight of them, indicating that, for these types of equipment, solutions for lower noise emissions are available.

However, since emission levels of outdoor equipment have dropped over the last years also thanks to the Directive and its requirements on noise limits and marking, it can be concluded that citizens exposed to them are better off now than they would have been



without the OND, even if they may still be exposed to harmful noise emissions. This is confirmed by the generally shared opinion of stakeholders against the repeal of the Directive, as detected in the different consultation activities carried out.

### **Did the Directive raise awareness among consumers encouraging a “buy quiet” attitude?**

The OND provisions appear not to be sufficient to motivate consumers to buy equipment producing lower noise. The Directive establishes specific obligations on noise marking and communication of noise data, to inform consumers and raise awareness about noise emissions of outdoor equipment. The ultimate goal is to encourage them to prefer quieter machinery over noisier alternatives.

There are different factors that impact consumer choice and hinder the OND in reaching its objective in this area:

- first, non-professional purchasers and users of the equipment under the scope of the Directive lack knowledge and awareness about noise emissions. This is widely agreed by all stakeholders reached and documented in the literature<sup>29</sup>. As a consequence, the average consumer does not have a clear understanding of the noise unit measure (dB) used for the noise marking established by the OND. Through the open public consultation, users of outdoor equipment (83%) considered the current noise marking moderately clear to not clear at all;
- second, there seems to be a general expectation among consumers that the types of products covered by the OND are noisy and that similar products are equally noisy. Stakeholders consulted pointed out that the type of equipment covered by the OND is generally known to be noisy and consumers may pay less attention to this characteristic assuming that no perceivable differences exist between noise emissions of similar machinery;
- third, the current marking requires a proactive attitude by the consumer to compare different products in order to identify the most noise efficient one. However, the preconception that similar equipment will be equally noisy and the lack of at least a basic understanding of what a 1 or 2 dB difference concretely means are not favourable conditions for this to happen. Although a majority of respondents to the open public consultation recognised that the OND had positive effects in improving the level of information provided to consumers and users (almost 55%, corresponding to 52% of professional users and more than 55% of representatives of private enterprises and of trade, business or professional associations), stakeholders also generally agree that the current noise marking is seen as not easy to read, understand and use for the average consumer.

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<sup>29</sup> Among others: Carletti, E. and F. Pedrielli (2016). Outdoor machinery: a reliable statistical approach for a new noise labelling based on current noise emission marking data, available at: [https://www.iiav.org/archives\\_icsv\\_last/2016\\_icsv23/content/papers/papers/full\\_paper\\_106\\_20160314103705778.pdf](https://www.iiav.org/archives_icsv_last/2016_icsv23/content/papers/papers/full_paper_106_20160314103705778.pdf); Brereton, P. and J. Patel (2016). Buy quiet as a means of reducing workplace noise, available at: <https://core.ac.uk/download/pdf/81712329.pdf>.

Rather than noise emissions, information collected from stakeholders indicates that general performance is the key criterion considered for outdoor equipment, followed by energy efficiency, safety and price. Moreover, users who responded to the OPC mentioned that while they tend to consider noise emission levels when buying or renting outdoor equipment, they prefer quieter equipment only if it offers similar features/performances to other noisier alternatives. Interestingly, the noise emission level seems to play a more important role than weight and aesthetics. Further, while price remains one of the key drivers of consumer choice, respondents to the OPC as individuals in their personal capacity indicated that, on average, they would be prepared to pay up to 12% more for quieter outdoor equipment. This is an interesting finding to be taken into account, even if the respondents may not be representative of the “average consumer” (due to possible selection bias), and the difference between “stated preferences” and “revealed preferences” in reality should be considered.

Confirming that noise emission levels are still a low importance purchasing criterion, only a fifth of the rental organisations that replied to the CATI interviews<sup>30</sup> within the “Supporting study” reported offering noise emissions among the research criteria on their website.

Manufacturers and rental companies reported that demand for quieter equipment is greater among public purchasers (33%) than among private or professional users (22% and 20% respectively), as from the CATI interviews within the “Supporting study” (see **Table 2**). This appears to be particularly relevant for equipment used for cleaning and waste collection services (for which up to 91% of manufacturers recognised a moderate to large demand). This was further confirmed by the manufacturers that replied to the open public consultation. They indicated that while information about noise emission is provided to customers mostly in all sectors, this is usually required by customers only for cleaning and waste collection, processing and recycling equipment. Respondents indicated that stronger demand for silent products exists also for power generators and cooling equipment. Power generators are often used in specific contexts where excessive noise can be problematic. This is the case for example of movie sets where power generators are used while filming, hence the need for more silent equipment.

**Table 2: Demand for quieter equipment from different categories of customers**

	Not at all / to a small extent	To a moderate extent	To a large / very large extent	Total	Total respondents
For business	48%	30%	20%	100%	479
For consumers	42%	34%	22%	100%	226

<sup>30</sup> Page 47, <https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/90f4d795-e192-11e8-b690-01aa75ed71a1>

For public authorities	34%	28%	33%	100%	183
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Source: “Supporting study” - CATI interviews

However, while noise emissions in general tend to be a secondary purchasing criterion, the type of customer affects the relative importance of the product features. For instance, occasional or leisure consumers tend to be more focused on the price, while professional users aim to buy high-performance equipment that allows them to complete the job in the shortest amount of time possible. Public authorities, local ones in particular, may on the contrary be more interested in low noise equipment for machines employed during night time or early in the morning (e.g. street cleaning machines).

**Have non-certified products reached the market? If so, were they identified, and their commercialisation blocked? How has the number of non-compliant equipment, or notifications of it, changed since 2007? Have Member States established appropriate authorities and measures to ensure conformity of relevant equipment?**

Effective and comprehensive market surveillance is one of the key issues of the enforcement of the EU legislative framework. Complying with the requirements of the OND poses a burden on manufacturers as resources need to be allocated to the reduction of noise emission, measurements and conformity assessment. While these costs may be deemed acceptable when applied to everyone and enforced equally, gaps in market surveillance would undermine the level playing field, putting compliant manufacturers at a competitive disadvantage compared with those who ignore the legislation.

While market surveillance authorities are established in all Member States, only some of them are responsible for compliance with the OND: out of the about 800 MSAs established in the EU Member States, only 91 are responsible for compliance with the OND (against for example the 233 in charge of compliance with the Machinery Directive).

This lower number of dedicated MSAs can be explained by several factors. Noise emission measurement is an extremely technical procedure, and specific training should be provided to responsible authorities. In this regard, it makes sense for some Member States to focus expertise in fewer authorities so that they use their resources more efficiently. However, all stakeholders consulted within the “Supporting study” agreed that the current resources (human and economic) allocated to national MSAs are not sufficient to allow for effective enforcement of the OND. In particular, it was highlighted that additional resources should be made available to provide adequate training to market surveillance officers.

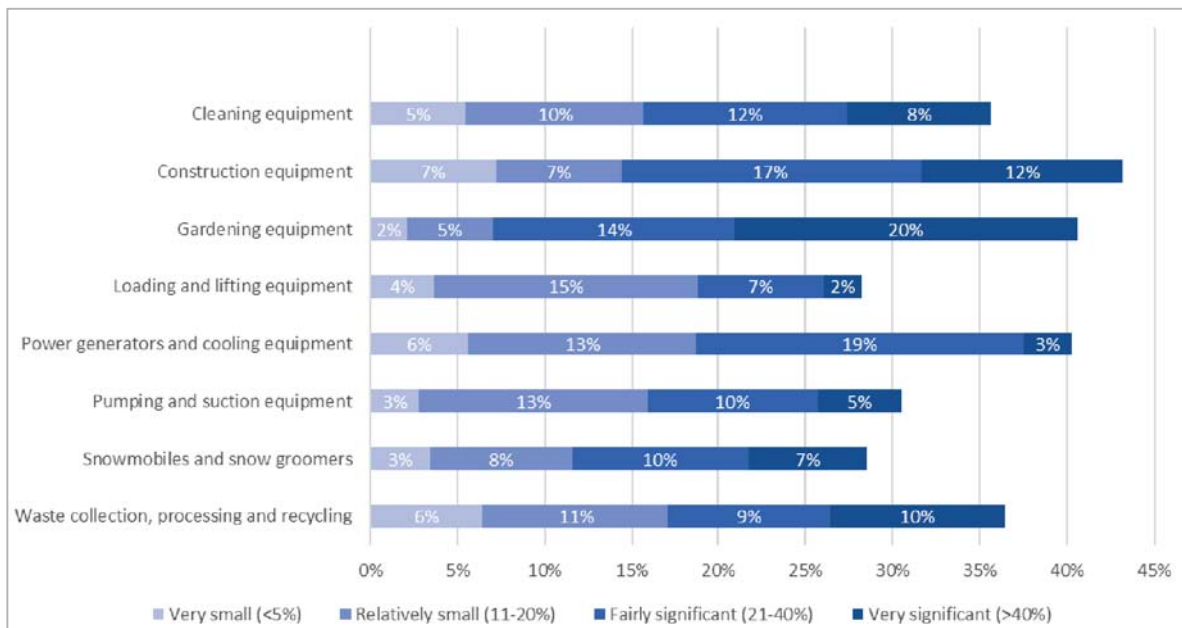
MSA used the ICSMS platform to share information on their market surveillance activities, results and experiences. In the period 2016-2018, about 70 compliance reports were input into the system, focusing on certain types of equipment such as chainsaws, power generators, air compressors, pressure washers, tillers, high-pressure water jet machines, lawnmowers, hedge trimmers and brush cutters. About 60% of the equipment

reviewed was found in compliance with the requirements of the Directive on the product and the documents. On the contrary, the main causes of non-conformity were due to rather formal issues, such as the absence or a non-compliant EC declaration of conformity, the absence of the noise marking on the product and incomplete or inaccurate information provided on the product.

Although more than half of the consulted stakeholders consider that the OND had a positive effect on the prevention of non-compliant equipment on the market (about 56% of respondents to the open public consultation, with higher rates among individuals, when on the contrary, only 38% of representatives of private enterprises and of trade, business or professional associations agreed on that), there is a general recognition that non-conform equipment still reaches the market mostly undisturbed. However, no general statistics were identified to support this view.

Stakeholders' views on the share of non-compliant equipment on the market are quite scattered. As shown in **Figure 3**, less than half of respondents took a stand, and the opinions expressed are very diverse.

**Figure 3: According to your experience, which sectors have the largest share of non-compliance with the requirements of the Directive, and what is the share of non-compliant products on the market?**



Source: Open public consultation

Weighting the answers from the open public consultation, according to the stakeholders consulted the gardening sector has the largest share of non-compliant equipment, followed by construction, power generators and cooling. While this data cannot be taken as a definitive indication of the share of non-compliant equipment currently on the market, it represents the stakeholders' perception of the status quo. In particular, stakeholders are convinced that smaller, cheap equipment, mostly destined for private use and imported from non-European countries, tends to be more at risk of non-compliance than professional equipment.

Market surveillance activity is mainly exercised ex-post on equipment already on the market. The most significant ex-ante control is, on the contrary, carried out by notified bodies, for equipment subject to noise limits. Although not imposed by any legislation, synergies between MSAs and NBs, as well as with the sectorial economic operators, could lead to better results in preventing non-compliant equipment from reaching the market. About half of the respondents to the survey to MSAs and NBs recognised that this type of collaboration is missing in their country, or not fully working.

However, ensuring market safety and enforcing EU harmonisation legislation on health and safety of industrial and consumer product in the single internal market and at the external borders for imported products, is not limited to the respect of the obligations deriving from the OND, but it is a quite horizontal issue. In particular, problems with market surveillance and enforcement in the Member States mean that EU manufacturers may not enjoy a competitive edge in the EU market as a result of the implementation of the Directive: although official data are not available, consulted sectorial stakeholders mentioned that there is still a large number of non-compliant outdoor equipment imported from non-EU countries that are unfairly competing with their EU counterparts.

On the basis of the general recognition that the whole market surveillance framework needs to be rethought and improved, the Commission drafted in December 2017 a proposal (within the “Goods package”) to address the significant number of non-compliant products on the EU market<sup>31</sup>. At the end of the ordinary legislative procedure in the European Parliament and the Council, the Regulation (EU) 2019/1020 on market surveillance and compliance of products<sup>32</sup> was adopted in June 2019, to become applicable from 16 July 2021. The provisions on “coordinated enforcement and international cooperation” – including in particular the “Union Product Compliance Network” – will be applicable already from 1 January 2021.

### **By merging previous legislation, did the Directive simplify legislation improving stakeholders’ activities?**

As mentioned above (see **Section 2.2.**), the OND merged and replaced seven product Directives and two procedure Directives applied to specific types of equipment, at the same time extending the population of outdoor equipment subject to noise limits or noise marking. This simplification brought greater clarity to the legislative framework and improved the activity of the concerned economic operators and stakeholders, as indicated also by the results of the open public consultation: more than 90% of the respondents who expressed their opinion agreed that “the Directive has ensured harmonisation of rules and procedures across the EU for the covered outdoor equipment” and “by merging

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<sup>31</sup> Commission Communication “The Goods Package: Reinforcing trust in the single market”, COM(2017) 787 final, 19.12.2017 <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2017:787:FIN>. Press release: “Safe products in the EU Single Market: Commission acts to reinforce trust” [https://europa.eu/rapid/press-release\\_IP-17-5301\\_en.htm](https://europa.eu/rapid/press-release_IP-17-5301_en.htm).

<sup>32</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products (OJ L 169, 25.6.2019, p. 1).

previous legislation, the Directive improved the effectiveness and internal coherence of EU legislation”.

Among other aspects, it was noticed that the OND became a reference point for manufacturers, notified bodies and national authorities. All of them can, in fact, find all information required (types of equipment, markings, noise limits, conformity assessment procedures, noise measurement methods and test codes, etc.) in one single document, for the whole EU and according to the national transposition acts of the Member States.

Even if the simplification of previous legislation was welcomed by stakeholders, they pointed out, through the consultation activities carried out within the “Supporting study”, that the classification and grouping of products that are currently applied might cause difficulties for manufacturers in understanding whether a product is actually covered by the Directive and increase the risk of arbitrary inclusion or exclusion of equipment from the scope of the OND. In fact, some categories may cover different types of equipment, spanning from small electric products to larger ones powered by combustion engines. An improvement on definitions of outdoor equipment in scope of the Directive was requested by several sectoral actors.

**Were noise limits set achievable? Are there specific types of equipment that represent a challenge in meeting the standards?**

By complying with them in a large majority, as shown by the market surveillance reports provided by the Member States (see **Section 3.1.**) and the information available in the ICSMS system, manufacturers have proven that the noise limits set by the Directive for specific outdoor equipment were indeed achievable, by using different available technologies (combustion engines, electrical power, batteries, etc.). Moreover, in the consultation activities carried out within the “Supporting study”, no stakeholder mentioned a specific type of equipment for which it was particularly difficult from a technical point of view to reach the required noise reduction by complying with the noise limits established for outdoor equipment listed in Article 12.

However, when designing a product, manufacturers need to balance different technical features often in conflict between each other, taking into account not only the requirements on noise emission reduction laid down in the OND, but also the safety requirements from other EU legislation. In general, the choice of which features to privilege aims at developing products that will attract consumers, but at the same time legal obligations must be fulfilled.

For instance, safety components or protections for a machine to comply with specific requirements of the Machinery Directive [2006/42/EC](#), can lead to more vibrations and consequently to higher noise emission levels; or, a more powerful tool will be less energy efficient, while less polluting equipment may need to use an engine requiring more ventilation through additional fans and more openings that would increase the noise produced by the machine, as in the case of equipment covered also by the Non-Road Mobile Machinery Regulation (EU) [2016/1628](#).

If achieving the required noise reduction may not be technically difficult as such, when this objective is put into the context of a complex machine where different features (performance, energy efficiency, safety, weight, noise, cost, etc.) must be balanced, reaching the same result may represent a challenge, in particular in terms of R&D costs to achieve the necessary technical improvements.

**Are current conformity assessment procedures effective? Was the given choice a benefit allowing flexibility, or did it create confusion?**

Conformity assessment procedures make reference to test codes and measurement methods to be used to perform the measurement, as defined in the OND also through European or international standards for each specific equipment. Test codes and measurement methods, and the related standards, have not been updated since entry into force of the Directive itself, therefore several of them are not in line with technological development and would need to be revised. This would require to amend the legal provisions of the Directive. More than a third of the manufacturers that responded to the open public consultation reported a low degree of satisfaction with this specific aspect of the conformity assessment, indicating that the procedures are poorly adapted to technical progress.

The interrelation between the OND and other EU legislation, in particular the Machinery Directive, also causes issues of coherence and efficiency. Both require the measurement of noise emissions, but the former looks at the sound power and the latter at sound pressure, and they often require that the respective measurements should be done with different methods, even based in different versions of standards.

Moreover, the lack of a clear and uniform procedure to determine the uncertainties related to measurements in the OND may cause inconsistency between guaranteed sound power levels depending on the subject performing the measurement and the method used. Uncertainty as such is always correlated to all measurement operations, and in the OND it is needed to establish the guaranteed sound power level, calculated as the sum of the measured sound power level and the uncertainty (as laid down in Article 3). The determination of the uncertainty is therefore fundamental to ensure that declared guaranteed sound power levels are legitimate, reliable and comparable. Nevertheless, the OND does not include a procedure to determine the uncertainty, which led to practical problems for manufacturers and notified bodies when transposing the measured sound power level of noise emission to the guaranteed sound power level to be declared in the noise marking. This gap is partly filled by an agreed method between notified bodies, and also by some indications included in the “Guidelines for the application of Directive 2000/14/EC”.

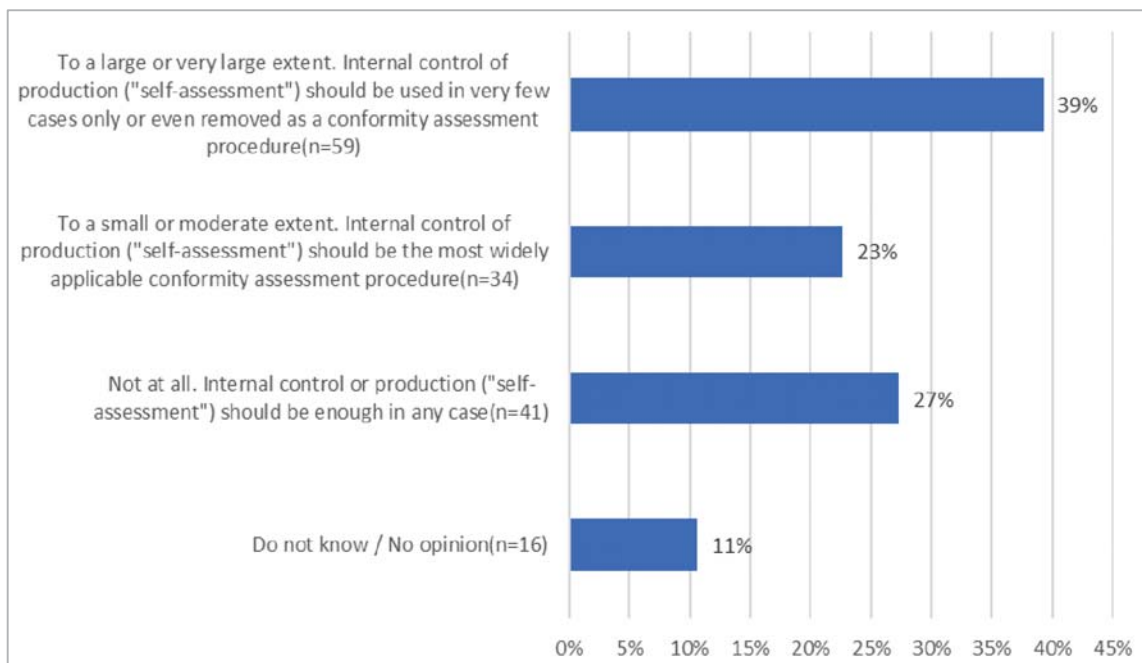
The three procedures allowed by the OND for Article 12 equipment subject to noise limits and marking were developed in order to allow enough flexibility to manufacturers depending on the type of products and company organisation. So, companies that have the resources can develop an internal “Full quality assurance” (Annex VIII) system to determine in-house the measured sound power level, the uncertainties and the guaranteed value. Manufacturing companies producing unique or tailored equipment can employ the

“Unit verification” (Annex VII) process, while in all other cases the procedure of “Internal control of production with assessment of technical documentation and periodical checking” (Annex VI) is used.

In terms of these conformity assessment procedures with third-party intervention, no specific concerns were raised. However, it is not clear whether this contributed to ensuring that only compliant products are placed on the EU market. Stakeholders reported different opinions in this regard: on one side there are manufacturing companies mostly advocating a “self-assessment” system, as an extension of the applicability of the internal control of production procedure (Annex V) currently allowed by the OND for Article 13 equipment subject to noise marking only; on the other, consumer organisations, MSAs and also a few sector organisations consider the third-party conformity assessment as the first line of control to ensure the compliance of products reaching the market.

Opinions expressed through the open public consultation also represent this diversity of views. An equal mix of different stakeholders (private individuals, sector organisations, public authorities, sector experts, etc.) support both positions which confirms the complexity of this dialogue (see **Figure 4**).

**Figure 4: Do you think that third party conformity assessment procedures (with the intervention of a notified body) contribute to ensuring that only compliant products are placed on the EU/EEA market?**



Source: Open public consultation

For adequate and effective conformity assessment procedures, it is necessary to ensure the uniform quality of the notified bodies. Several stakeholders reported that the assessments performed by NBs have not always the same level of quality and reliability across the entire EU. As mentioned above, noise emission measurement is an extremely technical procedure, and a number of factors can impact its results, from the skills and experience of the professionals working in the NB to the equipment available.



**Was there an increase in the international trade of outdoor equipment? Was competition from extra-EU manufacturing companies affected by the lower noise standards set by the Directive?**

A general agreement was found through the different consultation activities carried out in the “Supporting study” on the fact that the OND allowed for better trading across borders inside the EU; but quantitative data are scarce.

Available intra-EU trade data for 2000-2007<sup>33</sup> showed that equipment covered by Articles 12 and 13 performed better than equipment that is not covered, with more constant increases over time. While this could be due to different factors, the fact that the OND prevented the emergence of different regulations at the national level may be one of them.

The issue of extra-EU trade, on the contrary, is more complex. All stakeholders interviewed and desk research conducted highlighted that the EU is at the forefront in terms of regulation of the noise emissions of outdoor equipment, taking into account the information and resources available at international level, as from the World Health Organisation and countries like the United States of America, Canada, Japan and Australia. Therefore, on the one hand, European manufacturers have to comply with stricter regulations than non-EU producers; on the other hand, non-EU manufacturers will have to comply with the stricter EU limits if they wish to sell their products in the EU. As a consequence, European manufacturers should be able to propose to foreign markets more advanced products possibly more appealing to customers abroad; in contrast, non-European manufacturers have to catch up on R&D to design products in compliance with EU regulation, giving a competitive edge to EU producers.

As a result, one would expect an increase of exports towards non-EU countries and a decrease in imports. This, however, does not seem to be the case. Available extra-EU trade data<sup>34</sup> does not point in any of these directions, and both import from and export to non-EU countries increased over that period in line with the overall market trend. An assessment for a limited group of products is in Annex 8.

Stakeholders interviewed for the “Supporting study” mentioned that when going abroad EU manufacturers have to deal with customers who (like their EU counterparts) are not particularly sensitive to reducing noise emissions, but they are more interested in equipment performance. This obliges some EU producers to adapt their products to these preferences by changing the design, increasing the power and even removing noise reduction elements to reduce weight and increase power. As a result, rather than favouring the competitiveness of EU producers, the stricter noise emissions thresholds set by the OND could undermine the competitiveness of EU companies selling abroad.

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<sup>33</sup> Data extracted from Eurostat <https://ec.europa.eu/eurostat/> (ESTAT “EU trade since 1988 by HS6 [DS-016893]” and Prodcom - Statistics by product and codes for specific equipment types). For more information, see the “Supporting study” (2018).

<sup>34</sup> See the “Supporting study” (2018).

**Table 3** reports the views of rental and manufacturing companies that answered the CATI interviews within the “Supporting study”. According to the majority of the respondents, the OND did not have any impact on the respondents’ business either in their home country, in the EU market or outside the EU. Interestingly respondents consider that the OND made intra-EU trade slightly more difficult than extra-EU. This is probably due to the fact that while manufacturers have to meet the requirements set by the OND for the EU market, they do not have to do so for extra-EU exports. In this sense, the impact of the OND on extra-EU trade is less felt than the one on intra-EU trade.

**Table 3: Extent to which the OND made it easier or more difficult to conduct business abroad**

	Much more difficult/ Somewhat difficult	No impact	Somewhat easier/ Much easier	Don't know	Total
In the home country	24%	54%	14%	8%	538
In the rest of the EU	24%	51%	17%	8%	387
In other extra-EU countries	16%	53%	22%	9%	306

Source: “Supporting study” - CATI interviews

Similarly, only about 30% of the respondents to the open public consultation believe that the OND has had a positive impact on competition from manufacturing companies outside of the EU. This perception is even lower, about 25%, for representatives of private enterprises and of trade, business or professional associations.

### **Is the “NOISE Application” database an effective tool?**

The “NOISE Application” database (as discussed in **Section 3** – see also **Annex 6** for the statistics of the database and **Annex 7** for the analysis of entries of the database for some equipment) has the potential to be a useful tool, but it needs improvements. In 2007 and in 2016, two studies (“NOMEVAL” and “ODELIA”), conducted to determine the need to and feasibility of updating the noise limits, highlighted the limitations of the database:

- incorrect equipment type was registered;
- electrical and combustion engine powered equipment was often mixed;
- technical parameters were often missing or clearly out of range, especially for Article 13 equipment;
- data from important manufacturers were found missing;
- no clear correlation of the evolution of the noise emission levels for different types of equipment during the years of operation of the Directive.

In particular, the “ODELIA” study was able to rely only on 77% of total data available in the database while the publicly accessible research function of the database was taken offline in 2016 due to the low quality and reliability of the output data.

Some of the issues reported were due to the data input method used over the first years of existence of the database. Manufacturers were sending paper documents to the European Commission that then had to be manually entered into the database. This two-step procedure led to mistakes and false data that undermined the reliability of the database.

In recent years the tool was upgraded to be filled directly online. However, this tool is still considered outdated, the user interface not user-friendly, and the management of companies’ profiles and equipment registered not sufficiently easy and flexible. Manufacturers, for example, have problems in registering their “brand names” and the system to validate/accept the requests for authorised representatives is not working.

The database should also ideally provide a clear picture of the market and the manufacturers, and other operators, active in the sectors covered by the OND. However, over the years there has not been strict control over the users registering in the database. Manufacturing companies could, for example, create multiple accounts or authorised representatives could register the same company creating a risk of double counting. Also, information on manufacturers that sent their EC declaration of conformity by e-mail or postal mail was not always recorded.

On the other hand, the data exporting features of the database (the “public output”) appear to be limited and not sufficient to comply with the objective of providing comprehensive information on the status of the market for outdoor equipment.

The database as it is will most likely stop working by 2020. In fact, the “NOISE Application” uses the Adobe ColdFusion web application development platform: this technology is outdated, and Adobe will stop its support in 2025. Also, the informatics services of the Commission, in the context of a wider efficiency assessment exercise, decided to stop their technical support by the end of 2020. This means that after that date the database will no longer be functional.

Given the current shortcomings of the database and its limited access and functionalities, it is clear that, if the report, collection and publication obligations ex Article 16 are to be kept (and there are reasons to do so) a complete revision of the database is to be envisaged. All the stakeholders highlighted the need for refurbishment of the tool. In the absence of such action, manufacturers would prefer the obligation to be lifted.

### **Are there unexpected or unwanted effects?**

Two main risks for unexpected or unwanted effects related to the operation of the Directive have been identified in the “Supporting study”:

#### ***1) Risk of undermining the level playing field in the sector***

The problems with market surveillance and enforcement highlighted above prevent the OND from reaching its full potential. Indeed, gaps in market surveillance mean that non-conform products on the market risk to undermine the competitiveness of compliant companies. This is especially the case because consumers often do not understand (or do not care much about) the value and importance of reduction of noise emissions and the information provided by the related product marking. As price remains one of the key purchasing criteria for the average consumer, the risk is that market demand for cheaper products may push the production or import of non-compliant products.

As mentioned above, the work of notified bodies would also benefit from the greater consistency provided by the OND requirements. Nevertheless, it was reported by several stakeholders consulted within the “Supporting study” that conformity assessment procedures conducted by notified bodies are not always consistent across the EU: differences in the application of the test codes or in the determination of the uncertainty in relation to noise emissions measurements risk limiting the effect of the Directive.

## ***2) Risk of hindering technological development***

As mentioned above, the widespread use of electric engines instead of combustion engines allows reducing sound power levels for some types of equipment. But, at the current state of the art, this type of technology cannot yet deliver the same level of operational performance as combustion engines (in terms of power, autonomy, portability) and for this reason, at the moment, electric equipment is more likely to be used by leisure or casual users than by professionals. However, while the OND establishes specific noise limits for combustion-engine driven equipment (as for builders’ hoists for the transport of goods, construction winches and lifts trucks), in other cases electric and combustion engines equipment are subject to the same noise limits. This may have hindered the development of products capable of offering better performances at a similar noise level of the combustion engine version of the same equipment, and, on the other hand, the current noise limits could be considered to be not strict enough to encourage the development of more performant electric equipment, taking into account the differences in sound power levels.

Another way the OND could have hindered technological development is by diverting resources from R&D in other technology areas to noise reduction. As discussed above, manufacturers have to balance different features when developing a product. Having to comply with the OND obliges manufacturers to allocate part of the R&D budget to the reduction of noise emission possibly having to divert resources that could have been used to develop other technologies. This issue was however not specifically reported by manufacturers and, as mentioned, it is difficult to clearly identify the exact amount of investment made in R&D on noise control and reduction, as R&D is usually a holistic process.

## **5.2. Efficiency of the Directive**

**Did the Directive reduce the administrative burden for stakeholders’ activities?**

The administrative burden of the OND is generally related to the compliance and conformity procedures. For manufacturers producing equipment not previously covered by equipment specific Directives, the OND introduced some new costs, in particular with respect to conformity assessment procedures. Regarding construction machinery, lawnmowers, tower cranes, welding generators, power generators and compressors, which were previously covered by the product and procedure Directives merged into the OND, the consulted stakeholders agreed that the merger brought greater clarity, and it provided a single reference point for both manufacturers and notified bodies.

For notified bodies and market surveillance authorities, the change in administrative burden brought by the Directive was largely identified as non-existent or minimal (71% of notified bodies and 73% of market surveillance authorities consulted within the “Supporting study” suggested either a neutral impact or an increase of 0-25% of their administrative burden). However, the notified bodies observed that certain investments had to be made in order to perform the tasks required by the Directive, including investments in equipment, personnel training, yearly surveillance, and information and clarification acquisition and dispersal. It was noted that the costs of accreditation are a source of burden for notified bodies, especially where there are very few manufacturers for certain types of outdoor equipment subject to noise limits. However, only 3% of the notified bodies suggested that the Directive had strongly increased their administrative burden. Similarly, handling new products and setting up teams of noise specialists can add to the burden for MSAs, yet no respondents indicated a strong increase in administrative burden. These costs naturally depend on the extent to which market surveillance takes place.

### **What administrative costs arise due to compliance and conformity assessment procedures?**

For equipment listed under Article 13 (subject to noise marking only), the OND allows for internal control (“self-assessment”), while for equipment listed under Article 12 (subject to noise limits), it allows for a choice between three types of conformity assessment procedure with third-party intervention of a notified body. To follow the compliance procedures, manufacturers must have sufficient personnel resources or the ability to hire an expert, as well as knowledge, time, and financial resources.

**Table 4** displays the costs of self-assessment (“Internal control of production, Annex V) by company size based on turnover, as estimated through the CATI interviews carried out within the “Supporting study”. The costs increase somewhat for the bigger companies. This can potentially be explained by larger and more complicated equipment produced by bigger companies, but due to the complexity of the range of products provided by the participating companies, this could not be conclusively confirmed.

**Table 4: Costs of self-assessment according to Annex V for manufacturers by company size based on turnover**

Company size (turnover)	Time (in days)	Cost
Less than EUR 2 million	12	EUR 1,900
Between EUR 2 and 10 million	11	EUR 2,100
Between EUR 10 and 50 million	14	EUR 2,300
More than EUR 50 million	17	EUR 3,700
<b>Average</b>	<b>13</b>	<b>EUR 2,350</b>

Note: The costs increase for the bigger companies can potentially be explained by larger and more complicated equipment produced by bigger companies, but due to the complexity of the range of products provided by the participating companies, this could not be conclusively confirmed.

Source: “Supporting study” - CATI interviews

On the other hand, according to the CATI respondents, the conformity assessment procedure according to Annex VI (“Internal control of production plus assessment of technical documentation and periodical checking”) costs on average EUR 2,250, with an average turnaround of 7 days. It has to be noted that almost all respondents to this question were companies with a turnover below EUR 10 million.

The average cost of assessment according to Annex VII (“Unit verification”) was reported to be EUR 6,550 (around EUR 4,650 for smaller companies), with the average turnaround of 7 days. For both Annex VI and Annex VII, the relatively low number of responses did not allow for a meaningful segmentation by size. However, also for Annex VII more than 70% of respondents had a turnover of EUR 10 million or less.

Larger companies mostly rely on their internal quality assurance system developed in compliance with Annex VIII (“Full quality assurance”). As a consequence, this cost should be compared with the corresponding self-assessment cost figure reported by companies in the same category.

**Table 5** details the costs of conformity assessment according to Annex VIII per company turnover, including the cost of the system required. Again, the costs are higher for bigger companies.

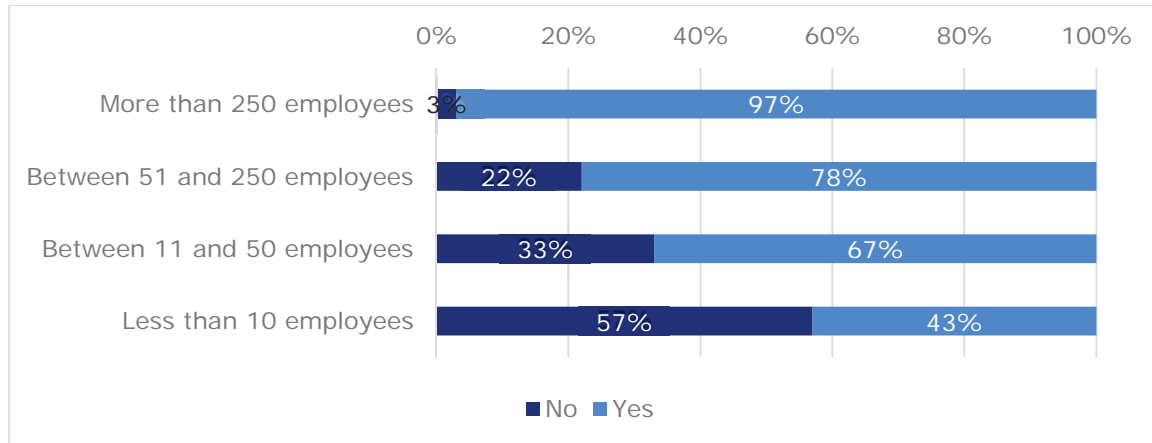
**Table 5: Costs of conformity assessment according to Annex VIII for manufacturers per company turnover**

Company size	Time (in days)	Audit procedure cost on the system	QA System set-up cost
Less than EUR 2 million	9	EUR 4,950	EUR 7,500
Between EUR 2 and 10 million	8	EUR 5,500	EUR 21,150
Between EUR 10 and 50 million	6	EUR 10,450	EUR 42,600
More than EUR 50 million	10	EUR 21,300	EUR 46,700
<b>Average</b>	<b>8</b>	<b>EUR 8,350</b>	<b>EUR 30,800</b>

Source: “Supporting study” - CATI interviews

Given the high implementation costs and skills required to develop and use it, access to this kind of system also increases with the size of the company. As shown in **Figure 5**, the bigger the company, the more likely it is that it will have developed an internal quality insurance system.

**Figure 5: Frequency of development of an internal QA System by company size**



Source: “Supporting study” - CATI interviews

It is assumed that the cost of performing a measurement using the internal quality assurance system is similar to the cost of self-assessment according to Annex V. Notified bodies also have to carry out yearly audits on the quality assurance systems. Assuming the cost of this audit requirement to be a quarter of the cost of the initial cost, it would range between EUR 1,000 and EUR 5,000 per year depending on the company size. All in all, over ten years it is estimated that audits on the quality assurance system cost to a company between EUR 15,000 and EUR 70,000 depending on its company size (EUR 30,000 on average).

The notified bodies reported that the cost to the client for the conformity assessment procedure under each Annex is up to EUR 5,000 ex Annex VI, up to EUR 2,000 ex-Annex VII, and up to EUR 8,000 ex-Annex VIII. However, the response rate among notified bodies was low and does not allow for a reliable comparison of costs.

In general, the average cost of a conformity assessment with third-party involvement has been determined by the evaluation of the internal market legislation for industrial products. Based on a survey of 128 notified bodies and a programme of 201 interviews, including industry associations and companies, it identified the cost to be in the range of EUR 30,000 to EUR 50,000 per company per annum, or EUR 3,000 to EUR 4,000 per product.

On the basis of the estimated number of manufacturing companies producing each equipment covered by the OND, it was possible to estimate the annual compliance cost. It has to be noted that the estimates change on the basis of the assumed number of measurements per year per type of equipment. CATI results indicate that, on average, a manufacturing company conducts six measurements in a year per type of equipment. This could depend, for example, on the existence of different versions of the same equipment type.

On average, a manufacturing company conducts six measurements in a year per type of equipment. **Table 6** presents the cost range of compliance for equipment covered by Articles 12 and 13. As a result, the compliance cost with the Directive ranges from EUR 18 million to EUR 27 million.

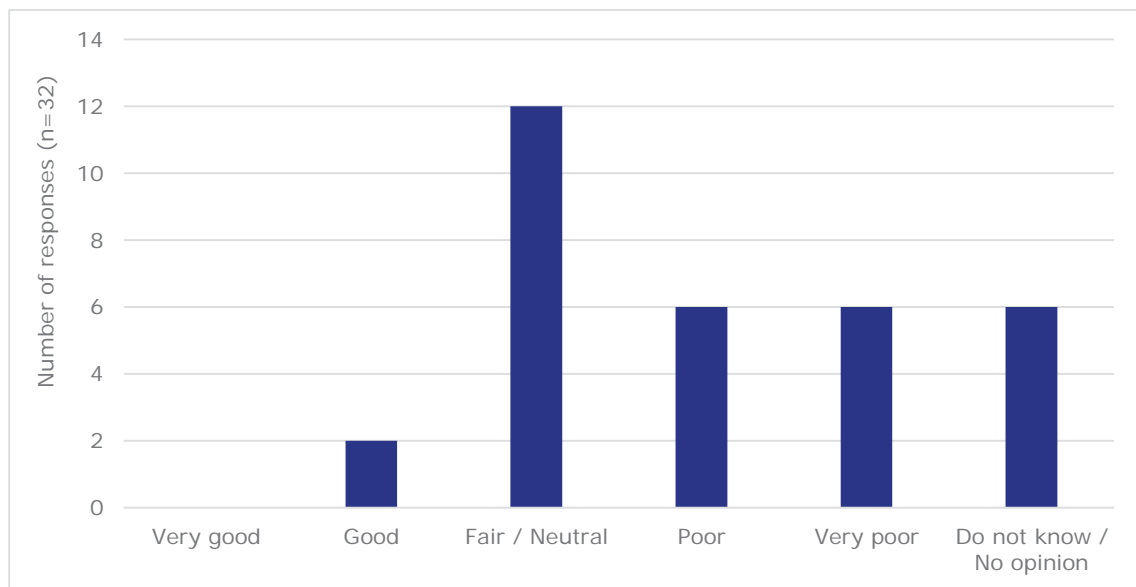
**Table 6: Estimated total compliance costs**

	Lower end	Higher end
Article 12	EUR 8 million	EUR 10 million
Article 13	EUR 10 million	EUR 17 million
<b>Total</b>	<b>EUR 18 million</b>	<b>EUR 27 million</b>

Source: “Supporting study” - CATI interviews

In the open public consultation manufacturer respondents were asked to evaluate the conformity assessment procedures regarding implementation, administrative and information burdens. As presented in **Figure 6**, the majority considers the procedures to be fair/neutral.

**Figure 6: How can the conformity assessment procedures of the Directive be considered with regard to implementation, administrative and information burden?**

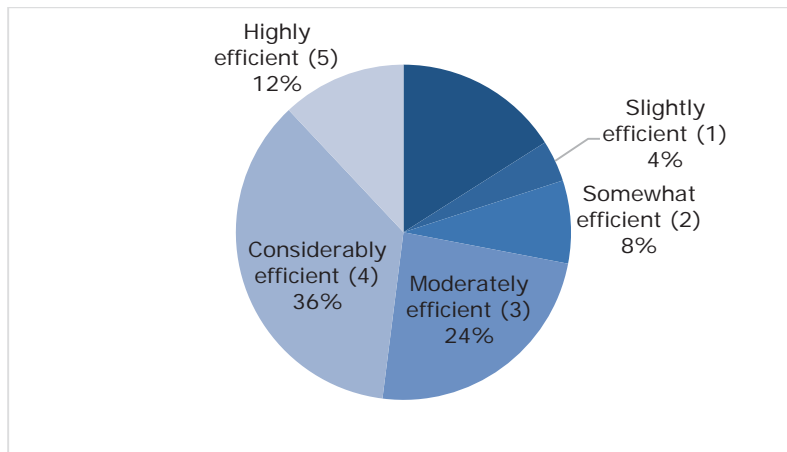


Source: Open public consultation

The respondents were also asked to rate the efficiency of the conformity assessment procedures on a scale from 0 to 5 on selected aspects. As presented in **Figure 7**, for the procedure according to Annex V the majority of aspects are ranked at moderate efficiency (3 out of 5), however technical documentation is more commonly ranked considerably efficient (4 out of 5).



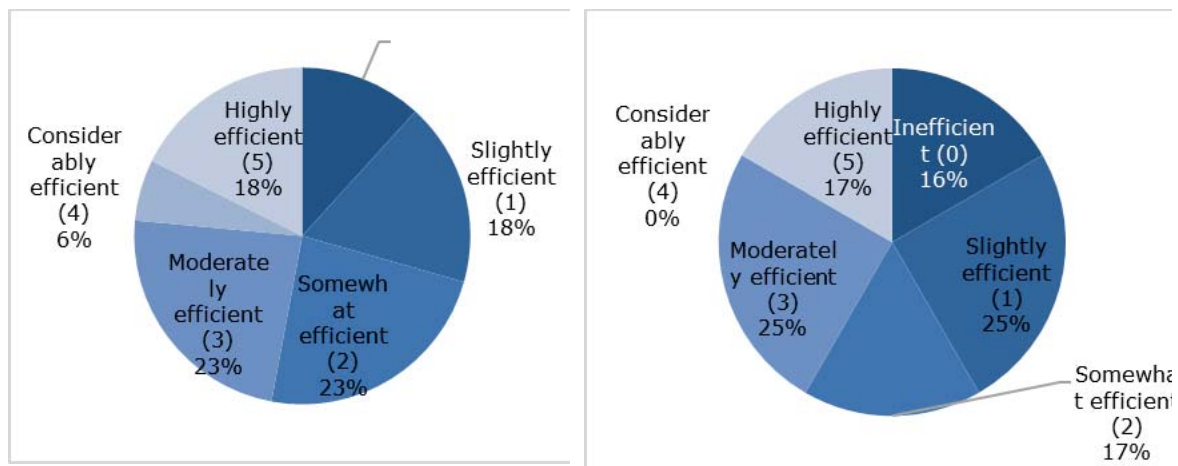
**Figure 7: Efficiency of the conformity assessment procedure according to Annex V**



Source: Open public consultation

As presented in **Figure 8**, opinions of manufacturers are somewhat more divided on the efficiency of the conformity assessment procedure according to Annex VI and Annex VII. Annex VI is more commonly assessed as either somewhat efficient (2 out of 5) or moderately efficient (3 out of 5), with 23% each, while Annex VII is more commonly assessed as either slightly efficient (1) or moderately efficient (3) with 25% each.

**Figure 8: Efficiency of the conformity assessment procedure according to Annex VI and to Annex VII**



Source: Open public consultation

From their point of view, notified bodies and market surveillance authorities considered that providing the choice between different conformity assessment procedures is an adequate way to balance the need for noise limits and information to users with some degree of flexibility for industry, without creating confusion or unnecessary difficulty.

The majority of the consulted stakeholders consider that the overall costs for manufacturers from following the requirements of the OND are proportionate to the benefits gained, as long as they are sufficiently and equally enforced. Nevertheless, as mentioned above, the gaps in market surveillance and enforcement undermine the level playing field on the single market, putting compliant manufacturers at a competitive disadvantage due to the investments they have made to comply.

There is disagreement among different stakeholder groups whether the current third-party conformity assessment procedures should be replaced by internal / self-assessment. Manufacturer representatives consider the self-assessment a more efficient way of quality assurance with lower costs, while consumer organisations, notified bodies and market surveillance authorities consider that it would be less reliable than third-party assessment, leading to negative impacts for consumers and the environment. These stakeholders expressed the view that third-party conformity assessment acts as a “first line of control” to prevent that non-compliant products reach the market. In addition, according to the analysis of the results of the open public consultation, 49% of the respondents felt that self-assessment should be used in very limited cases only or be removed entirely. Therefore, the need to minimize costs needs to be carefully balanced against the reliability of the conformity assessment procedure and the information provided to users, as well as ensuring the level playing field on the single internal market, especially where market surveillance is still insufficient.

### **Did the Directive introduce unnecessary burdens for manufacturers and other economic operators?**

While the focus of the OND is controlling the noise emissions of outdoor equipment in the environment, the limits and requirements mainly impact manufacturers and other economic operators. Therefore, the benefits and costs brought by the Directive fall largely on different stakeholder groups. The open public consultation respondents familiar with the Directive considered that some excessive administrative burden had been brought by the implementation of the Directive, particularly by the third-party conformity assessment procedures, and the reporting obligations on collection of noise data. The respondents considered that these requirements, particularly providing information for the “NOISE Application” database, do not generate any clear environmental or health benefits.

Some of the consulted stakeholders did express the opinion that some increase in burden compared to the pre-OND era is acceptable, as no benefits will be achieved without some investment in compliance and conformity processes. The majority of stakeholders acknowledge that the OND has had a positive impact on the overall reduction of noise emission levels by outdoor equipment.

**Table 7** presents the view of the CATI respondents within the “Supporting study” on how the noise performance impacts the final price of the product as paid by the customer. Across all sectors, for more than half of the respondents, the noise performance has no impact on the final price. In these cases, the burden introduced by the Directive is not necessarily fully passed on to the consumer. However, it is also noticeable that in specific sectors the impact on price is more evident: this is the case for cleaning equipment, power generators and cooling equipment, and waste collection, processing and recycling equipment. Cleaning and waste collection, processing and recycling equipment are typically needed by public and local authorities to provide related services to their citizens. As mentioned, this type of customer is more interested in less noisy equipment in order to perform these activities during the night. Power generators are often used in

specific contexts where excessive noise can be problematic: this is the case for example of movie sets where power generators are used while filming, hence the need for more silent equipment. In this case, being a valuable feature of the equipment, lower noise emission has a stronger impact on the final product price.

**Table 7: Impact of noise performance to the price paid by the final customer**

	No difference	Increase of 5%	6% - 10%	11% - 25%	26% - 50%	> 50%	Cheaper for customers
All sectors	57%	17%	14%	9%	1%	0%	1%
Cleaning	<b>44%</b>	16%	20%	12%	4%	4%	0%
Construction	59%	19%	15%	4%	1%	0%	1%
Gardening	54%	14%	21%	7%	0%	4%	0%
Loading and lifting	63%	14%	15%	5%	1%	0%	1%
Power generators and cooling	<b>35%</b>	18%	20%	20%	3%	0%	3%
Pumping and suction	59%	17%	8%	11%	3%	1%	1%
Snowmobiles and snow groomers	33%	0%	67%	0%	0%	0%	0%
Waste collection, processing and recycling	<b>40%</b>	23%	10%	27%	0%	0%	0%

Source: “Supporting study” - CATI interviews

Manufacturing companies responding to the OPC also gave the impact of noise performance to the final price of their equipment. For two-thirds of the respondents, the increase falls between 1 and 20 per cent.

55% of the manufacturers participating to the OPC reported that information on noise emission level is a criterion offered to and required by the customers, 44% reported that the information is offered but not required, and 6% that it is neither.

**Are there elements of the Directive that require more resources (manpower, time, etc.) in comparison with others?**

R&D costs for technical compliance and third-party conformity assessments for outdoor equipment subject to noise limits are identified by the stakeholders as the most expensive and time-consuming elements of the Directive.

Out of the 150 respondents to the OPC that are familiar with the OND, 65% considered that the Directive had a positive to strong positive effect on research, development and innovation on equipment; among them, 62% of professional users and 61% of representatives of private enterprises and trade, business or professional associations. It

was, however, observed that noise limits need to be feasible and sufficiently ambitious to stimulate innovation and improve noise performance.

The limited importance given by consumers at the moment of purchase to noise performance was considered an inhibiting factor on the manufacturers' motivation to invest in noise reduction R&D. Indeed, the lack of a competitive advantage in relation to noise performance, in combination with the conflict between noise limits and other legal requirements (such as exhaust emissions or machinery safety), was seen as a negative factor for noise-specific R&D, and the consequent R&D expenses to be disproportionately high on compliant enterprises. According to the CATI interviews carried out within the "Supporting study", it is estimated that about 5% of the turnover is spent on overall R&D with small differences across the different sectors.

It is difficult for stakeholders to indicate the amount of R&D spent on noise reduction. R&D budgets are usually more holistic and include many other product features on top of noise emissions. As such, any data on this specific aspect needs to be considered with caution. Based on CATI responses, the "Supporting study" estimated that between 2.5% and 7% of total R&D expenditure is spent on noise reduction. Interestingly, manufacturers of cleaning equipment and of power generators and cooling tend to invest more than producers in other sectors, 7% and 5% on average respectively against 3.5% of average for the other sectors.

The estimated expenditure on R&D on noise reduction ranges between EUR 40 million and EUR 120 million. **Table 8** provides the average value per sector. It has, however, to be considered that this value is not constant over the years and it follows the production cycle. Also, some of the investment in R&D on noise reduction is not borne by companies but passed on to the consumers. This means that the cost is also spread among the final users of the equipment, especially in cleaning equipment, power generators and cooling equipment, and waste collection, processing and recycling equipment categories. For example, it is estimated that about 17 million units of gardening equipment have been sold in 2017. This would mean that, on average, EUR 0.50 have been passed on to each customer to cover R&D cost related to noise reduction.

**Table 8: Estimated expenditure in R&D as share of sector turnover**

	Estimated turnover	R&D Expenditure	R&D on noise reduction expenditure
Cleaning equipment	EUR 1 billion	EUR 48 million	EUR 4 million
Construction machinery	EUR 21 billion	EUR 1 billion	EUR 31 million
Gardening equipment	EUR 4 billion	EUR 200 million	EUR 8 million
Loading and lifting equipment	EUR 7 billion	EUR 300 million	EUR 10 million
Power generators and cooling equipment	EUR 3 billion	EUR 130 million	EUR 8 million
Pumping and suction equipment	EUR 1.5 billion	EUR 70 million	EUR 3 million
Snowmobiles and snow groomers	EUR 0.2 billion	EUR 10 million	EUR 0.3 million
Waste collection, processing and	EUR 2.5 billion	EUR 120 million	EUR 3 million

	Estimated turnover	R&D Expenditure	R&D on noise reduction expenditure
recycling			
<b>Total</b>	<b>EUR 40 billion</b>	<b>EUR 1.8 billion</b>	<b>EUR 67 million</b>

Source: “Supporting study” - CATI interviews

The third-party conformity assessment is also somewhat resource-consuming for notified bodies, who suggested that the effort to demonstrate compliance with the OND could be more significant than for those of other applicable EU legislation, in particular for the evaluation of measurement uncertainties for outdoor equipment in Article 12.

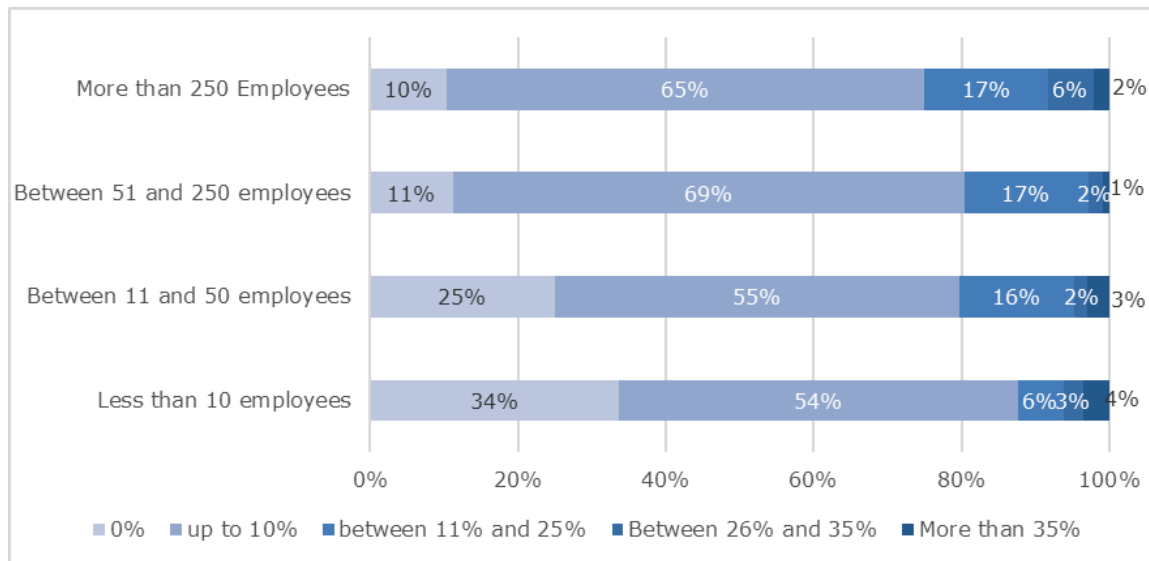
### **Are SMEs disproportionately affected by the Directive’s requirements in comparison to larger enterprises?**

Fixed compliance costs can be expected to have a larger impact on SMEs, as due to smaller sales volumes they have a more significant impact on the company finances, and due to smaller personnel numbers and other non-financial resources, it can be more difficult for SMEs to meet new and stricter requirements. Based on the CATI interviews carried out within the “Supporting study”, for the majority of manufacturers of outdoor equipment in the scope of Directive 2000/14/EC, the improved noise performance does not significantly impact the price of the product, which could mean that the investment made in R&D cannot be recouped very quickly from the sales.

As mentioned above, having to carry out conformity assessment procedure with the intervention of notified bodies for outdoor equipment subject to noise limits, implies costs in terms of economic, time and administrative resources. While bigger companies may be able to get a better deal with the conformity assessment (e.g. by having internal laboratories and quality assurance procedures), smaller companies may experience higher administrative costs and delays to the production. The smaller the company, the less likely is it that they have developed an internal quality assurance system.

Regarding R&D costs, the consulted stakeholders noted that larger companies have more resources to allocate to R&D. It was also suggested that larger companies have larger sales volumes, making it easier for them to compensate for increased R&D expenses. They are also more likely to have access to experts and laboratories. In addition, SMEs have less control over their suppliers, leading to less control of components and tools, and therefore higher design costs. **Figure 9** presents the R&D expenditures on noise reduction as a percentage of total R&D expenditures per company size. Each bar represents the total number of companies within a size category. The percentages in the bars represent the proportion of companies within the size category that have the same level of expenditure on R&D on noise reduction. The figure shows five different levels of expenditure on R&D on noise reduction as shown in the legend at the bottom of the figure. We can see for example that 17% of the companies with more than 250 employees spend between 26% and 35% of their total R&D expenditure on noise reduction. In comparison only the 6% of companies with less than 10 employees have the same level of R&D expenditure on noise reduction.

**Figure 9: Expenditure on R&D on noise reduction (% of total R&D) by company size**



Source: “Supporting study” - CATI interviews

Overall, stakeholders did not have a clear opinion on whether the OND has had an effect on SMEs’ ability to compete in the market. 22% of the open public consultation respondents suggested no effect, 15% suggested negative to strong negative effect, 16% suggested positive to strong positive effect, and 47% expressed no opinion. Similar conflicting results have been found among professional respondents and representatives of private enterprises and trade, business or professional associations. In particular, 53% of the manufacturing companies thought that SMEs are disadvantaged both by the efforts they have to put into complying with the noise limits, and the need to follow the third-party conformity assessment procedure set in the OND, in comparison to larger enterprises. The third-party conformity assessment costs, in particular, were again highlighted as particularly difficult for the SMEs to bear. However it was pointed out that SME-produced equipment has the same health impacts as machines produced by larger companies, and thus the testing procedures need to be comparable. It was also observed by one stakeholder that while SMEs may struggle to employ noise experts full-time, they could still hire consultants only when needed, reducing, therefore, the related cost.

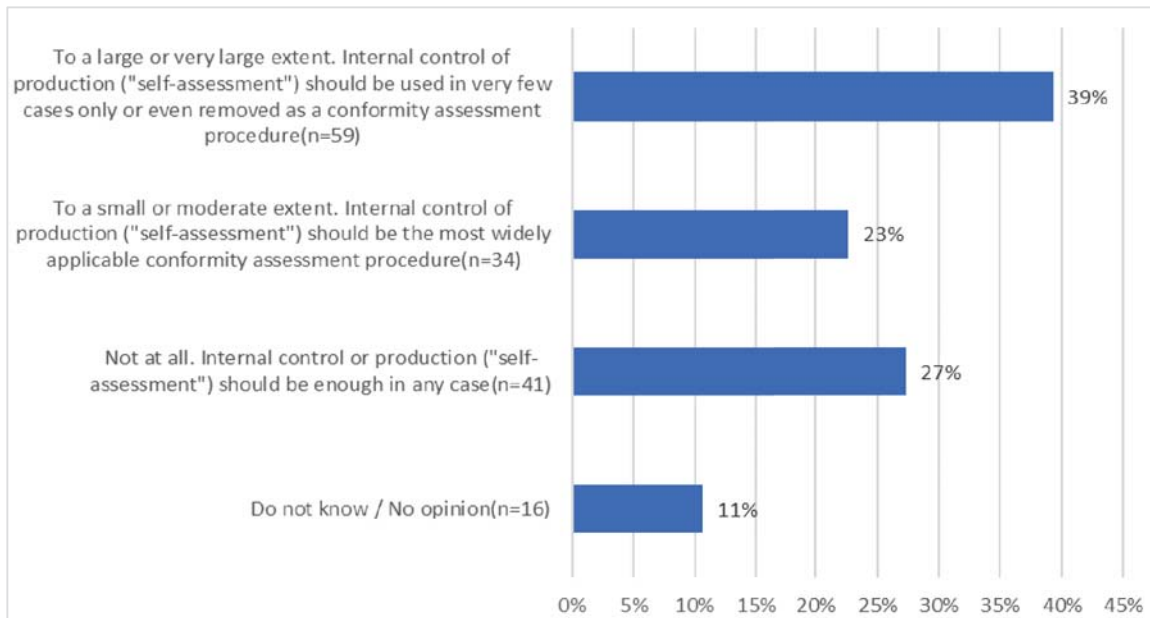
**Could ensuring an internal market for outdoor equipment and protecting the health and well-being of citizens and the environment be achieved at a lower cost?**

Switching to conformity assessment procedures based on internal control (“self-assessment”) is seen as a potential way of meeting the goals of the OND at a lower cost, as it would eliminate the costs involved in third-party certification. Sector organisations recognised that when the OND came into force, companies did not have the required knowledge to perform the measurement nor the needed equipment; however, the same stakeholders affirm that the situation has changed radically, and at present manufacturers (both SMEs and large enterprises) have the skills to do the measurements in-house and would be ready to move to a system based on self-assessment. The CATI interviews conducted with manufacturers within the “Supporting study” seem to support this statement as the majority of respondents (manufacturers of outdoor equipment subject to noise limits) have developed an internal quality assurance system.

Other stakeholders, however, especially consumer and environmental organisations, as well as national market surveillance authorities, consider third-party certification to be the most reliable option and a requirement to guarantee a level playing field in the single market. Nevertheless, several stakeholders expressed concerns about the quality and reliability of measurements performed by some notified bodies, suggesting that there should be more effective controls on their activities.

Opinions expressed through the open public consultation are representative of this diversity of views. An equal mix of different stakeholders (private individuals, sector organisations, public authorities, sector experts, etc.) support both positions which confirms the complexity of this dialogue (see **Figure 10**). Among the different groups of respondents, it can be inferred that trade associations and companies are vastly in favour of “self-certification”, while consumer associations and citizens are rather against, and national authorities are divided.

**Figure 10: Do you think that third party conformity assessment procedures (with the intervention of a notified body) contribute to ensure that only compliant products are placed on the EU/EEA market?**



Source: Open public consultation

On the other hand, the existence of diverging test methods between the OND and the Machinery Directive (MD) for the same product is also a source of costs for the manufacturers. The cost of self-assessment according to the OND is estimated at EUR 2,350 and a turnaround time of 13 days. While the costs of noise measurement according to the MD are not known, duplicate costs for duplicate measurements can be assumed.

In general, 56% of manufacturers responding to the OPC expressed the opinion that health and well-being of citizens could not have been protected at a lower cost, and 50% thought that the internal market could not have been ensured at a lower cost with respect to noise reduction efforts, against 22% and 34% respectively.

As a summary of the results of the evaluation of the Directive in terms of efficiency, as collected in the “Supporting study” and reflected above, **Table 9** (next page) provides an **overview of identified costs and benefits of the OND**, for the different categories interested: citizens/consumers, industry/businesses and administration, as described in the previous sections. Costs and benefits are described from a technical and economical point of view, and assessed in terms of qualitative and quantitative/monetary (when possible) impacts. In particular, the quantitative impacts are estimated on the basis of the information collected in the consultation activities carried out within the “Supporting study”, in respect of reduction of noise emissions of outdoor equipment, the costs of performing conformity assessment, and the R&D investments in developing products with lower noise emissions.

The methodology used in the “Supporting study” to obtain the estimates is presented in **Annex 3, point d) Data analysis - Economic impact**.



**Table 9: Overview of identified costs and benefits of the OND**

Type of cost/ benefit	Description	Citizens/Consumers		Industry/Businesses		Administration	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
<b>Environmental and health benefits</b>	Changes in noise emission levels Environmental benefit Continuous benefit	High positive impact	Reduction of noise emissions, between 2 and 3 dB for equipment in Article 12, approximately 1 dB for equipment in Article 13: EUR 86 million / year <sup>35</sup>	N/A	N/A	N/A	N/A
<b>Intra-EU trade opportunities</b>	Increase in cross-border sales Economic benefit Continuous benefit	N/A	N/A	Easier cross-border trade within EU, due to harmonised rules	Minor positive impact	N/A	N/A
<b>Extra-EU trade opportunities</b>	Increase in cross-border sales Economic benefit Continuous benefit	N/A	N/A	More difficult cross-border trade, due to different / lack of noise limits outside EU	Minor negative impact	N/A	N/A
<b>Increased final price to the customer</b>	Reflection of noise performance in final price Indirect cost Economic cost Recurring cost	Negligible to low negative impact	Minor increase in final price of the product	Negligible to low impact	Minor increase in final price of the product	N/A	N/A
<b>Conformity assessment</b>	Costs of performing conformity assessment Economic/staff costs Compliance cost Recurring cost	N/A	N/A	High negative impact	EUR 18 million to EUR 27 million / year	Negligible to low negative impact	Investment in equipment Investment in personnel training Yearly inspections Information acquisition and dispersal
<b>R&amp;D costs</b>	Investments in developing products with lower noise emissions Indirect cost Economic/staff costs Compliance cost Recurring cost	N/A	N/A	High impact	EUR 40 million to EUR 120 million / year	N/A	N/A
<b>Costs from overlap with other Directives /</b>	Costs of testing twice with different methods Direct cost	N/A	N/A	Medium negative impact	Double cost of conformity assessment Time taken	N/A	N/A

<sup>35</sup> This value is the monetized benefit and represents the annual average sum that the households affected by noise from outdoor equipment would be willing to pay to reduce in some dB the noise limits of these equipment in order to lessen the annoyances by them created. The methodology for its estimation is presented in section 5.5. (pages 80-84) and Annex II of the “Supporting Study”

<b>Regulations</b>	Economic/staff cost Recurring cost Unexpected cost						
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*Source: "Supporting study" and further elaboration*

### **5.3. Relevance of the Directive**

#### **Was the Directive relevant to the needs of the users and the environment?**

As explained in Section 5.1, exposure to noise can be hazardous and lead to significant health problems for the people exposed.

While there is legislation protecting workers exposed to noise, private users or people exposed to noise do not always benefit from the same level of protection.

Noise affects also the environment. Cities, in particular, are highly affected by noise pollution due to the growing urbanisation, traffic congestion and construction. The OND was introduced with the specific aim to lessen the noise impact on the environment and especially in urban areas. In this sense, the Directive was indeed necessary and relevant to adequately tackle the referred problems, as explained above in particular with respect to reduction of noise emission levels.

#### **Is the Directive still relevant to the needs of the users and the environment?**

Despite the OND, noise levels are still an issue for public health as reported in the consultation activities mentioned in the previous section. Growing urbanisation and work automation have led to the use of more outdoor equipment and, therefore, also more noise. The same increase can be noted in consumer equipment. This increase in the number of outdoor equipment on the market is felt to have counterbalanced the positive effect of the Directive in reducing noise emission levels<sup>36</sup>.

Certain sources of noise are more likely to expose users to high noise emissions and to result in annoyances or hazardous effects on citizens' health. In particular, local environment offices have pointed out that construction and demolition areas are the greatest sources of noise in relation to outdoor machinery, followed by community and neighbour noise.

A significant share of the interviewees stressed that neighbour and community noise are relevant categories when it comes to complaints. The number of yearly complaints reported by interviewees varies drastically (from a few dozens to hundreds), but it has to be considered that these numbers are probably low estimations and that the real extent of this kind of problems could be larger. Finally, it was also mentioned that in many cases it is not the noise per se that is problematic, but disrespectful behaviour in the use of the tools (e.g. gardening equipment).

In the professional sectors linked to these sources of noise, in particular construction, gardening and waste collection industries, noise emissions are still reported to be at a sensitive level for workers and are sometimes higher than the 80 dB(A) threshold above which preventive measures should be taken in workplaces. In addition, the noise emitted by equipment used in these industries is likely to impact EU citizens, especially in urban areas.

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<sup>36</sup> See the "Supporting study" (2018) for specific references.

Stronger demand for quieter equipment could be a significant market driver that could put pressure on manufacturers to produce less noisy products even in the absence of specific legal requirements.

However, interviewees agree that the noise level of outdoor equipment is not a purchasing driver for the average consumer (this was confirmed by the participants in the CATI interviews within the “Supporting study”).

The demand for quieter equipment slightly varies according to the type of costumers. As shown in **Table 10**, according to the manufacturers who took part in the CATI interviews within the “Supporting study”, public authorities are the ones with the highest interest in low noise emission equipment in comparison with professional/leisure consumers.

**Table 10: Demand from business, consumers and public authorities to provide quieter equipment, according to manufacturers (in percentage and per number of respondents)**

Demand from the market	Not at all/ to a small extent	To a moderate extent	To a large extent/very large extent	Total
Business	53% (201)	30% (116)	17% (64)	100% (381)
Consumers	44% (75)	36% (61)	20% (34)	100% (170)
Public authorities	38% (49)	27% (35)	35% (46)	100% (130)

Source: “Supporting study” - CATI interviews

In any case, it seems that there is still a need to raise awareness among consumers. Consumers are generally unaware of the health impact of noise emission and do not have the knowledge to make an informed choice when purchasing outdoor equipment. As discussed, the OND did not fully accomplish its objective of raising awareness among consumers and encouraging a “buy quiet” attitude. Overall, more effort should be put into increasing public awareness towards noise emission, and more information could be provided to the buyer in order to allow a greater understanding of the noise level.

### **Was the Directive relevant to the needs of the industry?**

One of the objectives of the Directive, together with the protection of the well-being of citizens, was to ensure an efficient European internal market for outdoor equipment and preventing fragmentation. The majority of the consulted stakeholders did indeed give credit to the OND for having prevented individual national approaches to noise limits in the Member States.

If the majority of stakeholders recognised the positive effect of this EU-wide regulatory effort to prevent the market from fragmenting along national lines, sector organisations did not identify any advantage with regards to foreign markets. As discussed above, outside Europe there is much less attention to noise emissions from both policymakers and consumers.

Regarding cheaper products from outside the EU entering the EU market, it was noted by the stakeholders on several occasions that market surveillance on this aspect is lacking as

regards non-compliant equipment within the EU market. The CATI respondents within the “Supporting study” did not identify any significant impact of European noise limits to their business outside the EU.

Thus, while the OND is relevant with regards to the needs of the industry to have a harmonised set of rules across the EU, the Directive and the stricter limits it imposes did not bring any relevant advantages to EU companies in terms of their compliance with foreign legislation.

### **Is the Directive still relevant to the needs of the industry?**

The majority of stakeholders assessed the impact of the OND on trade within the EU internal market positively. This suggests that the Directive is still relevant for the needs of the industry, in the sense that it continues to prevent fragmentation of the market. In line with this perspective, almost none of the stakeholders would be in favour of repealing the Directive.

An aspect that is considered not in line with the current needs of the industry is the third-party conformity assessment. When the OND came into force, companies did not have the specific knowledge required to measure noise emissions. Today, manufacturers have the skills to perform the measurements themselves and could rely on self-assessment instead of the third-party conformity assessment. This seems to be confirmed by the CATI interviews conducted with manufacturers within the “Supporting study”, according to which 68% of respondents developed in-house quality assurance systems.

Some stakeholders suggested, however, that more recently the Directive has no longer had a positive effect, as noise measurement methods and test codes have not been updated (in particular with respect to the standards included in the legal texts) and the push for lower noise limits has therefore stagnated.

### **5.4. Coherence and complementarity of the Directive**

The pieces of legislation in the main focus for this evaluation are (see also **Section 2.1.** for more details on them):

- the Machinery Directive 2006/42/EC (MD),
- the Non-Road Mobile Machinery Regulation (EU) 2016/1628 (NRMM),
- the Environmental Noise Directive 2002/49/EC (END), and
- the Directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise).

### **Are there any overlaps/conflicts with other EU legislation? Does the Directive complement other EU legislation/policies?**

The OND being part of a wider network of EU legislation aiming to reducing noise as source, it is necessary to take into account the related interconnections. Considering that for the noise health impacts, the source of noise is not in itself relevant, but the noise

levels and length of exposure are the deciding factors, a comprehensive approach to noise levels regulation is both valid and necessary.

The OND, in conjunction with the Machinery Directive (MD), provides for the requirement of information to be included about the noise emissions, to allow the evaluation of noise levels in the workplace, and selection of equipment with lower noise emission levels.

The Machinery Directive, among its health and safety requirements, contains also provisions aimed to reduce noise emissions in the design and manufacturing of products. It makes use of harmonised standards and addresses operator noise exposure / sound pressure level rather than sound power level. As confirmed by the interviewed stakeholders and the survey respondents, the divergence in measurement methods and test codes means that where a piece of equipment falls under the scope of both Directives, manufacturers have to perform two different types of tests to achieve compliance with both. Even if there is a close relationship between the OND and the MD, while not discussing test codes, the solutions to reduce operator noise are not necessarily the same as the solutions to reduce environmental noise, as the operator can be protected by local shielding or changing the operator position<sup>37</sup>.

The Non-Road Mobile Machinery Regulation covers small gardening and handheld equipment and construction machinery which are also in the scope of the OND, as well as snowmobiles which are among the suggested equipment to be added to the OND according to the “ODELIA” study. It sets emission limits for engines with different power ranges and lays down the procedures to be followed for type-approvals. In certain cases, the OND requirement to reduce noise emissions and the NRMM Regulation requirement to produce less polluting equipment can be difficult for the manufacturers to meet at the same time. An example given by sector organisations had to do with Diesel engines: In order to meet the emission requirements of the NRMM Regulation, formerly commonly used Indirect Injection (IDI) engines are increasingly replaced with Direct Injection engines, which are intrinsically noisier than the IDI engines. In addition, the new engines will generate more heat, requiring larger and therefore noisier fans.

Consulted stakeholders were somewhat aware of these overlaps between the OND and the MD and the NRMM. 44% of the respondents to the open public consultation that were familiar with the Directive agreed or strongly agreed that overlaps or conflicts with other EU legislation exist, making reference in particular to these two pieces of legislation. The percentage was higher among particular stakeholder groups: more than 50% for professional respondents, and more than 55% for representatives of private enterprises and trade, business or professional associations. At the same time 41% of the respondents did not present an opinion, while 15% disagreed with the statement.

With respect to the Environmental Noise Directive 2002/49/EC and to Directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of

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<sup>37</sup> <https://ec.europa.eu/docsroom/documents/4985/attachments/1/translations>

workers to the risks arising from physical agents (noise), no overlaps or conflicts were identified.

The stakeholder opinion on the OND's complementarity with other EU legislation is largely positive. 62% of the respondents to the OPC agreed that the Directive complements other EU legislation, while only 9% stated that it does not, and 29% expressed no opinion. Similar positions have been expressed by professional respondents.

### **Does the Directive leave gaps?**

The uncertainty in noise measurement procedures. This was described by interviewees as a crucial point of the current measurement process. A method has been agreed among the notified bodies to bridge this gap, but the variability of guaranteed sound power levels remains, depending on the subject performing the measurement.

One of the objectives of the OND is to provide information to citizens on noise emissions, and thereby improve customer choice and encourage a “buy quiet” approach. However, consumers currently do not seem to possess sufficient interest or awareness of noise levels and the potential effect of exposure to noise to use them as a basis for purchasing decisions. In this sense, the current OND proved not to be sufficient to motivate consumers to buy equipment producing lower noise levels, as was confirmed by the interviewed stakeholders. As a direct consequence, if there is no demand for reduced noise emission, manufacturers would have no incentive to offer equipment that is less noisy than required by the Directive.

In order for EU citizens to be able to benefit, estimated in EUR 86 million / year<sup>38</sup> of consumers savings, from the additional noise information provided in line with the OND, a way needs to be found to provide consumers with enough knowledge that they actually understand such information, and can use it to inform their purchasing decisions. In addition, previous literature has found that plain information may not be enough to trigger changes in purchasing behaviour. Yet, national support schemes demonstrate that a combination of information and an economic incentive can steer purchasing decisions.

Concerning the scope of the Directive and the lists of equipment covered according to Articles 12 (subject to noise marking and limits) and 13 (subject to noise marking only), the open public consultation provided conflicting results. While more than half (53%) of the respondents to the open public consultation considered that the current scope is no longer adequate and the lists of equipment need to be updated, a majority (67%) of representatives of private enterprises and trade, business or professional associations believed that the current scope is appropriate and the lists of equipment are complete and exhaustive. Among professional respondents, positions are more balanced (45% considering the scope appropriate, and 39% no longer appropriate).

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<sup>38</sup> See table 9

At the same time, the majority of the respondents of the different typologies expressed no opinion on the costs potentially associated to such changes. Previous studies proposed lists of new equipment to add to the Directive or to be moved from Article 13 to Article 12 or vice-versa, in light of the available technical information.

**By merging previous legislation, did the Directive improve the internal coherence of EU legislation?**

The Directive is seen by almost all the consulted stakeholders (in particular, more than 90% of the respondents to the OPC who expressed an opinion on the specific question) as having improved the internal coherence of EU legislation, preventing divergence of different national standards and regulations.

**Are there any overlaps/conflicts with other national or non-EU legislation? Does the Directive complement national or non-EU legislation/policies?**

Of the OPC respondents who were familiar with the Directive, 41% had no opinion on whether the OND conflicts or overlaps with non-EU or national legislation, while 44% were of the opinion that it does, and 15% that it does not. This perception is even higher among professionals and representatives of private enterprises and of trade, business or professional associations.

Of the manufacturers responding to the CATI interviews in the “Supporting study”, 69% report selling their products globally, compared to 16% selling only to the domestic market and 11% selling in the EU. For those stakeholders who sell their products both in and outside the EU, this means spending resources on a feature that will not improve their competitiveness in a potentially significant part of their market. Many of the consulted manufacturers who operate in the global market did not consider the impacts to be particularly significant, however, with 53% of the manufacturers responding to the CATI interviews considering that noise limits harmonisation has no impact on their business outside the EU.

National policy instruments are used in conjunction with the OND, to encourage the use of quieter equipment. Voluntary schemes and incentives<sup>39</sup> are used to make noise reduction more attractive and accessible to entrepreneurs and consumers, and indicate an increased national awareness of this specific issue. The consulted stakeholders had cautiously positive opinions on the efficiency of such national incentives in driving the market towards less noisy products, noting that these incentives can increase awareness of noise levels and the value of producing and buying quieter equipment if both customers and manufacturers recognise their added value. In addition, if they provide sufficient financial incentive to the manufacturer, such national initiatives may encourage technological advancements in the field of noise control, which would eventually benefit the entire European market.

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<sup>39</sup> For instance, the “MIA-Vamil” tax relief scheme in the Netherlands, the “Blauer Engel” label in Germany, and the “Nordic Swan Ecolabel” in Denmark, Finland, Iceland, Norway and Sweden.



A share of 37% of the open public consultation respondents who were familiar with the Directive thought that the OND complements non-EU legislation/policies, while 25% disagreed and 39% presented no opinion.

### **5.5. EU added value of the Directive**

#### **Would the same results in relation to the strategic objectives have been possible without the EU intervention?**

The key results of the OND have been identified by previous studies and by the consulted stakeholders in the “Supporting study” as follows:

- 1) By harmonising the rules and procedures previously regulated by multiple pieces of legislation, the Directive has simplified the legal framework and improved stakeholders’ activities.
- 2) The Directive raised awareness among policy makers about the issue of noise emissions produced by outdoor equipment.
- 3) The Directive has prevented the proliferation of different national regulations in the Member States ensuring that European manufacturers could trade their products without obstacles across Europe.
- 4) By establishing limits to noise emissions by outdoor equipment the OND contributed to the safeguarding of citizens’ well-being and of the environment.

The key question is whether these results could have been achieved without the EU intervention.

Concerning the simplification of the legal framework, given that the OND resulted in the merger of a number of product / sector specific different EU Directives, it is difficult to imagine any other way to achieve the same result other than via an EU level simplification exercise. While this could have taken various forms (including complete deregulation at EU level), action had to be taken at EU level to simplify the pre-existing regulatory regime.

About increased awareness, it must be considered that at the time the Directive came into force the issue of exposure to noise emissions from outdoor equipment was starting to appear on the policy agenda of EU Member States. In the years after the Directive was implemented, many Member States and local authorities became more and more proactive about limiting exposure to noise. Incentive strategies (as in the Netherlands or in Italy) have been put in place, or specific limitations to the utilisation of noisy equipment have been implemented in some countries.

This indicates increasing attention towards noise emissions and the protection of citizens exposed to them, which can at least partly be attributed to the awareness of the potential problem of noise emissions raised by the introduction of the OND.

On the need to prevent the proliferation of different national regulation, the stakeholders consulted for the “Supporting study”, when asked about a scenario without EU intervention, recognised the high risk of diverging national regulations being introduced in some Member States.

It is plausible to imagine that without intervention at EU level, Member States may have implemented a variety of different rules and requirements, creating potential obstacles to manufacturers selling their products abroad.

The legal obligation established by Article 12 of the Directive forced manufacturers to invest resources in the research and development of special design, mechanisms and strategies to reduce noise emissions. Over the years, technological developments not necessarily linked to noise emissions (e.g. the electric engines) have surely contributed to the reduction of noise emissions. However, and the majority of the stakeholders participating in the open public consultation agreed, technological development and the market itself would not have been sufficient to reach the result we have today. First of all, as mentioned above, manufacturers have to balance several aspects when designing a product and, considering the low importance given to noise emissions by consumers, it is probable that other aspects would have been prioritised. Secondly, technological developments do not affect all types of equipment in the same way. For example, there are still combustion engine-based products that cannot yet be replaced by electric ones. Finally, technological advancements happened also thanks to the OND which, as recognised by several stakeholders, had a positive effect on research, development and innovation of equipment covered by the Directive.

Finally, despite the highlighted shortcomings of the OND, none of the stakeholders consulted was in favour of repealing it. It is generally agreed and recognised that the results achieved would not remain if the Directive was withdrawn.

It was mentioned that the legislative gap that would be created would expose manufacturers to legal uncertainty and potentially different legal requirements across the Member States. Over the years, Member States have adopted complementary rules to incentivise the production of quieter products and discourage the use of noisy equipment during certain periods or in certain areas. These initiatives prove that there is a renewed interest in the protection of wellbeing of citizens and in the absence of EU legislation it is possible that the Member States would step in.

Even if the free circulation of products was still ensured (e.g. through mutual recognition), different legal requirements would put manufacturers in countries with stricter regulation at a disadvantage compared to their peers in the Member States applying looser rules. Also, phenomena such as forum shopping could arise.

In terms of protection of citizens’ health and wellbeing, and of the environment, there is a perception that the OND, even with its limitations, managed to force manufacturers not to neglect the noise emitted by their products. Without this legal obligation, many stakeholders agreed that noise emission control would be put aside in favour of other features (e.g. performance or energy efficiency) as it is the case in extra-EU markets.

## 6. CONCLUSIONS

With respect to the specific evaluation questions, the key findings and conclusions on the main aspects of the operation of the Outdoor Noise Directive 2000/14/EC can be summarised as follows.

In terms of the **effectiveness** of the Directive to meet its objectives, especially the protection of the health and well-being of citizens and the environment by reducing permissible noise emission levels of outdoor equipment in scope, the evaluation found that such noise emission levels have dropped over the last 20 years, as evidenced by both the available data and the opinions of the consulted stakeholders. Nevertheless, several concerned equipment are still above the sound power level considered dangerous to hearing and general health (estimated at 90 dB), which indicates that there is room for improvement.

Consumer behaviour also impacted the effectiveness of the OND. A proactive attitude and more awareness could have led consumers to prefer quieter equipment pushing the market to dismiss more noisy versions. The legal provisions on their own proved insufficient to motivate consumers to buy less noisy equipment. Non-professional purchasers and users of the equipment under the scope of the Directive still lack knowledge and awareness about noise emissions, and the noise marking alone is not enough to drive consumer choice.

Given the low market demand for quieter equipment, in the absence of the OND, manufacturers would direct R&D investment towards those product characteristics that are more attractive to customers (e.g. performance, safety, energy efficiency). Even if technological developments could have driven improvements in noise emissions in any case (as for example for electric engines), the Directive forced manufacturers to invest resources in the research and development of special designs, mechanisms and strategies to reduce noise emissions of outdoor equipment. This is in particular the case of equipment subject to mandatory noise limits (Article 12), while for equipment subject to noise marking only (Article 13), the Directive was not sufficient to encourage manufacturers to develop less noisy products to the same degree.

In addition, shortcomings in market surveillance, mostly dependent on the lack of sufficient resources allocated to this specific area, also undermined the ability of the Directive to comply with its objectives. Nevertheless, although the OND did not reach its full potential, citizens exposed to noise emission from outdoor equipment are still better protected as compared to how they would have been without the Directive.

With respect to ensuring an internal market for outdoor equipment by preventing obstacles to the free movement of such equipment, the Directive simplified the pre-existing legal framework. This brought greater clarity and improved the activity of all stakeholders. In addition, the OND prevented the emergence of different regulations at national level that may have hindered the intra-EU circulation of the concerned equipment. While there is a general agreement that the OND allowed for better trading across borders inside the EU, trade data to assess the concrete impact is scarce.

As regards **efficiency** in the implementation of the Directive, different types of costs and benefits have been identified in the evaluation. Among the benefits brought by the OND, the health and environmental benefits are the most obvious and significant. While the stakeholders observe the positive impact of ensuring harmonised regulation within the EU and express some concern over the effect of stricter noise limits inside than outside the EU, they do not perceive significant impact on their business in terms of internal or external trade.

Covering many different types of equipment and versions of the same type, the classification and grouping of products currently applied might cause difficulties for manufacturers in understanding whether a product is actually covered by the Directive.

The conformity assessment procedures foreseen by the OND address adequately the different needs of the manufacturers, although the lack of a possibility of an internal control procedure for certification (“self-assessment”) for equipment under Article 12 is seen as a constraint by manufacturers, and as a guarantee by consumers and market surveillance authorities.

Conformity assessment costs are identified as one of the most significant costs to the manufacturers. In particular, such costs are increased for companies that have to test separately for both OND and other Directives, more commonly the Machinery Directive. Nevertheless, the need to have adequate conformity assessment procedures must be related to the still insufficient market surveillance, in the OND sector as in others as a horizontal issue, as identified in the “Supporting Study” and other sources.

The current test codes and measurement methods for the majority of the equipment covered by the OND are not in line with technological development and would need to be revised. Moreover, the lack of a clear and uniform procedure to determine the uncertainty of measurements in the OND may cause inconsistency between guaranteed sound power levels depending on the subject performing the measurement.

The “NOISE Application” database, while not particularly costly in terms of monetary spending, presents significant operational limitations (incorrect or incomplete data registered, different types of equipment not clearly defined, missing technical parameters for equipment on the market, etc.). Consequently, the majority of the stakeholders considered the tool as burdensome and not entirely reliable in inputs and outputs.

Research and development is another expensive element of the Directive, with the estimated annual costs of approximately EUR 40 million to EUR 120 million. However, it should be noted that while undoubtedly a consequence of the Directive, increased R&D cost should not be seen as a purely negative element, for the objective benefits in terms of more performant equipment.

Concerning the **relevance** of the Directive, the evaluation confirmed that its original objectives are as valid today as when it was first proposed. In particular, the objectives of ensuring the free movement of outdoor equipment, reducing permissible noise levels to protect the health and well-being of citizens as well as to protect the environment, and to

provide information to the public on such noise emissions, continue to be fully relevant. When the OND came into force, it filled an existing gap concerning the protection of citizens exposed to noise emissions produced by outdoor equipment operated by other users, private or professional.

According to the information collected through different sources during the years of operation of the OND – including the studies carried out, the stakeholder consultations and the “NOISE Application” database – it is estimated that for equipment under Article 12, the OND produced a reduction in noise emission expressed in sound power level between 2 and 3 dB.

Twenty years after the introduction of the OND, the growing urbanisation has led to the use of more outdoor equipment and therefore also increased noise production. Especially consumer equipment has undergone a massive increase in numbers thanks to low-cost products available on the internet and in supermarkets.

This increase in the number of equipment on the market and in use has had a counterbalancing impact on the positive effect of the Directive in reducing noise emission levels, renewing the need for pressure on the manufacturers to produce less noisy equipment. Such pressure could come from two sources: the market or the legislation. In the absence of market demand for quieter equipment, it is still up to the legislator to set limits to noise emissions for the outdoor equipment safeguarding wellbeing and health of citizens.

With regard to the industry, while the OND addressed the need for harmonisation and legal certainty across the EU, from an international trade perspective, the Directive and the stricter limits imposed did not bring significant advantages nor helped to comply with foreign legislation. However, almost none of the stakeholders would be in favour of repealing the Directive, given the potential risk of the development of multiple national standards.

An aspect that some stakeholders considered not fully in line with the current needs of the industry is the third-party conformity assessment. When the OND came into force companies were missing the specific knowledge required to measure noise emissions, and the task of performing the conformity assessment was entrusted to notified bodies. Today, many manufacturers have the skills to perform the measurements themselves and could rely on a self-assessment instead of the third-party conformity assessment.

In terms of **coherence** and complementarity of the Directive with other EU legislation, some problems were identified for manufacturers, stemming from differing requirements with other legislative acts applying to the same machinery. In particular, differences in requirements with the Machinery Directive mean that some equipment must be tested twice, while the requirements of the Non-Road Mobile Machinery Regulation on emissions make it difficult for some equipment to comply with both. The lack of uncertainty measurement in the Directive leaves a variability of guaranteed sound power levels, depending on the subject performing the measurement.

Nonetheless, the evaluation recognised that the OND is a coherent part of a wider, comprehensive network of environmental noise legislation in the EU.

In certain Member States, the OND is supported by voluntary national incentive schemes addressed to increase awareness of noise levels and the value of producing and buying quieter equipment.

In terms of external coherence and complementarity of the Directive with non-EU national or international legislation, no major difficulties were identified in regard to the relationship between the OND and extra-EU legislation.

Finally, concerning the **EU added value** of the Directive and the results achieved in relation to the strategic objectives, despite its limitations, the Directive achieved a number of key results that would not have happened without it. Therefore, an EU approach remains the most appropriate response and is more likely to achieve the objectives set by the Directive than the national approaches.

In fact, the Directive prevented the proliferation of different national regulations, and there is the perception that without it, new national regulations might have emerged. Due to the Directive's requirements, noise levels decreased in the past twenty years despite the limited market demand.

Even though current noise limits and measuring methods may not be in line with state of the art, the Directive still obliges manufacturers to balance the research on higher performance equipment with the OND requirement regarding noise emissions. Without the Directive, given the absence of market pressure by consumers, it is likely that producers of outdoor equipment would neglect this aspect in favour of other features. For all these reasons, none of the stakeholders consulted was in favour of repealing the OND.

Taking into account all the above, the outcome of the evaluation is positive: **the overall conclusion** is that the Outdoor Noise Directive [2000/14/EC](#) is generally considered as effective, efficient, relevant and coherent, and has EU added value. In fact, the OND simplified the existing legislative framework, thus bringing more clarity for all stakeholders. The OND effectively contributed to reduce noise emission by outdoor equipment, and ensured that manufacturers invest resources in the research and development of special designs, mechanisms and strategies to reduce noise emissions of outdoor equipment. Given the limited market demand for quieter equipment and the scarcity of national incentives, the OND was and still is the primary force driving noise reduction for this type of equipment.

Nevertheless, there are a number of critical aspects that affected the operation of the OND. This concerns in particular the lack of adaptation to the technical progress of core elements of the Directive:

- the scope and in particular the lists of outdoor equipment covered and their definitions, as well as the extent of the requirements for each type of equipment (subject to noise limits or to noise marking only);

- the noise limits for specific types of outdoor equipment, on the basis of the available information on their technical and economic feasibility, within the overall objective of continued reduction of noise emission at source;
- the European and international standards used for establishing the test codes and the noise measurement methods for each type of outdoor equipment, also providing for an effective mechanism to update them when necessary;
- the relevant conformity assessment procedures, adapting them to possible changes in the scope and in noise limits, considering also the relevance and impact of different solutions based on “self-assessment” (procedures based on internal control) and “third party” intervention (procedures requiring the participation of a notified body), as well as the relationship with the still current gaps in market surveillance;
- in the obligation of collection of noise data and the related tool to manage such obligation, taking into account the problems raised from the operation and effectiveness of the “NOISE Application” database;
- the alignment to the New Legislative Framework, with the relevant provisions from Decision No 768/2008/EC on economic operators, market surveillance, notified bodies, conformity assessment etc..

Also, insufficient market surveillance is a factor undermining the effectiveness of the Directive in its main objectives, especially in terms of legal and technical compliance of products placed on the EU market, as well as competitiveness of EU economic operators.

## **Annex 1: Procedural information**

### **1. LEAD DG, DeCIDE PLANNING / CWP REFERENCES**

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

Decide planning: PLAN/2016/301.

### **2. ORGANISATION AND TIMING**

The Inter-Service Steering Group (ISSG) for the evaluation consisted of representatives of the Secretariat-General (SG), the Legal Service (LS), and the Directorate-Generals for Environment (DG ENV), Justice and Consumers (DG JUST), and the DG GROW itself. After the kick-off meeting held on 18 May 2017, it met another time in 2017, three times in 2018 and another time in 2019.

### **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 is mainly based on an evaluation study, back-to-back with the impact assessment study, outsourced to a consultant. The “Supporting study for an evaluation and impact assessment of Directive 2000/14/EC on noise emission by outdoor equipment” was carried out by the experts of Valdani e Vicari Associati (VVA) and consortium between May 2017 and July 2018; the final reports have been delivered in October 2018 and published in the Commission’s sectoral website on Outdoor Noise Equipment linked to the “EU publications” website<sup>40</sup>.

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<sup>40</sup> Evaluation report: <https://publications.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/90f4d795-e192-11e8-b690-01aa75ed71a1>.



Other previous studies have been also used as sources of information, in particular the “NOMEVAL” study in 2007. The complete list of studies is included in **Section 3.2**.

More detailed information on the quality and reliability of the evidence collected, the sources and the methodology used is available in the evaluation study itself, in particular in **Section 4** “Method” and in **Annex 3** “Methods and analytical models for data collection”.

## **Annex 2: Synopsis report of the stakeholders' consultations**

### **a) Interviews with EU and national stakeholders and survey of market surveillance authorities and notified bodies**

Within the “Supporting study”, interviews at national level were conducted in 16 Member States, selected to ensure interviews distribution across Europe and different market sizes. About 100 organisations and environmental offices have been reached out in 16 MSs<sup>41</sup>. However, only consumer / environmental associations in 4 MSs<sup>42</sup> showed interest in participating in the study. Also only environmental offices in 3 MSs<sup>43</sup> were available for an interview.

On the other hand, the responsiveness of national organisation has been low. Stakeholders included EU-level industrial sectorial organisations, national consumer and environmental associations and offices, consultants and sector experts, and the European Committee for Standardisation (CEN).

Overall, the study team completed 32 interviews, on the basis of specific interview guides.

The survey of market surveillance authorities and notified bodies listed 62 MSAs in 32 EU Member States and EEA-EFTA-MRA-CU countries, and 59 NBs in 20 EU Member States and EEA-EFTA-MRA-CU countries.

### **b) CATI interviews**

The computer-assisted telephone interviewing (CATI) interview process was carried out between September 2017 and April 2018, addressed in particular to manufacturers (using a questionnaire with 23 questions) and to rental and leasing companies (using a questionnaire with 47 questions).

Inputs were collected from 441 manufacturers and 98 rental and leasing companies, mainly based in the EU. About 370 manufacturing companies were SMEs and more than two-thirds micro or small enterprises.

### **c) Open public consultation**

The “Open public consultation on an evaluation and possible revision of the Outdoor Noise Directive [2000/14/EC](#)” was launched by the Commission through the EUSurvey service on 23 January 2018 and ran for 12 weeks until 18 April 2018. It aimed to collect

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<sup>41</sup> Austria, Bulgaria, Croatia, Czech Republic, Denmark, Germany, Finland, France, Italy, Lithuania, Netherlands, Poland, Portugal, Spain, Sweden and United Kingdom.

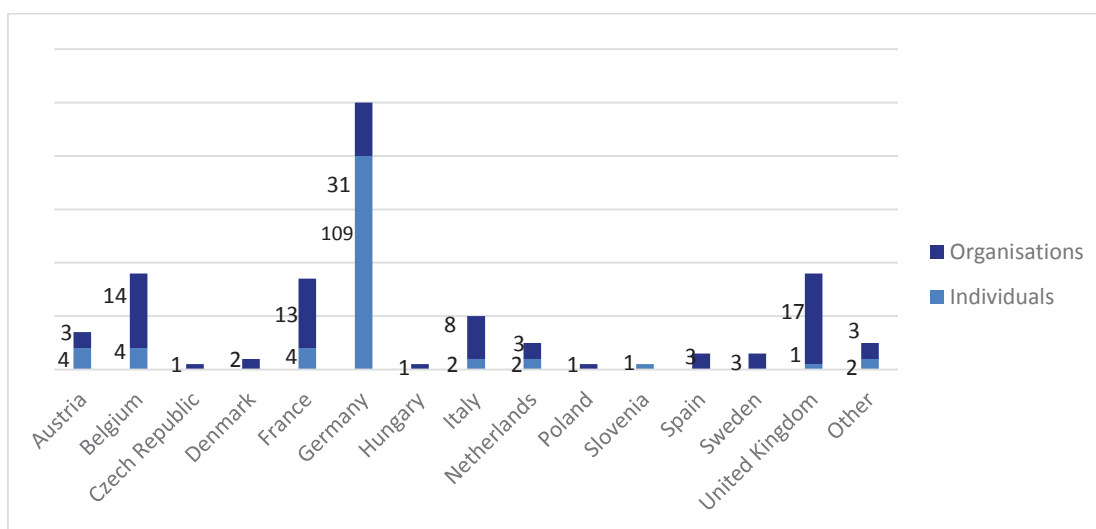
<sup>42</sup> Croatia, Finland, France and Germany.

<sup>43</sup> Bulgaria, France and Germany.

contributions from all interested parties, stakeholders, organisations and citizens in general who are affected by the Directive, its current functioning or any potential future modifications.

232 stakeholders (129 responding as individuals, 103 in their professional capacity or on behalf of an organisation) responded to the OPC (see **Figure A3.1**), with an acceptable level of participation and significance of results, compared to similar initiative recently launched by the Commission.

**Figure A2.1: Country of origin of the participants to the open public consultation (N=232)**



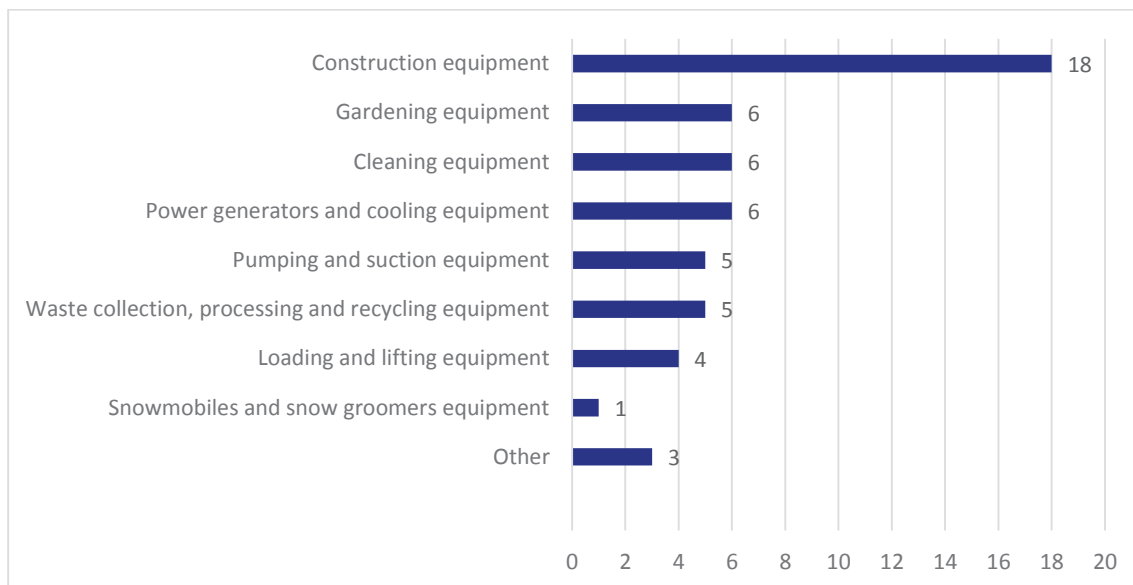
Different types of organisations (n=103) took part in the open public consultations including:

- Private enterprises (n=38)
- Trade, business or professional associations (n=24)
- Regional and local public authorities (n=14)
- International or national public authority (n=9)
- Non-governmental organisations, platforms or networks (n=5)
- Professional consultancies, law firms, self-employed consultants (n=3)
- Research and academia (n=3)
- Other (n=7)<sup>44</sup>

The majority of the private enterprises represented are large enterprises (72%, n=23). About 84% (n=32) of them are manufacturers of outdoor equipment covered by the Directive and in particular of construction equipment (47%, n=18) (see **Figure A3.2**).

<sup>44</sup> Out of the 7 respondents who indicated other: 1 is a public enterprise, 2 are manufacturers of machines, 1 is a notified body, 1 is an organism in charge of standards, 1 is a local authority and 1 is an NGO.

**Figure A2.2: Type of equipment produced or distributed by the private enterprises which took part in the open public consultation (n=38)<sup>45</sup>**



As for respondents included in the trade, business or professional associations, 88% (n=21) of them are business organisations. All of the trade, business or professional associations represent manufacturers of outdoor equipment covered by the Directive or companies using such equipment.

129 participants in the open public consultation responded as individuals<sup>46</sup>. Out of these, only 5% (n=12) reported to be users of outdoor equipment while the majority (45%, n=105) reported to be exposed to noise emissions by outdoor equipment. All the users of outdoor equipment (n=12) are using or buying mostly gardening equipment.

Out of the 232 participants, 39% (n=91) have detailed knowledge of the Directive, its objectives, the limits and the requirements/obligations that it imposes. 25% is aware of the existence of the Directive but not of all its specific contents. About 35% (n=82), mostly either people exposed to noise from outdoor equipment or users of such equipment, indicated that they did not know the Directive. They were not asked questions related to the functioning of the OND but a set of questions investigating their experience with sources of outdoor noise and usage habits.

A more extensive “Summary report of the public consultation on an evaluation and possible revision of the Outdoor Noise Directive” was published in December 2018 on [https://ec.europa.eu/info/sites/info/files/summary\\_report\\_opc\\_ond.pdf](https://ec.europa.eu/info/sites/info/files/summary_report_opc_ond.pdf).

<sup>45</sup> Some of the respondents are active in several sectors.

<sup>46</sup> Individuals here relate to the stakeholder category (as opposed to the respondents who participated on behalf of an organisation).

### **Annex 3: Methods and analytical models for data collection**

The methods and analytical models for data collection within the “Supporting study for an evaluation and impact assessment of Directive 2000/14/3C on noise emission by outdoor equipment”, on which the evaluation is based, were implemented around 4 main tasks:

#### **a) Review of the literature**

The task was carried out in three steps.

1. The study used several search tools (e.g. Google Scholar, EBSCO, ScienceDirect) to identify a long list of relevant articles.
2. Out of these articles, about 60 were selected on the basis of relevance, chronological and reliability criteria.
3. Shortlisted literature was analysed, and the outcomes were fed into the report.

Academic and policy literature on technical and economic aspects of outdoor equipment noise, as well as on the environmental, social and health impacts of noise were sought in international sources (e.g. WHO, green and white papers, EC evaluation studies, position papers, EU project results) and in key national documents in the local language (e.g. National research projects, National Health Council reports). The literature review also identified experiences from other key trading partners (such as the USA, China, South Korea, Japan, Brazil etc.).

#### **b) Stakeholders’ consultations**

One of the key sources of information for the “Supporting study” was the consultation conducted with different types of stakeholders that are directly affected by the Directive at EU and national levels. This included direct interviews, computer-assisted telephone interviewing (CATI) interviews, and an open public consultation. See **Annex 2** for the synopsis report for these activities.

#### **c) Case study**

One case study was carried out in the Netherlands about two relief schemes that have been active since 2001. The *Milieu-investeringsaftrek* (MIA, Environmental Investment Deduction) and the *Willekeurige afschrijving milieu-investeringen* (Vamil, Voluntary Depreciation on Environmental Investment) are fiscal incentives that offer entrepreneurs the opportunity to make investments in environmentally friendly techniques in a fiscally attractive way.

For this case study, 14 documents were reviewed, and two interviews were conducted, one with the Ministry for Infrastructure and the Environment of the Netherlands and the other with the Netherlands Enterprise Agency.

#### **d) Data analysis - Economic impact**

The economic impact of the policy options of the Outdoor Noise Directive 2000/14/EC was carried out making reference primarily to the costs that must be borne by manufacturing companies:

- costs of the noise marking / self-assessment;
- cost of third-party conformity assessment procedures (3 types);
- research and development (R&D) costs.

The main source of information for the estimation of these cost items are the CATI interviews conducted with manufacturing companies.

The model for the estimation of the administrative costs, noise marking and conformity assessment procedures, was based on the following items:

- average costs of procedure;
- average turnaround (days);
- average number of procedures per year (only for conformity assessment);
- average number of equipment types produced by companies;
- cost of setting up the internal quality assurance system;
- cost of conformity assessment on the internal quality assurance system.

The average yearly cost of a specific procedure per equipment type (EUR) was calculated as:

$$\frac{\text{Average costs of procedure} \times \text{Average number of procedures per year}}{\text{Average number of equipment types produced by companies}}$$

The total administrative burden for the conformity assessment was calculated multiplying the average cost of the three procedures (weighted on the basis of the CATI results) per the number of companies manufacturing equipment falling under Article 12 (or number of companies producing equipment for which a new limit is proposed). When different variants of the same type of equipment are subject to different requirements (e.g. power generators have different requirements depending on their kW) a weighting factor was applied to the number of companies producing that specific type of equipment (based on the assumption that some companies will produce all variants while others will focus only on specific ones).

The total cost of administrative burden for the noise marking was calculated in a similar manner.

For R&D costs the model was based on:

- estimated sector turnover;
- number of companies in the sector and affected by changes to the OND;
- % of turnover spent on R&D;
- % of R&D expenditure spent on noise reduction;
- impact on R&D expenditure in case of new or lower noise limits.

R&D expenditure per sector was calculated as a percentage of the sector turnover on the basis of the expenditure reported by manufacturers interviewed through the CATI (on average 5%).

R&D expenditure of companies affected by the OND was calculated as follows:

$$\frac{\text{Total sector expenditure on R\&D} \times \text{Estimated number of companies affected}}{\text{Estimated number of companies}}$$

#### Annex 4: Legislative acts within the EU environmental noise framework

The Outdoor Noise Emission Directive 2000/14/EC (OND) is part of a wider environmental noise legislative framework established in the EU, including the following legislative acts:

1. **Directive 2003/10/EC**<sup>47</sup> on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) lays down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to noise, and in particular the risk to hearing. It is part of the EU legislation on occupation safety and health (OSH) to ensure health and safety of work, referring to Article 153 of the Treaty on the Functioning of the European Union (TFEU).

The Directive defines the physical parameters that serve as risk predictors, such as peak sound pressure, daily noise exposure level and weekly noise exposure level. It sets exposure limit values and exposure action values in respect to the daily and weekly noise exposure level as well as peak sound pressure.

The employer shall assess and, if necessary, measure the levels of exposure to noise to which workers are exposed. Carrying out the risk assessment, the employer must give particular attention to level, type and duration of exposure, exposure limit/action values, health effects spreading from particular sensitivity of the worker, interactions with other risks (ototoxic substances, vibrations), the exposure to noise beyond normal working hours under his responsibility, and noise caused by warning signals at work. The risks arising from exposure to noise shall be eliminated or reduced to a minimum, by working methods or equipment that require less exposure to noise, instructions on the correct use of equipment, technical measures (shield, noise absorbing coverings) or organisational measures in order to reduce duration and intensity of exposure. If risk cannot be banned by other means, the employer has to provide properly fitting personal protective equipment (hearing protectors).

The exposure limit values must not be exceeded. If they are exceeded, the employer has to take adequate measures immediately in order to reduce the exposure.

2. The **Environmental Noise Directive 2002/49/EC**<sup>48</sup> (END) relates to the assessment and management of environmental noise, defined as “unwanted or harmful outdoor sound created by human activities, including noise emitted by means of transport, road traffic, rail traffic, air traffic, and from sites of industrial activity”. It is the main

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<sup>47</sup> Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 42, 15.2.2003, p. 38).

<sup>48</sup> Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise (OJ L 189, 18.7.2002, p. 12).



EU instrument to identify noise pollution levels and to trigger the necessary action both at Member State and at EU level. To pursue its stated aims, the END focuses on three action areas:

- the determination of exposure to environmental noise,
- ensuring that information on environmental noise and its effects is made available to the public, and
- preventing and reducing environmental noise where necessary and preserving environmental noise quality where it is good.

The END applies to noise to which humans are exposed, particularly in built-up areas, in public parks or other quiet areas in an agglomeration, in quiet areas in open country, near schools, hospitals and other noise-sensitive buildings and areas. It does not apply to noise that is caused by the exposed person himself, noise from domestic activities, noise created by neighbours, noise at work places or noise inside means of transport or due to military activities in military areas.

3. The **Machinery Directive 2006/42/EC**<sup>49</sup> (MD) establishes essential health and safety requirements for machinery, to promote the free movement of machinery within the internal market and to guarantee the highest level of protection for users. The MD contains specific requirements on reduction of noise emissions in design and manufacturing of products, and to provide the related information in the technical file and instructions (points 1.5.8. and 1.7.4.2.(u) respectively of Annex I “Essential health and safety requirements”).

As safety components listed in Annex V, “systems and devices to reduce the emission of noise” can be acoustic/insulation enclosures, attenuation guards, mufflers (silencers), active noise reduction devices etc., intended to be fitted to machinery, in addition to the design and construction measures of the machine itself to reduce noise emission at source. Among the most advanced solutions, active noise reduction devices can add a sound specifically designed to cancel or attenuate undesirable sound, by using a power source with electronic and digital signal processing systems, in particular for low frequency noise. The most critical aspects of these technical solutions to reduce noise are related to the interaction with the health and safety features of the machine: sometimes noise reduction can go against a higher level of protection, for example when removing guards as sources of vibrational noise, or adding enclosures that would make the machine less usable or ergonomic, or fitting active devices which would cause electromagnetic disturbance.

The majority of the equipment in the scope of the OND is covered also by the MD with respect to the related health and safety aspects, and several standards used in the OND as noise measurement methods and test codes are harmonised European standards under the MD.

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<sup>49</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006, p. 24).

4. The **Non-Road Mobile Machinery Regulation (EU) 2016/1628**<sup>50</sup> (NRMMR) defines emission limits for NRMM engines for different power ranges and applications. It also lays down the procedures engine manufacturers have to follow in order to obtain type-approval of their engines, as a prerequisite for placing their engines on the EU market. The NRMM Regulation aims to protect health of EU citizens and the environment, and improves air quality in the EU, while ensuring the good functioning of the internal market for NRMM engines.

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<sup>50</sup> Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

## Annex 5: Standards referred to in the OND

Reference	Name	Item of Directive 2000/14/EC	Status (September 2020)
EN 206(1:1990)	Concrete - Performance, production, placing and compliance criteria	Concrete-breakers and picks, hand-held (Annex III, Part B, 10)	Latest version <b>EN 206:2013+A1:2016 Concrete - Specification, performance, production and conformity.</b> Currently under revision: <b>EN 206:2013+A1:2016/FprA2</b> (September 2020).
EN 500-4 rev. 1:1998	Mobile road construction machinery - Safety - Part 4: Specific requirements for compaction machines	Compaction machines - Vibratory plates, vibratory rammers, explosive rammers and walk-behind vibrating rollers (Annex III, Part B, 8 (iii))	Withdrawn, replaced by <b>EN 500-4:2011 Mobile road construction machinery - Safety - Part 4: Specific requirements for compaction machines</b> , harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 20.7.2011.
EN 786:1997 (1996)	Garden equipment - Electrically powered walk-behind and hand-held lawn trimmers and lawn edge trimmers - Mechanical safety	Lawnmower (Annex I, 32) Lawn trimmer/lawn edge trimmer (Annex I, 33)	Withdrawn, replaced by <b>EN 786:1996+A2:2009 Garden equipment - Electrically powered walk-behind and hand-held lawn trimmers and lawn edge trimmers - Mechanical safety</b> , harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 18.12.2009 until 19.3.2019, then also withdrawn; no replacement available. <b>EN 50636-2-91:2014 Household and similar electrical appliances - Safety - Part 2-91: Particular requirements for walk-behind and hand-held lawn trimmers and lawn edge trimmers</b> gives the method of calculating the kinetic energy in clause 22.103.
EN 791:1995	Drill rigs - Safety	Drill rigs (Annex III, Part B, 17)	Withdrawn, replaced by the series <b>EN 16228:2014 Drilling and foundation equipment - Safety</b> , parts 1 to 7, harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 13.2.2015. Currently under revision: <b>EN 16228-1:2014/prA1, EN 16228-2:2014/prA1, EN 16228-3:2014/prA1, EN 16228-4:2014/prA1, EN 16228-5:2014/prA1, EN 16228-6:2014/prA1, EN 16228-7:2014/prA1</b> (September 2020).
EN 840-1:1997	Mobile waste containers - Part 1: Containers with 2 wheels with a capacity from 80 l to 390 l for comb lifting devices - Dimensions and design	Refuse collecting vehicles (Annex III, Part B, 47)	Withdrawn, replaced by <b>EN 840-1:2020 Mobile waste and recycling containers - Part 1: Containers with 2 wheels with a capacity up to 400 l for comb lifting devices - Dimensions and design.</b>
ISO 1180:1983	Shanks for pneumatic tools and fitting dimensions of chuck bushings (ISO 1180:1983/Add1:1985)	Concrete-breakers and picks, hand-held (Annex III, Part B, 10)	Last reviewed and confirmed in 2013; Amendment <b>ISO 1180:1983/Add 1:1985</b> , last reviewed and confirmed in 1995: the 1983 and 1985 versions remain current.
EN ISO 3744:1995	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane (ISO 3744:1994)	Basic noise emission standard (Article 3 d), Annex III, Parts A and B)	Withdrawn, replaced by <b>EN ISO 3744:2010 Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane (ISO 3744:2010)</b> , harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 8.4.2011.
EN ISO 3746:1995	Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:1995/Cor	Basic noise emission standard (Article 3 d), Annex III, Part A)	Withdrawn, replaced by <b>EN ISO 3746:2010 Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)</b> , harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 8.4.2011.

Reference	Name	Item of Directive 2000/14/EC	Status (September 2020)
	1:1995)		
<b>ISO 6395:1988</b>	Acoustics - Measurement of exterior noise emitted by earth-moving machinery - Dynamic test conditions (ISO 6395:1988/Amd 1:1996)	Dozers (Annex III, Part B, 16) Dumpers (Annex III, Part B, 18) Excavators (Annex III, Part B, 20) Excavators-loaders (Annex III, Part B, 21) Graders (Annex III, Part B, 23) Loaders (Annex III, Part B, 37) Piling equipment (Annex III, Part B, 42)	Withdrawn, replaced by <b>ISO 6395:2008</b> Earth-moving machinery - Determination of sound power level - Dynamic test conditions, last reviewed and confirmed in 2015.
<b>ISO 7960:1995</b>	Airborne noise emitted by machine tools - Operating conditions for woodworking machines	Building site band saw machines (Annex III, Part B, 4) Building site circular saw benches (Annex III, Part B, 5)	Last reviewed and confirmed in 2013: the 1995 version remains current. Now under review (September 2020)
<b>ISO 8528-10:1998</b>	Reciprocating internal combustion engine driven alternating current generating sets - Part 10: Measurement of airborne noise by the enveloping surface method	Power generators (Annex III, Part B, 45) Welding generators (Annex III, Part B, 57)	Last reviewed and confirmed in 2014: the 1998 version remains current. Now under review: <b>ISO/CD 8528-10</b> Reciprocating internal combustion engine driven alternating current generating sets - Part 10: Measurement of airborne noise by the enveloping surface method.
<b>EN ISO 9001(:1994)</b>	Quality management systems - Requirements	Full quality assurance (Annex VIII, 3.3.)	Latest version <b>EN ISO 9001:2015</b> Quality management systems - Requirements (ISO 9001:2015), harmonised and cited in the OJEU under Regulation (EC) No 765/2008, Decision No 768/2008/EC and Regulation (EC) No 1221/2009 since 11.12.2015.
<b>ISO 9207:1995</b>	Manually portable chain-saws with internal combustion engine - Determination of sound power levels - Engineering method (Grade 2).	Chain saws, portable (Annex III, Part B, 6)	Withdrawn, replaced by <b>EN ISO 22868:2011</b> Forestry and gardening machinery - Noise test code for portable hand-held machines with internal combustion engine - Engineering method (Grade 2 accuracy) (ISO 22868:2011), harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 20.7.2011. To be replaced by <b>FprEN ISO 22868</b> Forestry and gardening machinery - Noise test code for portable hand-held machines with internal combustion engine - Engineering method (Grade 2 accuracy) (ISO/FDIS 22868:2019), currently under development.
<b>ISO 10884:1995</b>	Manually portable brush-cutters and grass-trimmers with internal combustion engine - Determination of sound power levels - Engineering method (Grade 2)	Brush cutters (Annex III, Part B, 2)	Withdrawn, replaced by <b>EN ISO 22868:2011</b> Forestry and gardening machinery - Noise test code for portable hand-held machines with internal combustion engine - Engineering method (Grade 2 accuracy) (ISO 22868:2011), harmonised and cited in the OJEU under the Machinery Directive 2006/42/EC since 20.7.2011. To be replaced by <b>FprEN ISO 22868</b> Forestry and gardening machinery - Noise test code for portable hand-held machines with internal combustion engine - Engineering method (Grade 2 accuracy) (ISO/FDIS 22868:2019), currently under development.
<b>ISO 11094:1991</b>	Acoustics - Test code for the measurement of airborne noise emitted by power lawn mowers, lawn tractors, lawn and garden tractors, professional mowers, and lawn and garden tractors with mowing attachments	Hedge trimmers (Annex III, Part B, 25) Lawnmowers (Annex III, Part B, 32) Leaf blowers (Annex III, Part B, 34) Leaf collectors (Annex III, Part B, 35) Scarifiers (Annex III, Part B, 49) Shredders/Chippers (Annex III, Part B, 50)	Withdrawn, replaced by <b>ISO 5395-1:2013</b> Garden equipment - Safety requirements for combustion-engine-powered lawnmowers - Part 1: Terminology and common tests, amended by ISO 5395-1:2013/Amd 1:2017. Amended by <b>ISO 5395-1:2013/Amd 1:2017</b> Annex G (Vibration test code -- Hand-arm vibration and whole-body vibration).

## Annex 6: “NOISE Application” database – Statistics

<sup>51</sup>Notes:

- Discrepancies in overall figures of copies of EC declarations of conformity (DoCs), registered users, manufacturers and authorised representatives are due to registration of several reference persons and e-mail addresses for each entity, or to missing data when introducing information.
- Manufacturers can be EU or non-EU based, when authorised representatives and notified bodies must be EU-based.

Number of copies of DoCs / notifications in total: 31014

Number of copies of DoCs / notifications related to Article 12 equipment: 12167

Number of copies of DoCs / notifications related to Article 13 equipment: 18805

Number of copies of DoCs / notifications per Member State:

- Austria 495
- Belgium 1152
- Bulgaria 1
- Czech Republic 22
- Denmark 60
- Finland 152
- France 275
- Germany 2999
- Ireland 10
- Italy 925
- Luxembourg 204
- Netherlands 22
- Poland 11
- Spain 170
- Sweden 216
- United Kingdom 3610

Number of registered users:

- Manufacturer 346
- Authorised representative 70
- Notified body 37
- Member State 54

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<sup>51</sup> updated in October 2019)

Number of manufacturers per country:

• Austria	9
• Belgium	12
• Brazil	1
• Bulgaria	1
• Canada	2
• China	5
• Czech Republic	1
• Denmark	4
• Finland	3
• France	12
• Germany	57
• India	2
• Ireland	1
• Italy	22
• Japan	3
• Korea	2
• Liechtenstein	2
• Netherlands	3
• New Zealand	2
• Slovakia	3
• Slovenia	1
• South Africa	2
• Spain	6
• Sweden	6
• Switzerland	2
• Turkey	1
• United Kingdom	69
• United States	22

Number of authorised representatives per country:

• Austria	1
• Belgium	7
• Bulgaria	1
• Estonia	1
• Finland	1
• France	1
• Germany	9
• Greece	1
• Hungary	2
• Italy	5
• Netherlands	4
• Spain	2
• United Kingdom	2