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EVALUATION

of

Directive 2011/65/EU

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on the review of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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Glossary

Term or acronym	*Meaning or definition*
AdCo	Administrative cooperation groups – informal groups cooperating on market surveillance
BBP	Benzyl Butyl phthalate
Cd	Cadmium
CE	European conformity mark signifying compliance with the European requirements
CEAP	Circular economy action plan – Communication COM/2020/98
Cr-(VI)	Hexavalent chromium
DBP	Dibutyl phthalate
Deca-BDE	Decabromodiphenyl ether
DEHP	Bis(2-ethylhexyl) phthalate
DIBP	Diisobutyl phthalate
EEA	European Economic Area
EEE	Electrical and electronic equipment
FTE	Full-time equivalent
Hg	Mercury
LED	Light-emitting diode
Member States	Member States as addressed under the RoHS Directive ('Text with EEA relevance'): 27 Member States of the European Union plus three States of the European Economic Area (Norway, Iceland, Liechtenstein)
NGO	Non-governmental organisation
NLF	New Legislative Framework
OPC	Online public consultation
Pb	Lead
PBB	Polybrominated biphenyls
PBDE	Polybrominated diphenyl ethers
POPs	Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants (OJ L 158, 30.4.2004, p. 7)

R&D	Research & development
RAC	Committee for Risk Assessment, set up under Article 76(1)(c) of Regulation (EC) No 1907/2006
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)
RFID	Radio frequency identification (tags)
RoHS	Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)
SEAC	Committee for Socio-economic Analysis, set up under Article 76(1)(d) of Regulation (EC) No 1907/2006
SME	Small and medium-sized enterprises
Waste EEE	Waste electrical and electronic equipment (or WEEE)
WEEE Directive	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38) /
XRF	X-ray fluorescence

1 INTRODUCTION

1.1 Purpose of the evaluation

Under Article 24(2) of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)[1] (referred to below as 'the RoHS Directive' or 'the Directive'), the Commission must review the Directive no later than 22 July 2021[2] and present a report to the European Parliament and the Council. This document presents an evaluation of the Directive in line with the Commission's policy on better regulation. The results of this evaluation may feed into any subsequent proposal to revise the Directive[3], and any non-legislative follow-up action.

The context is set by the European Green Deal[4] and the 2020 circular economy action plan[5] (CEAP). The Green Deal identifies electronics as a 'resource-intensive' sector, together with textiles, construction materials and plastics, while, in the CEAP, electronics are part of one of the seven key product value chains selected for action to increase circularity. The electrical and electronic equipment (EEE) sector is evolving fast, and its products are becoming more diverse and complex. EEE production and sales are increasing and at the same time the products' use phases are becoming shorter. This is generating an increasing volume of waste electrical and electronic equipment (WEEE), and creating an environmental challenge: how to disassemble and recycle complex products? The presence of certain hazardous substances in EEE prevents today's products from being recycled tomorrow and hampers circular economy ambitions. Furthermore, it poses risks to the environment and human health, especially when WEEE does not enter the designated disposal route, which is still too often the case. In addition, the current CEAP includes an action on '[reviewing] EU rules on restrictions of hazardous substances in electrical and electronic equipment and [providing] guidance to improve coherence [i.e. consistency] with relevant legislation, including REACH and Ecodesign'. Other relevant initiatives that set policy priorities have been taken into account, such as the chemicals strategy for sustainability[6] or the sustainable product policy[7]. Furthermore, in December 2022, an evaluation of the WEEE Directive[8] was launched (see details in chapter 2.2).

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1 Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

2 Whilst preparations for the general review started before 22 July 2021, the timetable was amended, to align it with other actions relating to sustainable products and chemicals listed in the European Green Deal.

3 Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the review of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment, COM(2023)760.

4 COM(2019) 640 final.

5 COM(2020) 98 final.

6 COM(2020) 667 final.

7 See also COM(2022) 142 final: proposal for a regulation on ecodesign for sustainable products.

8 Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), OJ L 37, 13.2.2003, p. 24, repealed by Directive 2012/19/EU of the European

1.2 Scope of the evaluation

This evaluation covers Directive 2011/65/EU including amendments[9] and its implementation in all EU Member States[10], from the transposition deadline of 2 January 2013[11] until December 2022. Accordingly, this report analyses both issues relating to the legislation itself, and to its transposition and application in the Member States.

1.3 Evaluation criteria covered

In line with the Commission's Better Regulation Guidelines[12], this report assesses the Directive according to the following **five evaluation criteria.**

- ✓ **Effectiveness.** How well has EU legislation achieved its objectives of (a) reducing hazardous substances in EEE in the EU and thus protecting human health and the environment at different stages of the value chain (e.g. production), and (b) contributing to the harmonisation and functioning of the internal market?
- ✓ **Efficiency.** Have the obligations arising from the RoHS Directive been implemented in an economically efficient way and is there potential for further synergies to improve outcomes while minimising costs and administrative burden, including the impact on small and medium enterprises (SMEs)?
- ✓ **Relevance.** Are the issues addressed by the RoHS Directive still relevant to current needs (e.g. new hazardous substances) and does the Directive help with issues addressed by wider EU policies on chemicals, circular economy, raw materials etc.? Is the Directive in line with the policy priorities and related initiatives adopted subsequently, as set out in the European Green Deal, the CEAP or, for example, in the chemicals strategy for sustainability[13]?
- ✓ **Coherence.** How coherent (consistent) and connected is the RoHS Directive with EU-wide policy objectives on circular economy? What inconsistencies and overlaps might there be between the Directive and related legislation on hazardous substance restrictions, electronics and waste, such as Regulation (EC) No 1907/2006 ('REACH Regulation')[14], Regulation (EC) No 850/2004 ('POPs Regulation')[15] and Directive 2009/125/EC (Ecodesign)[16] measures?

Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38).

9 The latest consolidated version of Directive 2011/65/EU encompassing 80 amendments is available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20230301

10 NB: The United Kingdom was still a Member State of the European Union at the time of the stakeholder consultations related to this evaluation of the RoHS Directive.

11 In line with Article 25 of Directive 2011/65/EU.

12 SWD(2021) 305 final

13 COM(2020) 667 final.

14 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC (OJ L 396, 30.12.2006, p. 1).

15 Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants (POPs) (OJ L 158, 30.4.2004, p. 7).

16 Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (Text with EEA relevance) (OJ L 285, 31.10.2009, p. 10).

✓ **EU added value.** What is the added value of the Directive compared to what Member States could have reached acting alone at national, regional and international level?

1.4 Evaluation process

The Commission's work on this evaluation was supported by an external contractor. The external study (referred to below as 'the evaluation study') was finalised in March 2021[17]. Most of the data presented here were taken from this evaluation study.

In March 2021, another study was launched to propose options to improve the deficiencies identified in the evaluation study and to assess their possible impacts. As it became apparent during the work that no full impact assessment is necessary, the work shifted to filling data gaps for the evaluation. This second support study ('second support study')[18] was published in May 2023. In order to have more complete results, this staff working document has been supplemented and therefore published later than originally planned.

The main steps undertaken, and sources of information used for this evaluation are presented in the following sub-sections. More information on the methodology and process followed for this evaluation (including on the consultation of stakeholders) can be found in Annex V.

1.4.1 Desk research

Relevant data and literature were identified, screened and reviewed, including: legal acts and documents relating to implementation of the Directive; exemption evaluation reports and reports on hazardous substance restrictions[19]; EEE statistics from Eurostat[20]; and relevant impact assessment studies.

1.4.2 Consultations

A number of stakeholder consultation activities took place.

- The Commission published an evaluation roadmap for the RoHS Directive in 2018, which was open for public feedback from 14 September 2018 to 12 October 2018 and received 20 responses[21].

- An online public consultation (OPC) organised by the Commission was open for 12 weeks, from 13 September 2019 until 6 December 2019[22]. In total, 163 responses were collected. 125 responses (77%) were submitted directly via the 'Have Your Say' portal. The other 38 responses (23%) were submitted via a

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17 European Commission, Directorate-General for Environment, Support for the evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment: final report, Publications Office, 2021, https://data.europa.eu/doi/10.2779/89335.

18 Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) - https://op.europa.eu/en/publication-detail/-/publication/b9188764-f465-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-286516984

19 https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en#ecl-inpage-623

20 https://ec.europa.eu/eurostat/web/waste/overview

21 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1891-Hazardous-substances-in-electrical-electronic-equipment-evaluation-of-restrictions_en

22 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1891-Restriction-of-hazardous-substances-evaluation

representative of the Enterprise Europe Network from the United Kingdom (UK) who uploaded a file with 38 (23%) company responses to the general part of the survey, as part of an answer to the OPC. Most replies came from respondents in the UK (51 responses) and Belgium (32 responses), followed by Germany (25) and Japan (16). Almost half of the replies, 77, were from respondents outside the EU (Japan, UK, Switzerland, others)[23].

- In parallel to the OPC, an in-depth survey (questionnaire) was shared with Member State authorities involved in implementing the RoHS Directive. A total of 20 responses were received, of which one was not counted in. Of the respondents, 13 completed the questionnaire fully, while 6 responded partially. Responses were provided by authorities from 15 Member States and Norway.

- Between October 2019 and March 2020, three focus group meetings were organised covering the following topics: (i) for Member States authorities regarding assessment of implementation and enforcement of the Directive, (ii) for NGOs regarding effectiveness and efficiency as well as environmental and health aspects, (iii) for business associations regarding effectiveness and efficiency as well as costs and benefits aspects and (iv) external and internal coherence.

- 15 in-depth interviews with targeted stakeholders (e.g. manufacturer, distributor, NGOs) were held, partly as follow-up to stakeholder input provided via the OPC.

- A virtual workshop was held in March 2020 to present the preliminary findings of the study and provide stakeholders with another opportunity to give input. Around 125 individuals joined the webinar. It brought together representatives from 12 Member States and 53 representatives from NGOs and industry. The organisations that had been interviewed and some people from the focus groups took part in the workshop. Moreover, prior to the workshop, 25 organisations sent contributions.

1.4.3 Quantitative analysis

To assess the effectiveness of the RoHS Directive quantitatively, an evaluation 'baseline scenario' (in which the Directive was assumed not to exist) was established in the evaluation study. The analysis made it possible to estimate the amount of harmful substances which were avoided to be placed on the market.

1.5 Methodological limitations and robustness of findings

1.5.1 Stakeholder consultation

- The contribution from civil society and non-governmental organisations (NGOs) was limited, including their participation in the dedicated focus group. This is due mainly to the lack of staff working on the RoHS Directive in those categories of stakeholders.

[23] Through, at the time the OPC was open, the United Kingdom was still an EU Member State.

- In the OPC, the vast majority of respondents were 'business organisations', which is understandable as the Directive concerns internal market harmonisation.

- To mitigate the limited participation by NGOs, supplementary methods were used. For instance, on 12 December 2019, a focus group with NGOs discussed the Directive's effectiveness and efficiency with regards to environmental and health aspects.

1.5.2 Data limitations

Despite considerable efforts made during the evaluation process, data collection was inadequate in certain crucial respects, outlined below.

- Data is lacking on the concentration of hazardous substances in EEE waste per category of product; sufficient data was not available on the weight of the 'homogeneous materials' in the EEE for which the maximum concentration values are regulated. Therefore, the model developed to determine the quantitative impact of the RoHS Directive on the quantities of hazardous substances in EEE is limited to mercury, lead and cadmium[24].
- Availability of data is limited for the period before and around implementation of the RoHS Directive, and for more recent years. The model developed to quantify the impacts of the RoHS Directive on the quantities of hazardous substances focused on the baseline and the period when the first RoHS Directive (2002/95/EC) was in place.
- It was not possible to collect precise information from the literature review or through interviews. Some of the stakeholders interviewed and focus group participants indicated that this could be due to the lack of a reliable monitoring framework before the first RoHS Directive (2002/95/EC) and the possibility that sufficient amounts of RoHS-compliant EEE had not yet reached the end of their life cycle. Therefore, estimations and assumptions had to be made. For example, the concentration of hazardous substances in EEE components without an exemption were assumed to be 0% by weight, even though the maximum allowed threshold value would be higher under Annex II to the RoHS Directive.
- It is almost impossible to relate a reduction in hazardous substances in EEE to one specific piece of legislation or initiative in a reliable manner. Over the years, other legislative developments and instruments have also had an impact on the use of RoHS-restricted substances. This includes the REACH Regulation at EU level, but also national initiatives.
- As regards the data on costs and benefits:
    - companies were not able to provide precise data on the percentage of turnover spent on RoHS compliance, either in terms of their initial investment cost or operating expenditure;
    - some companies found it easier to provide full-time equivalent (FTE) estimates, the highest estimates having been provided by businesses representing EEE categories 3 ('IT and telecommunications equipment)', 8 ('medical devices')

[24] Deca-BDE was considered, but insufficient data prevented further analysis and conclusions.

and 9 ('monitoring and control instruments including industrial monitoring and control instruments)[25];

- there was sufficient data for an estimate of costs, but not for an overall assessment of the costs;

- due to the lack of precise data on the reduction in the amount of hazardous substances used in EEE, it was largely impossible to quantify the benefits in terms of reduction in hazardous substances on the market (see above).

The above data limitations have restricted the analysis substantially. Triangulation of sources was critical in making the findings more robust. Where primary data was not available, the evaluation relied on literature and experts' opinions. The report needs to be read with these caveats in mind; it cannot provide a precise assessment, but the findings reflect the order of magnitude of the impacts.

2 WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

2.1 Objective of the intervention

The key objectives of the RoHS Directive are: to reduce the amount of hazardous substances in EEE to protect human health and the environment; and to facilitate the environmentally sound recovery and disposal of waste EEE. The Directive also aims to ensure the functioning of the internal market[26] through harmonisation of Member State legislation[27]. Moreover, besides the key provisions on substance restrictions, the RoHS Directive also includes a number of provisions aimed at enabling the reuse and repair of EEE containing restricted substances, to help promote resource efficiency and circular economy objectives.

2.2 Description of the intervention

EEE is a highly diverse product group characterised by fast innovation cycles, which lead to continuous changes in equipment features, performance and materials used. EEE contains various substances that may present hazardous characteristics and thus pose a risk to the environment and to human health during the production and use of EEE, and the collection, treatment and disposal of waste EEE. Several Member States have addressed these problems by introducing national requirements.

In response to the challenges outlined above, in 2000, the European Commission proposed EU legislation to address human health and environmental concerns and to harmonise EEE-related legislation across Member States[28]. As a result, the European Parliament and the Council adopted Directive 2002/95/EC on the restriction of the use of

[25] Annex I to the RoHS Directive lays down the 11 categories of EEE covered by this Directive.

[26] Recital 2 of the RoHS Directive reads: 'The disparities between the laws or administrative measures adopted by the Member States regarding the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) could create barriers to trade and distort competition in the Union and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to lay down rules in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE'.

[27] The RoHS Directive is also relevant for the European Economic Area (EEA).

[28] COM(2000) 347, 2000/0159 (COD) (OJ C 365E, 19.12.2000, p. 195).

certain hazardous substances in EEE (the 'RoHS 1 Directive')[29] and Directive 2002/96/EC on waste electrical and electronic equipment (the 'WEEE Directive'). The latter sets rules for the collection, treatment, recycling and disposal of WEEE, to contribute to more sustainable production and consumption. However, even if WEEE were collected separately and sent for recycling, the hazardous substances it contained would likely pose a risk to health and the environment. Restricting the use of these hazardous substances is likely to increase the possibilities for WEEE recycling, to make recycling more profitable and to decrease the negative health impact on workers in recycling plants.

2.3 Point(s) of comparison

The RoHS 1 Directive was revised in 2011, leading to the adoption of Directive 2011/65/EU. The aims of the revision/recast process were: (i) to improve the Directive in terms of implementation, enforcement and coherence; (ii) to review the measures provided for in the Directive, in particular with a view to including two additional categories[30] of equipment in the scope (categories 8 and 9: medical devices and monitoring and control instruments respectively); and (iii) to amend the list of restricted substances. The objectives of the revised Directive remained the same: to protect human health and the environment, to ensure environmentally sound recovery and disposal of waste EEE, and to ensure the functioning of internal market.

The key changes from Directive 2002/95/EC to Directive 2011/65/EU are summarised below.

- The Directive's scope was gradually extended to cover all EEE, cables and spare parts[31]. The initial Directive specifically called for the scope to be reviewed in respect of EEE. The scope was then amended to strengthen the objectives of the Directive, in particular to promote a circular economy in the EU.

- Provisions were added on regular reviewing of the list of restricted hazardous substances and amending them by delegated acts, to ensure consistency and coherence between different pieces of EU legislation.

- The exemption mechanism was improved, with clearer and more transparent rules on granting, renewing or deleting exemptions and on exemption applications and required documentation.

- Provisions were added to improve consistency with other EU legislation and especially with the New Legislative Framework[32] (e.g. CE marking and declaration of conformity) and REACH (for example, exemptions under Article 5(1)(a) and

[29] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 37, 13.2.2003, p. 19).

[30] There are 11 categories of electrical and electronic equipment listed in Annex I to the RoHS Directive.

[31] As defined under Article 3(1) and (2) and not falling under the exclusions laid down in Article 4 of Directive 2011/65/EU.

[32] The New Legislative Framework set harmonised requirements for placing products on the EU market and was adopted in 2008. Some provisions in the RoHS Directive are due to the NLF. For more information: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en.

amendments to the list of restricted substances under Article 6(1) must be consistent with the respective REACH provisions).

- At a later stage, the number of restricted substances was increased from six[33] to ten[34].

The RoHS Directive evolved over time as both restricted substance coverage and product scope were enlarged, based on assessments[35] concluded in accordance with the Directive. The current Directive 2011/65/EU and its key operative provisions are described below.

2.3.1 Scope

Since July 2019, the Directive has had an 'open scope', meaning that, unless explicitly excluded, any product that meets the definition of EEE as laid down in Article 3(1) of RoHS Directive falls within its scope.

Article 3(1) defines EEE as equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current. According to Article 3(2), the term 'dependent' means 'with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function'. As such, even equipment with a minor function dependent on electric currents or electromagnetic fields is considered an EEE.

Article 2(1) determines that the Directive applies to EEE falling within the 11 categories set out in Annex I to the Directive.

Article 2(4) provides various exclusions to the scope, for example:

- large-scale stationary industrial tools;
- large-scale fixed installations;
- means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- non-road mobile machinery made available exclusively for professional use; and
- active implantable medical devices.

2.3.2 Substance restrictions

The central mechanism of the RoHS Directive is the substance restriction laid down in Article 4(1). Under this Article, Member States must ensure that EEE placed on the market, including cables and spare parts, does not contain hazardous substances (or their compounds) in concentrations above a specified limit value (by weight) tolerated in

[33] Lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers were restricted under Directive 2002/95/EC.

[34] The restriction of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) was introduced by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances, OJ L 137, 4.6.2015, p. 10.

[35] Assessments, reports and studies concerning the review of Directive's scope and list of restricted substance are available at https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en#ecl-inpage-623.

homogeneous materials. The 10 substances currently restricted[36] are listed in Annex II to the RoHS Directive, along with their maximum tolerated concentration values. The restrictions cover whole substance groups like elementary mercury and all mercury compounds. This is in accordance with the whole life cycle approach and is meant to contribute to the simplicity of the restrictions.

Article 6(1) lays down a procedure for a periodic review of Annex II and specifies that the first review was due by July 2014. Subsequently, Commission Delegated Directive (EU) 2015/863[37] added four phthalates to Annex II. The second paragraph of Article 6(1) contains criteria for the review and amendment of the list of restricted substances in Annex II. The first criterion is that amendments should be 'coherent' (consistent) with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006 ('REACH Regulation'). The Commission must also take special account of whether a substance, including items which consist of this substance and have a very small size or very small internal or surface structure, or a group of similar substances, could: have negative impact during EEE waste management operations, give rise to uncontrolled or diffuse release into the environment; lead to unacceptable exposure of workers; or be replaced by substitutes or alternative technologies (see Article 6(1), third paragraph). At the end of the process, the Commission should adopt delegated acts to amend Annex II.

2.3.3 Derogations and time-limited exemptions

Firstly, Articles 4(4) and 4(5) lay down several **derogations** from the substance restrictions in Article 4(1) which reflect the 'repair as produced' principle. Article 4(4) determines that the substance restrictions in Annex II do not apply to cables or spare parts for repairing, reusing or updating functionalities or for upgrading the capacity of a number of specified EEE categories. The dates which are linked to these derogations coincide with the dates of the scope extension to the new EEE categories[38].

In addition, Article 4(5) determines that the substance restrictions do not apply to reused spare parts for specified types of EEE, provided that:

- reuse takes place in auditable closed-loop business-to-business return systems;
- the consumer is notified of reuse of spare parts; and
- reused spare parts are recovered from EEE placed on the market before a specified date.

These derogations aim to facilitate the repair and reuse of EEE and therefore contribute to the EU's resource efficiency and circular economy objectives.

Furthermore, Article 4(6) of the Directive allows **time-limited and application-specific exemptions** for applications listed in Annexes III and IV, to which the substance restrictions do not apply. The industry can submit applications for time-limited

[36] Lead (0.1%), mercury (0.1%), cadmium (0.01%), hexavalent chromium (0.1%), polybrominated biphenyls (PBBs) (0.1%), polybrominated diphenyl ethers (PBDEs) (0.1%), bis(2-ethylhexyl) phthalate (DEHP) (0.1%), butyl benzyl phthalate (BBP) (0.1%), dibutyl phthalate (DBP) (0.1%) and diisobutyl phthalate (DIBP) (0.1%).

[37] OJ L 137, 4.6.2015, p. 10-12.

[38] For example, category 9 of Annex I, industrial monitoring and control instruments, came under the scope of RoHS in July 2017. Article 4(4)(e) exempts cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of industrial monitoring and control instruments placed on the market before 22 July 2017.

exemptions. Annex III exemptions can apply to all EEE categories, while Annex IV lists applications specific to medical devices and monitoring and control instruments.

Article 5(1) defines the process and criteria whereby the European Commission includes or deletes EEE materials and components for specific applications in Annexes III and IV. This is the case where *any* of the following conditions is fulfilled:

- elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- substitutes are not reliable; and
- the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits.

The availability of substitutes and the socioeconomic impact of substitution must also be taken into account. Decisions on the duration of any exemptions take into account any potential adverse impacts on innovation. Life cycle thinking on the overall impacts of the exemption should apply, where relevant. Amendments can only be made to Annexes III and IV through individual delegated acts.

When assessing whether to add, amend or delete exemptions, the Commission requests external experts to evaluate exemption requests from industry and to assess if any of the criteria in Article 5(1)(a) is met. The exemption assessment consists of different phases, including a clarification, consultation, evaluation and reporting phase. In the process, several questionnaires are usually shared and at least one public online consultation is conducted, involving applicant, stakeholders and sector experts. Technical discussions are held at this stage to ensure transparency for all stakeholders. At the end of the process, the Commission's consultants provide it with a report including recommendations that the Commission considers when taking its decision.

The Annexes to the RoHS Directive currently contain 18 pages of time-limited detailed exemptions (as of December 2022)[39], covering many different technical applications e.g. lighting equipment, medical devices, basic electrical components and lead-containing alloys used in EEE. Some exemptions have expired but remain for sake of clarity in the Annexes with their expiry date. Over time, exemptions that previously covered a wide scope of applications have been made more specific and, where possible, their scope has been limited to certain applications for which alternatives are not available or practical. This gives effect to a requirement reflected in Recital 19 to the Directive according to which, 'Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.' As a result, the technical complexity and level of detail of the exemptions have increased over time.

[39] Some older exemption entries do not show an expiry date but have one based on the articles of the Directive.

2.3.4 Declarations of conformity and CE marking

The main obligation in Article 4(1) of the RoHS Directive is incumbent upon the manufacturer of an EEE, defined[40] as 'any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured and markets it under his name or trademark.' Manufacturers are to draw up the required technical documentation and carry out the internal production control procedure[41].

When these procedures demonstrate that EEE complies with the requirements, manufacturers draw up an EU declaration of conformity[42] and affix the CE marking[43] to the finished product. Additional obligations concerning record keeping and identification of EEE are also applicable. In the absence of evidence to the contrary, EEE bearing the CE marking are presumed to comply with the Directive.

[40] Article 3(6) of the RoHS Directive.

[41] Article 7 of the RoHS Directive.

[42] In accordance with Article 13 of the RoHS Directive.

[43] In accordance with Articles 14 and 15 of the RoHS Directive.

3 HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

3.1 Transposition of the RoHS Directive and delegated acts

Under Article 25 of the RoHS Directive, Member States must, by 2 January 2013, have adopted and published the laws, regulations and administrative provisions necessary to comply with the Directive and then communicated those provisions to the European Commission. All Member States have adopted legislation transposing the RoHS Directive into national law and most Member States have adopted legislation specifically focusing on hazardous substances in EEE.

The RoHS Directive has to date been amended by 80 Commission delegated directives[44], many of which amend Annexes III and IV. In the consultation, many Member States said that amendments to the Directive are transposed through subsequent amendment of the national legislation, with some referring to 'dynamic links' in their national legislation (see chapter 4.1.5). Private stakeholders, mainly from the electrical and electronic business community, expressed concerns about the RoHS's effectiveness as a directive, rather than a regulation, which is seen as a more efficient legal form for handling the frequent updates. This issue is explored further in Section 4.

3.2 Implementation and enforcement

The Directive's provisions on market surveillance are central to its implementation and enforcement. Article 18 requires Member States to carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008 as amended by Regulation (EU) 2019/1020[45]. These Articles (Chapter III of the Regulation) outline the EU's market surveillance framework and checks on products entering the internal market. They require that each Member State designate a national authority which will be tasked with surveillance of the national market (here on the basis of the RoHS Directive and national implementing legislation).

The RoHS Directive refers in various provisions to the 'competent national authority', to whom economic operators[46] should send information and documentation to demonstrate that EEE complies with the Directive's requirements (Articles 7, 8, 9 and 10).

Member States use different measures for checking compliance with the RoHS Directive. Checking that marking obligations are complied with is the simplest and most economical way. This document-based check typically focuses on checking that the CE marking is present and has been correctly applied, and that the declaration of conformity is present and valid. Although only four Member States clearly said they use this approach to market surveillance for the RoHS Directive, further feedback on non-

[44] As at December 2022.

[45] Regulation (EU) 2019/1020 on market surveillance and compliance of products amended Regulation (EC) No 765/2008, replacing Articles 15 to 29 of Regulation (EC) No 765/2008 by corresponding provisions. These amendments are applicable from 16 July 2021.

[46] According to Article 3(10) of the Directive, 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor.

conformity issues suggested that this approach is widely used among Member States. More complex types of testing involve the use of X-ray fluorescence (XRF) spectrometers[47] by a number of Member States[48], and, for certain substances, laboratory testing, used by at least five Member States[49].

An administrative cooperation (AdCo) group supports enforcement of the Directive and helps to ensure it is applied consistently[50]. The group sometimes organises market surveillance joint actions, among other activities. For instance, in 2016, the RoHS AdCo group conducted a joint project on USB cables and contacts[51]. It aimed to assess compliance levels and to promote harmonised enforcement of the RoHS Directive across Europe. Results of risk-based checks have shown that, of the 157 products tested, 38 (24%) contained excessive levels of an RoHS-restricted substance, mainly lead in solders. Technical documentation was inspected for 18 products, and found to be non-compliant for 8 (44%). Labels on 109 of the 157 products were checked and 67 of these (61%) were non-compliant. Similar results were obtained in 2019 in tests on products with LED lamps and/or batteries; 25% of the products tested contained more than the tolerated maximum concentration of an RoHS-restricted substance[52]. Appropriate enforcement measures were taken by the relevant national authorities. Additionally, economic operators were informed of these results and referred to guidance on working preventively to comply with the requirements in the RoHS Directive.

Private stakeholders expressed the view that the overall level of compliance with the Directive is satisfactory, and that its implementation mechanisms function as intended. However, enforcement activities reveal high non-compliance levels for some product categories. In addition, market surveillance authorities report that requests for further evidence of compliance from economic operators in the supply chain are often unsuccessful.

In the year 2012, the import of EEE was 2,75 times higher than the export of EEE from the EU[53]. Between 2014 and 2020 the monetary import of EEE increased[54]. This is relevant as market surveillance authorities reported practical difficulties in enforcing the provisions in cases of non-compliant imported EEE and in contacting authorities outside

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[47] XRF spectrometers are elemental analysers designed to detect inorganic elements such as chromium, bromine, cadmium, mercury and lead, in homogeneous polymeric materials. The particular advantage of 'hand held' or 'portable' XRF instruments is that they enable analytical measurements to be taken in situ. The operator can then make a more informed decision on what, if anything, to investigate in subsequent laboratory tests.

[48] Czechia, Finland and Sweden.

[49] Greece, Lithuania, Austria, Finland and Sweden.

[50] European cooperation on market surveillance takes place through informal groups of market surveillance authorities, called administrative cooperation (AdCo) groups. The members of these groups are appointed by Member States and represent national authorities responsible for market surveillance in a given sector.

[51] RoHS AdCo 2016 joint project on USB cables and contacts, https://www.kemi.se/en/publications/enforcement-reports/2016/enforcement-12-16-rohs-adco-joint-project-2016.

[52] RoHS AdCo 2019 joint project on LED-lamps and batteries, https://www.kemi.se/en/publications/enforcement-reports/2020/enforcement-14-20-rohs-adco-joint-project-2019.

[53] In tonnes - https://www.eea.europa.eu/data-and-maps/figures/imports-and-exports-of-electrical

of the EU, despite the obligation that the economic operator needs to be established in the EU (Article 4(1) of Regulation (EU) 2019/1020).

According to an impact assessment on product-related harmonisation legislation[55] published in 2017, an estimated 23% to 28% of EEE products did not comply with RoHS. The study also analysed non-compliance reports available in the EU Safety Gate Database[56] for 2013-2020, from which the following key points could be extrapolated for the RoHS Directive.

1. The presence of lead in EEE is the most-frequently mentioned reason for non-compliance.
2. For any given year, Sweden has the highest number of reports. This might be because Sweden takes a more stringent approach to market surveillance than other Member States, or because it has a greater propensity to file reports.
3. China is by far the most cited country of origin for RoHS-non-compliant goods.
4. The number of non-compliance reports submitted in 2019 is significantly higher than for all other years. This might reflect one or a combination of the following factors:
   - a change in market surveillance approaches in Member States;
   - a change in reporting approaches in Member States; and
   - all else being equal, an increase in the number of non-compliant products.

Different market surveillance approaches and methods of reporting non-compliance might bias the available data. Therefore, it is not possible to draw strong conclusions on the level of compliance with the Directive. In this regard, efforts are being made to harmonise methodologies and criteria for assessing risks and to strengthen consistency in different market surveillance activities under Regulation (EU) 2019/1020

3.3 Interactions with other EU policies and legislation

The RoHS Directive has strong links to chemicals legislation like the REACH Regulation or the POPs Regulation. Substances can only be considered for inclusion on the list of restricted substances if inclusion would be in line with existing legislation. Amendments to the list of exemptions should not weaken the protection level afforded by the REACH Regulation. Those points are to be regularly taken into account by reviewing the list of restricted substances or the exemption list. In addition, scope exclusions and deviations from substance restrictions as the 'repair as produced' principle required special consideration to avoid inconsistencies between the different legislations.

The RoHS Directive is part of EU harmonisation legislation for manufactured products, and is therefore covered by its uniform framework for market surveillance.

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54 Trade by commodity and NACE Rev. 2 activity [EXT_TEC05__custom_2012768]

55 Impact assessment accompanying the proposal for a regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products (2017) *https://eur-lex.europa.eu/resource.html?uri=cellar:105e4f9b-e4b1-11e7-9749-01aa75ed71a1.0001.02/DOC_1&format=PDF*.

56 The Safety Gate system enables quick circulation of information about non-food dangerous products among the national authorities responsible for product safety in the single market countries.

https://ec.europa.eu/safety-gate-alerts/screen/webReport

The chemicals strategy for sustainability promotes a safe and sustainable-by-design approach and non-toxic material cycles, stating, '[…] it is necessary to ensure that substances of concern in products and recycled materials are minimised. As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case-by-case analysis.*'*

Closely linked to the substance restrictions under the RoHS Directive are ecodesign requirements laid down by the Ecodesign Directive[57] and its implementing measures. Some products (e.g. fluorescent lamps) and their energy consumption are closely related to the use of hazardous substances and thus to RoHS requirements. To further reduce the negative environmental impacts of products over their lifetime, the Commission proposal for an ecodesign for sustainable products regulation (ESPR) would broaden ecodesign requirements and extend their scope[58]. Adoption of the proposed regulation and implementation through product–specific delegated acts will be of relevance to interaction with the RoHS Directive.

Like the WEEE Directive, as explained in detail above, the RoHS Directive also interacts with many pieces of EU legislation on waste, such as Directive 2000/53/EC ('End-of-life Vehicles Directive').

[57] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10-35).

[58] COM(2022) 142 final.

4 EVALUATION FINDINGS

The Better Regulation Guidelines require evaluations to assess the **effectiveness, efficiency, coherence, relevance and EU added value**. To operationalise the assessment, an evaluation matrix was developed, which breaks the criteria down into evaluation questions (see Annex III). Results of the assessment are presented below, structured around three main guiding questions covering all the criteria.

- To what extent was the RoHS Directive successful and why? (Effectiveness, efficiency and coherence)
- How did the EU intervention make a difference? (EU added value)
- Is the intervention still relevant? (Relevance)

4.1 To what extent was the RoHS Directive successful and why?

Overall response

The RoHS Directive helped to reduce the relative amount of hazardous substances in EEE placed on the EU market and thus to protect human health and the environment. It contributed to WEEE treatment by reducing the level of hazardous substances per item of EEE in that waste stream. Consequently, there is reason to believe that waste management processes overall have become safer, although only limited quantitative evidence is currently available. The reduction in hazardous substances in WEEE is partially counterbalanced by the increasing volumes of WEEE generated in Europe.

Furthermore, by providing for harmonised substance restrictions at EU level, the Directive produced economic benefits by creating a level playing field for businesses in the internal market, increasing legal certainty, and in some cases stimulating innovation through substitution. The Directive has also paved the way for RoHS-like legislation to be developed around the world.

As for costs arising from the Directive, most appear to be linked to the exemption system and product development to comply with substance restrictions. However, businesses, and competent authorities in the Member States, found it difficult to dissociate the costs for RoHS from the costs linked to other compliance or enforcement activities related to EEE.

Two coherence issues were identified for the Directive, both closely related to each other:

- *procedures for deciding on exemptions and review and amendment of the list of restricted substances, which were seen to have led to inefficiencies and administrative burden;*
- *concerns regarding synergies and consistency in application between the RoHS Directive and related legislation (e.g. REACH, Ecodesign), including concerns about the coherence of approaches to substance evaluation.*

The success of legislation is measured largely by how well it meets its objectives. In this respect, the evaluation sought to identify:

- the factors driving or hindering the RoHS Directive's progress in achieving its objectives (the Directive's *effectiveness*);
- the extent to which the needs of the Directive are met in the most cost-effective ways (the Directive's *efficiency*) and with the least possible burden; and

- whether the Directive is internally coherent and functions well in conjunction with other relevant legislation (the Directive's *coherence*).

The main conclusions of this analysis are set out below.

4.1.1 The RoHS Directive achieved its primary objective of restricting and thereby reducing the use of certain hazardous substances in EEE

The evaluation study findings **suggest that the RoHS Directive contributed to a reduction in hazardous substances in EEE put on the EU market**.

The evaluation study contained an analysis assessing the scale of the reduction in hazardous substances in EEE. Some assumptions had to be made here, and the used model was limited by the availability of quantitative data on the content and reduction in hazardous substances in EEE (see also chapter 1.5.2). The analysis assumed that economic operators in question complied with the Directive, even though as indicated in Chapter 3.2 there may be a certain level on non-compliance in the EEE sector, which would result in higher amounts of hazardous substances in EEE.

As the impact of other legislative developments and instruments, such as the introduction of the REACH Regulation, could not be quantified, the reduction in hazardous substances in EEE cannot be attributed to RoHS alone. As an example, there are several acts restricting lead (e.g., in packaging[59], batteries[60], vehicles[61]), but they do not directly restrict hazardous substances in EEE although their positive effect could indirectly result from the fact that secondary material streams used for EEE manufacturing contain less lead due such restrictions. Other pieces of legislation do not directly restrict hazardous substances on environmental reasons but e.g. by introducing migration limits (e.g., under the Directive 2009/48/EC[62]) it is reasonable to expect a reduction of hazardous substances in articles including EEE. Besides legal requirements, it is expected that other initiatives/measures as labels/certificates, requirements for the public sector, financial incentives or internal company requirements have a significant impact on the reduction of hazardous substances in EEE (see also the second support study).

The quantitative analysis in the evaluation study estimates that, between the introduction of RoHS 1 in 2003 and 2016, restricted substances (cadmium, lead and mercury only) were reduced by around two thirds[63]. While the precise scale of the reduction cannot be

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[59] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste - OJ L 365, 31.12.1994, p.10.

[60] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC - OJ L 266, 26.9.2006, p.1.

[61] Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles - OJ L 269 21.10.2000, p. 34.

[62] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys - OJ L 170, 30.6.2009, p. 1–37

[63] As presented in Appendix II to the evaluation study.

The baseline estimations are based on the limited data available on the concentration of hazardous substances in a selection of products. These products and their concentrations have been used as proxies for their entire category.

determined with certainty and estimates are not precise measurements, the finding that the concentration of hazardous substances in EEE declined with introduction of the RoHS 1 Directive is deemed valid.

For the other substances, i.e. hexavalent chromium, PBDEs, PBB and the phthalates, the second support study indicates a reduction in EEE over the years. Similar to the previous findings, it cannot be attributed to the RoHS Directive alone as many substances were about to be phased-out by other regulatory pressure and changed demands on the market.

The evaluation study also indicated that the average lifespan of EEE has decreased[64]. For instance, the lifespan of personal computers fell by more than 50% from 4-6 years in 1997 to 2 years in 2005[65]. In combination with the increase in electrified equipment (e.g. for 'smart homes'), this suggests that the number of products in the WEEE stream has been increasing, a finding supported by other sources[66, 67]. For the EU, the WEEE stream has a current annual growth rate of 2%[68].

The increasing volume of WEEE generated in Europe (see also 4.2.1.) is included in the quantitative analysis and it should be emphasised that this significantly offset the reduction in hazardous substances in WEEE in total.

Another shortcoming in the quantitative analysis is that the time-limited exemptions under the Directive were not considered. The exemptions cover a significant amount of hazardous substances. In the second support study a rough estimation of the most relevant exemptions for lead indicates a quantity of over 10 000 tonnes[69], which shows the relevance.

Looking at five applications, mostly relevant to categories 1-7 and 10 of Annex I, exempted since the adoption of the RoHS 1 Directive, valid for three different substances and subsequently renewed, an estimate suggests that for many exemptions, the volume of hazardous substances covered has fallen over time, but it was unclear whether this was related to the exemption system under the RoHS Directive. The amount of mercury in fluorescent lamps has been reduced over the years, partly due to the narrowing down the scope of the relevant exemptions. For one application concerning lead, there was no decrease in volume over the last 20 years. For another application, no reliable information was available on the volume of hazardous substance[70].

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[64] Evaluation study: with latest estimates in 2012/2013.

[65] Habib et al., 'What gets measured gets managed – does it? Uncovering the waste electrical and electronic equipment flows in the European Union', *Resources, Conservation & Recycling* 181 (2022), Article 106222.

[66] Global E-waste Monitor UNU-IAS, 2017.

[67] Eurostat 2020 – WEEE by waste management operations.

[68] COM(2019) 640 final.

[69] Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) - https://op.europa.eu/en/publication-detail/-/publication/b9188764-f465-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-286516984

[70] Study underpinning the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) - https://op.europa.eu/en/publication-detail/-/publication/b9188764-f465-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-286516984.

The introduction of the 'open scope' had an impact in further reducing the total amount of hazardous substances in EEE. According to stakeholders from the medical sector the reduction in hazardous substances in category 8 (medical devices) was small due to many justified exemptions. This is plausible as on the one hand, many exemptions for medical devices expired[71] and on the other, many new exemptions are listed in Annex IV of the Directive. For category 9 (monitoring and control instruments), the relevant association estimated that most hazardous substances (around 99%) were avoided comparing the years 2004 and 2019. This could not be confirmed in the evaluation study.

For category 11, a case-study on the United Kingdom suggests that e.g. 200 kg lead, 110 kg PBDE and 100 kg hexavalent chromium are saved between 2019 and 2025 by the inclusion of category 11 in the scope of the Directive.

A decreasing trend of the amount of hazardous substances was suggested by stakeholder during the consultation activities. And in the OPC, most respondents among the expert stakeholders thought that the RoHS Directive was helping to reduce the use of hazardous substances in EEE produced both in and outside the EU (Figure 1).

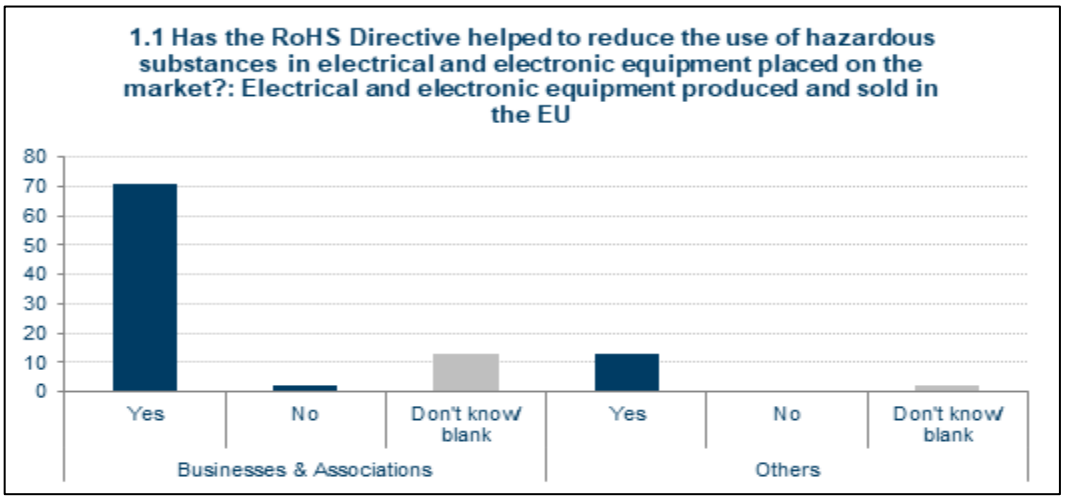

Figure 1: Expert OPC responses: reduction in use of hazardous substances in EEE (N=101)

In the same OPC, Member States' representatives (N=15, 70% of all responses received) also gave a positive assessment of the effectiveness of the Directive. However, while in general most respondents thought RoHS had reduced the use of hazardous substances in EEE, they highlighted that it was difficult to provide a precise quantified estimate due to a lack of comprehensive data on the concentrations of hazardous substances in EEE.

As to *which* substances were reduced the most, expert stakeholders from businesses and associations (N=86, 75%) indicated in the OPC that the RoHS Directive had particularly impacted on the use of lead, mercury and hexavalent chromium in EEE, but less on other hazardous substances covered (see also Annex V).

[71] Evaluation Study – For example, exemptions No. 21, 24, 28, 30, 32, 33 IIa, 38 under Annex IV

The quantitative analysis, with estimates for lead, mercury and cadmium, found that lead accounted for the largest part of the reduction. This is in line with lead's broad range of electrical and electronic applications, though some applications (e.g. in solders or alloys) are thought to be still covered by time-limited exemptions. For lead and mercury, the findings of the project 'urban mine platform' under the ProSUM Project[72] confirmed that there had indeed been a reduction. However, it was found that the amount of cadmium placed on the market had increased in recent years under this project, which conflicts with the results of the evaluation study.

4.1.2 Achieving a reduction in hazardous substances is expected to have positive effects on human health and the environment.

The complex correlations between a reduction of hazardous substances and the effects on human health and the environment are difficult to quantify. Different legislation contributes to those effects and there are, after all, cumulative health and environmental benefits, which are described in a study[73]. The following conclusions can be drawn as to the magnitude of the **environmental effects** concerning the RoHS Directive.

- The reduction in hazardous substances results in lower levels of harmful emissions during WEEE treatment and recycling processes, provided the WEEE is properly disposed of and treated. However, sound recycling practices need to be in place, so that emissions are carefully managed. Important requirements on limiting emissions, including emissions of restricted substances under RoHS, are laid down by Directive 2010/75/EU[74] and Directive 2008/105/EC[75].
- The average collection rate of WEEE in the EU was 45.9% in 2020[76], meaning that more than half of WEEE (around 4.7 Mt) was not properly collected and escaped the designated waste management systems. Of this amount, some was recycled under non-compliant conditions (1.12 Mt), some scavenged for valuable components (0.64 Mt), some disposed of as part of residual waste (0.6 Mt), and some legally exported (0.29 Mt)[77]. The remaining WEEE (2.09 Mt) is unaccounted for, including possibly illegally exported.
- Waste treatment or recovery operations not specially equipped to treat WEEE can have adverse environmental impacts through higher emissions. Once the substances are released in the environment, for instance via air, dust, or water, they can harm the

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72 http://www.urbanmineplatform.eu/composition/eee/elements.

73 Study on the cumulative health and environmental benefits of chemical legislation (2017): https://op.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

74 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions - OJ L 334 17.12.2010, p. 17.

75 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy - OJ L 348, 24.12.2008, p. 84.

76 Measured as the weight of WEEE collected relative to the average weight of electronic equipment put on the market in the 3 preceding years, i.e. 2017-2019. See https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment&oldid=556612;

77 Considering 11 countries in Europe

ecosystem. For example, over time mercury emissions can bio-accumulate along the food chain and cause serious toxication. A reduction in the hazardous substances in WEEE treated in this way can reduce those unwanted emissions and prevent adverse impacts.

- Exported WEEE may be processed using inadequate or unsafe WEEE recycling techniques that do not meet the same protection standards as those in the EU. In particular, there is a high risk that WEEE exported illegally from Europe will cause severe damage to the environment and to human health, for example when processed in small workshops using very basic methods such as manual disassembly and open incineration without emission-control techniques.

As for the **effects on human health**, the evaluation study came to the conclusion that both waste workers and, to a lesser extent, consumers are generally exposed through three different routes: inhalation, skin contact or ingestion[78]. There is a risk that improper use or accidents (e.g. breaking of mercury containing discharge lamps) can lead to health damage. Table 1 summarises the possible health damages from excessive exposure to four RoHS substances and also includes a reference to the relevant EU legislation defining exposure limits of workers.

Table 1: Potential health damage and occupational exposure limits of hazardous substances (Source: evaluation study)

Substance[79]	Potential health damage	Occupational exposure limit (EU)
Cadmium and its inorganic compounds **048-001-00-5**	Harmful if inhaled – H332. Harmful in contact with skin – H312. Harmful if swallowed – H302.	8 hours limit value: 0.001 mg/m³ (inhalable fraction) Transitional measures until 11.7.2027 Binding occupational exposure limit value (Directive 2004/37/EC on carcinogens or mutagens at work)
Chromium(VI) compounds **024-017-00-8**	May cause cancer by inhalation – H350i. May cause an allergic skin reaction – H317.	8 hours limit value: 0.005 mg/m³ Transitional measures until 17.1.2025 *Binding occupational exposure limit value* *(Directive 2004/37/EC oncarcinogens or mutagens at work)*
Lead **082-001-00-6**	Harmful if swallowed or inhaled. H302 + H332. May damage fertility or the unborn child – H360Df. May cause harm to breast-fed children – H362 (other lead entry) May cause damage to organs through prolonged or repeated exposure – H373.	8 hours limit value: 0.15 mg/m³ *Binding occupational exposure limit value* *(Directive 98/24/EC on risks related to chemical agents at work)*

[78] K. Grant, F.C. Goldizen, P.D. Sly, M.-N. Brune, M. Neira, M. van den Berg, et al. Health consequences of exposure to e-waste: a systematic review - The Lancet Global Health, 1 (6) (2013), pp. e350-e361.

[79] Index No & hazard statement code from the harmonised classification in Annex VI (Part 3, Table 3) to Regulation (EC) No 1272/2008 (CLP). The index No refers to the main chemical and does not include chemicals specified elsewhere in the Annex (unless indicated otherwise.

Mercury **080-001-00-0**	Fatal if inhaled – H330. May damage the unborn child – H360. Causes damage to organs through prolonged or repeated exposure – H372.	8 hours limit value: 0.02 mg/m³ *Recommended indicative occupational exposure limit value* (Directive 2009/161/EU)

The evaluation study also found that workers in EEE manufacturing and recycling plants are more exposed than other people. For instance, in a 2014 study[80] on workers' exposure at three e-waste recycling plants in Sweden, where significantly higher levels of chromium, lead and mercury were found in recycling workers than in other workers.

A higher risk for workers is anticipated when WEEE is processed outside the designated waste management systems, as the presence of hazardous substances (see Table 1) is less evident and/or less stringent occupational health and safety measures are taken. In addition, EU occupational requirements do not apply to exported WEEE.

In view of this and the significant amount of exported WEEE, it is worth highlighting that, as reported in several studies[81], the impact of the RoHS Directive on human health, especially on workers, is most visible outside the EU.

The stakeholders' views on the impact of workers' health are divided. Businesses and industry associations pointed out that EU workers are not significantly impacted by the RoHS-induced reduction in hazardous substances in EEE, as numerous measures to protect health and safety standards in the EU were already in place (as reported in the Table 1 above). NGOs highlighted that, regardless of measures already in place, the reduction in hazardous substances in EEE triggered by the Directive had still had a positive impact on the health of workers exposed to hazardous substances both during manufacturing but also at the end of these products' life.

[80] A. Julander et al., 'Formal recycling of e-waste leads to increased exposure to toxic metals: An occupational exposure study from Sweden', *Environment International*, Volume 73, December 2014, Pages 243-251.

[81] K.A. Asante, T. Agusa, C.A. Biney, W.A. Agyekum, M. Bello, M. Otsuka, et al., Multi-trace element levels and arsenic speciation in urine of e-waste recycling workers from Agbogbloshie, Accra in Ghana, Sci Total Environ, 424 (2012), pp. 63-73.

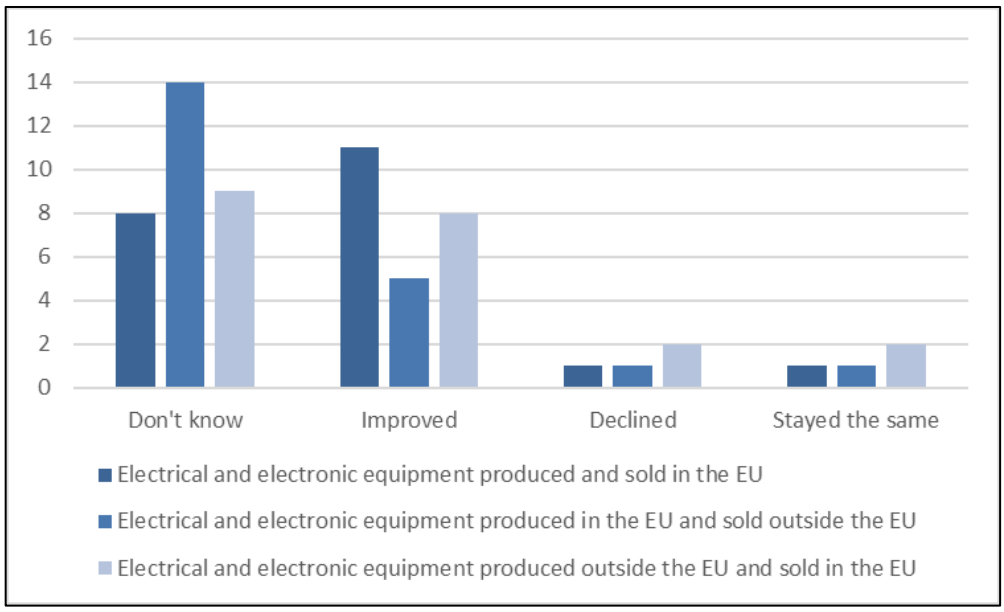

Figure 2: Member States' survey responses – Has the safety of electrical and electronic equipment for human health improved, stayed the same or declined over the last 10 years? (N=21)

Figure 2 shows that for products produced and sold in the EU, around half of the respondents (9 of N=21) agree that the health and safety aspects of EEE have improved in the last decade.

One example concerned the positive impact on workers' health in the mercury-added lamp manufacturing sector where, as a result of the RoHS Directive, the permitted mercury content in the manufacturing of fluorescent lamps was reduced[82]. Workers initially used to pour liquid mercury into the lamps, with around 50% loss and spillages occurring; as a result, the workers and surrounding workspace would become contaminated with mercury and exposed workers would be affected by mercuriosis. With the maximum allowed quantity reduced, manufacturers started to use different techniques, such as strips, pellets or amalgam, where the mercury would be contained and eventually released within the lamps; as a result, no mercury spillages and high exposure would occur. However, other legislation, such as occupational health regulations, have certainly also made a significant contribution to this effect.

4.1.3 The RoHS Directive has contributed to the environmentally sound recovery and disposal of waste EEE

If the amount of hazardous substances in EEE has decreased over time, it can also be concluded that, **at the end of the EEE life cycle, such substances entered the waste stream in smaller quantities**. For instance, the evaluation study analysis[83] corroborating Eurostat data on EEE waste streams with data provided by the Urban Mine Platform database[84], concluded that the amount of lead contained in WEEE generated in the EU[85]

[82] Many respective exemptions were not extended in the last review and are due to expire in 2023.

[83] Appendix III.

[84] http://www.urbanmineplatform.eu/composition/eee/elements

[85] Including the United Kingdom.

has been decreasing since 2011, from around 70 kilotons to 28 kilotons in 2020. Knowing that the number of products in WEEE streams has increased in the last few years, it is therefore reasonable to assume that the decrease in lead seen in WEEE is due to a decrease in the amount of lead in individual items of EEE.

As for the **impact of the RoHS Directive on the recovery and disposal processes applied to waste EEE**, disentangling the effects of the two complementary pieces of legislation, WEEE and RoHS Directive, on waste EEE treatment is not straightforward (e.g. the WEEE Directive identifies a set of *materials and components* of EEE that should receive selective treatment, while the RoHS Directive identifies the *substances* in EEE). Overall, however, it can be concluded that the RoHS Directive has had an impact on waste EEE treatment beyond the requirements of the WEEE Directive as it contributed to reduce the amount of hazardous substances in WEEE.

The amount of WEEE being collected and treated is increasing (see Figure 3). The WEEE Directive and the RoHS Directive have contributed to this positive trend. As the RoHS Directive has driven down the amounts of hazardous substances in EEE, the concentrations in mixed WEEE have diminished too. These material streams can more easily meet product requirements (e.g. under the REACH Regulation or POP Regulation) and thus be recycled.

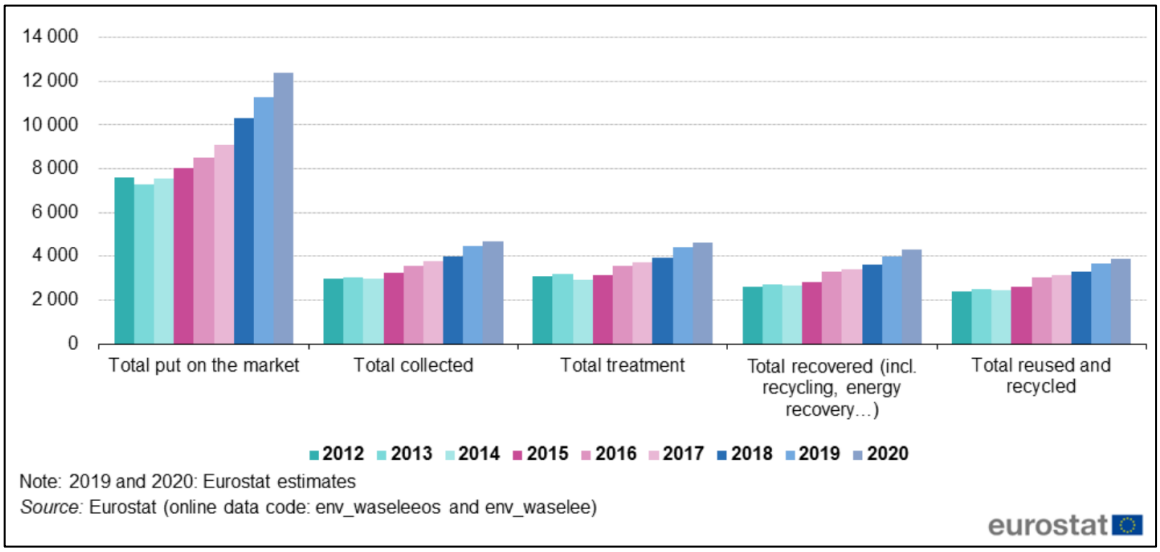

Figure 3: EEE put on the market and WEEE collected and treated (in thousand tonnes), EU 28

The RoHS Directive also contributes to the objectives of the circular economy. Article 4(4) and 4(5) of the Directive contain provisions for cables and spare parts, which are excluded from the substance restrictions. Additionally, time-limited exemptions in Annexes III and IV provide another possibility for ensuring the continued availability of spare parts for older devices that depend on them. This helps to avoid premature end of life for EEE. However, the provisions, some of which are due to expire, are not clearly summarised in one comprehensible paragraph, and might need to be updated in view of the new objectives.

4.1.4 By introducing harmonised restrictions, the RoHS Directive has created a level playing field for all manufacturers, thus effectively contributing to the functioning of the internal market

The evidence gathered, mostly from the established legal framework and its implementation and from the consultation responses, suggests that RoHS introduced a

harmonised set of rules for establishing a level playing field for the movement of EEE across Europe. All Member States have adopted legislation which transposes RoHS into national law. Harmonised application of the Directive was further enhanced by the alignment of the Directive with the New Legislative Framework (NLF)[86] whereby RoHS 2[87] introduced requirements regarding CE marking, conformity assessment and other obligations on economic operators. Uniform application of general provisions and harmonised implementation facilitate a consistent framework for different product regulations. This makes the rules easier to understand, increases legal certainty and supports the smooth functioning of the internal market.

Also worth mentioning here is the process of reviewing and amending the list of restricted substances in Annex II to the Directive through delegated act, for example, on the basis of a proposal from a Member State. This process provides a means of keeping up with the need for further harmonisation.

Findings from the OPC confirmed the positive contribution the Directive has had on the functioning of the internal market. Similarly, in the targeted survey of Member State authorities, 55% agreed that RoHS contributed to free movement of EEE in the EU.

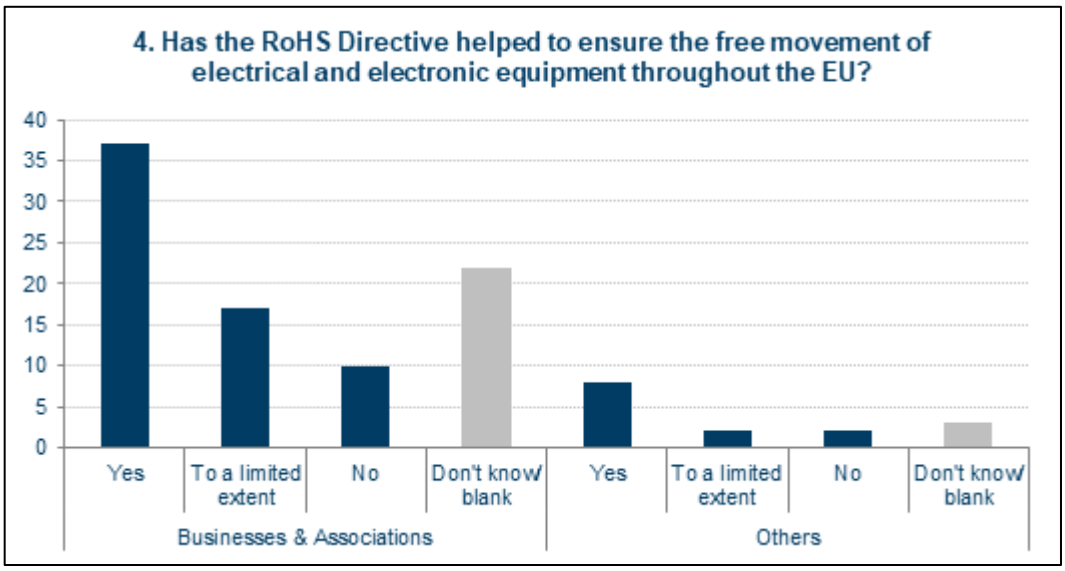

Figure 4; Expert OPC responses: Free movement of EEE in the EU (N=101)

However, during the stakeholder workshop organised as part of the evaluation study, several stakeholders from Member States and from industry expressed concerns about the administrative burden linked to the transposition of the delegated directives amending the RoHS Directive. The workshop participants asked whether another form of legal instrument, i.e. a regulation, would help reduce this burden.

[86] New legislative framework, consisting of Regulation (EC) 765/2008 and Decision 765/2008/EC, as already outlined in Section 3 of the document.

[87] There were no such obligations at the EU level under RoHS 1 Directive.

Any amendments made to the legislation through delegated directives concerning the exemptions in Annexes III and IV requires resources from the Member States to transpose the provisions into national law and to notify the Commission of the national rules. There is a risk that legal uncertainties can arise concerning content and timing (e.g. different adoption dates within the transposition period). If the Directive were converted into a regulation, any changes to the regulation would apply directly. Follow-up work in the form of transposition would be significantly reduced, both for Member State administrations and for the Commission (see also 4.1.6). However, this has to be weighed against the Member States' interest to integrate flexibly the remaining provisions into their existing legal systems.

4.1.5 Regulatory benefits counterbalance the regulatory costs

As evidenced from the above effectiveness analysis, the RoHS Directive has produced wider environmental and health benefits, even though other initiatives contributed to the same objective. For example, it has reduced damage to the environment and human health, generated economic benefits, levelled the playing field for businesses in the internal market and created legal certainty. Table 2 below summarises the assessment of the **regulatory benefits** that stem from and can be attributed to the RoHS Directive. It has proved difficult to quantify the monetary benefits as they mainly relate to the protection of the human health and the environment.

Table 2: Assessment of the benefits of the RoHS Directive

Benefit		Assessment
Environmental benefits		
Avoided emissions of hazardous substances from WEEE	The reduction in hazardous substances in EEE results in lower environmentally damaging emissions during WEEE recycling processes.	Achieved to some extent. The impact differs depending on the recycling practices used in Europe compared to developing countries. Non-compliant products can reduce the positive effect. Overall, assessed to have had positive impacts on the environment in the EU and in third countries where WEEE is processed.
Improved recyclability of EEE	The RoHS Directive has led to a reduction in hazardous substances used in EEE and consequently in WEEE (with a time lag depending on the product lifetime). Material streams from WEEE are less contaminated by certain hazardous substances, making the materials easier to recycle.	Achieved.
Contribution to circular economy	The RoHS Directive promotes the use of certain spare parts and the reuse of certain recovered spare parts to make it easier to repair EEE.	Achieved to some extent. Industry applies respective exemptions.
Health benefits		

Benefit		Assessment
Reduction in the exposure of hazardous substances for workers in production and WEEE recycling plants	The reduction in hazardous substances in EEE triggered by the Directive had a positive impact on the health of workers exposed to hazardous substances during manufacturing and especially at the end of life of these products.	Achieved. The benefits do not differ by product group. Overall, assessed to have had positive impacts on human health in the EU and in third countries where WEEE is processed.
Fewer negative health effects for consumers	The chance that consumers are exposed to hazardous substances decrease with the reduction in hazardous substances contained in EEE. Therefore, the restrictions under RoHS have had a positive impact on the health of consumers.	
Market efficiency benefits		
Proper functioning of the internal market	The RoHS Directive has made a positive contribution to the functioning of the internal market by creating a level playing field and thus ensuring the free movement of EEE on the EU market.	Achieved, not quantifiable. Non-compliant products can reduce the positive effect.
Increase in innovation	The RoHS Directive has had a positive impact on innovation to substitute restricted substances. In some cases, time-limited exemptions triggered the innovation process. In others, when innovation was already underway, the RoHS Directive reduced the time needed to complete the process.	Achieved to some extent.

On the benefits related to innovation, for instance, most stakeholders acknowledged that the Directive has made a positive contribution to innovation as it has stimulated substitution to use EEE that contain less harmful substances (see Figure 5). One such example is related to innovation in the lighting industry. Following the entry into force of time-limited exemptions for the use of mercury in certain lamp categories, there have been new investments and software innovation in mercury-free LED technology[88]. However, certain stakeholders representing categories 8 and 9 of Annex I to the Directive[89] reported negative impacts on innovation as the need to allocate resources to find alternatives to RoHS substances in their products reduced the resources available to conduct research and development.

[88] The RoHS 1 Directive entered into force in 2003. At a later stage, the ecodesign requirements for lamps under Commission Regulation (EC) No 244/2009 supported further innovation.

[89] Category 8: Medical devices, category 9. Monitoring and control instruments including industrial monitoring and control instruments.

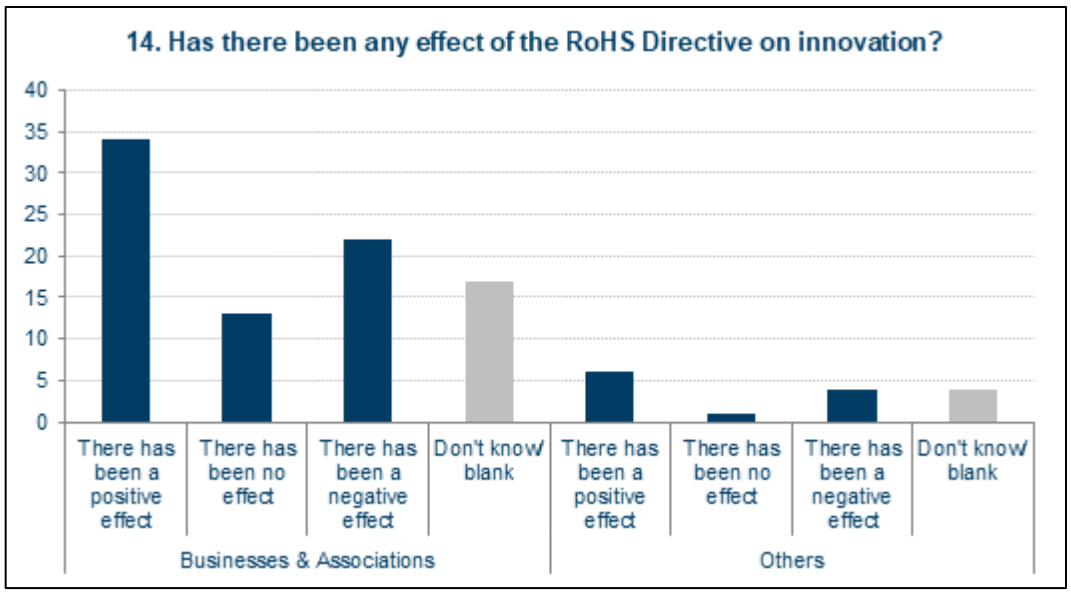

Figure 5: Expert OPC responses: Effect on innovation (N=101)

In regulatory terms, the above benefits can be categorised in benefits related to improved wellbeing (health and environmental benefits) and market efficiency benefits (benefits related to improving the internal market and boosting innovation), as shown in Figure 6. In addition, the global impact of the EU's RoHS Directive is a regulatory benefit that exceeds the benefit to the internal market (see point 4.2.1).

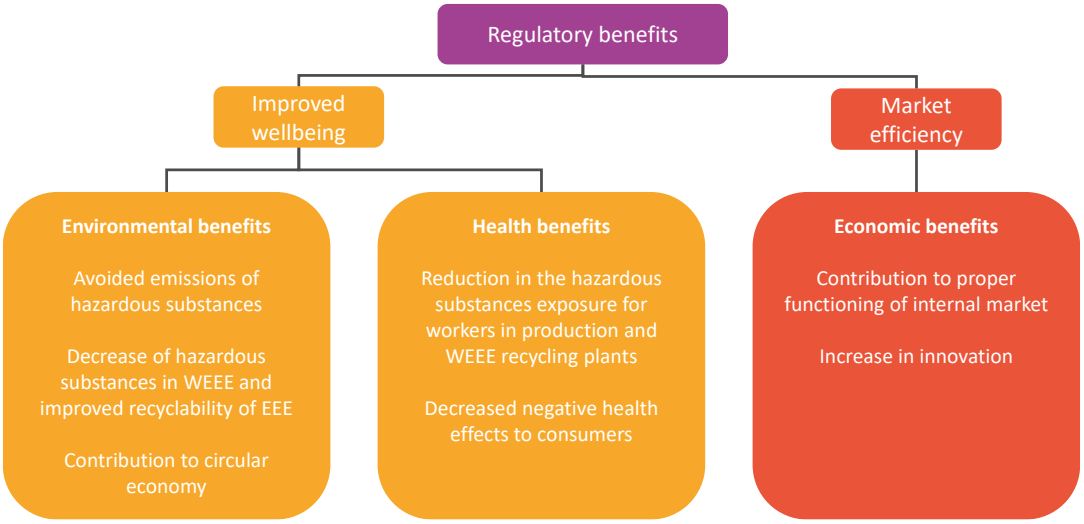

Figure 6: Overview of the regulatory benefits of the RoHS Directive (Source: evaluation study)

The **regulatory costs** can be broken down into three categories, information **compliance costs, engineering compliance costs, and enforcement & implementation costs**.

Information compliance costs

The compliance costs for businesses related to the RoHS Directive include collecting and reviewing information, gathering supply chain information, costs related to dedicated IT systems to manage all required information, and costs related to the exemption system.

The Directive sets out the specific obligations of manufacturers in Article 7, of importers in Article 9, and of distributors in Article 10. When placing EEE on the market, the manufacturer must ensure that they have been designed and manufactured in accordance with the substance restrictions. This includes the conformity assessment procedure, carried out here as internal production control, which includes technical documentation, quality management in manufacturing, affixing the CE marking and issuing the EU declaration of conformity. Importers and distributors must ensure that the manufacturer has fulfilled their obligations. All economic actors must make available the requisite information (e.g. the serial number of the EEE or the contact point) and must ensure that further information can be made available to competent authorities upon request.

In addition to the costs for manufacturers, there are also costs for raw material suppliers as they have to provide information to the manufacture as input to create the mandatory technical documentation. The information must be managed and provided throughout the whole supply chain, which creates costs for these companies.

However, it is not possible to quantify the costs of compliance with the RoHS Directive. Companies bundle tasks related to general compliance or administration, and do not typically have one team specifically in charge of RoHS compliance but teams responsible for compliance with a long list of pieces of legislation. The staffing costs in FTEs related to the RoHS Directive depend on many factors, such as the size of the company or the EEE categories produced. For many businesses (N=11) that report having fewer than 3 FTEs, the average is 0.28 FTE per year; larger companies may have more.

Most compliance costs stem from the general requirements for placing products on the market (e.g. providing technical documentation). Some costs are fixed and stay the same, even for producers of equipment that fell in scope when the Directive was extended.

Companies (in particular EEE manufacturer) that still require time-limited exemptions also face another form of compliance costs. Some businesses already use substituted hazardous substances in their products. Some do not have to apply for an exemption, as exemptions under the RoHS Directive are valid for all companies and thus the costs are carried by one company or one consortium (see more under point 4.1.6). The main costs are linked to preparing the application form and answering questions during the evaluation process.

Applying for an exemption under the RoHS Directive is free of charge, unlike the authorisation process under REACH where fees are charged in line with the polluter-pays principle[90]. A fee for processing requests for exemptions was brought in in April 2023[91] under the UK's new RoHS legislation, which was based on the EU RoHS Directive.

Engineering compliance costs

[90] Article 62(7) and Title IX of REACH.

[91] https://www.gov.uk/government/consultations/fees-for-processing-applications-for-exemptions-from-rohs-regulations (23-01-2023).

Manufacturers indicated that another major cost driver is the cost of technical compliance to comply with the hazardous substance restrictions in their product (in the product development phase). In the business focus group, participants noted this includes R&D costs and the cost of validating alternatives. Those engineering costs mainly occurred in around 2002 when the RoHS Directive came into force and restricted the use of certain substances.

There are national and European funds and programmes (e.g. InvestEU, Horizon Europe, LIFE)[92] that support research and innovation to achieve phasing-out hazardous substances.

Another increase in costs is expected when the scope extends from RoHS 1 to RoHS 2 and the four phthalates are included in the list of restricted substances. For many companies, the cost of investing in finding alternatives fall over time as the EEE sector develops. Once alternatives exist and are available, R&D investments are no longer needed to replace the hazardous substances. However, some companies may struggle to find reliable substitutes and others may have applications for which alternatives are not expected to be available in the near future.

For EEE that remain excluded by time-limited exemptions, companies continue to spend on R&D to seek substitutes or to redesign their products with different ambitions. The cost of applying for an exemption may be an incentive to seek opportunities to substitute hazardous substances in products rather than to collect and submit the extensive data required to make a substantiated application.

Enforcement & implementation costs

Based on the responses received from 10 Member States, the range of FTEs needed to enforce and implement per Member State is between 0.3 to 4.75 FTE per year. The total budget including staffing costs ranges from EUR 10 000 to over EUR 400 000 per year. For most Member States, the enforcement costs are higher than the implementation costs. The enforcement of the substance restrictions appears to be the largest cost heading.

The cost of transposing amendments via delegated directives into national legislation is the main cost involved in implementation. Out of the 15 responding Member States, 10 indicated that they have to transpose these changes 'manually' in the national legislation and five said that they have 'dynamic' links to Annexes III and IV to the RoHS Directive, which means they have cross-reference to the European legislation without specifying the content. According to the Member States, 'manual' transposition requires between two and 12 months, though most indicated it took considerably less than 12 months. A rough estimate of the cost of implementing four delegated directives is between EUR 9 178 and EUR 55 066 per year and per Member State. Assuming that 2/3 of all Member States (18) lack 'dynamic' links, the yearly costs involved in transposing delegated acts is estimated at between EUR 165 000 and EUR 991 000.

The main cost for the European Commission is in running the exemption system. The European Commission spends on average the equivalent of 1.0 FTE per year on in-house

[92] https://investeu.europa.eu/index_en
https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-2020_en
https://cinea.ec.europa.eu/programmes/life_en

staffing and around EUR 150 000 per year on studies to amend Annexes III and IV[93]. Under Article 5(1)(a), it amends the Annexes by issuing specific delegated acts. Since the RoHS 2 Directive entered into force in 2011, around 80 delegated acts were adopted under the RoHS Directive (as at December 2022). Not all exemption requests resulted in a delegated directive. Some were considered unjustified for an exemption, some were merged into one act and some were withdrawn by the applicant. That means that there were more exemption requests submitted and evaluated than delegated acts adopted.

The number of exemption requests has increased over the years. One reason is that exemptions in several entries had to be more specific, which creates technical complexity and requires a higher level of detail (see also Chapter 2.2.3). The other reason is that different expiry dates for EEE categories related to one exemption entry increases further the number of entries.

The number of pages for exemptions has also increased over the years. In 2003, there was only one annex with one page. In 2011, two annexes were adopted and the number of pages increased to six. In 2022, the list of exemptions ran to 18 pages, with some listed exemptions having already expired.

The number of exemption requests with decisions pending has accumulated over the years. By December 2022, over 60 exemption requests were pending, most being requests to renew existing exemptions.

Figure 7 gives an overview of the regulatory costs associated with the RoHS Directive.

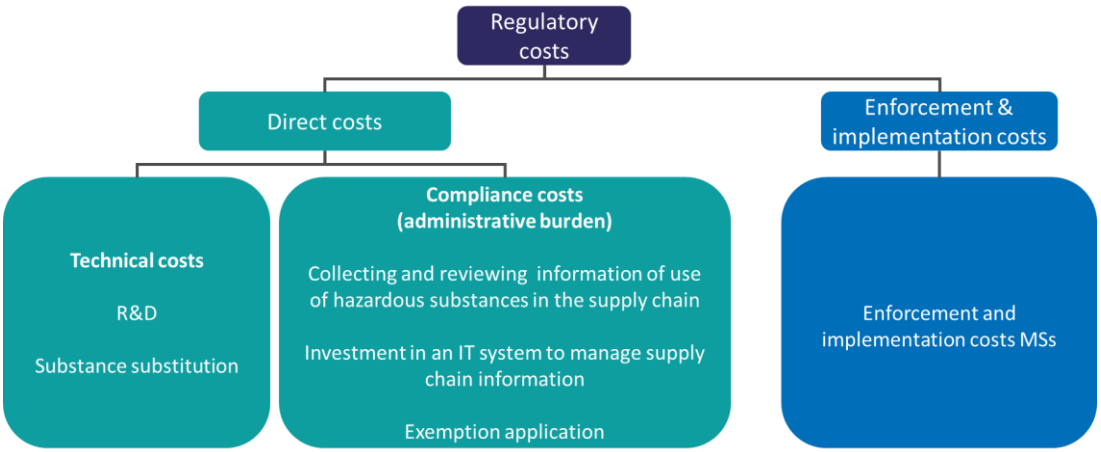

Figure 7: Overview of regulatory costs for the RoHS Directive (Source: evaluation study)

Conclusions

Although the costs and benefits cannot be quantified in monetary terms, the benefits in terms of improved wellbeing or market efficiencies can be assumed to be of higher value than the compliance and implementation costs. The costs for industry in complying with the RoHS Directive are expected to be partly offset by the economic benefits. This applies especially to the costs spread over more than 20 years in which a directive has

[93] Average costs for the years 2017-2022; the costs for external contracts fluctuate significantly over years depending on the number of requests.

been in place. Prioritising a healthy environment and good public health plays a key role in achieving a more sustainable industry. According to the Evaluation Study, stakeholders also generally agreed that the costs of the Directive were justified. Annex IV gives an overview of the estimated costs and benefits of the Directive.

4.1.6 The exemption process is not sufficiently transparent and efficient

The evaluation process concluded that certain provisions on exemptions to the Directive (Article 5, Annexes III and IV) lack transparency, efficiency and internal coherence.

On the issue of internal coherence, some stakeholders stated that they have found gaps, contradictions, overlaps or missing links within the Directive. On closer examination of these statements, it appears that it is rather a question of understanding and unclear wording, which leads to different interpretations by stakeholders. Some of the issues raised do not concern the exemption process and they are tackled in point 4.1.9.

Many stakeholders identified the exemption procedure as an area in need of improvement. They highlighted the need to:

- improve the transparency and predictability of the exemption process;
- reduce the length of the process to evaluate and grant exemptions;
- increase the validity period of exemptions and the length of transition periods.

Exemption process

By running targeted surveys and interviews, the evaluation study ascertained that the Directive's main issue of transparency and predictability concerns the lack of clarity and/or guidance on the methodologies to use for the exemption procedure.

The Commission's RoHS website (section 'Implementation')[94] provides information about the procedure and the timeframe of the exemption process. It includes a guidance document published in 2012 and the application form to request an exemption to guide stakeholders on the process and in planning any exemption request.

Since 2011, all applications for an exemption must contain the elements described in Annex V. However, the evaluation found that many applications contained only superficial or outdated information on these points (for example, life cycle assessments not in line with official standards), indicating the need to clarify and update these points.

The Commission published an exemption evaluation methodology based on Article 5(1)(a) of the RoHS Directive in November 2020[95]. However, to date, no official EU guidance documents have been adopted to explain the methodology to use when making Article 5(1)(a) applications.

It could not be confirmed that obliging economic operators to justify their request for an exemption in a regular term encourages the substitution of hazardous substances in EEE (see 4.1.1).

[94] https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

[95] Study underpinning the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15) – Chapter A.10.0 Exemption Methodology https://op.europa.eu/o/opportal-service/download-handler?identifier=ce50dc9c-6c19-11eb-aeb5-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.

This assessment also found that some applications repeated the same arguments and time periods needed to make the substitution as used in previous applications, even many years later. This can significantly hamper substitution and undermine other efforts to substitute hazardous substances. With regular reviews, it is important not to start from the beginning and not to re-evaluate the same arguments made in previous applications.

In line with the Better Regulation guidelines, and in addition to the consultation phase in the technical exemption assessment, the Commission publishes the draft delegated acts for feedback for four weeks on the Have Your Say website[96].

In addition to the need to improve the transparency of the exemption process itself, three stakeholders mentioned that it is **difficult to track changes to exempt applications and the publication of new, reformulated, and deleted exemptions**. To date, the current and consolidated version of the RoHS Directive including the annexes is available online via EurLex and on the Commission's RoHS website. The European Commission also publishes frequent updates to the list of RoHS exemptions with the validity period and the related rolling plan[97]. While this list does not have any legal status, it assists stakeholders in tracking exemption changes and the validity of exemptions for which a renewal has been requested. Stakeholders can also subscribe to platforms[98] run by the consultants assisting the Commission with exemption evaluations, which publish regular updates on new studies and consultations. These platforms are project-related and depend on the consultants commissioned.

Criteria for exemptions

Stakeholders felt that Article 5(1)(a), which lays down provisions on the criteria for granting, renewing or revoking exemptions, lacked clarity.

One example provided by a Member State competent authority was whether a socio-economic assessment is a 'set' part of the methodology to be applied under Article 5(1)(a) of the RoHS Directive. On this point, one business association stated that according to the current interpretation of the RoHS Directive, it is not possible to grant an exemption based on additional factors mentioned in Article 5(1), such as the availability of substitutes and the results of a socioeconomic assessment; these elements should become set criteria under the Article 5(1) RoHS methodology. Another business association indicated the need for a clear socioeconomic assessment under Article 5(1) and suggested seeking the expertise of the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) under the REACH Regulation in the RoHS socio-economic assessment.

On the third criterion[99] in Article 5(1)(a), stakeholders indicated the need for the process and methodology for the decision on exemption applications to clearly set out how to quantify and evaluate the 'total environmental and human health benefits of an innovative new technology'. Clear guidance on how to quantify and evaluate the total

96 https://ec.europa.eu/info/law/better-regulation/have-your-say_en

97 European Commission, Implementation of the RoHS Directive, https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en.

98 The Oeko-Institut 'RoHS evaluations' platform enables stakeholders to register for notifications on studies and consultations, see: https://rohs.exemptions.oeko.info/registration.

99 *The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.*

environmental and human health benefits would reduce the costs to industry in drafting exemption applications.

The Commission published a guidance document for RoHS exemption requests on its website[100], where the criteria are further interpreted. However, it seems that for stakeholders not all questions are answered.

Duration of process

Several stakeholders pointed out that the time required to evaluate and grant an exemption has increased from 12-18 months in 2006 to 3 years or more in 2020 (they indicated up to 40 months). The average time it takes to evaluate exemptions and run the decision process to amend the annexes is over 24 months (status December 2022).

The stakeholders who raised this point explained that, in their view, excessively long timeframes for evaluation puts significant legal and planning uncertainty on European companies, and this has an impact on their competitiveness.

The timeframe for making an exemption decision depends on several factors. One factor is that changes on exemptions must be integrated in the annexes by adopting individual delegated directives. This means that every change to an exemption requires a full decision-making process to adopt a delegated directive. These administrative requirements can multiply the workload and increase the length of the process.

Another factor is related to the resources available for the exemption process. For the Commission, resources are needed to manage and evaluate exemptions and manage the process of preparing, consulting on and adopting the delegated act. For the applicant, it is crucial to have sufficient resources to put together a quality application and communicate during the clarification and consultation phase. Especially where specialised technologies are covered by an exemption, the contributions made by other stakeholders (e.g. users of alternative technology) are essential to verify claims in the application. If sufficient resources are not available, the process can take longer as it is harder to obtain the information needed to make a balanced assessment. In fact, the trend observed in recent studies (e.g. under Pack 26[101]) is that fewer stakeholders are now contributing to exemption evaluations, which could be related to a high workload.

Another issue is linked to the fact that different categories and maximum exemption durations are specified for exemptions from different EEE categories. This results in different expiry dates for the same material or technical application[102], which require individual applications and evaluations (increasing the administrative costs). This approach results in more entries, making the exemptions more complicated and less comprehensible for stakeholders and enforcement authorities alike. Lastly, this approach

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100 https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

101 Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of creatinine and blood urea nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26)

102 For example, lead in copper alloy covered by exemption 6(c) in Annex III has three different expiry dates.

ties up more resources on each side, with limited effectiveness, and it can delay other decision-making processes.

Validity and transition periods

Under Article 5(2) of the RoHS Directive, exemption entries are **valid** for up to five or seven years, depending on their EEE category listed in Annex I. For example, medical devices (category 8), which often take a long time to develop, test and validate and have a longer lifetime than other EEE, may be valid for up to seven years. Applicants often request exemptions for a maximum validity period, but do not always substantiate their request.

Stakeholders indicated that longer validity periods should be granted for substances/products when substitutes will be available in the short-term. Although categories 8 and 9 already have longer validity periods of up to seven years, the industry is in favour of longer validity periods due to the elaborate process of product checks and validations before these products can be approved for the market.

Under Article 5(6) of the RoHS Directive, if an application for renewal is rejected or an exemption is revoked, the **transition period** must be set at between 12 and 18 months. In past technical assessments of exemption requests, some technical applications were found to no longer require an exemption, but a transition period of 12 months still had to be included in the decision. However, other technical assessments found that for technical applications that no longer meet the criteria in Article 5(1)(a), a transition period of 18 months would still have considerable socio-economic impacts as it takes longer than this to adapt complex supply chains. Also, where it is foreseeable that the exemption criteria will no longer be met at a specific date, beyond 18 months, the Commission must grant the exemption and enable stakeholders to re-apply for the exemption. The new application must be evaluated again, which takes on average 12 months. These limitations can lead to more administrative work, longer validity periods than justified and reduces the predictability of decisions on exemptions for stakeholders.

4.1.7 The substance restriction process is not sufficiently transparent and efficient

The evaluation process indicated that the process to review and amend the list of restricted substances in Annex II is not sufficiently transparent or predictable for stakeholders.

Article 6, which lays down provisions for reviewing and amending the list of restricted substances, contains the procedural requirement that any amendments of Annex II should be periodically assessed, either by the Commission at its own initiative or following a proposal submitted by a Member State. The Commission must also consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.

Although no official guidance has been adopted, a practical guidance for the substance restriction methodology based on RoHS Article 6 was prepared for the Commission as part of a study. This guidance was published in February 2021[103].

[103] Study underpinning the review of the list of restricted substances and assessing a new exemption request under RoHS 2 (Pack 15) – Chapter A.1.0 Methodology for Identification and Assessment of Substances for Inclusion in the list of restricted substances https://op.europa.eu/o/opportal-

The last review of new substances covered by Annex II was initiated in 2015 and a technical report published in February 2021. Seven substances or substance groups were evaluated, with no delegated act yet adopted based on Article 6(3). An informal working group including private-sector stakeholders was created to facilitate information exchange between stakeholders and the Commission[104]. The process included four consultation rounds with stakeholders and three stakeholder meetings. As for the preparation of all delegated acts, the Member States expert group was also consulted[105].

Several industry stakeholders are of the opinion that the methodology for reviewing the list of restricted substances under Article 6 should adopt elements of the methodology for identifying and restricting substances under the REACH Regulation, such as the socioeconomic assessment. It should also take account of the expertise of the SEAC and RAC. In line with the 'one substance, one assessment' principle in the framework of the chemicals strategy for sustainability, the Commission sees potential to create synergies with existing procedures regulating hazardous substances and to improve coherence between different pieces of legislation.

4.1.8 Lack of clarity and adaptation provisions to reflect latest developments

Stakeholders in the evaluation process often mentioned the need to clarify the terms and procedures and to issue more guidance documents. This includes updating existing guidance documents, since the current 'Frequently Asked Questions' document was produced in 2012[106].

Examples include the question as to whether lamps come under category 5 'lighting equipment' or under the EEE category of the final product, and questions on the scope of the Directive. Stakeholders had many questions regarding the meaning of 'large-scale applications' within the scope exclusions in Article 2(4), with some aspects explained in the FAQ document.

Some stakeholders asked for clarification of radio frequency identification (RFID) applications. RFID is typically described as a small chip (or tag), which can store information digitally and be attached to a wide range of products. The Commission answered the question regarding scope, whether the RoHS requirements should apply to the RFID only or also to related article, in the current set of FAQ. Stakeholders may still require further clarification as the market for RFID tags has expanded in recent years.

Currently, Article 2(4)(i) of the RoHS Directive specifies that the Directive must not apply to photovoltaic panels (PVP) intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a specified location to produce solar energy for public, commercial, industrial and residential applications. This exclusion does not apply to incorporated parts, e.g. pocket calculators, and it should help achieve the aim to increase the share of renewable energy in energy production.

However, there are some arguments in favour of reviewing this scope exclusion. First, the installation of PVP has continued to rise strongly. Second, the vast majority of PVP

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service/download-handler?identifier=ce50dc9c-6c19-11eb-aeb5-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=.

104 Expert group E03063 https://intragate.ec.europa.eu/regexpback/screen/expert-groups/details?groupId=3063.

105 Expert group E02810 https://intragate.ec.europa.eu/regexpback/screen/expert-groups/details?groupId=2810.

106 https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en

technologies currently installed (Crystalline silicon, cadmium telluride and perovskite) are reliant on applications that require the use of lead and/or cadmium in concentrations higher than the limits set in Annex II to the RoHS Directive.

The waste management of these PVP is becoming an increasingly pressing concern. PVPs have been included in the scope of the WEEE Directive since 2012 and are subject to its requirements. This includes the provisions on separate collection, extended producer responsibility and treatment.

The challenge for this exclusion is to protect human health and the environment from hazardous substances that modern PVP contain, while not significantly restricting the installation and development of new solar cells in Europe and enabling a fast transition to a fossil fuel free energy sector.

4.1.9 Lack of coherence (consistency) with other related pieces of legislation and policy goals

EU legislation does not function in isolation. It interacts with other areas of EU action and the RoHS Directive is no exception. The RoHS Directive makes explicit links and references to other pieces of legislation and vice versa, and the practical effects of the Directive influence the functioning or effectiveness of other legislation, and vice versa.

86% of respondents (N=74) under the OPC indicated that there was an issue of 'external coherence', i.e. coherence (consistency) between the RoHS and related legislation. 8 out of 15 respondent Member States also indicated an issue of external coherence. The regulatory mapping and subsequent consultation activities carried out as part of the evaluation study found that at least 15 EU legislative measures are directly related to the RoHS Directive[107].

The main issue of the RoHS Directive's external coherence was found to be the overlap between the substance restrictions laid down in the RoHS and the substance restrictions laid down in Regulation (EC) No 1907/2006 ('REACH Regulation'), by Directive 2009/125/EC ('Ecodesign Directive') and Regulation (EU) 2019/1021 ('POPs Regulation').

The above-mentioned pieces of legislation contain mechanisms to restrict the presence of certain substances that could also affect EEE. The mechanisms can differ, which complicates the issue, and can create confusion for stakeholders. The Commission is coordinating these different mechanisms and their outcome to improve external coherence between those pieces of legislation. For example, the Commission published a common understanding paper in 2014 on managing regulatory action on the same chemical substances under REACH and the RoHS Directive[108].

The maximum concentrations of substances to be tolerated in EEE have not been changed since they were introduced in the RoHS Directive. However, technical and scientific progress has resulted in changes in the concentration limits for some of these substances in other chemicals legislation such as REACH or POPs.

For example, Annex I to the POPs Regulation restricts, among others, the placing on the market of articles containing more than 500 mg/kg PBDE. However, EEE under the

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[107] See Appendix IV to the evaluation study available at https://data.europa.eu/doi/10.2779/89335.

[108] European Commission, REACH and Directive 2011/65/EU (RoHS) a common understanding Ref. Ares(2014)2334574 14/07/2014.

scope of the RoHS Directive is excluded from this restriction. The RoHS Directive allows up to 1000 mg/kg PBDE in homogenous material in EEE. However, PBDE is no longer intentionally added to EEE material above 500 mg/kg, which is suggested by the fact that no RoHS exemption covers new EEE applications. The main use of PBDE as a flame retardant requires considerably more than 1000 mg/kg.

It could be argued that PBDE in EEE coming from recycled WEEE streams and residual concentrations between 500-1000 mg/kg may still be relevant for EEE. However, under the POP Regulation it was shown that maximum concentration levels of PBDE in waste can be lowered to 500 mg/kg and, under certain conditions, even lower in future[109]. That means there might be no longer a need for the concentration range between the POP concentration level of 500 mg/kg and the RoHS concentration level of 1000 mg/kg.

Reducing the concentration limits set in Annex II to the RoHS Directive would be in line with the EU chemicals strategy for sustainability towards a toxic-free environment. Doing so would also increase coherence between both pieces of legislation.

There are other aspects of inconsistency between legislation too. For example, the POPs Regulation restricts the substance hexabromobiphenyl without any maximum concentration level. This substance is part of the group of polybrominated biphenyls (PBB), which is restricted by the RoHS Directive, which sets a maximum limit of 1000 mg/kg in homogenous material.

On the links between RoHS and REACH, REACH established mechanisms that restrict the use and placing on the market of specified substances in articles, including EEE. The most relevant mechanisms to this end are 'restrictions' (Title VIII, Annex XVII) and 'authorisations' (Title VII, Annex XIV). Some entries under Annex XVII of REACH contain exemptions for articles in the scope of the RoHS Directive, such as the entries for lead[110], OctaBDE[111] and DecaBDE[112] and the listed phthalates[113]. Currently, RoHS and REACH both contain provisions regulating the use of substances listed in Table 3.

Table 3: Overview of substances covered both by REACH and RoHS (Source: evaluation study)

Substance	REACH
Lead	Entry 63 under Annex XVII Entries 10, 11 and 12 under Annex XIV (Lead compounds)
Mercury	Entries 18 and 18a under Annex XVII
Cadmium	Entry 23 under Annex XVII
Hexavalent chromium	Entry 47 under Annex XVII Entries 16-22 and 28-31 under Annex XIV (Chromium-(VI) compounds)
PBB	Entry 8 under Annex XVII
PBDE	Entry 67 under Annex XVII (DecaBDE)[114] Entry 45 under Annex XVII (OctaBDE)

[109] OJ L 317, 9.12.2022, p. 24-31 - Regulation (EU) 2022/2400 amending Annexes IV and V to POPs https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2400.
[110] Annex XVII REACH, entry 63, par. 8, sub k.
[111] Annex XVII of REACH entry 45 paragraph 3.
[112] Annex XVII REACH, entry 67, par 4 sub d.
[113] Annex XVII REACH, entry 51, par 4 sub h.
[114] This entry is expected to be removed after the listing of DecaBDE under Annex I to Regulation (EU) 2019/1021 (POPs Regulation).

Substance	REACH
DEHP	Entry 4 under Annex XIV and Entry 51 under Annex XVII
BBP	Entry 5 under Annex XIV and Entry 51 under Annex XVII
DBP	Entry 6 under Annex XIV and Entry 51 under Annex XVII
DIBP	Entry 7 under Annex XIV and Entry 51 under Annex XVII
Substances listed in Appendix 12 to REACH: Cadmium and its compounds Chromium-(VI) compounds Lead and its compounds	Entry 72 under Annex XVII

Therefore, the main issue raised by stakeholders regarding coherence between the RoHS Directive and the REACH Regulation concerns the perception that these two pieces of legislation amount to double regulation of substances in EEE[115]. A considerable number of stakeholders (n=66/N=101), mainly businesses but also some Member States, indicated that restricting the same substances under both the RoHS and REACH directives creates legal uncertainty. Stakeholders indicated that restrictions of a substance under RoHS and REACH may differ in terms of:

- maximum concentration values;
- scope of the legislation;
- exemptions and their expiry dates;
- differences in spare parts;
- product information requirements; and
- documentation requirements.

Industry stakeholders provided the following specific examples of perceived incoherence under the OPC of the evaluation:

- Entry 72 of Annex XVII references Appendix 12, which includes concentration levels in restrictions of cadmium, hexavalent chromium and lead that are lower than the levels set under the RoHS. Certain textile items such as fabric straps for electronic fitness monitors, watches and similar devices are covered by both REACH and RoHS. Some stakeholders stated that this creates an unintentional overlap and contradiction in the requirements. However, it is unclear how the different maximum concentration values correspond to each other and to what extent this affects other stakeholders.
- Entry 51 'phthalates' of Annex XVII states that EEE is excluded from the scope of RoHS but spare parts, components and supplied parts might not be EEE and thus they are restricted under REACH to a maximum concentration of 0.1% by weight of the plasticised material in the article. However, spare parts are not covered by the RoHS restrictions and excluded under Article 4(4) and 4(5). The relevance of this problem is unclear though.

Stakeholders indicated that these differences may give rise to legal uncertainty. This may also result in problems in enforcing the provisions. However, it seems that these

[115] An 'article' is defined under REACH as an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. This definition also covers EEE.

inconsistencies only apply to some stakeholders, and that to resolve the issue it would be sufficient to issue a clarification.

As for the potential overlap between the RoHS and the Ecodesign Directive, close to 40% of OPC respondents (n=86/N=101) indicated that there are unnecessary overlaps, gaps and contradictions between the RoHS and the Ecodesign Directive. 4 of the 15 respondent Member States[116] made the same observation.

Despite the relatively high percentage of stakeholders mentioning coherence issues, only a few provided specific examples. A reason for the high share of questions on coherence might be the increasing electrification of many devices (e.g. internet of things).

In addition, a number of stakeholders under the OPC highlighted the connection and need for future coherence between the RoHS and the EU's circular economy policy, in particular with the 2020 circular economy action plan (CEAP) and the chemicals strategy for sustainability. The RoHS has considerable links to EU policy on the circular economy, as it facilitates sound and safe WEEE treatment and recycling and reduces the scope to keep circulating hazardous substances in products. Exemptions under the RoHS Directive enable the use of certain spare parts and the reuse of certain recovered spare parts containing restricted substances to facilitate the repair of EEE.

In relation to coherence to other related initiatives, terms such as 'closed-loop return systems' used in the Directive should be aligned with other CEAP initiatives. Another example would be suggestion to flag the presence of hazardous substances in EEE due to an exemption in a future digital product passport.

4.2 How did the RoHS Directive make a difference?

Overall response:

The RoHS Directive yields benefits for environmental protection, human health and for the internal market. While similar levels of environmental and health protection could well have been achieved at national level, the full added value of the RoHS Directive is in facilitating the internal market.

Harmonising rules to ease the free exchange of goods across the EU were cited as a reason for proposing legislation on this subject in 2000, since several Member States had adopted or developed legislation on hazardous substances in electronics. The same level of harmonisation could not have been achieved without the RoHS Directive. The Directive also provides clear EU added value in its influence on third countries, , which would not have happened without harmonisation at EU level.

This section evaluates the EU added value of the Directive by exploring whether the objectives could have 'been better achieved at EU level' than could be reasonably expected by taking action at national level. The key points to assess are whether the Directive produced results beyond what would have been achieved by Member States acting alone and the Directive's added value for individuals and businesses in the EU.

[116] Norway also indicated unnecessary overlaps, gaps and contradictions exist between the RoHS and the Ecodesign Directive.

The key aspect where the RoHS Directive has made a difference, compared to similar action taken at Member State level, **is in facilitating the internal market.**

In particular, since it entered into force, the RoHS Directive has improved the consistency of national conditions and resolved the fragmentation in the regulation of hazardous substance restrictions regarding EEE in the EU. National legislation on EEE and WEEE was in place or in preparation when the RoHS Directive was implemented in the early 2000s. Legislation governing WEEE was either planned or already in place in more than half of the EU's 15 Member States and for six out of 15 Member States for hazardous substances in EEE, including lead and cadmium[117].

In the absence of a harmonised regulation at EU level, this legislation would have most likely remained in place and potentially even more countries could have passed similar legislation. One can assume that national-level legislation would have contributed to the protection of human health and the environment by setting national standards. However, the examples cited above neither covered the same products or substances as the RoHS Directive, nor did they set equal standards. Therefore, national legislation would have led to varying levels of protection. Given the constraints in resources in other EU Member States, it is reasonable to assume that some countries would not have adopted or enforced RoHS-like legislation fully. This in turn could have had negative effects on protection levels. Setting EU-wide standards as the RoHS Directive does solves this issue.

The inconsistency of national legislation in terms of scope (both products and substances) and limits highlights that the added value of the RoHS Directive is more clear cut in facilitating the internal market. With regards to the internal market, the proposal for RoHS legislation noted that '*diverging requirements on the phasing-out of specific substances could have implications on trade in electrical and electronic equipment*.'[118] As the distribution of EEE does not happen in one state, it can be assumed that, without harmonised provisions, companies would face immensely higher costs to comply with all national laws.

The EU RoHS Directive contributed to the functioning of the internal market as it sets **harmonised substance restrictions standards across countries.** It was **assessed as overwhelmingly positive in providing EU added value,** in particular:

- the RoHS Directive creates a large market for the same EEE;
- the RoHS Directive simplifies the trade of EEE in the EU;
- the RoHS Directive supports innovation and the use of hazardous substance-free products.

4.2.1 The RoHS Directive has a global impact

The RoHS Directive influenced considerably the development of regulatory frameworks regarding hazardous substances in EEE in third countries. Several stakeholders and business associations consulted for the study have confirmed that this is still valid.

According to literature and statements by business associations, the 2002 adoption of RoHS has '*led to a global change in the design of electronic products, as multinational*

[117] Austria, Germany, Finland, Denmark, Sweden and the Netherlands.

[118] Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment, COM/2000/347/Final.

companies who sell into the EU's market often opted to use the EU's stringent standards across their global production to save production costs'[119]. The first harmonised standard under RoHS became the basis for the international standard. With the current European harmonised standard EN IEC 63000:2018 governing technical documentation, the new standard removed some specific wording used in the previous EU RoHS Directive.

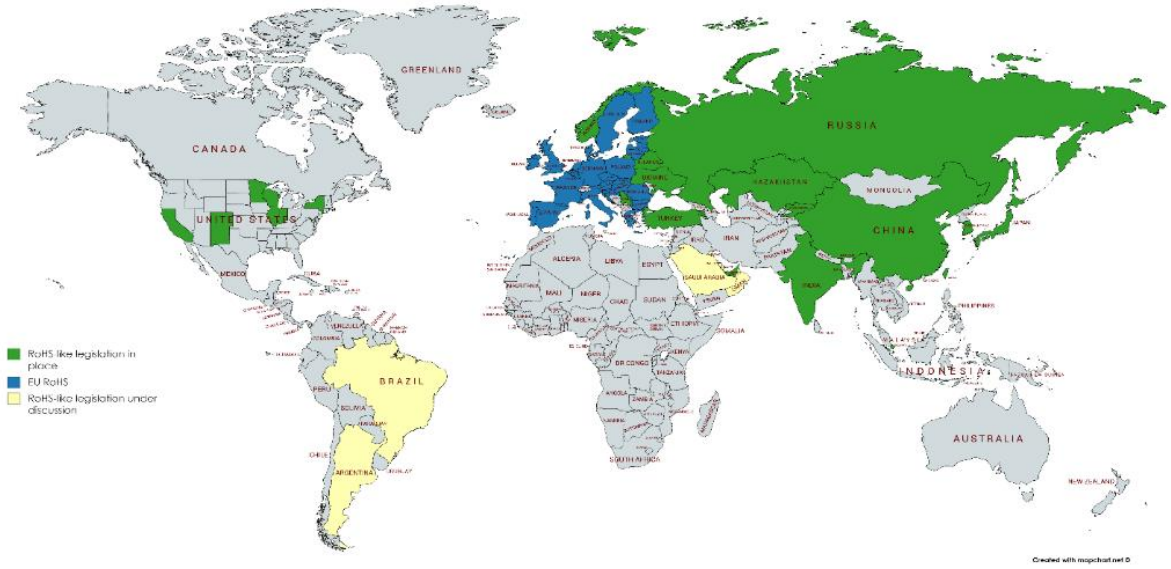


Figure 8: RoHS Directive and RoHS-like legislation in the world (Source: evaluation study)[120]

A considerable number of non-EU countries[121] have adopted legislation that is highly similar to RoHS. These are shown in green in Figure 8. The number of third countries with RoHS-like legislation is likely to increase in the near future, as draft legislation is being discussed in more jurisdictions, including the Gulf Cooperation Council member countries[122], Brazil and Argentina. These countries are highlighted in yellow in the map.

Although the RoHS Directive does not restrict the export of EEE, it is assumed that exports of WEEE placed on the European market, or new EEE with a reduced volume of hazardous substances due to the substance restrictions under RoHS has a major impact. In 2019, the EU Member States exported 119 279 tonnes of WEEE containing hazardous substances and 14 557 tonnes of non-hazardous WEEE. Since secondary (treated) material streams such as non-ferrous metals make up almost 1.9 m tonnes of exports[123], and illegally exported waste is not included in these figures, the impact goes beyond the WEEE material stream.

4.3 Is the RoHS Directive still relevant?

Overall response:

119 *The Brussels effect: how the European Union rules the world*, Anu Bradford, 2020.
120 Illustration based on *The Brussels Effect*, Anu Bradford, 2020.
121 According to DigitalEurope and JBCE, RoHS was taken up in about 40 jurisdictions outside the EU, https://www.digitaleurope.org/wp/wp-content/uploads/2020/06/DIGITALEUROPE-initial-views-on-the-revision-of-the-EU-RoHS-Directive.pdf.
122 Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, and Oman.
123 Eurostat – data code ENV_WASTRDMP – 2020 / export / non-ferrous metal / EU 27.

The EU objectives in the context of the RoHS Directive are still relevant and are expected to remain so for the foreseeable future. These include the protection of human health and the environment from hazardous substances in waste EEE.

The objectives of the RoHS Directive correspond to a large extent to the current and future needs of the EU and the relevance of the Directive remains high. Some aspects could be identified that can have a negative impact on the Directive's future relevance, in particular the slow adaptation of restrictions and exemptions and the limited degree of flexibility to respond to new needs.

This section covers the RoHS Directive's suitability to respond to changes and challenges in the EEE sector regarding the current hazardous substance restrictions and possible future restrictions, and to current and foreseeable challenges linked to the treatment of WEEE. The **initial needs that led to the formulation of the Directive remain valid** and **the Directive still corresponds to these needs to a high extent.**

4.3.1 Identification of needs

The two key needs linked to the Directive's objectives as outlined in Article 1 are to reduce and prevent the content of harmful substances in EEE to achieve the protection of human health and protection of the environment. Directly linked to these two needs – and to some extent necessary to fulfil them – are the requisites:

- for a sound recovery and disposal of waste EEE;
- to take into account technological and scientific progress; and
- to ensure a well-functioning internal market.

The need for a sound recovery and disposal of waste -EEE is covered in detail in the WEEE Directive (see 2.2 or 4.1.3.). However, harmful substances require certain treatment activities to avoid exposure for workers and to avoid releasing emissions into the environment. Reducing the volume of harmful substances facilitates the sound recovery and disposal of WEEE to achieve a high recovery rate.

New developments in product design and changes in manufacturing processes lead to constant developments in the materials and substances used. It is therefore essential that the RoHS Directive is equipped with a process that **takes account of technological progress** and responds to it accordingly. On the one hand, this may involve new evidence that certain substances should be classified as hazardous, and the need to drive technological progress towards substituting these substances. On the other hand, in the exemption process, technological developments should also be assessed from the point of view of whether use of the substance offers considerable benefits that justify an exemption. New developments in trade via e-commerce are also having an impact, in particular on implementation and market surveillance.

All these factors are put into the context of the increasing use of EEE in people's daily lives. The volume of electrical and electronic equipment put on the market in the EU rose from 7.6 million tonnes in 2012 to a peak of 12.4 million tonnes in 2020 (see Figure 3)[124]. Though the RoHS Directive has banned many substances and contributed to the phase-out of those substances in EEE, it can be assumed that electrical appliances still contain

[124] Eurostat (env_waseleeos) and Eurostat (env_waselee).

hazardous substances that would need to be tackled to protect human health and the environment. This includes looking at the stages of collection, recovery and disposal at end -of -life of these appliances.

4.3.2 Correspondence between the Directive's original objectives and the current and future environment, health and internal market needs

Protecting human health and the environment and safeguarding the functioning of the internal market are principles enshrined in the Treaties of the European Union and they remain as valid as ever. Collecting stakeholders' views on the correspondence between the Directive's original objectives, how well they reflected and, more importantly, whether they still reflect, current and future environmental, technical, economic, and social conditions and needs, was one of the targets of the OPC. In summary, the consultation results on the **need** for EU legislation are as follows:

- **protect human health**: 73% (strongly) agree; 27% (strongly) disagree (N=101);
- **protect the environment**: 75% (strongly) agree; 25% (strongly) disagree (N=101).

These results are in line with the results from the Member State consultation, which found the majority were in strong agreement with these needs.

The OPC results for the **internal market** were slightly more nuanced. 65% of respondents agreed and 35% disagreed (N=101). However, the majority of OPC respondents and all Member States (except one) affirmed the need for EU legislation on hazardous substances in EEE to ensure a well-functioning EU internal market.

4.3.3 Aspects that may impact the RoHS Directive's relevance

The majority of private-sector stakeholders (n=57/N=101) did not see the need to change the **list of restricted substances** in Annex II to the RoHS Directive. Several respondents saw the need to either list new substances, de-list existing substances or change the concentration values of the substances that are currently restricted. The feedback obtained from the Member State consultation showed that a large majority of respondents considered it necessary to update of the list of substances.

New substances on the market or new identified hazards of substances (e.g. endocrine disruption or persistence) can pose risks to human health and the environment. A regular and efficient update of the list of restricted substances to tackle such risks would ensure that the Directive remains relevant.

Given the increase in mechanical waste treatment as part of a **circular economy**, workers can be exposed to increasing levels of chemicals originating from WEEE. Depending on the lifetime of the EEE, the product may have been placed on the market before the restrictions came into force (13 years for large household appliances (2005) or 30 years for photovoltaic panels), which can increase the risk for workers. The timeline for restrictions coming into effect lags behind the potential risks, with the risk that the information about the presence of hazardous substances in WEEE gets lost as time passes.

Another timeframe-related challenge is that higher ambition for recycling can interfere with contaminated waste streams, where hazardous substances are not restricted at that time, for example due to a lack of efficiency of the process. However, horizontal chemical legislation such as REACH can cover restrictions for EEE.

As a result of the decision taken under the Basel Convention to make all WEEE transboundary movements subject to the prior informed consent procedure, it is possible that more WEEE might be remain in and be treated within the EU in future.

Stakeholders view the **exemption process** as indispensable to meet the specifics of certain products, industries and manufacturing processes. However, deficiencies in the exemption process, in particular issues of efficiency (see 4.1.6), can have a negative influence on the relevance of the Directive. The process must strike the right balance between stringency and well-founded criteria for an exemption, the effort required to apply for an exemption and the effort required to carry out an adequate and thorough, but not too lengthy, evaluation of the application.

So far, the objective is to achieve a gradual phase-out of hazardous substances in EEE. In the past, narrowing the scope of exemptions could lead to significant savings of hazardous substances. Today there are exemption requests for low volumes of hazardous substances, for example the application for exemption 37 in Annex IV indicated less than 1 gram of lead. Other exemption requests only apply to a few manufacturers, such as exemption 41 in Annex IV requested by one manufacturer for a single specific system. Given the efficiency and the future challenges in handling more individual exemption requests, it is questionable whether the standard procedure for time-limited exemptions for such exemptions are adequate and whether the effort involved justifies the process.

By contrast, some exemptions cover many tonnes of hazardous substances, such as exemption 7(a) in Annex III for lead in high melting temperature solders covers between 150 and 9 400 tonnes of lead per year. For other exemptions, there is evidence of alternatives, but the socio-economic distortion for the market would be unacceptable for society. In these cases, an in-depth investigation could help make thorough decisions.

There are other incentives used, other than regulatory measures, to reduce the volume of hazardous substances in EEE (see also the second support study). For example, there are requirements stemming from eco fee modulation under extended producer responsibility (e.g. in France), a chemicals tax for certain chemicals in EEE (e.g. in Sweden) or voluntary agreements or requirements in the supply chain adopted by more ambitious companies to phase out hazardous substances (e.g. IBM or Hewlett-Packard).

5 CONCLUSIONS AND LESSONS LEARNED

The RoHS Directive has helped to reduce hazardous substances in EEE in the EU. Collecting quantitative and reliable data on the reduction of hazardous substances in EEE is challenging. A quantitative estimate made in the evaluation study shows that there is a total reduction of hazardous substances in EEE between 2003 and 2016, even though shortcomings in the analysis method and assumptions lead to a less robust quantitative result. The substance restrictions of the RoHS Directive alone did not lead to this reduction.

The reduction of hazardous substances in EEE has thus increased the protection of human health and the environment at different stages of the value chain (especially in production and disposal). However, providing quantitative and reliable data to prove the positive impacts between the reduction of hazardous substances and the human health / the environment is difficult.

The Directive has also contributed to the harmonisation and functioning of the internal market by providing uniform rules for the restriction of hazardous substances for

producers of EEE in the EU. These were taken over by the relevant industry sector. However, inspections by enforcement authorities suggest that some product categories have high levels of non-compliance, which can mitigate the positive effects. In addition, exchanging compliance information along the supply chain poses problems in practice.

The evaluation process also concluded that the Directive remains relevant. The need to protect human health and the environment and to contribute to the environmentally sound recovery and disposal of waste EEE by restricting of the use of hazardous substances in EEE remains relevant and will continue to be in the near future. The Directive's EU added value is also prominent, and the evidence collected during the evaluation process suggests that the same level of harmonisation could not have been achieved in the absence of the RoHS.

Nevertheless, there are aspects that work less well. Regarding innovation, the RoHS Directive prompted investments in finding substitutes for hazardous substances that in many cases led to the development of alternatives. However, industry perceives the investments associated with the inclusion of medical equipment and monitoring and control instruments in the Directive's scope as considerable due to their area of application and the comparatively long-life cycles of these product categories. In general, it was difficult to quantify the costs for stakeholders as it is not possible to disentangle the costs of compliance with the RoHS Directive and separate them from the costs of compliance with other legislation.

The evaluation process identified a need to clarify and improve the methodologies for assessing exemptions and for reviewing and amending the list of restricted substances to give stakeholders more certainty on the grounds for restricting new substances and for adopting exemptions. In addition, the methodologies should be updated to reflect technological developments and be more coherent (consistent) with other procedures under legislation governing chemicals. Increasing the robustness and efficiency of the process would help maintain stakeholder confidence in the process and ensure a high level of cooperation between all parties involved. The frequent amendments of the Annexes pose an administrative burden for authorities and stakeholders, who questioned whether a directive was the most efficient legal form.

The process also flagged the need to clarify some definitions. It may be necessary to revise the Directive's provisions on scope exclusions to ensure that the selection of EEE excluded from the Directive's scope is sufficiently clear and updated in line with the latest technical and economic developments.

Regarding external coherence, the process identified overlaps between the substance restrictions laid out in the RoHS Directive and similar provisions laid down by the Ecodesign Directive or the REACH and POPs Regulation. For example, overlaps or incoherencies in the scope, definitions, limit values or mechanisms to deviate from the restrictions may give rise to a fragmented regulatory landscape and, in some cases, to a lack of clarity and certainty for Member State authorities and industry. However, many perceived coherence issues can find an answer in legislative and non-legislative documents, even if these are not formulated in a sufficiently comprehensible and transparent manner and the concerns expressed often relate only to individual areas without their broader impact being substantiated. Finally, the RoHS Directive had remarkable influence beyond European Union borders, with similar laws adopted in approximately other 40 jurisdictions around the world. The Directive is considered to be

a global benchmark for reducing toxic substances in EEE, with potentially significant environmental and health benefits worldwide.

5.1 Lessons learned

Overall, the RoHS Directive functions well. The restrictions have been implemented and have contributed to a reduction in the volume in hazardous substances in EEE. However, most conclusions were made on qualitative assessments. There is a need to introduce indicators, which are reproducible and can measure progress and success of the RoHS Directive.

Some aspects in the Directive need to be updated to improve coherence and to reflect technical developments on the market. There is a need to inform stakeholders and to provide guidance, in particular on the scope of the Directive or the exemption procedure.

The evaluation highlighted that the processes for deciding on exemptions and updating substance restrictions under the RoHS Directive are to some extent lacking transparency and efficiency and can be improved in terms of scientific robustness. In addition, revising the Directive in the future can be an opportunity to simplify, to streamline with other legislations and to align with other policy objectives.

6 ANNEX I: PROCEDURAL INFORMATION

Lead DGs and internal references

The evaluation (PLAN/2018/3000) has been coordinated by the European Commission's Directorate-General (DG) for Environment, supported by an interservice steering group (ISG) involving representatives of DG Communications Networks, Content and Technology, DG Internal Market, Industry, Entrepreneurship and SMEs, DG Energy, DG Justice and Consumers, DG Research and Innovation, the Joint Research Centre, DG Taxation and Customs Union, DG Trade, DG Health and Food Safety, the Legal Service and the Secretariat-General. The group steered and monitored the evaluation's progress and ensured that it met the necessary standards for quality, impartiality and usefulness.

Organisation and timing

The Commission published a roadmap[125] for the evaluation of the RoHS Directive on 14 September 2018; feedback on this roadmap was received until 12 October 2018.

The consultation strategy was published jointly with the publication of the RoHS Directive's evaluation roadmap, mentioned above. The strategy set out a number of consultation activities, comprising a public consultation and targeted consultation in the form of interviews and surveys. While a detailed consultation synopsis is provided in Annex V, a brief explanation of consultation activities follows here.

To maximise stakeholder engagement, the evaluation followed the targeted consultation approach. In this context, the OPC was launched on 13 September 2019 and remained open for 12 weeks until 6 December 2019 to obtain input on the questions examined in the report. In total, 163 responses were collected. In parallel to the OPC, an in-depth survey (questionnaire) was shared with Member State authorities involved in implementing the RoHS Directive.

Between October 2019 and March 2020, three focus groups were organised, covering the following topics: (i) assessment of the Directive's implementation and enforcement; (ii) effectiveness and efficiency – environmental and health aspects; (iii) effectiveness and efficiency – costs and benefits aspects; and (iv) external and internal coherence. In the same period, in-depth interviews were organised with stakeholders, partly as follow-up interviews to input provided via the OPC.

A workshop was held towards the end of the study, in March 2020, to present the preliminary findings of the study and provide stakeholders with another opportunity to provide their input.

To supplement input from the stakeholder consultation, a stakeholder workshop was organised in March 2020 (online, due to the COVID-19 restrictions). The workshop was attended by 125 stakeholders from public authorities, industry representatives (economic operators and their representatives at EU and national level) and other stakeholders, including NGOs and academic experts.

[125] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1891-Hazardous-substances-in-electrical- electronic-equipment-evaluation-of-restrictions_en

Exceptions to the Better Regulation guidelines

No exceptions were made to the Better Regulation guidelines[126] during this evaluation.

Evidence, sources and quality

The evaluation was supported by a study that among other things provided support on stakeholder consultation. This study was launched in March 2019 and performed by a consortium led by Ecorys[127]. The study was completed in March 2021[128].

The following key studies and reports were taken into account:

- legal acts and documents related to the Directive's implementation[129];
- studies and report related to exemption and restriction assessment[130].

7 ANNEX II. METHODOLOGY AND ANALYTICAL METHODS USED

This annex provides a brief and transparent account of the methods and sources employed during the RoHS Directive evaluation, including the limitations (e.g. data) encountered.

Central to the methodology used during the evaluation process were the evaluation questions (and sub-questions) developed on the basis of the five evaluation criteria: effectiveness, efficiency, coherence, relevance and EU added value. To gather information and data to enable a thorough analysis of the Directive's operation and progress, the following **main sources** were used by the Ecorys-led consortium who provided the support study:

- literature review
- desk and databases research
- stakeholder consultation, including interviews and targeted surveys
- focus groups
- reports by market surveillance authorities
- legal, policy and technical sources

The **analytical approach to evaluate the Directive** included:

- analysis of consultation findings
- triangulation of stakeholders' views
- qualification and quantification of costs and benefits estimates
- etc.

[126] https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

[127] Study 'Support for the evaluation of Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)' commissioned by DG Environment under the Implementing Framework contract No ENV.F.l/FRA/2014/0063.

[128]https://publications.europa.eu/en/publication-detail/-/publication/926420bc-8284-11e9-9f05-01aa75ed71a1/language-en/format-PDF.

[129] https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en#ecl-inpage-617.

[130] *See* consultant final reports published at https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en#ecl-inpage-621.

Unfortunately, data collection proved to be a significant challenge which impacted the quality of the analysis and robustness of findings. For instance:

- Data is lacking on the concentration of hazardous substances in EEE waste per category of product, and there was insufficient data available on the weight of the 'homogeneous materials' in the EEE for which the maximum concentration values are regulated.
- Availability of data is limited both for the period before and around implementation of the RoHS Directive, as well as for more recent years. It was not possible to collect precise information from the literature review or through interviews. Some interviewed stakeholders and participants in the focus groups indicated this could be due to the lack of a reliable monitoring framework in place before the first RoHS Directive (2002/95/EC) and the fact that a relevant amount of RoHS-compliant equipment placed on the market might have not yet reached end of life. Therefore, estimations had to be made.
- As regards the data on costs and benefits:
  - Companies were not able to provide a precise estimate of the percentage of turnover spent on RoHS compliance both in terms of their initial investment cost and operating expenditure. Therefore the data was not sufficient to put together an overall assessment of the costs, but sufficient to put together an estimate of the costs.
  - Companies found it easier to provide FTE estimates, the highest estimates having been provided by businesses representing EEE categories 3, 8 and 9[131].
  - The quantification of benefits was to a large extent not possible due to the lack of precise data on the reduced amount of all hazardous substances as a consequence of the RoHS Directive.

Robustness of analysis and conclusions

The input provided by stakeholders during the consultation process remained limited for some important data The data limitations outlined above put a substantial strain on the analysis. To address possible information and data gaps, after completion of the OPC, a stakeholder workshop was organised to present the initial findings and test them against a broad range of stakeholders. Triangulation of sources played a critical role in ensuring that the findings were robust. Where primary data was not available, the evaluation relied on literature and expert opinions. As a result, and on the basis of the additional input received, the evaluation was accordingly refined and, where necessary, revised. The report needs to be read with these caveats in mind – while the report cannot provide a precise assessment, the findings reflect the order of magnitude of the impacts.

[131] Annex I of the RoHS Directive lays down the 11 categories of EEE covered by this Directive, as follows: 1. Large household appliances; 2. Small household appliances; 3. IT and telecommunications equipment; 4. Consumer equipment; 5. Lighting equipment; 6. Electrical and electronic tools; 7.Toys, leisure and sports equipment; 8. Medical devices; 9. Monitoring and control instruments including industrial monitoring and control instruments; 10. Automatic dispensers; 11. Other EEE not covered by any of the categories above.

8 ANNEX III. EVALUATION MATRIX AND DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

This annex presents the evaluation matrix which served as the organising framework of the evaluation work and answers to the questions by evaluation criterion. All the evaluation criteria – effectiveness, efficiency, relevance, coherence and EU added value – are addressed in the matrix. The analysis and evidence collected via the matrix provided the main points substantiating the assessment in Section 4 – Evaluation findings.

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
Effectiveness					

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
Question 1: What have been the (quantitative and qualitative) effects of the RoHS Directive? 1.1 What have been the (quantitative and qualitative) effects of the RoHS Directive on trends in the production and trade of EEE containing hazardous substances, and the recovery and disposal of EEE waste?	Trends in the production and trade of EEE containing hazardous substances Volume of hazardous substances recovered and disposed of adequately Estimate of the proportion of EEE waste which actually causes harm to human health and the environment	There is a clear decline in trends in the use and trade of substances There is a clear trend in the volume of substances recovered and disposed of adequately	The RoHS restrictions on use of hazardous substances in EEE have contributed to reducing significantly the amount of hazardous substances put on the EU market. Such reduction is also reflected in electronic waste, as the WEEE stream will contain less hazardous substances. Consequently, waste management processes may become safer, although there is currently limited quantitative evidence to confirm this. Beyond its specific objectives to reduce hazardous substances, RoHS contributed to innovation by pushing for substitution towards reliable, non-toxic EEE and their components. By reducing the amount of hazardous substances in EEE and by allowing (under specific conditions) the reuse and repair of spare parts, the RoHS Directive also positively contributed to the objectives of the EU Circular Economy Action Plan. Finally, the Directive has paved the way for RoHS-like legislation to be developed	Evaluation staff working document (‘Evaluation SWD’) – Section 4.1 Evaluation study, pp. 46-59.	Databases Key stakeholder interviews/focus groups Targeted surveys Public consultation Relevant literature

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
1.2 Beyond the objectives of the Directive, what other significant changes, both positive and negative, could be linked to the Directive, if any?	Opinion of the stakeholders on other unexpected positive/negative changes resulting from the Directive	Positive/negative changes resulting from the Directive are identified, such as market innovation	around the world. In fact, the RoHS example is looked upon and 'imitated' by numerous countries.		
1.3 What has been the impact of the Directive outside of the EU?	Evidence/examples of positive/negative changes resulting from the Directive outside of the EU (e.g. adoption of similar legislation, with consequent economic, social and environmental impacts)	Identified positive/negative changes resulting from the Directive outside of the EU, such as the adoption of similar legislation, and related impacts			
Question 2: To what extent have the objectives of the RoHS Directive been achieved? 2.1 To what extent have manufacturers, importers, distributors and authorised representatives in the EU and its Member States met their obligations?	Opinion of the stakeholders on the level of compliance to the obligations of the Directive	Stakeholders agree that manufacturers, importers, distributors and authorised representatives in the EU and its Member States met their obligations No cases of non-compliance of EU Member States	Evidence points to different approaches to conduct market surveillance across Member States. This results in often non-comparable results regarding compliance levels. By reducing the amount of hazardous substances in EEE products placed on the market, RoHS has had a positive impact on the environment and human health in Europe and in developing countries where informal recycling processes are the norm.	Evaluation SWD – Section 4.1 Evaluation study, pp. 60-72.	Key stakeholder interviews/focus groups Targeted surveys Public consultation Reports by market

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
2.2 Has the Directive contributed to protecting human health and the environment, including via the environmentally sound recovery and disposal of waste EEE?	Opinion of the stakeholders on the contribution of the Directive to health and environmental objectives	A majority of stakeholders agree that the negative effect on human health and the environment of controlled hazardous substances in EEEs has been reduced due to the Directive	By introducing harmonised restrictions, the Directive created a level playing field for all manufacturers thus effectively contributing to the proper functioning of the internal market. Despite the difficulties presented by different approaches for enforcing and monitoring the implementation of the Directive in the Member States, it can be concluded that compliance levels are high. One key aspect has been identified as having hindered the effectiveness of the Directive: the exemption process, due to its complexity and length.		surveillance authorities
2.3 Has the Directive contributed to the proper functioning of the internal market for relevant products, establishing a level playing field for all manufacturers, independently of their origin (EU or non-EU), size, or market type (i.e. primary or secondary)?	Opinion of the stakeholders on the contribution of the Directive to the proper functioning of the internal market for relevant products Evidence that the Directive has led to the establishment of a level playing field for all manufacturers between EU Member States	Stakeholders agree that the Directive has led to the establishment of a level playing field for all manufacturer No cases of distorted competition			
2.4 Which main factors (e.g. implementation by Member States, actions by stakeholders) have	Influence of the measures of the Directive	Evidence that the measures contributed to achieving the objectives of the			

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
contributed to, or stood in the way of achieving any of the objectives of the Directive within the expected timeframe?	Degree of influence of the measures of the Directive Influence of external factors Degree of influence of external factors	Directive, consistent with intervention logic Stakeholders agree that the measures of the Directive have played an important role Evidence that external factors contributed to achieving the objectives of the Directive, consistent with the intervention logic Stakeholders agree that external factors have played a role			
Efficiency					
Question 3: What are the costs and benefits (monetary and non-monetary) associated with	RoHS 1 implemented but not RoHS 2 (social benefits or costs arise from the difference of	Stakeholders or literature identify cost differences between Member	The RoHS Directive led to wider environmental and health benefits, such as reducing damage to the environment and human health. The RoHS Directive also	Evaluation SWD – Section 4.1	Targeted survey Key stakeholder

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
the implementation of the Directive since its adoption in 2011 for the different stakeholders, economic actors in all stages of the EEE life cycle and society at large, at national and EU level? Are there significant distributional differences between Member States?	the actual and the baseline scenario) Direct benefits: Decrease of human morbidity, increase of ecosystem services, resource efficiency Indirect benefits: third-country adoption of legislation based on the RoHS Directive, and related social, environmental and/or economic benefits Stakeholder opinions on the what the benefits of the Directive are Evidence of specific examples of cost differences or congruence between Member States, with a graphic display of quantitative results where appropriate	States Stakeholders or literature identify drivers of cost differences between Member States and how these relate to the state of implementation	led to economic benefits such as increasing the level playing field for businesses in the internal market, creating legal certainty, and sometimes spurring innovation through substitution. The compliance costs of the RoHS Directive for businesses include collecting and reviewing information, gathering supply chain information, costs related to a dedicated IT system to manage all required pieces of information, and costs related to the exemption system. The technical costs for businesses include complying with the hazardous substances restrictions in their product (i.e. product development). The highest costs seem to be related to the exemption system and product development to comply with substance restrictions. As the Directive's scope widened, more investment in research and development was needed for some businesses and thus additional costs were incurred due to the increased scope of substances and EEE. The enforcement of the substance	Evaluation study, pp. 73-84.	interviews/focus groups Public consultation Relevant literature

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
	Evidence of the drivers and consequences of cost drivers between Member States		restrictions appears to be the largest cost driver. It is important to note that both businesses and Member State competent authorities found it difficult to disentangle the costs for the RoHS Directive from the costs associated with other compliance or enforcement activities related to EEE. There is not sufficient data to confidently state that there are differences among Member States.		
Question 4: To what extent are the costs justified, given the benefits the RoHS Directive has delivered?	Benefit-cost ratio Opinion of stakeholders whether the costs of the Directive are justified by the benefits delivered	Benefits exceed costs	Based on the analysis undertaken it could be concluded that benefits (especially the environmental and health benefits) of the RoHS Directive outweigh the Directive's costs (to businesses and Member State authorities). Stakeholders also generally agree that costs of the Directive are justified.	Evaluation SWD – Section 4.1Evaluation study, pp. 84-85.	Targeted survey Key stakeholder interviews/focus groups Public consultation Relevant literature
Question 5: How proportionate were the costs for different stakeholder groups?	Cost estimate broken down by source and type of economic sector involved (e.g. producers, recyclers, manufacturers and re-manufacturers, and authorities) Share of stakeholders agreeing that the costs	Varying proportion of costs relative to turnover of each respective sector The majority of stakeholders agree that the costs are justified by the	Based on the available evidence, the majority of the costs of the RoHS Directive lie with the manufacturers of electrical and electronic equipment. Furthermore, a significant cost of the RoHS Directive also lies with the competent authorities and enforcement agencies. Based on the estimates provided by businesses, there are indications that manufacturers in categories 3, 8 and 9	Evaluation SWD – Section 4.1 Evaluation study, pp. 85-88.	Targeted survey Key stakeholder interviews/focus groups

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
	are justified by the benefits	benefits	bear relatively higher costs than manufacturers in other categories.		
Question 6: How efficient has the exemption system from substance restrictions been?	Costs associated with inefficiencies from the review and exemption system (e.g. administrative burden, lack of flexibility, responsiveness) Reasons for inefficiencies in the review and exemption system Expected savings if inefficiencies were absent	High level of costs caused by review and exemption system Inefficiencies are identified	The substance restrictions exemption system has been found to be complex and inefficient in a couple of ways. Firstly, the administrative burden associated with the exemption system is seen to be significant, although there is not enough available evidence from the literature and stakeholder consultation to quantify this cost. Secondly, the process of handling exemption requests is said to be slow. These factors lead to costs for the manufacturers. A number of key areas for improvement of the exemption system have been identified by stakeholders. These areas have varying implications for compliance costs for businesses, implementation costs for the European Commission and costs to society.	Evaluation SWD – Section 4.1 Evaluation study, p. 89–92.	Targeted survey Key stakeholder interviews/focus groups Interviews Public consultation
Question 7: Is the form of the legal instrument (directive) the best fit to efficiently achieve the set objectives?	Description of other possible types of legal instruments that could have achieved the same result Description of the	Identification of other types of instruments and their relative efficiency	There is not a clear conclusion on whether another form of legal instrument would be a better fit to achieve the objectives under the Directive. There are good arguments that a regulation could be more efficient than a directive in restricting hazardous substances in EEE because an EU	Evaluation SWD – Section 4.1 Evaluation study,	Targeted survey Key stakeholder interviews/focus groups

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
	likelihood of other instruments achieving the same result or better than a directive		regulation is more efficient at handling frequent updates of the legislation than an EU directive. However, there are also good arguments that the Directive works well and that administratively a regulation could still be open to different enforcement practices.	pp. 92-93.	Relevant literature
Question 8: What factors could have improved efficiency by strengthening the delivery of the objectives while minimising unnecessary costs and avoiding administrative burden?	Opinion of stakeholders indicating that the Directive has caused unnecessary regulatory burden or complexity Description of most relevant examples of regulatory burden and complexity, creating unnecessary regulatory costs Qualitative descriptions of good and bad practices emerging from stakeholder consultations	The same examples of unnecessary regulatory burden or complexity are identified by multiple stakeholders Elements of the Directive that could be simplified or are superfluous are identified Practices in the implementation of the Directive described by stakeholders emerge as overly costly, or on the contrary, particularly efficient	The evidence from the consultation activities suggests that the Directive's implementation has caused some unnecessary burden and complexity. As a result, a number of areas of possible improvement for the Directive have been identified. These suggestions are related to the need to have more guidance on the FAQ document, the exemption system, the way the Directive is implemented and enforced, as well as the overlaps between RoHS and other legislative instruments.	Evaluation SWD - Section 4.1 Evaluation study, pp. 93-96.	Targeted survey Key stakeholder interviews/focus groups Public consultation Desk research

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
Coherence					
Question 9: To what extent is the RoHS Directive internally consistent and coherent?	Existence of gaps within the Directive Existence of contradictions, overlaps or missing links within the Directive	There are no gaps within the Directive There are no contradictions, overlaps or missing links within the Directive	The main issue of internal coherence concerns the lack of clarity regarding the methodology to be applied for: ▪ Article 5: adaptation of the Annexes III and IV (exemptions) to scientific and technical progress ▪ Article 6: Review and amendment of list of restricted substances in Annex II Minor issues of internal coherence concern the unclear definitions for large-scale stationary industrial tools (LSIT) and large-scale fixed installation (LSFI). Further clarification or guidance concerning these definitions may be necessary. Some Member States have indicated that the scope of RoHS may require some adaptation or clarification.	Evaluation SWD – Section 4.1 Evaluation study, pp. 98-101.	Legal, policy and technical sources Targeted survey Key stakeholder interviews/focus groups Public consultation
Question 10: To what extent is the RoHS Directive coherent with other EU environmental policy objectives, in particular those of the WEEE Directive and	Existence of contradictions, overlaps or missing links with other EU sectoral instruments (e.g. POPs Regulation, Battery	There are no contradictions, overlaps or missing links with other EU sectoral instruments	The overlap between the substance restrictions laid down in the RoHS Directive and those laid down in the REACH Regulation, the Ecodesign Directive and the POPs Regulation has been found to be the main external	Evaluation SWD – Section 4.1 Evaluation study,	Legal, policy and technical sources Targeted survey

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
circular economy policy, covering waste management, the use of chemicals as well as product design?	Directive…) Existence of contradictions, overlaps or missing links with the regulatory processes under REACH Evidence that the common understanding paper addresses overlaps between REACH and the Directive	There are no contradictions, overlaps or missing links between the Directive and the regulatory processes under REACH The common understanding paper of REACH and the Directive are compatible	coherence issue. These acts contain mechanisms which can restrict the presence of certain substances, which would also affect EEE. However, this legislation also contains considerably different mechanisms regarding, for example, the identification of substances for restriction, limit values and exemptions. Stakeholders indicated that such differences may lead to legal uncertainty. Further clarification on the delimitation between the substance restrictions under RoHS and substance restrictions under the mentioned overlapping legislation may be necessary.	pp. 101-114.	Key stakeholder interviews/focus groups Public consultation
Relevance					

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
Question 11: To what extent do the objectives of the RoHS Directive correspond to the needs of the EU? 11.1: How well do the original objectives of the Directive correspond to current environmental, technical, economic and social conditions and needs, with regards to the use of EEE, and their end-of-life treatment within the EU?	Stakeholders' opinions on whether original objectives are (in)sufficient to meet needs of key target groups Description of environmental, technical, economic, and social trends in the EU and their impact on EEE use and their end-of-life handling (e.g. circular economy and waste management requirements) Description of the development of EEE waste treatment and recycling technologies since the adoption of the Directive Development of EEE manufacturing and treatment techniques	Evidence found in different types of documents confirming whether the Directive supports/contradicts new developments Stakeholders are of the opinion that their needs are met Stakeholders make reference to fact that original objectives are (in)sufficient to meet needs of key target groups Stakeholders agree that standards set to protect health and the environment are appropriate Stakeholders agree that the measures of	The needs of the EU in the context of the RoHS Directive are still valid and will continue to exist at least into the foreseeable future. These include, among others, the protection of human health and the environment from hazardous substances in EEE and waste EEE. The analysis showed that the objectives of the RoHS Directive correspond to a large extent to these needs of the EU and that the Directive's relevance is still high. Some aspects could be identified that can have a negative impact on the Directive's future relevance. This includes the frequency of updating the list of restricted substances, which is considered by some stakeholders as too infrequent. Another aspect is the (partial) coherence (consistency) with other legislation, which detracts from the Directive's relevance.	Evaluation SWD – Section 4.3 Evaluation study, pp. 115-122.	Relevant literature Key stakeholder interviews/focus groups Public consultation Targeted survey
11.2: Does the RoHS Directive still effectively address the most relevant hazardous substances used in EEE and set relevant standards and obligations					

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
to protect human health and the environment? 11.3: How relevant are the provisions of the Directive to achieving its environmental objectives? 11.4: To what extent do problems addressed by the Directive still persist within the EU?	The extent to which the articles of the Directive are still relevant to achieving the environmental objectives	the Directive address environmental objectives of the Directive			
Question 12: Has the RoHS Directive been flexible enough to respond to new issues?	Development and/or use of new hazardous substances in EEE, or of new hazards, and subsequent technical waste management requirements Degree of flexibility allowed within the Directive to adapt to technical and scientific progress (i.e. Article 5 and 6	New hazardous substances in EEE or new risks and practices associated with substances are covered by the Directive Technical and scientific developments that should affect the scope of the Directive have been addressed	The RoHS Directive has not been flexible enough to respond adequately to all developments in recent years. The most notable aspects identified during the evaluation are issues about the exemption process, which is seen as too slow, too complex and too time-consuming for certain (smaller) companies. These sometimes serious deficiencies in the process reduce the Directive's relevance. The exemption process was pointed out as a type of bottleneck that creates planning uncertainty in the industry due to the reason that it is carried out too slowly.	Evaluation SWD – Section 4.3 Evaluation study, pp. 122 – 126.	Desk research Key stakeholder interviews/focus groups Targeted survey
EU added value					

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
Question 13: What is the added value resulting from the RoHS Directive compared to what is likely to have been achieved by the Member States in its absence?	Description of the situation where there is no EU Directive and Member States implement relevant legislation at national level Opinion of stakeholders on the Directive's additional value (e.g. higher level of ambition, less administrative costs) compared to what could reasonably have been achieved at national level Evidence/examples of additional/lower value that has resulted from the Directive compared to what could reasonably have been achieved at national level Opinion of the stakeholders on whether	Stakeholders identify the Directive's additional value in terms of higher benefits, lower costs, evidence / examples of additional value Stakeholders agree that there is a need for regulating hazardous substances in EEE at EU level A majority of stakeholders identify negative consequences linked to stopping or withdrawing the Directive	The RoHS Directive yields benefits for the protection of the environment, health and for the internal market. While it is not unlikely that similar levels of environmental and health protection could have been achieved at national level, the full added value of the RoHS Directive becomes clear with regard to the facilitation of the internal market. Harmonising standards to ease the free exchange of goods across the EU was already cited as one motivation for proposing legislation on this subject matter in 2002. The evidence collected for this study, including the statements from business stakeholders, suggests that the same level of harmonisation could not have been achieved in the absence of RoHS.	Evaluation SWD – Section 4.2 Evaluation study, pp. 127-133.	Public consultation Key stakeholder interviews/focus groups Relevant literature Stakeholder conference

Evaluation (sub) question	Indicators/Descriptors	Judgement criteria	Details on answers	Analysis (cross-reference)	Data sources
	the issues addressed by the Directive continue to require action at EU level Evidence/examples that the issues addressed by the Directive continue to require action at EU level Opinion of stakeholders regarding the likely consequences of stopping or withdrawing the Directive Evidence/examples that stopping or withdrawing the Directive would have positive /no/negative consequences				

9 ANNEX IV. OVERVIEW OF BENEFITS AND COSTS ESTIMATES

		Citizens/Consumers		Businesses		Administrations		[Other …] _ specify	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
		Cost or Benefit description							
Mark the type of cost/benefit, each on a separate line: **Costs:** **Direct compliance costs** (adjustment costs, administrative costs, regulatory charges) **Enforcement costs:** (costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation) **Indirect costs** (indirect compliance costs or other indirect costs such as transaction costs)	**Type:** Choose **one-off or recurrent**	No quantification available	No costs are expected for citizens/consumers	9 = 0 FTE 13 < 3 FTE 12 > 3 FTE 15 – not to be specified / unknown (n=49 operators) per business, p.a.	Costs are related to collecting and reviewing data, product development, providing supply chain information, maintain IT management systems and to the exemption system	COM: In the past, COM: ~ 1.2 FTE Member States: 0.3 – 4.75 FTE Per country, p.a. EUR 10 000 – 400 000 Per country, p.a.	COM: Costs for staff managing Directive and external costs for consultants Member States: Enforcement and Implementation (n=10 MS)	-	-

Benefits: **Direct benefits** (such as improved wellbeing: changes in pollution levels, safety, health, employment; market efficiency) **Indirect benefits** (such as wider economic benefits, macroeconomic benefits, social impacts, environmental impacts)	No quantification available	Decreased negative health effects to consumer. A quantification is not possible due to the lack of data Protection of the environment by reducing emissions of hazardous substances	No quantification available	Directive levels the playing field and creates legal certainty for businesses. It can also spur innovation through substitutions Waste management market Reduction in the hazardous substances exposure for workers in production and WEEE recycling plants	-	-	No quantification available	Creation of similar legislation outside of the EU Contributes to circular economy, improving recyclability of EEE, thus reducing resource consumption and reducing CO_2 emissions

Information on costs extracted from stakeholder consultations

Direct costs

In the OPC and targeted consultations and interviews, businesses indicated that it is easier to estimate the number of FTEs needed to comply with the RoHS Directive than the direct yearly operational cost and initial investment cost. Some 95 businesses and business associations provided an answer on the number of FTEs involved. Their response can be broken down as follows: 22 responded 'none'; 36 responded 'other'; 37 provided FTE estimates and 12 of those were business associations. Table 1 below shows the breakdown **by type of economic actor and by businesses and business association.**

Table 1: Breakdown of companies who submitted FTE estimates (n = 95)

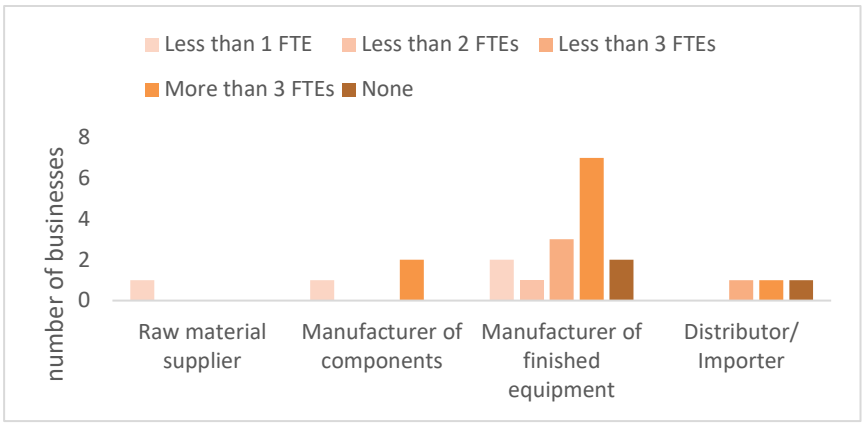
		Number of businesses	Number of business associations
Raw material supplier		1	6
Distributor /importer		3	0
Manufacturer of components	5	5	
Manufacturer of finished components	24	22	
Other	6	11	
Unknown	10	2	
Total	49	46	

More precisely, Table 1 shows:

- 13 respondents indicated a range of 1-3 FTEs working on RoHS compliance and 12 respondents indicated a range of more than 3 FTEs.
- 9 of the respondents indicated that a range of more than 3 FTEs are manufacturers of components or finished EEE.
- 9 respondents indicated that they do not have FTEs working on compliance with RoHS.
- 13 respondents indicated 'other'. Those respondents either indicated that it was hard to estimate the number of FTEs or that the number of FTEs was significantly higher than 3. These respondents were primarily among respondents on behalf of business dealing with EEE falling under RoHS categories 3, 8, 9, and 11.

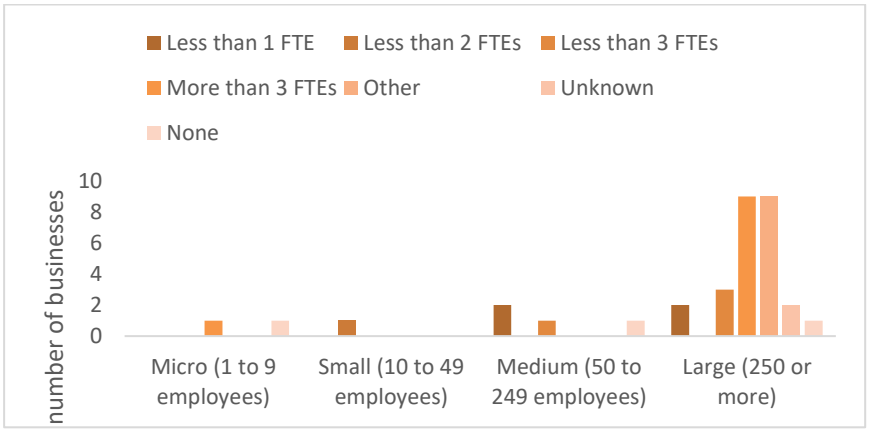
Figures 1 and 2 below, based on data collected as part of the OPC, show the number of FTEs working on compliance to RoHS, by type of company and by organisational size.

Figure 1: Number of FTEs working on compliance with RoHS, by type of company (n=49)



Source: OPC

Figure 2: Number of FTEs working on compliance with RoHS, by organisational size (n=49)



Source: OPC

Implementation and enforcement

Table 2: Cost estimates for enforcement and implementation by Member State authorities (n=10)

	FTE	Budget
Enforcement	0.15 - 2.75	EUR 10 000 - EUR 30 000 excluding personnel costs EUR 15 000 - EUR 40 000 including personnel costs EUR 72 000 - EUR 125 000 including personnel costs and market surveillance
Implementation	0.15 - 2	EUR 100 000 - EUR 125 000 including personnel costs
Enforcement and implementation (if roles are combined)	0.3 - 2	EUR 100 000 – EUR 400 000 including personnel costs EUR 43 100 (including all environmental research and analysis, not just RoHS Directive implementation, which might be 5% of the total budget) - excluding costs for personnel EUR 10 000 including personnel costs

Source: Member State survey and other estimates received from Member States

10 ANNEX V. STAKEHOLDER CONSULTATION – SYNOPSIS REPORT

1. Introduction

The Commission collected opinions of citizens, stakeholders, competent authorities, and third countries. A wide range of consultation activities was employed to reach out to this diverse group. This report provides an overview of the consultation strategy and the individual activities. In addition, it reports on the number of people and organisations engaged and provides some of the main outcomes.

2. The consultation strategy

The consultation strategy was published jointly with the publication of the RoHS Directive's evaluation roadmap[132]. To further elaborate the consultation strategy, the research team mapped the stakeholders, identifying all relevant groups and suitable consultation tools to reach out to them. The aims of the consultation were to collect information, data, evidence and opinions and to complement the desk research. The stakeholder consultation activities consisted of:

- a feedback period on the RoHS Directive's evaluation roadmap, which ran from 14 September 2018 to 12 October 2018;
- an OPC, which ran from 13 September 2019 to 6 December 2019;
- an in-depth survey (questionnaire) shared with Member State authorities involved in implementing the RoHS Directive, in parallel to the OPC;
- three focus groups, organised between October 2019 and March 2020;
- in-depth interviews, organised partly as follow-up interviews to input stakeholders provided via the OPC;
- a workshop organised towards the end of the study in March 2020 to present the study's preliminary findings and provide stakeholders with another opportunity to provide their input.

Many stakeholders shared their experiences with implementing the Directive and provided additional supporting evidence. Information was collected on all five evaluation criteria covered by the evaluation: effectiveness, efficiency, relevance, coherence and EU added value.

The following sections provide information on all consultation activities. Each section provides an overview of the nature and number of respondents. The sections also summarise the main outcomes of each of the consultation activities.

3. Online public consultation

3.1 Participants

The OPC remained open for 12 weeks, in line with the requirements of the Better Regulation guidelines. The questionnaire for the OPC was uploaded to the EU Survey

[132] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1891-Restriction-of-hazardous-substances-evaluation

website and translated by the translation service of the European Commission into 24 languages.

The OPC was open to anyone interested. The questionnaire was structured into three sections. The introductory section collected some background information on the respondents. The second section contained questions tailored to respondents who self-identified as non-experts, while the third section targeted experts, i.e. stakeholders with specific knowledge on hazardous substances in EEE. The questions in each section reflected the level of expected knowledge of the respondents and were thus more detailed for experts than for non-experts. Every respondent filled in two out of the three sections of the questionnaire, with the introductory section being filled in by everyone. Depending on their profile (non-expert or expert), respondents also filled in either the second or third section of the questionnaire. In total, 163 responses were collected, of which 125 responses (77%) were directly submitted via the EU Survey website. In addition, a representative of the UK's Enterprise Europe Network submitted additional 38 responses (23%) to the general part of the survey from companies via an uploaded file as part of an answer to the OPC. One completely empty response was removed from the sample.

The majority of replies came from respondents in the UK (51 responses) and Belgium (32 responses), followed by Germany (25) and Japan (16 responses) (Table 1). Almost half of the replies, 77 responses, were from respondents outside the EU (Japan, United Kingdom, Switzerland, others)[133].

Table 4 Overview of country of origin of respondents to the OPC

Country	Responses	%	Country	Responses	%
Belgium	32	20%	Lithuania	1	1%
Denmark	1	1%	Netherlands	2	1%
Finland	2	1%	Portugal	2	1%
France	6	4%	Spain	2	1%
Germany	25	15%	Sweden	4	2%
Ireland	2	1%	Switzerland	1	1%
Israel	1	1%	United Kingdom	13 (+38)	31%
Italy	7	4%	United States	8	5%
Japan	16	10%	**Total**	**163**	100%

Note: as mentioned above, we considered 162 responses for the analysis.

About four out of five respondents indicated that they have specific knowledge in the policy field and/or on the RoHS Directive. Therefore, a clear majority (63%) of respondents filled in the longer and more detailed version of the public consultation, while 61 respondents (37%) filled in the shorter and more general version. Companies and business associations submitted more than 70% of all responses (see Table 2 below). As

[133] At the time the OPC was open, the UK was still a Member State.

mentioned above, a significant share of these (16 replies) was from Japanese companies; this could be an indication of the importance of the RoHS Directive for international trade.

Table 5 Distribution of responses by stakeholder group

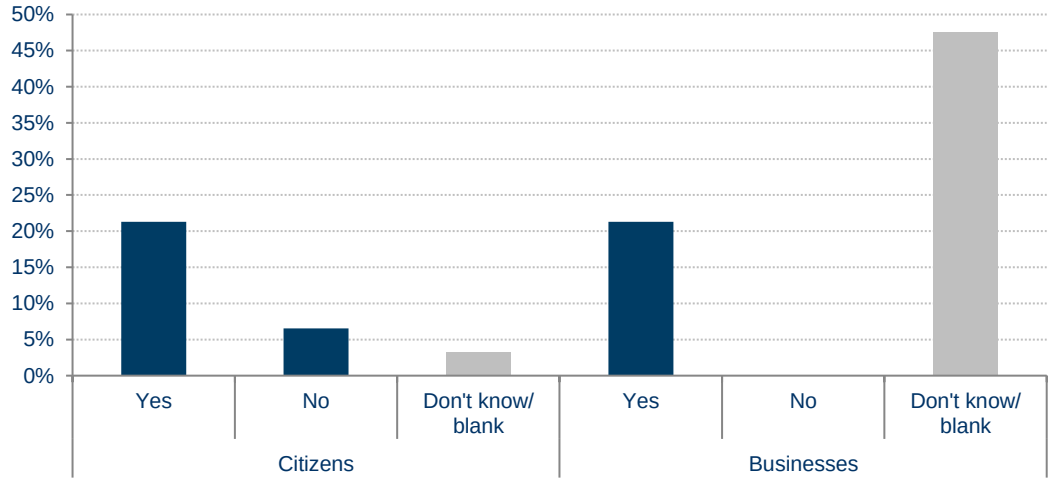
Stakeholder type	Responses	%
Business association/ Company	128	79%
Academic/research institution	1	1%
EU citizen	22	13%
Non-EU citizen	2	1%
NGO	2	1%
Other	3	2%
Public authority	5	3%

Because of the sample size, self-selection and unequal geographical distribution, the responses to these questions should not be considered representative of a wider sample or of citizens of the EU overall.

3.2 Outcome of the questionnaire for the non-experts

Questions for non-experts mostly focused on respondents' perceptions. They explored the perceived safety of products for consumers, and explored whether respondents were willing to accept potential trade-offs between the safety of EEE for the environment and health on the one side, and the cost of EEE on the other side. The questions further explored the recycling habits of respondents as well as the perceived added value of EU interventions in this policy field.

Figure 1 Number of responses by category: Has the legislation helped to reduce the use of hazardous substances in electrical and electronic equipment?



For this section of the questionnaire, which targets non-experts, out of the 62 replies collected, one business association provided one completely empty response. As such, the research team considered 61 replies for this sample instead of 62. 42 responses (69%) were from businesses, 18 (30%) from individuals and 1(1%) from an NGO (considered in the

category ‘citizens’ in Figure 2). The majority of the respondents recognised that the RoHS Directive helped to protect human health and to reduce damage to the environment, either fully or to a limited extent. Although 42% of respondents agreed that the legislation has helped to reduce the use of hazardous substances in EEE, 69% of the businesses indicated that this impact of the legislation was unknown.

Most of the businesses (93%, in total 39) and citizens (95%, in total 18) agreed on the necessity of restrictions on hazardous substances in EEE to protect the environment.

3.3 Outcome of the questionnaire for experts

A total of 101 respondents filled in the part of the OPC questionnaire for experts and not the non-experts’ questions. Businesses and their associations submitted 86 responses (85%), with the remaining 15 (15%) coming from academia, NGOs, public authorities and individual experts. Therefore, the results of this part of the public consultation are very much driven by perceptions of industry representatives.

Similar to the respondents to the general part of the public consultation, a substantial majority of respondents to the specific parts agreed that the Directive has helped reduce the use of hazardous substances in EEE and thus helped protect the environment.

Information from respondents suggests that implementing the RoHS Directive has resulted in additional costs for businesses. A majority of respondents indicated that they had incurred one-off costs and increased operational costs due to implementing the Directive.

Figure 2 Number of responses by category: Have you made any initial investment to comply with RoHS?

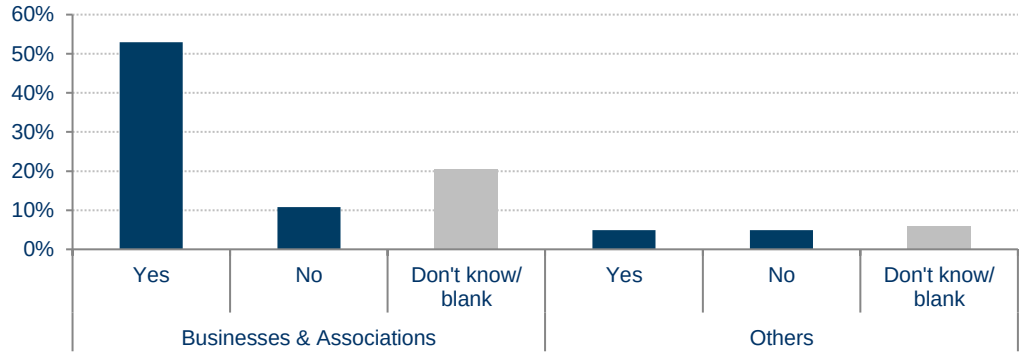
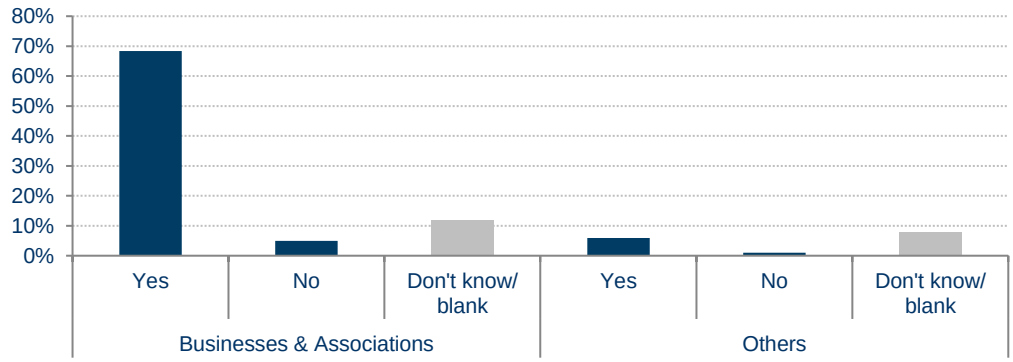
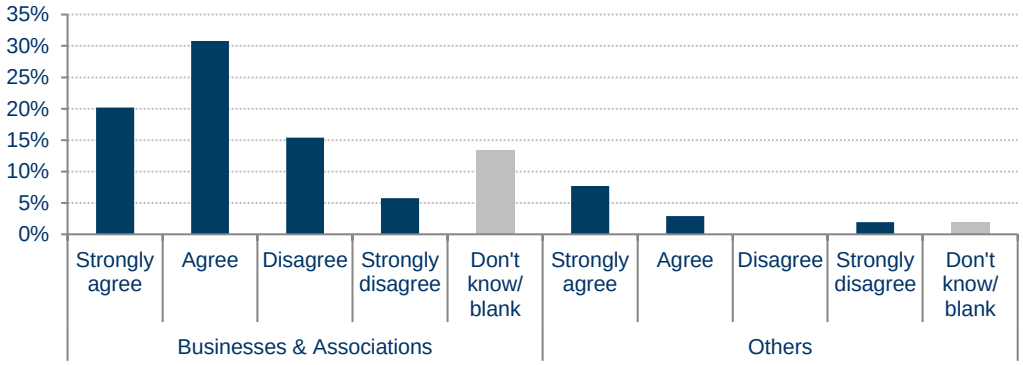


Figure 3: Number of responses by category: Has your operational costs / the operational costs for the companies you represent increased due to compliance with RoHS?



A majority of stakeholders stated that legislation such as the RoHS Directive is still needed to protect the environment, with 75% of respondents to the expert questionnaire agreeing with this statement. More than one in two respondents also indicated that the Directive simplifies trade within the EU. In line with this, three out of four respondents would expect negative consequences if the RoHS Directive were to be withdrawn.

Figure 4 Number of responses by category: There is still a need for EU legislation on hazardous substances in electrical and electronic equipment to protect the environment?



3.4 Additional input and position papers

In addition to a set of closed questions, respondents were invited to provide additional details and information in open questions. The two questionnaires allowed space for respondents to share any additional information as desired and provided the opportunity to upload a position paper.

In total, 40 (25%) respondents (out of 163 respondents) provided additional information[134]. 17 (10%) respondents pointed out several overlaps between the RoHS Directive and other EU legislation such as the Ecodesign Directive, the REACH Regulation, the Energy-related Products (ErP) Directive, the Waste Framework Directive and the Persistent Organic Pollutants (POPs) Regulation. In their responses, several participants to the public consultation focused on the exemption system. For example, they considered the duration of the exemption process to be too lengthy and asked for longer exemption periods in cases where research is exhaustive and no substitutes available. Two stakeholders also pointed out the needs and limitations of specific sectors, including medical equipment and entertainment lighting.

4. Questionnaire to Member States

4.1 Participants

A targeted questionnaire was developed for Member State competent authorities in charge of implementing the RoHS Directive. Special attention was paid to information likely to be held exclusively or predominantly by Member State authorities. In addition, the Member States were also asked about the state of implementation of the Directive in their respective jurisdictions. The questionnaire was launched in the second half of September 2019 and a

[134] This includes a number of comments concerning the questionnaire, as well as responses such as 'None', and responses pointing to position papers.

reminder was sent by the Commission to respondents at the end of October 2019. A reminder was also sent to respondents who had entered their email contact in the system but not yet responded.

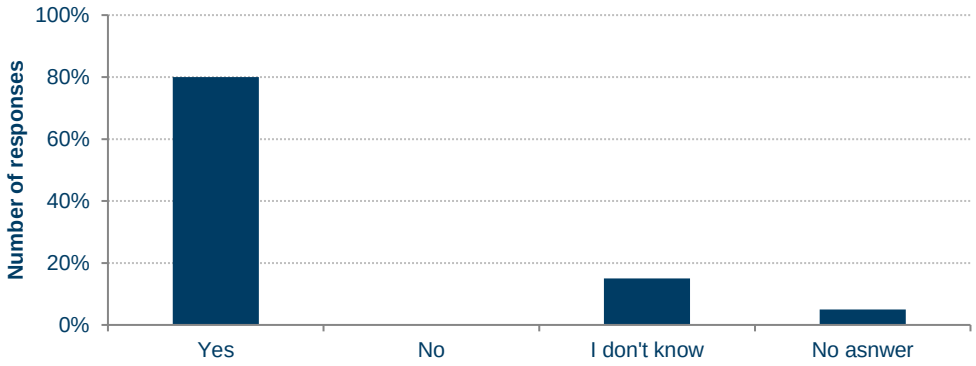
A total of 20 responses were received. 13 (65%) respondents fully completed the questionnaire, whereas six (30%) responded partially. Responses cover 15 Member States as well as Norway.

Figure 5 Overview of Member States that responded to the questionnaire

4.2 Outcome

Member State representatives responding to the targeted survey overall assessed the Directive positively in terms of achieving its objectives. A clear majority of respondents stated that the safety of EEE for humans and the environment had improved in the last 10 years, and that RoHS led to reduced use of harmful substances in EEE.

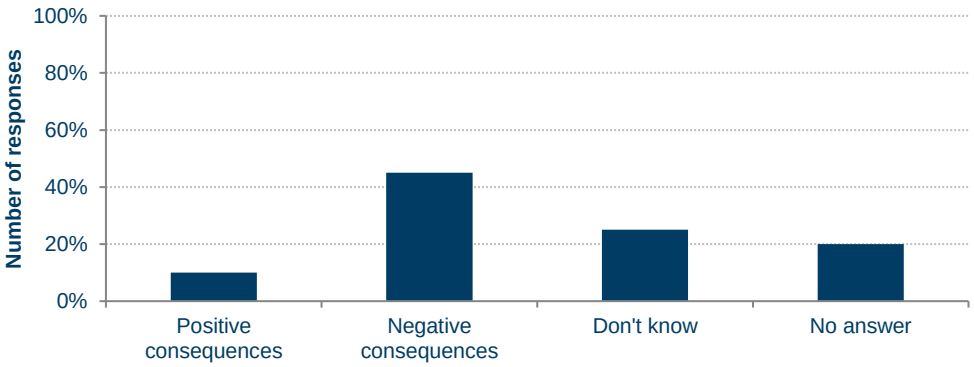
Figure 6 Responses to the question: Has the RoHS Directive helped to reduce the use of hazardous substances in electrical and electronic equipment in the EU?



Member State representatives responding to the survey indicated that withdrawing the RoHS Directive would have negative consequences for achieving the Directive's four

objectives. Eleven respondents believed that withdrawing the Directive would have negative consequences for the protection of human health and for the environmentally sound recovery and disposal of WEEE. Thirteen Member States believed a withdrawal would have negative consequences for the protection of the environment, and 9 respondents expected that it would have negative consequences in terms of ensuring a well-functioning internal market.

Figure 7 Responses to the question: What consequences do you think the withdrawal of the RoHS Directive would have for achieving the objectives of the Directive? - Ensuring a well-functioning internal market



All Member State representatives *agreed* (5 respondents, 25%) or *strongly agreed* (10 respondents, 50%) that the restriction of hazardous substances in EEE continued to require action at EU level.

5. Focus groups

1 Participants

Three focus groups were organised in the context of this study, with a view to gathering views from representatives of Member State competent authorities, the business association, and NGOs. The participants in the focus group expressed interest in the activity and were therefore invited. The topics covered were:

- assessment of the Directive's implementation and enforcement
- effectiveness and efficiency – environmental and health aspects
- effectiveness and efficiency– costs and benefits aspects
- external and internal coherence

2 Outcome

Assessment of the Directive's implementation and enforcement

The first focus group with relevant Member States authorities from 8 countries (10 participants) was held on 22 October 2019 in Brussels. The emphasis of the first focus group was on the implementation and enforcement processes currently in place across the countries, as well as on the Directive's effectiveness and efficiency. Furthermore, the baseline methodology developed by the project team to assess the likely impact of the Directive was presented and discussed. Member State competent authorities attending the focus group considered that there was a lack of clarity regarding market surveillance and asked for further guidance from the Commission.

Effectiveness and efficiency – environmental and health aspects

The second focus group with NGOs took place on 12 December 2019. Three organisations attended, bringing together 3 participants and 3 members of the research team. The participants discussed whether the RoHS Directive is effective and efficient in achieving its environmental- and health-related objectives. Overall, they agreed that the Directive is delivering on its objectives, although they still see room to improve. They discussed how the RoHS is implemented and if there are aspects that hinder its effectiveness and efficiency. For example, they noted that granting too many exemptions can undermine the Directive's effectiveness.

Stakeholders from the NGO focus group stated that one of the Directive's main benefits is that many companies changed and started understanding the need for efficient management of chemicals.

Effectiveness and efficiency – costs and benefits aspects / External and internal coherence

The third focus group, this time involving 10 representatives of business associations, was organised on 4 March 2020. In addition to gathering information and evidence on the effectiveness, efficiency and coherence of the RoHS Directive from the point of view of business associations, the focus group intended to collect examples for the Directive's potential impacts and effects on business operators. More specifically, the focus group explored various effects of the Directive, e.g. its benefits, impact on innovation and the circular economy, the impact and shortcomings of the exemption system, as well as the costs incurred by businesses to comply with the Directive.

The first part of the meeting focused on effectiveness and, more especially, on the impact of the RoHS Directive on innovation, competitiveness and internal market. The group also considered the potential situation without the RoHS Directive. On this latter issue, the stakeholder agreed that leaving the matter of the RoHS Directive to the Member States would not have been better. The second part of the focus group focused on efficiency - more specifically, the RoHS Directive's costs and benefits. This provided the opportunity to validate and discuss the estimated investments costs identified by the team. The third and last part of the meeting focused on the Directive's internal and external coherence. During the last session, stakeholders' inputs indicated that there are several overlaps between the RoHS Directive and other EU legislation.

6. Targeted interviews

1 Participants

The interviews were conducted between July 2019 and February 2020 with relevant stakeholders from EU Member States and from other relevant countries, including Japan. Scoping interviews were performed at an early stage and then more structured interviews were used to complement information from desk research and other consultation activities.

Overall, 15 interviews were performed: 11 with businesses, 3 with authorities from Member States and 1 with a consultancy / research institute. The research team tailored the interview questionnaires for each interviewee, thus making it possible to focus on the most relevant topics for each interview. Common points of discussions included the Directive's cost and benefits, its impact on innovation, and its consistency with other EU legislation. The research team interviewed experts that:

- contacted the research team;
- were suggested by DG ENV;

- replied to the OPC and for which a follow-up interview was deemed useful.

The interviews with Member State authorities were also used as an opportunity to follow up on information already provided via the specific questionnaire. In one case, the agency interviewed was different from the one that responded to the questionnaire.

2 Outcome

All the interviewees agreed that the RoHS Directive should stay in place and that the situation would not have been better without it. The Directive allows for effective enforcement on a level playing field, mainly due to the CE marking. However, across Europe there are different enforcement cultures and thus scenarios.

Overall, the interviewees agreed that the compliance cost increased from RoHS 1 to RoHS 2. This was because the latter directive came with requirements for CE labelling and further technical documentation.

As in the OPC, the interviewees pointed out the overlaps and coherence issues with other EU legislation, especially REACH, the POPs Regulation, and the Ecodesign Directive. The interviewees agreed on the international dimension of RoHS and the opportunities and challenges arising from the fact that a growing number of countries are implementing RoHS-like legislation. For instance, it is difficult for non-EU states to understand the RoHS Directive; hence, there is not full harmonisation across the globe.

The interviews with Member State competent authorities focused on issues related to the Directive's implementation and enforcement (e.g. inspections and controls, sanctions, etc.), exploring how the Directive has affected the authorities. The authorities cited problems in enforcement activities regarding exemptions, and stressed that technical documentation is complex and hard to follow for someone who is not a technician, which causes difficulties in enforcement.

Furthermore, the business associations stressed several issues with the exemption system; e.g. it is too lengthy and generates significant administrative burdens. Also, R&D is somehow limited under the Directive, as money is spent on compliance and exemption processes.

7. Workshop

The workshop was held in March 2020. Due to the ongoing COVID-19 crisis, it was organised as an online webinar. The research team invited all the organisations that:

- contacted the research team during the study;
- were recommended by the European Commission for consultation;
- participated in the consultation activities;
- were identified during the mapping of stakeholders.

Around 125 individuals (including the research team and the European Commission) joined the webinar. It brought together representatives from 12 Member States (among which 3 national institutions replied to the questionnaire), the European Commission, and 53 representatives from NGOs and industry. The organisations interviewed, and those that took part in the focus groups also participated in the workshop. Ahead of the workshop 25 organisations sent a contribution.

The workshop covered the five criteria set out in the EU Better Regulation guidelines, i.e. effectiveness, efficiency, coherence, relevance and EU added value. It provided the

participants with the opportunity to comment on the study's preliminary findings for each criterion, which they received prior to the webinar. The stakeholders devoted considerable attention to the Directive's impact on innovation, the costs and administrative burden related to the different categories of EEE covered under RoHS and the Directive's consistency with the circular economy initiative.

Overall, participants agreed with the study's preliminary findings. However, it was highlighted that further qualitative and quantitative data from the stakeholders could be used, and that the definition of innovation could contribute to assessing the Directive's impact on this matter more precisely.

The workshop also represented a last call for data and evidence; participants were given the possibility to provide final feedback (in written form) both during and after the workshop – 15 organisations sent a contribution.