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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

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1 INTRODUCTION

The General Product Safety Directive (the 'Directive') was adopted on 3 December 2001, it entered into force on 15 January 2002 and the deadline for its transposition by the Member States was 15 January 2004.

The Directive applies to all non-food consumer products to the extent that there are no specific provisions with the same safety objective in other EU legislation, such as EU harmonisation legislation (hereafter 'harmonised legislation') for specific products. The Directive also establishes the EU Rapid Alert System (Safety Gate[1]/RAPEX), which enables quick exchange of information between EU/EEA Member States and the European Commission on measures taken on dangerous non-food products posing a risk to consumers and other users.

The current health crisis has highlighted the importance of the Directive in providing a safety net for consumers, being one of the main pieces of legislation that help remove dangerous products (especially products such as face coverings, hand disinfectants and protective gloves). The Safety Gate/RAPEX system set up by the Directive also enables authorities to take swift action to protect the health and safety of consumers in the EU.

Under Article 19 of the Directive, the European Commission must present a report on the implementation of the Directive to the Council and Parliament every three years following transposition. The first implementation report was published in 2009. The Commission continued to monitor the implementation of the Directive in the Member States and presented its findings in the impact assessment report that accompanied the Product Safety and Market Surveillance Package in 2013. The impact assessment report, which included the results of data collection on implementation issues, was considered equivalent to an implementation report. In view of the process to revise the Directive, the findings of this third implementation report were considered in the evaluation and subsequently in the impact assessment of the revised Directive.

For the purpose of this report the Commission used the findings of the Study for the preparation of an implementation report of the General Product Safety Directive[2].

1.1 Scope of the report

This report was drawn up pursuant to Article 19(2) of the Directive and includes information on:

- the safety of consumer products, in particular on improved product traceability;
- the functioning of market surveillance and RAPEX;
- standardisation;
- the measures taken on the basis of Article 13 of the Directive.

The geographical scope of this report covers all EU Member States as well as European Economic Area (EEA) countries: Iceland, Liechtenstein and Norway. It covers the period 2013-2018 and, where available, data from 2019 and 2020 as well.

[1] Safety Gate is used to reflect the planned change of the name of the EU rapid alert system for non-food dangerous products (now RAPEX).

[2] https://ec.europa.eu/info/files/study-preparation-implementation-report-gpsd_en

1.2 **Overview**

1.2.1 Objectives and scope of the Directive

The Directive requires all consumer products placed on the EU market to be safe. It applies to non-food consumer products that are not subject to specific EU legislation governing the safety of the products concerned. It is also applicable to the safety aspects or risks of products which are subject to specific safety requirements imposed by Union law, to the extent that the specific EU harmonised legislation makes no specific provisions with the same safety objective. The Directive therefore constitutes a safety net that ensures that all products and risks to consumers' health and safety are covered by the safety requirement set by the Directive, even if they are not covered by any specific EU legislation.

The Directive applies to all sales channels, offline and online.

1.2.2 Obligations of economic operators and Member State authorities

The Directive establishes a general obligation on producers to only place on the market products that are safe, and to provide information to consumers and to Member State authorities. The producers must set up a minimum system of traceability and must take appropriate corrective measures in the event that dangerous products are found on the market, such as action to withdraw or recall the product. Distributors have a duty of care obligation to ensure compliance with the applicable safety requirements.
Member State authorities must ensure that products placed on the market are safe and monitor compliance by producers and distributors with the obligations set by the Directive.
The Directive doesn't set any specific direct obligations on the online marketplaces. It may be noted that in accordance with Article 14 of Directive 2000/31, hosting service providers are not liable for the information stored at the request of a recipient of the service, on condition that upon obtaining actual knowledge or awareness of illegal activity or information, for instance by means of a sufficiently precise and adequately substantiated notice, they act expeditiously to remove or to disable access to the information.

Given the increasing role that online marketplaces play in the current supply chain, the Commission facilitated the signature of the Product Safety Pledge (signed by 11 online marketplaces to date), which is a set of voluntary commitments to improve the safety of products sold on these online marketplaces by third-party sellers.

1.2.3 Institutional and enforcement aspects

The Directive establishes the Rapid Alert System for non-food consumer products (Safety Gate/RAPEX). This system enables the Commission and Member State authorities to circulate information on measures taken by Member State authorities and economic operators on products posing a serious risk to the health and safety of consumers. Information on less than serious risks can also be circulated under RAPEX (though this accounts for less than 1% of all notifications). The RAPEX system can be opened to non-EU countries on the basis of a specific international agreement signed between the EU and the applicant country. Under Article 15 of the Directive, the Commission implements this Directive with the assistance of a committee composed of representatives from the Member States (the 'GPSD Committee'). In addition, Article 10 of the

Directive sets up a network of Member State authorities with the aim of further enhancing administrative cooperation (the 'Consumer Safety Network').

Given that the Directive forms part of the EEA Agreement, the same rules and mechanisms apply to EFTA countries that apply the EEA Agreement: Norway, Iceland and Liechtenstein.

2 Application and regulatory developments

2.1 Safety of consumer products

With the growing share of e-commerce and emerging new technologies (such as artificial intelligence, the internet of things, interconnected products), the definition of safety given in the Directive is being challenged in many ways. The Directive gives a definition of a safe product that is formulated widely enough to give rise to uncertainties about its interpretations. It does not explicitly cover risks related to emerging threats, such as cybersecurity risks, software malfunction or risks inherent in products with artificial intelligence or machine learning capabilities. Consequently, most national authorities lack interpretation and practice related to new technology products and have called for the development of guidance at EU level.

Products containing new technologies pose specific difficulties for market surveillance authorities, for instance, the lack of knowledge on possible risks that these products represent, or the need to clarify the responsibilities of different authorities/economic operators.

Concerning online sales, in most countries market surveillance activities are conducted mostly on traders located in their own country. The procedure can be either similar to that used for products sold in physical stores, or it specifically focuses on online checks of online marketplaces. Authorities that carry out enforcement action on traders selling dangerous products and located in non-EU countries reported that they use the mechanism provided by the Product Safety Pledge.

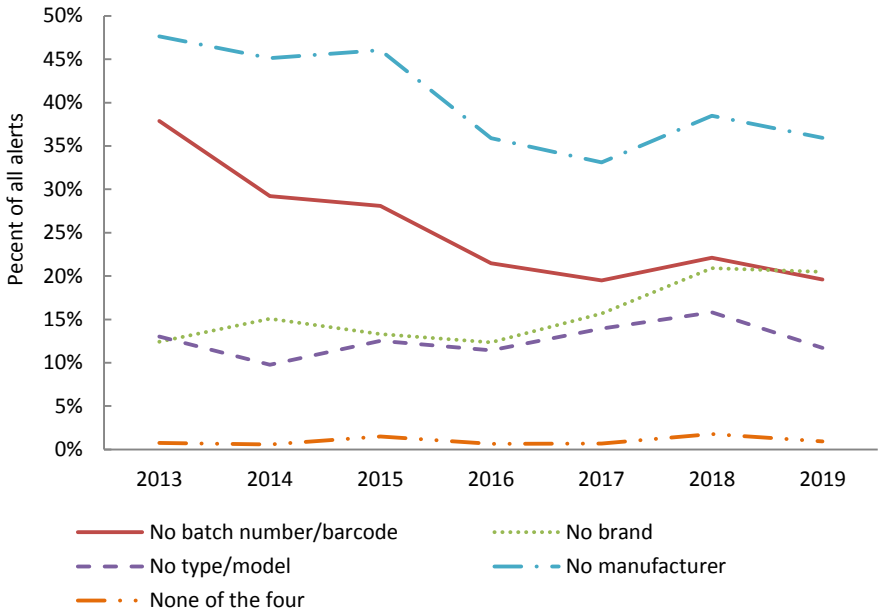
2.2 Traceability

Most Member States' transposition legislation complies with the Directive in that they make it mandatory to indicate the name and contact details of the producer and a product reference or, where applicable, the batch number on products or packaging. However, application of these requirements is not uniform: it may vary according to the characteristics of the products, it may extend the obligation beyond the producer, or require additional data, and these differences create uncertainties for businesses operating across Europe.

At present, the Directive's provisions on traceability are not sufficiently explicit to ensure the collection of complete information on product supply chains and distribution. The data available in the Safety Gate/RAPEX demonstrates that product traceability is often insufficient. In 2019, 36% of alerts for dangerous products lacked information about the manufacturer; 20% of alerts were for products of unknown brand or batch number/barcode; and 12% were for products with no type or model information.

Figure 1, based on alerts registered in the Safety Gate/RAPEX, shows that the only improvement in the availability of information was on the product manufacturer and on the batch number/barcode (i.e. fewer alerts lacked this information). There is no clear trend indicating an improvement on other aspects of traceability information.

Figure 1: Share of Safety Gate/RAPEX alerts with unknown product information (2013-2019)



Source: Study for the preparation of an implementation report of the GPSD, from Safety Gate/RAPEX data, retrieved in January 2020 (calculation on basis of full dataset, number of alerts concerning consumer products with serious risks 2013-2019).

The same data also reveal that missing product information is more typical for specific types of products such as laser pointers, lighters, jewellery and decorative articles. These products all fall within the scope of the Directive and are not subject to sector-specific harmonisation rules. It follows that product categories under the Directive are more likely to lack relevant information items essential to trace them.

2.3 Functioning of market surveillance

The market surveillance system under the Directive appears to be operating under considerable resource constraints. In a 2018 evaluation of the product safety-related actions funded under the EU Consumer Programme[3], authorities indicated limited staff/financial resources for market surveillance and enforcement as a factor most frequently undermining the level of achievement. Also market surveillance of online markets poses issues, especially related to direct imports from outside the EU.

[3] See Civic Consulting (2018), ex-post evaluation of the Consumer Programme 2007-2013 and mid-term evaluation of the Consumer Programme 2014-2020, Part 1 – Mid-term evaluation of the Consumer Programme 2014-2020 and European Commission.

2.3.1 Market surveillance cooperation with other public authorities and with customs

There are different institutional models for market surveillance at the national level, often characterised by a high degree of fragmentation of responsibilities. Cooperation between authorities – customs and other authorities included – comprises a whole range of activities such as information exchanges, regular meetings, informal cooperation and joint training courses. The improved use of several systems such as the Safety Gate/RAPEX, the ICSMS[4] and the Wiki confluence platform[5] is great value added to the authorities' work.

Cooperation between market surveillance authorities (hereafter MSAs) and customs is very intense and regular in several aspects of this work. In most countries, customs authorities conduct checks on behalf of the MSAs without being a market surveillance authority in their own right. Some countries[6] take a different approach and designate the customs authorities as a MSA in its own right, so customs officials can take samples, have them tested and decide how to proceed further.

2.3.2 Joint actions and coordinated activities of market surveillance authorities

The aim of joint actions and coordinated activities[7] is to promote and coordinate cooperation for the purpose of applying Directive 2001/95/EC and ensuring a consistent approach to implementing product safety legislation across the internal market. This typically covers: coordinated sampling and testing of non-food products found on EU/EEA markets, risk assessment, exchange of expertise and best practices and implementation of an effective communication strategy.

A high number of market surveillance authorities participate regularly in coordinated actions that has resulted in identifying a considerable number of dangerous products. To provide assistance to the Consumer Safety Network, the Commission has co-funded 14 joint actions on market surveillance by these authorities during the reporting period. Most joint actions have resulted in the identification of a significant number of dangerous products, leading to notifications in Safety Gate/RAPEX for 13 categories of products. The ongoing Coordinated Activities on the Safety of Products (CASP) 2020 and CASP 2021 projects likewise follow the implementation approach of joint sampling, testing, risk assessment and best practice exchange to carry out market surveillance actions in the EU/EEA Member States.

2.3.3 Recalls and other corrective measures

Under Article 5(3) of the Directive, producers and distributors are required to immediately notify respective authorities in case a product that they have placed on the market poses safety risks to the consumer.

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[4] Information and Communication System on Market Surveillance: ICSMS represents an IT platform which purpose is to facilitate communication between market surveillance authorities in Europe.

[5] Wiki confluence is a web-based corporate collaboration software, widely used by market surveillance authorities.

[6] Finland, France and Latvia.

[7] Between 2008 and 2018, joint actions were funded and implemented by the European Commission's Consumer Programme, under the category of grant agreements. Since 2018, the implementation modality and financing of joint actions was replaced by a procurement framework funded fully by the European Commission. Currently they are called Coordinated actions on the safety of products.

When products are found to be dangerous, Member States must ensure that they are recalled, withdrawn or prohibit their placing on their market, and they must also inform the Commission without delay via the Safety Gate/RAPEX. In the notification, Member States provide information on the product and the measures adopted. Data from RAPEX contains 5 983 recalls covering 2013-2019 in the EU/EEA, showing an increasing trend. Recalls and other corrective measures are organised in practically all countries, both on a voluntary and a mandatory basis.

2.3.4 Injury databases

The EU-funded project "European Injury Database"[8] (IDB) provided some data on product-related injuries and accidents in the EU, but only a minority of Member States collected injury data systematically.

The creation of online databases (comprising data related to statistics on dangerous products and injuries, risk assessment, market surveillance history, findings and fines) could provide better information for businesses, may have a deterrent effect on non-compliant companies and may improve consumer warnings for dangerous products. There has also been a suggestion to create a system to collect data on product-related injuries, preferably at the EU's initiative.

2.3.5 New regulatory developments related to market surveillance

On 20 June 2019, Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products was adopted, amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011. This Regulation brings in new market surveillance provisions for products subject to EU harmonised rules, while rules for non-harmonised products are set by the Directive. The majority of authorities and other stakeholders confirmed that having different rules for harmonised and non-harmonised products was problematic. It was suggested that aligning the Directive with the obligations and enforcement powers detailed in the harmonised market surveillance legislation would facilitate better enforcement action.

The Notice on the market surveillance of products sold online[9] sets out good practices for market surveillance of products sold online and for communication with businesses and consumers. The Notice concerns the application of the Directive and of Regulation (EC) No 765/2008 and it aimed to achieve a more uniform and coherent application of the rules governing products sold online.

2.4 Safety Gate/RAPEX and cross-border cooperation

The number of alerts sent to the Rapid Alert System for non-food consumer products has increased progressively over the years, remaining above 2 000 alerts a year since 2012. The system circulated 2 243 alerts in 2019[10] and 2 253 alerts in 2020[11] across Europe.

[8] https://ec.europa.eu/health/sites/default/files/indicators_data/docs/idb_flyer_en.pdf

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.250.01.0001.01.ENG, OJ C250, 1.8.2017, p. 1–19

[10] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/RAPEX.2019.report.EN.pdf

The Safety Gate/RAPEX is the key channel for market surveillance authorities to communicate and cooperate with their counterpart authorities in the EU/EEA. MSAs cooperate with authorities in other EU/EEA countries once a month or more often using Safety Gate/RAPEX and frequently using other tools (ICSMS, Wiki confluence). However, there are delays in notifications, often due to complex market surveillance structures, or other factors such as the lack of testing facilities or insufficient human or financial resources. This often causes delays, resulting in a lag in the notification period of an average of two weeks between detection of a dangerous product and notification in the system. Also the lack of sufficient information to trace notified products prevents authorities from taking action.

In line with the reported inconsistencies of risk assessments, additional action can be taken to harmonise and improve risk assessment approaches of MSAs, building on current guidelines and tools[12].

On the basis of a Memorandum of Understanding signed in 2006, selected information on products originating from China and notified in RAPEX are shared with Chinese authorities for their follow-up. Chinese authorities then report back to the Commission on follow-up action. The administrative arrangement of November 2018 also enables automated exchange of selected information on dangerous non-food consumer products between the EU's Safety Gate/RAPEX system and Health Canada's RADAR system.

2.4.1 Impact of COVID-19

The COVID-19 crisis has created high demand for protective equipment such as face masks, medical devices and hand sanitisers. As regards products covered by the Safety Gate/RAPEX alert system, Member States notified national measures taken against dangerous products linked to COVID-19, together with active market surveillance action on personal protective equipment, and online sales, particularly of masks. So far, over 200 RAPEX notifications on products related to the COVID-19 crisis (face coverings, hand disinfectants, gloves) have been made since March 2020[13].

2.4.2 RAPEX guidelines

In order to improve the functioning of the RAPEX system, under Annex II, point 8 of the Directive, the Commission must regularly update guidelines concerning the joint management of the Rapid Alert System by the Commission and the Member States. Commission Decision 2010/15/EU was the first update of the guidelines, followed and repealed by Commission Implementing Decision (EU) 2019/417[14].The impact of the revised guidelines is visible in the following example: as from November 2018 the guidelines specified that if a chemical substance in a product is already banned or restricted under EU legislation, the product can be considered

[11] https://ec.europa.eu_safety_consumers_consumers_safety_gate_statisticsAndAnualReports_2020_RAPEX_2020_report_EN.pdf

[12] Study for the preparation of an Implementation Report of the General Product Safety Directive, 2020.

[13] Please note that this data is subject to change.

[14] Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334).

to pose a serious risk without requiring a specific risk assessment. This guidance has facilitated the notification procedure on measures taken against dangerous chemical products.

2.4.3 Training

Joint training courses are regularly organised involving multiple market surveillance authorities and also other authorities, such as customs. At EU level, training and sharing of best practices of market surveillance authorities include the E-enforcement Academy project, which was carried out between December 2016 and December 2019. To safeguard, revise and update all project materials and components, a second project is being launched in 2021. Similarly, it aims to provide, update and maintain high-quality training and learning materials to support the work of national consumer protection authorities and the network of authorities responsible for consumer product safety (Consumer Safety Network) with a view to create common tools and methods to tackle the challenges of online trade and e-enforcement.

2.5 **Standardisation**

2.5.1 Decisions on safety requirements and standardisation requests

Commission Decisions EU (2015) 547 and EU (2014) 59 adopted safety requirements for two product types: alcohol-powered flue-less fireplaces and laser products[15]. Subsequently, the standardisation request was published for both products and the standardisation work is ongoing[16].

2.5.2 Decisions on references of standards

Over the reporting period, the European Commission referenced 67 standards under the Directive for the following product types:

- gymnastic equipment
- stationary training equipment
- child use and care articles
- bicycles
- internal blinds
- lighters
- children's clothing
- floating leisure articles
- cigarettes (ignition propensity)
- child protective products
- audio, video and similar (safety requirements)
- information technology equipment (safety - general requirements)

[15] In addition to the standards referenced, a number of standardisation requests under the Directive are active, of which some have already been issued before 2013.

[16] Commission Implementing Decisions C(2015) 8011 final and C(2015)557 final.

In 2019, 17 standards were withdrawn and replaced by revised standards[17]. All remaining standards were re-referenced and included in the Implementing decision, to create a complete list of references, as specified in recital 26 of the Implementing Decision.

2.5.3 The standardisation process under the Directive and potential improvement

Article 4 of the Directive provides for a standardisation process consisting of four steps:

1. the Commission issues a decision to set safety requirements to be met by the standard;
2. the Commission issues a formal request to European standardisation organisation (ESOs) to develop standard(s);
3. the ESOs develop a standard compliant with safety requirements;
4. the Commission issues a decision on the referencing of the standard in the OJ EU.

The length and complexity of the standardisation process inevitably builds delays, and is reported as burdensome and in need of simplification. Step 3 came in for particular criticism. The procedure of drawing up a European standard by the ESOs is subject to a number of requirements, such as the participation of all stakeholders, and the application of the consensus principle, which aims to reach unanimous agreement on the draft standard. Another general issue is that the procedure does not adapt to technical and scientific progress as fast as it should, while being based on a standardisation request (Step 2). Once this request is made, it may be overtaken by technical innovation rather quickly and this may become a problem if it takes a long time to develop the standard. This may lead to the standard becoming obsolete before being referenced.
Proposals from stakeholders to streamline the standardisation process suggest that the system could be made more efficient. Possible improvement could be achieved by dropping some of the steps, reducing the number of Commission decisions involved, or reducing the time it takes to adopt a standardisation request (Steps 1 and 2), and to publish a standard and its referencing in the Official Journal (Step 4). The involvement of two different Committees with Member States representatives is considered by the different groups involved to be inefficient and burdensome.

2.6 **EU case law on issues related to the General Product Safety Directive**

2.6.1 Measures based on Article 13 of the Directive

In some exceptional circumstances, Article 13 of the Directive allows the Commission to adopt temporary measures (valid for one year), via a decision, to eliminate a serious risk from certain products. It can be used in situations where the Member States significantly differ on the approach to managing the safety risk, and at the same time the risk must be managed with a high degree of urgency and can be eliminated only by adopting appropriate measures at EU level.

The latest occasion the Commission applied the procedure under Article 13 of the Directive was on 9 August 2011, when it adopted a decision on the compliance of standard EN 16156:2010 and the assessment of the ignition propensity of cigarettes[18].

[17] Commission Implementing Decision (EU) 2019/1698 of 9 October 2019.

[18] Commission Decision 2011/496/EU (OJ L 205, 10.8.2011, p.31-32).

3 CONCLUSIONS

The Directive has proven to be a powerful tool to ensure a high level of consumer protection. It has helped trace and remove huge volumes of dangerous products from the European market. The RAPEX system, set up by the Directive, has complemented the regulatory framework that applies to some key consumer products, such as toys, childcare articles and electrical appliances, with a well-functioning rapid exchange and alert system.

However, the Directive was adopted at a time when new technology products and connected devices were rare, which is no longer the case. Such developments challenge the current definition of product safety and bring new risks or change the way existing risks could materialise (for example cybersecurity affecting product safety), and these risks must be reflected and duly taken into account. Further challenges stem from the growing scale of online sales, with new operators selling products online. The Directive should ensure the same level of product safety, irrespective of the channel that they are sold to consumers.

The purpose of Article 5(1) of the Directive is that, in the event of a safety problem, dangerous products present on the market can be traced and swiftly removed if necessary to avoid putting consumers at risk. The Directive does not further specify the traceability requirement, and there are differences in detail as to how the rules are applied in the Member States. Particularly in the context of online sales, the lack of information on how to trace products and producers remains a practical problem for enforcement authorities and certain economic operators. An analysis of RAPEX data confirms that certain product categories are over-represented among dangerous products in that they lack at least two of three key information items needed for traceability (brand, type/number of product, batch number/barcode).

Market surveillance under the Directive has been successful, as indicated by the steady number of over 2 000 RAPEX notifications per year. Nevertheless, in an increasingly global market with more and more products coming to the EU from non-EU countries, there is a need for further coordination of market surveillance activities between the Member States, including cooperation with customs authorities. Coordination could be stepped up further by improving the exchange of information and best practice between Member State authorities, and by taking measures to increase institutional and financial capacity. Enhancing the overall framework and providing appropriate tools (especially tools to aid online market surveillance) would considerably increase effective enforcement by the authorities.

The European Commission provides for the development of European standards to make the general safety requirement more operational. However, given the length of the standardisation process under the Directive, there is a considerable lag between the start and the end of the standardisation process. During this period, there is a lack of criteria to assess product safety and a resulting uncertainty for economic operators and market surveillance authorities.