ANNEX

GUIDELINES FOR THE MANAGEMENT OF THE EUROPEAN UNION RAPID INFORMATION SYSTEM 'RAPEX' ESTABLISHED UNDER ARTICLE 12 OF DIRECTIVE 2001/95/EC (THE GENERAL PRODUCT SAFETY DIRECTIVE) AND ITS NOTIFICATION SYSTEM

PART I

SCOPE AND ADDRESSEES OF THE GUIDELINES

1. *Scope, objectives and update*

1.1. Scope

The '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' (the 'Guidelines') are adopted by the Commission[(1)] under Article 11(1) and Annex II, point 8, of Directive 2001/95/EC (the 'GPSD'). The Commission is assisted by an advisory committee composed of the representatives from EU Member States and established under Article 15(3) of the GPSD.

Point 8 of Annex II to the GPSD states that: 'The Commission shall prepare and regularly update, in accordance with the procedure laid down in Article 15(3), guidelines concerning the management of RAPEX by the Commission and Member States.'.

Article 11 of the GPSD prescribes that Member States should inform the Commission of measures taken which restrict the placing on the market of products — or require their withdrawal or recall — to the extent that such information is not eligible for the type of notification Article 12 of the GPSD provides for, nor does it qualify for any other notification under any specific Community legislation.

Article 22 of Regulation (EC) No 765/2008, provides that, where a Member State takes or intends to take a measure that prevents, restricts or imposes specific conditions on the marketing and use of products posing a serious risk to the health, safety and other relevant public interests of the end-users, it must immediately notify such a measure to the Commission using RAPEX.

Article 23 of Regulation (EC) No 765/2008 provides that Member States must make available to the Commission the information at their disposal, and not already provided under Article 22, on products presenting a (less than serious) risk.

Article 16 of the GPSD provides an obligation for Member States and the Commission to make available to the public information relating to risks to consumer health and safety posed by products. It would therefore be opportune that all information on measures adopted against products posing a risk, insofar as product safety is at stake, are contained in the system intended for this purpose. Member States are therefore encouraged to provide RAPEX with the measures adopted against products posing a risk and entering into the scope of application of the GPSD or Regulation (EC) No 765/2008. The information can be provided directly in RAPEX. In case the information has to be notified in another information system according to Regulation (EC) No 765/2008[(2)], the Member State can generate a RAPEX notification from within the information system (see Part II, Chapters 1.2(h) and 2.2 of these Guidelines).

Whereas the GPSD applies only to consumer products posing a risk to the health and safety of consumers, Regulation (EC) No 765/2008 applies to consumer products but also professional products covered by EU harmonisation legislation (such as certain medical devices and marine

equipment). It also covers a broader scope of risk, in addition to those related to the health and safety of consumers, such as security and environmental risks. Therefore, a risk can concern not only consumers but also, where Regulation (EC) No 765/2008 applies, other 'end-users'.

Risk Assessment Guidelines of Appendix 6 on Part III are an integral part of the RAPEX Guidelines. They are the instruments that enable determining the level of risk of a product and therefore help to identify the measures to be adopted.

The Risk Assessment Guidelines refer to the level of risk as well as to the possible injuries caused by a single product. The risk assessment for a single product must be accompanied by sound risk management. For example, the risk level for a defective household electrical appliance posing a risk of fire may be only 'low', meaning that the probability of a single appliance causing a fatal fire during the lifetime of the appliance is less than one in a million. Nevertheless, if millions of the defective appliances have been placed on the market, it is almost inevitable that fatal fires will occur if appropriate measures are not taken.

Member States[(3)], applicant countries, countries which are parties to the European Economic Area (EEA) Agreement as well as other non-EU countries and international organisations that are granted access to RAPEX (on the conditions defined in Article 12(4) of the GPSD), participate in the system according to the rules provided for in the GPSD and these Guidelines[(4)].

1.2. **Objectives**

The objectives of these Guidelines are to:

(a) streamline the processes for the notification mechanisms;

(b) set out the notification criteria for the notification mechanisms;

(c) define the content of notifications and follow-up notifications sent under the notification mechanism, in particular what data are required and which forms are to be used;

(d) establish follow-up activities to be taken by Member States upon receipt of a notification and the type of information to be provided;

(e) describe the handling of notifications and follow-up notifications by the Commission;

(f) set deadlines for the various types of action taken under the notification mechanisms;

(g) set out the practical and technical arrangements needed at Commission and Member State level for the notification mechanisms to be employed effectively and efficiently; and

(h) establish risk assessment methods and, in particular, criteria for identifying serious risks.

1.3. **Update**

The Guidelines will be regularly updated by the Commission in accordance with the advisory procedure on the basis of experience and new developments in the product safety area.

2. ***Addressees of the Guidelines***

The Guidelines are addressed to all Member States authorities acting on product safety and participating in the RAPEX network, including market surveillance authorities responsible for monitoring the compliance of products with safety requirements and authorities in charge of external border controls.

3. *Products*

3.1. Products covered by these Guidelines

These Guidelines cover two sets of products: the products covered by the GPSD and the products covered by Regulation (EC) No 765/2008.

3.1.1. *Products covered by the GPSD*

Under Article 2(a) of the GPSD, consumer products for the purpose of these Guidelines are:

(a)	'products intended for consumers'	— products that are designed and manufactured for and made available to consumers;
(b)	'migrating products'[(5)]	— products that are designed and manufactured for professionals, which are likely, however, under reasonably foreseeable conditions, to be used by consumers. These are products manufactured for professionals that are made available to consumers, who can purchase and operate them without any special knowledge or training, e.g. a power drill, an angle grinder and a table saw designed and manufactured for professionals, but also supplied on the consumer market (i.e. consumers can readily purchase them in shops and operate them on their own without any special training).

Both products intended for consumers and migrating products can be given to consumers free of charge, can be purchased by consumers and can be provided to consumers in the context of a service. All three situations are covered by RAPEX.

According to Article 2 (a) of the GPSD, products provided to consumers in the context of a service are to be considered as including:

(a) products supplied to consumers that are taken away and used outside the premises of a service provider, such as cars and lawn-mowing machines rented or leased in rental shops, and tattoo inks and implants (that are not classified as medical devices) implanted beneath the skin of a consumer by a service provider;

(b) products used on the premises of a service provider, provided that consumers themselves actively operate a product (e.g. start the machine, have the option of stopping it, and affect its operation by changing its position or intensity during use). Sun-beds used in tanning salons and fitness centres are examples of such products. Use of the products by consumers must be active, and involve a significant degree of control. Merely passive use, such as the use of a shampoo by a person whose hair is washed by a hairdresser, or the use of a bus by its passengers, does not qualify as use by consumers.

3.1.2. *Products covered by Regulation (EC) No 765/2008*

Under Regulation (EC) No 765/2008, products for the purpose of RAPEX are to be considered the products according to the scope and definitions contained in Article 15 of the same Regulation whether intended for consumers or for professional users.

3.2. Products not covered by these Guidelines

These Guidelines do not cover:

(a) Products that are covered by specific and equivalent notification mechanisms established by other EU legislation, notably:

(i) food and feed and other products covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council[6];

(ii) medicinal products covered by Directive 2001/83/EC of the European Parliament and of the Council[7], and Directive 2001/82/EC of the European Parliament and of the Council[8];

(iii) medical devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council[9];

(iv) active implantable medical devices covered by Council Directive 90/385/EEC[10].

(b) Products that are not covered by the definition of a 'product' as laid down in Article 2(a) of the GPSD, notably:

(i) second-hand products or products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect (Article 2(a) of the GPSD);

(ii) equipment used or operated by a professional service provider to supply a service, e.g. equipment on which consumers ride or travel and equipment which is operated by a service provider and not by the consumer (recital 9 of the GPSD);

(c) Products which do not enter into the definition of product contained in Article 15(4) of Regulation (EC) No 765/2008.

4. *Measures*

4.1. Types of measures

Preventive and restrictive measures can be taken in relation to products posing a risk either on the initiative of the economic operator who placed and/or distributed it on the market ('voluntary measures'), or as ordered by an authority of a Member State competent to monitor the compliance of products with the safety requirements ('compulsory measures').

For the purpose of these Guidelines, the compulsory measures and voluntary measures are defined as follows:

(a) Compulsory measures : measures adopted or decided to be adopted by Member State authorities, often in the form of an administrative decision, which oblige an economic operator to take preventive, corrective or restrictive action in relation to a specific product that they made available on the market.

(b) Voluntary measures :

(i) preventive and restrictive measures adopted on a voluntary basis by an economic operator, i.e. without any intervention of an authority of a Member State;

(ii) recommendations and agreements with economic operators in their respective activities concluded by Member State authorities; this includes agreements which are not in written form and result in preventive or restrictive action taken by economic operators in their respective activities in relation to products posing a serious risk that they made available on the market.

4.2. **Categories of measures**

Article 8(1)(b) to (f) of the GPSD provides a list of the different categories of measures that are notifiable under RAPEX when the conditions for notification are fulfilled, including the following measures:

(a) marking a product with appropriate warnings on the risk(s) it may present;

(b) making the marketing of a product subject to prior conditions;

(c) warning consumers and end-users of the risks that could be posed by a product;

(d) temporary ban on the supply, offer to supply and display of a product;

(e) ban on the marketing of a product and any accompanying measures, i.e. measures required to ensure compliance with the ban;

(f) withdrawal of a product from the market;

(g) recall of a product from consumers;

(h) destruction of a withdrawn or recalled product.

For the purpose of RAPEX, the term ‘withdrawal’ is used exclusively for measures aimed at preventing the distribution, display and offer of a product posing a risk to consumers or other end-users, while the term ‘recall’ is used only for measures aimed at achieving the return of such a product that has already been made available to consumers or other end-users by a producer or distributor.

4.3. **Requirements of the measures**

Under Article 12(1) of the GPSD and Article 22 of Regulation (EC) No 765/2008 concerning serious risks, both compulsory and voluntary measures are to be notified in RAPEX.

Preventive and restrictive measures adopted on a voluntary basis by an economic operator, i.e. without any intervention of an authority of a Member State concerning a product posing a serious risk and the related preventive or restrictive measures initiated by an economic operator should be immediately notified to the competent authorities of Member States as indicated in Article 5(3) of the GPSD and in Article 22(2) and (3) of Regulation (EC) No 765/2008.

All categories of preventive and restrictive measures taken in relation to the marketing and use of consumer products posing a serious risk to the health and safety of consumers or, in the case of products covered by Regulation (EC) No 765/2008, posing a serious risk to the health, safety or other relevant public interests of the end-users are subject to the notification obligation under RAPEX.

4.4. **Exclusion of generally applicable compulsory measures**

Generally applicable acts adopted at national level and aimed at preventing or restricting the marketing and use of (a) generally described category(ies) of consumer products due to the serious risk they pose to the health and safety of consumers should not be notified to the Commission through the RAPEX application. All such national measures that apply to only generally defined categories of products, such as all products in general or all products serving the same purpose — and not to (categories of) products specifically identified by their brand, specific look, producer, trader, model name or number, etc. — are notified to the Commission under Directive (EU) 2015/1535 of the European Parliament and of the Council[11].

5. ***Risk Levels***

5.1. **Serious risk**

Before an authority of a Member State decides to submit a RAPEX notification, it always performs an appropriate risk assessment (see Part III, Appendix 6 of these Guidelines or the complementary EU general risk assessment methodology for products covered by Regulation (EC) No 765/2008[12]) in order to assess whether the product to be notified poses a serious risk to the health and safety of consumers or, in the case of products covered by Regulation (EC) No 765/2008, a serious risk to the health, safety or to other relevant public interests (for example, security or the environment) of the end-users, and thus whether one of the RAPEX notification criteria is met.

5.2. **Less than serious risk**

Notifications sent in accordance with Article 11 of the GPSD or Article 23 of Regulation (EC) No 765/2008 are generally considered as notifications for products posing a less than serious risk. Notifications of such products, contrary to notifications for products presenting a serious risk, do not necessarily involve an obligation for follow-up activities by other Member States unless the nature of the product or of the risk so requires (see Part II Chapter 3.4.6.1).

5.3. **Risk assessment method**

Part III, Appendix 6 to these Guidelines sets out a risk assessment method that can be used by Member State authorities to assess the level of risks posed by consumer products to the health and safety of consumers and to decide whether a RAPEX notification is necessary. Equally, you may need to consult the complementary EU general risk assessment methodology as referred to in Chapter 5.1 in case the product concerned is covered by Regulation (EC) No 765/2008.

A specific tool ('RAG' or Risk Assessment Guidelines[13]) is available on the RAPEX website and in the RAPEX application to perform risk assessments, which takes accounts of the principles provided for in Appendix 6.

5.4. **Assessing authority**

The risk assessment is always performed or checked by the authority of a Member State that either carried out the investigation and took appropriate measures, or which monitored the voluntary action taken with regard to a product posing a risk by an economic operator.

Any unclear issues are resolved by the RAPEX Contact Point (see Part II, Chapter 5.1) with the authority responsible before a notification is transmitted through the RAPEX application.

6. ***Cross-border effects***

6.1. **International event**

Under Article 12 of the GPSD and Article 22 of Regulation (EC) No 765/2008, a Member State submits a RAPEX notification only if it considers that the effects of the risk(s) posed by a product go or can go beyond its territory ('cross-border effects' or 'international event').

In the light of the free movement of products in the internal market, and the fact that products are imported into the EU through different distribution channels and that consumers buy products during stays abroad and via the internet, national authorities are encouraged to interpret the cross-border effects criterion in a fairly broad sense. An Article 12 of the GPSD or Article 22 notification of Regulation (EC) No 765/2008, therefore, is submitted where:

(a) it cannot be excluded that a product posing a risk has been sold in more than one EU Member State; or

(b) it cannot be excluded that a product posing a risk has been sold via the internet; or

(c) the product originates from a third country and is likely to have been imported into the EU through multiple distribution channels.

6.2. **Local event**

Measures adopted in relation to a product posing a serious risk that can only have a local effect (‘Local event’) are not notified under Article 12 of the GPSD. This applies in situations where an authority of a Member State has concrete and strong reasons to exclude the possibility that a product has been and or will be made available (by any means) in other Member States, e.g. measures taken with regard to a local product manufactured and distributed only in one Member State. In its evaluation, the authorities of the Member State have to take carefully into consideration the possibility that a product could be sold online or through new emerging distribution channels.

A notification in relation to a product posing a serious risk involving a local event only requires to be submitted to the Commission insofar as it involves information likely to be of interest to Member States from the product safety standpoint, and in particular if they are in response to a new type of risk which has not yet been notified, a new type of risk arising from a combination of products or a new type or category of products.

Such notification is to be submitted under Article 11 with reference to the second subparagraph of Article 11(1), of the GPSD.

(**1**) In other places of these Guidelines, the term 'Commission' generally refers to the RAPEX team established in the Commission department responsible for Directive 2001/95/EC and to the relevant Commission services, where appropriate.

(**2**) The Information and Communication System on Market Surveillance ('ICSMS'). This platform is aimed at facilitating communication between market surveillance bodies in the EU and in EFTA countries on non-compliant products.

(**3**) In the context of this document, the term 'Member States' must be interpreted as not precluding all other actors from being addressed by the provisions contained in these Guidelines.

(**4**) See the latest EC Implementing Decision published on https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

(**5**) See recital 10 of Directive 2001/95/EC.

(**6**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**7**) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**8**) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

(**9**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

(**10**) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

(**11**) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

(**12**) See EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76) providing guidance to authorities with relation to Article 20(2) of Regulation (EC) No 765/2008: http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations

(**13**) See https://ec.europa.eu/consumers/consumer-safety/rag/#/screen/home

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417, Division PART I.