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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[(1)], and in particular the third subparagraph of Article 11(1) and point 8 of Annex II thereof,

Having regard to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, setting out the requirements for accreditation and market surveillance on the marketing of products and repealing Regulation (EEC) No 339/93[(2)],

After consulting the Advisory Committee, set up by Article 15 of Directive 2001/95/EC,

Whereas:

(1) Article 12 of Directive 2001/95/EC establishes a European Union Rapid Information System ('RAPEX') for the rapid exchange of information between the Member States and the Commission on measures and action taken on products posing a serious risk to the health and safety of consumers.

(2) Point 8 of Annex II to Directive 2001/95/EC requires the guidelines to be regularly updated in the light of new developments and experience. Commission Decision 2010/15/EU[(3)] was the first and only update of the guidelines.

(3) In view of new developments and in order to ensure more efficient and effective notification procedures in line with best practice, a further update of the guidelines is required.

(4) Terminology and references have become obsolete as has the means of communication between the Commission and the Member States authorities and between the authorities themselves.

(5) New tools that have been developed over the last years for the proper functioning of RAPEX (wiki's, interface between RAPEX and other market surveillance systems) have to be taken into consideration in the guidelines.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417. (See end of Document for details)*

(6) Criteria for the RAPEX notification, following the new developments, have become unclear and need to be clarified.

(7) Cross-border online sales of goods have increased. This development needs to be reflected in the notification techniques as well as in the follow-up instruments to be used.

(8) Regulation (EC) No 765/2008 extends the application of RAPEX provided for in Article 12 of Directive 2001/95/EC also to products covered by that legislation. Extending the application of RAPEX raises some issues that need to be clarified in the guidelines.

(9) Regulation (EC) No 765/2008 applies to consumer products and to professional products such as some medical devices. That Regulation covers a broader scope of risks, other than 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 an indeterminate group of people referred to as ‘end-users’.

(10) Article 22 of Regulation (EC) No 765/2008 provides therefore that measures taken against products presenting a serious risk to health and safety or other relevant public interests should be notified via RAPEX.

(11) Directive 2001/95/EC and Regulation (EC) No 765/2008 are complementary and provide a system to improve the safety of non-food products.

(12) RAPEX helps to prevent and restrict the supply of products posing a serious risk to health and safety or, in the case of products covered by Regulation (EC) No 765/2008, also to other relevant public interests. It enables the Commission to monitor the effectiveness and consistency of market surveillance and enforcement activities in the Member States.

(13) RAPEX provides a basis for identifying the need for action at EU level and makes for consistent enforcement of EU product safety requirements and therefore contributes to the smooth functioning of the single market.

(14) The notification procedure established under Article 11 of Directive 2001/95/EC provides for an exchange of information between the Member States and the Commission on measures adopted on products posing a less than serious risk to the health and safety of consumers. It helps to ensure a consistent, high level of consumer health and to preserve the single market.

(15) Article 23 of Regulation (EC) No 765/2008 provides for an information support system where Member States make available to the Commission the information required by the same Article on products presenting a less than serious risk.

(16) According to the applicable legislation, Member States are not obliged to provide such information in the RAPEX system.

(17) 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.

(18) To ensure a coherent system of information for products posing a risk to the health and safety of consumers or, in case of products covered by Regulation (EC) No 765/2008, also to other relevant public interests, it would be desirable that available information concerning dangerous products covered by Article 23 of Regulation (EC) No 765/2008 could also be made available in the RAPEX system.

(19) In order to enable the functioning of the RAPEX system, guidelines should be drawn up on the various aspects of these notification procedures and, in particular, to establish the content of notifications. These should include the information to be contained in the notification, criteria for notifications involving risks that do not or cannot go beyond the territory of the Member State and criteria for the classification of notifications according to the degree of urgency. The guidelines should also lay down operating arrangements, including deadlines for the various steps of the notification and follow-up notification procedures as well as confidentiality rules.

(20) To ensure that notification procedures are properly applied, the guidelines should also set out risk assessment methods with criteria for identifying risks taking into consideration also the management of risks.

(21) In the light of point 2 in Annex II to Directive 2001/95/EC, the new guidelines include a set of risk assessment guidelines for consumer products and refer also to professional products, which specify the criteria for identifying serious risks.

(22) The guidelines should be addressed to all Member States authorities participating in the RAPEX network pursuant to Directive 2001/95/EC and Regulation EC No 765/2008, including market surveillance authorities responsible for monitoring the compliance of products with safety requirements and authorities in charge of external border controls,

HAS ADOPTED THIS DECISION:

Article 1

The guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC and its notification system are set out in the Annex to this Decision.

Article 2

Decision 2010/15/EU is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 8 November 2018.

For the Commission

Věra JOUROVÁ

Member of the Commission

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417. (See end of Document for details)*

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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[(4)] 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[(5)], 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