

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 II

EU RAPID INFORMATION SYSTEM ‘RAPEX’ ESTABLISHED UNDER ARTICLE 12 OF THE GENERAL PRODUCT SAFETY DIRECTIVE

5. RAPEX networks

5.1. RAPEX National Contact Points

Each Member State establishes a single RAPEX Contact Point to operate RAPEX at national level. The Member States decide within which national authority to set up the RAPEX contact point. Each Member State also organises its national RAPEX network to ensure the efficient flow of information between the national contact point and the various authorities participating in RAPEX. (See Part I Chapter 5.4 and Part II, Chapter 1.2).

5.1.1. Organisation

Each Member State gives the national Contact Point the resources and information it needs to perform its tasks and, in particular, to operate the system with effective back-up/business continuity.

The RAPEX Contact Point has a separate email account for RAPEX, accessible to all officials in that contact point (e.g. rapex@ ...). Professional or private email accounts of officials in charge of the RAPEX Contact Point should not be used as the email account of the RAPEX Contact Point. The RAPEX Contact Point also has a direct phone number through which it can be reached during and outside working hours.

5.1.2. Tasks

The main tasks of the RAPEX Contact Point are to:

- (a) organise and steer the work of the national RAPEX network, in accordance with the rules set out in these Guidelines;
- (b) train and assist all authorities in the network in the use of RAPEX;
- (c) ensure that all RAPEX tasks stemming from the GPSD and these Guidelines are performed correctly and, in particular, that all required information (i.e. notifications, follow-up notifications, additional information, etc.) is provided to the Commission without delay;
- (d) transmit information between the Commission and the national market surveillance authorities and authorities in charge of external border controls;
- (e) check and validate the completeness of the information received from all authorities before transmission to the Commission through the RAPEX application;

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- (f) check before submitting a notification whether a product has already been notified or information on that product has been exchanged through the RAPEX application (to avoid any duplication);
- (g) participate in RAPEX Contact Point Working Group meetings and other events on the operation of RAPEX;
- (h) suggest possible improvements to the operation of the system;
- (i) inform the Commission immediately of any technical problems with the functioning of the RAPEX application;
- (j) coordinate all national activities and initiatives carried out in relation to RAPEX;
- (k) explain to stakeholders how RAPEX operates and clarify their obligations, particularly for the business notification obligation set out in Article 5(3) of the GPSD.

5.2. **RAPEX networks established at EU and national levels**

5.2.1. *The RAPEX Contact Point Network*

The Commission organises and steers the work of the RAPEX Contact Point Network. This network consists of all RAPEX Contact Points appointed in the Member States and European Economic Area (EEA) countries.

The Commission regularly convenes meetings of the RAPEX Contact Point Network to discuss the operation of the system (e.g. to communicate the latest developments concerning RAPEX, to exchange experience and 'know-how'), and to improve cooperation between the RAPEX Contact Points.

5.2.2. *RAPEX networks established at national level*

The RAPEX Contact Points organise and steer the work of their own 'RAPEX national network'. The network consists of:

- (a) the RAPEX Contact Point;
- (b) market surveillance authorities responsible for monitoring the safety of products; and
- (c) authorities in charge of external border controls.

RAPEX Contact Points are encouraged to provide for the organisation and operation of the RAPEX national network so as to ensure that all the authorities involved are aware of their roles and responsibilities as regards the operation of RAPEX. This should be consistent with the information contained in these Guidelines.

The RAPEX Contact Points are encouraged to facilitate regular and continuous exchange of information and discussion with their national network in order to discuss with all the authorities involved how RAPEX is organised, how it operates and, if necessary, to give training courses.

5.3. **RAPEX internal communication tools, practical and technical arrangements for RAPEX and best practice**

5.3.1. *Languages*

The use of languages in notifications and follow-up notifications, as well as communications between the RAPEX Contact Points and the Commission, must take account of the objectives of RAPEX and must ensure a rapid exchange of information between Member States and the Commission on products posing serious risks.

To facilitate the work of the network, Member States authorities are encouraged to use the existing EC eTranslation webpage to ensure all Member States understand what is being communicated through RAPEX.

A link to this translation tool to submit documents or extracts from texts for translation from and into all EU languages⁽¹⁾ is available in the collaborative space. (See Part II, Chapter 5.3.2).

5.3.2. RAPEX online tools

(a) RAPEX system

The Commission has established and maintains a web-based application for use as a communication tool for the purpose of RAPEX. Member States use this system to create and submit notifications and follow-up notifications through the RAPEX application, and the Commission uses it to validate and distribute the documents it receives.

The Commission provides access to the system to all RAPEX Contact Points, competent national authorities and the relevant Commission departments. The Commission lays down the rules for granting access to the system and gives access to as many users as possible, taking into account needs and technical limitations.

Where the RAPEX system is temporarily not operational (for reasons other than regular and planned maintenance work), Member States should only submit notifications of serious risks to the Commission (i.e. ‘Article 12 notifications’, ‘Article 12 notifications requiring emergency action’ or ‘Article 22 of Regulation (EC) No 765/2008 notifications’).

The submission of other notifications and follow-up notifications is suspended until the RAPEX system is re-established. While the system is not operational, RAPEX notifications should be sent to the Commission by email to: just-rapex@ec.europa.eu or to another email address communicated in advance. If email transmission is not possible, RAPEX notifications are sent to the Commission by any other means considered appropriate⁽²⁾.

(b) ‘Product Safety Business Alert Gateway’

The ‘Product Safety Business Alert Gateway’ (also known as the ‘Business Gateway’) is intended to simplify the practical aspects of the obligation on producers and distributors, or their authorised representative, under Article 5(3) of the GPSD to notify the competent national authorities of the Member States if they know or ought to know, on the basis of the information in their possession and as professionals, that a product they have placed on the market is dangerous.

The ‘Business Gateway’ consists of two elements: (i) the notification template and (ii) the online database. The notification template is reserved for use by producers and distributors to inform the competent national authorities of the Member States that a product they have placed on the market is dangerous, in line with their obligation under Article 5(3) of the GPSD. The online database is intended for use by Member States national authorities responsible for receiving notifications of dangerous consumer products submitted by producers and distributors. The competent national authority may use the information provided to submit a RAPEX notification if all criteria for this are met.

(c) Collaborative space

The Commission also manages a collaborative space to exchange information between the Commission and the Member States competent national authorities. This includes the EU Consumer Product Safety platform, open to the RAPEX Contact Points and their colleagues working on product safety issues in the competent national authorities for all RAPEX-related issues. Requests for access to the space must be made by the RAPEX Contact Points in the relevant Member State and authorised by the Commission.

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This space also includes a section, managed by the Commission, containing useful tips and information on the functioning of RAPEX and input from the Member States.

(d) 'RAG tool'⁽³⁾

The Commission has developed this tool available on the RAPEX website to facilitate the risk assessment of products notified through the RAPEX system, in accordance with the principles laid down in Appendix 6.

5.3.3. *Contact details*

The Commission provides the RAPEX Contact Points with the contact details of the Commission's RAPEX team, including names, email addresses and telephone numbers.

The RAPEX Contact Points provide the Commission with their contact details, including the names of officials working within the Contact Point, the name and address of the authority where the RAPEX Contact Point is established, the email addresses and phone numbers of officials. Any changes to the contact details are immediately communicated to the Commission by the RAPEX Contact Point. The Commission publishes and updates a list of contact details of the RAPEX Contact Points on the RAPEX website.

Member States process contact details including personal data in application of the EU's data protection legislation. On the information exchange through RAPEX, Member States should process personal data ensuring that it circulates and is distributed only as far as it is strictly necessary.

5.3.4. *Operation of RAPEX outside regular working hours*

RAPEX operates non-stop. The Commission and the RAPEX Contact Points ensure that officials responsible for operating RAPEX can always be contacted (by phone, e-mail or other equally effective means) and that they can take whatever action is necessary, including in an emergency and outside regular working hours, such as weekends and holidays.

The Commission provides the RAPEX Contact Points with an emergency telephone number, which should be used to contact the Commission RAPEX team outside of working hours, with priority over any other communication channels.

The RAPEX Contact Points provide the Commission with their contact details, including the phone numbers of officials who can be contacted during and outside working hours. Any changes to the contact details are immediately communicated to the Commission by the RAPEX Contact Points.

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- (1) <https://webgate.ec.europa.eu/etranslation/translateDocument.html>
- (2) There is no need to send notifications via the Permanent Representation of a Member State to the EU.
- (3) See Part I, Chapter 5.3 of these Guidelines.

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