

Company notifications within the context of the RAPEX system

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The RAPEX system lives off information. Unsurprisingly, the requirement for companies to notify the authorities of hazardous products is considered to be a key prerequisite for functioning market surveillance. With this in mind, company notifications will be examined more closely below in light of the new guidelines.

Which products require notification?

A duty to notify the market surveillance authorities exists for consumer and migrated products in accordance with [Directive 2001/95/EC on general product safety](#) and for products subject to an EU harmonizing statute in accordance with [Regulation \(EC\) No. 765/2008](#) setting out the requirements for accreditation and market surveillance relating to the marketing of products. It is immaterial whether the aforementioned products are intended for consumer use or are confined exclusively to the B2B market.

Who is required to make notification, and what are the prerequisites?

The duty to notify the authorities of irregularities in connection with the aforementioned product groups generally rests upon the affected economic operator, i.e. the manufacturer, the manufacturer's agent, the importer or the distributor.

The first prerequisite for notification is that the product poses a serious risk to public health and safety or to another legal interest protected by harmonizing legislation. Examples of such interests are pets and other objects (pursuant to Article 4(1) of the Machinery Directive, Directive 2006/42/EC), as well as consumer protection and environmental interests.

The affected economic operator must also have voluntarily taken preventive or restrictive measures on the market to avert the existing hazard. If such measures are ordered by the supervisory authorities, the authority makes notification of those measures through the RAPEX system.

Finally, the possibility cannot be ruled out that the risk will have a cross-border impact. However, such an impact should only be assumed in the rarest of exceptional cases consistent with recent developments at the Commission level for more effective design and use of the RAPEX system (Recital 52 to the Recreational Craft Directive, Directive 2013/53/EU).

Is notification required for less than serious risks?

Notification requirements through the RAPEX system for voluntary measures relating to low-risk products do not exist in accordance with Directive 2001/95/EC or Regulation (EC) No. 765/2008. However, pursuant to Article 16 of Directive 2001/95/EC, supervisory authorities are required to notify consumers about all product risks.

In the interests of promoting the coherence of the notification system and of effectively satisfying these notification requirements, the new RAPEX guidelines encourage supervisory authorities to provide notification through the RAPEX system of all measures taken with regard to products, for all product groups equally.

Consequently, it may be assumed that notification is intended even for voluntary measures relating to low-risk products. After all, the authorities cannot effectively comply with the EU Commission's recommendations unless they are informed about all risks and measures.

In what period of time must notification be made?

In general, the competent authorities are to be notified immediately of existing risks and the measures taken. In case of less than serious risks, the competent supervisory authority is to be notified within ten days at the latest, regardless of whether the investigations are still ongoing or have already been completed. In case of serious risk, the notification period is shortened to three days, beginning on the date on which the company learned or should have learned about the risk.

Practical notes

It is to be assumed that the new RAPEX guidelines have raised the awareness of supervisory authorities on the subject of company notifications. Accordingly, companies should proactively communicate with the authority even for low-risk products and should consult with them in each individual case in order to determine whether notification has to be made. In accordance with the [European Commission's guidelines](#), notification can only be dispensed with in case of "isolated circumstances or products" which do not require verification, monitoring or other actions by the authorities and which do not provide information useful for risk assessment and consumer protection, e.g. because it is clear that the risk pertains to a limited number of well-identified products (or batches) and the manufacturer or distributor has solid evidence that the risk is entirely manageable.

Companies who fail to make a report, or those who file late or inaccurate reports, may be subject to fines of up to 10,000 Euros.

Further links:

[The new RAPEX guidelines](#)

[Business Gateway](#) for notifying the competent authorities of measures taken



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