Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance)

CHAPTER V

Exchanges of information and rapid intervention situations

Article 11

Where a Member State takes measures which restrict the placing on the market of products — or require their withdrawal or recall — such as those provided for in Article 8(1)(b) to (f), the Member State shall, to the extent that such notification is not required under Article 12 or any specific Community legislation, inform the Commission of the measures, specifying its reasons for adopting them. It shall also inform the Commission of any modification or lifting of such measures.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall notify the measures concerned insofar as they involve 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 risk which has not yet been reported in other notifications.

In accordance with the procedure laid down in Article 15(3) of this Directive, the Commission shall, while ensuring the effectiveness and proper functioning of the system, adopt the guidelines referred to in point 8 of Annex II. These shall propose the content and standard form for the notifications provided for in this Article, and, in particular, shall provide precise criteria for determining the conditions for which notification is relevant for the purposes of the second subparagraph.

The Commission shall forward the notification to the other Member States, unless it concludes, after examination on the basis of the information contained in the notification, that the measure does not comply with Community law. In such a case, it shall immediately inform the Member State which initiated the action.

Article 12

Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX. It shall also inform the Commission without delay of modification or withdrawal of any such measure or action.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall follow the procedure laid down in Article 11, taking into account the relevant criteria proposed in the guidelines referred to in point 8 of Annex II.

Without prejudice to the first subparagraph, before deciding to adopt such measures or to take such action, Member States may pass on to the Commission any information in their possession regarding the existence of a serious risk.

In the case of a serious risk, they shall notify the Commission of the voluntary measures laid down in Article 5 of this Directive taken by producers and distributors.

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- On receiving such notifications, the Commission shall check whether they comply with this Article and with the requirements applicable to the functioning of RAPEX, and shall forward them to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.
- [F13] Detailed procedures for RAPEX are set out in Annex II. They shall be adapted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).]
- Access to RAPEX shall be open to applicant countries, third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to arrangements defined in these agreements. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Community.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 13

- If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States, it may, after consulting the Member States, and, if scientific questions arise which fall within the competence of a Community Scientific Committee, the Scientific Committee competent to deal with the risk concerned, adopt a decision in the light of the result of those consultations, in accordance with the procedure laid down in Article 15(2), requiring Member States to take measures from among those listed in Article 8(1)(b) to (f) if, at one and the same time:
 - a it emerges from prior consultations with the Member States that they differ significantly on the approach adopted or to be adopted to deal with the risk; and
 - b the risk cannot be dealt with, in view of the nature of the safety issue posed by the product, in a manner compatible with the degree of urgency of the case, under other procedures laid down by the specific Community legislation applicable to the products concerned; and
 - the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.
- 2 The decisions referred to in paragraph 1 shall be valid for a period not exceeding one year and may be confirmed, under the same procedure, for additional periods none of which shall exceed one year.

However, decisions concerning specific, individually identified products or batches of products shall be valid without a time limit.

- 3 Export from the Community of dangerous products which have been the subject of a decision referred to in paragraph 1 shall be prohibited unless the decision provides otherwise.
- 4 Member States shall take all necessary measures to implement the decisions referred to in paragraph 1 within less than 20 days, unless a different period is specified in those decisions.

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5 The competent authorities responsible for carrying out the measures referred to in paragraph 1 shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.