ANNEX I

REQUIREMENTS CONCERNING INFORMATION ON PRODUCTS THAT DO NOT COMPLY WITH THE GENERAL SAFETY REQUIREMENT TO BE PROVIDED TO THE COMPETENT AUTHORITIES BY PRODUCERS AND DISTRIBUTORS

1. The information specified in Article 5(3), or where applicable by specific requirements of Community rules on the product concerned, shall be passed to the competent authorities appointed for the purpose in the Member States where the products in question are or have been marketed or otherwise supplied to consumers.

2. The Commission, assisted by the Committee referred to in Article 15, shall define the content and draw up the standard form of the notifications provided for in this Annex, while ensuring the effectiveness and proper functioning of the system. In particular, it shall put forward, possibly in the form of a guide, simple and clear criteria for determining the special conditions, particularly those concerning isolated circumstances or products, for which notification is not relevant in relation to this Annex.

3. In the event of serious risks, this information shall include at least the following:

(a) information enabling a precise identification of the product or batch of products in question;

(b) a full description of the risk that the products in question present;

(c) all available information relevant for tracing the product;

(d) a description of the action undertaken to prevent risks to consumers.

ANNEX II

PROCEDURES FOR THE APPLICATION OF RAPEX AND GUIDELINES FOR NOTIFICATIONS

1. RAPEX covers products as defined in Article 2(a) that pose a serious risk to the health and safety of consumers.

Pharmaceuticals, which come under Directives 75/319/EEC[(1)] and 81/851/EEC[(2)], are excluded from the scope of RAPEX.

2. RAPEX is essentially aimed at a rapid exchange of information in the event of a serious risk. The guidelines referred to in point 8 define specific criteria for identifying serious risks.

3. Member States notifying under Article 12 shall provide all available details. In particular, the notification shall contain the information stipulated in the guidelines referred to in point 8 and at least:

(a) information enabling the product to be identified;

(b) a description of the risk involved, including a summary of the results of any tests/analyses and of their conclusions which are relevant to assessing the level of risk;

(c) the nature and the duration of the measures or action taken or decided on, if applicable;

(d) information on supply chains and distribution of the product, in particular on destination countries.

Such information must be transmitted using the special standard notification form and by the means stipulated in the guidelines referred to in point 8.

When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States shall provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available. They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93[(3)] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC[(4)] in the case of a new substance. The guidelines referred to in point 8 shall define the details and procedures for the information requested in that respect.

4. When a Member State has informed the Commission, in accordance with Article 12(1), third subparagraph, of a serious risk before deciding to adopt measures, it must inform the Commission within 45 days whether it confirms or modifies this information.

5. The Commission shall, in the shortest time possible, verify the conformity with the provisions of the Directive of the information received under RAPEX and, may, when it considers it to be necessary and in order to assess product safety, carry out an investigation on its own initiative. In the case of such an investigation, Member States shall supply the Commission with the requested information to the best of their ability.

6. Upon receipt of a notification referred to in Article 12, the Member States are requested to inform the Commission, at the latest within the set period of time stipulated in the guidelines referred to in point 8, of the following:

(a) whether the product has been marketed in their territory;

(b) what measures concerning the product in question they may be adopting in the light of their own circumstances, stating the reasons, including any differing assessment of risk or any other special circumstance justifying their decision, in particular lack of action or of follow-up;

(c) any relevant supplementary information they have obtained on the risk involved, including the results of any tests or analyses carried out.

The guidelines referred to in point 8 shall provide precise criteria for notifying measures limited to national territory and shall specify how to deal with notifications concerning risks which are considered by the Member State not to go beyond its territory.

7. Member States shall immediately inform the Commission of any modification or lifting of the measure(s) or action(s) in question.

8. 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 the Member States.

9. The Commission may inform the national contact points regarding products posing serious risks, imported into or exported from the Community and the European Economic Area.

10. Responsibility for the information provided lies with the notifying Member State.

11. The Commission shall ensure the proper functioning of the system, in particular classifying and indexing notifications according to the degree of urgency. Detailed procedures shall be laid down by the guidelines referred to in point 8.

ANNEX III

PERIOD FOR THE TRANSPOSITION AND APPLICATION OF THE REPEALED DIRECTIVE

(REFERRED TO IN THE FIRST SUBPARAGRAPHE OF ARTICLE 22)

Directive	**Period for transposition**	**Period for bringing into application**
Directive 92/59/EEC	29 June 1994	29 June 1994

ANNEX IV

CORRELATION TABLE

(REFERRED TO IN THE SECOND SUBPARAGRAPH OF ARTICLE 22)

This Directive	**Directive 92/59/EEC**
Article 1	Article 1
Article 2	Article 2
Article 3	Article 4
Article 4	—
Article 5	Article 3
Article 6	Article 5
Article 7	Article 5(2)
Article 8	Article 6
Article 9	—
Article 10	—
Article 11	Article 7
Article 12	Article 8
Article 13	Article 9
Articles 14 and 15	Article 10
Article 16	Article 12
Article 17	Article 13

Article 18	Article 14
Article 19	Article 15
Article 20	—
Article 21	Article 17
Article 22	Article 18
Article 23	Article 19
Annex I	—
Annex II	Annex
Annex III	—
Annex IV	—

(**1**) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Commission Directive 2000/38/EC (OJ L 139, 10.6.2000, p. 28).

(**2**) OJ L 317, 6.11.1981, p. 1. Directive as last amended by Commission Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).

(**3**) OJ L 84, 5.4.1993, p. 1.

(**4**) OJ 196, 16.8.1967, p. 1/67. Directive as last amended by Commission Directive 2000/33/EC (OJ L 136, 8.6.2000, p. 90).