

Proposals for the guideline on the assessment of chemical risks in the European rapid alert system RAPEX

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RAPEX, the EU's rapid alert system for hazardous consumer products, was introduced to facilitate the rapid and efficient exchange of information between the market monitoring authorities in the EU member states and the EU Commission regarding consumer products or cosmetics sold on the European market that are harmful to health. However, the criteria for deciding when a "serious risk" exists and a RAPEX notification is to be submitted by the member states are not satisfactorily defined. The existing guidelines do not distinguish between the assessment of short-term risks such as injury due to fire, explosions, electric shocks or foreign substances and medium to long-term risks that may be caused by microbiological contamination or chemical substances.

From the point of view of the Federal Institute for Risk Assessment (BfR), the RAPEX system does not yet adequately cover the "serious health risks" that can be caused by chemical ingredients in consumer products or cosmetics. The BfR therefore recommends adaptation of the guideline for RAPEX notifications to the specifics of the assessment procedure for chemical risks in consumer products.

In the following, the BfR expresses its opinion on the aspects that are of importance for the uniform assessment of health risks due to chemical substances in consumer products. In the view of the BfR, the health risk assessments to be drawn up should take account of the following points: the hazard potential of the substance, the potential severity of damage and an exposure assessment, in other words the degree to which consumers come into contact with the substance through use of the product in question. The prepared risk assessments should further be published in a database to which all member states have access so that they can be used as a basis for decision-making in similar cases.

The assessment of risks in the case of microbiological contamination of products is not part of this concept paper.

The full version of the BfR Information in German is available on <http://www.bfr.bund.de/cm/343/vorschlaege-zum-leitfaden-zur-bewertung-chemischer-risiken-im-europaeischen-schnellwarnsystem-rapex.pdf>