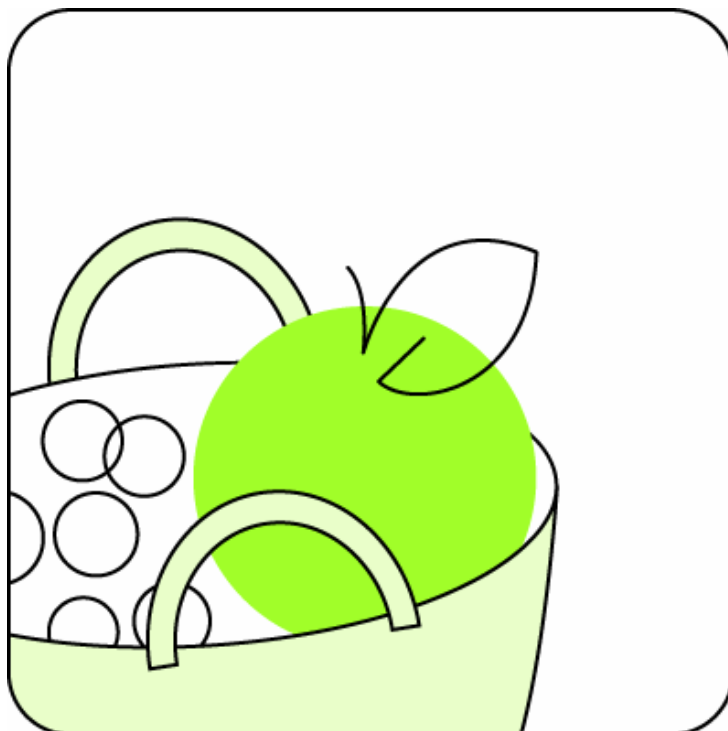




EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate B - Consumer Affairs

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**Annual Report  
on the operation of the Rapid Alert System  
for non-food consumer products (RAPEX)  
2005**



# Annual Report on the operation of the Rapid Alert System for non-food consumer products (RAPEX) 2005

## I. Introduction

The EU consumer policy strategy for 2002 – 2006 <sup>1</sup> calls in particular for the **effective enforcement of consumer protection rules**.

Efficient co-operation and consistent action of the public authorities responsible for the enforcement of consumer safety legislation is key to the functioning of the Internal Market and the achievement of a high common level of protection throughout the EU. Information exchange is an important element of such co-operation, in particular when rapid action is necessary. In the area of non-food consumer product safety, the Rapid Alert System RAPEX ensures such information exchange. The legal basis for RAPEX is the General Product Safety Directive 2001/95/EC (GPSD). Chapter V deals specifically with exchange of information and rapid intervention situations. Details of the functioning of the system are provided in the Guidelines adopted by the Commission in April 2004.

RAPEX serves as a single rapid alert system for dangerous consumer products. All non-food products intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions, are included within the scope of RAPEX, with the exception of pharmaceutical and medical products for which specific mutual information arrangements exist.

The objective of RAPEX is to ensure the rapid exchange of information among Member States and the Commission on measures taken in the Member States to prevent, restrict, or impose specific conditions on the marketing or use of consumer products because such products cause a serious risk to the health and safety of consumers. RAPEX covers both mandatory enforcement measures taken by the competent authorities and voluntary measures taken autonomously by producers and distributors or agreed with the authorities.

Thus, the RAPEX system aims at:

- preventing risks to consumer health and safety in the EU, by banning the supply to consumers of products which pose a serious risk, and where necessary withdrawing products from the market or recalling them from consumers, or taking any other appropriate protection measure;
- ensuring a high consistent level of product safety in the EU and the effective functioning of the internal market by contributing to the consistent enforcement of Community product safety legislation;
- facilitating the monitoring of effectiveness and consistency of market surveillance and enforcement activities in the Member States;
- identifying the need and providing a basis for action at Community level, where necessary.

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<sup>1</sup> COM (2002) 208 Final

## II. Operation of the RAPEX system

When a product presenting serious risk to consumers' health and safety is identified on the market in a Member State, the authority (designated as "the National Contact Point") of that Member State informs the European Commission – Directorate-General Health and Consumer Protection (SANCO) - of the measures taken to prevent the risk. Voluntary actions taken by producers and distributors or agreed between authorities and the economic operators are also notified by the authority.

The Commission examines the notification for completeness and quality as well as the compliance of the information provided with the requirements of the GPSD and the RAPEX Guidelines. If needed, the Commission asks the notifying Member State authority for complementary information. The information is disseminated to all the Member States' National Contact Points, normally in five languages (Spanish, German, English, French, and Italian), in view of an appropriate follow-up by national authorities. Such follow-up is in particular necessary when the dangerous product has been placed on the market of other Member States than the one of the notifying authority. Member State authorities are subsequently required to inform the Commission of their follow-up activities and conclusions.

In addition to the 25 Member States, also the EFTA/EEA members Norway, Iceland and Lichtenstein participate in RAPEX as well as the Accession Countries Bulgaria and Romania. Countries from other regions of the world, such as China, Canada and the United States, are taking an increasing interest in RAPEX.

## III. Objective and main trends in 2005

This report provides an assessment of the operation of the RAPEX system in 2005, in accordance with the Annual Policy Strategy which requires "*the assessment of the effectiveness of the revised GPSD in the enlarged EU*". The report includes a number of statistics, in particular the number of notifications, including a comparison with previous years, the notifying country, the origin of the notifications and the categories of notified products, as well as the nature of risk.

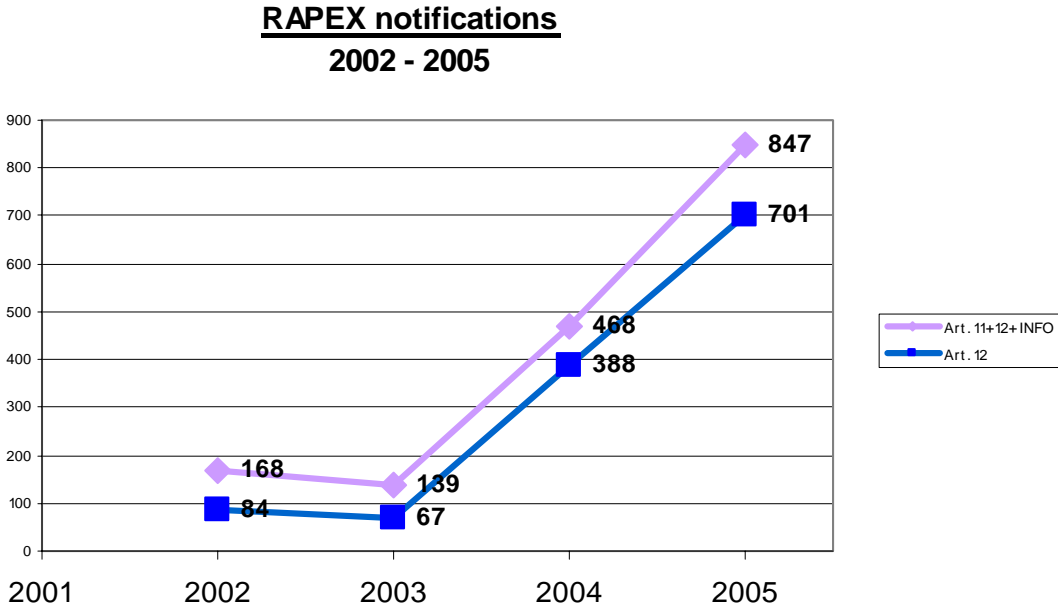
It should be stressed that these are statistics on the functioning of the RAPEX system, but they do **not** provide a statistically representative description of the overall situation of dangerous products on the market. This depends on the fact that not all the measures taken in case of products involving serious risks, mandatory and voluntary, are notified as required. Furthermore, the enforcement activities of the Member States are mostly based on post-marketing surveillance and cannot catch all the dangerous products on the market. In order to avoid confusion in comparing the figures provided in these statistics with other figures based on RAPEX notifications elaborated for instance by the authorities of the Member States or trade associations, it should be kept in mind that only notifications validated by the Commission during the period 1 January to 31 December 2005 are taken into account here, independently from the date of transmission by the National Contact Points and the date of publication by the Commission.

- Statistics – Analysis

In 2005, the Commission received 847 notifications. 701 of these notifications were published as notifications under Article 12 of the GPSD (measures taken by the competent authorities or voluntarily by producers and distributors for products representing a serious risk). 125 notifications did not qualify for treatment as Article 12 cases for various reasons and were disseminated to the National Contact Points for information only, and 21 were treated as notifications under Article 11 (measures taken by the competent authorities on products posing a lesser risk). 40 % of the corrective actions were taken on a voluntary basis. All data

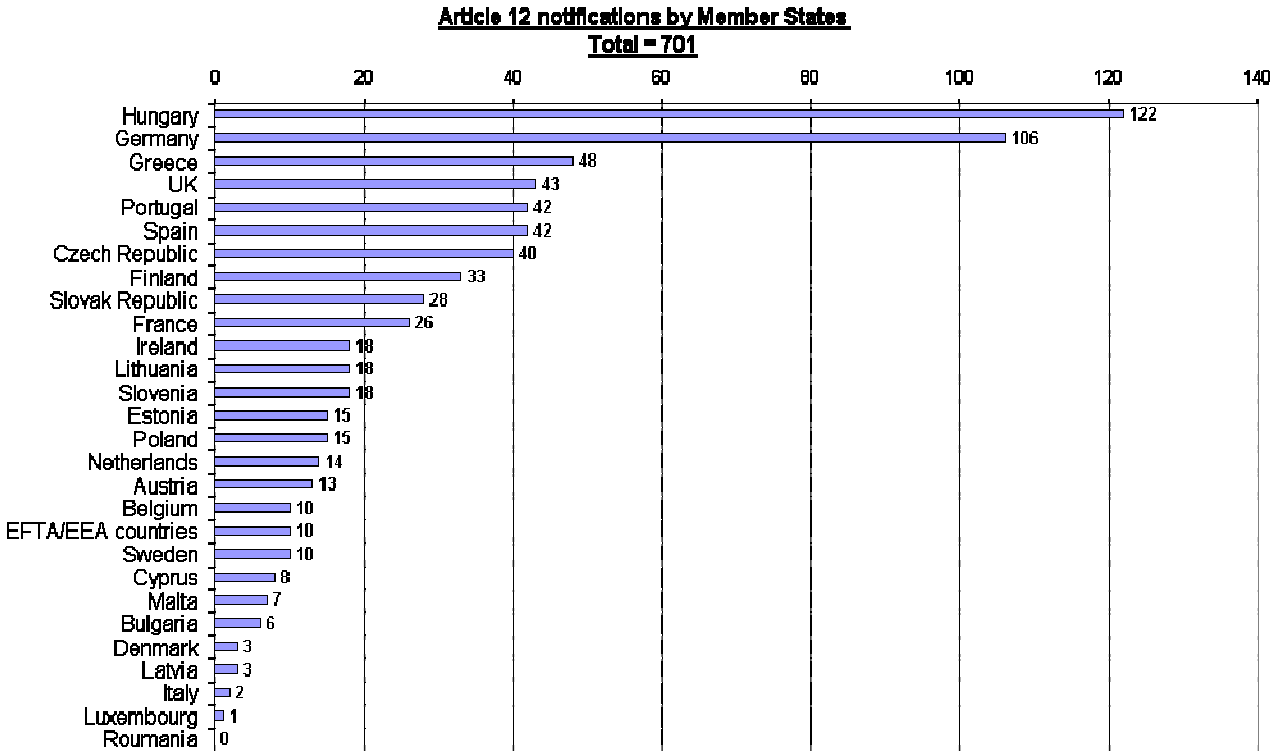
should be interpreted taking into account the different sizes of the countries concerned and the different productions and market structures across the EU.

**(1) Number of notifications 2001-2005**



The statistics show that the application of the system and the transmission of notifications to the Commission have risen steeply during the last few years. In the second year after the entry in force of the revised GPSD in January 2004, the number of serious risk notifications has almost doubled from 388 in 2004 to 701 in 2005.

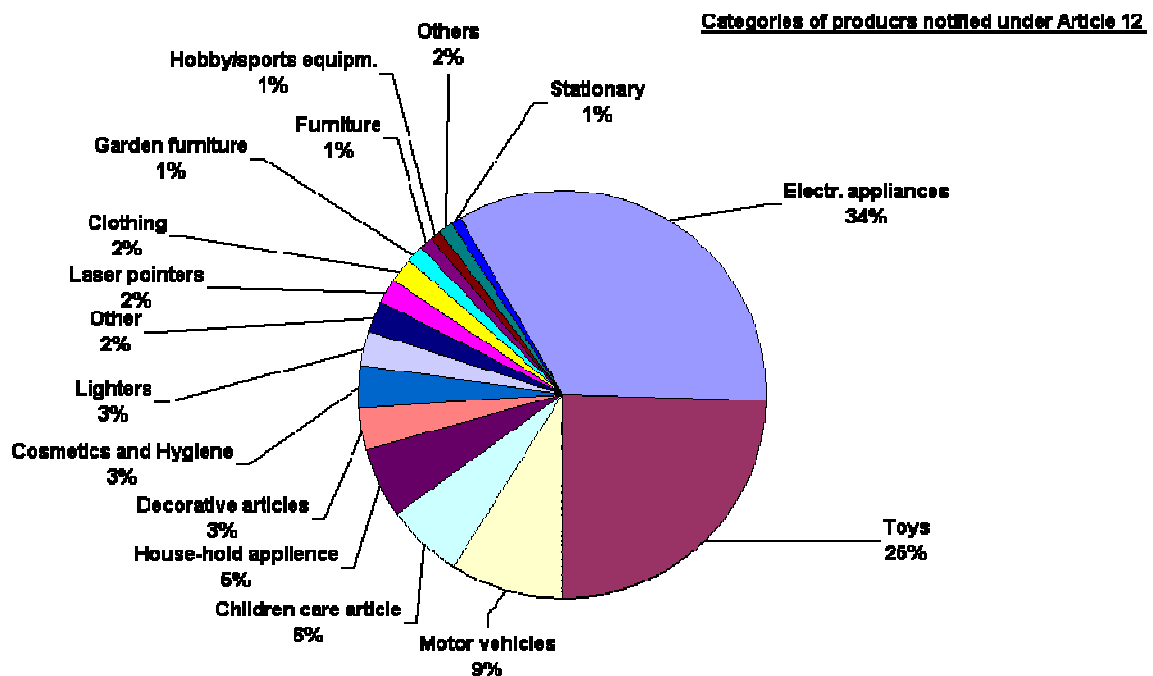
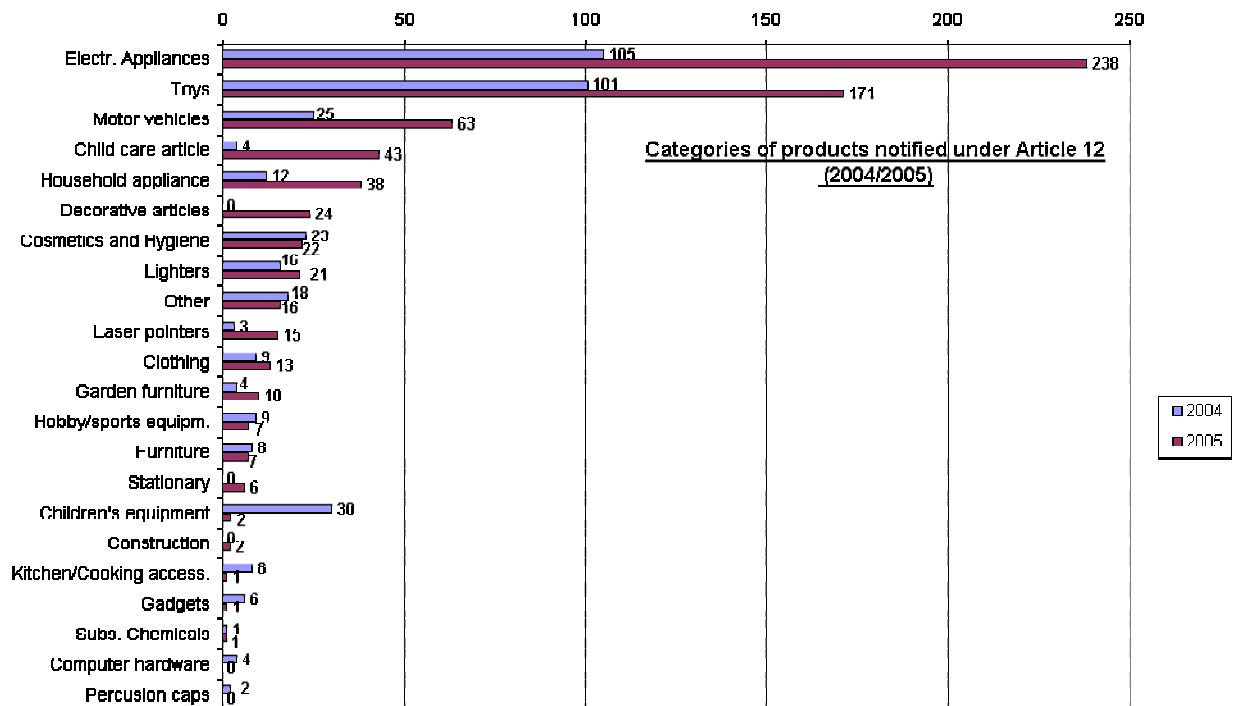
**(2) Art. 12 notifications by Member State**



It is worth noticing that in 2005 all EU Member States and the EFTA/EEA states sent notifications to the Commission. For the first time Bulgaria has participated with 6

notifications. As in 2004, Hungary with 122 notifications (17%), and Germany, with 106 (15%) have been the most active notifying countries.

### (3) Categories of products notified

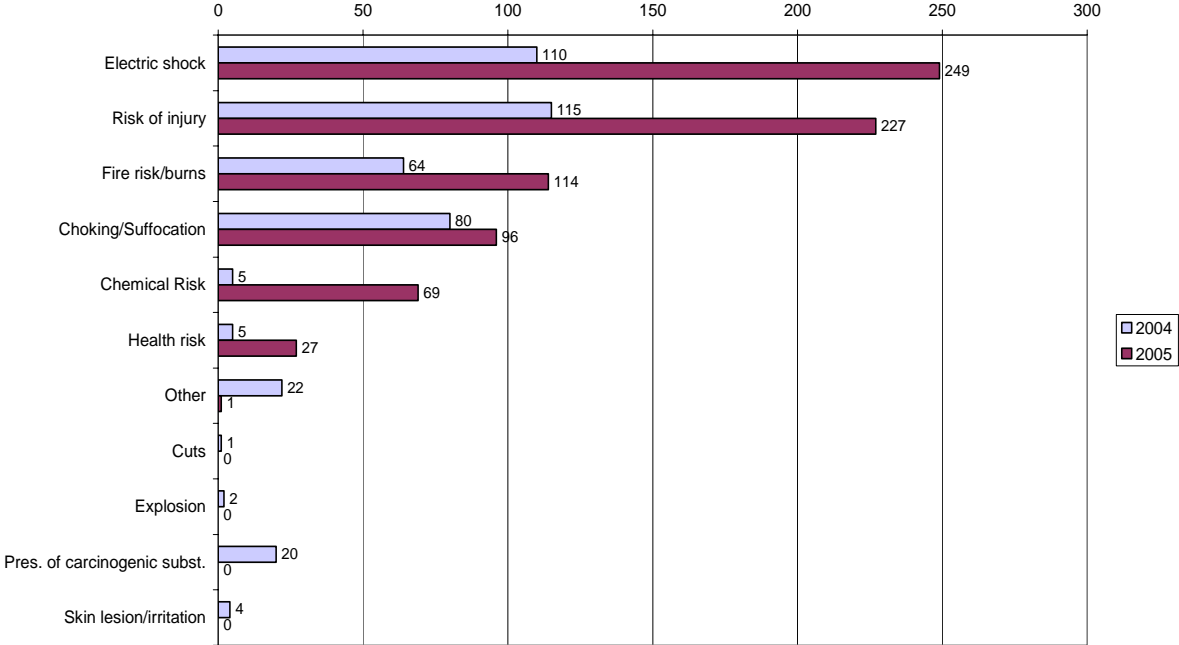


More than half of the 701 serious risk notifications concern two categories of products: electrical appliances with 238 notifications (34%) and toys with 171 (25%). This picture is similar to the situation in 2004. One noticeable difference compared to last year is the

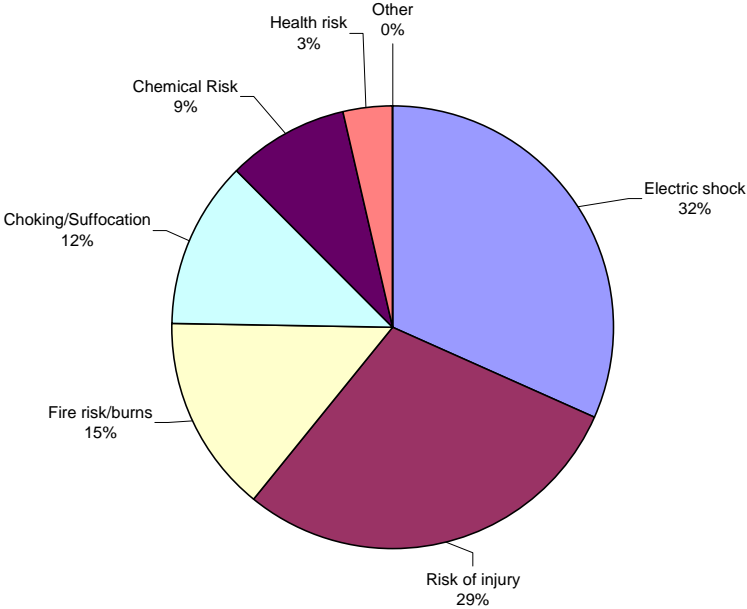
increased number of notifications related to motor vehicles: 63 in 2005, compared to 25 in 2004.

**(4) Nature of the risk**

**Products notified under Article 12 by nature of the risk (2004/2005)**

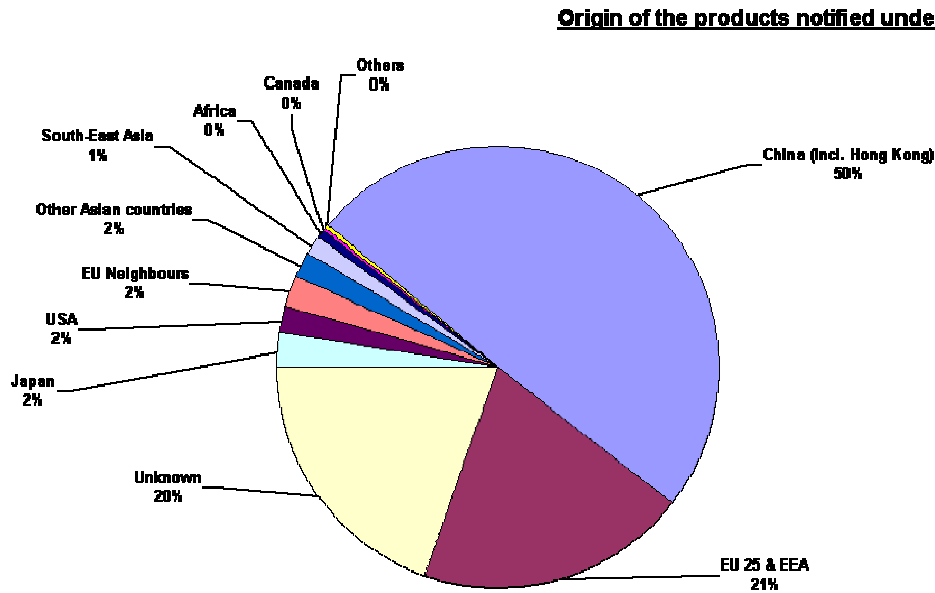
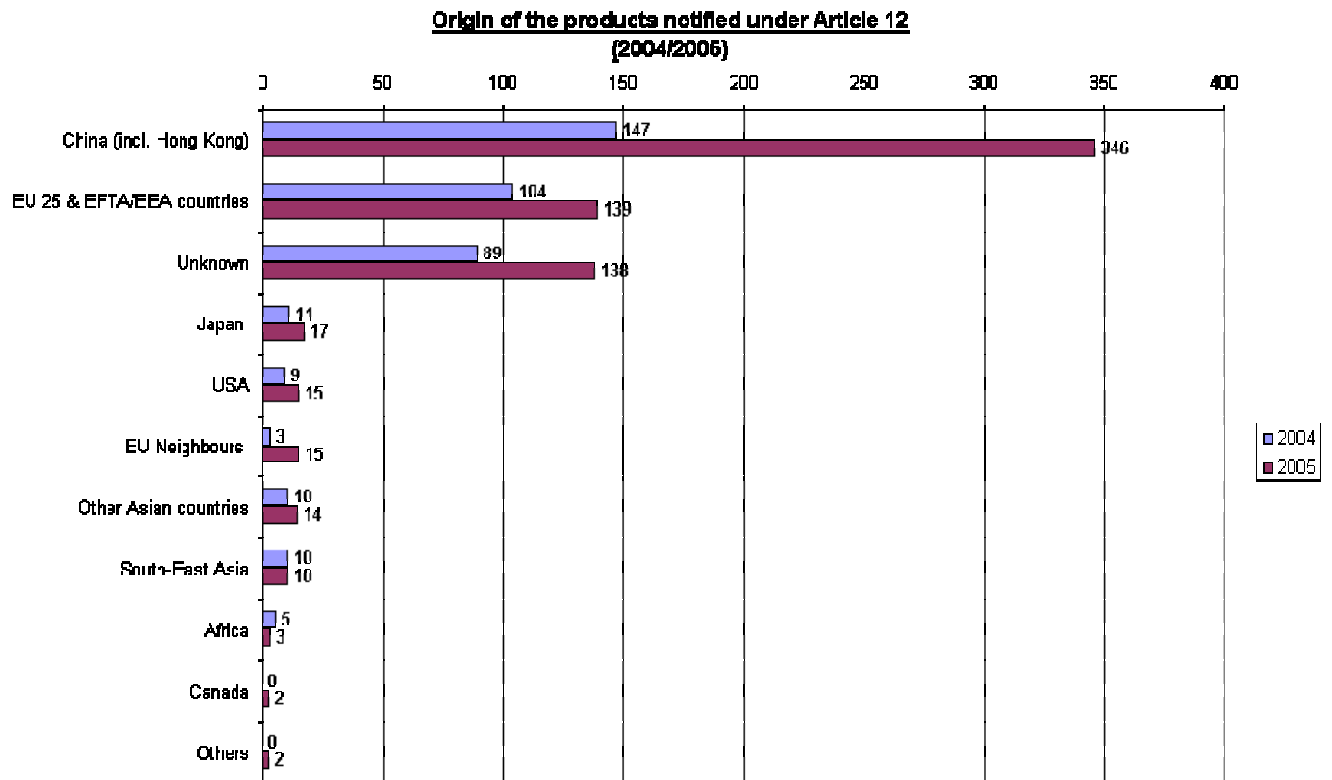


**Products notified (%) under Article 12 by nature of the risk**



In 2005 the Commission received 249 notifications (32%) identifying electric shock as the main danger. This is consistent with the percentage of notifications concerning electrical appliances which is shown in the chart on product category above. With 29% the risk of injury is the second most frequently notified category followed by fire risk or burns coming third with 15%. It should be noted that some notifications present more than a single risk, and thereby increase the total number of risks beyond the total number of notifications.

(5) Origin of the products



In accordance with the tendency of the previous years, the highest number of notifications concern products originating from China. They represent half of all notifications (346),

followed by products originating from the European Economic Area (EEA) which covers the EU Member States and the three EFTA/EEA countries Iceland, Liechtenstein and Norway (21%). 20% of the notified products were of unknown origin. This high percentage for products of unknown origin is a limiting factor when assessing the presence of dangerous products in the EU.

#### **IV. Main developments**

Enlargement: In March 2005 decisions were taken by the Association Councils to give full access to the RAPEX system to Bulgaria and Romania. Training sessions for these two countries were organised for officials in charge of the operation of RAPEX. Links to RAPEX for Bulgaria and Romania were operational as of the second half of 2005.

RAPEX access to third countries: Currently, discussions are taking place to grant read-only access to China and the United States. Since a considerable number of notified products are originating from China, the access of Chinese authorities to the RAPEX information will be an effective means of enhancing the safety of products imported from China.

Moreover, since many products are sold in and are circulating between the EU and US markets, an exchange of information through the RAPEX system on products causing serious risks could help improving international co-operation on product safety and thereby raising the overall level of product safety.

Risk Assessment Guidelines: The consistent implementation of the GPSD requires a coherent use of agreed criteria and tools for the assessment of the safety of consumer products. Guidance for such assessment is provided by the RAPEX Guidelines. However, experience has shown that the effective practical application of the Guidelines requires further work. Against this background the Commission has set up a Working Group for the Improvement of the Risk Assessment Guidelines consisting of 16 experts from 11 Member States. The intention is to adopt improved Guidelines possibly in late 2007.

Training: In 2005, 8 training sessions took place in order to strengthen the capacities of the national officials in charge of the operation of the RAPEX system. In particular, seminars held in Norway, Finland, Estonia, Latvia and Portugal addressed national focal points in different administrations. Furthermore, 3 training sessions were organised in Brussels for Romanian, Bulgarian and Hungarian National Contact Points. Further training seminars are planned for 2006.

IT development: Directorate-General Health and Consumer Protection (SANCO) is currently preparing a general platform for all its Rapid Alert Systems. The new system, GRAS (Generic Rapid Alert System), will function as a common IT basis for all Rapid Alert Systems of the Directorate-General. It will cover in particular biological and chemical risks, food and feed as well as dangerous products alerts. The new system is planned to be operational towards the end of 2006.

Practical/technical developments: During 2005 several improvements were made on the practical/technical side:

- The current notification form has been modified in order to put it in line with the RAPEX Guidelines and make it more user-friendly. The new notification form is planned to be operational in February 2006.
- Furthermore, a new common notification form has been created for toys covering both the notification requirements (safeguard clause) of Directive 88/378/EEC on the Safety of Toys and the RAPEX system. The new form is planned to be available in the beginning of February 2006.
- All notifications are translated into five languages by the Commission: Spanish, German, English, French, and Italian. In order to speed up the translation process, a direct link has been created to the translation software of DG Translation.

## V. Conclusions

Three main indications can be drawn from the assessment of functioning of the system in 2005:

- the urgent need for **improvement of the participation in the system by certain Member States**,
- the need for measures to **reduce the inflow of dangerous products from certain non-EU countries** and
- the urgency to **improve the quality of the notifications** presented.

The RAPEX system is developing rapidly. All Member States are now actively participating in the system and in 2005 there has been an increase of more than 80% of serious risk notifications over the previous year. However, the very uneven distribution of notifications (and reactions) between Member States persists beyond any possible justification. Some Member States urgently need to improve their participation in RAPEX. The Commission will discuss this issue with the concerned Member States, in order to identify the source of the problem and contribute to the solution.

As in previous years, a high share of dangerous products notified originated from non-EU countries, in particular from China. This trend is increasing. Therefore, in addition to reinforcing co-operation with the authorities of such countries, it is important to ensure a better co-operation between the market surveillance and the customs authorities to help preventing dangerous products from entering the EU Internal Market.

Finally, with the considerable increase of the number of notifications presented, timeliness and quality of the notifications are crucial for the effectiveness of RAPEX. Timeliness goes hand in hand with the quality of the information provided. When important elements are missing, in particular such information as the product identification, it is not appropriate to disseminate the notification to the other Member States. Without the product identification the surveillance inspectors will not know which product is concerned and consequently will not be able to ensure a follow up to the notification.

In 2005 the most frequent reasons for non-dissemination were

- **lack of or unclear description of the product**
- **lack of or unclear description of the risk**

In addition to the measures to improve further the functioning of the RAPEX system, in 2006 further efforts will be made in order to ensure a closer monitoring of the follow-up given to the notifications. The objective is to ensure that effective and consistent measures are taken timely throughout the EU in order to prevent risks to consumer health and safety in relation to the dangerous products notified.