



EUROPEAN COMMISSION

# Keeping European Consumers Safe

## 2008 Annual Report

on the operation of the Rapid Alert System  
for non-food consumer products

# RAPEX



**RAPEX**  
KEEPING EUROPEAN CONSUMERS SAFE



The Directorate-General for Health and Consumers of the European Commission manages the Rapid Alert System for non-food consumer products (RAPEX). This report describes the activity of RAPEX in 2008.

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Further information on the Directorate-General for Health and Consumers is available at:

[http://ec.europa.eu/dgs/health\\_consumer/index\\_en.htm](http://ec.europa.eu/dgs/health_consumer/index_en.htm)

The RAPEX weekly overviews can be consulted at:

<http://ec.europa.eu/rapex>

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## 2008 Annual Report

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# RAPEX



Directorate-General for  
Health & Consumers





# Foreword

## **Dear readers,**

It is with immense satisfaction that I present you with the RAPEX Annual Report 2008.

This year's Report carries a special significance, as it marks the 5th year of activity of the system. As is normally the case on the occasion of important anniversaries, allow me to give a brief overview of the past few years.

When the system as we know it today began its activity in 2004, around 140 notifications were registered. In 2008, this number has grown more than 10 times, reaching almost 1 900 notifications ...and it is still growing!

But RAPEX is more than a numerical success. These five years have witnessed a sea change in the cultural and political landscape of product safety, particularly in the non-food area. RAPEX has not only adapted to all these changes; more than that, it has been the real catalyst for many of them.

In 2004 and 2007, twelve new European partners joined RAPEX, bringing new markets and national market surveillance authorities to the system. The massive worldwide recalls of familiar consumer products in 2007, most of which concerned toys, seriously shook the confidence of consumers and underlined the importance of having a product safety system that functions well. Since then, Europe has doubled the efforts already deployed to building up a strong international partnership for ensuring global product safety. At the same time, we all have become more aware that product safety, rather than being an expendable luxury, is a major social, political and economic concern.

In the past years, we have joined forces with our main trading partners, China and the United States, and we have laid down the basis for enhanced cooperation and exchange of information. In China, we are harvesting the results of our cooperation with the Chinese authorities that began in 2006. The role played by RAPEX in this successful context, initially as a tool for conveying information on dangerous products and later as the blueprint for building up a Chinese domestic market surveillance tool, has been instrumental.

RAPEX has also prompted us to take a closer look at product supply chains worldwide. We now have a clearer idea of how goods flow from the factory to shelves and have identified the weak links in the chain. With this knowledge, we are better prepared to act where it is needed.

I oversee all types of consumer products that people use in their homes, for sport, for leisure and elsewhere. My job is to make sure that no harm comes to people from these products. This is particularly true in the area of toys and child safety in general. Protecting children is the area where Europe has made a real difference for European consumers in the past year<sup>1</sup>, and it is no coincidence that toys feature prominently in the RAPEX system.

The balance of these past five years has exceeded even the most optimistic projections. This has given us the motivation to go ahead and prepare RAPEX to face future challenges. As the world has entered the worst economic crisis of this century, it is my duty as the European Commissioner responsible for consumer policy to remain vigilant and not to allow this crisis to become an excuse for lowering quality and safety. This is why, in 2008, a particular impulse has been given to fine tuning the RAPEX engine: streamlining the RAPEX guidelines and the risk assessment method will contribute to a more efficient implementation of product safety rules in Europe and set a fine example of delivery worldwide.

The Report is also an occasion to renew my gratitude to all of you. RAPEX is your success. Behind RAPEX there is the daily work of the Member States' governments and market surveillance authorities, the responsible attitude of those economic operators who voluntarily take action towards unsafe products, the vigilance of consumer organisations and stakeholders, the efforts of standardisation organisations to set safer standards, the support of the European Parliament, the attention of consumers who everyday check the RAPEX website and, of course, the tireless RAPEX team.

**Meglana Kuneva**

*European Commissioner for Consumer Affairs*

<sup>1</sup> "Europe and you in 2008", see in particular the section: "The EU acts to keep children safe" at: <http://ec.europa.eu/snapshot2008/>

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# 1

## RAPEX ACTIVITY IN 2008 – EXECUTIVE SUMMARY

### The role of RAPEX in supporting product safety

The Community Rapid Information System for non-food consumer products – RAPEX<sup>2</sup> – is Europe's tool for efficient communication between enforcers and information to consumers on dangerous products. In the context of a global economy affected by recession, ensuring that only safe products are placed on the European market has become an increasingly challenging endeavour. This requires appropriate legislation and rigorous enforcement, safe product engineering and production, commitment from all economic operators in the supply chain and close cooperation between trading partners. If an unsafe product is found on the market or at border controls, it must be taken out of circulation rapidly and efficiently to protect consumers. This Report shows the **growing success of RAPEX** in this mission.

### What was achieved in 2008?

In 2008, the **total number of measures to stop unsafe products notified through RAPEX** was 1866, marking a **16% increase** over the previous year. The constant growth in the number of notifications over the past five years is mainly due to the increasing awareness and attention given to product safety by national authorities and accorded by the business sector, resulting in more frequent and effective controls of consumer products to check their safety.

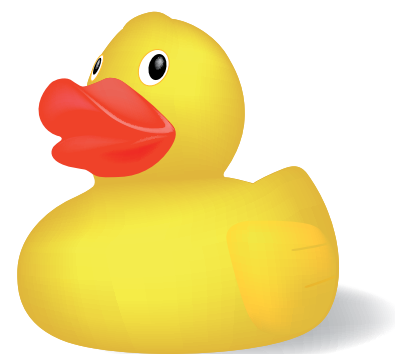
In line with previous years, in 2008 **childcare articles** (toys and children's equipment), **electrical appliances and motor vehicles** were the groups of products for which the highest number of notifications were issued, while the most common risks observed were **injuries, chemical risks or choking**.

### Compliance by businesses

Businesses took corrective measures on their own initiative (and not only when so ordered by the competent authorities) in 48% of all cases, which is in line with 2007 data.

In June 2008, the Commission presented the results of its thorough screening of the EU product safety system, including an **evaluation of the safety measures put in place by businesses in the toy supply chain** in a report by independent experts. The main conclusion, in short, was that product safety cannot be guaranteed by final product testing alone, but that it has to be a key part of the "quality culture" of an organisation and needs to be embedded in the entire product supply chain.

Commissioner Kuneva signed a **voluntary agreement with the European toy industry** in which the industry embarked on a common mission to spread best safety practices through the sharing of expertise, education and training and closer cooperation with national authorities. A similar agreement was signed in December with toy importers and retailers to further improve toy safety in Europe.



<sup>2</sup> For a detailed explanation about the functioning of RAPEX, please see Chapter 5.

## Enforcement

At the end of 2008, a final draft of improved **RAPEX Risk Assessment Guidelines** was ready, thanks to fruitful collaboration with more than 70 stakeholders (Member States, companies and industry associations, testing houses and others). These guidelines will make risk assessments and the understanding of "serious risk to the health and safety of consumers" more consistent throughout Europe.

To support Member States' market surveillance and coordination between authorities from different countries, in 2008 the Commission awarded a financial contribution of EUR 2.6 million to **four joint market surveillance actions**. These **actions** focus on: toys for children under three years, sun beds and solarium services, cords and drawstrings in children's clothing and a follow-up to the successful EMARS project (Enhancing Market Surveillance through Best Practice).

To improve enforcement capacity in the Member States, the European Commission organised, as in previous years, **RAPEX seminars in the Member States** for national market surveillance and customs authorities. This year, training sessions took place in Bulgaria, Malta and Portugal.

In order to facilitate an objective evaluation of each country's performance, the Commission engaged the Member States in a common effort to develop a **system for collecting harmonised data and indicators**.

## Developments relating to specific products and risks

In April 2008, the Commission adopted a temporary Decision requiring Member States to ensure that certain **magnetic toys** placed on the market display a warning about the health and safety risks they pose. The revision process for the European standard on **child-resistant lighters** was launched in July, while the Decision to prohibit their sale was extended.

The Commission adopted a safety requirements Decision and issued a mandate in June for the European Committee for Standardization (CEN) to develop a standard on the technical requirements for **reduced ignition propensity cigarettes**. A Decision which entails presumption of conformity to products compliant with the European safety standard was adopted in December regarding **baby-walkers**.

At the end of 2008, several Member States notified harmful effects on the health of consumers who were in contact with leather footwear or furniture, due to the presence in these goods of a powerful biocide, **DMF (Dimethyl fumarate)**, used to prevent mould. As a result, the Commission will adopt at the beginning of 2009, in agreement with the Member States, a measure to ban the presence of DMF in all consumer products.





### International cooperation

In November 2008, the Commission's Directorate-General for Health and Consumers and the **Chinese** Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) signed an upgraded Memorandum of Understanding (MoU) on cooperation arrangements. The extended MoU strengthens the original version in view of the significant progress made in cooperation with China over the last three years, by including a clearer reference to the RAPEX-China system and the possibility of coordinated surveillance campaigns.

With respect to cooperation with the **United States**, the Commission welcomed the adoption of the US Consumer Product Safety Improvement Act, which enables the Consumer Product Safety Commission (CPSC) to share confidential product safety information with foreign governments and agencies once the details of such exchanges are agreed.

In October 2008, the Council of the European Union authorised the European Commission to enter into negotiations with the **Swiss Confederation** with a view to achieving greater cooperation and removing technical barriers to trade in the areas of consumers, food safety and health.

The Commission and the CPSC, together with AQSIQ, conducted a series of **joint outreach seminars** in China on EU and US safety requirements for clothing, toys, and electrical appliances. **A high-level EU-China-US trilateral product safety summit**, hosted by Commissioner Kuneva in Brussels on 17 November 2008 sent a strong political signal of the determination of all sides to keep product safety at the top of the international political agenda.

On 17-21 November 2008, the Commission organised and hosted an International Product Safety Week bringing together the main global actors and stakeholders in the product safety field, with a view to raising the level of cooperation and achievement in product safety on the global market and ensuring safety throughout the entire supply chain.



# 2

## RAPEX STATISTICS

### 2.1 Notifications

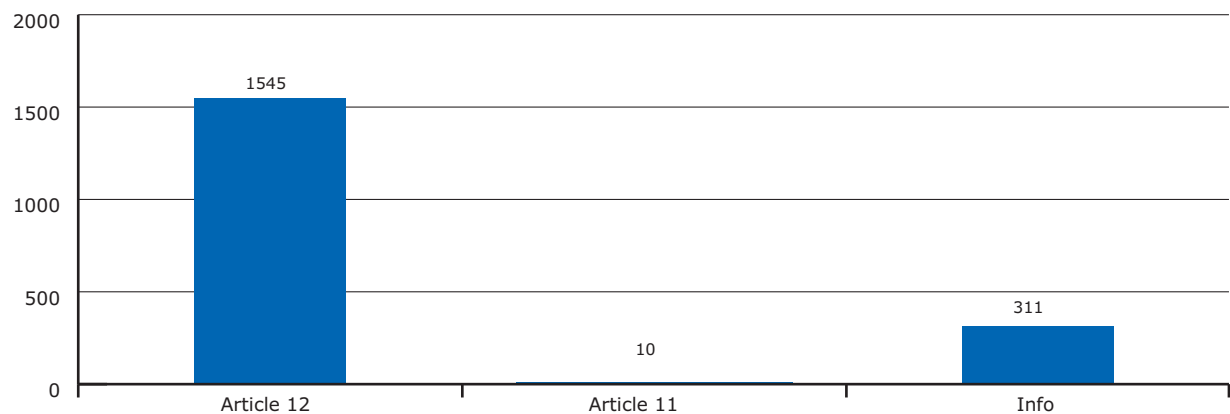
#### 2.1.1 Total number of notifications

##### Situation in 2008

In 2008, the European Commission distributed **1 866** notifications through the RAPEX system:

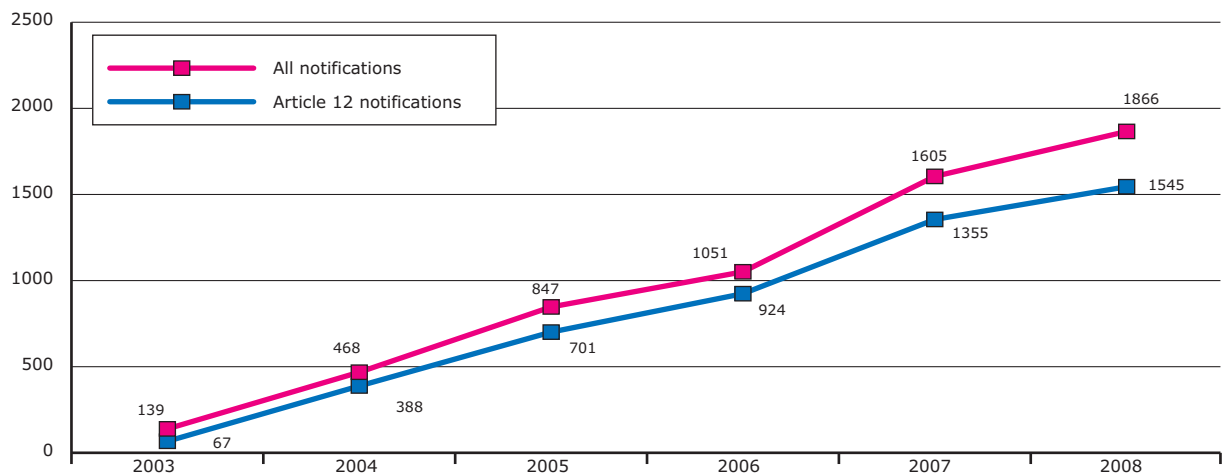
- **1 545** of these notifications were distributed to Member States as notifications under Article 12 of the GPSD (measures taken by competent national authorities or voluntarily by economic operators with regard to products presenting serious risks to the health and safety of consumers);
- 10 notifications were distributed to Member States under Article 11 of the GPSD (measures taken by competent national authorities with regard to products posing moderate risks);
- 311 notifications were distributed to Member States for information purposes only, as they did not qualify for distribution under either Article 12 or Article 11.

**Figure 1 - Total number of notifications**



##### Comparison with previous years

**Figure 2 - Number of notifications 2003-2008**



**The total number of notifications** validated by the European Commission has risen gradually over the past few years. In the fifth year since the transposition of the revised GPSD into the national laws by Member States (15 January 2004), the number of notifications has quadrupled from 468 (in 2004) to 1866 (in 2008).

In 2008, the total number of notifications rose by 16% (1 866 notifications distributed in 2008 compared to 1 605 in 2007), which is the lowest increase since 2004 (53% in 2007, 24% in 2006, 81% in 2005).

The total number of notifications distributed through the RAPEX system concerning products posing a serious risk is constantly increasing. This can be ascribed to increasing awareness and attention given to product safety by national authorities and the business sector, more frequent and more effective controls of consumer products on the market, joint market surveillance actions carried out by national authorities, the EU enlargement in 2004 and 2007, and finally to several training actions and seminars provided by the European Commission for different stakeholders.

**The number of Article 12 notifications** has grown by 14% compared to 2007 (1 545 notifications were distributed in 2008 compared to 1 355 notifications in 2007). In 2007, the number of Article 12 notifications increased by 47% compared to 2006.

**The number of notifications distributed for information purposes only** has increased by 31% compared to 2007 (311 notifications distributed in 2008 compared to 238 notifications in 2007). This results mainly from the fact that the European Commission applied a more consistent approach than in previous years when assessing notifications distributed through the RAPEX system. As a result, notifications of products which were difficult for other authorities to identify (i.e. the brand, model number and pictures of the product were not provided) were more frequently distributed for information purposes only. This ensured that all Member States were made aware of an existing safety problem, often linked to a specific product category, but they were not obliged to undertake follow-up activities with regard to any products that could not be identified. Such an approach is necessary to ensure an efficient and effective use of Member States' resources and to guarantee that the main focus is placed on dangerous consumer products that are easily identifiable and thus can be subject to immediate preventive or restrictive measures.

**In the following charts, the figures only concern notifications that were distributed through the RAPEX system under Article 12 of the GPSD (1 545 notifications). Notifications distributed through the system under Article 11 of the GPSD, and notifications sent for information purposes, are not covered by the detailed statistics below.**

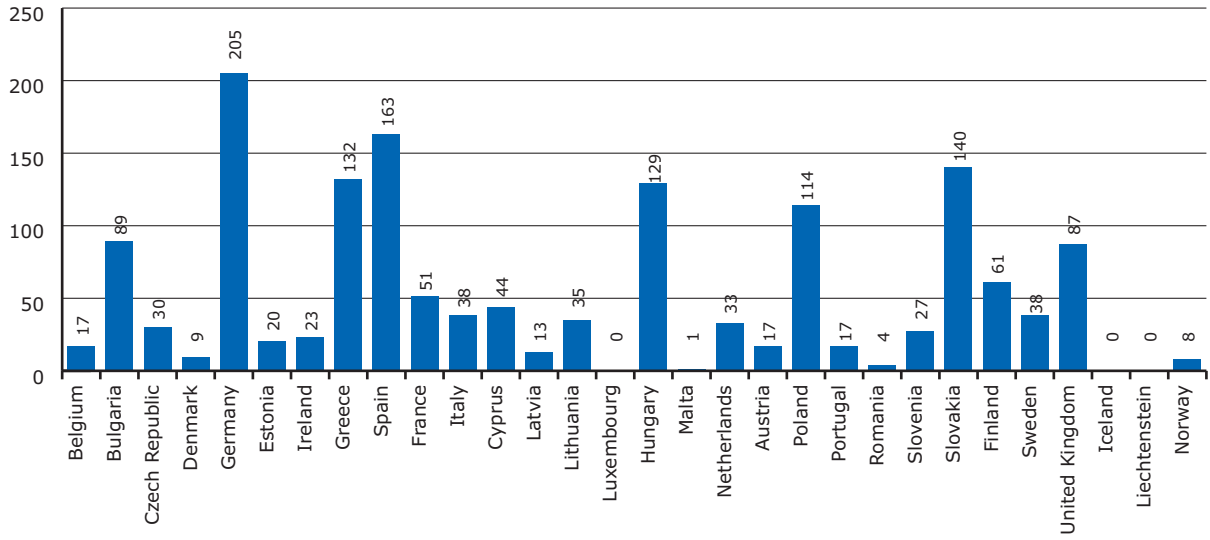
### 2.1.2 Notifications by notifying country

#### **Situation in 2008**

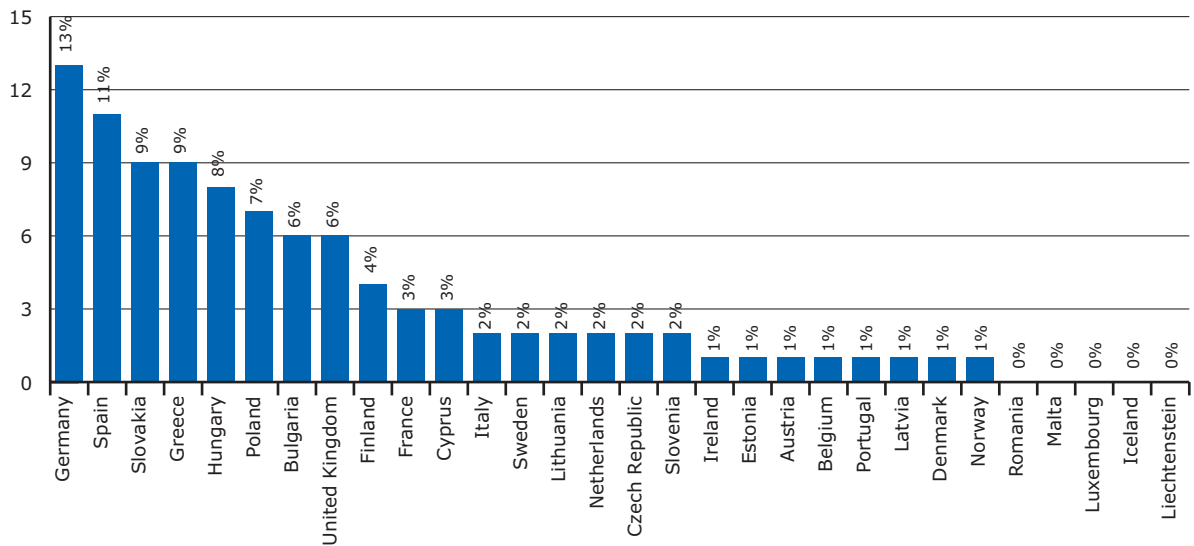
In 2008, 26 EU Member States and Norway sent notifications through the RAPEX system. The following five most frequently notifying countries accounted for 50% of all notifications:

- Germany (205 notifications, 13%),
- Spain (163 notifications, 11%),
- Slovakia (140 notifications, 9%),
- Greece (132 notifications, 9%)
- Hungary (129 notifications, 8%).

**Figure 3 - Number of notifications by notifying country (absolute values)**



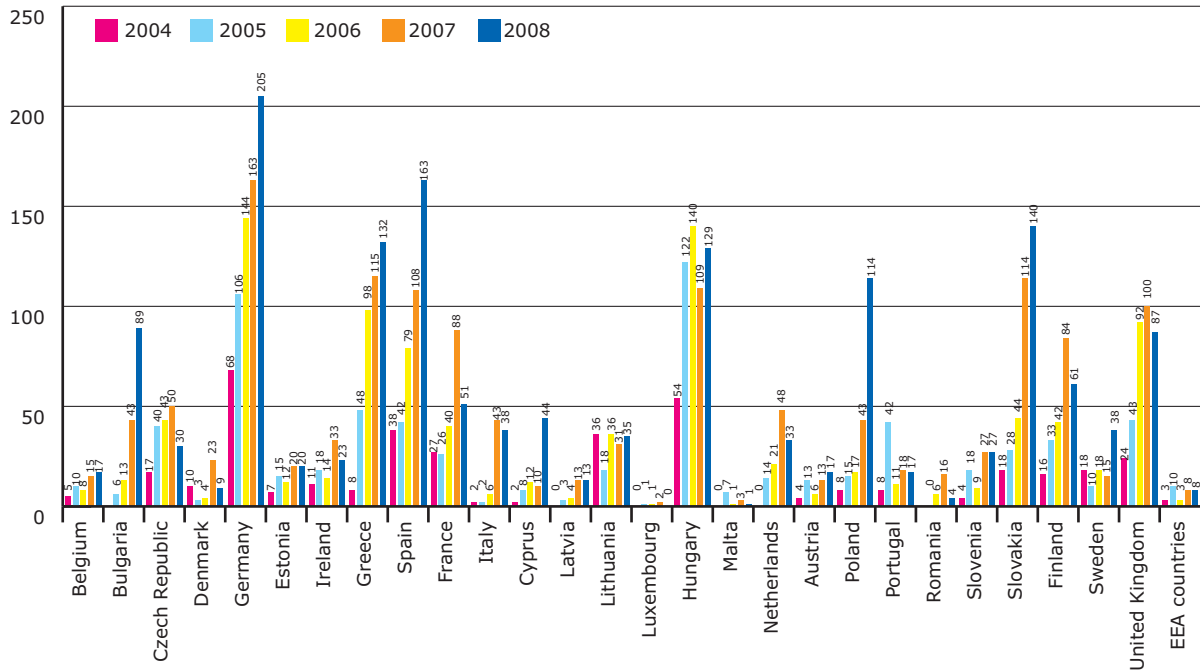
**Figure 4 - Notifications by notifying country (%)**



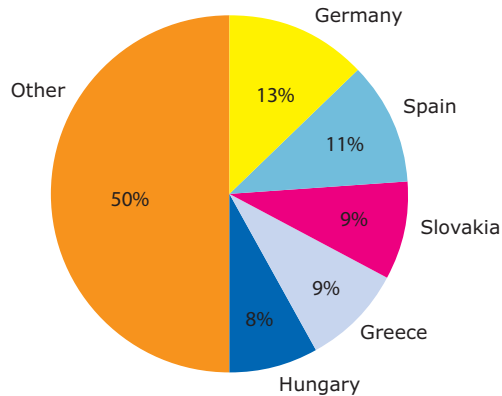
### Comparison with previous years

In 2008, 12 countries increased their activities in the RAPEX system and notified more dangerous products than in 2007. However, the gap between the countries with the highest and the lowest number of notifications increased compared to 2007. This is reflected in the fact that the total share of the five most frequently notifying countries (i.e. Germany, Spain, Slovakia, Greece and Hungary) increased again from 44% in 2007 to 50% in 2008.

**Figure 5 - Number of notifications by notifying country - comparison previous years**

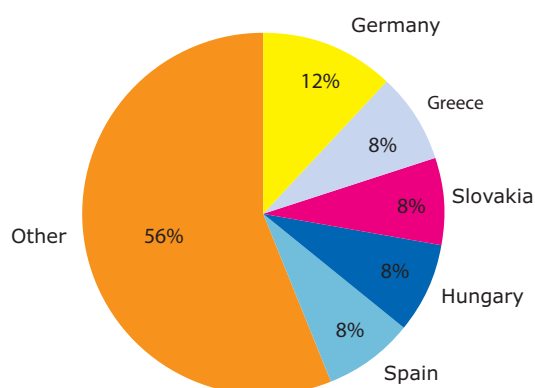


**Figure 6 - The five most frequently notifying countries in 2008**





**Figure 7 - The five most frequently notifying countries in 2007**



It should be stressed that the RAPEX statistics do not reflect all market surveillance activities carried out in Member States. The participation of countries in RAPEX is the result of various factors, such as the different way in which the national market surveillance networks are organised, the different size of the countries, and the different production and market structures that exist across the EU. All these factors should be taken into account when reading these statistics.

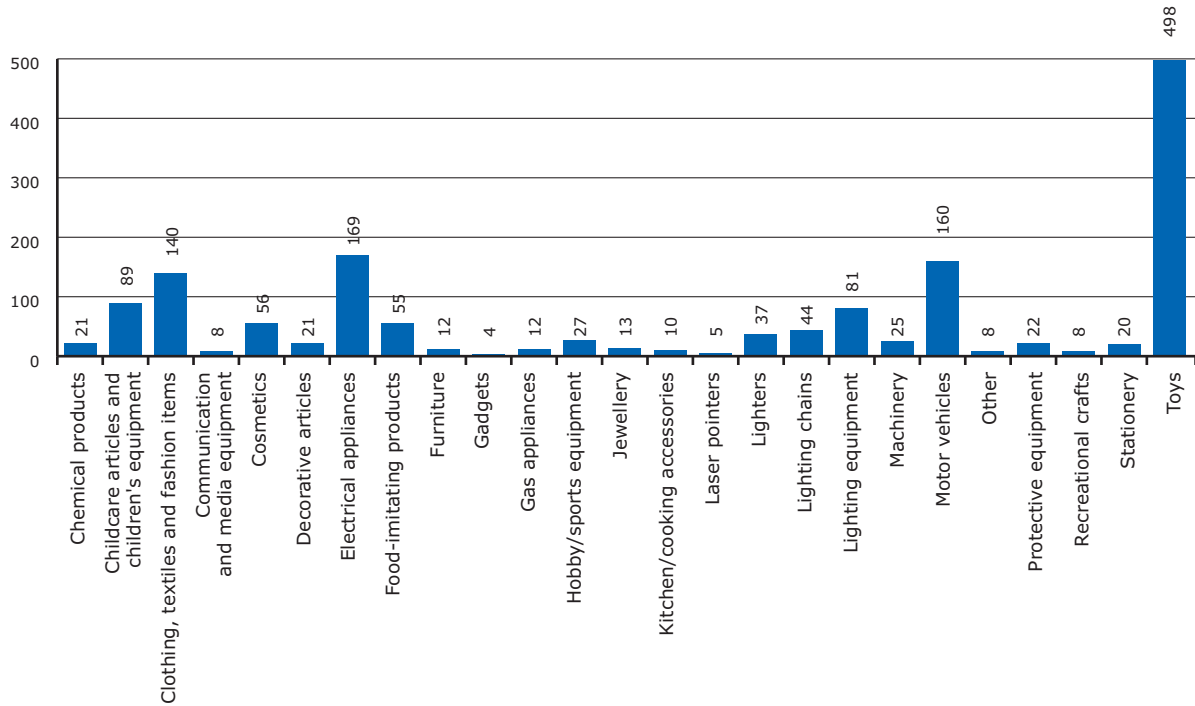
### 2.1.3 Notifications by product category

The product categories most frequently notified through the RAPEX system were:

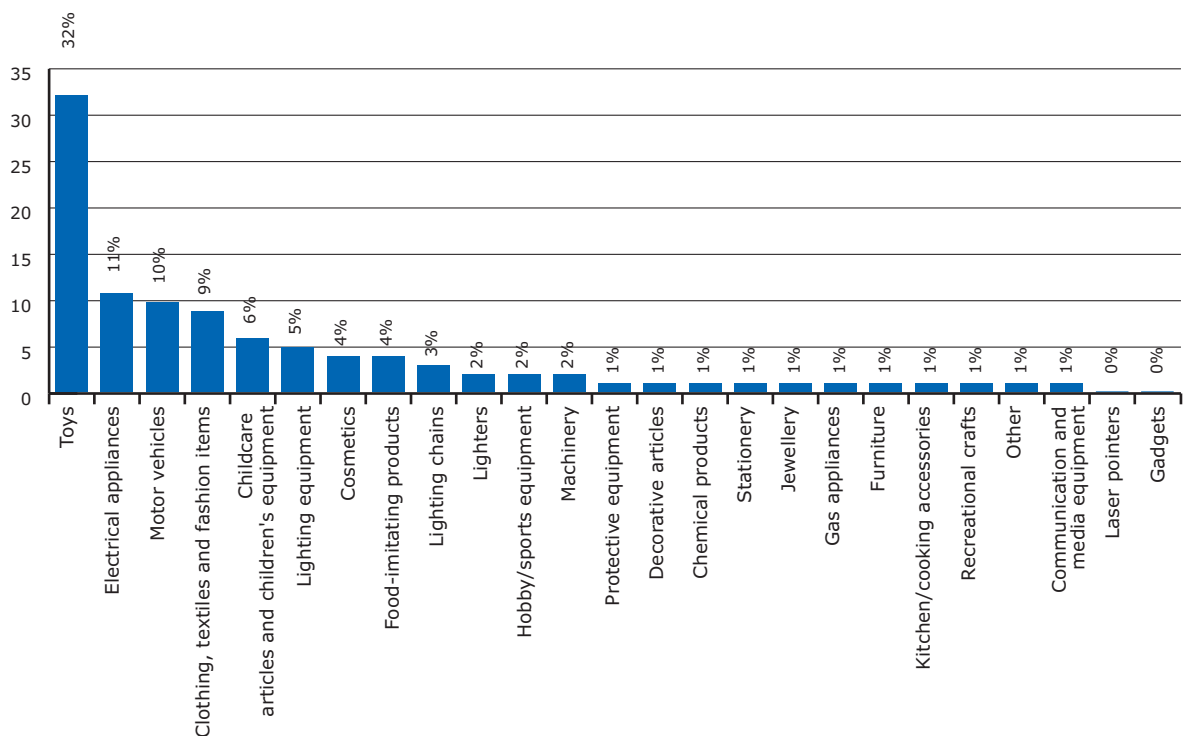
- toys (498 notifications, 32%),
- electrical appliances (169 notifications, 11%),
- motor vehicles (160 notifications, 10%),
- clothing, textiles and fashion items (140 notifications, 9%),
- childcare articles and children's equipment (89 notifications, 6%).

These categories of products accounted for almost 68% of all products notified in 2008. Toys, electrical appliances and motor vehicles accounted for 53% of all notifications distributed through the RAPEX system in 2008, which is in line with the RAPEX results from years 2007 (58%) and 2006 (57%).

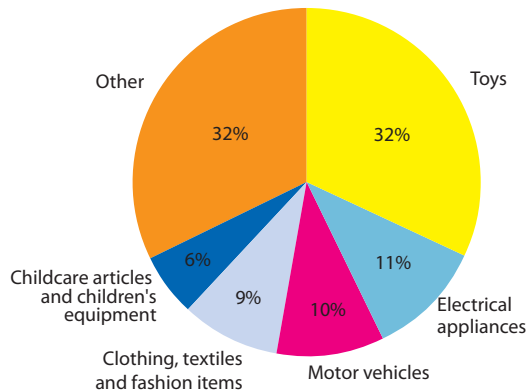
**Figure 8 - Number of notifications by product category (absolute values)**



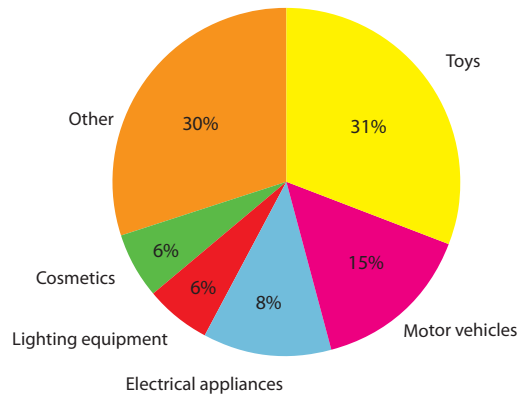
**Figure 9 - Number of notifications by product category (%)**



**Figure 10 - The five most frequently notified product categories in 2008**



**Figure 11 - The five most frequently notified product categories in 2007**



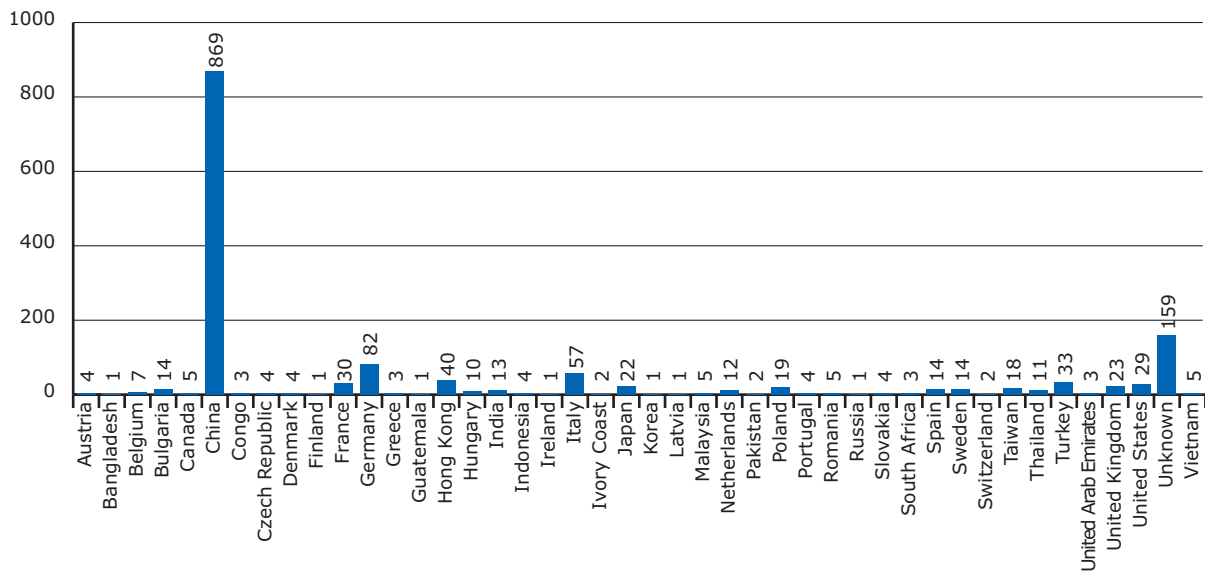
#### 2.1.4 Notifications by country of origin of the notified product

China (including Hong Kong) was indicated as the country of origin of notified products in more than half of the cases in 2008 (909 notifications, or 59% of all notifications sent through RAPEX). Over the years, products of Chinese origin have been the most frequently notified through RAPEX. This reflects a significant market penetration of Chinese-manufactured consumer products in European markets and it is the reason behind various projects launched in the last few years both at European and national level, often in close cooperation with the Chinese government. The growing number of Chinese-made products notified through RAPEX can also be seen as indicative of the focus of action of market surveillance and customs authorities in the campaign to recover from the confidence crisis in 2007 and there is no evidence to ascribe it to the falling quality of products of Chinese origin compared to previous years.

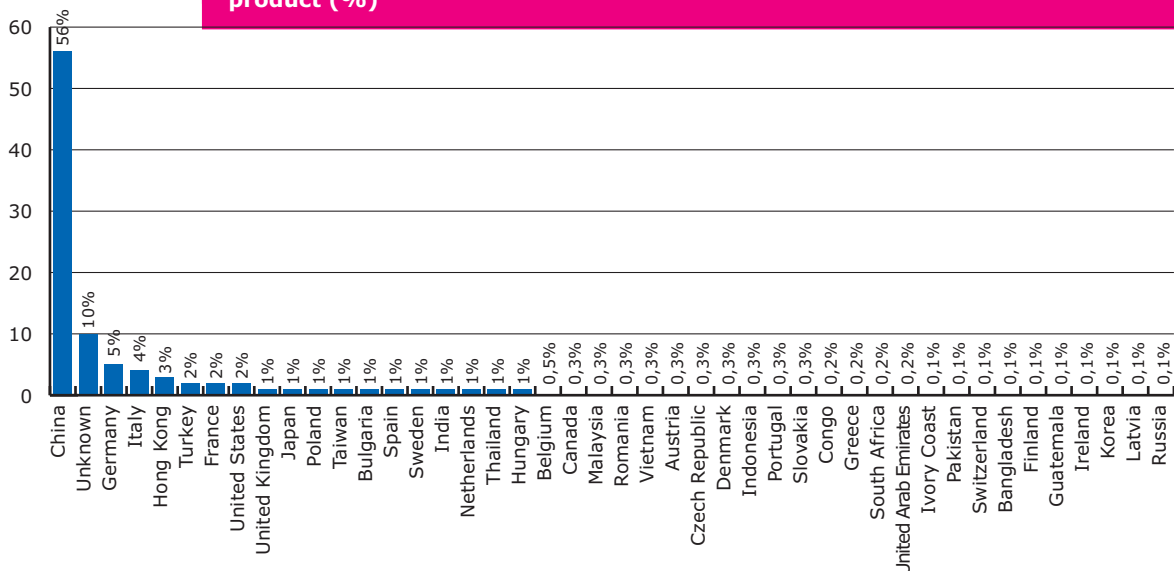
313 notifications (20% of all notifications sent through RAPEX) concerned products originating from the 27 EU Member States and 3 EFTA/EEA countries. This is fully in line with the data of the previous years (22% in 2007, 21% in 2006 and 20% in 2005).

159 notifications (10% of all notifications sent through RAPEX) contained no information about the country of origin of the notified product. Although this figure is still fairly high, it should be seen as a significant improvement in the operation of the RAPEX system, as the number of cases with an unidentified country of origin has decreased from 23% in 2004 to 10% in 2008. This is an excellent indicator that the enforcement action of market surveillance authorities in Europe is increasingly focusing on traceability.

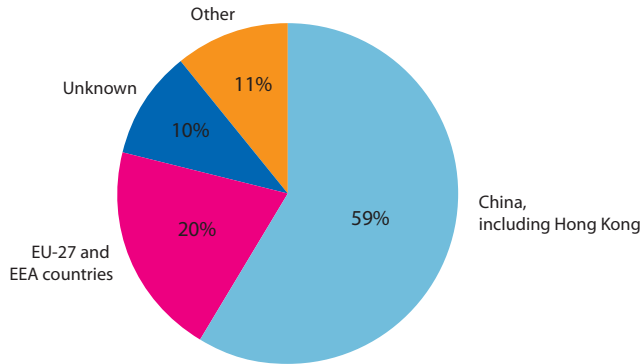
**Figure 12 - Number of notifications by country of origin of the notified product**



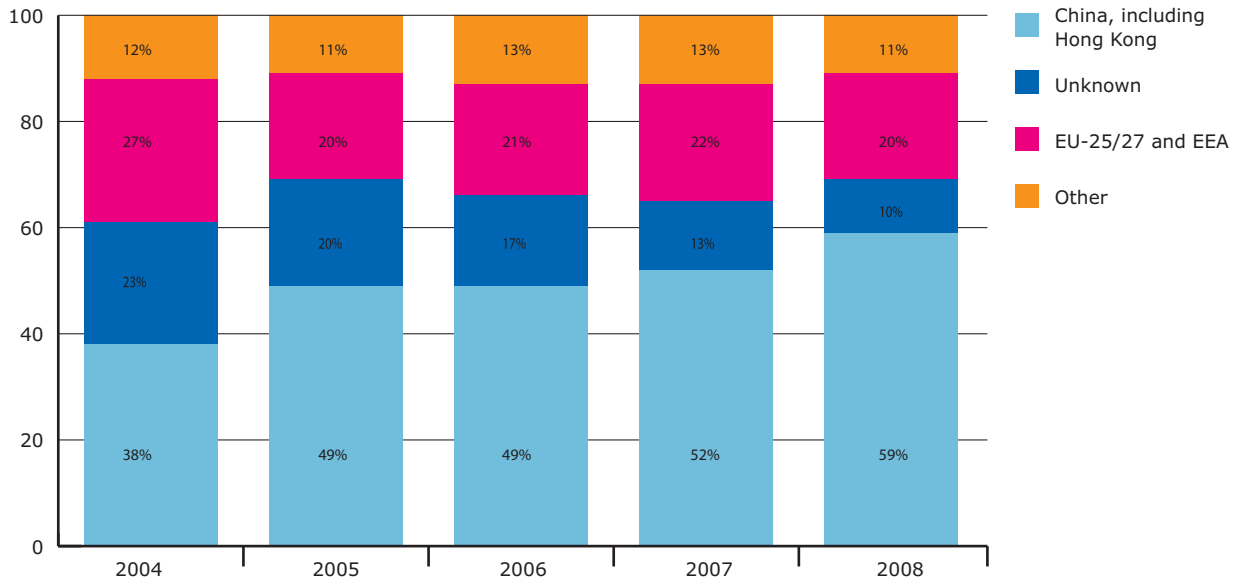
**Figure 13 - Notifications by country of origin of the notified product (%)**



**Figure 14 - Notifications by country of origin of the notified product**



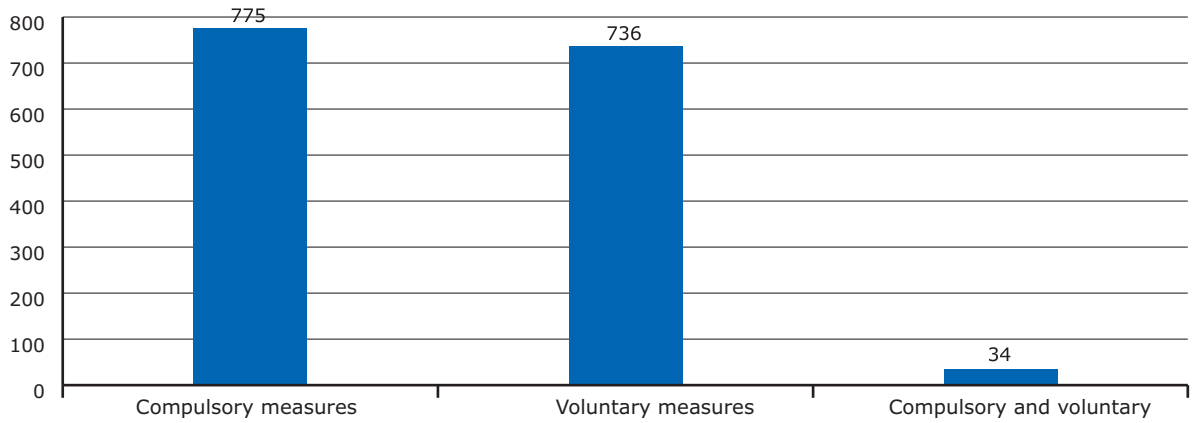
**Figure 15 - Notifications by country of origin of the notified product - comparison previous years**



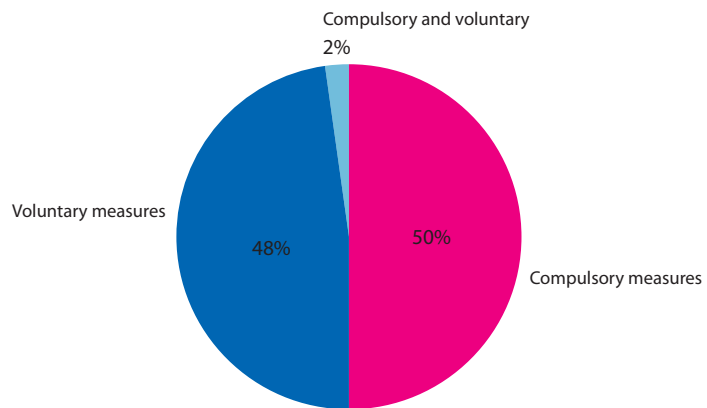
### 2.1.5 Notifications by type of measure

775 out of 1 545 RAPEX serious risk notifications concerned compulsory preventive and restrictive measures ordered by the national authorities (50% of the total number). In 736 notified cases (48%), the economic operators took the necessary preventive and restrictive measures on a 'voluntary' basis, i.e. complying with their legal obligations without the formal intervention of a national authority. In 34 cases (2%), compulsory measures were complemented by 'voluntary' actions taken by an economic operator. This is comparable to last year's results.

**Figure 16 - Number of notifications by type of measure (absolute values)**



**Figure 17 - Notifications by type of measure (%)**



**Figure 18 - Number of notifications by type of measure per country (absolute values)**

<b>Jan-Dec 2008</b>	Compulsory measures	Voluntary measures	Compulsory and voluntary	<b>TOTAL</b>
Belgium	2	15		<b>17</b>
Bulgaria	88	1		<b>89</b>
Czech Republic	28	2		<b>30</b>
Denmark		9		<b>9</b>
Germany	31	168	6	<b>205</b>
Estonia	19	1		<b>20</b>
Ireland	1	22		<b>23</b>
Greece	41	91		<b>132</b>
Spain	143	20		<b>163</b>
France	3	45	3	<b>51</b>
Italy	32	4	2	<b>38</b>
Cyprus	30	14		<b>44</b>
Latvia	4	9		<b>13</b>
Lithuania	33	2		<b>35</b>
Luxembourg				<b>0</b>
Hungary	125	4		<b>129</b>
Malta	1			<b>1</b>
Netherlands	20	9	4	<b>33</b>
Austria	10	6	1	<b>17</b>
Poland	12	102		<b>114</b>
Portugal	7	10		<b>17</b>
Romania	4			<b>4</b>
Slovenia	19	8		<b>27</b>
Slovakia	59	65	16	<b>140</b>
Finland	42	19		<b>61</b>
Sweden	4	34		<b>38</b>
United Kingdom	13	72	2	<b>87</b>
Iceland				<b>0</b>
Liechtenstein				<b>0</b>
Norway	4	4		<b>8</b>
	<b>775</b>	<b>736</b>	<b>34</b>	<b>1 545</b>

### 2.1.6 Notifications by type of risk

The five most frequently notified risk categories were:

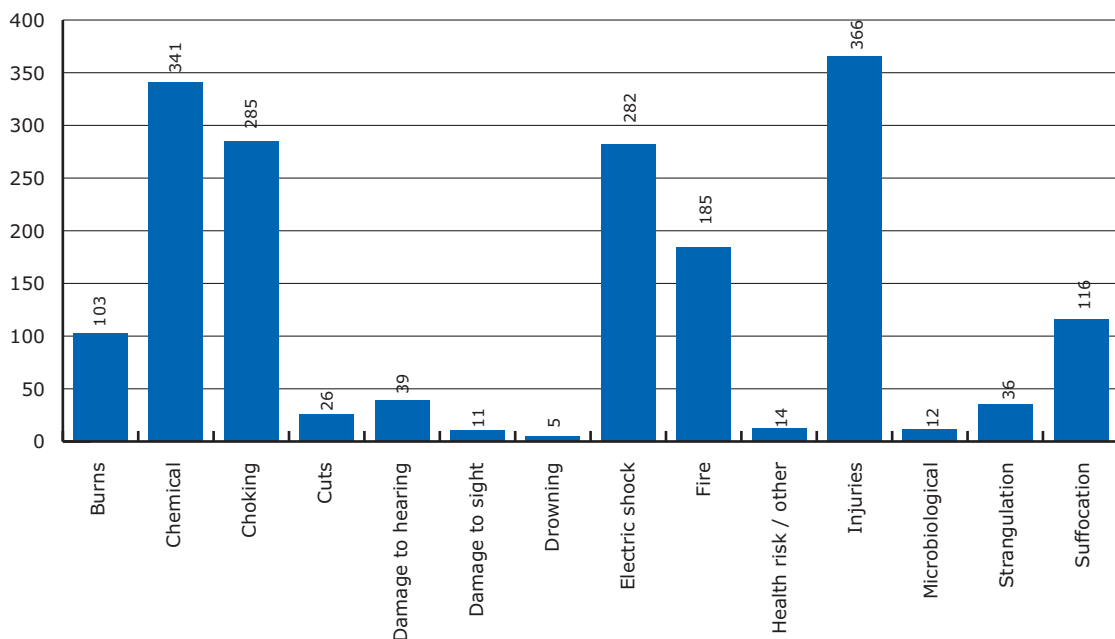
- injuries (366 notifications, 20%),
- chemical (341 notifications, 19%),
- choking (285 notifications, 16%),
- electric shock (282 notifications, 15%),
- fire (185 notifications, 10%).

The total number of risks falling into these five risks categories accounts for 80% of all risks.

It should be noted that some RAPEX notifications concern products presenting more than one risk (e.g. a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to excessive levels of a substance whose use is restricted). Therefore the total number of notified risks is higher than the total number of notifications.

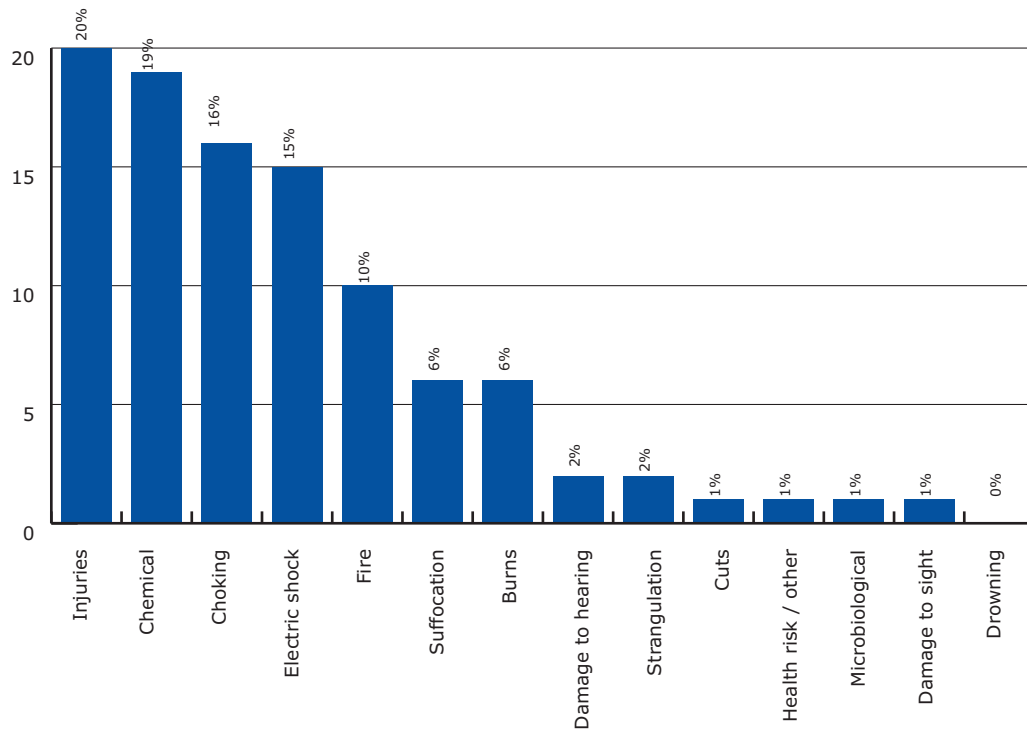
On the basis of the RAPEX data, it can also be concluded that each product category is likely to expose consumers to specific types of risk. For example, the main risks arising when playing with unsafe toys are choking (often associated with the presence of small parts) and a chemical risk (often associated with high levels of chemical substances like phthalates, lead and other heavy metals), while the most common risk for electrical products is, as might be expected, the risk of getting an electric shock, often combined with the risk of fire.

**Figure 19 - Number of notifications by type of risk (absolute values)**

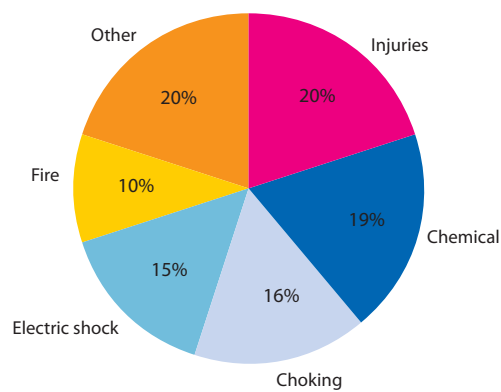




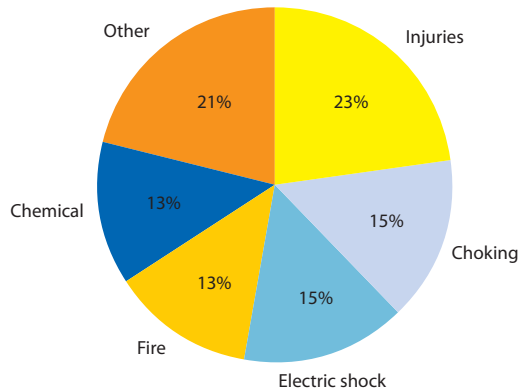
**Figure 20 - Notifications by type of risk (%)**



**Figure 21 - The five most frequently notified types of risk in 2008**



**Figure 22 - The five most frequently notified types of risk in 2007**

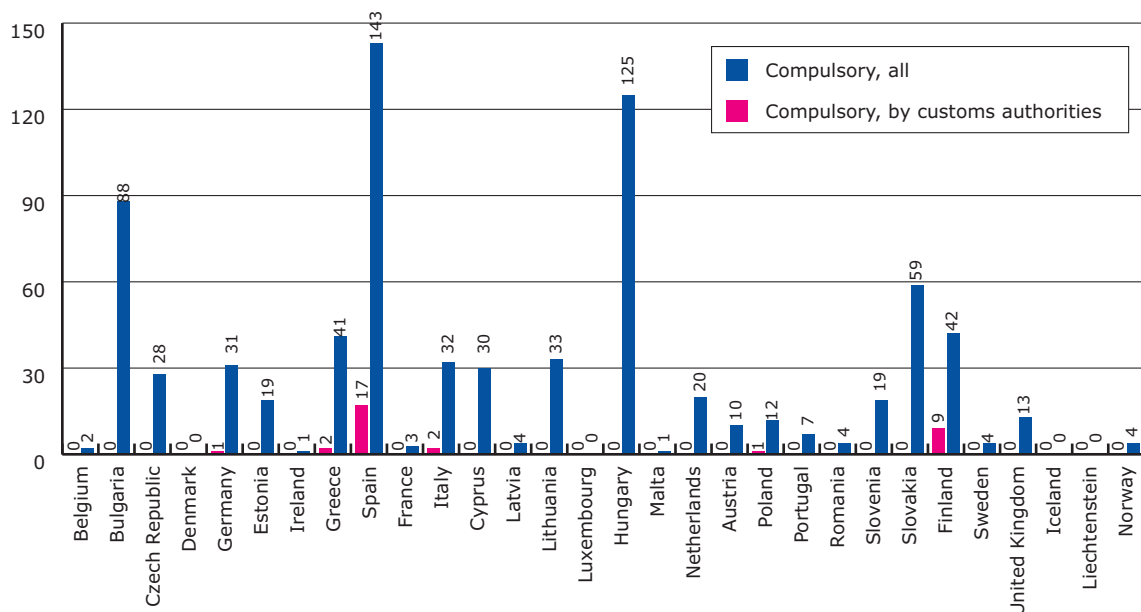


### 2.1.7 Notifications initiated by the activities of the customs authorities

As stated above, 775 out of the 1 545 RAPEX notifications relating to products posing a serious risk concerned preventive and restrictive measures ordered by the competent national authorities (50% of the total number). 32 of these 775 notifications concerned measures that were adopted by the customs authorities (mainly rejection of imports).

This figure indicates that in some countries the customs authorities are more involved in taking the decision to stop imports of dangerous products but it does not give a full picture of the activity of the customs authorities because in many other countries such measures are taken directly by the market surveillance authorities and are reflected in the total figure for compulsory measures notified through the RAPEX system (see Figures 16 to 18 - type of measure).

**Figure 23 - Number of notifications concerning compulsory measures initiated by the customs authorities (absolute values)**



## 2.2 Reactions

### 2.2.1 Total number of reactions

In 2008, Member States and EFTA/EEA countries sent in total 1 745 reactions to all notifications distributed through RAPEX. 1 704 reactions were sent regarding Article 12 notifications (97.6%), 1 reaction was sent concerning an Article 11 notification (0.1%) and 40 reactions were sent regarding notifications for information (2.3%). 44% of all the Article 12 notifications (i.e. 682 out of 1 545 Article 12 notifications) received at least one reaction.

**In the following charts, the figures only concern reactions to notifications that were distributed through the RAPEX system under Article 12 of the GPSD – serious risk (1 704 reactions).**

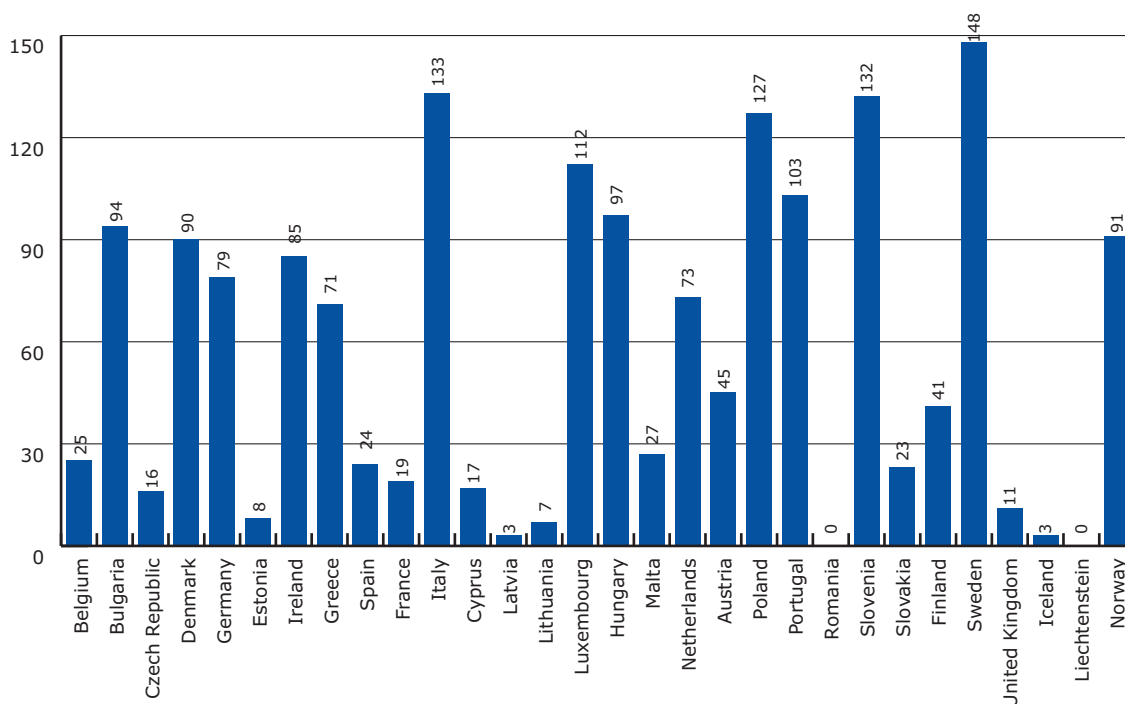
### 2.2.2 Reactions by reacting country

In 2008, all Member States (except Romania), Norway and Iceland have sent reactions to RAPEX notifications.

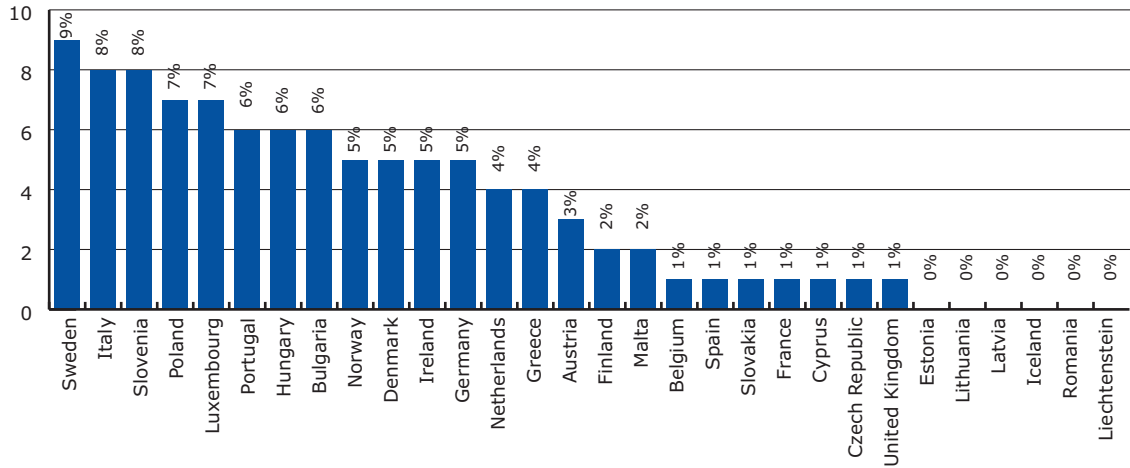
The following five countries accounted for 39% of all reactions:

- Sweden (148 reactions, 9%),
- Italy (133 reactions, 8%),
- Slovenia (132 reactions, 8%),
- Poland (127 reactions, 7%),
- Luxembourg (112 reactions, 7%).

**Figure 24 - Number of reactions by reacting country (absolute values)**



**Figure 25 - Reactions by reacting country (%)**

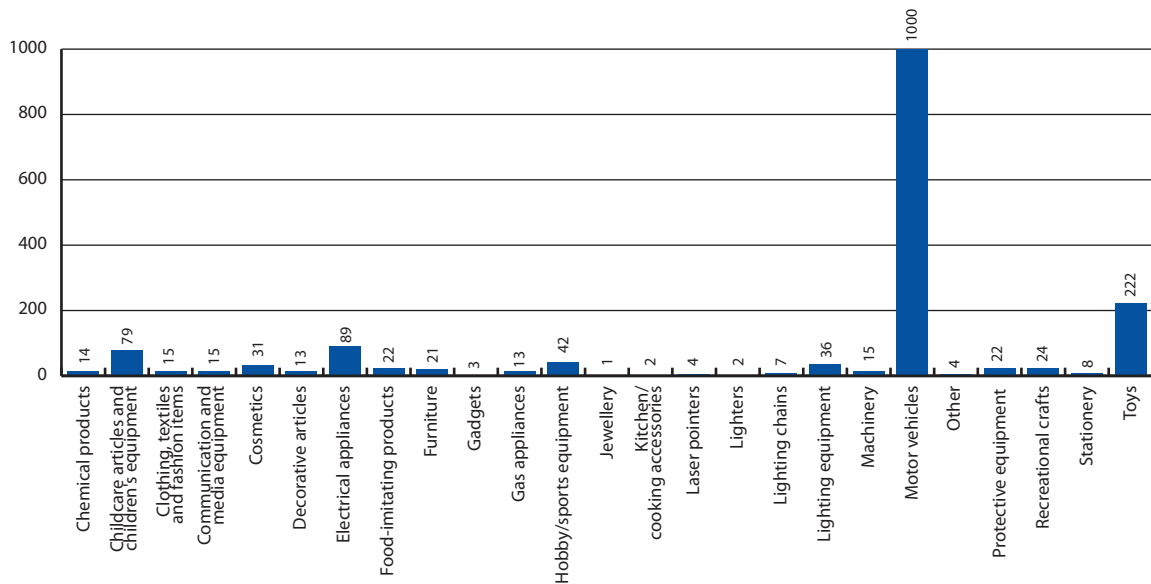


### 2.2.3 Reactions by notified product

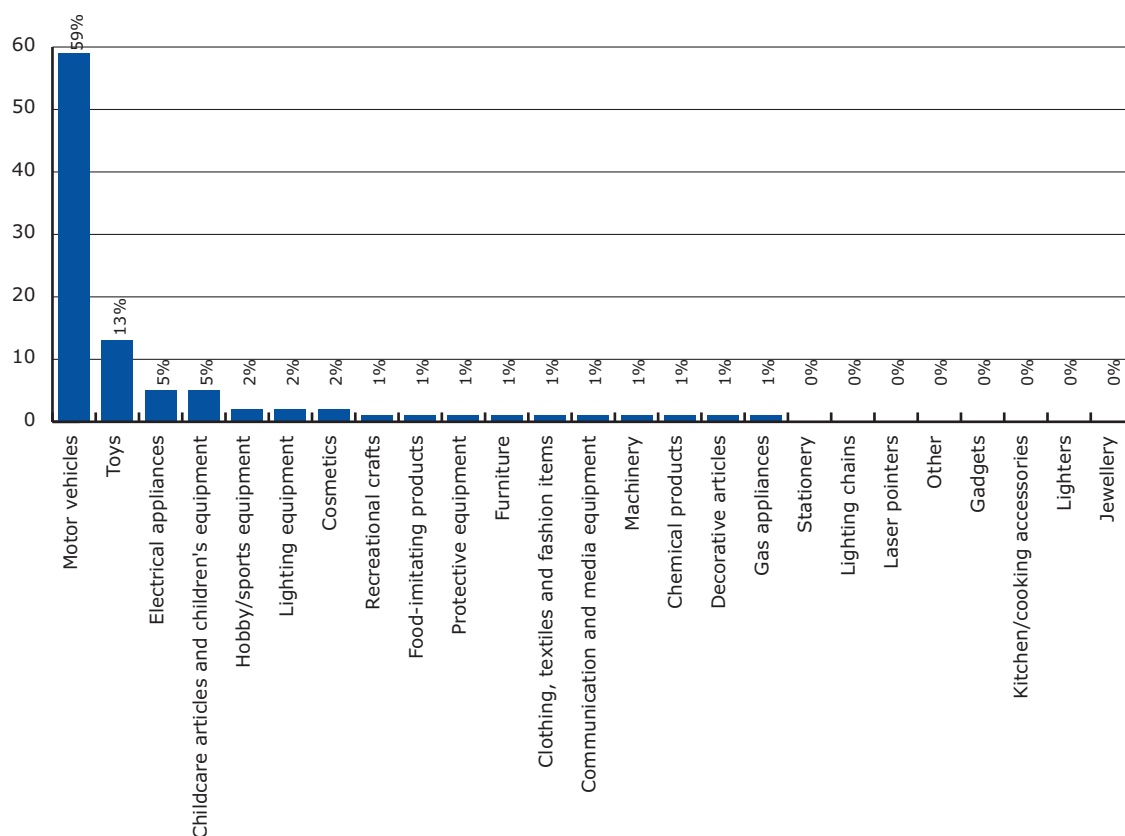
Notifications concerning motor vehicles generated the most reactions (59% of all reactions). 85% of all reactions received concerned RAPEX notifications for the following five product categories:

- motor vehicles (1000 reactions, 59%),
- toys (222 reactions, 13%),
- electrical appliances (89 reactions, 5%),
- childcare articles and children’s equipment (79 reactions, 5%),
- hobby/sports equipment (42 reactions, 2%).

**Figure 26 - Number of reactions by product category of the original notification (absolute values)**



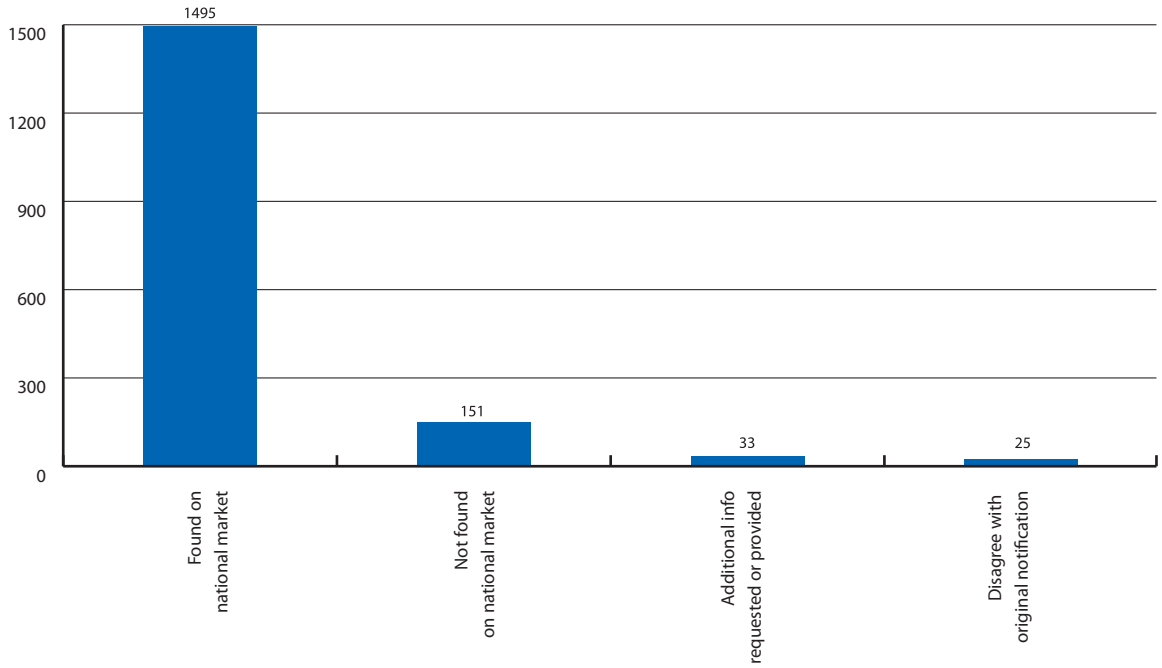
**Figure 27 - Reactions by product category of the original notification (%)**



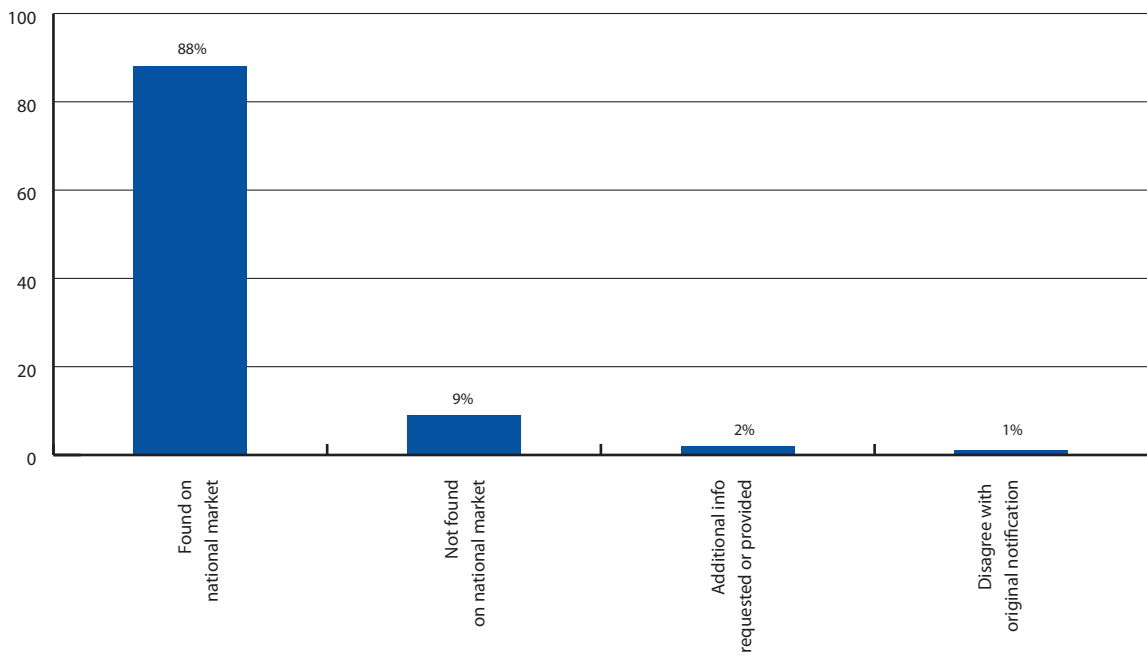
#### 2.2.4 Reactions by type of reaction

In an overwhelming number of reactions received (1495 reactions, 88% of all reactions), Member States stated that the notified product was found on their market and that adequate preventive or restrictive measures were adopted at the national level. In 33 reactions (2%), the reacting country requested additional information on the case. In 25 reactions (1%), the reacting country did not agree with the information provided in the notification, mainly with the conclusions of the risk assessment presented by the notifying Member State. In 151 reactions (9%), Member States informed the Commission that the notified product was not found on their markets.

**Figure 28 - Number of reactions by type of reaction (absolute values)**



**Figure 29 - Reactions by type of reaction (%)**



## 2.2.5 Reactions by type of notified risk

More than half of the reactions received were sent in response to notifications about consumer products posing a risk of injuries (931 reactions, 51%) and a risk of fire (324 reactions, 18%). These two risks are clearly linked to motor vehicles, which accounted for 59% of all reactions received.

The five most frequently notified risk categories were:

- injuries (931 reactions, +/- 51%),
- fire (324 reactions, +/- 18%),
- chemical (180 reactions, +/- 10%),
- choking (135 reactions, +/- 7%)
- electric shock (80 reactions, +/- 4%).

Some reactions concerned products that presented more than just one risk: therefore the total number of notified risks (1 837) is higher than the total number of reactions to Article 12 notifications (1 704).

**Figure 30 - Number of reactions by type of risk of the original notification (absolute values)**

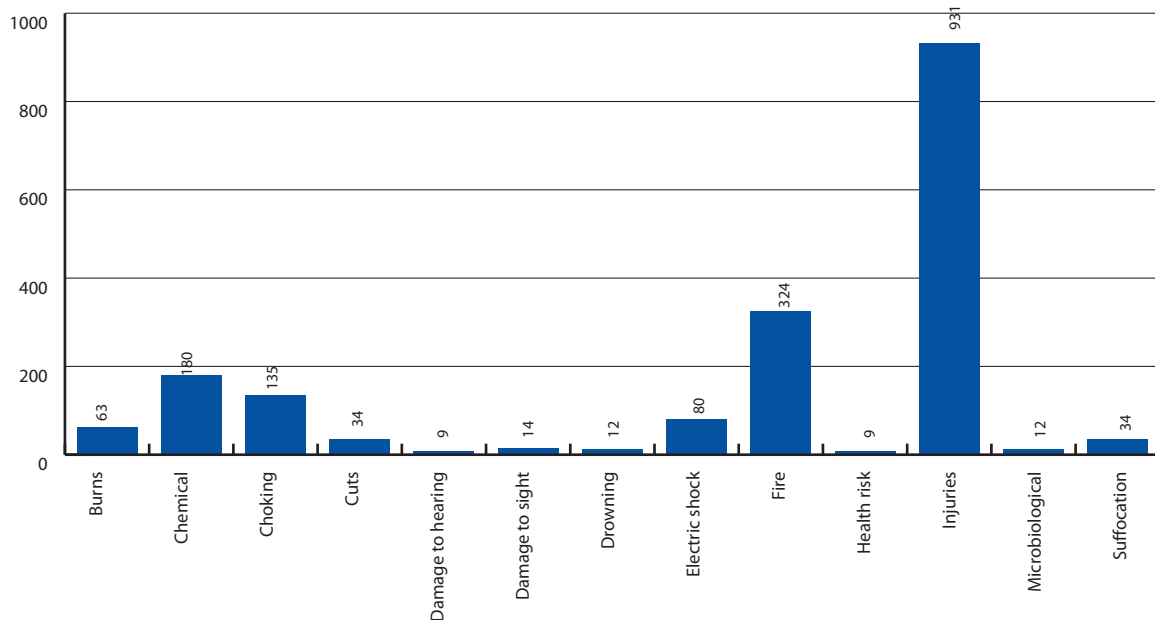
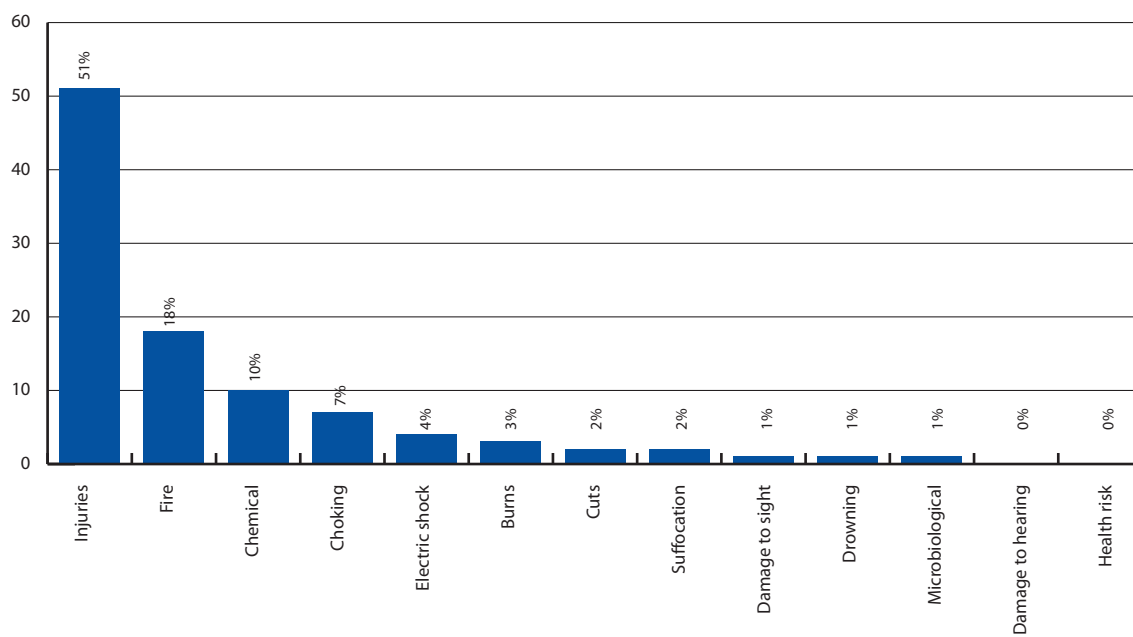


Figure 31 - Reactions by type of risk of the original notification (%)





# 3

## KEY DEVELOPMENTS IN 2008

### 3.1 Enforcement

Enforcement is a top priority of the EU Consumer Policy Strategy 2007-2013<sup>3</sup> because it plays an important role in achieving the long-term objectives of empowering EU consumers and ensuring that they are protected from serious risks and threats that they cannot tackle as individuals.

#### 3.1.1 RAPEX and other product safety indicators

##### **The Consumer Market Scoreboard**

In 2008, the Commission published the first edition of the Consumer Market Scoreboard, a publication that monitors the performance of markets in terms of economic and social outcomes for consumers. Product safety has been chosen as one of the main indicators because it plays a major role in building consumer welfare and confidence.

RAPEX indicators were used to illustrate the activity of market surveillance authorities in different Member States, but the number of product notifications should not be used as an accurate assessment of a country's performance in terms of product safety.

In the long run, the Scoreboard aims to provide a real tool to identify where the internal market is not functioning well for consumers, and where intervention may be needed. The main challenge for the future is to develop, together with the Member States, a system for the collection of harmonised data that will allow the Commission to publish relevant indicators which thoroughly describe each country's performance in this field.

##### **The Eurobarometer**

In order to better understand the European consumer, several Eurobarometer surveys have been launched over the past years.

In 2008, a **Eurobarometer on Consumer Protection in the Internal Market**<sup>4</sup> interviewed 26,746 European citizens from all 27 Member States.

With respect to non-food product safety, survey findings show that 17% of consumers and 25% of retailers think that, essentially, all products are safe. 48% of consumers and 55% of retailers think that a small number of products are unsafe.

As many as 75% of EU27 consumers had heard of non-food products being recalled from the market, and 10% had been directly or indirectly affected by such a product recall.

The **Eurobarometer on Business attitudes towards cross-border sales and consumer protection**<sup>5</sup> presented the retailer's perspective on cross-border trade and sales activities.

Referring to non-food product safety, where consumer perceptions are positive, those of the retailer tend to be too. An obvious exception is in Romania, where 38% of consumers believe that a significant number of products are unsafe, while just 15% of retailers share this opinion.

The overwhelming perception of both consumers and retailers that a small number of products are unsafe is in line with the proportion of those retailers who have had products they distribute recalled from the market, and those who have had complaints about the safety of the products they sell: 21% and 14% respectively.

3 [http://ec.europa.eu/consumers/overview/cons\\_policy/doc/EN\\_99.pdf](http://ec.europa.eu/consumers/overview/cons_policy/doc/EN_99.pdf)

4 [http://ec.europa.eu/consumers/strategy/docs/eurobar\\_298\\_report\\_final\\_en.pdf](http://ec.europa.eu/consumers/strategy/docs/eurobar_298_report_final_en.pdf)

5 [http://ec.europa.eu/consumers/strategy/docs/fl224%20eurobar\\_cbs\\_analrep.pdf](http://ec.europa.eu/consumers/strategy/docs/fl224%20eurobar_cbs_analrep.pdf)

In addition, 45% of retailers confirmed having carried out tests to make sure the products they were selling were safe and 21% indicated that some of the products they distributed had been recalled or withdrawn in the past 12 months.

### 3.1.2 Better tools and capacity building

#### 3.1.2.1 Risk Assessment Guidelines

During 2008, the Commission Working Group for the Improvement of the RAPEX Risk Assessment Guidelines, consisting of experts from Member States, submitted a revised draft of the Guidelines to a public consultation. Stakeholders largely accepted the draft and provided well over 500 comments for further improvement. These comments were included in a further revision following the final meeting of the Working Group at the end of 2008. Thus the introduction of the improved Risk Assessment Guidelines can be expected during the first half of 2009.

#### 3.1.2.2 Joint market surveillance actions

With the growing complexity and internationalisation of product supply chains, close cooperation between the Member States' market surveillance authorities is becoming increasingly important. To support the Member States with their cross-border activities, in 2008, the Commission awarded a financial contribution of EUR 2.6 million to four joint market surveillance actions. The joint actions focus on: toys for children under three years, addressing magnets, small parts and heavy metals; sun beds and solarium services, addressing the new limits for UV radiation; cords and drawstrings in children's clothing, addressing the strangulation risk of such products; and a follow-up of the successful EMARS project (Enhancing Market Surveillance through Best Practice).

The three-year EMARS project was concluded at the end of 2008 and produced a number of important results including a best practice handbook for market surveillance (which can be downloaded from the project's website: [www.emars.eu](http://www.emars.eu)) and a Rapid Advice Forum. This Forum provides market surveillance officers with access to the expertise of their colleagues in other Member States in a fast and informal manner.

The follow-up project (EMARS2) will take forward the results achieved during the first phase, and aims to further strengthen cooperation between the Member States on consumer product safety by further promoting the use of the Rapid Advice Forum, extending the knowledge base, updating the Handbook, establishing an EU-wide training programme for market surveillance inspectors and coordinating the authorities' input into standardisation.

#### 3.1.2.3 RAPEX Seminars

In 2008, as in previous years, the European Commission organised RAPEX seminars in the Member States. This year, the training sessions took place in Bulgaria, Malta and Portugal. From the beginning of 2006, a total of 23 Member States hosted RAPEX seminars.

These seminars are organised for the benefit of the national market surveillance and customs authorities. Although the main focus at the seminar is the operation of RAPEX, other relevant aspects of product safety are also presented and discussed, such as: the European legal framework for consumer products, obligations for national authorities and businesses according to product safety law, risk assessment of consumer products and latest developments in the product safety area.





## 3.2 Compliance by businesses

### 3.2.1 Product safety measures in the supply chain

Following the large-scale toy recalls during the summer of 2007, the Commission carried out a thorough screening of the EU product safety system. This included setting up an independent group of experts (with representatives of national enforcement authorities, industry, consumers and conformity assessment organisations) with the mission of conducting an evaluation of the safety measures put in place by businesses in the toy supply chain. In June 2008, the results of this effort were presented with the publication of a report entitled "Evaluating Business Safety Measures in the Toy Supply Chain"<sup>6</sup>. The main conclusion of the research was that product safety cannot be guaranteed by final product testing alone, but that it has to be a key part of the "quality culture" of an organisation and needs to be embedded in the entire product supply chain. The research also found that it is the smaller players in the market, such as small European importers and traders and small Chinese manufacturers, who tend to be the weak link in the product safety chain. A second area where weaknesses have been detected is in relation to the expertise available within certain Member States' enforcement authorities and the role of testing laboratories. The report sets out a series of practical recommendations addressed to each of the stakeholders in the supply chain to strengthen safety controls.

### 3.2.2 Safety pacts: partnership and voluntary agreements with the private sector

To engage the toy sector more actively in the implementation of the relevant recommendations, Commissioner Kuneva, together with Toy Industries of Europe, signed a voluntary agreement<sup>7</sup> in which the industry committed to spread best safety practices through the sharing of expertise, education and training of business operators and closer cooperation with national authorities. In December 2008, the Commission signed a similar agreement with toy importers and retailers. An important part of this agreement consists of the development of clear safety guidelines to outline the systems and procedures that can be put in place to ensure that products meet the required standards, thereby aiming to help the smaller actors in the market in particular.

### 3.2.3 GPSD Business Application

An online system called "Business Application" was developed by the European Commission for businesses and national authorities in the Member States and EFTA/EEA countries. This system was established in order to simplify the practical application of the obligations of producers and distributors (as laid down in Article 5(3) of the General Product Safety Directive) to notify the competent national authorities of any dangerous consumer products placed on the EU market.

6 [http://ec.europa.eu/consumers/citizen/my\\_safety/docs/safety\\_measures\\_toy\\_supply\\_chain.pdf](http://ec.europa.eu/consumers/citizen/my_safety/docs/safety_measures_toy_supply_chain.pdf)  
7 [http://ec.europa.eu/consumers/safety/projects/index\\_en.htm?updatedtoys#toys](http://ec.europa.eu/consumers/safety/projects/index_en.htm?updatedtoys#toys)



The “Business Application” consists of two elements:

- a notification form that will be used by producers and distributors to notify dangerous products to national authorities, and
- a database, which will be used by the competent national authorities to handle all notifications of dangerous products submitted by businesses.

The application should speed up the submission of notifications (thanks to the use of the Internet), ensure that notifications are received by all Member States at the same time and harmonize the layout and content of the notifications submitted.

The “Business Application” will be operational from early 2009.

### 3.3 Developments relating to specific products and risks

#### 3.3.1 Article 13 Decision: warnings on risks from magnets in toys

On 21 April 2008, the Commission adopted a Decision<sup>8</sup> requiring Member States to ensure that toys containing small accessible magnets that are placed or made available on the market display a warning about the health and safety risks they pose. Magnets used in toys have not only become more powerful but also detach more easily, thus presenting serious risks if ingested as they can perforate the stomach or the intestines. In the absence of dedicated provisions in the current legislation and the relevant safety standard (undergoing revision), the Commission decided to adopt this temporary measure which remains valid until 21 April 2009.

#### 3.3.2 Measures to address risks from Dimethyl fumarate (DMF)

From September to December 2008, the Commission received six RAPEX notifications from France, Poland and Sweden relating to the presence of Dimethyl fumarate (DMF) in leather furniture and footwear. Severe dermatitis in several hundred consumers was reported, causing itching, redness, irritation and respiratory troubles in certain cases.

The non-authorised biocide DMF, which protects products against moulds, was identified by clinical tests as the cause of the damage to health.

At the end of 2008, the Commission initiated a Community Measure under Article 13 of the General Product Safety Directive 2001/95/EC to ban the presence of DMF in all consumer products as of 1 May 2009.

#### 3.3.3 Lighters

In 2008, the Commission adopted specific child safety requirements to be met by European standards for lighters. This allowed the Commission to launch, on 9 July 2008, the revision process of the European standard EN 13869:2002: Lighters- Child-resistance for lighters - safety requirements and test methods.

The Commission also adopted a follow-up Decision extending, for the second time, the validity of the requirements put in place in 2006, thus prohibiting the sale of non-child-resistant and novelty lighters to consumers until 11 March 2009.

<sup>8</sup> OJ L 114, 26.4.2008, p. 90–93  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:114:0090:0093:EN:PDF>



### 3.3.4 Reduced ignition propensity cigarettes

Each year, an estimated minimum of 1,000 fatalities<sup>9</sup> are encountered in the EU as a result of upholstery, furniture or textiles catching fire due to cigarettes that are carelessly left unattended by someone smoking in bed or while under the influence of alcohol, illicit drugs or medication. Victims include smokers and non-smokers, children as well as adults, and fire-fighters. The fires also cause significant economic damage.

A number of cigarette fires could be prevented through the introduction of reduced ignition propensity (RIP) cigarettes. Such cigarettes self-extinguish when left unattended and therefore can no longer ignite the material on which they have been placed. They are commercially available in large parts of the United States and in Canada.

On the basis of the safety requirements for RIP cigarettes developed previously, the Commission proposed to Member States a detailed mandate for CEN to develop a standard on the technical requirements that such cigarettes should fulfil, with due consideration to be given to the existing standard ASTM E2187, applicable in the United States, where appropriate, and in Canada. Member States accepted, and the mandate was passed on to CEN who accepted it and referred it to the International Organisation for Standardisation (ISO) for the actual development work since CEN does not dispose of the relevant experts. Within ISO, experts from two Technical Committees (TCs) will jointly undertake the work: TC 92 on Fire Safety and TC 126 on Tobacco and Tobacco Products.

Thus the introduction of fire-safe cigarettes in the EU can be expected in the coming years, following successful completion of the work of CEN and ISO respectively.

### 3.3.5 Children's products/childcare articles

To help prevent many childhood accidents, the Commission adopted on 22 December 2008 a Decision aimed at referencing the European safety standard for baby walkers EN 1273:2005 in the Official Journal<sup>10</sup>, according to Article 3 and 4 of the GPSD. In this way, all products manufactured according to this standard are presumed to be safe. Moreover, economic operators and market surveillance authorities will have a clear, quick and single reference for making, importing or checking safe baby walkers.

## 3.4 International cooperation towards global governance

### 3.4.1 Bilateral cooperation

While this section describes in more detail the cooperation with certain countries, the Commission is also in dialogue with many other countries and regional organisations which are not specifically mentioned here.

#### **China**

In 2008, 59% of the RAPEX notifications concerned products of Chinese origin, including Hong Kong. Given the high proportion of notifications relating to products of Chinese origin, cooperation with the Chinese authorities on product safety has been further intensified.

On 17 November 2008, the Commission's Directorate-General for Health and Consumers and the Chinese Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) – the Chinese Ministry responsible for ensuring the safety of exported Chinese

<sup>9</sup> The ASPECT Consortium. Tobacco or Health in the European Union. Past, present and future. European Commission, 2004 [http://ec.europa.eu/health/ph\\_determinants/life\\_style/Tobacco/Documents/tobacco\\_exs\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_exs_en.pdf)

<sup>10</sup> [http://ec.europa.eu/consumers/safety/euro\\_standards/babywalkers.pdf](http://ec.europa.eu/consumers/safety/euro_standards/babywalkers.pdf)

consumer products – signed an upgraded Memorandum of Understanding (MoU) on cooperation arrangements<sup>11</sup>.

The extended MoU strengthens the original version in view of the significant progress made in cooperation with China over the last three years, by including a clearer reference to the RAPEX-China system – the dedicated IT system that provides AQSIIQ with access to information on dangerous products of Chinese origin that are registered under RAPEX – and the roles of both sides in this respect. It also provides for further opportunities to cooperate, for example by undertaking joint enforcement actions, mentions the established working groups between the Commission and AQSIIQ, and clarifies the confidentiality understanding regarding the exchange of information. Moreover, it foresees a role for the Member States and stakeholders in the cooperation framework.

The RAPEX-China system allows the Chinese authorities to tackle the safety issue at source, thereby enhancing the safety of imports. AQSIIQ reports to the Commission quarterly on the follow-up actions taken on the basis of the RAPEX data. Between September 2006 and August 2008 (reports received before end of 2008), AQSIIQ has investigated and, where necessary, taken measures in relation to 599 RAPEX notifications. On average, AQSIIQ investigates 80 RAPEX cases over the three-month reporting period.

In 51% of the cases, investigations resulted in preventive or restrictive measures being adopted either by AQSIIQ or voluntarily by the Chinese manufacturer/exporter. These measures included export bans, corrective actions and strengthened supervision over Chinese companies. In 49% of the cases investigated, no measures were taken, mainly owing to the lack of available information about the Chinese manufacturer or exporter. This figure shows that identification of the responsible Chinese companies remains the biggest challenge for AQSIIQ in carrying out follow-up activities to notifications transmitted through the RAPEX-China system. It should also be noted that there has been a change in the types of measures adopted by AQSIIQ with regard to dangerous products notified by the EU. During the reporting period between June and August 2008, for the first time AQSIIQ decided to resort more frequently to strengthened supervision over a company rather than an export ban.

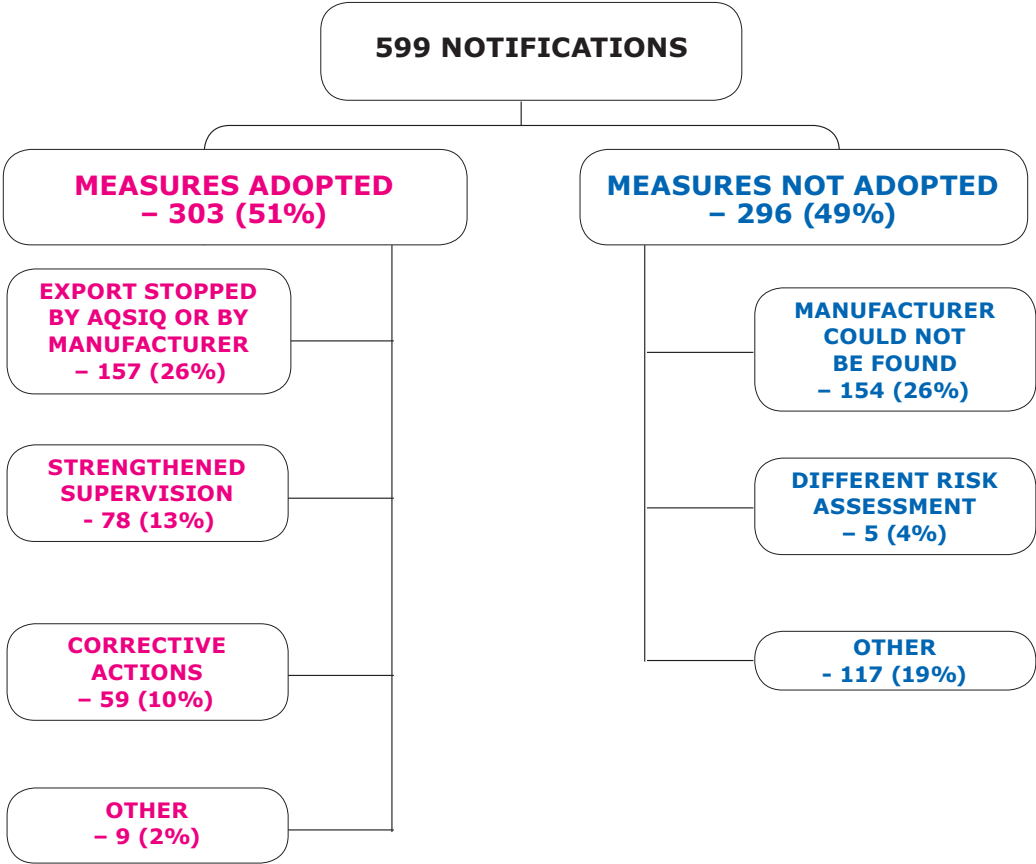


<sup>11</sup> For the full text of the upgraded MoU, please see:  
[http://ec.europa.eu/consumers/safety/int\\_coop/docs/memorandum\\_china\\_annexes.pdf](http://ec.europa.eu/consumers/safety/int_coop/docs/memorandum_china_annexes.pdf)



**Chart**

Actions taken by AQSIQ (total figures)



## United States

Europe and the United States face many similar challenges concerning the safety of products. As many products are common to both markets, a strong transatlantic relationship in this area is of key importance. Both sides agree that the exchange of information and best practice is vital to keep consumers on both sides of the Atlantic safe from dangerous products. In the course of 2008, a closer and more frequent dialogue was established between European and US regulators. The most notable development was the adoption of the US Consumer Product Safety Improvement Act. The new law enables the Consumer Product Safety Commission (CPSC) – the US federal authority in charge of product safety – to share confidential product safety information with foreign governments and agencies.

Product safety cooperation with the CPSC takes place both in the context of dialogue, established between the CPSC and the Commission's Directorate-General for Health and Consumers under the 2005 Guidelines for Information Exchange and on Administrative Cooperation, and under the framework of the Transatlantic Economic Council (TEC) and the EU-US High-Level Regulatory Cooperation Forum (Forum).

Following the first TEC meeting in November 2007, where the safety of imported products was identified as a priority for future work, the Forum submitted its report "Towards enhanced cooperation on the safety of imported products" to the May 2008 TEC meeting. TEC endorsed the conclusions and recommendations set out in the report and, at its meeting in December 2008, reviewed the progress made in implementing those recommendations. Significant progress in terms of intensified bilateral cooperation was recorded in the field of consumer products, including toys. As regards toys, the CPSC and the Commission have set up a Toy Safety Working Group to function as a focal point for discussing matters relating to toy import safety. The talks have increased mutual understanding and allowed for the identification of further points for discussion.

## Japan

In the framework of the 17th Japan-EU Summit, held on 23 April 2008 in Japan, the two parties agreed to strengthen cooperation in the area of product safety at international and bilateral levels. In a joint statement it was agreed, in particular, to explore possibilities for strengthening cooperation and exchanging information on non-food product safety policies and on publicly available information concerning recent major recalls and withdrawals from the market of dangerous non-food products, including those imported from third countries.

## Switzerland

On 20 October 2008, the Council of the European Union authorised the European Commission to enter into negotiations with the Swiss Confederation with a view to achieving greater cooperation and removing technical barriers to trade in the areas of consumers, food safety and health.

The Commission's negotiation mandate in the consumers' sector is broad and covers two major areas: non-food product safety and consumer protection cooperation (CPC) in the area of financial interests. The objective of the negotiations in the consumer sector is to prepare the agreement that would strengthen cooperation between the European Community and Switzerland by aligning legislation and requirements for products, exchanging information on dangerous products and participating in joint projects and initiatives. Negotiations started in November 2008.







### 3.4.2 Trilateral cooperation (EU-China-US)

In September 2008, the Commission and the CPSC, together with AQSIQ, conducted a series of joint outreach seminars<sup>12</sup> in China on EU and US safety requirements for clothing, toys, and electrical appliances, with a view to promoting respect of the applicable safety requirements and further enhancing the safety of imported products. Product safety is an area of mutual concern for the three parties and, in the past years, all have made significant efforts. Considering the interdependence in this area, moving to the next level in cooperation and adding tripartite initiatives to the existing fruitful bilateral contacts was therefore a logical step.

This outreach was followed by a high-level EU-China-US trilateral meeting hosted by Commissioner Kuneva in Brussels on 17 November 2008, to further the common agenda and to send a strong political signal of the determination of all sides to keep product safety at the top of the international political agenda, recognising that open markets can only be built on strong and secure management of global product supply chains. The parties agreed to priority areas for action, including product traceability and cooperation on safety standards for toys and children's products<sup>13</sup>.

### 3.4.3 Multilateral cooperation

#### **OECD Roundtable**

On 23 October 2008, the Commission took part in the Roundtable on International Consumer Product Safety hosted by the OECD's Committee on Consumer Policy (CCP). The Roundtable aimed at informing participants of consumer policy developments and regulatory approaches by providing examples of challenges and examining how domestic and international product safety systems could respond to them. The Roundtable brought together a large gathering of product safety policy officials and enforcement regulators, as well as representatives from consumer and industry associations.

The participants reached the following conclusions: greater intergovernmental coordination and cooperation is required to ensure that international product safety frameworks protect consumers; the CCP should provide assistance to countries to coordinate actions; and governments must make efforts to harmonise product safety standards internationally, take a more proactive approach to product safety failure, increase resources available to regulators, take a risk-based approach to surveillance and enforcement, and develop a rapid international information exchange system. The work continues in 2009-2010.

### 3.4.4 International Product Safety Week

The second edition of the International Product Safety Week took place between 17 and 21 November 2008 in Brussels. The aim was to convene in one place at the same time the main global actors working in the product safety field, with a view to raising the level of cooperation and achievement in product safety on the global market and ensuring safety throughout the entire supply chain<sup>14</sup>.

The event began on Monday, 17 November with the signature of an upgraded Memorandum of Understanding on cooperation arrangements between the Commission and the AQSIQ. The signing ceremony was followed by the first high-level Tripartite Summit between the EU, the US and China, to enhance global governance of product safety. Commissioner



<sup>12</sup> For the full text of the Joint Press Statement, please see: [http://ec.europa.eu/consumers/safety/int\\_coop/docs/trilateral\\_joint\\_statement\\_en.pdf](http://ec.europa.eu/consumers/safety/int_coop/docs/trilateral_joint_statement_en.pdf)

<sup>13</sup> For the full text of the Joint Press Statement, please see: [http://ec.europa.eu/consumers/safety/int\\_coop/docs/high\\_level\\_trilateral\\_jps.pdf](http://ec.europa.eu/consumers/safety/int_coop/docs/high_level_trilateral_jps.pdf)

<sup>14</sup> For an overview of the programme and presentations please visit: [http://ec.europa.eu/consumers/safety/int\\_coop/productsafetyweek\\_en.htm](http://ec.europa.eu/consumers/safety/int_coop/productsafetyweek_en.htm)

Kuneva met with her US and Chinese counterparts to discuss how product safety can be improved and ensured throughout the global supply chain, with the aim of laying a firm basis for further cooperation on product safety issues. This meeting was of particular significance given that it was the first 'trilateral' gathering of the partners at this level.

These high-level meetings were followed by a series of conferences and seminars in which experts from a broad range of organisations involved in consumer product safety shared expertise and practical experience, including:

- A meeting of the regulators' International Consumer Product Health and Safety Caucus (ICPSC) to discuss cooperation and mutual challenges in the global governance of product safety. The ICPSC is a platform to facilitate the exchange of information on consumer product safety issues between government authorities in the area of governmental policy, legislation and market surveillance.
- The 4<sup>th</sup> European meeting and training symposium of the International Consumer Product Health and Safety Organisation (ICPHSO), an organisation dedicated to the health and safety issues related to consumer products manufactured and marketed in the global marketplace. ICPHSO provides a forum for the exchange of ideas and sharing of information among government, industry, trade associations, consumer organisations, legal representatives, academia, standards makers and interested individuals.
- The closing conference of a PROSAFE (informal network of Member State authorities) project on Enhancing Market Surveillance through Best Practice (EMARS). The project aims to ensure a basic level of expertise and practical experience in the market surveillance organisations of Member States within the EEA.
- The EU-China Regulators' Working Group on the rapid alert system for unsafe products and the related exchange of information between the EC and China (RAPEX-China).
- The 3<sup>rd</sup> EU-China Market Surveillance Seminar, which addressed the latest developments in Europe in market surveillance under the General Product Safety Directive and the EU New Legislative Framework and relevant developments in China. This year's seminar focused on product traceability in global supply chains.



# 4

## ONGOING AND FUTURE CHALLENGES

### 4.1 Traceability

Traceability serves to identify economic operators in the entire supply chain for consumer products. With this information, corrective measures can be effectively put in place. Traceability has steadily grown in importance due to the integration and globalisation of markets and global sourcing of products. As the journey from the factory floor to the store shelf often spans the globe, ensuring the safety in the whole supply chain has become more challenging. High-profile alerts on non-food consumer goods worldwide have recently highlighted the need for better traceability, also to ensure effective recall procedures.



The GPSD contains general obligations for producers to provide consumers with the necessary information to trace the origin of a product or to display the identity of the producer or details of the production batch on the product or its packaging. Nevertheless, it is up to the Member States to adopt concrete measures to implement such obligations. The number of notifications in which the product is untraceable has decreased in comparison with previous years. However, as those products that pose a serious risk and whose country of origin is unknown account for 10% of notifications, there is room for further improvement. The statistics under the RAPEX-China system have also made it clear that problems with traceability - not being able to trace the manufacturer of the product - are a major reason why the Chinese authorities cannot take corrective actions or stop dangerous goods at source. The reports indicate that the lack of corrective measures from AQSIQ in almost half of the cases investigated was often due to the fact that they could not trace the Chinese companies responsible for manufacturing or exporting the notified dangerous products into the EU.

Further improvements can be expected as a result of the recently adopted Decision 768/2008/EC, which requires the indication of the name and address of the manufacturer - and, in the case of imported products, both the importer and the manufacturer - as a general principle for Community harmonisation legislation. However, significant efforts are needed to ensure effective international traceability. As a result of the high-level EU-China-US trilateral meeting held in Brussels on 17 November 2008, the three parties agreed to explore possibilities to develop harmonised approaches, where possible, for product traceability systems.

The EU-China Trade Project has also recently commissioned a study by a private expert to investigate the commercial, technical, legal and political feasibility of a post-manufacturing traceability system along the supply chain between China and the EU. The results and other collected inputs inform further discussion within the Commission, and subsequently with our counterparts and other stakeholders, on improving traceability in the global context and on the way forward in this important area. Traceability was also the focus of the third EU-China Market Surveillance Seminar organised in Brussels on 21 November 2008.

### 4.2 New RAPEX Guidelines

In 2008, the Commission decided to revise the "RAPEX Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC" (the "RAPEX guidelines"), which were adopted in 2004 in the form of a Commission Decision (2004/418/EC)<sup>15</sup>. The decision to revise the RAPEX guidelines resulted mainly from the need to clarify the provisions of the guidelines and to adjust the operation of the system to best practices that will ensure more efficient and effective functioning of the system.

The new RAPEX guidelines will clarify the application of many existing provisions, such as those that regulate the notification criteria, the scope of the system, the application of

<sup>15</sup> OJ L 151, 30.04.2004, p.83.

different notification forms and the examination of notifications by the Commission. The Commission also plans to introduce new provisions on the languages used in RAPEX in order to more rapidly and effectively exchange information on dangerous products with the Member States.

Furthermore, the Commission intends to address in the new guidelines those aspects of the RAPEX operation that, up until now, lack detailed guidance, and which over the years have proved to be necessary for the consistent application of RAPEX notification obligations by all Member States. The new guidelines will regulate, for example, the confidentiality issue, the permanent withdrawal of a notification from the system, the temporary removal of a notification from the RAPEX website and the investigations carried out by the Commission in order to assess the safety of the product notified through RAPEX.

The new RAPEX guidelines will also include the new risk assessment method to be used by national authorities in order to assess the level of seriousness of risks posed by a product and to decide whether rapid intervention is necessary. The Commission Decision introducing the new RAPEX guidelines is expected to be adopted in the first half of 2009.

### 4.3 The relation between RAPEX and the rapid alert system to be set up by the New Legislative Framework applying to harmonised products

On 9 July 2008, a new legislative framework for the marketing of products, consisting of Regulation (EC) No. 765/2008<sup>16</sup> and Decision 768/2008/EC<sup>17</sup>, was adopted. One of the objectives of these measures is to establish a reinforced market surveillance and customs control framework for products covered by Community harmonisation legislation, and to enhance the traceability of products. Furthermore, the Regulation foresees the development of a Community Rapid Information System which models itself on the RAPEX system under the GPSD.

The Commission is currently preparing guidelines to clarify the relationship between the market surveillance framework under the new Regulation and the GPSD, as well as exploring the link between the Community Rapid Information System covering the needs of the Regulation and the currently operational RAPEX system and Contact Point network.

<sup>16</sup> OJ L 218, 13.8.2008, p. 30

<sup>17</sup> Ibid., p. 82





#### 4.4 GRAS – new IT system

One of the most important ongoing projects in the area of product safety is the implementation of the Generic Rapid Alert System, called the “GRAS platform”. This system will function as a generic online platform for all rapid alert systems managed by the Health and Consumers Directorate-General of the European Commission, including RAPEX.

The development of the new platform has progressed more slowly than originally foreseen.

The objectives of the application have not changed and it is still the Commission’s intention to establish as soon as possible a first version of the new online application for RAPEX which will ensure a more rapid and efficient operation of the system both at the national and the European level, and which will significantly improve access to the system for the local market surveillance and customs authorities of Member States and EFTA/EEA countries.

#### 4.5 Cooperation with customs authorities

The Commission continues to support and enhance cooperation between national market surveillance and customs authorities and to encourage the more active participation of customs authorities in the RAPEX system.

The Commission also pursues its initiative to promote the circulation of key RAPEX data through the EU-level customs mechanism for exchanging alerts on incoming non-compliant cargos (Risk Information Form – RIF).

In addition, the Commission co-organised a seminar on “Preventing imports of dangerous products”, which took place in Austria in April 2008, with the aim of strengthening contacts, exchanging best practices and improving cooperation between customs and market surveillance experts. The seminar produced three recommendations:

- to enhance the cooperative network between customs and market surveillance authorities;
- to improve risk information;
- to share experience, knowledge and best practices on cooperation and controls.

Experts from both fields (customs and market surveillance) are to take part in a pilot project on certain high risk goods and/or sectors in order to test and improve the effectiveness of cooperation.

#### 4.6 Transparency and consumer confidence

The success of the RAPEX system relies upon transparency and effective communication. The constant exchange of information with the relevant national authorities in the Member States is complemented by a continuous effort to raise awareness among consumers about the decisive role played by RAPEX in ensuring the safety of the products they buy.

The European Commission and the Member States disclose to the general public, via the Internet or printed publications, regularly updated information concerning products posing serious risks to the health and safety of consumers. By having access to information such as the brand name, the country of origin or by seeing pictures of harmful products, consumers can identify and more easily avoid dangerous products.

For the national authorities, there is more information in the RAPEX system, which is helpful in their cooperation with producers (including importers) and distributors. For instance, the identification of manufacturers and suppliers is protected as a business secret and therefore is not public, save in exceptional circumstances of overriding public interest. However, the authorities have such information at their disposal, together with various tools which allow them to determine, together with the producers and distributors, the measures to be taken. This allows them both to communicate about the safety issue in broad terms, with a view to allowing economic operators to assess whether they may need to contact the authorities for closer examination of their products, and also to specifically address problems regarding products considered dangerous, with the aim of ensuring that products of precisely the same origin are effectively removed from the markets.



# 5

## MORE DETAILS ABOUT THE RAPEX SYSTEM

### 5.1 Objective

The objective of RAPEX is to ensure that information about dangerous non-food consumer products found in one Member State is rapidly circulated among all the other national authorities and to the European Commission for follow-up, with the aim of preventing the supply of these products to consumers.

This European level coordination adds value to the surveillance and enforcement actions taken at national level and increases the overall safety level of consumer goods placed on the European market. Thirty countries currently participate in the system, including all EU Member States and the EFTA/EEA countries: Iceland, Liechtenstein and Norway.



### 5.2 The legal basis of RAPEX

The Directive on general product safety 2001/95/EC (GPSD)<sup>18</sup> provides the legal framework for RAPEX. In addition, the Commission introduced the RAPEX Guidelines (Decision 2004/418/EC<sup>19</sup>), which aim to facilitate the effective and consistent application of the provisions of the GPSD related to the notification procedure.

The GPSD is available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT>

The RAPEX Guidelines are available at:

[http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418R\(01\):EN:HTML](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418R(01):EN:HTML)

The RAPEX system is used to exchange information on dangerous, non-food, consumer products, including those covered by "sectoral" Directives (e.g. toys, cosmetics, electrical appliances, personal protective equipment, machinery, motor vehicles). This is because most of the specific "sectoral" provisions do not provide for a similar rapid information exchange system.

However, some of these "sectoral" Directives foresee a notification procedure known as the "Safeguard Clause", but its aim – to check the grounds for national measures which seek to restrict the free movement of products – differs from the RAPEX objectives. The RAPEX system allows for a rapid exchange of information on dangerous products in order to protect the health and safety of consumers.

Sectoral legislation relevant to consumer protection includes:

- Toys Directive 88/378/EEC (revised Directive in 2009)
- Low Voltage Directive 2006/95/EC
- Machinery Directive 98/37/EC
- Cosmetics Directive 76/768/EEC
- Motor Vehicles Directive 70/156/EEC
- Personal Protective Equipment Directive 89/686/EEC

Sectoral Directives are available on the EUR-Lex website: <http://eur-lex.europa.eu/>.

Two guidance documents clarify the relationship between the GPSD and the sectoral Directives. They are available at: [http://ec.europa.eu/consumers/safety/rapex/key\\_docs\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/key_docs_en.htm)

<sup>18</sup> OJ L 11, 15.1.2002, p. 4.

<sup>19</sup> OJ L 151, 30.04.2004, p.83.

## 5.3 When is RAPEX used?

### 5.3.1 RAPEX Notifications

According to the GPSD, the national authorities of Member States notify the European Commission, via the RAPEX system, of those measures taken to prevent or restrict the marketing or use of consumer products posing a serious risk to the health and safety of consumers and which may be available in at least two European countries. This obligation is laid down in Article 12 of the GPSD (see box).

#### What products are concerned by measures notified?

RAPEX is dedicated only to **non-food consumer products**, which are defined as:

- products which are intended for consumers;
- products which, even if not intended for consumers, are accessible to them (for example, a machine tool, originally intended for professional use, but which can be purchased in a shop by a consumer);

RAPEX covers consumer products that were purchased by consumers, as well as products provided to consumers in the context of a service, or products that are in the premises of the service providers and involve an active use by the consumer (for example, hairdryers in hotels or sun beds, if operated almost exclusively by the consumer).

The most frequently notified consumer products are: toys, motor vehicles, electrical appliances, lighting equipment, cosmetics, children's equipment, clothing and household appliances.

The RAPEX system does not cover all consumer products. Certain products such as food, feed, medical devices and pharmaceuticals are excluded from the scope of RAPEX because information about such products is exchanged through specific alert systems established at European level. For example, the Rapid Alert System for Food and Feed (RASFF) is used to exchange information about dangerous food and feed.

#### What measures can be taken?

Member States notify through RAPEX dangerous consumer products that were subject to both measures ordered by national authorities and/or actions taken 'voluntarily' by producers and distributors. The most common measures are **sales bans, withdrawals** of dangerous products from the market and **recalls** of dangerous products from consumers.

#### What is a serious risk?

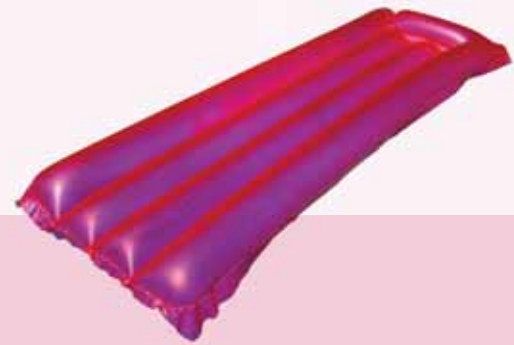
Products notified through the RAPEX system have to pose a "serious risk" to the health and safety of consumers. A "serious risk" is defined by the GPSD as one which requires rapid intervention by the public authorities, and includes risks of which the effects are not immediate. The national authorities are obliged to assess the risks posed by a product they intend to notify (using the risk assessment method provided in the RAPEX Guidelines), as only those products which pose a serious risk are required to be notified through RAPEX.

#### What is the cross-border effect?

National authorities of Member States exchange information about dangerous products through RAPEX only if there is







evidence or reasonable suspicion that these products can be found on the markets of at least two countries participating in the system.

### 5.3.2 Other types of information exchanged

The RAPEX system is also used for the exchange of other information on dangerous products available in Member States and the adopted preventive or restrictive measures taken.

For example, Member States submit to the Commission through the RAPEX system information on measures ordered by the national authorities in relation to products that present only a moderate risk for consumers. These notifications come under Article 11 of the GPSD.

Furthermore, the RAPEX system is used to circulate information on products posing risks to consumers, which, nevertheless, cannot be correctly identified by national authorities due to insufficient product identification (e.g. brand, model number, pictures of the product and its packaging are not available). These notifications are distributed for information purposes only.

#### Information exchanged through RAPEX

##### RAPEX notifications

- Notification under Article 12: notifications of measures ordered by the national authorities, or actions taken 'voluntarily' by producers or distributors in relation to products presenting a serious risk.

##### Other information

- Notifications under Article 11: notifications of measures ordered by the national authorities in relation to products presenting a moderate risk.
- Notifications 'for information': notifications of measures ordered by the national authorities, or actions taken 'voluntarily' by producers or distributors in relation to dangerous products, disseminated for information purposes due to insufficient product identification.

## 5.4 How does RAPEX work?

The RAPEX system relies on close cooperation between the European Commission and the national authorities of the Member States.

### 5.4.1 Role and obligations for national authorities

Each Member State has designated competent market surveillance authorities and granted them with the necessary powers to take measures in order to prevent or restrict the marketing or use of dangerous products. More specifically, the national authorities are competent to take samples of consumer products placed on the market, to test them in laboratories and – in cases where these products pose risks to consumers – order producers and distributors to stop their sale, withdraw them from the market and/or recall them from consumers.

In addition, each country participating in the system has also established a single national RAPEX Contact Point which coordinates the operation of the RAPEX system at national level.

When the national authorities or a producer/distributor take measures which prevent or restrict the marketing or use of a consumer product posing serious risks to the health and safety of consumers, the RAPEX Contact Point submits to the Commission – using a standard notification form – information about this product and provides details on:

- product identification – name, brand, model, description, picture;
- risks posed by the product – type of risk, results of laboratory tests and risk assessment;
- measures adopted to prevent risks – type of measure, scope, duration, date of entry into force;
- distribution channels of the notified product – manufacturer, exporter, importer, distributors and countries of destination.

The Commission examines the information provided with regard to its compliance with the GPSD and the RAPEX Guidelines and checks its completeness. The result of this process is called validation. In particular, a notification is not validated if another country has already notified measures against the same product and same risk – i.e. if the RAPEX network has already been alerted.

If the examination conducted by the Commission leads to validation, information is circulated to the national RAPEX Contact Points in all countries participating in the system. All RAPEX Contact Points then forward this information to the competent national authorities, which then check whether the notified product is present on the market and if it is necessary to take appropriate action. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the Commission through the RAPEX system. This feedback is called “reactions”.

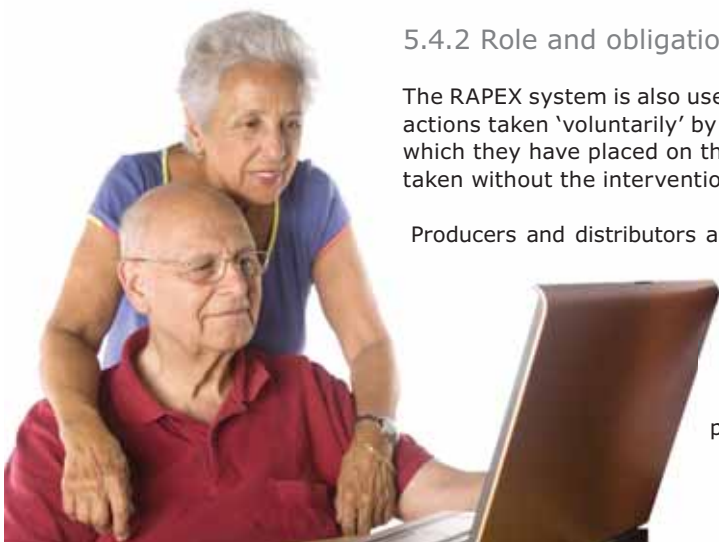
A **notification** consists of information provided by Member States concerning measures or actions taken for products presenting a serious or a moderate risk to consumers.

A **reaction** is information provided by Member States in response to a “validated” notification. A reaction normally contains information about the presence of the notified product in other Member States and the measures taken therein.

#### 5.4.2 Role and obligations for producers and distributors

The RAPEX system is also used to exchange information about the preventive or restrictive actions taken ‘voluntarily’ by producers and distributors in relation to dangerous products which they have placed on the market. ‘Voluntary’ action in this context means measures taken without the intervention of the public authority.

Producers and distributors are in a prime position to assess whether products they place on the market are dangerous because, as professionals, they have the information about the product and have contact with consumers. Therefore, once they become aware that a product is dangerous, they must immediately inform the competent authorities and the RAPEX Contact Point in their country, clearly identifying the product in question, the risks it poses and the information necessary to trace it. They must also





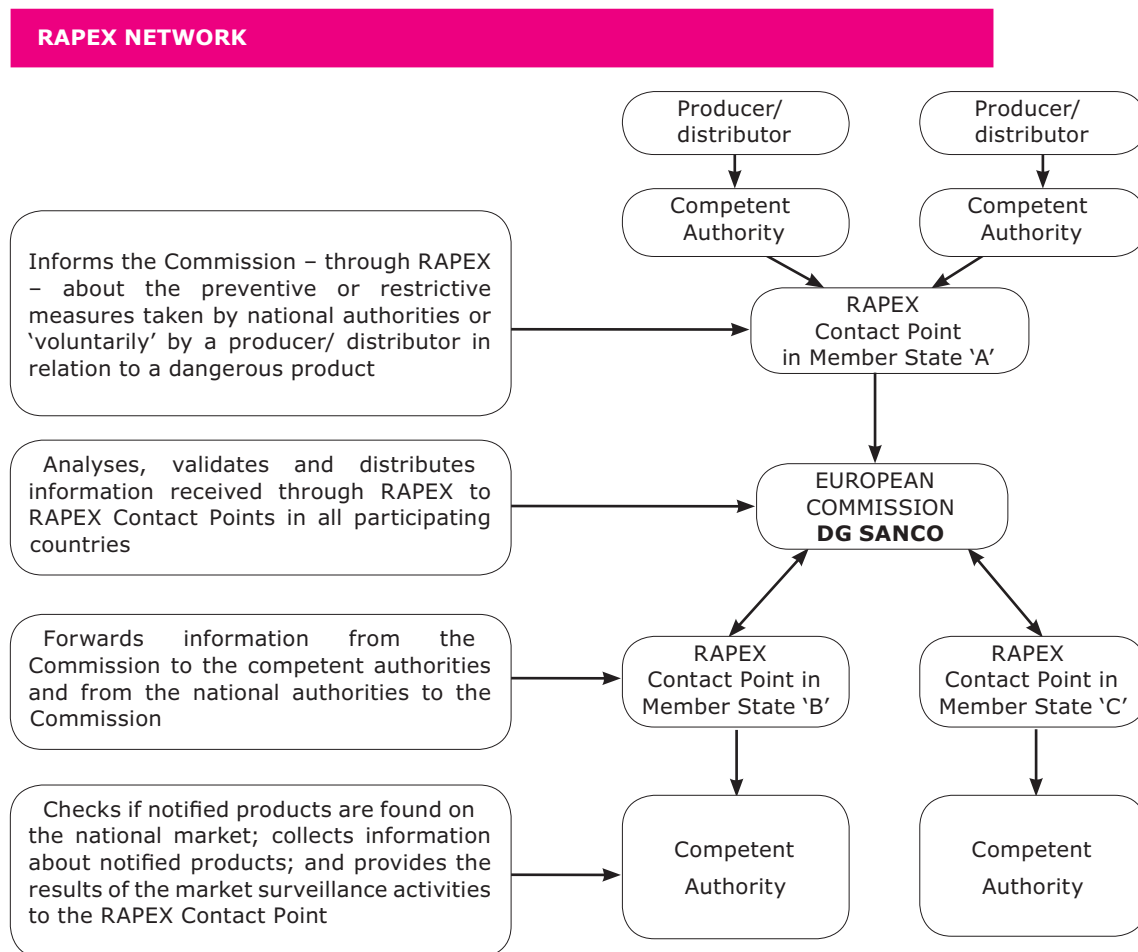
inform the authorities of any measures taken to prevent further risks to consumers. First contact with the national authorities should be established as soon as possible and even before all the required information is available.

This information is then conveyed to the Commission by the RAPEX Contact Point via the RAPEX system, and consequently to other countries participating in the RAPEX system.

The obligation of economic operators to inform the authorities about dangerous products is a key element in the market monitoring procedure set up by the GPSD. National authorities are able to monitor whether the companies have taken appropriate measures to address the risks posed by dangerous products and to assess if additional measures are necessary.

To simplify the practical application of the notification obligation of producers and distributors, the Commission has developed an online application called 'Business Application', which will enable economic operators to submit notifications Europe-wide to national authorities through the Internet. For more information on the application, please read Chapter 3.2.3.

The figure below illustrates the cooperation between the European Commission, the national RAPEX Contact Points and national market surveillance authorities.



## 5.5 The RAPEX website

The Commission publishes weekly overviews of RAPEX notifications on products posing serious risks to consumers, as well as product safety news and information about major events held in the consumers' arena, on the RAPEX website: <http://www.ec.europa.eu/rapex>.

The RAPEX weekly overviews provide information on the product, the nature of the risk posed and the measures taken to prevent these risks. This information enables consumers to check whether the products they use or plan to purchase have been subject to RAPEX notifications.

# 6

## GLOSSARY

<b>AQSIQ</b>	General Administration for Quality Supervision, Inspection and Quarantine of the People's Republic of China
<b>Article 11 notification</b>	Notifications of measures or actions taken for products presenting a moderate risk
<b>Article 12 notification</b>	Notifications of measures or actions taken for products presenting a serious risk
<b>Compulsory measures</b>	Measures ordered by national authorities (e.g. ban of sales, informing consumers, withdrawal from the market, recall from consumers) or by the customs authorities (e.g. rejection of import)
<b>CEN</b>	European Committee for Standardization
<b>CPSC</b>	United States Consumer Product Safety Commission
<b>EEA countries</b>	(as used in this report) countries that are members of the European Economic Area (EEA) but are not members of the European Union, namely Norway, Iceland and Liechtenstein
<b>EU-27</b>	All EU countries
<b>'For information only' notification</b>	Notifications of measures or actions taken which the Commission disseminates to the National Contact Points for information only because they do not fall under the scope of Article 12 or Article 11 of the GPSD
<b>GRAS</b>	Generic Rapid Alert System, a general IT platform for all rapid alert systems of the Directorate-General for Health and Consumers
<b>National Contact Point</b>	Representative of the network of all national market surveillance authorities considered by the European Commission as the single contact point for that country
<b>Reaction</b>	Information provided by Member States in response to a "validated" notification. A reaction normally contains information about the presence of the notified product in other Member States and the measures taken therein.
<b>'Voluntary' measures</b>	Corrective measures 'voluntarily' taken by the producer or distributor (e.g. stopping of sales, informing consumers, withdrawal from the market, recall from consumers) on the business' own initiative, without the intervention of a public authority



# 7

## IMPORTANT WEBSITES

**RAPEX:**

<http://ec.europa.eu/rapex>

**EU Commission, Directorate-General for Health and Consumers:**

[http://ec.europa.eu/dgs/health\\_consumer/index\\_en.htm](http://ec.europa.eu/dgs/health_consumer/index_en.htm)

**EU Commission, Directorate for Consumer Affairs:**

[http://ec.europa.eu/consumers/index\\_en.htm](http://ec.europa.eu/consumers/index_en.htm)

**EU Commissioner for Consumer Affairs, Ms Meglena Kuneva:**

[http://ec.europa.eu/commission\\_barroso/kuneva/index\\_en.htm](http://ec.europa.eu/commission_barroso/kuneva/index_en.htm)

**EU Commission, Directorate-General for Enterprise and Industry – “New Approach” Sectoral Directives:**

[http://ec.europa.eu/enterprise/sectors\\_en.htm](http://ec.europa.eu/enterprise/sectors_en.htm)

**EU Commission, Directorate-General for Taxation and Customs Union:**

[http://ec.europa.eu/taxation\\_customs/index\\_en.htm](http://ec.europa.eu/taxation_customs/index_en.htm)

**Business notifications:**

[http://ec.europa.eu/consumers/safety/rapex/guidelines\\_business\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/guidelines_business_en.htm)

**Lighters:**

[http://ec.europa.eu/consumers/safety/prod\\_legis/prod\\_legislation\\_lighters\\_en.htm](http://ec.europa.eu/consumers/safety/prod_legis/prod_legislation_lighters_en.htm)

**Toys:**

[http://ec.europa.eu/enterprise/toys/index\\_en.htm](http://ec.europa.eu/enterprise/toys/index_en.htm)





# 8

## THE NATIONAL CONTACT DETAILS

### National RAPEX Contact Points

A list of all the contact details of the national RAPEX Contact Points is available at:  
[http://ec.europa.eu/consumers/safety/rapex/guidelines\\_states\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/guidelines_states_en.htm)

### Product safety information for consumers per country

#### Austria

Ministry of Social Affairs and Consumer Protection: [www.produktsicherheit.gv.at](http://www.produktsicherheit.gv.at)  
Austrian Consumers Information Association (Verein für Konsumenteninformation):  
[www.konsument.at](http://www.konsument.at)  
Austrian Road Safety (Kuratorium für Verkehrssicherheit): [www.kfv.at](http://www.kfv.at)  
Große schützen Kleine (regional initiative for child safety):  
[www.grosse-schuetzen-kleine.at](http://www.grosse-schuetzen-kleine.at)

#### Belgium

[www.economie.fgov.be](http://www.economie.fgov.be)  
[www.economie.fgov.be/protection\\_consumer/security/home\\_nl.htm](http://www.economie.fgov.be/protection_consumer/security/home_nl.htm)

#### Bulgaria

Ministry of Economy and Energy – in charge of consumer protection:  
[www.mee.government.bg](http://www.mee.government.bg)  
Commission for Consumer Protection: [www.kzp.bg](http://www.kzp.bg)

#### Cyprus

[www.mcit.gov.cy](http://www.mcit.gov.cy)

#### Czech Republic

Ministry of Industry and Trade: [www.mpo.cz](http://www.mpo.cz)  
Czech Trade Inspection: [www.coi.cz](http://www.coi.cz)  
State Health Institute: [www.szu.cz](http://www.szu.cz)  
Consumers Defence Association – SOS: [www.consumers.cz](http://www.consumers.cz)

#### Denmark

Informationscenter for miljø og sundhed:  
[www.miljoeogsundhed.dk/default.aspx?node=281](http://www.miljoeogsundhed.dk/default.aspx?node=281)  
The Danish Consumer Council: [www.forbrugerradet.dk/english/](http://www.forbrugerradet.dk/english/)

#### Estonia

Consumer Protection Board: [www.tka.riik.ee](http://www.tka.riik.ee)

#### Finland

Finnish Consumer Agency: [www.kuluttajavirasto.fi/en-GB/](http://www.kuluttajavirasto.fi/en-GB/)

#### France

[www.minefi.gouv.fr/DGCCRF](http://www.minefi.gouv.fr/DGCCRF)

#### Germany

Federal Institute for Occupational Safety and Health (RAPEX contact point): [www.baua.de](http://www.baua.de)  
Federal Office of Consumer Protection and Food Safety (single contact point for cosmetics and daily commodities): [www.bvl.bund.de](http://www.bvl.bund.de)

#### Greece

[www.efpolis.gr](http://www.efpolis.gr)

### Hungary

Hungarian Authority for Consumer Protection: [www.nfh.hu](http://www.nfh.hu)  
Central database on unsafe and prohibited products: [www.piacfelugyelet.hu](http://www.piacfelugyelet.hu)

### Iceland

[www.neytendastofa.is](http://www.neytendastofa.is)

### Ireland

National Consumer Agency: [www.consumerconnect.ie](http://www.consumerconnect.ie) – e-mail: [ask@consumerconnect.ie](mailto:ask@consumerconnect.ie)  
Health and Safety Authority: [www.hsa.ie](http://www.hsa.ie)  
Irish Water Safety: [www.iws.ie](http://www.iws.ie)

### Italy

Ministero dello Sviluppo Economico, Direzione Generale Armonizzazione Mercate e Tutela dei Consumatori, Ufficio D4 Sicurezza prodotti: [www.sviluppoeconomico.gov.it](http://www.sviluppoeconomico.gov.it)

### Latvia

[www.ptac.gov.lv](http://www.ptac.gov.lv)

### Liechtenstein

Amt für Handel und Transport (Office of Trade and Transport): [www.aht.llv.li](http://www.aht.llv.li)

### Lithuania

State Non Food Products Inspectorate: [www.inspekcija.lt](http://www.inspekcija.lt)

### Luxembourg

[www.ilnas.lu](http://www.ilnas.lu)

### Malta

[www.msa.org.mt/marketsurveillance/index.html](http://www.msa.org.mt/marketsurveillance/index.html)

### Netherlands

Voedsel en Waren Autoriteit (Dutch Food and Consumer Product Safety Authority):  
[www.vwa.nl](http://www.vwa.nl) – e-mail: [meldkamer@vwa.nl](mailto:meldkamer@vwa.nl)

### Norway

Directorate for Civil Protection and Emergency Planning: [www.dsb.no](http://www.dsb.no)  
Norwegian Pollution Control Authority: [www.sft.no](http://www.sft.no)  
Norwegian Food Safety Authority: [www.mattilsynet.no](http://www.mattilsynet.no)

### Poland

[www.uokik.gov.pl](http://www.uokik.gov.pl)

### Portugal

[www.consumidor.pt](http://www.consumidor.pt)

### Romania

National Authority for Consumer Protection: [www.anpcnet.ro](http://www.anpcnet.ro)

### Slovakia

Ministry of Economy of the Slovak Republic: [www.economy.gov.sk](http://www.economy.gov.sk)  
Slovak Trade Inspection: [www.soi.sk](http://www.soi.sk)  
Public Health Institute of the Slovak Republic: [www.uvzsr.sk](http://www.uvzsr.sk)

### Slovenia

Market Inspectorate of the Republic of Slovenia: [www.ti.gov.si/en/](http://www.ti.gov.si/en/)

Health Inspectorate of the Republic of Slovenia: [www.mz.gov.si/en/](http://www.mz.gov.si/en/)

National Chemicals Bureau of the Republic of Slovenia: [www.uk.gov.si](http://www.uk.gov.si)

### Spain

Instituto Nacional del Consumo: [www.consumo-inc.es/Seguridad/home.htm](http://www.consumo-inc.es/Seguridad/home.htm)

### Sweden

Swedish Consumer Agency: [www.konsumentverket.se](http://www.konsumentverket.se)

### United Kingdom

[www.berr.gov.uk](http://www.berr.gov.uk)



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## THE COMMISSION'S RAPEX TEAM

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European Commission

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