Product Safety in the European Union¹

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Abstract

In the field of product safety, common Community rules are designed, part of which is also a rapid exchange of information on consumer products that threaten health and safety of consumers — RAPEX. This thesis explains working of RAPEX and analyzes the data of the annual reports of 2008 and 2009. The next part of thesis describes The Rapid Alert System for Food and Feed that is actually one of the most important tools in ensuring food and feed safety. Its main purpose is to inform members of the system if there are products dangerous for human health on the market, to ensure a rapid action.

Key words

RAPEX, RASFF, food, feed, safety product safety, national market surveillance authority, national contact point.

JEL Classification: L15

Introduction

The European Union's consumer protection policy is based on the principle that quality of products is creating on the market intra the supply and demand. In term of state surveillance are crucial protection of life and health of consumers and the resultant requirement for such product safety that the consumer does not pose any risk. Although the product safety is a fundamental requirement that products have to comply with, it is necessary to remember the cases and situations where products do not meet this requirement, but for consumers pose a serious risk to their life and health. Such situations should be remembered, especially with regard to the principle of free movement of goods in large European market. Therefore it was built in the European Union system for the rapid exchange of information - RAPEX on non-food dangerous products, which may occur on the European Union market.

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Over thirty years of its existence, the Rapid Alert System for Food and Feed (RASFF) has become one of the biggest achievements in the integrated EU approach to the food safety. Its core is the transmission of special notifications if there has a serious danger of hazardous products occurred - either products placed on the market, or "just" entering the country. After sending a notification the country concerned can take proper steps to ensure that there will be no harm on human health done.

The aim of this thesis is firstly to present a rapid alert system for non-food consumer products, to clarify its way of working and characterize its objectives and tasks, secondly to clarify the nature of the RASFF operations and to present and explain the system statistics in the European Union but also in the Slovak Republic in 2008. The next chapter discusses the current situation of dangerous non-food products and analyses data from reports of those products by the individual criteria for the years 2008 and 2009. The thesis points out product categories, which appear in the reports more often.

1 The RAPEX system in European Union

The issue of consumer safety was incorporated into "EU Consumer Policy Strategy 2002-2006" in the European Union. It demanded the establishment of common rules of Community measures for the effective implementation of the consumers' general safety. An important part of these rules is to exchange information on consumer products if they are threatened by health and safety of consumers. For this purpose, the European Commission established the system called *RAPEX - Rapid Alert System for non-food consumer products* that operates since 2003 by *Directorate General for Health and Consumer Affairs* (DG SANCO).

The RAPEX is the European system for fast and effective informing consumers about dangerous non-food products and weekly updated database of communications that originate from producers or distributors, who found dangerous products on the market, and announce that fact voluntarily to the competent national authority or it is a case of dangerous products identified by the national market surveillance authorities. The *dangerous product* means a product that constitutes a danger to the consumer under normal or reasonably foreseeable conditions of use or maintenance. The *non-food consumer products* are defined according to RAPEX annual report as products, which are intended for consumers, and products, which even if not intended for consumers, are accessible to them.

RAPEX system is the ground for developing and adopting measures to protect the market. It serves to ensure the rapid exchange of notifications on the incidence of unsafe consumer products among the European Commission, twenty-seven European Union member states and three countries of the European Economic Area (Iceland, Liechtenstein and Norway) in order to protect the health and safety of consumers. Member States shall inform each other of measures taken to prevent the occurrence of dangerous products on the market of European Union. The RAPEX reports all dangerous consumer products, excluding food and feed, which monitors by the Rapid Alert System for Food and Feed (RASFF) and medicines, medical devices, medical

equipment and devices, that are covered by other systems. Another task of RAPEX is monitoring the function effectiveness of market surveillance in individual countries.

The legislative basis of the RAPEX system at community level is *The Directive on* general product safety 2001/95/EC (GPSD). The GPSD is covering the improved traceability of products, functioning of market surveillance, standardisation work and Community prohibition measures. According to GPSD manufacturers and distributors of non-food products have to notify immediately the competent national authorities that have launched a product that is dangerous for customers. The objective set of procedures to facilitate compliance with this requirement and provide rapid and clear information for effective consumer protection. The GPSD determines that producers and distributors put on the market only safe products, and requiring them to take all necessary precautionary measures to protect the consumer. To these measures appertain also the obligation of producers and distributors to notify to the appropriate national authority, which is set up in each of the member states, that their product available on the market could be dangerous for consumers. If the manufacturer or distributor finds that its product is dangerous, it must inform the responsible authorities by means of established notification procedures. Depending on the nature of the hazard or risk of consumers, these authorities may require accomplishment of the additional steps, for example tracing the products on the market, prohibiting further distribution, public information or product recall. Products notified through the RAPEX system shall constitute a serious risk to health and safety of consumers. A definition of serious risk is in the GPSD and it is one, which requires rapid intervention by public authorities and includes risks whose effects are not immediate. The National authorities have a duty to assess risks posed by a product that is intended to notify. They do this using the method of risk assessment, which is in the RAPEX Guidelines. Only those products that pose a serious risk must be notified through RAPEX system.

Exchange of information in the RAPEX system through notifications is defined in Articles 11 and 12 of GPSD. The Article 12 defines RAPEX notifications as communication on measures ordered by national authorities, or actions taken 'voluntarily' by manufacturers or distributors in relation to products that pose a serious risk. The Article 11 defines other notification as Communication of the measures ordered by national authorities in respect of products, which present a moderate risk. The RAPEX system provides also notifications 'for information', that are notifications of the measures ordered by national authorities, or actions taken 'voluntarily' by manufacturers or distributors in relation of dangerous goods distributed for informational purposes only due to lack of product identification. The most common measures are sales bans, withdrawals of dangerous products from the market and recalls of dangerous products from consumers.

The Commission introduced also the RAPEX Guidelines that clarify Member State authorities' obligations to notify dangerous products to the Commission. These guidelines palliate consistent application of GPSD, especially the notification procedure and improve the functioning of RAPEX system. The safety of certain non-food consumer products that may be dangerous for consumers are regulated separately in the following sectoral directives: Toys Directive 88/378/EEC, Low Voltage Directive 2006/95/EC, Machinery Directive 98/37/EC, Cosmetics Directive 76/768/EEC, Motor Vehicles Directive 70/156/EEC and Personal Protective Equipment Directive 89/686/EEC. The following products are excluded from RAPEX because they are covered by equivalent notifi-

cation mechanisms established by Community legislation pharmaceuticals covered by Directives 75/319/EEC and 81/851/EEC; active implantable medical devices covered by Directive 90/385/EEC, medical devices covered by Directive 93/42/EEC, and in vitro diagnostic medical devices covered by Directive 98/79/EC; food and feed covered by Regulation (EC) No 178/2002.⁵

The system aims to prevent the distribution of supply and sale of unsafe products. The main subjects in this system are producers, distributors and especially national authorities or central contact points in each Member States. The role of these subjects is very considerable.

The Member States have designated competent authorities of surveillance and supported them with the necessary powers to take measures to prevent or restrict the marketing or use of dangerous products. The national authorities are competent to take samples of products, tested them in laboratories, and ask the producers and distributors to stop selling the products, withdraw them from the market or recall them from consumers if these products pose risks to consumers.

Each country that participates in the RAPEX system has also created a national RAPEX contact point. The aim of the contact point is to coordinate the operation of the RAPEX system at the national level and submit to the European Commission information about products that pose a serious risk to the health and safety of consumers. The national RAPEX contact point use in that activities a standard notification form, which contains information about dangerous product, its identification, the risks posed by the product, the measures to prevent these risks and information about distribution channels of the notified product. The national RAPEX Contact Point inform the European Commission through the RAPEX system about the preventive or restrictive measures, that are taken by national authorities or 'voluntarily' from the producer or distributor in relation to a dangerous product.

The European Commission analyzes, verifies and distributes the information obtained from the RAPEX system. If the examination conducted by the Commission leads to validation, the information is distributed to the national RAPEX Contact Points in all participating countries. The national RAPEX Contact Point in other Member State forwards information from the European Commission to the competent authorities and from the national authorities to the European Commission. Then a competent authority in this Member State verify if notified products are found on the national market, gather information about the products and provides the results of market surveillance activities to the RAPEX Contact Points. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the European Commission through the RAPEX system and this feedback is called "reactions". 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.

An important part of the system forms producers and distributors that are in a prime position to assess whether products they place on the market are dangerous. A

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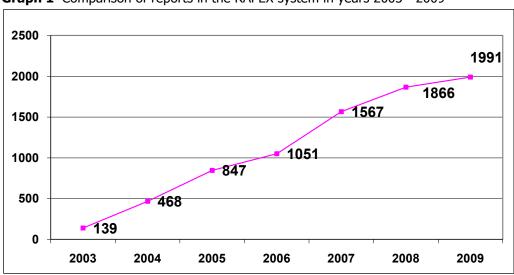
Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC. Retrieved February 18, 2010 from http://www.epha.org/IMG/pdf/Commission_Guidelines_on_RAPEX.pdf

significant thing is that they have the information about the product and have contact with consumers. If they find out, that product poses the risk for the consumers; they have to inform the competent authority and the RAPEX contact point in their country immediately. The producers and distributors have to inform the national authorities about any measures taken to prevent further risks to consumers as soon as possible. The information is transmitted to the European Commission through the RAPEX Contact Point via the RAPEX system and then to others countries participating in the system.

The RAPEX system established by the GPSD supplementing the existing regulatory framework that applies to some key consumer products such as toys, cosmetics, clothing, electrical appliances and lighting equipment, personal protective equipment and vehicles through a special scheme for the rapid exchange of alerts and warnings. The success of the RAPEX system reckon on the transparency and good communication. The effective cooperation between the European Commission, the national RAPEX Contact Points and national market surveillance authorities is very important for good RAPEX system functioning.

2 The RAPEX system report

Most of the RAPEX contact points are special ministries or commissions that have the competence to adopt binding measures, legislative guide and also have control mechanisms. The RAPEX system improves and the Member States approached effective to its implementation from year to year. The system will gradually join the countries Bulgaria, Romania (2005) and even China (through the system AQSIQ), Turkey and USA.



Graph 1 Comparison of reports in the RAPEX system in years 2003 - 2009

Every Friday, the European Commission publishes a weekly overview of dangerous products published by national authorities. This weekly overview reports any information about the product, potential dangers and measures that were taken by the notifying country. The report contains a description of the product, the photograph, the country where the product was identified as a dangerous country of origin, product category, producer, impending danger and the measures taken. Every week is reported by an average of 50 products in the European Union countries.⁶

The total number of reports distributed through the RAPEX system has steadily increased since 2004. After five years the number of reports has quadrupled from 468 (in 2004) to 1 991 (in 2009), as it is shown on Graph 1. In 2009, increased the number of notifications compared to 2008 by more than 6%. Increase of the RAPEX notifications can be attributed to more effective product safety enforcement by national authorities, greater awareness amongst businesses of their obligations, enhanced cooperation with third countries and actions aimed at building networks between Member States, coordinated by the European Commission.⁷

European standards for product safety will increasingly improve, as demonstrate the disappearance of a record number of dangerous products from shop shelves in the European Union states. The number of dangerous products withdrawn from the European Union market in 2009 has increased, which means that the RAPEX system works better, its capacity is increasing and the market is becoming less of dangerous goods, especially toys. Member States are much more active and control is focused right direction.

2.1 Reports by country, by risk category and country of origin

Five Member States issued in 2009, more than 40% of all RAPEX notifications on products that mean a serious risk to consumer health and safety:

Spain: 219 reports (11%) Germany: 189 reports (11%) Greece: 159 reports (8%) Bulgaria: 122 reports (6%) Hungary: 119 reports (6%)

Compared to 2008, the percentage of first-fives in the total number of notifications decreased by 10%, which indicates that other countries are increasingly involved in the tracking system of dangerous products. Slovakia experienced a decline in notifications from 114 in 2008 to 84 in 2009. This decrease could be due to more effective control, but also lower imports from China.8

⁶ RAPEX – Latest notification. Retrieved November 29, 2009, from http://ec.europa.eu/consumers/dyna/ rapex/rapex_archives_en.cfm>

⁷ Consumers: The RAPEX annual report of 2008, the number of unsafe products is increasing. Retrieved November 29, 2009, from http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/594&format= HTML&aged=0&language=SK&guiLanguage=en

⁸ RAPEX statistics (1 January – 31 October 2009). 1-8. Retrieved November 29, 2009, from http://ec.europa.eu/ consumers/safety/rapex/docs/stats 01-10 2009.pdf RAPEX statistics (November 2009). 1-8. Retrieved February 29, 2010, from http://ec.europa.eu/consumers/ safety/rapex/docs/stats_11_2009.pdf

Notifications certified during 2009 include 26 product categories. Five most notified product categories generated 62% of all notifications:

Toys: 471 reports (24%)

• Clothing, textiles and apparel: 395 reports (20%)

Motor vehicles: 140 reports (7%)

• Electrical Appliances: 137 reports (7%)

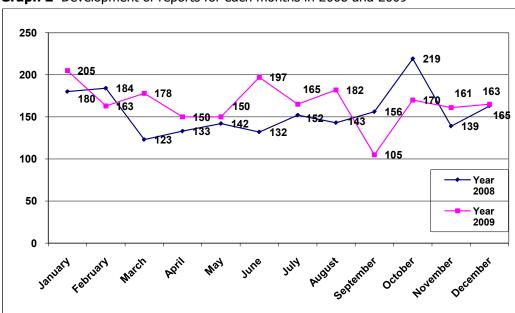
Cosmetics: 81 reports (4%)

The notifications tested in 2009, covers 14 different types of risks. The next five most frequently reported risk category comprised 78% of all notifications:

Chemical: 492 reports (25%)Injuries: 405 reports (20%)Choking: 261 reports (13%)

Electric shocks: 213 reports (11%)Strangulation: 183 reports (9%)

Even last year's report showed an increase, and also claimed that the safety standards of goods in the European Union are improving. The executive explained that the total number of warnings has increased since "the capacity of the RAPEX system to increase due to training programs among the competent authorities of the Commission and Member States". In 2009, increased its activities in 23 countries in the RAPEX system, which is twice the previous period. As it is shown on the Graph 2, number of reports in 2009 year culminated around 150 per month.



Graph 2 Development of reports for each months in 2008 and 2009

RAPEX statistics (December 2009). 1-8. Retrieved March 22, 2010, from http://ec.europa.eu/consumers/safety/rapex/docs/stats_12_2009.pdf

Risk categories and products in 2009 are more - or less the same as it was for the same period in 2008. The five main risk categories in 2008 were injuries, chemical dangers, suffocation, electrical shock and fire. Categories choking hazard, electric shock and fire, are less frequently reported in 2009. On the other hand, the chemical hazard risk category increased number of notifications from 275 in 2008 to 492 notifications in 2009, what is an increase from 18% to 25% of all notifications. Also, the risk category of choking registered increase in reports from 27 notifications in 2008 to 261 notifications in the period in 2009, what is increase from 2% to 13%. This is due to the increase of dangerous products from the category of clothes, textiles and fashion accessories.

More than half of the dangerous products notified in 2009 came from China, including Hong Kong (1 012 notifications, 51%). Compared to 2008, this is an increase of 10% but from the total number of products it announced a decrease of 8%. The Member States or EFTA / EEA countries had 336 notifications (17%) in total. The group of 21 Member States was listed as the country of origin of the notified products. From all the reports were 124 notifications (6%), which did not include information on the origin of the product. If we compare the same reference period of last year, the number of notifications for products that originate from third countries is growing. The notifications from third countries grew up from 10% to 13%, what reflects the fact that a number of reports where the country of origin is not known has been declining. The proportion of notified products that originate from Member States, EEA / EFTA decreased from 21% to 17%. 9 These relatively high figures indicate that the control authorities of the Member States should focus its activities not only to products that originate from third countries, but also closely monitor the safety of consumer products in the European Union. It also appears that further attention should be paid to the education of European producers and distributors in branch of safety requirements related to consumer products.

3 Rapid Alert System for Food and Feed (RASFF)

The **Rapid Alert System for Food and Feed** (also known as "RAPID" respectively as "RASFF") allows rapid and efficient exchange of information between Member States and the European Commission if there are food or feed safety risks to human health identified. The RASFF system has been designed for *rapid exchange of information relating to actions that its members take to ensure food and feed safety.* The legal basis of the RASFF is the European regulation **ES/178/20-02 RASFF** laying down general principles and requirements of food law, establishing the European Communities Food Safety Authority and laying down procedures relating to food safety.

The RASFF **members** are all the European Union member states (including the Slovak Republic), the European Commission itself and the Organization of the EFSA (European Food Safety Authority), together with Norway, Liechtenstein and Iceland.

The members of RASFF achieve the rapid exchange of information through sending special notifications. The system differentiates between **market notifications** and

⁹ RAPEX statistics (1 January – 31 October 2009). 1-8. Retrieved November 29, 2009, from http://ec.europa.eu/consumers/safety/rapex/docs/stats_01-10_2009.pdf

border rejections. Their use depends on the fact *where* a dangerous product has been identified. *Market notifications* are about products found on the Community territory (the territory of European Union) for which a health risk was reported. Products that are subject of a *border rejection* never entered the Community and were sent back to the country of origin, destroyed or give another destination.

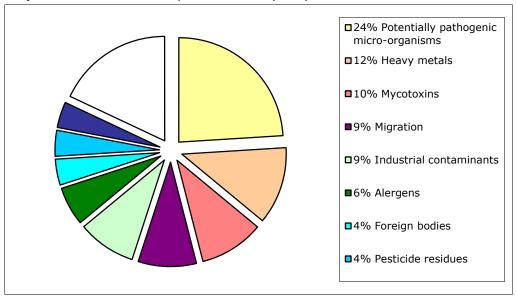
Market notifications then - depending on the intensity of risk identified pro-ducts pose to human health - divide into *information* and *alert notifications*. Alert notifications shall be sent for identification of more dangerous products as in the case of information notifications.

In 2008 there have been - totally - 528 alert notifications recorded (which means a 45% decline compared with the previous year 2007, when 952 RASFF notifications have been reported). On the other hand, there have been an increase of information notifications and border rejections - in 2007 there were 761 information notifications recorded, a year later, there were 1138 notifications. Number of border rejections has increased from 1211 in 2007 to 1377 in 2008.

This information shows us an increase in total number of notifications - despite the fact that the number of alert notifications declined. The highest decrease (in the number of alert notifications) has been in the product category *fish, crustaceans and mollusks* (and within this category particularly *fish*, with an decrease of more than 127%).

According to the number of alert notifications by **identified risk**, the RASFF system recorded up to 24% of *potentially pathogenic microorganisms*, 12% of *heavy metals* and 10% of *mycotoxins*. *Industrial contaminants* and *migration* recorded 9% of alert notifications. Amongst the border rejections, however, mycotoxins represent 56% within the total number of notifications (i.e. the sum of alert, information notifications and border rejections) and far outweigh all other hazardous substances (there have been recorded 931 mycotoxins notifications, while the second most numerous risk group - potentially pathogenic microorganisms - recorded 452 notifications). The high number of mycotoxins notifications is primarily because of their content in *nuts*, *nut products and seeds* (699 notifications).

Graph 3 Alert notifications by identified risk (2008)



Amongst the alert notifications recorded by the RASFF system in 2008, the highest percentage belonged to the **product category** *fish*, *crustaceans and mollusks* (up to 20%). The second largest category, *meat and meat products*, recorded 13% of notifications. Product category *fruit and vegetables* recorded 9%, *cereals and bakery products* 8%, *nuts, nut pro-ducts and seeds* recorded 7% and *milk and dairy products* 5% of notifications. *Confectionery, honey and royal jelly* together with *dietetic foods and food supplements* and *herbs and spices* consistently recorded 4% of the total number of alert notifications.

Graph 4 Alert notifications by product category (2008)

| 20% Fish, crustaceans and molluscs | 13% Meat and meat products | 9% Fruit and vegetables | 8% Cereals and bakery products | 7% Nuts, nut products and seeds | 5% Milk and milk products | 4% Confectionery, honey and royal jelly a lekvár | 4% Dietetic foods and food supplements | 4% Herbs and spices | 26% Others

3.1 The RASFF system in the Slovak Republic

The Slovak republic is a member of the RASFF system, the institution res-ponsible for this system in SR is the State Veterinary and Food Administration. This institution offers information about all kinds of RASFF notifications on its web page www.svssr.sk.

The trends of decrease of alert notifications and increase of information notifications and border rejections, recorded in the 2007/ 2008 interannual comparison (Slovak republic re-corded a decrease of alert notifications from 51 to 17, which means a decrease by 200%; in-formation notifications recorded an interannual increase from 4 in 2007 to 25 in 2008) did not continue in the next – **2008/2009 comparison**. Quite the contrary – for alert notifications the-re was an interannual increase recorded (from 17 to 21) and for information notifications there was a decrease from 26 in 2008 to 14 in 2009.

Table 1	ormati	on and alert no	Juncau	ons companso	11 (200	10/2003)	
Information notifications				Alert notifications			
2008		2009		2008		2009	
Food of vegetable origin	15	Food of vegetable origin	8	Food of vegetable origin	11	Food of vegetable origin	15
Food of animal origin	8	Food of animal origin	3	Food of animal origin	3	Food of animal origin	4
Migration	3	Migration	3	Migration	3	Migration	2
OVERALL	26	OVERALL	14	OVERALL	17	OVERALL	21

Table 1 Information and alert notifications comparison (2008/2009)

Conclusion

Although the increase of notifications has caused some incursion on the RAPEX system, it is a clear indicator of improved consumer protection at the European level. Increasing the number of reported actions taken directly by economic subjects to prevent risks that entail consumer products, also suggests that responsible business firms take product safety seriously and fulfil its obligations imposed by the GPSD. A significant increase in the number of notifications in RAPEX system during previous years is a clear sign that the market surveillance under the GPSD has been successful. Nevertheless, in the increasingly globalized market with more products coming into the European Union from third countries, is a need for further coordination of activities in the field of surveillance between Member States, including cooperation with customs authorities. In that coordination could help the implementation of common agreed best practices, increased exchange of information between Member States through existing

IT tools and the greater role of the European Commission in establishing common priorities for the market surveillance.

It is interesting to observe the situation in each country. The number of notifications by the Member State cannot be directly linked to the level of product safety in its market. There are many reasons why some Member States may have more notifications than others: a very effective mechanism of control, large market, and large amounts of imports. In general, European countries which have major markets, many imported products, and have the highest number of inspectors will find more dangerous products and thereby have more notification via the RAPEX system, like smaller countries. ¹⁰

All European Union countries contribute to the RAPEX system by detection and reporting of new dangerous products and by ensuring appropriate corrective action based on received information. More than 20 of them stepped up its activity in the system in 2009 and compared with the previous period reported more dangerous products. The highest number of notifications has been in 2009 from Spain, Germany, Greece, Bulgaria and Hungary. Slovakia has moved from third to ninth position. Notifications sent by these countries represent 40% of all notifications on products posing a serious risk sent through this system.

The Rapid Alert System for Food and Feed has been designed for rapid exchange of information relating to actions that its members take to ensure food and feed safety. The RASFF members are all the European Union member states together with Norway, Liechtenstein, Iceland, the European Commission itself and the Organization of the EFSA. The members of RASFF achieve the rapid exchange of information through sending special notifications (alert and information notification, or border rejection). In 2008 there have been 528 alert notifications recorded, which means a 45% decline compared with the year 2007. On the other hand, there was an increase of information notifications and border rejections - from 761 to 1138 among information notifications and from 1211 to 1377 among border rejections.

These trends have been captured also in the Slovak republic, but did not continue in the next interannual comparison (2008/2009). Quite the contrary, for alert notifications there was an increase recorded (from 17 to 21) and for information notifications there has been a decrease from 26 in 2008 to 14 notifications in 2009.

The general product safety is extremely broad issue and extends to the activities of various ministries and national authorities and requires close cooperation not only at national but also at Community level. At Community level is currently developing a new information system *GRAS - Generic Rapid Alert System*. The implementation of the GRAS is one of the most important ongoing projects of product safety that ensure more effective function of the alert system on the European markets.

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¹⁰ Questions and answers on the Community rapid alert system for non-food dangerous consumer products (RAPEX), Brusel. Retrieved November 29, 2009 from http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/167&format=HTML&aged=0&langua

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