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RAPID ALERT SYSTEM FOR FOOD PRODUCTS IN THE EUROPEAN UNION AND ITS POSSIBLE EXTENSION TO OTHER COUNTRIES IN THE REGION.

The development of harmonised regional strategies
for food safety and the implementation
of food security communication networks.

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Overview

This paper introduces the European Community's Rapid Alert System. It explains the legal basis of the system, the detailed procedures of its application and how the system works. Proposed improvements to the System are discussed, as are the underlying principles for such a communication network. The paper concludes by highlighting further opportunities for agreements with other similar systems, including those developed by third countries or other organizations, and the creation of a network to cover the entire European region.

1. Introduction

The globalisation of trade in foodstuffs is a phenomenon destined to accelerate as tariff and non-tariff barriers are removed. It is particularly marked in the European Community where the creation of a common market and then of a single market have allowed food supplies to circulate freely throughout the fifteen Member States and be purchased by more than three hundred million consumers. The abolition of health controls across the Community's internal borders has given rise to a need for new instruments to deal with situations where dangerous products could circulate without any controls. The creation of a rapid alert system is one of these instruments.

The Member States felt the need from a very early stage to exchange information regarding the safety of food products placed on the market. For the single market to run smoothly national health authorities must have confidence in their counterparts' control of the situation in other

¹The opinions expressed by the authors do not necessarily reflect the position of the European Commission.

Member States and in the transparency of the system. One of the conditions on which the proper functioning of the market depends is the speed with which information about risks relating to consumer products (that may be placed on the market) is made known and the accuracy of such information.

2. Description of the European Union's Rapid Alert System

2.1 The legal basis

The European Community has had a rapid alert system since 1978. It was first established by a Council decision as a general short-term warning system to deal with immediate and serious threats to the health and safety of consumers. This decision was replaced in 1989 by another Council decision to set up a Community system for the rapid exchange of information on dangers arising from the use of consumer products. This decision was in turn replaced by a specific provision in Council Directive 92/59/EEC of 29 June 1992, regarding the general safety of products. Article 8 of this Directive currently provides the legal basis for the European Community's rapid alert system for both the food sector and other consumer products. Although destined to be modified in the near future it is nevertheless worth briefly mentioning the principles that have underpinned the Community system for many years.

The Member States have a duty to provide information in the case of a serious and immediate risk to the health of consumers. Such information should be provided as a matter of urgency. It is applicable to all consumer products, food and non-food, insofar as these products are not already covered by specific equivalent provisions in other Community acts.

Strictly speaking Member States are obliged to inform the Commission only in cases where the dangerous product could be sold outside the territory of the Member State that has identified the specific risk. But in practice, as the single market becomes ever more integrated it is becoming increasingly difficult to be sure that a product will not go beyond the borders of a given Member State and therefore it is better to notify in any case.

The Directive also sets down the Commission's responsibilities: first, to ascertain that the information falls within the scope of the Directive and second, to forward the information to all the other Member States.

There are currently two liaison networks: the food products network and the non-food products network. The list of contact points and officials responsible for these two networks, complete with addresses, telephone and fax numbers, is confidential and may only be given to members of the network. The list enables members to keep in touch with the Commission and Member States so that minor points can be clarified quickly and easily. When new information of general interest is provided through such inter-Community contacts, the Member State that initiated the bilateral contact informs the Commission. Only information received or confirmed through contact points in the Member States can be considered as having been received through the rapid exchange of information procedure.

The food sector network has progressively developed harmonised procedures and criteria based on consensus among the Member States. From a practical point of view, the system has

constantly evolved to integrate, as far as possible, all that current computer and information technology has to offer.

2.2 Detailed procedures for the application of the Community system for the rapid exchange of information.

- 2.2.1 This system has been essentially designed so that information can be exchanged rapidly in the event of a serious and immediate risk to the health and safety of consumers. It is impossible to lay down specific criteria as to what precisely constitutes an immediate and serious risk; in this regard, the national authorities will therefore judge each individual case on its merits. As soon as a serious and immediate risk is detected, the national authority shall consult, insofar as possible and appropriate, the producer or distributor of the product concerned. Their point of view and the details they supply may be useful both to the administrations of the Member States and to the Commission in determining what action should be taken to ensure that the consumer is protected with the minimum of commercial disruption. To this end, the Member States should endeavour to obtain as much information as possible on the products and the nature of the danger, without compromising the need for rapidity.
- 2.2.2 As soon as a Member State has detected a serious and immediate risk, the effects of which extend or could extend beyond its territory, and measures have been taken or decided on, it shall immediately inform the Commission. All available details will be given, in particular on:
- a) information to identify the product;
 - b) the danger involved, including the results of any tests/analysis which are relevant to assessing the level of risk;
 - c) the nature of the measures taken or decided on;
 - d) information on the supply chains where such information is available.
- 2.2.3 If the Member State considers certain information to be confidential, it should specify this and justify its request for confidentiality, bearing in mind that the need to take effective measures to protect consumers normally outweighs considerations of confidentiality. It should also be remembered that precautions are taken in all cases, both by the Commission and by the members of the network in the various Member States, to avoid any unnecessary disclosure of information likely to harm the brand image of a product or series of products.
- 2.2.4 The Commission shall verify that the information received complies with the notification criteria, contact the notifying country, if necessary, and forward the information immediately by electronic mail to the relevant authorities in the other Member States with a copy to each permanent representation; these authorities may also be contacted by telephone at the time of sending the e-mail. The Commission may also contact the Member State presumed to be the country of origin of the product to carry out the necessary verifications.

- 2.2.5 At the same time, when it considers it necessary and in order to supplement the information received, the Commission can in exceptional circumstances institute an investigation of its own and/or convene the appropriate Committee. In the case of such an investigation being undertaken the Member States shall supply the Commission with the requested information to the best of their ability.
- 2.2.6 The other Member States are requested, wherever possible, to inform the Commission without delay of the following:
- a) whether the product has been marketed in its territory;
 - b) supplementary information it has obtained on the danger involved, including the results of any tests/analyses carried out to assess the level of risk; and in any case they must inform the Commission as soon as possible of the following:
 - c) measures taken or decided on;
 - d) when the product mentioned in this information has been found within their territory, but no measures have been taken or decided on, and the reasons why no measures are to be taken.
- 2.2.7 When a Member State intends, apart from any specific measures taken because of serious and immediate risks, to modify its legislation by adopting technical specifications, the latter must be made known to the Commission at the draft stage, in accordance with Directive 98/34/EC², referring if necessary to emergency measures.

2.3 How the system works

The rapid alert system covers the fifteen Member States and the countries of the European Economic Area (Norway, Liechtenstein and Iceland). It does not cover other countries.

Each Member State and associated country must establish an official food-product contact point to liaise with the Commission contact point in the rapid alert network.

From a practical point of view, the system has, over time, developed three levels of information to be exchanged between the Member States and the Commission: warning notifications, information notifications and news.

2.3.1. Warning notifications

These notifications warn about risk factors for products that have already been placed on the market in more than one Member State and require immediate action to find and withdraw them from the market. The warnings are sent out by the official contact points of the Member States and associated countries when a problem has been detected and measures have been or are going to be taken. Sometimes, however, the media is faster and the Commission is informed by the press before the notification is sent out via the rapid alert network. In this case the Commission immediately contacts the country that is the source of the information to seek confirmation or further information about the problems.

² Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

2.3.2 Information notifications

The activities of the rapid alert system have steadily been extended, on a voluntary basis, to situations that may not require immediate action (because the product at fault has not been put on the market), but where the information is useful to the other participants in the network. The results of the safety monitoring carried out on imported food products at point of entry to the Community (or the European Economic Area) is one such case. Since non-compliant products could be a risk they are not allowed into the Community and will not therefore be put on the market. Nevertheless it is useful to disseminate such information so that the other Member States and associated countries can make sure these products do not turn up at the border checkpoints of another Member State and that future shipments are subjected to the appropriate checks. The Commission therefore circulates this information for the same reason as the warnings.

2.3.3 News

Other useful information about health and safety problems in respect of foodstuffs, which the Commission has not been informed of by a Member State or associated country in a warning or information notification, but which it thinks may be of interest to the monitoring authorities, is sent out on the network as "News". An example of this is information from the monitoring systems of third countries about products that tend to be found on international markets. Information from the Canadian Food Inspection Agency, the US Food and Drug Administration (FDA), the Australia and New Zealand Food Agency (ANZFA) and others have in the past helped to identify food products on the European market that have already been subjected to controlling measures in these countries.

Owing to the as yet incomplete Community harmonisation of standards for contaminants and microbiological criteria, warning and information notifications are often based on levels in excess of national standards and criteria. In all cases the Commission's services assess the information received and decide which category they come under for dissemination by the rapid alert system.

2.4 Communication with third countries

There is no provision for the participation of third countries in the rapid alert network established by Directive 92/59/EEC: with the exception of the European Economic Area, such participation is beyond the scope of this Directive. Nevertheless, although there is no legally binding basis, the Commission informs the appropriate authorities of third countries through diplomatic channels in two circumstances:

- When investigations into the marketing of a food product that has been the subject of a warning notification reveal that the product has been exported to a third country, the authorities of the third country are informed of this.
- When an information or warning notification concerns a food product imported from a third country, the authorities of the third country are informed of the notification, if possible by sending them a copy of the health certificate required for importing this food

product, so that they can take the necessary steps to correct and avoid repetition of the problem.

3. Proposed improvements to the European Community's Rapid Alert System for food products

The system established by Directive 92/59/EEC has been functioning for ten years, in the course of which the problems that have surfaced have been compensated for by a flexible approach, on a voluntary basis, there being general consensus between the Commission and the Member States.

The Commission has made a proposal for a regulation of the European Parliament and Council establishing the general principles and prescriptions of food legislation, setting up the European Food Authority and laying down the procedures regarding the safety of foodstuffs. This proposal contains provisions aimed at establishing a new rapid alert system, as a network, to give notification of direct or indirect risks to human health deriving from foodstuffs or animal feed.

The scope of the proposal is to extend the rapid alert system to all food products destined for human and animal consumption, and to encompass all direct and indirect risks whether the effects are immediate or not. It is also to be extended to cases when, for reasons of consumer safety, a foodstuff or animal feed is refused entry by the competent authorities at European Union border checkpoints.

The network will link up the Member States, the Commission and the new European Food Authority. When a member of the network has information regarding a serious direct or indirect risk to human health associated with a foodstuff or animal feed, the information should be forwarded immediately to the Commission via the rapid alert network. The Commission will therefore remain the central hub of the system. The Authority may then complete the notification with any scientific or technical information to facilitate rapid and appropriate risk management.

In the case of a batch being rejected by the competent authorities at border checkpoints, the Commission will immediately have to inform all the contact points in the network, all the border checkpoints in the European Union as well as the competent authorities of the country of origin. Likewise, when investigations reveal that foodstuffs or animal feed that have been the subject of a rapid alert may have been exported to a third country, the Commission will have to provide the authorities of this third country with all the necessary information.

Finally, participation in the rapid alert system could be extended to third countries or international organisations through agreements between the Community and these countries or organisations, and in ways that would have to be defined in the agreements.

4. The underlying principles of a European food safety communication network

The European Community has gained much experience in operating a food risk information network for its fifteen Member States. The system only works correctly if the work of centralising the information, analysing it and redistributing it to all the participants in the network is orchestrated by a single body. In the European Community, the Commission plays this role. If such a network were to be established for the whole of Europe, a similar body would have to be identified to play this role.

Moreover, the Codex Alimentarius has adopted directives concerning the exchange of information in food control emergency situations (CAC/GL 19-1995), and the exchange of information between countries regarding refusal to allow foodstuffs to be imported (CAC/GL 25-1997). These directives provide the basis for structured exchanges of information between an importing country and an exporting one. They are also relevant to, and must be taken into account in, the setting up of information exchange systems in networks linking several countries, groups of countries and/or organisations.

If a rapid alert system is to be set up for the whole of Europe all the partners must reach agreement on the underlying principles of the system. These principles may be summarised as follows.

4.1 Reciprocity

Each country wishing to participate in the European rapid alert system must be in a position to offer its partners the same quality of information that it receives, which presupposes the setting up of systems for information gathering, analysing and tracing food products equivalent to those of the partners in the network.

4.2 Pro-activity

The system must be pro-active, not a passive information system that simply puts information on an Internet site. Each country wishing to participate must establish an official national contact point. The list of national contact points must be available to all the participants in the network with addresses, e-mails, telephone and fax numbers. Information regarding the risks and measures taken must be sent without delay to each contact point.

4.3 Precision

The information sent over the rapid alert network must be accurate and clearly defined. The food product in question must be described as accurately as possible including the quantities of product involved, the dimensions and type of packing, the manufacturer's batch number or the use-by date, trade names and any specific labelling such as trademarks and other identifying labels, the name and address of the producer, the manufacturer, and the seller or importer. Information about the marketing and distribution of the product in question is essential to trace the products as quickly as possible. Measures taken to reduce or eliminate the risks must also be described accurately, identifying the bodies that oversee their withdrawal from the market, the impounding of products and their eventual destruction.

4.4 Certainties

The nature of the identified risk must be clearly defined on the basis of objective observation. The precise nature and extent of the danger must be known with certainty and the information must identify the contaminating agent or toxin and, if possible, contamination levels and their possible effect on consumers. The results of laboratory tests are an important part of this information. Nevertheless, if there is a clear link between the consumption of a foodstuff and serious effects on consumer health, it should be made known without waiting for final confirmation, even if the agent responsible has not yet been expressly identified.

4.5 The All Clear

Withdrawal of a product from the market can have a serious economic impact on the sector. When the source of the risk has been eliminated and the dangerous product has been effectively removed from the market, an “all-clear” message should be put out over the network to inform all the contact points and allow the national authorities to relax their controls.

5. Conclusion

The European Community can draw on its long experience operating a rapid alert system for foodstuffs. This experience now enables it to propose to the Council and the European Parliament substantial improvements to the system, broadening its scope and clarifying its relations with third countries. This proposal also contains opportunities for agreements between the Community rapid alert system and other systems developed by third countries or organisations. Although the creation of a network to cover the entire European region is no mere Utopian idea, all the parties involved must agree on the fundamental principles governing the development and functioning of such a network.