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Food Risk Communication

1) INTRODUCTION AND SCOPE

The question I will be addressing in this paper is that of the tension and balance between the protection of public health by providing information to the public concerning a potential health risk, and the protection of the reputation of companies and products. In my view, this question concerns the regulation of access to and disclosure of information, but also goes beyond this matter to what I am calling here "risk communication", using this term in a personal manner. When using the term "risk communication" I am referring to the increasing activities of Authorities in communicating the existence of a risk to public health to other Authorities and to the general public, and how this communication can have an enormous impact on the market, spread very quickly and lead to situations close to panic.

This is particularly the case with general food alerts that *recommend* the withdrawal of a product from the market. The effect on related businesses can be very damaging, sometimes more serious that any typical sanction. In my experience economic losses caused by a food alert frequently surpass the amount of any fine known to me, by a minimum of ten times. In fact I could name several companies that went into bankruptcy as a result of a food alert on their product. Furthermore, regulation on disclosure of information does not always apply correctly to this kind of situation; sometimes there is not even one clear authority to be held responsible for the alert because the system is an international network. In the event of a general food alert including a recommendation for the withdrawal of a food product from the market, the crisis is unleashed no matter whether no particular brand or company name is communicated.[1]

In principle, sanctions are pre-established by Law, adopted after a procedure offering guarantees to the affected party and the presumption of innocence applies. Should authorities act with similar care when taking the decision to communicate a risk, a decision that may have a serious economic impact? Can we expect the respect of *due process* when adopting the decision to communicate a risk, at least in those cases where impact is likely to be considerable?

[1] As an example of this, in April 2008, a Food Alert was issued concerning Ukrainian sunflower oil, accusing the product of a high content of hydrocarbons, a substance whose limits were not regulated until two years afterwards, and only for products coming from Ukraine. At the time, EFSA declared that there was neither imminent nor serious risk to health. The alert made the headlines in all the Spanish media, due probably to the fact that it was announced in a press conference by the head of the Spanish Food Safety Authority (AESAN). They did not mention any brand or company, nor did they sanction any company, but losses were enormous for all companies involved in the trade of this product.

I consider four possible scenarios in which a health risk could be communicated, each of which could be the subject of different legal regulations and consequences.

i) Communication affecting a wide range or a category of food products. Food Alerts. This is the case when Authorities inform the public of the existence of a risk to health posed by a category of food products or a food product that is widely consumed and easily recognised by the public. This case usually adopts the form of a food alert, although there are many food alerts affecting only one specific food product or even one production lot of a food.

ii) A case of disclosure of data affecting a brand or a company. As opposed to the previous situation, this refers to the case in which data about a specific brand or company are disclosed. Sometimes, disclosure of a name can be made as the result of a sanction, but often disclosure happens at a preliminary stage or during the investigations.

iii) When the communication is issued by the Authorities. In this case it is the Authority which communicates the general risk or the name or brand considered to be putting public health at risk.

iv) When the communication is made by individuals, private organisations or companies. In this case it is a private person, company or association who alerts the public about a name or a brand or warns the public about a product. This is rather a question of national Law.

The intended purpose of this paper is to provide a brief analysis of the present legal framework applicable to these situations and decisions.

EUROPEAN UNION, Legal Framework

I) The right of consumers to be informed

II) The protection of the reputation of products and companies

III) Communication of Risks. Food Alerts: conditions and procedure.

IV) Legal Remedies

I) The right of consumers to be informed about health risks

The attainment of a high level of health protection must be ensured in the definition and implementation of Community activities and policies and the Community will contribute to the protection of the health of consumers, according to articles 152, 153, in relation to Article 3.1.p of the Treaty establishing the European Community.

On the other hand, Article 255 of the Treaty establishing the European Community regulates the right of citizens to obtain access to the documents of the European institutions, a right that must be balanced with other public or private interests. The specific regulation of this right will be determined by the Council, without prejudice to each institution's own rules of procedure.

Article 255 TEC.

1. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to European Parliament, Council and Commission documents, subject to the principles and the conditions to be defined in accordance with paragraphs 2 and 3.

2. General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the Council, acting in accordance with the procedure referred to in Article 251 within two years of the entry into force of the Treaty of Amsterdam.

3. Each institution referred to above shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents

Following this mandate of the Treaty, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 was adopted, governing public access to European Parliament, Council and Commission documents and establishing the right to access the documents of institutions, within the limits of Article 4 of the same Regulation. Among these limits is the protection of the commercial interest of natural and legal persons.

In the specific field of European Food Law, one of the aims of Regulation 178/2002 is to provide the basis for the assurance of a high level of protection of human health, as per Article 1 of this Regulation. This is also a general objective of Food Law, according to Article 5.1 of the Regulation.

The Principle of Transparency is established by Section 2 of Chapter II of Regulation 178/2002 and, more specifically, Article 10 of this Regulation grants the right of consumers to be informed of health risks. This right to information is not absolute but will depend on the nature, seriousness and extent of the specific health risk and the information provided to the consumer on that risk must be "appropriate", an expression that in my interpretation means proportional (as governed by the principle of proportionality).

Without prejudice to the applicable provisions of community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

Furthermore, one of the missions of the European Food Safety Authority is to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its competency, as per Article 23. j) of Regulation 178/2002.

In the field of Food Law, the right of consumers to be informed of health risks exists not only *vis à vis* the State but also *vis à vis* food and feed companies. Food and feed companies have the obligation to inform consumers and the authorities of the existence

of any health risks of which they are aware or have reasons to suspect, as per Articles 19 -for food operators- and 20 -for feed operators- of Regulation 178/2002.

The obligation of food and feed companies to inform the public and the authorities of the health risks they know of or have reason to suspect depends on the existence of one factual premise, namely, that the health risk is the result of the company's failure to comply with safety requirements. Compliance with this obligation to inform the public must respect the principle of proportionality, not only because this is a general principle of European Law, but also because the same articles 19 and 20 condition the recall of product to the non-existence of other measures sufficient to achieve a high level of health protection. Furthermore, the obligations defined in these articles are rather loosely defined, in my opinion, because the concept of compliance with safety requirements is itself not accurate if this compliance is not determined by clear legal requirements, which is not always the case.

In my view, and bearing in mind the possible economic consequences of the measures imposed upon food and feed business operators, the maximum possible determination of legal concepts conditioning these obligations (safety requirements, the circumstances in which one should have known of a risk, or measures sufficient to achieve a high level of health protection) is essential in order to comply with the minimum requirements of legal certainty. This is particularly important in the case of Food Law, where so many different food-legal cultures and authorities intervene. This is a recurrent problem in the application and interpretation of food law and has been from the beginning.

Finally, some scholars, such as Professor Bernd van der Meulen, consider that Article 2 and 8 of the European Convention on Human Rights, as interpreted by the European Court of Justice of Human Rights in the Guerra case and Öneryildiz case, implies the obligation of Authorities to inform consumers of any serious health risk -including risks posed by food- of which they may be aware[2].

II) The protection of the reputation of products and companies.

In addition to the right of consumers to be informed of any health risk, European Law also protects reputation and professional secrecy, as per Article 287 of Treaty establishing the European Community.

[2] Bernd van der Meulen, *Transparency & Diclosure*. EFFL 5/2007

The members of the institutions of the Community, the members of committees, and the officials and other servants of the Community shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components.

In the context of Competition Law -perhaps the area in which European institutions have most direct authority over individuals- the protection of professional secrecy is related to the protection of reputation, and is covered by the right to the presumption of innocence.

This is the opinion of the Court of First Instance (Third Chamber) in its Judgement of 12 October 2007 (Case T-474/04)

78 The Court considers, further, that, since the Commission's findings relating to an *infringement committed by an undertaking are capable of infringing the principle of the presumption of innocence, those findings must, in principle, be regarded as confidential as regards the public, and therefore as being of the kind covered by the obligation of professional secrecy. This principle stems, inter alia, from the need to respect the reputation and dignity of the person concerned as that person has not been finally found guilty of an infringement (see, by analogy, Case T-15/02 BASF v Commission [2006] ECR II-497, paragraph 604). The confidentiality of such information is confirmed by Article 4(1)(b) of Regulation No 1049/2001, which provides that information, whose disclosure would harm the protection of privacy and the integrity of the individual, is to be protected. Finally, the confidentiality of that information cannot depend on whether, and to what extent, it is of probative value for the purpose of proceedings at national level.*

…

80 In the present case, as the Court has pointed out in paragraph 74 above, the applicant did not have standing to bring an action against the peroxides decision, given, in particular, that its participation in the infringement was not referred to in the operative part even though it contested the merits of the grounds of that decision in which its participation in the infringement was mentioned. Such a situation is contrary to the principle of the presumption of innocence and infringes the ***protection of professional secrecy****, as interpreted in paragraphs 75 to 78 above,* ***which require that respect for the reputation and dignity*** *of the applicant be ensured. The disputed information must therefore be held to be covered by the obligation of professional secrecy within the meaning of Article 287 EC. In that regard, the Court would point out, finally, that the Commission itself accepted, during the hearing, that it could have*

published the peroxides decision by limiting itself to finding that the applicant had participated in the administrative procedure and to closing the investigation in its regard by reason of the limitation period. It must be held that, in those circumstances, there is therefore no public interest in publishing the disputed information that is capable of prevailing over the applicant's legitimate interest in having such information protected.

The obligation to maintain professional secrecy is covered by the principle of the presumption of innocence, stemming from the need to respect the reputation of the affected person. Considering that a food alert can put the reputation of the company at risk and that to launch a food alert is an interim measure[3] that can be adopted *inaudita parte*, the respect of the presumption of innocence implies -in my view-, that no food alert should be launched without a minimum activity of risk assessment adequate for destroying this presumption and that a balance must be established between the information provided to the public and the seriousness of the health risk.

The reputation of companies and brands is protected by Food Law. In the first place, because this protection is implicit in the respect for the principle of proportionality and because Article 50 of Regulation 178/2002 conditions recourse to the Rapid Alert System for food and feeds to the existence of a serious direct or indirect risk to human health. Furthermore, the use of the Rapid Alert System is specifically subject to the requirements of confidentiality as per Article 52 of Regulation 178/2002, particularly when affecting information covered by professional secrecy.

In fact, the information provided by the Rapid Alert System for Food and Feed (RASFF) does not disclose the name of affected companies. However, one can not overlook the fact that when information is communicated through this system, leaks can occur at any of the contact points, particularly if the alert affects a well known product, and the authority considers that the public should be informed of it or if the media is interested in the story. For this reason, in my view, proportionality when communicating a health risk by means of a Food Alert should be assessed not by the content or the wording of the alert but by its predictable effect.

III) Communications of Risks. Food Alerts, conditions and procedure.

a) Conditions

Article 50 of Regulation 178/2002 conditions recourse to Rapid Alert System for food and feeds to the existence of a serious direct or indirect risk to human health. The Article uses the term *shall* inform, so we must deduce that the member of the Rapid Alert System is obliged to use it when aware of serious direct or indirect risk to human health.

Article 10 of the Regulation 178/2002 conditions the taking of informative appropriate action to the existence of reasonable grounds for suspecting that a health risk exists. Obviously, any action taken must respect the principle of proportionality.

Therefore, we can consider that the pre-conditions for communicating a health risk to the public are: i) that there are reasonable grounds to believe that the risk exists and ii) that the risk is a serious one. Additionally, any action taken must be appropriate which in my interpretation means proportional.

Regulation 178/2002 does not specify what should be understood as a "serious risk" or as "reasonable grounds", but it at least implies that not every possible risk to health needs to be communicated to the public immediately and that, in any event, the decision must be made on grounds that could be contested by affected parties if they are not reasonable grounds, or lack the scientific basis to be considered reasonable. In any case, the reasonability of these grounds should be open to examination possibly by a Court, which will particularly have to take into account the respect of the principle of proportionality.

The European Court of Justice has already adjudicated on the concept of a risk to human health that could justify a refusal to import a food product from another Member State. This situation may be different to that of communication of risk, but is a reference to what might be interpreted as a "serious" health risk[4] justifying a restrictive measure. In any case, it is clearly not enough to simply allege the existence of a risk to health: there must be some dimension to the risk, to justify appropriate action.

As for what are reasonable grounds, I think there are similarities with the situation of the scientific grounds allowing recourse to the precautionary principle, in the sense that

[3] It is an interim measure, in my opinion, because it is difficult to imagine a food alert where there is no urgency. Where the discovery of a food risk does not present itself as urgent, then the adoption of a more formal decision or regulation would be the appropriate reaction.

it is not enough to allege scientific uncertainty in order to automatically resort to the precautionary principle: this *uncertainty* must be the result of some serious preliminary research allowing its justification. No decision can be taken on the basis of a purely hypothetical risk. On the contrary *The duty imposed on the Community institutions by the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection means that they must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research, as the Commission has itself emphasised in the Communication on Consumer Health and Food Safety*. Judgement of the Court of First Instance (Third Chamber) of 11 September 2002, the case T-70/99,Alpharma[5].

In consequence, there will be reasonable grounds to believe that a health risk exists when a reasonable investigation activity has been carry out in order to determine the existence of a risk that is more serious than a hypothetical risk.

b) Procedure

Articles 3.13 of Regulation 178/2002 contains a definition of risk communication that is wider than that of merely informing the public of a risk health. According to this Article, Risk communication is the *interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;*

The procedures and administrative competences involved in taking a decision to inform the public of a health risk are not very clear in my opinion, nor is it clear what is to be done in case of conflicting opinions between the several parties with competence to communicate a risk, as we saw recently in the Bowland Dairy Case, where the Court had to order the Commission to withdraw a warning concerning a health risk with which the British authorities did not agree[6].

According to Article 40 of Regulation 178/2002, competence to communicate a risk seems to reside both with the European Commission and with the European Food Safety Agency. The European Commission will inform of the risk-management decisions and

[4] Without elaborating extensively on this point, I could mention, as examples, the Judgement in the cases Van der Velt (C 17/93 Judgement of 14 July 1994) and Bellamy (C 123/00 Judgement of 5 April 2001).
[5] In a similar sense, the Judgement the Court of First Instance of 11 September in the case Pfizer (T 13/99), or the Judgement of 9 September 2003 in the case Monsanto (C 236/01)
[6] Order of the Court of First Instance of 12 September in case T.212/06

the Authority of the scientific grounds for the risk. However, the difference between the two powers/competencies is not very clear, since to take a decision to inform the public of a risk to health is in itself a risk-management decision, irrespective of the nature of the information. Again, it is not clear what should be done when the decisions of the Commission and the Authority do not coincide. This is the case, for example, when the Commission *recommends* the withdrawal of a product on health grounds, but the Agency informs that public health is not at seriously at risk and other national authorities resort to protection of consumers' interests since the health grounds are not solid enough to support their action[7].

Article 40.

Communications from the Authority

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.
The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

The procedure for communicating a risk is based on the rapid alert system. The nature of this system determines the effect of the communication. This effect is ruled by Article 50 of Regulation 178/2002.

Article 50

[7] This was the case of the Ukrainian sunflower oil alert, in April 2008, for example.

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.
2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;

(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs. Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 51

Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52 establishes that the use of the system is subject to confidentiality. However, confidentiality is difficult to guarantee with so many participants in the system, in different countries, particularly if the alert affects a well-known product.

Confidentiality rules for the rapid alert system

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

Article 55 regulates on a General plan for crisis management. The Commission shall draw up, in close cooperation with the European Food Safety Authority, hereinafter referred to as «the Authority», and the Member States, a general plan for crisis management in the field of the safety of food and feed. The General plan should serve to enforce legal certainty by specifying the situations of risk prompting the use of the Rapid Alert System and the appropriate reaction.

According to Article 55.2

The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

The general plan for crisis management was adopted by Decision 2004/478/EC of 29 April 2004.

The plan defines a crisis situation as exceptional and conditional to the presence of a serious health risk that cannot be dealt with by resorting to articles 53 and 54 of Regulation 178/2002. The general plan includes the gathering of scientific information related to the crisis, the development of a communication strategy that will include preliminary contact with stakeholders where necessary and, in particular, when information is released in relation to a specific commercial brand or name. The communication of the crisis will ensure transparency, in accordance with the principles for public information provided for in Article 10 of Regulation No 178/2002 and general confidentiality rules will continue to apply.

IV) Legal remedies.

There is no specific regulation of legal remedies to the use of the Rapid Alert System in Regulation 178/2002, for example, there is no procedure for consultation or allegations on the part of the affected company to be followed before launching an alert[8]. Consequently, most affected parties must resort to the legal procedures against measures implementing the alert in their own countries. These legal actions may serve to question the actions of their national authorities, but not the European one.

Under the provisions of Article 263 of the Treaty on the Functioning of the European Union, any natural or legal person may institute proceedings against an act addressed to that person or which is of direct and individual concern to them. Furthermore, the Court of Justice can suspend the contested act, if it considers that circumstances so require, under Article 278, or adopt interim measures, under Article 279 and according to Article 104 of the Rules of procedure of the Court of First Instance of the European Communities.

However, it is one thing to annul an order and another to annul its effects, which can only be achieved by removing them and, normally, by compensating the damages caused by an illegal order. The Community's non-contractual liability under the second paragraph of Article 288 EC for unlawful conduct by its institutions is dependent on the coincidence of a series of conditions: the unlawfulness of the conduct alleged against the institutions, the fact of damage and the existence of a causal link between the conduct alleged and the damage reported. In practical terms, in my opinion, European

[8] A food alert can potentially have more damaging effects than a sanction, but a sanction cannot be adopted without respecting a pre-established due procedure.

Case Law on extra contractual liability tends to be restrictive[9], particularly dealing with a situation like the protection of public health, where the powers of the Authorities are very discretional.

In fact, an interim measure was adopted in the Bowland Dairy case. However, no compensation for damages was granted. Equally, in another case seeking compensation for damages caused by a Food Alert, no compensation of damages was granted either, in the Malagutti case[10] .

[9] In the sense that the conduct of the institution must consist of a sufficiently serious breach of a rule of law intended to confer rights on individuals (Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, paragraph 42). It is the liability of an international organisation.
[10] Judgement of the Court of First Instance of 10 March 2004, Case T-177/02.

SPAIN, Legal Framework

I) The right of consumers to be informed

II) The protection of the reputation of products and companies

III) Communication of risks. Food Alerts, conditions and procedure.

IV) Legal remedies

I) The right of consumers to be informed

The Spanish Administrative Procedure Act, Ley 30/1992, grants the public the right to access to information, provided that the person has a legitimate interest in the matter. There some exceptions to this right, basically that the information should not be protected by industrial nor commercial secrecy, affect the security of the State, refer to the political activity of the government (i.e. which is not governed by administrative Law), affect the investigation of crimes, etc.[11]

Under Spanish Law, the key concept in the regulation of the right to access to information in the hands of the authorities, lies in the idea of legitimate interest in the matter. Legitimate interest is defined in Article 31 of the Spanish Administrative Procedure Act, Ley 30/1992, and includes the interests of those who promote or could be affected by administrative activity. It can be enjoyed both by individuals and groups. It should be noted that the concept of "legitimate interest" is the result of a reform of a law that previously referred to the narrower concept of "direct interest". Furthermore, Section 43 of the Spanish Constitution recognises the right to health protection, which should be considered as a legitimate interest of any individual. Section 51 of the Spanish Constitution makes the public authorities responsible for securing the protection of consumers and users and, by means of effective measures, for safeguarding their safety, health and legitimate economic interests.

[11] These rights are regulated principally by Articles 31, 35 and 37 of act 30/1992.

In addition, articles 2.1.c; 2.2.m; 2.2.n; 4.6.b and 4.6.e.3 of Spanish Act 11/2002 of 5 July establishing the Spanish Food Safety and Nutrition Agency, attributes to the Agency the competency for informing the public of a food health risk, even on its own initiative. The information provided by the Agency must be based on science, take into account the precautionary principle and respect individual privacy and intellectual and commercial property, all of which will be subordinate to the protection of public health.

Again, in my view, due to the wide definition of the Agency's powers of communication and the potentially conflicting interests it is bound to take into account, the principle of proportionality is the key interpretative concept. The principle of proportionality is a requirement of Spanish General Administrative Law and, more specifically in the field of Health Law, a requirement of Article 28 of the Spanish Health Act. In this Article proportionality means the use of the least restrictive measure possible.

Finally, companies are obliged to inform consumers on the risks posed by the goods they supply, according to articles 8.1.d and 12 of the Spanish Consumers Act -RD Legislativo 1/2007 of 16 November- which establishes both this obligation on the part of the companies and the right of consumers to be properly informed on the goods they acquire.

II) The protection of the reputation of products and companies.

Section 18 of the Spanish Constitution guarantees the right to honour, personal and family privacy and own image. Honour amounts to reputation and, for a time, it was arguable whether Section 18 of the Spanish Constitution and Act 1/1982 applied to a company's reputation. This was -in obiter dicta- denied by Judgement 214/1991 of Spanish Constitutional Court. However a later judgement 139/1995 of the Spanish Constitutional Court admitted that legal persons do have honour. This constitutional doctrine was confirmed by the Spanish Supreme Court in Judgement of 9 October 1997 and others.

The civil protection of these rights is implemented by Spanish Act 1/1982 of 5 May[12]. Under this Law companies may also claim for damages, and Spanish Act 2/1984 of 26

[12] However, some Courts are sometimes reluctant to apply this law to companies and prefer to protect their reputation under article 1902 –general liability for damages-, a position which, in my opinion, is contrary to the doctrine of the Constitutional Court.

March grants any person or company the right to require a rectification, meaning that they can require any media to rectify any harmful and inaccurate information affecting them.

Furthermore, Article 9 of the Spanish Unfair Competition Act, 3/1991 considers it unfair competition to inform or spread information to denigrate someone's reputation, except when the information is accurate, true or adequate.

III) Communication of risks. Food Alerts, conditions and procedure.

a) Food Alerts as an administrative decision

Communication of health risks is normally made through the Rapid Alert System. It takes the form of a message addressed to the other authorities in the network and, sometimes, communications of health risk are transmitted directly to the press. Therefore, the decision to communicate a risk does not necessarily take the traditional form of an administrative act as required by Spanish Law, where this kind of act- as opposed to mere act of procedure- should be personally notified to affected parties[13], motivated[14] and subject to administrative appeal. Due to the lack of direct communication to the affected party, who can learn of the alert via the press or through the alert's implementing measures, it is sometimes difficult for the party to know who is responsible for a food alert or the exact legal and scientific motivation for the alert.

According to Spanish Law[15], in case of urgency, interim measures can be taken before starting any administrative procedure, *inaudita parte.* In that case, the administrative procedure must start within 15 days and the decision to initiate the administrative procedure will confirm, modify or cancel these interim measures. A decision to communicate a risk using the Rapid Alert System can adopt the form of an interim measure in case of urgency; or rather recommend/order the adoption of interim measures by the implementing authorities. However, the fact that an administrative decision is provisional does not mean that a valid justification of the urgency is not needed. The valid justification of interim measures is specified under Spanish Law: they must be necessary to protect affected interests, they must not cause damages that are

[13] Article 58 of Spanish administrative procedure Act, Ley 30/1992
[14] Article 54 of Spanish administrative procedure Act, Ley 30/1992
[15] Article 72 of Spanish administrative procedure Act, Ley 30/1992

impossible or very difficult to repair and the situations in which they can be adopted must be established by an Act of Parliament[16].

In any case, the initiation of a food alert, whether it is considered to be an interim measure or a proper administrative act, is in my opinion an administrative decision that must be subject to administrative law and respect the procedure and conditions of its adoption like any other any administrative decision. The non respect of these conditions makes the decision null and void, according to Spanish Law[17].

The Spanish Supreme Court has adjudicated on this matter, in a case where the Ministry of Health claimed that a Food Alert was not an administrative decision that could be reviewed by a Court or challenged by affected companies, but rather an internal administrative communication that could be not the object of such a challenge because it was not the final administrative decision on the matter. This was the case of ASOLIVA, the Judgment of Spanish Supreme Court of 27 June 2007. The Court said that when the State acts within its competencies and informs of a serious risk for health, it is issuing a proper administrative act rather than a recommendation because it is leaving little choice to the other authorities – members of the network – but to react accordingly. The Supreme Court did not go as far as to say that the order communicated by means of the Rapid Alert System was an administrative legally-binding order, but it affirms that it is a proper administrative act because of its predictable effects, a proper administrative decision that must be adopted according to administrative law, can be reviewed by a Court and, accordingly, be challenged by affected parties[18].

If the decision to issue a Food Alert is an administrative act, it also means that it has to be taken respecting the procedure established by Spanish administrative law, that is, fundamentally, that the decision must be taken by the competent organ according to Law and following the due administrative procedure[19]. It also means that this decision can only be taken when the conditions established by Law are present.

b) Competent Authority and Procedure.

[16] Article 72.2 and 3 of Spanish Administrative Procedure Act, Ley 30/1992
[17] Article 62 of Act 30/1992
[18] The European Court of First Instance seemed to have no doubts either about this matter, in the Bowland Dairy case.
[19] Otherwise the act would be null and void, as per article 62.1 of Spanish administrative procedure Act, Ley 30/1992.

As indicated, it is fundamental to any administrative act to be produced by the competent organ and following the appropriate procedure, otherwise it will be null and void[20]. As I said, in my interpretation of applicable law and precedents of case law, communicating a risk to the public is an administrative act.

Competency for risk communication in Spain belongs to the Spanish Food Safety and Nutrition Agency (AESAN)[21]. The Agency was created by Act 11/2001 of 5 July establishing the Spanish Food Safety and Nutrition Agency and its competencies include both the determination of risk (a technical, scientific process) and the management and communication of the risk (an administrative decision-making process), according to Article 2.1 c of Act 11/2001. It is an autonomous agency with full capacity to act, according to Article 1 of Royal Decree 709/2002 establishing its Bylaws.

One of the objectives of the Spanish Food Safety and Nutrition Agency is to act as a national reference centre in the communication of food risks, particularly in situations of crisis or emergency (Article 2.1.c of Act 11/2001). Similarly, Article 2.2 m of Act 11/2001 empowers the Agency to take appropriate measures to inform the public of any real or potential risk to health, which the Agency is also obliged to do under Article 10 of Regulation 178/2002. Furthermore, the Spanish Food Safety and Nutrition Agency will promote any necessary action to inform consumers (Article 2.1.m). The Agency will communicate on its own initiative any relevant information to consumers, particularly in situations of food crisis. The Agency will take its decisions based on objective scientific data and formal risk analyses, with the aim of protecting health and public interest, according to the precautionary principle (Article 4.6.b.).

In its risk communication function, as well its other competences, the Agency may exercise any administrative powers required for the accomplishment of its objectives, powers that must comply with the requirements of Act 30/92 on Administrative Procedure (Arts. 1.3 and 1.4 of Act 11/2002 and Article 3 of its Bylaws, adopted by RD 709/2002., as well as Arts 42.2 and 45.1 of Act 6/1997 on the Organisation and Functioning of the General Administration of the State). In consequence, a decision taken by the Agency to exercise its competence as regards risk communication must comply with Administrative Law. The decision must be adopted by the competent body, following the legal procedure, as required by Article 53.1 of Act 30/1992.

[20] See note 17
[21] This does not mean that other authorities in Spain cannot communicate risks, because the protection of health is a competence shared by central, regional and even local government. In any case, communication of risk is a central and natural competence of AESAN.

Furthermore, said administrative act must be appropriate (proportional) to the objectives of the Law, as per Article 53.2 of Act 30/1992.

According to Article 2.2.n of Act 11/2001, it is within the Agency's functions to establish a procedure for action during food crises and alerts, including a general risk-communication plan (Article 12 g of the Agency's Bylaws), and to prompt executive action from the competent authorities when faced with a food crisis. This communication will be made by the President of the Agency, who adopts the general procedure for action and who is, in addition, the Agency's spokesperson in situations of crisis (Article 7 of the Bylaws).

Article 31 of AESAN's Bylaws and Article 4.9 of Act 11/2001, provides for the constitution of a crisis committee (in relation to Article 53 of Article 30/1992). The Executive Director and the Head of the Communications Office are members of the committee, but will refrain from carrying out any communication of risk without the express authorisation of the President of the Agency (Article 31 of AESAN bylaws).

As concerns the manner of communicating the risk, Article 2.2.n of Act 11/2001 establishes that it is a function of the Agency to adopt a general procedure for action to be taken in situations of food emergencies or crises. The procedure must include a general risk-communication plan, as the Agency "*will communicate on its own initiative any information relevant to the public, particularly in situations of food crisis*", as per Article 6 e) 3 of said Act 11/2001. Therefore, the Agency will establish a general plan for risk communication and a specific one for situations of crisis and emergency (Article 4.6.e.3.).

The General Operational Procedure for Food Crises was adopted in 2006 and is published on the Agency web page. The plan is based on articles 55, 56 and 57 of Regulation 178/2002. The Communication Plan, called General Procedure for Communication of Risks to the Public, was adopted in 19 June 2007 by the Executive Board.

c) Conditions upon which a food alert can be issued.

The factual conditions allowing the Spanish authorities to issue a food alert through the Rapid Alert System are, basically, established in articles 10 and 50 of Regulation 178/2002 and articles 26 and 28 of Spanish Health Act[22].

[22] At the present moment, there is proposal for a Spanish Food Safety Act, not considered in this paper.

According to Article 10 of Regulation CE 178/2002, the communication of risks must be taken on reasonable grounds when public health is at risk, and must be proportional to the nature of the risk. According to Article 50, the use of the Rapid Alert System is mandatory in case of a serious risk to health[23].

Articles 26, 28 of the Spanish Health Act 14/1986 do not deal specifically with the communication of risks or food alerts, but would be also applicable since they regulate recourse to extraordinary measures to be taken in the presence of serious and imminent risk to health, or the suspicion of a serious and imminent risk to health. These measures must be taken in accordance with the proportionality principle, and will be those that least affect the commerce of foodstuffs. It must be stressed that the kind of health risk allowing the authorities to resort to the extraordinary measures contemplated in Article 26 of Spanish Health Act is a serious and imminent risk, other kinds of risk would permit other kinds of responses[24]. Not every health risk is serious and imminent. According to the Spanish Supreme Court in its ASOLIVA Judgement of 17 June 2007, a serious and imminent risk for health does not exist when the information on the substance motivating the alert is based on 10 year old WHO report, nor can it be justified on the premise that all product must be safe, if we have not previously defined what a safe product is[25].

As far as respect for proportionality is concerned, the Spanish Health Act requires proportionality when adopting extraordinary measures to protect public health (Article 26 in relation to Art 28 of Act 14/1988 of 6 June). Proportionality, as required by Article 28 of the Spanish Health Act, means that the most restrictive measures would be reserved to the most extreme situations and if there are several admissible measures the least restrictive must be chosen, according to the Judgment of 6 June 1988 of the Spanish Supreme Court.

Moreover, respect for the principle of proportionality is not only a specific requirement of Food Law but of general administrative Law. Article 53.2 of Spanish Act 30/1992 on Administrative Procedures imposes the respect for due procedure and proportionality to ensure that actions that may have a very aggressive impact on the market are taken on serious factual grounds and in proportion with the actual risk. Proportionality is also a

[23] I refer here to my earlier comments when dealing with the European legal framework.
[24] The law does not specify what these other responses could be, but clearly not extraordinary measures limiting trade, free enterprise and property. One can think of informative campaigns, voluntary measures or new regulations setting new standards applicable for new foods produced under the new regulations.
[25] In the absence of specific previous legislation on the matter.

constitutional requirement arising from one of the general principles of Law: Justice (Constitutional Court Judgement STC 49/1999 of 5 April and STC 55/1996 of 28 March). Furthermore, proportionality is a general principle of European Law and is specifically applied to the Precautionary Principle, as per Article 7 of Reg. 178/2002 and, among others, the Judgement of the European Court of Justice of 5 May 1998, case C180/96, Commission v. U.K.; Judgement of the European Court of Justice of 9 September 2003, case C236/01, Monsanto; Judgement of the European Court of Justice of 16 October 2000, case C217/99, Commission v. Belgium.

Finally, AESEAN's General Procedure for Communication of Risks to the Public[26] requires the existence of special circumstances in order to initiate the communication of a risk to the public *within the framework of this General Procedure*. The Procedure should be activated if one of the following circumstances exists (part 3): i) a serious and imminent risk, ii) a situation of food crisis, iii) in case of a new, non-evaluated risk, requiring specific recommendations for consumption, iv) if there is public or media demand for information. It is also necessary to check with the Regional Governments (the competent authorities in the matter) that the immediate withdrawal of the product is not possible. According to this Procedure, therefore, two factors should be taken into account: the seriousness of the hazard and whether the media is already aware of the problem.

IV) Legal remedies available to challenge a communication of food risk

a) Administrative proceedings

A decision to communicate a heath risk can be opposed by affected parties, in the Court or by means of an administrative reversal. A prior administrative appeal is required by Spanish Law in some cases before bringing an action to Court. In other cases, the previous administrative appeal is only an option but affected parties can oppose the administrative resolution directly before the Court[27].

If the communication is made by the Spanish Food Safety and Nutrition Agency, no clear administrative procedures have been established to challenge the decision and as the Agency is an independent body subordinated to the Ministry of Health, an administrative reversal before the Ministry is not possible except when specifically

[26] Approved by resolution of the Executive Board on 19 July 2007.

established. This is not the case for communication of risks, even if some decisions of lower authorities could be reviewed by hierarchically-superior authorities within the Agency. However decisions to communicate a food risk can only be adopted by the higher authorities in the Agency, and therefore no other administrative authority has the power to reverse it but only the Court. Therefore, a decision to communicate risk in Spain can be opposed voluntarily via administrative procedure or directly at Court. At least, this is my opinion, but there is no clear judicial precedent on the matter.

However, is not rare that when taking a decision on communicating a risk, due to its non-formal administrative nature, the authorities claim that they did not take a decision at all that can be reviewed by a Court. In this case, the legal nature of the communication will be determined by its content and effect rather than its form. This was the case in the in ASOLIVA Judgment of the Spanish Supreme Court. It is true that Courts generally do not consider information provided by authorities as the final administrative decision they can review, but this consideration normally applies to a normal administrative proceeding in which the information is only a part. In my opinion, a decision to communicate a risk, when it takes on some dimension and is communicated to the public is a final decision with effects that can not easily be reversed. As far as the nature of the act of communication is concerted, the Supreme Court in its Judgment of 3 March 2009 is of this opinion when considering that an alarmist communication made by the Director General of Health of the Regional Government of Madrid was illegal because it went beyond the requirements of the protection of confidentiality. The Supreme Court affirms that there exists an obligation of confidentiality on the part of the Administration, an obligation that binds not only civil servants -as established on the Civil Servants Act of 1964- but all persons working for the administration, an obligation that was also binding for the General Director, in this case. The obligation to secrecy was not, however, absolute, but was subordinated to more important interests such as informing the public of a serious food risk.

b) Consequences of illegal communication of risk. Compensation for damages.

Again, the question is not to annul an administrative decision, but its effects. Spanish administrative law regulates the extra-contractual liability of the State, a liability that is strict in the sense that does not depend on the illegality of State behaviour. However, the Supreme Court has been restrictive so far when dealing with liability arising out of communications of risk made by the State.

[27] Typical administrative recourse include *alzada*- compulsory and to the superior authority - and *reposición* - optional, to same authority-.

In its Judgement of 3 March 2009, the Supreme Court refused to establish the liability of the State even if it declared that the communication on the health hazard made by the authorities was illegal. There was no liability because there was no causal link between State activity and damages.

In this specific case, the information provided to the media by the General Director was inappropriate and disproportionate. If the administration believes that it should inform the public of some facts it should do so in the most objective manner possible and limit the negative consequences of this communication as far as possible. Having said that, the Supreme Court refuses to grant any indemnity to the affected company, because it judges that the losses and damages suffered by the company were, in this particular case, caused by its own behaviour and not by the certainly inappropriate communication made by the Authorities.

This adjudication is made after analysing the specific facts at a stage where there was an order to stop the activity some weeks before the administration decided to make the case known to the public, and -in the opinion of the Court- this non-contested order was the cause of the damages to the company rather than the later information to the press.

In the case dealing with damages caused by the withdrawal of olive pommace oil from the market, where losses were mainly caused by the collapse of the market, a similar situation has resulted so far. On the one hand, the Supreme Court annulled the order to withdraw the product because it considered that it lacked justification and was disproportionate[28], but on the other hand the same Supreme Court has refused the liability of the State[29] -both of the Central and Regional Governments- with the argument that the companies were to be held responsible for the damages suffered as a consequence of their product being unsafe, which appears contradictory to its previous statement.

In conclusion, the Supreme Court acknowledges the possibility of claiming non-contractual liability from the State as a result of an inappropriate communication of risk, if a causal link can be established between unlawful communication and losses. However, usually the Court refuses to consider the existence of this link, following an

[28] Judgement of the Spanish Supreme Court of 27 June 2007, confirmed by the Judgement of 12 September 2008 and more.
[29] Lower Courts took opposite decisions in this case, some admitting the liability and other refusing it, but the Supreme Court seems to have adopted, so far, the criteria of refusing liability, in their Judgments of 4 March, 13 May 2009 and more. At this time, an appeal to the Constitutional Court has been filed.

extended and strict interpretation of Spanish Law on State liability. One could think that the Courts -both the Spanish and the European- tend to have a different opinion depending on the moral or economic consequence of their decision but, of course, this is would be not possible...

CODEX

I must be indicated that within CODEX official standards there are two that affects communication of risk: *The Working Principles for Risk Analysis for Food Safety for Application by Governments* (*CAC/GL 62-2007)* and *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995).

These standards include the respect to principle of proportionality and confidentiality.

Vicente Rodríguez Fuentes
Seville, 9 February 2010.