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Update of Italian Law Guidelines

Update of Italian Guidelines on Rapid Alert System for Food and Feed: some explanation in a shaded internal legislative framework.

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On 13 November 2008 new Guidelines on Rapid Alert System for food and feed (hereinafter "the Guidelines") were adopted by the Italian competent authorities. These Guidelines repeal those adopted on 15 December 2005 in order to bring national framework into line with new European legislation (Hygiene Package).

Italian Competent Authorities

Italian Constitution establishes that concurring legislationapplies to public health and food law. Consequently regional legislative bodies are entitled to rule in these fields, accordingly to general principles set out by national legislation and in compliance with the Italian Constitution and with the constraints deriving from EU legislation and international obligations.

The result is a complex institutional framework requiring a co-operation between different authorities (national legislative bodies and regional entities) which usually reach a number of agreements in the contest of the *Permanent Conference for the relationship between the State and the Regions*. These

agreements are not strictly binding, because their enforceability requires each Region to implement the accord.

As ruled by decree no. 193/2007 (laying down national implementation of Hygiene Package and penalties), Italian competent authorities for the application of Hygiene Package are Ministry of Welfare (former Health Ministry), Regions and Local Health Units (Aziende Sanitarie Locali, ASL).

Field of Application

The Guidelines aim to implement the Rapid Alert System for Food and Feed (hereinafter, RASFF) at the national level. Consequently the field of application is food related activities as defined by Regulation (EC) 178/2002 (articles 2 and 3). In particular, Guidelines provide for national rules to be applied to situation where a "*direct or indirect risk to human health deriving from food or feed*" is detected. As stated by point 3 of the Guidelines such situation is to be identified where: a) food is deemed unsafe accordingly to article 14 of the Regulation (EC) 178/2002; b) feed is deemed unsafe accordingly to article 15 of the Regulation (EC) 178/2002. Italian Guidelines provides for a third case of direct or indirect risk to human health: lack of compliance with "*the limit as ruled by laws relating to food safety*". The latter provision is intended to apply where non-compliance depends on a breach of a law relating to food (or feed) but it sounds repetitive as long as provisions under article 14 (or 15 for feed) of the Regulation EC 178/2002 cover all the situations of risk in the food consumption.

It is stated that Guidelines shall not be applied where unsafe food is intended to be treated in order to eliminate the detected risk. Additionally, Guidelines shall not be applied for lack of compliance with *process hygiene criteria* as ruled by Regulation EC no. 2073/2005. It is clear that "process hygiene criterion" is not strictly related to product-safety but, at the same time, it remains unmistakable that a serious breach of process standards may originate a food borne risk to human health. Guidelines' provision excluding *sic et simpliciter* breaches to *process hygiene criterion* from the field of application of National Rapid Alert System does not clarify this point so that, where non compliance with process hygiene criteria is checked, competent authorities are only obliged to verify that necessary corrective actions has

been put in place.

Guidelines also arrange for a notification of a direct or indirect treat to human health can arise from data under the means of internal safety procedures which each food business operator must put in place as ruled by article 5 of Regulation EC no. 852/2004.

It is to note that a specific provision establishes that notification under the RASFF can be addressed in specific circumstances "*where the possibility of harmful effects on health is identified but scientific uncertainty persists*". This provision clearly recalls art. 7.1 of Regulation EC 178/2002 (laying down precautionary principle) but it omits to specify conditions and limits of such a application as they are detailed under the mentioned article 7 and clarified by several judicial statements on the subject.

National Contact Points

National contact points dealing with the management of the RASFF are: Health and Veterinary Offices operating at the local level (ASL), offices operating at the regional level and, as national central authority established at the Food Safety and Nutrition General Directorate under Ministry of Welfare (former Health Ministry). A network between these offices is established in order to assure a continual flow of information and a clear conferral of competencies between low, intermediate and top authorities.

As ruled by the mentioned decree no. 193/2007, ASL is the competent authority to verify that food business operator comply with food law and, where a non-compliance is identified, to order appropriate remedies are put in place by such operator as ruled by Regulation EC no. 882/2004, article 54. ASL is also the competent authority to apply penalties for breaches to hygiene package, as ruled by decree no. 193/2007.

Guidelines states that where non-compliance is identified by sampling, a second official sampling is not required in order to launch an alert, unless lacking compliance has been identified "*by a private claim on tampered pre-packed foodstuff*". Having regard to the rationale of such provision, it could be suggested to consider "private claim" as including a consumer claim but also situations where tampered items are detected by other food business

operators by meaning of safety internal procedures.

Some statements of the Guidelines directly affects the implementation of article 19 of Regulation EC no. 178/2002 on crisis management. Local authorities (ASL) must verify that food business operator have immediately initiated procedures to withdraw harmful food. It is to say that food operator who omitted to rapidly recall unsafe product is responsible for the penalties provided by decree no. 190/2006 (laying down penalties for the breaches to articles 17, 18, 19 and 20 of Regulation EC 178/2002).

ASL is also committed to acquire information related to practical modalities of recall and storage of collected product deemed unsafe. From this point of view, it is of some interest to note that, as ruled by the Guidelines, ASL must acquire detailed information about clients supplied with unsafe product (complete address, batch, the date of minimum durability or “use by” date, quantity supplied and other business papers). Guidelines also specify that ASL shall verify product recall at the level of all wholesalers supplied with unsafe product. On the contrary, random check are provided in respect of final retail or other business operator operating at the level of final consumption. Severity of hazard, shelf life and scale of business are the main factors highlighted by Guidelines in respect of addressing random checks. Local proceeding authority must inform regional contact point of all collected information and taken actions.

It is to bear in mind that as provided by Regulation EC no. 882/2004, article 54, the competent authority can order specific measures as the withdraw or recall and any other measure the competent authority deems appropriate to eliminate or reduce the risk. Further on where an order of withdrawn (or another order) has been addressed under the meaning of the mentioned art. 54, lack of compliance to such order is a criminal offence under Italian laws (Italian criminal code, article 650).

Procedures to be applied in respect of avoiding detected risk are also provided. Three cases are mentioned. Firstly, as ruled by article 7 of Regulation EC no. 2073/2005, where non-compliance consists of unsatisfactory results of safety microbiological criteria and the involved products are not yet at retail level, unsafe product may be submitted to

further processing by a treatment eliminating the hazard in question (final retail level is *expressis verbis* excluded).

Secondly, Guidelines allow food business operator to process the product for purpose different from the prior use on condition that safety is assured. This is a wide clause which do not properly define the “different purpose”. On this way it is disputable whether a process eliminating the treat may allow “human consumption” of such (treated) product. Additionally, it is to be considered that, under national law decree no. 327/1980, where a “direct and high” hazard is identified, the dangerous product - which is normally confiscated - must be rapidly destroyed.

Thirdly, as a final clause, Guidelines state that where no treatment can be addressed in order to eliminate the detected risk, the unsafe product must be destroyed.

Regional contact points are entitled of a number of activities related to transmission of information from local level (ASL) to national contact points and *vice versa*. Namely, Regions are also entitled of risk communication as pertinent under Regulation (EC) 178/2002 articles 19 and 20. Regions must inform consumers of the sanitary risk detected by meaning of regional media as well as internet official web-site.

It is to remember that food operator is the primary responsible to inform the consumers about food related risks. Private operator, under the meaning of General food law, article 19, is obliged to “*effectively and accurately inform*” the consumers of the reason for its withdrawal, where the product may have reached the consumer and, if necessary (where other measures are not sufficient), to recall from consumers products already supplied to them. Italian decree no. 190/2006, article 4, provides for penalties for the breach of such obligation unless the national provision specifies the modalities to comply with requirements of effectiveness and accuracy. This should result in a difficult application of mentioned penalty.

Finally, the top National contact point is established at the Italian Food Safety and Nutrition General Directorate under Ministry of Welfare which is competent to manage the flow of information with European network and to

control the application of such Guidelines by local and regional authorities.

Training and Compliance of staff performing official control

Guidelines requires each Region to carry out a training program aiming to ensure the correct and uniform implementation of regulations laying down the management of Rapid Alert System. The multilevel legislative resulting from Constitutional provisions strongly requires an important effort to harmonize as long as possible the regional and local application of food law.

A second meaning to comply with obligations ruled by EU food safety law is audit which is to be intended as "*a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives*" (Reg. EC 882/2004, article 2). Guidelines expressly recall such technique in order to uniformly implement RASFF. It is to say that Italian staff performing official controls are heavily implementing audit techniques which are a *quid novi* in the field of official practice. A second important target of these training programs should be the correct identification of law applicable which remains one of dark tools of the current national food law. **Conclusion**

From an Italy-based point of view, entry into force of Regulation EC no. 178/2002 and Hygiene Package did not result in a serious and comprehensive repealing of internal national laws previously adopted in the field of manufacturing, processing and retailing food.

Italian legislator, by mean of mentioned decree no. 193/2007, only repealed internal legislative acts transposing EC directives "killed" by directive EC 2004/41 and Regulation EC 852/2004 but it kept in force a number of internal laws (notably, Italian Law no. 283/1962 and the implementing regulations decree no. 327/1980) overlapping with safety objectives and rules established by EC food law.

The result is a legislative framework where two different approaches are at stake: the European regulation oriented to a "preventive approach" where, being the primary responsibility addressed to food business operator, a number of provisions are drafted with flexible (and imprecise) terms such as

“where appropriate”, “if necessary”, “suitable”, “adequate” or “sufficient”. In the EU legal framework, official control has been designed consequently.

On the other side, food related internal laws, previously adopted, address safety obligations, bans and penalties in a more detailed and in a repression-oriented way. Such a situation can result in a more understandable framework where the role of primary responsible which EU laws consciously addressed to food business operator may be avoided or sensibly reduced.

For sure, Italian official control bears in mind that where a conflict between EU food regulation and national laws is identified, community law should prevail as ruled by Court of Justice jurisprudence. Nevertheless such a statement is not a satisfactory solution for a number of situations where a contrast between EU and national law cannot be clearly addressed and diverse provisions, with dissimilar rationale, stand still.

The *optimum* should have been a repealing of all previously adopted internal laws overlapping with new EU food law and providing a set of new national legal framework with penalties and remedies compliant with preventive EC approach. To date, internal legislator failed to reach such a goal leaving food business operators, lawyers and official control to deal with a shaded legal framework where the unenforceability of national provisions for contrast with EU prevailing law sometimes can result in a *probatio diabolica*.

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