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Compliance with EU Food Regulation: what if traceability and food recall are not enough?

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Glass shards; unlabelled allergens; inedible inks; Escherichia coli outbreaks; bone fragments in beef products; food contaminated by inattentive or poorly trained employees. The list may go on indefinitely, but the result will always be the same, *i.e.* the high regulatory pressure on the food operator and its business. The latter indeed ends up facing several 'counterparts' at the same time, namely clients, control authorities, media and consumers. Consequently, the continuity of the business may be jeopardized by a significant and serious regulatory action from the public authority such as seizures, product recall and destruction, civil fines and even the possibility of criminal charges.

This contribution focuses on the extent to which EU regulatory framework on food may hamper the ongoing operations of food manufacturers once a crisis erupts. Taking into consideration recent developments of European food policy and case-history, this paper discusses how integration of legal, regulatory and technical expertise may improve the efficacy of a food manufacturer's "crisis management plan".

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EU food market: a regulatory overview

Since its very beginning, European action in the domain of food trade moved towards the phasing in of safety obligations, as well as more integration, mutual cooperation and assistance between public authorities. Although still permeated with marked considerations, early EC directives on product safety already show increasing care about health. This is evident if only one pays attention to the 1992 directive on general product safety which states that "*safe product shall mean any product which […] does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons*" (Directive 92/59/EEC now replaced by Directive 2001/95/EC), However, the veritable breakthrough occurs with the Maastricht Treaty, whose Art. 129 gives the European Commission a degree of **legal competence in the area of public health protection** for the first time. The overarching aim is that products placed on the EU market must be safe.

As of today, **European Food Safety** has a well-planned strategy integrating both Community and individual National requirements. Furthermore, the Rapid Alert System for Food and Feed (RASFF) and the intensive training program, managed by the Commission Services, are two further successful instruments of the EU Food Law. Reg. EC No 178/02 hereinafter, also General Food Law (GFL), that gave rise to a number of innovations.

Firstly, GFL addresses general principles of Food Law, namely risk analysis, precautionary principle, protection of consumers' interests and principles of transparency. In more detail, **risk analysis is the *grundnorm* on which the EU food law is based**. This is the main tool upon which the regulation relies in seeking to achieve its primary two-fold objectives: a high protection of human health and free movement of foodstuffs. The concept of risk analysis splits the process into three sub-parts: risk assessment, risk management and risk communication.

For instances, the market approval of a novel food requires the product is evaluated as safe; a labeling or marketing health claim needs to be scientifically substantiated in order to be use on the EU market. Likely, the use of an additive or a flavoring in a food usually requires technological justification as well as a science-based scrutiny of all relevant scientific data. In other terms the EU decision making process concerning foodstuffs always includes a risk assessment phase upon which the scientific and technical experts (risk assessors) and legislators (risk managers) takes the decision, having regard to other legitimate factors, if appropriate. While risk assessment aims at gathering independent scientific information from many sources to justify a use and use level, risk management is based on utilizing that risk assessment information to arrive at legislative requirements, both by the EU institutions and Member States' to

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develop EU legislation. Finally, risk communication takes the risk assessment and risk management information and consolidates it into messaging targeting the various EU institutions, Member States, as well as general outreach to consumers, carried out by the Commission.

Secondly, the establishment of a general framework on risk assessment and risk management was accompanied by the establishment of an **independent Authority dealing with risk assessment, i.e.** The European Food Safety Authority, (EFSA). The outcome of this effort was the establishment of new and wide-ranging **obligations for food business operators** (safety requirements, traceability and crisis management tools, product presentation).

A **general outline on food control** within the Single Market was introduced, which also took into consideration import and export of food. Such a brand-new set of rules must be integrated with a number of sectoral legislations laying down – amongst others - prescriptions for specific products (novel foods, baby foods, dietary supplements, products of animal origin et cetera) or aspects (such as Food Hygiene, Chemical Safety Requirements et cetera), specific product safety and quality requirements and presentation rules (for instances, labelling and advertising).

GFL also strengthened the functioning of the **Rapid Alert Standard for Food and Feed** (RASFF), a network of EU Member States, the European Commission, the European Food Safety Authority (EFSA) and other partners providing a tool for quick exchange of information whenever a risk to food or feed safety is identified. When a RASFF member has any information about a serious health risk from food or feed, it must immediately inform the European Commission using the RASFF system. The European Commission then immediately notifies the other members in order to take the appropriate actions. This can include withdrawing or recalling a product from the market to protect consumers' health. All incoming information is assessed by the Commission and forwarded to all RASFF members using one of the four types of notification, *i.e.*:

- **Alert notifications** are sent when food or feed presenting a serious risk are available on the market and when rapid action is required;
- **Information notifications** are used in the same situations, but when the other members do not have to take rapid action because the product is not on the market or the risk is not considered to be serious;
- **Border rejections** concern food and feed consignments that have been tested and rejected at the external borders of the EU (and the EEA) when a health risk has been detected;

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- Any information related to the safety of food and feed products which has not been communicated as an alert or an information notification, but which is judged valuable for the control authorities, is transmitted to the members under the heading **News**.

In operational terms, it means that what happens in Sweden may be immediately be known in Italy: any lack of safety, any "food crisis" may be rapidly communicated throughout Europe. Indeed, the RASFF's members must take action depending on the type of notification and immediately inform the Commission of the measures taken. They may, for example, withdraw or recall the product from the market. In addition, border rejections are transmitted to all border posts – i.e. all 27 EU Member States, as well as EU "cooperators; Iceland, Liechtenstein, Norway and Switzerland. This is to ensure that the rejected product does not re-enter the EU through another border post.

Case study (part I): *As a disaster may arise*

2015 summer was very hot in Italy. Why did it matter?

Company A supplies rice around the world, with a core business in rice for re-packaging, for preparing various food preparations and for catering. A day of October, the Quality Manager receives a complaint by a client (another food business operator, manufacturing food preparations for Final Retailers) about the registered presence of metal fragments of a size of about 1 mm in a lot of rice supplied by the Company.

The Quality system of the Supplier entered immediately into action and the reason for the contamination was detected: the prior summer some storage silos underwent sand blasting and cleaning in order to reduce the possibility of contamination of the product during storage. Because of the hot temperature during the summer when this work was being performed, some joints in one of the silos was subjected to unusual expansion which trapped the fine metal fragments found in the rice stored in that silo.

While the rice Supplier was diagnosing the problem, it did not involve its national or EU food safety authorities; however, its customer did inform its National food safety authority (Competent Authority) of the problem. The Customer made use of all National food safety requirements as well as the EU rules on RASFF, filing an *alert notification*. As a consequence, the Supplier faced a tremendous pressure from other customers based in other EU member States and had to seriously consider initiating a recall of 4-months of rice production.

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Traceability and Product's withdrawal: mandatory requirements versus (higher) voluntary standards

Main safety obligations under EU food law include both traceability and the obligation of market withdrawal as soon as food placed on the market is determined or confirmed to be unsafe. It is widely known that voluntary norms (e.g. SQF, BRC and IFS) give substance to such obligations in much more stringent terms.

The actual rational of traceability is to allow targeted and timely market withdrawal of the suspect product. From the Competent Authority's point of view, the rationale is to enable competent safety authorities to obtain, in a short time, information on affected product and/or suspected cause.

The law defines 'Traceability' as the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution. GFL does not mention **food contact materials** but there is no doubt that these materials are included in what is required to be traced. In more detail, Article 18 GFL only requires Food (or feed) business operators (FBOs) "*to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed*". Secondly, FBOs are "*requested to identify the other businesses to which their products have been supplied*. To this end, systems and procedures must be written and put in place". In addition to the general requirements, **sector-specific legislation** applies to certain categories of food products (fruit and vegetables, beef, fish, honey, olive oil) so that consumers can identify their origin and authenticity. There are also special traceability rules for genetically modified organisms (**GMOs**), which ensure that the GM content of a product can be traced and requires accurate labelling so that consumers can make an informed choice. In the case of animals, producers must now "tag" every animal with details of their origin and, when animals are taken for slaughter, stamping them with the traceability code of the abattoir (slaughtering facility). The tools used (ear tags, passports, bar codes) may vary from one country to another but must guarantee the same quantity and quality of information. It is fairly obvious that Art. 18 does not require the so called 'internal product traceability', which is related to flows that are internal to processing practices. Nor does GFL pinpoint which information is necessary, nor the temporal deadline by which the FBO must be able to identify or supply the information requested by the control authority.

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On the contrary, voluntary norms found in the Global Food Safety Initiatives (GFSI) recognized third party certification schemes such as SQF, BRC and IFS Falso requires **internal management**. It is indeed clear that tracing only entry and exit, overall traceability will be limited as the in-between information will not be traced. Therefore, in case of necessity, the FBO will not know precisely where the source of risk resides and as a result will be forced to larger withdrawals. SQF, BRC and IFS also requires a specific timeframe for the tracing of a batch or lot of the food and periodical testing of traceability system.

Food crises in the past have revealed that documentary records or a basic consistency with mandatory general legal requirements are not always sufficient to allow full traceability of suspect foods. It is no coincidence that further (legal) requirements have been laid down with regard to foods of animal origin by successive regulation.

Food Recall according to EU Law

The regulation of food recall is enshrined in Art. 19 GFL ('Withdrawal, Recall and Notification'). On the EU market food withdrawal is mandatory as "*a food business operator considers or has reason to believe that a food, which it has imported, produced, processed, manufactured or distributed is* ***not in compliance with the food safety requirements***" (Art. 19(1) GFL). Grounds for mandatory recall include three main elements:

a) Lack of compliance with food safety requirements;

b) FBO's knowledge or reason to believe that lack compliance exists;

c) Food is not under the immediate control of FBO;

If the above conditions exist, then the FBO must immediately initiate procedures to withdraw the food in question from the market and inform the competent authorities. Moreover, if the product may have reached the consumer, the FBO is under obligation to "*effectively and accurately inform the consumers of the reason for its withdrawal "*and *"if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection*" (Art. 19(1) GFL).

The wording of Art. 19 GFL casts some **doubts** as regards the meaning of "food safety requirements". On this point, some authors take the stance that Art. 19 is conceived to referring specifically to Art. 14 GFL, which bears the heading "Food safety requirements", whereas others refers to ***all*** **legal requirements regarding food safety**.

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Also under dispute is the matter of what exactly is mandatory under Art. 19: the first paragraph only provides for the obligation to "initiate procedure of withdrawal" which may be quite different from the obligation to carry out the whole withdrawal; GFL does not contain a legal definition of **withdrawal**. However, definitions of withdrawal and recall are provided by Directive 2001/95/EC, according to which: "withdrawal" means "*any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer*"*(Art. 2, letter h)*, which takes for granted that the products concerned are not under consumer's control/possession. The same directive establishes that "recall" means "*any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor*" (Art. 2 letter g).

The setting of the scope of the above-mentioned definitions plays a role in a number of situations in which the lack of compliance with some mandatory requirements may not or does not result in the food being harmful to health, for instance in case of contamination above maximum residue limits. Additional requirements apply where food is in breach of food safety requirements is injurious to human health. More specifically, Art. 19(3) GFL establishes that where there is evidence or "reason to believe" that food placed on the market is injurious to human health, the FBO must (1) immediately inform the competent authorities the action taken to prevent risks to the final consumer; and (2) not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Case study (part II): *As a disaster may arise and turn in a near-miss*

At the time when the Supplier was following up on a potential food safety problem and carrying out batch analysis and other quality management measures, the Competent Safety Authorities discovered that there were no written programs by the Company on recalls; the Company's Crisis Unit, who was responsible for recalls never met since it was learned that the Company had not appointed someone to lead the Crisis Unit. This situation continued until the Company Management received a formal request from the local Competent Authority to disclose a complete customer list for customers supplied in the last four (4) months.

At that point a team of specialists, including food technicians and food lawyers, was called to operate alongside the company in order to manage the crisis situation. Anyone that has experience in crisis management understands how important speed and knowledge are in order to effectively manage a crisis/recall.

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When the Crisis Management Support Unit started, short terms objectives were agreed upon and immediately implemented:

1. Assessment of the actual level of safety's concern was established, taking into consideration all available information. Medical literature was scrutinized and regulatory insights were analyzed regarding the acceptable dimensions of foreign bodies. A renowned scientist was contacted to address an opinion on the danger of metal fragments having dimensions less than 7 mm or greater than 25mm (bodies bigger than 25 mm are deemed safe as they are difficult to swallow and are easily visible, whereas bodies less than 7 mm are not generally harmful to a normal adult as they are unlikely to cause choking (see also FDA cpg sec. 555.425 foods, adulteration involving hard or sharp foreign objects). Other scientific studies indicate 4 mm as dangerous minimum size if the user recipients are children older than 3 years (Consumer Product Safety Commission (1995).

2. The Crisis Team developed Position Papers and templates to meet requests from customers, media and competent authority including; all relevant legal side effects were considered: civil liability, accident, torts, prospective criminal prosecution.

3. Efforts were made by the Team to close the RASFF's alert in the shortest time: The team also acted with all relevant actors operating within the RASFF to obtain the acceptability of the closure of the alert, based on the current understanding and interpretation of the GFL provisions.

After 3 weeks of intense work, the EU-wide alert on rice was dismissed, no criminal prosecution was filed against the company and customers were given clear and exhaustive grounds to understand that the accidental presence of small bodies (7-25 mm) in rice wasn't a safety concern and the product met current EU and country food safety requirements.

"Unsafe food": a questionable issue…

The crucial question is what is "unsafe food" from a regulatory point of view, since safe or unsafe have many different definitions and legal understandings. Art. 14 Reg. No 178/2002 lays down some "*food safety requirements*" which aim at addressing food that may be (a) injurious to health or (b) unfit for human consumption.

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Legal standards require unsafe food to be ascertained taking into consideration, firstly, the normal conditions of use of the food by the consumer, at each stage of production, processing and distribution; secondly, the information provided to the consumer, including information on label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects.

It should be noted that such general standards are conceived as a subsidiary point of reference which applies whether and insofar as specific regulations do not exist. It could be the case of microbiological criteria or contaminants. The lack of standards is to be put in relation with the fact that at least at a certain extent, contamination is inevitable in certain food chains.

That said, unsafe food is a twofold concept, which covers both injurious and unfit or unwholesome food.

In determining whether any food is **injurious** to health, regard shall be made to the following:

- the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- the probable cumulative toxic effects;
- the particular health sensitivities of a specific category of consumers for which the food is intended.

The definition does not require evidence of injury to occur related to the term "probable effects". Moreover, it provides for the long-term evaluations, which fall within the EFSA competence regarding risk assessment.

Unsafe food also includes being "**unfit** for human consumption" according to its **intended use**, for reasons of **contamination**, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay. The provision does not identify specifically what kind of contamination makes the food unsafe which creates a number of issues.

It is clear that a number of unanswered questions still exist, such as:

- Does harmless contamination fall within the meaning of "unfit food" as provided for by the provision of GFL?
- What kind of legal and regulatory reasoning is expected to be carried out in order to properly assess the contaminated food as an unsafe product?

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- To what extent may a Food Business Operator invoke "intended use" as a defense claim?
- Is untraceable food susceptible to be withdrawn?

These are some of the questionable issues in which food law and food science may help to trace a way out of troubles. The only way to provide answers to these and other unresolved Competent Authorities food safety regulations and Directives is for food manufacturer's to continually challenge the current interpretations and by resolution of food manufacture failures.