

## The new EU regulations for food safety

Nicola Comodo, Guglielmo Bonaccorsi

*Department of Public Health, University of Florence, Italy*

*Correspondence to: Nicola Comodo, Department of Public Health, University of Florence, V.le G B Morgagni 48, 50134 Firenze, Italy.*

*E-mail: nicola.comodo@unifi.it*

### Abstract

The globalisation of food production has caused profound modifications in the primary logic concerning the safety and quality of food products. This situation has caused a progressive and radical change in the principles that have inspired new European Union (EU) legislation. Since the beginning of the 21<sup>st</sup> century, the EU has been following the so-called 'harmonisation' of food law, to ensure both the alimentary well being and nutritional health of all of its citizens (more than 455 million) and the free exchange of food commodities across all of the member states.

*Key words: safety, quality, hygiene, harmonisation, food, nourishment*

### The inspirational principles of the norms known as the "Hygiene package": the framework of new perspectives on food safety

At the beginning of the 1980s, all member states of the World Trade Organisation (WTO) subscribed to international agreements regarding strategies for food production and its marketing. These agreements, known as TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights), GATT (General Agreement on Tariffs and Trade), GATS (General Agreement on Trade in Services) and TRIMS (Agreement on Trade-Related Investment Measures) [1] signalled the beginning of a new, globalized, commercial strategy on food products which has also caused important repercussions within the European boundaries, but with some fundamental differences.

In fact, as the European Union (EU) has progressively expanded, until its present membership of 25 states, profound changes in the strategies of the production and commercialisation of food products have taken place following a perspective which - according to our judgement - poses greater attention to the consumers' rights than in other countries or continents [2,3].

In spite of these differences, in a relatively brief time the above cited agreements have determined a new, 'supracontinental', sphere of reference, abandoning the old 'logical' concepts concerning "safe consumption" based mainly on regional production and local and reasonable consumption towards a *globalized* market and consumption. Due to the possibilities of rapid transportation of people and products, local markets have been reduced to "typical niches". In many cases, they now represent a sort of

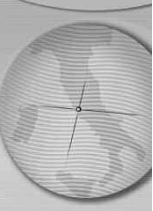
gastronomic memory of tradition and customs about which some European Union (EU) regulations were passed [4-6].

The concept of 'alimentary globalisation' is progressively extending from food commodities (the so-called *hardware* of the production and distribution systems) to buying behaviour and consumer habits (*software* of the same system). These realities have often found obstacles in the social attitudes of EU citizens. There is a growing fear of risk and danger towards the consuming of food that is not 'native' to the EU or to a country with a solid economic basis and tradition [7,8]. This has sometimes created a hostile climate towards the food market in which the role of any single individual is mainly passive, and alimentary choices are often imposed by the distribution system adopted by large companies [9-11].

This enlarged European or "supracontinental" scenario, with its incompletely solved problems, represents the framework in which modern ideas about food safety and quality must be revisited. The consumers' protection, much more than in the past, becomes a priority all over Europe, since it deals with citizens who live, work, move and eat in a great nation of 25 member states without boundaries, but whose origin, culture, traditions, attitudes, values, income are different [12].

The so-called "New Approach" Policy [10] regards revising the standards, which had once governed the European world of food production until the 1980s: an attempt by the "young" EU to create some basic rules regarding technical 'harmonisation' was among its leading goals.

The changes signalled a significant conceptual evolution - from those of the "old" Economic



European Community (EEC), whose main interest was to build a space of free commerce, to a virtual space of shared values that the present EU is trying to realise [2,13,14].

The EU is trying to create a whole legislative body in which both the mutual recognition of methods of food production and the lowering of barriers regarding food imports among all of its member states can take place, as specified in the preamble to Regulation 178/2002 [15].

Finding and establishing common and shared rules to govern the complex world of food production and its commercialisation for its 455 million EU citizens has been a difficult job and is still in progress. The choice of tools for the government of food safety had originally been political, i.e. the EU Commission chose some norms upon which all the laws would be based, and then translated into a series of common directives and regulations for all the member states [2,15-20].

The first difficulty towards "harmonization" has been the choice of cultural models and values from which the foundations of the new Food Law were to be derived. This choice has been translated into the definitions of the common principles of civil values to which all future norms will be applied [13]:

- striving for a high level of food security and standard of health for all EU citizens;
- the application of the so-called 'precautionary principle' as the discriminating value among commercial choices which entail elements of law, economics, biology, medicine, and ecology [1,3,16];
- ascribing a key-role and key responsibilities to food producers given that they are directly involved in the choices regarding both the safety of the processes for food production and the economic options to realise these.

According to these principles, the EU has chosen its operational tools to govern food safety:

- self-management of food production through the accomplishment of specific Hazard Analysis and Critical Control Points (HACCP) plans, each one of which is calibrated to deal with the kind of production and/or food commodity [9,21-23];
- the ability to trace and track all food products (tracing aims to assure the safe origin of all raw materials, tracking to give the producers and food inspectors the possibility of blocking the distribution of suspected items and withdrawing them from the market) [15,17].
- Correct labelling as an informative tool for the consumer so as to assure transparency of economic choices, ingredients reported (some

of which may be dangerous even in micro-traces), caloric and nutritional contents [14,24].

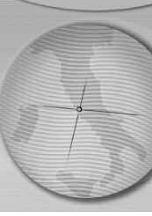
Through the correct application of these technical self-boundaries, the free circulation of food products all across the EU could be safe and economically suitable.

### The evolution of the EU Food Law

Since the second half of the 1990s, the EU has made legislative choices designed for the realisation of a coherent and "mature" corpus. From the previous "recipe-laws" or vertical norms - i.e. specific directives for one product or commercial category - the perspective of harmonisation has evolved.

A few comprehensive laws have been established, in which the leading common principles and technical references have been described. The application of these norms could and should follow the development of technological devices in this sector. These norms have been instituted *de facto* - within EU Law - EU Food Law as an independent branch of the legislative corpus characterised by its own peculiarities.

In this perspective, it is important to underline the influence of parallel claims according to voluntary norms of certification, such as the International Standardisation Organisation (ISO) which had been born in very different commercial sectors from that of food production, and have been imposed even in this area. In fact, the ISO has issued many documents, guidelines and authorised numerous manuals regarding correct hygienic practices. In these documents, there is a clear link between the HACCP system and the ISO 9000-2000 family: the norms, at first voluntary as regards to their adoption and application by the producer, are now followed and recognised as being a part of the EU legislative corpus. They are now considered practical and fit for integration into any future technological development. However, they must not be considered 'cemented' into the official regulatory system. This is the application logic behind the Technological Rule that has been codified in Directive 94/19. The decree states that it represents "...a technological specification or requirement whose observance is obligatory *de jure* or *de facto* for marketing and use in a member state...The prescribed and administrative legislative regulations of a member state that make reference either to technical specifications or to other requisites, the observance of which confer a presumption of conformity with the specifications established by the aforesaid regulations, constitute *de facto* technical regulations...".



All this is translated into a series of directives, reference documents and regulations that have succeeded each other in a sequential - and logical - order of time.

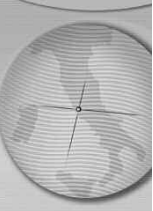
The first of these are the Directives and Reference documents, i.e. the instruments capable of affirming and imposing the guide-values and reference framework of regulations. These measures have been followed by EU Regulations, which act on a pre-established topic or, rather, on a *unified legislative reality*. All of these have been inserted into the fertile ground of "harmonisation".

From this point of view, the succession of EU legislative food actions appears logical and consequential:

- the first step was made by Health Directive 93/43 [25], in which several concepts, such as the sharing of a common methodology of risk prevention, are affirmed (even if it deals more specifically with danger/s), i.e. the HACCP system, which is based mainly upon a series of mutual guarantees (the knowledge and transparency of self-control plans) among producers and between producers and consumers, so as to offer a safe final product. Furthermore, the importance of education and training is identified for the first time as the key to control the processes;
- this was followed by the Green Paper (1997) [13] and the White Paper (2000) [2], in which the driving concepts of risk analysis, scientific plausibility, measurement of the level of danger to comestibles and the affirmation of the precautionary principle were introduced. This last principle is only partially compatible with risk evaluation and management; according to our opinion, it is much more a *political conclusion* than a technical solution (see above);
- by the adoption of regulation 178/2002 [15] the European Union chose the tools for the concrete realisation of the principles affirmed in the above-mentioned documents. In particular, it defined the vast sphere in which the health of consumer-citizens is set forth, without ignoring the problems of animal health and of the veterinarian commodities. A new and more complete definition of food is provided, according to which food is referred to anything that can reasonably be swallowed. Consumer trust must be sought after and safeguarded, since it was undermined by several emergencies (e.g., BSE) that have brought the perception of food safety in the EU to a very low level. Lastly, the European Authority for Food Safety was created to guarantee the scientific correctness of Risk Analysis (RA);
- finally, EU Regulations 852, 853, 854, and 882 [17-20], which make up the so-called "Hygiene Package", were created in April 2004. Although not directly connected to food business rules, Regulation 2073/2005 was passed. This last is a fundamental measure in defining the new microbiological thresholds for risk analysis on many food matrixes. Overall, the Hygiene Package organically revised many topics that had already been the subject of legislation. It abolished several directives, widening and perfecting the provisions with a view to new economic and technical logic.

In particular, Regulation 852/2004 "reassesses" the application of the HACCP system by extending it to the control of primary production. It widens the horizons of the manuals of Good Manufacturing Practices (GMP) through the adoption of EU manuals. This regulation also reinforces the roles of the Permanent Committee for the food chain and the health of animals by creating effective legislation for specific objectives for human - (rather than) animal - health. It conditions the safeguarding of traditional production methods and/or those methods subjected to particular geographic constraints to the respect of the health objectives mentioned in the document.

- Regulations 853 and 854/2004 apparently deal with only foodstuffs of animal origin. In reality they include and adopt criteria that can be extended to the entire food production. In particular, Regulation 854/2004 deals with responsibilities and tasks that are not at all new. It introduces the professional figure of official specialised assistants, who are similar to Italian prevention technicians. This new figure must carry out official controls by *auditing*, that is a systematic, independent examination to ascertain whether given activities and the correlated results conform to the dispositions provided for and whether these dispositions have been implemented efficaciously and are adequate for attaining specific objectives. "The Audit" considers the documentation concerning risk analysis presented by the economic operator more than the consequences of once used repressive rules.
- Regulation 882/2004 testifies to the evolution of the official controls from "merit" control to "method-procedure" control. This Regulation delineates the methodology of surveillance and high-profile analysis in accordance with the principles of proportioning of risk to product



quality/quantity. The identification of EU and national reference laboratories are noted. They must dictate uniform standards to all accredited national laboratories on the subject of official controls and self-management control. The logic is, once again, the ISO-type, in which values are sought that can be certified by a third party (in this case, the EU itself) in order to produce a set of common characteristics that can be shared by all the member states.

#### **Advantages for consumers and firms: Re-organisation or incompatibility?**

It is our opinion that a logical consequentiality that links together the principles and instruments described above exists. It appears obvious, but not predictable, that the EU fundamental mandates regard the protection of consumer health. Commercial logic must be subordinated to this aim. In fact, in a painstaking analysis of the strategies and instruments implemented for the realisation of consumer protection, it is often pointed out – see the preamble of Regulation 178/2002 [15] and of the norms which composes the “Hygiene Package” – that the boundary that separates the safety requirement from the necessity for free trade is not well delineated. Risk analysis could be the key to realising both of these objectives, even if the primary priority of law must be the health protection of all citizens [22,26,27].

In many passages of the legislative documents cited above there still seems to be a continuation of giving more attention to the freedom of businesses practices rather than to the health of citizen-consumers.

Thus, suspicions remain that food operators can and perhaps will influence future directives given the “democratic nature” of risk analysis (RA). Even if the two preliminary steps of RA – risk assessment and risk management – remain the patrimony of the food industry and, secondarily, become a tool for controlling health professionals, risk communication, i.e. direct communication, inside and outside of the firm, must remain in the hands of EU public authorities. Some authoritative authors (Soby, Covello, et al.) [8,9,27-30] have in fact mentioned that risk-management strategies necessarily are realised by “engaging stakeholders”, that is by the involvement of all the participants in the food chain, including citizen-consumers.

Moreover, problems emerge regarding education and motivation towards the correct application of the RA on the part of public risk analysers such as veterinarians, medical

hygienists, prevention technicians, and dieticians [19,20,31]. Until now health professionals have worked to attain, above all, objectives that guarantee correct technical judgements. However, the consumer has not understood this because it is not immediately translated into consumer rights. Consumers essentially demand three objectives: health security, food safety, and a request for nutritional content [11,30-32].

To solve this apparent dyscrasia among the risk analysers, political decision-makers, industrialists and citizens it will be necessary to create and manage correct strategies of communication, i.e. to make food messages simple [28-30].

There are still several knots to unravel. One of these concerns the application of the precautionary principle: according to us, on the one hand, it is seen as a safety measure, and on the other it is seen as a protectionist ploy.

The European Authority of Food Safety has a great deal of work to do. Its work will be neither conclusive nor decisive if it is not translated into simple, low-cost instruments of immediate interpretation, particularly for the monitoring of safety procedures at a local level and in the smaller commercial operative realities, which in many nations continue to represent a great part of food production firms.

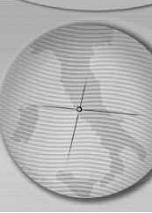
Some results have already been obtained. Industrialists have already assumed responsibilities to safeguard guarantees of protection of food safety. On the other hand, the logic of self management throughout the entire food chain – and the use of HACCP systems [33] – have gradually been imposed together with the parallel affirmation of the logic of quality in ISO-like certification<sup>3</sup>.

#### **Conclusions**

In comparison to the last few years, when any simple homogeneous application of methods of health safeguards regarding consumers in all of the EU states (HACCP) seemed a pure cultural abstraction, the “young” European Union has taken giant steps with regards to food safety. It has established an unquestionable right on the part of all its citizens to such protection.

A clear point of reference has been defined, in which all governments can and must make their own legal choices. They can defend economic interests regarding production, but must protect their own residents. Citizen representation has become guaranteed even through normative options: a Decision of the Commission on Oct. 9, 2003 instituted a European Consulting group of consumers and new and revised labelling of





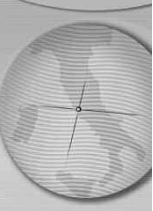
packaged food became law-Directive 2003/89. These options also foresee an appropriate consumer 'voice' within the government of the EU. Self-management has been a scientific tool as well as having been translated into instruments of management of the processes anticipated in the regulations. (Note: the attention to temperature control, in particular the maintenance of the cold /supra-cold chain, which is cited many times in regulation 852/2004 and others that have followed). There has been more and more attention paid to safety including aspects of quality according to the principles that are expressed in ISO norms 9000-2000 (i.e., attention should be paid to lawsuits, to client trends, to the satisfaction of the consumer).

Much work remains to be done. The first set of problems with which the enlarged Union will be dealing with regards the practical application of the principles described above to the States that have recently joined the Union (from Eastern Europe, etc.). Their traditions in the sphere of official controls, self-awareness of citizen-consumer rights, the use of quality logic not subordinated just to economic logic, necessarily represent a step backwards with respect to the "historic" states of the EU [34,35]. Lastly, there is the point that the European Authority for Food Safety will have to deal with very attentively and with overriding objectivity; the problem of the capacity of the HACCP-instrument to manage the numerous aspects of food safety [33,36,37]. Up to now, the scientific literature on this topic has been considered too "young" and too scarce to be able to express itself in any conclusive manner in any public health system that is searching, with always greater vigour, for evidence of the effectiveness of the EU responses and interventions.

It is necessary, therefore, to maintain those promises that can be viewed in recent food laws and to underwrite a "value-related pact" in which the EU government and the scientific community above all commit themselves to respecting its citizen-consumers. These citizens are now more and more often claiming their own right to make informed choices regarding food and nutrition.

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