THE EUROPEAN UNION FOOD SAFETY SYSTEM: PRINCIPLES, PROCEDURES, ORGANIZATION AND SCIENTIFIC BASIS

Vittorio SILANO

Medical School, II University of Rome, Italy

Miami, 20 January 2013
The European Union has reached its current status through a long-term process involving a growing number of Member States.

- Since 25 March 1957: Belgium, Italy, Luxembourg, France, Netherlands and Germany;
- Since 1 January 1973: Denmark, Ireland and United Kingdom;
- Since 1 January 1981: Greece;
- Since 1 January 1986: Portugal and Spain;
- Since 1 January 1995: Austria, Finland, Sweden;
- Since 1 May 2004: Cyprus (Greek part), Czech Republic, Estonia, Hungary, Latvia, Malta, Poland, Slovakia and Slovenia;
- Since 1 January 2007: Bulgaria, Romania

Between the Treaty of Rome, establishing in 1957 the European Economic Community (with 6 Member States), and the Treaty of Lisbon in 2009, currently applicable to the European Union (EU) (with 27 Member States), there are as many as 52 years and many Treaties through which the legal basis of this Organization has been amended several times, resulting in a substantial enlargement and strengthening.
THE CURRENT SYSTEM OF FOOD/ FEED SAFETY IN THE EUROPEAN UNION (EU)

In 2002, Regulation (EC) n. 178, a framework modernization legislation applicable to all stages of production, processing and distribution, export/import of food and feed (from farm to fork) has:

- adopted innovative principles, procedures and organizational arrangements to protect human/animal health and consumers’ interests in relation to food/feed and ensure the functioning of the internal market;

- established the European Food Safety Authority (EFSA), a new scientific Agency competent for risk assessment and communication;

- marked the start of the deep revision, updating and integration process of the existing specific food/feed safety European regulations, resulting in the adoption of a high number of innovative measures.
PART I - GENERAL PRINCIPLES IN THE FOOD/FEED LAW: RISK ANALYSIS

- Food/feed law is based on risk analysis consisting of risk assessment, risk management and risk communication. Risk is a function of the probability and the severity of an adverse health effect, consequential to a hazard.

- Risk assessment steps are: hazard identification and characterization, exposure assessment and risk characterization, based on scientific evidence and on excellence, independence, objectivity and transparency.

- In their decision-making, risk managers have to take into account the results of risk assessment and, in case of no compliance, provide explanations (see Cloning and GMOs).
GENERAL PRINCIPLES IN THE FOOD/FEED LAW: PROPORTIONALITY, NON-DISCRIMINATION, COHERENCE AND RE-EXAMINATION

• **Proportionality** (i.e. among different measures to achieve a specific safety objective, the less restrictive one should be adopted. Risk-benefit analysis should be considered a specific expression of such a principle in risk management).

• **Non discrimination and coherence** (i.e. comparable cases should be managed with similar approaches and new situations should be managed with approaches coherent with previous ones).

• **Re-examination** (i.e. risk and related management need to be re-assessed whenever new relevant data become available).
GENERAL PRINCIPLES IN THE FOOD/FEED LAW: TRASPARENCY

• **During the preparation, evaluation and revision of food law**, open and transparent public consultation, directly or through representative bodies, shall be held (except where the urgency of the matter does not allow it).

• **Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health**, public authorities shall take appropriate steps, depending on the nature, seriousness and extent of that risk, to inform the general public of the nature of the risk to health and of any other element.

• **Many obligations aiming at ensuring transparency of risk assessment apply to EFSA’s organization and procedures.**
GENERAL PRINCIPLES IN THE FOOD/FEED LAW: THE PRECAUTIONARY PRINCIPLE

- **When**, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

- The application of precautionary principle has resulted to be the most controversial: (i) «zero tolerance» for colibacteria in a pasteurized milk product (Melkunie case) or for *Listeria monocytogenes* in fish products devoid of chemical preservatives (*Hahn Case*); (ii) the destruction of fish meal presumably contaminated with mammalian bone fragments (Bellio case) and the total ban of the use of specific antibiotics as feed additives.
GENERAL PRINCIPLES IN THE FOOD/FEED LAW: CLEAR RESPONSIBILITIES OF FOOD/FEED BUSINESS OPERATORS

Food/feed business operators have:

- the responsibility to prevent that, through their activities in the food/feed chain, unsafe (risky) products enter the market;

- a key role, not only in complying with relevant safety regulations, but also in carrying out risk assessment in relation to their activities;

- the responsibility of ensuring systems which allow traceability of food and feed products to undertake, when needed, withdrawal and recall;

- the duty of collaborating with risk managers in case of urgent, emergency or crisis response and of notifications through the RASFF.
PART II- THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

- EFSA was established in 2002, as the EU Scientific Agency in charge for risk assessment and risk communication for the all food/feed chain as well as for animal and plant health.

- The analysis of the specificities of the EFSA’s legal basis, structure and organization clearly indicate that EFSA represents the distillation of many lessons learnt from previous experiences (e.g. BSE) and a major step forward in the development of scientific advice provision based on excellence, independence, objectivity and transparency.

- The scientists working for EFSA are assembled in ten Panels with sectoral competences (i.e. AHAW; ANS; BIOHAZ; CEF; CONTAM; FEEDAP; GMO; NDA; PLH and PPR) and in one Scientific Committee, competent for scientific coordination and multi-sectoral tasks.
THE SCIENTIFIC PANELS AND SCIENTIFIC COMMITTEE OF EFSA

• About 20 qualified scientific experts, coming from the Academia and other scientific Institutions within and outside the EU (i.e. third countries), are appointed in each EFSA’s Scientific Panel for a term of three years, following a selection process, mainly based on proven scientific excellence within needed disciplines, among all the responders to a specific call for manifestation of interest and their CVs.

• At the beginning of each three-years term, a chairman and two vice-chairmen are elected by a secret ballot of all the members of each Panel/Committee. Ad hoc expert working groups are also established as needed by making use of the EFSA’s expert data base including thousands experts.

• The Scientific Committee consists of the chairs of the 10 Panels and six external members selected through the above-mentioned procedure. Chairs and vice-Chairs are also elected.
INDEPENDENCE OF EFSA’S EXPERTS AND MANAGEMENT BOARD

• Therefore, scientists providing opinions for EFSA, are not EFSA’s employees, whereas the EFSA’s staff makes possible the work of these experts within the EFSA organizational framework. Moreover, appointed experts may remain in office for only two consecutive terms, in any case following two renewed ad hoc applications and selections.

• Similarly, the members of the EFSA’s Management Board are not representing Member States, but are selected among qualified volunteers with a procedure involving also the European Parliament.

• Ad hoc policy for avoiding conflicts of interest of the experts appointed in Panels/Committee and in working groups have been adopted based on annual and case by case declarations of interests and on a complex screening procedure that may end up with the partial or complete exclusion of the expert already selected due to the scientific value.
THE ANNUAL DECLARATIONS OF INTERESTS

• The annual declaration deals with current activities and those completed in the last five years concerning: (i) Ownership or other investments, including shares; (ii) Membership of a Managing Body or equivalent; (iii) Membership of a Scientific Advisory Body; (iv) Employment; (v) Consultancy/advice; (vi) Research funding; (vii) Intellectual property rights; (viii) Other membership or affiliation; (ix) Interests of close family members.

• The analysis of the annual declaration of interest may result in the ineligibility as an expert or as a chair or vice-chair in spite of the high professional expertise.

• In addition to the experts, annual Declarations of Interests are made also by all members of the EFSA’s Management Board and Advisory Forum.

• All the Annual Declarations are published in EFSA's in the Declaration of interests database.
Other declarations of interests

• All EFSA experts are also asked to declare any specific interests which might be considered prejudicial in relation to any specific item on the agenda of any meetings they attend. Any interests declared is reported in the minutes of meetings.

• If a conflict of interest is identified, it is recorded in the minutes and EFSA takes the measures specified in the procedure for handling conflicts of interest, generally consisting in the exclusion of the expert from the discussion of the agenda item.

• *Ad hoc* policies and guidance documents on how to avoid possible conflicts of interests have been adopted and published by EFSA.
OTHER MEASURES TO ENSURE EFSA’S INDEPENDENCE

• EFSA has a clear accountability to the European Institutions (i.e. European Commission, Parliament and Member States) and responds to their requests as well as self-tasking;

• The EFSA budget (i.e. about 80 millions euro per year) is decided, in the framework of the yearly European Commission budget, by the European Parliament;

• Some regulations, such as that on nutritional and health claims, foresee the possibility of conveying comments to the European Commission on EFSA’s opinions and receiving replies.
SPECIFIC FEATURES OF EFSA AND ITS MISSION IN RISK ASSESSMENT

• The EFSA’s approach to risk assessment consists in applying formally-adopted methodologies, often through a public consultation process and publication in its Scientific Journal. In case of public consultations, any comment not accepted is subject to a specific reply by EFSA.

• EFSA risk assessment opinions and other documents, produced in response to requests from the European Commission, Parliament or Member States or decided through self-tasking, are adopted by consensus (minority opinions, if any, are always noted, with their motivations, in the text of the opinion).

• Each risk assessment opinion is published immediately after adoption in the EFSA’s Journal, in a standard format making possible the full understanding of the underlying reasoning.
SPECIFIC FEATURES OF EFSA AND ITS MISSION IN RISK ASSESSMENT

• To carry out risk assessment throughout the whole food/feed chain, EFSA’s Scientific Committee and Panels have adopted as many as about 100 innovative/harmonized methodologies through public consultations and have applied them to thousands cases.

• Between 2003 and 2012, more than 3000 scientific outputs have been published in the EFSA Journal. As many as 2200 of these outputs are scientific opinions adopted, since EFSA’s inception, by its Scientific Committee and Panels in their respective areas of competence, whereas the remaining ones are mainly technical reports and documents on related issues.

• All the EFSA’s opinions and other documents can be easily accessed at no cost on line in the EFSA Journal.
MAIN PRIORITY ISSUES IN THE RISK ASSESSMENT AGENDA IN THE EU

- Genotoxic and carcinogenic substances (EFSA 2005 and 2012);
- Identification of emerging risks (EFSA 2007, 2012, on going);
- Benchmark Dose (BMD) approach (EFSA 2009);
- Risk/benefit assessment of food (EFSA 2010);
- Nanomaterials (EFSA 2009, 2011, on going);
- Genotoxicity testing strategies (EFSA 2011);
- Traditional botanical food supplements and the Compendium (EFSA 2004, 2009a, 2009b, 2010 and 2012, on going);
- Threshold of Toxicological Concern (EFSA 2012);
- Endocrine disruptors (on going);
- Chemical mixtures (on going);
- A harmonised risk assessment approach applicable, although with some specificities, throughout the all food/feed sector;
- Constant updating of adopted opinions in relation to new data.
### PART III: IMPLEMENTATION OF THE PRINCIPLES, PROCEDURES AND ORGANIZATIONAL ARRANGEMENTS PROVIDED BY REG. (EC) 178/2002 THROUGH SECTORIAL REGULATIONS

<table>
<thead>
<tr>
<th>Intentionally-added substances to food /feed</th>
<th>Non-intentionally-added substances to food/feed</th>
<th>Food/Feed Hygiene and Control</th>
<th>Other sectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Flavourings (Reg.872/2012)</td>
<td>• Feed chemical contaminants (Directives 32/2002-6/2010) Biological contaminants (R. 2073/2005)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Enzymes (Reg.1332/2008)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Plant protection products (Reg. 396/2005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Food packaging materials (Reg. 1282/2011)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Intentionally-added substances to food and feed**: Additives (Reg. 1129 and 1130/2011), Flavourings (Reg.872/2012), Enzymes (Reg.1332/2008), Plant protection products (Reg. 396/2005), Food packaging materials (Reg. 1282/2011).


- **Other sectors**: Novel Foods (258/1997-on going), GMOs (Reg.1829 and 1830/2003), Voluntary food nutritional and health claim (Reg.1924/2006 and 432/2012), Mandatory food labelling (Reg.1169/2011).
Milestones in food safety in the EU: approach to food additives (2008-2020)

- Definitions, prescriptions, uses and labelling of food additives (Reg. 1333/2008);
- Uniform procedure for authorizing food additives (Reg. 1331/2008 and 234/2011) including very detailed data requirements;
- Purity specifications for food colours (Directive 3/2011) and additives other than food colours (Directive 67/2010);
- Positive list of permitted food additives in specific food categories and maximum levels as well as in food additives, flavourings and enzymes (Reg.1129, 1130 and 1131/2011);
- The intensive systematic and non-systematic re-evaluation programme of already authorized food additives.
- Scientific opinion for submission of food additives evaluations (EFSA 2012)
EFSA’s guidance document on the evaluation of the applications for authorisation of a new food additive or to a modification of an already authorised food additive

• This document consists of four sections: (i) chemistry and specifications; (ii) existing authorizations and evaluations; (iii) uses and exposure assessment; and (iv) toxicological studies.

• The assessment of the exposure to food additives is based on information on known or anticipated human exposure to the proposed additive or toxicologically relevant components of the additive from food, and any other potential dietary sources.

• A minimal toxicity dataset applicable to all additives has been developed under Tier1, while Tier2 tests, generating more extensive data, are required for compounds demonstrated to be absorbed and/or (geno)toxicity in Tier1 tests. Tier3 tests should be performed on a case-by-case basis, taking into consideration all the available data, to elucidate specific endpoints identified as needing further investigation.
NON SYSTEMATIC RE-EVALUATION PROGRAMME OF FOOD ADDITIVES (2000- ON GOING)

- Twenty-seven additives (E 952, E 210-213, E249-252, E 901, E 473-474, E 234.235, E 218-219, E 214-215, E 173, E 160d, E 129, E124, E 122, E110, E 104, E 102, E 968, and E 320) have been re-evaluated so far and the ri-evaluation of aspartame is on going (a public consultation has started only a few weeks ago).

- ADIs withdrawn: Red 2 G and propyl-parabens

- ADIs reduced: Sunset yellow FCF (from 2.5 to 1.0 (temporary) mg/kg bw and day), Ponceau (from 4.0 to 0.7mg/kg bw and day) and Yellow quinoline (from 10.0 to 0.5mg/kg bw and day).
THE EU SYSTEMATIC RE-EVALUATION PROGRAM OF FOOD ADDITIVES STARTED in 2010 (REG.257/2010)

- An essential tool of the systematic re-evaluation program is the possibility for EFSA to undertake a timely call for data on additives undergoing re-evaluation with the activation of the interested food companies and their associations in providing data.

- Five food colours (E 123, E 151, E 154-155 and E 180) were re-evaluated by 15 April 2010 and 13 additional food colours (E 100, E127, E132-133, E142, E159a-159d, E 161b, E 161g and E170) by 31 December 2010.

- ADIs withdrawn: Brown FK and Litolrubine

- ADI significantly reduced: Amaranth (from 0.5 to 0.15 mg/kg bw and day), Brilliant Blue FCF (from 10 to 6 mg/kg bw and day) and Caramel E 150c (from 200 to 100 mg/kg bw and day)

- All the remaining 16 food colours as well as conservatives and antioxidations (E 200-203, E 210-215, E218-E252, E 280-E285, E300- E 321 and E 586) to be re-evaluated within 31 December 2015;

- All the emulsifying stabilizing and gelifying agents (E 322, E 400-419, E 422-495, E 1401-1451) as well as E 551, E 620-625, E105 ans E 1103) to be re-evaluated within 31 December 2016;

- All the remaining food additives other than sweeteners to be re-evaluated within 31 December 2018

- All food sweeteners (except aspartame) to be re-evaluated within 31 December 2020.
Milestones in food safety in the EU: approach to food flavourings (1996-2012)

- In 1996, when food flavourings were mainly used on the basis of the tradition and of limited data, Regulation (EC) No 2232 established the procedure for drawing the Community list of authorized food flavourings following individual evaluation of requested safety data;

- Since then, a complex risk assessment methodology has been applied to all flavourings for whom interested food companies organizations have provided the data requested for the safety evaluation;

- In 2012, Reg. 872 has provided the new EU list of flavourings authorized for use in food, in some cases with restrictions. It includes over 2,100 substances, whereas all those not in the list have been prohibited after a phasing out period. Moreover, 400 additional substances will remain on the market until EFSA concludes their evaluation,
• THANK YOU VERY MUCH FOR YOUR KIND ATTENTION