

SCIENTIFIC COMMITTEE & ADVISORY FORUM UNIT

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DEFINITION AND DESCRIPTION OF “EMERGING RISKS” WITHIN THE EFSA’S MANDATE

(adopted by the Scientific Committee on 10 July 2007)

Having regard to Articles 23f and 34 of Regulation (EC) 178/2002, an emerging risk to human, animal and/or plant health is understood as a risk resulting from a **newly identified hazard** to which a significant exposure may occur or from an unexpected **new or increased** significant exposure and/or susceptibility to a **known hazard**.

An assessment of emerging risk is characterized by the **early detection** of facts related to that risk derived either from research and/or from monitoring programs or episodic observations. Assessment of emerging risks must be flexible to accommodate changes in the conditions that affect the risks and also improvements in the methods of detection. Assessment of emerging risks is distinct from the assessment of risks under emergency (or crisis) conditions, as the latter are dealt with through established Commission procedures (*)¹.

The evidence supporting the identification of an emerging risk should preferably be in the form of an “indicator” (e.g. measurement and/or observation) and of a trend over time or space. Ideally, an “indicator”, should be reliable, sensitive, quantifiable and should provide the information on the nature of the hazard (agent/process involved) and the source of the risk. For evaluation of an indicator, its relevance and value for predicting problems affecting human health, animal health, animal welfare and/or plant health should be confirmed. Moreover, tools and methods for the detection and measurement of an indicator and for effective monitoring should be in place.

Indicators may point to a specific emerging risk in different ways, either directly or indirectly related to the food chain. For instance, the identification of the lack of safety conditions making possible or likely the intermittent or sustained release of a toxic or radioactive agent from a chemical or nuclear power plant, respectively, is clearly an indicator of an emerging risk. The detection at significant levels of toxic or radioactive chemicals on or in vegetables grown near the releasing plant, provides however a more direct indication of the nature and extent of the emerging risk. Similarly, the detection of

¹ Commission Decision 2004/478/EC concerning the adoption of a general plan for food/feed crisis management. Official Journal of the European Union L 160/98.

an exotic virus in an animal or plant population would be a form of an indicator, while an outbreak of human, animal or plant disease caused by that virus would be a more direct indicator.

Risks that do not conform with the above definition include risks characterized by a sudden appearance, such as food or feed contamination episodes due to e.g. events associated with bioterrorism, or the sudden release of a toxic or radioactive cloud. Such events in fact are likely to be dealt with under emergency procedures that include the provision of scientific advice. Similarly, emerging risks do not include risks associated with the inadvertent or accidental intake of food or feed that are not in compliance with recognized safety requirements, although immediate action may be needed to prevent further exposure or damage to the health of patients.

Evaluation of data concerning specific indicators normally requires the gathering of additional data, in order to be properly assessed and so to be of use. For instance, the occurrence of exotic viruses in specific animal population groups or products is likely to be indicative of an emerging risk, but other factors may need to be determined in order to define the extent and implications of such a risk.

EXAMPLES OF EMERGING RISKS AND THEIR INDICATORS

The following are examples of emerging risks in relation to the areas covered by the EFSA's mandate:

1. New research data indicating previously unknown toxic properties of substances occurring in food or feed.
2. New trend in diseases of unknown etiology affecting humans, animals or plants.
3. Occurrence or outbreaks associated with exotic threats such as those posed by serotype 8 of Bluetongue, or the Flavivirus, Usutu virus, or the emergence of multiple antimicrobial-resistant Salmonella or Campylobacter spp.
4. Analytical and diagnostic results obtained with new methods capable of detecting viruses as causes of foodborne illnesses that were previously rarely diagnosed because of the lack of adequate methods.
5. Conditions likely to lead to consequential events e.g.:
 - (i) major energy black outs which affect large geographical areas;
 - (ii) identification of the lack of safety conditions that increase the likelihood of release of toxic or radioactive clouds from a chemical or nuclear power plant, respectively; and
 - (iii) detection of highly toxic contaminants in an irrigation water reservoir.

6. Unusual agronomic and weather conditions capable of promoting the proliferation of toxin-producing fungi (e.g. aflatoxins, ochratoxins and patulins), the production of toxic metabolites by plants (e.g. glycoalkaloides, cyanogenic glucosides, furocoumarines), or enhancing the aggressiveness of less virulent pathogens.
7. New plant production methods, e.g. new harvesting techniques, storage or transportation methods as well as new biotechnological techniques may promote new (unexpected) or re-occurring stress related natural toxins in plants and plant products.
8. New animal production methods for delivering food producing animals but which are capable of promoting new (unexpected) or re-occurring production-related infections and non-infectious diseases and stress reactions in animals, and impairing their welfare.
9. Unexpected adverse effects on the environment resulting from emission of liquid, solid and airborne pollutants, including antimicrobial residues, or from pesticides/GMOs which affect non target species.
10. Occurrence of outbreaks of infestations with herbivorous plant pests associated with climate change, species hybridization.
11. Symptomless carriers of pests, for which no routine detection methods are available, able to transfer the pest to native plant species.

In each case the indicators which may be relevant for the above-mentioned examples of emerging risks are likely to differ from one example to another. Depending on the specific example, relevant indicators may derive from scientific research monitoring activities laboratory investigations and data from organizations competent in energy provision, weather forecasting and industrial accident risk analysis.