Annex B – Different frameworks of risk assessment

It may be confusing that at least two different risk assessment frameworks are used, each with its own definitions. One is common in engineering and accident prevention, in particular the framework adopted by ISO for the safety of machines (ISO 12100) and for product safety in general. Another is used for food and feed safety (adopted by the WHO and FAO), and for chemical safety (WHO IPCS, TGD). As RAPEX notifications may involve both physical hazards and chemical substances, market surveillance authorities may encounter both frameworks. In this annex, we briefly explain the differences between these two frameworks.

Schemes of the risk assessment process

A. ISO 12100, ISO/IEC Guide 51:1999 and ISO/IEC Guide 73:2002

Risk management			
	Risk assessment		
		Risk analysis	
			Source[1] identification
			Risk estimation
		Risk evaluation	
	Risk treatment		
		Risk avoidance	
		Risk optimization	
		Risk transfer	
		Risk retention	
	Risk acceptance		
	Risk communication		

[1] in Guide 51, the term 'hazard' is used, defined as a potential source of harm.

The most general term here is "Risk management", which consists of the elements "Risk assessment", "Risk treatment", "Risk acceptance" and "Risk communication". Within "Risk assessment in turn two steps are distinguished: "Risk analysis" and "Risk evaluation"; etc.

B. IPCS Risk assessment Terminology, Key Generic Terms used in Chemical Hazard/Risk Assessment; WHO/FAO framework for risk analysis in food; EU Technical Guidance document on Risk Assessment (TGD)

Risk analysis		
	Risk assessment	
		Hazard identification
		Hazard characterisation[2]
		Exposure assessment
		Risk characterisation
	Risk management[3]	
		Risk evaluation
		Emission and exposure control
		Risk monitoring

	Risk communication	
		Interactive exchange of information about risks

[2] includes dose-response assessment; TGD uses 'effects assessment' as an overall term for hazard identification and dose-response assessment
[3] WHO/FAO have four components here: preliminary risk management activities; evaluation of risk management options; implementation of risk management decision; monitoring and review.

Here, the general term is "Risk analysis" consisting of the activities "Risk assessment", "Risk management" and "Risk communication"; etc.

Due to the different ways of dividing the process, it is not possible to simply make a correlation table to translate terms. For example, the ISO/IEC term *risk estimation* is more or less a combination of *hazard characterisation* and *exposure assessment*. *Risk evaluation* in the ISO/IEC framework can be compared with *risk characterisation* combined with *risk evaluation* in the IPCS terminology.

The following definitions are used in the IPCS document:

Risk
The probability of an adverse effect in an organism caused under specified circumstances by exposure to an agent.

Agent
Chemical substance, which may cause adverse effects such as injury or damage to health.

NOTE: in this definition, we extend the meaning of 'agent' from chemical substance to include physical hazards]

Risk assessment
A process intended to calculate or estimate the risk to a given target organism, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target organism.

The risk assessment process includes four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization.

Hazard identification

The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub) population.

NOTE: the result of this step should be a number of scenarios that may occur including the health outcomes (endpoints).

Hazard characterisation

The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

NOTE: the result of this step should be a justified conclusion about the severity of the adverse effects. The tool used fort this in the RAPEX Guidelines is the injury table.

Exposure assessment
Evaluation of the exposure of an organism, system, or (sub)population to an agent.

NOTE: General relevant parameters are frequency of contact with the product, exposure pathways, behaviour of person and vulnerability of person.

For chemical substances, exposure is usually expressed as mg substance per kg body weight that is taken up by inhalation, dermal contact or ingestion; specific parameters include e.g. evaporation or diffusion.

For physical hazards, relevant parameters can be the probability that a scenario will occur, energy transferred to a body part, etc.

Risk characterisation

The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions.

NOTE: the result of this phase is a conclusion on the expected risk level in terms of severity and probability. It may include a quantitative probability distribution of adverse effects, and confidence intervals or sensitivity analysis.