



PERGAMON



Meeting Report

The Risks of Risk Assessment in Foods

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This report is the outcome of a workshop organized by the International Life Sciences Institute–European Branch (ILSI Europe), on the “Risks of Risk Assessment in Foods” held on 18 February 1998 in Brussels, Belgium. The meeting discussed Risk Assessment as the principal means by which the European Union evaluates the potential harm arising from the use of existing and new products. The experiences of the parties involved have often shown that the concepts underlying risk assessment are complex and not always fully understood. There is an urgent need to familiarize industry, policy makers and the scientific community with developments in the basic principles and terminology of risk assessment. Therefore, the workshop aimed to review key areas in risk assessment and to provide an open forum for learning and discussion between all interested parties. © 1999 Elsevier Science Ltd. All rights reserved

Introduction—Professor M. Roberfroid (Catholic University of Louvain, Belgium): Workshop Chair

The provocative title of the workshop was suggested by Professor A. Dayan (St Bartholomew's and the Royal London School of Medicine and Dentistry, UK). Risk for man is a function of the probability of an adverse health effect and the severity of that effect consequential on a hazard in food, and can be predicted from determination of the hazard and human exposure to this hazard. For obvious reasons the experimental model cannot be humans, so there will always be the need to extrapolate the risk to man from the results of toxicological experiments in animals or *in vitro* systems. The process of toxicological evaluation is divided into two parts, one being the science-based characterization of adverse effects, which is called “dose–response assessment”, and the second being more the art of utilizing the scientific data base to predict risk which is called “exposure assessment” and “risk characterization”.

The human need for food is obvious, and food will present some risk because all potential hazards cannot be eliminated. Therefore, there is a clear need to be able to assess the risk of food consumption in order to protect the consumer.

Risk assessment is a popular topic in the media when, more often than not, the spectacular but not necessarily the most important risks are covered. The basis of the risk assessments carried out for food must be explained in a transparent way. In

this manner it will be possible to share the responsibility for risk assessments and learn together means by which to improve the way they are carried out.

Risk assessment methodology has developed in different ways in the different sectors of industry and regulatory activity, which can lead to confusion. Risk assessment does not provide a magic toolbox, but it can identify risk factors to help risk management. It is not a static science, indeed it requires continuous review to ensure the latest developments are covered. Better scientific understanding leads to lower risks from risk assessment and an improved consistency of decision making.

How risks arise—Professor R. Kroes (RITOX–University of Utrecht, The Netherlands)

Risk is the probability of an adverse effect in humans from a given exposure to a (mixture of) substance(s). However, risk is a relative word since the risk may be real or it may be perceived as such by society. Perceived risks may lead to expenditure of public and private funds, which may prove to be unnecessary once the perceived risk is evaluated in real quantitative terms.

Examples were given of such perceptions in The Netherlands, the consumption of transgenic maize expressing the kanamycin resistance gene was perceived as a danger to public health from the belief that resistance to antibiotics would increase. Such a flawed assessment ignored the existence of kanamycin resistant organism already present in the gut prior to the introduction of the new maize variety.

The development of a perceived risk often follows a predictable pattern; there is a scientific statement, followed by amplification in the press; this leads to political involvement and ultimately government action which 'validates' the perception of the real risk.

Some examples of risks to the public were reviewed and lessons drawn from each of the following.

The Spanish Toxic Oil Syndrome in the early 1980s where over 20,000 cases of atypical pneumonia were reported and more than 400 casualties occurred. Extensive investigations implicated ingestion of denatured rapeseed oil which had been illegally sold for human consumption as responsible, but the cause was never proven. The occurrence of sick people was the trigger for the concern, the degree of risk was altered by government intervention but it was not possible (even today) to carry out a quantitative assessment of the risk to which people were exposed.

The detection of dioxins in milk produced by cows grazing in the proximity of waste incinerators in The Netherlands in 1989 was reviewed. This finding became public and received a lot of attention in the press, which led to concern from politicians and the Government having to manage the risk. The perceived risk resulted in investment to improve the performance of incinerators and a standard was set for dioxin in milk.

The detection of the *Fusarium* mycotoxin fumonisin B₁ (FB1) in 98% of samples of maize imported into The Netherlands was a case where a perceived risk could be generated if the data were considered without full knowledge of the risk assessment process. A risk assessment was carried out using the median value of contamination and establishing the *per capita* intake of maize for the general population, "eaters only" and a high risk group (people with intolerance to gluten that replace several cereals in their diet with gluten-free maize and rice). When comparing the calculated Tolerable Daily Intake (TDI) to the calculated intake of FB1, it was concluded that "negative effects on the public health due to FB1 cannot be ruled out for certain groups in the population of The Netherlands".

This assessment is valid for "eaters only" and the gluten intolerance high risk group. A new, unjustified, perceived risk might occur, if this conclusion were reported with no appreciation that the TDI could be exceeded by a factor of less than 10 whereas the uncertainty factor used in the derivation of the TDI varied from 100 to 400.

These cases illustrate the urgent need to implement better quantitative measures for risk assessment, ideally based on a mechanistic understanding of the hazards in order to establish the probability of an adverse effect at a given exposure: a real RISK.

In a lively question session, the transformation of risk assessment into risk management policy was discussed. The risk managers need detailed information about the choice of possible options. Better quantification of risks and the associated costs of risk management options will lead to improved decision making. The more such information is available, the more risk managers are urged to do something.

Current definitions and approaches to risk assessment of food borne hazards—Dr G. Moy (World Health Organization, Switzerland)

It is the task of governments and the food industry to keep the level of risk in the food supply to a minimum level that is practical and technologically feasible. Perhaps the most useful tool available to determine realistic and socially acceptable risk levels for foodborne hazards is risk analysis. Risk analysis consists of risk assessment, risk management and risk communication processes. Risk assessment offers not only a scientifically sound and consistent method to estimate human risk, but also a logical framework for organizing data and allocating responsibility for analysis.

With implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) by the World Trade Organisation, the use of sound scientific risk assessment has become the foundation for health and safety requirements for food safety worldwide. Furthermore, the standards, guidelines and recommendations adopted by the Joint Food Agricultural Organisation and the World Health Organization (FAO/WHO) Codex Alimentarius Commission have become the *de facto* international reference in considering whether risk management decisions by governments may constitute non-tariff barriers to trade.

A number of definitions of risk were discussed, for example 'An estimate of the likelihood of occurrence of an adverse health effect consequent to a hazard in food', and for hazard 'A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse effect.' It is considered unlikely that there will be complete agreement on terminology. The risk manager provides the framework for the risk assessment process, for example by establishing default assumptions. The Delphi approach is preferred over consultation by Codex for gaining acceptance for terminology.

Over the last 3 years, FAO and WHO have convened a series of consultations to promote a more consistent and transparent approach to risk analysis by their member countries and Codex.

The importance of definitions of terminology were also discussed; they should be based on function (form should follow function). The definitions should help to shape thought processes otherwise they may impede scientific thinking.

The workshop was reminded that definitions are tied to a particular language and when translated into other languages must communicate the thoughts behind the definition

Ingredients, additives and contaminants—exposure and threshold in risk assessment—Dr S. Barlow (UK)

Risk assessment becomes the centre of attention for food consumers when it goes wrong, when they mistrust it or when they do not like the outcome. There is also a critical view that risk assessment is not worthwhile because it is based on feeding huge amounts of chemicals to rats which may not be the appropriate model for humans.

The thinking of René Truhaut together with other scientists working for the Joint FAO/WHO Expert Committee on Food Additives (JECFA) developed the concept of Acceptable Daily Intakes (ADI) for food additives in the early 1960s. The ADI concept was a further development of the work of Lehman and Fitzhugh, from the US Food and Drug Administration, in the early 1950s. Their approach was based on adding a large safety factor to the maximum safe dose determined in long-term animal studies to determine the safe intake for humans. Thus, the most frequently used procedures for risk assessment have changed little over the past 40 years. Does this reflect a lack of progress in the science of risk assessment or is it an indication that the methods have successfully stood the test of time?

The use of safety factors in risk assessment was illustrated by reference to an example from engineering. In 1954, Andre Coyne designed and built a very elegant dam, called the thin arch dam. Within 5 years it collapsed, illustrating that the safety factors used were presumably too small to cover the uncertainties of the unusual design. The margin of safety built into engineering projects is often small, because the physical behaviour of material under stress is usually predictable. The lesson for risk assessment of food is that the greater the uncertainty of the risk, the greater should be the margin of safety needed to build into the prediction of a likely safe intake.

The risk assessment for foods is complicated by the biological systems involved, which, unlike engineering systems, can occasionally behave in unpredictable ways. For this reason it is usual to use conservative models, add in large safety factors and then still equivocate on whether a particular intake of a food ingredient is absolutely safe.

Such conservative approaches have served the risk assessor well in reducing the number of occasions when things go wrong. However, this approach can also cause problems for the risk managers who have to implement strategies for reducing risk. Difficult decisions must be made; for example, it may be impossible to reduce the level of a carci-

nogenic contaminant (e.g. aflatoxin) to a level in food that would protect all members of society. In other circumstances, a risk may be successfully reduced but at great financial cost. The cost of the risk reduction may not be acceptable to the final consumer—for example the recent ban of sale of beef on the bone in the UK. Risk assessment techniques indicated that only three out of 2.2 million cattle likely to be eaten in 1998 would actually have contained infected dorsal root ganglia. The public has been vocal in objecting to this legislative ban, stating that they wish to make their own decisions about such low risks.

The ADI is defined by JECFA as ‘the amount of a food additive, expressed on a body weight basis that can be ingested over a lifetime without appreciable risk’. The inherent uncertainty in this statement stems from the use of the term ‘appreciable risk’. The assumption is that intake of a food ingredient below the ADI is safe for humans, but safe is not the same as zero risk.

Though there are critics of these classical risk assessment procedures, their application does, in most situations, offer good protection to the food consumer. In the case of food additives, there are not only relatively conservative ADIs but also confirmation from intake surveys that intakes of most additives are well below their respective ADIs. In cases where intakes approach or perhaps exceed the ADI then the EU has the appropriate legal framework to limit maximum use levels in foods and restrict the foods in which the additive can be used.

Some examples of risk assessments for components of food were reviewed:

Nitrate—A large safety factor was used to derive a very conservative ADI for nitrate largely because of the differences in which rat and humans handle nitrate in the body. Careful assessment of nitrate levels in foodstuffs, the frequency and amount in which they are consumed confirmed that even the 97.5th percentile consumers are within the ADI for nitrate intake.

Cyclamate—The value of human data in risk assessment is illustrated by the sweetener cyclamate. Cyclamate itself is not harmful but it is metabolized in the human gut to cyclohexylamine, which can cause damage to the testis in rats, dogs and monkeys. Comparison of the lowest doses resulting in testicular damage in the rat and monkey coupled with a careful assessment of the pharmacokinetics of cyclohexylamine enabled a determination of the levels in blood that result in damage to the testes. It was then possible to measure blood levels and clearance rates of cyclohexylamine in humans given different doses of cyclamate. In this way it was possible to determine the intake of cyclamate that will not result in testicular effects.

Canthaxanthin—This compound illustrates that traditionally used laboratory animals are not always good models for humans. This was discovered for

canthaxanthin because of its use by man for other purposes besides colouring of food: as a medical treatment for porphyria and as an oral cosmetic used to mimic a sun tan. Following administration of relatively large amounts in these two non-food uses, clinicians became aware that canthaxanthin deposited in the human retina. This had not been predicted from the laboratory animal tests. The current ADI for canthaxanthin was set applying a 10-fold safety factor to the dose in humans which just caused changes in the eye, which is also supported by recent monkey studies. The use of canthaxanthin in foods is very severely restricted and careful checks are made on human exposure to canthaxanthin from its use in animal feed.

The presentation was concluded with a review of the threshold of toxicological concern and its application in risk assessment. This approach is based on the concept that it should be possible to define an amount present in the diet for a chemical of unknown toxicity, below which it would not be expected to cause any adverse effects in man. Therefore it should be possible to scan the existing literature on toxicity and identify a threshold of no toxicological concern. In cases where human intake of a food component is below the threshold then no safety data need be generated (except perhaps for mutagenicity studies). This could be a useful approach for food packaging components, flavours and other food components where the intakes are very low.

In the US, a threshold of regulation set at 0.5 ppb has been adopted by the FDA for chemicals used in food packaging materials. This figure is based on extrapolation by mathematical modelling of data from acute, subchronic and carcinogenicity studies in animals and is highly conservative.

In answer to the questions posed at the beginning of the talk, it was concluded that risk assessment is based on a number of assumptions, all of which can and should be questioned. However, experience over time has shown that, in general, these are reasonable assumptions which can produce suitably cautious risk estimates. Because they are assumptions then they will not turn out to be correct all of the time.

Questions were raised about how intake surveys can account for variations in diet within Europe, and differences within population groups within the same countries. Each state will need to conduct intake surveys to assess local influences but if the Budget method, presently under discussion within Codex Alimentarius and the European Union, is adopted then this may reduce the need for detailed surveys.

Caution is needed for interpretation of those intake surveys based on the assumption that every food contained the highest possible levels of an additive or a contaminant.

Risks of microbial risk assessment—Professor M. van Schothorst (Nestlé, Switzerland)

Biological hazards arise from bacteria, viruses, fungi, protozoa, parasites and their metabolites which are present in foods at unacceptable levels. Most of them occur 'naturally' in plants, animals as normal components of fresh foods, raw materials and ingredients used for the production or preparation of food. In contrast to chemicals in food, biological hazards may increase or decrease and their risks for human health can often be prevented or minimized by the consumers themselves.

In cases where food has caused disease it was due to uncontrolled growth of micro-organisms. Consequently, prevention of foodborne microbial disease requires adherence to simple rules, namely preventing, eliminating or reducing the unacceptable growth, survival and spread of, or contamination with pathogens. This is the basis of the Hazard Analysis Critical Control Point (HACCP) concept, which is the basis for food safety management.

Microbial food safety can be managed without risk assessment, for example by raw material selection, product design, process control, good manufacturing processes, hygiene, good practices of food commercialization and use and HACCP.

Hazard analysis in HACCP involves collection and evaluation of information on hazards and conditions leading to their presence. Decisions can be taken about which hazards are significant for food safety and should be controlled. This is mostly a qualitative procedure, though some aspects such as sterilization or pasteurization can be quantified. The ILSI Europe decision tree can be used to determine the potential hazards of significance. Simple questions have to be answered such as: is the presence of a pathogen in a raw material probable? If the answer is Yes, then other questions dealing with survival, persistence or increase of the pathogen have to be addressed.

The risk assessment process is broken down into the four steps of :

- (i) hazard identification
- (ii) hazard characterization
- (iii) exposure assessment
- (iv) risk characterization.

Hazard identification and characterization—risk assessment of chemicals requires determination of the risk of the presence of a substance in a food and comparison with safe levels. Microbiological risk assessments start with a manifestation of the effect. People become ill after eating a food and the causative agent is identified through epidemiological investigations and laboratory analysis. It is important to determine the risk factors which were instrumental in causing the disease. These can be categorized into factors related to:

—the food [e.g. fat content, physical state (liquid or dry), background flora, buffering capacity]

—to the micro-organism (e.g. number, acid tolerance, adhesion, penetration and lesion factors, exotoxin levels)

—to the consumer (age, immune status, gastric acidity, nature of gut flora and pregnancy).

In hazard characterization, two categories of individuals have to be distinguished: those who belong to the normal population, and those who are more susceptible due to one or several of various risk factors. The impact (response) may vary from an acute diarrhoea or vomiting to chronic illness and even death.

Exposure assessment—this is based on assessment of prevalence of contamination in raw materials, survival of the microbes during processing, possibilities of recontamination, growth pattern, survival during preparation and growth prior to consumption. Many of these factors are difficult to estimate and quantify. Because of the many unknowns, microbiological risk assessment is in its infancy.

Risk characterization—it is necessary to define the micro-organism, its virulence and the target group of consumers with a knowledge of their consumption habits. It is then necessary to conduct quantitative food analyses, simulate the practices of distribution, preparation and use of the food. When available, the dose–response data can then be used to calculate the risk estimate with the attendant uncertainties.

The risks of risk assessment originate in part from the confusion over terminology. Risk analysis (including risk assessment) is a Governmental activity, which should not be imposed on the food production industry. Hazard analysis is an activity for producers or preparers of food in order to enhance safety. Moreover, risk assessment is not an element of HACCP, even if risk assessment may provide data which can be used in an HACCP study. There is a risk that risk assessment may be inappropriately imposed on the food industry.

Further risks arise from the misuse of risk assessment. Decisions may be based on inappropriate or absent data when wrong assumptions were made and uncertainties were not established. Risk assessments can be used as trade barriers, even when the WTO/SPS agreement specifies that risk assessment is the procedure to establish equivalence in food control.

Finally, when risk assessment data have been established by a government or a company, they may lead to credibility or liability problems. These data may be misinterpreted by laymen. To circumvent this risk, the establishment of food safety objectives as one of the risk management options should be encouraged.

However, risk assessment should be viewed positively since it may help us in decision making, in priority setting, in obtaining the necessary transparency and equivalence in food control. It may also improve consumer protection but it should be used with care, delicacy and wisdom.

Questions were asked about the possible move towards quantitative risk assessments in microbiology driven by risk managers, it was emphasized that quantitative techniques were not needed to ensure safe food but it was recognized that a push may come from this direction. It was stated that quantitative calculations were not required in the first instance. A better application of HACCP is preferred followed by some improvements towards quantitative risk analysis. One participant raised the much debated point of whether or not foods and meals as marketed, when ingested upon handling, meticulously complying with any label instructions, should be safe to all consumers, including the immuno-compromised segment of the population.

New issues need new approaches—Professor H.F. Woods (University of Sheffield, UK)

The questions posed in this presentation were as follows:-

- How robust are the current methods of risk assessment ?
- Do they need to be replaced or could they be refined and developed to make them more effective?
- Can the methods be applied to novel foods?

It was proposed that the methodology of risk assessment is robust enough to cope with the hazards associated with the intake of food chemicals which are best described as low-level delayed effect hazards but may not be entirely suitable for the assessment of novel foods.

The derivation of an ADI or Tolerable Daily Intake (TDI) for a contaminant has been well described and in general there is close agreement between expert committees within Europe when calculating and ADI or TDI for a particular chemical. In addition, there is little evidence that the application of the methodology has resulted in the failure to properly manage a significant chemical hazard.

In the UK the intake of food additives is surveyed by the Ministry of Agriculture, Fisheries and Food (MAFF) for both groups of additives and individual additives and other compounds through estimation of *per capita* intakes in man. For most additives, the estimates of *per capita* intake are less than 1% of the ADI for a 60-kg individual and in only five cases does the *per capita* intake exceed 10% of the ADI. This provides a feeling of reassurance, but there are circumstances where certain segments of the population may be at risk through

exceeding the ADI. These include those with toxicokinetic or toxicodynamic sensitivities (e.g. polymorphisms affecting cytochrome P450, those with physiology-based variations (e.g. body weight, selection of food in children); presence of disease leading to high intakes (e.g. diabetes leading to high intakes of artificial sweeteners); occasional excursions above the ADI on a short-term basis (an ILSI Europe expert group is looking at the latter question).

In the situations outlined above the refinement of the risk assessment process should be all that is required to improve the robustness of the methodology. One example of such a refinement is the use of science-based (as opposed to arbitrary) uncertainty factors for setting the ADI.

However, in the case of risk assessment for novel foods the refinement of existing procedures may not be sufficient. The safety considerations for a novel food depend (where possible) on the establishment of substantial equivalence. This approach uses traditional foods as the point of comparison for foods which have been modified or are new. The establishment of substantial equivalence is not in itself a safety or nutritional assessment.

The substantial equivalence position may also depend on the nature of the foodstuff being considered. A highly refined food derived from a genetically modified source may be substantially equivalent to the refined food from traditional varieties. For example, starch obtained from a genetically modified potato may be substantially equivalent to traditional potato starch, though the potato itself may differ from traditional varieties in a specific way or ways.

There are two sets of data required for the safety assessment of a processed food from a genetically modified source. One set is to establish substantial equivalence (where applicable) and the second set for the full safety assessment. The latter contains information relating to the genetic modification, its stability and containment but also includes a requirement for toxicological information. This leads to the need for new approaches for novel foods where:

—Animal testing is required and the novel food constitutes a significant proportion of the dietary mass, which in turn can lead to altered nutritional status. Therefore, there will be a need for specially formulated test and control diet.

—the assessment of allergenic potential may require some approaches in addition to that of substantial equivalence, this will depend on the circumstance. Where the transgene is from a known allergenic source then the test population could include sensitive individuals (though this would raise ethical problems). Alternatively, where the source of the transgene is an unsuspected or unusual source of allergen, then sensitive individuals could not be recruited into the test population and the modified food would require closely monitored

prospective studies to be part of the safety evaluation. This leads to a consideration of the need for post-marketing surveillance to provide data about the exposure to the food in larger populations of consumers. Though well established for pharmaceuticals, there are no systems in place for foods. The question of who should pay for such studies if they are deemed to be necessary is also relevant.

In conclusion, the methodology based on the ADI or TDI could be refined using techniques such as physiologically-based pharmacokinetic (PB-PK) and biologically based dose-response (BB-DR) modelling; these are, in general, at an early stage of development and insufficient data are available for their routine use. There is a challenge to toxicologists and legislators to incorporate into toxicity testing and risk evaluation as much human data as possible. There is also the need to identify reliable markers of chemical toxicity in man which would directly reflect and quantify damage caused by foods over a lifetime.

With regard to novel foods, then their safety assessment must be carefully considered and new methodology may be needed in relation to the long-term effects of such dietary components.

In the discussion session, reference was made to the distinction between drugs (chosen for their biological activity) and food ingredients (generally not biologically active). While the need for post-marketing surveillance was recognized for drugs, is it necessary for food ingredients? What would be the endpoints looked at in any surveillance programme for foods? It was recognized that these were important considerations which would need careful consideration in any request for post-marketing surveillance information.

A question was asked about the problem of identifying genetically modified foods or (derived) food ingredients. If they are difficult to identify then they would be difficult to monitor, which in turn could lead to difficulties in risk assessment. Professor Woods recognized the concern raised over GM foods but considered these to be perceived risks requiring careful explanation of how they are approved in order to alleviate the perceived risk.

How would risk assessments be carried out on novel foods which do not have a traditional counterpart for comparison? In such cases it may be necessary to carry out toxicological assessments of the novel food. The questioner asked if setting an ADI was appropriate for such novel foods. Professor Woods had participated in a UK Department of Health workshop recently addressing just this point. No final conclusions were reached on the most appropriate way forward.

Round-table discussion with all workshop speakers—chaired by Professor A. Dayan

The topic of risk communication was raised where clarity of risk assessment procedures, particu-

larly with regard to use of uncertainty factors, is essential for appropriate risk management and communication. It was stated that in uncertain cases there is a tendency to add extra factors for risk management.

Professor Woods responded to emphasize the need for openness and sharing of information about the basis of risk assessment. Communication should be based on acceptable risk from foods and appropriate information given to explain that zero risk is an impossible position in relation to eating (or any other human activity). Reference was made to the use of additional safety factors in some countries (e.g. extra safety factors for pesticide residues in infant foods), use of such additional factors should be based on scientific need and not emotion.

Dr Barlow explained that in some circumstances uncertainty factors have been reduced to take account of current levels of intake. It is the risk managers role to strike an appropriate balance in societies acceptance of risk.

The use of risk assessment techniques in microbiology was questioned, particularly the need for quantification if risks are to be compared and managed.

Professor van Schothorst explained that microbiologically safe food was a joint responsibility

between producers and consumers. Microbiology was not yet ready for quantitative risk assessment, but explained that communication was necessary at all stages of the risk assessment procedure to gain acceptance of the approaches taken.

The placing of a cost on a human life and using this as a basis for risk management decision was raised.

Professor Kroes indicated that this approach, though difficult, was already being used in health care and would likely spread to other fields within 10 years. This point was extended in a follow-up question referring to the approach of calculating the money spent per life saved for certain risk management decisions. Could this be a useful way of presenting risk management decisions?

Professor Woods referred to the privilege of developed countries that can look beyond the quantity of the food supply to its quality, this is not always true in developing countries. However, he recognized that attaching a price to the outcome of risk management decisions could be a useful way of presenting information.

Dr Barlow remarked that this is not always possible, for example, if the ADI was exceeded there is no quantitative risk information to tell how many people (if any) will be affected.