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Acrylamide – A case study on risk analysis

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ABSTRACT

The concept of risk analysis, as defined by WHO, foresees strict functional separation between risk assessment and risk management. However, at the same time, it also expects close cooperation between risk assessors and risk managers. This is not always the case, as exemplified by acrylamide, a heat-induced toxicant in foods. The proposed SAFE FOOD Risk Analysis Framework puts forward the need for institutionalizing the cooperation between assessors and managers by introducing two steps, framing and evaluation. The paper argues that if these steps had been introduced in 2002 it would have led to a more efficient risk management of acrylamide.

1. Introduction

In April 2002 it was reported from the University of Stockholm (SU) and the National Food Administration (NFA) in Sweden, that rather high levels of acrylamide (AA) could be found in normally cooked starch-rich food, compared to what had been reported earlier in other food commodities. AA was at the time a well known genotoxic carcinogen and the International Agency for Research on Cancer (IARC) had classified it as a probable human carcinogen, placed in group 2A. Due to its toxicity, the World Health Organization (WHO) had suggested a maximum residue limit (MRL) for drinking water at 0.5 μg/l and the European Commission (COM) was just about to issue its new MRL for drinking water at 0.1 μg/l. The reported levels in normal food, such as crisps and chips were in the mg/kg range, some four orders-of-magnitude higher. The information released at a press conference on April 24, in Stockholm, understandably generated a high interest, both among scientists and consumers.

The way that the risk analysis concept was applied before and at the press conference was criticised by some, while others gave their support (Löfstedt, 2003). This paper discusses whether interested parties could have acted differently in 2002, if the risk analysis process, as proposed by SAFE FOODS, had been implemented at a European level. The new risk analysis framework for food safety as proposed by SAFE FOODS is described in more detail in Section 6.

2. The Hallandsås incident

2.1. The incident

In late September 1997, fish died in a fish-culture in a brook downstream a draining area of a tunnel construction site at Hallandsås in the southwest part of Sweden, and paralysis of cows in a herd grazing around the brook caused alarm. The water in the brook was shown to contain very high levels, in comparison with existing regulatory limits in drinking water, of AA and *N*-methylol acrylamide and the same chemicals were also detected in the affected animals (Törnqvist, Ehrenberg, & Hagmar, 2000). Within days, media in Sweden were full of catastrophe reports from Hallandsås, situated at the Bjäre Peninsula, a major area for Swedish food production.

The local authority declared a state of emergency and a risk area was defined where consumers were advised not to drink the water from private wells. Within hours after the news was released, before any advice was issued from governmental agencies, major Swedish food companies refused to market vegetables, dairy products and meat from the area around Hallandsås. Information from governmental authorities was uncoordinated and sometimes contradictory. Panic did not break out, but the situation was very tense. Within a few days, the majority of Swedes knew that AA

Abbreviations: AA, acrylamide; CIAA, Confederation of the Food and Drink Industries of the EU; COM, European Commission; EFSA, European Food Safety Authority; EU, European Union; FAO, Food and Agriculture Organization; IARC, International Agency for Research on Cancer; JECFA, Joint Expert Committee on Food Additives; JIFSAN, Joint Institute for Food Safety and Applied Nutrition; MCDA, Multi-Criteria Decision Analysis; MoE, margin of exposure; MRL, maximum residue limit; MS, member state; NFA, National Food Administration; PAH, polycyclic aromatic hydrocarbon; SCF, Scientific Committee for Foods; SU, University of Stockholm; WHO, World Health Organization.

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was a toxic and carcinogenic compound, something that should not be found in food or drinking water. The media reporting was extensive.

Margareta Törnqvist's group at SU later analysed blood from workers exposed to the leakage water and found elevated levels of AA bound to haemoglobin. They also found rather high levels in controls, not exposed to the leakage water (Albin et al., 1998). In order to identify the origin of AA in these non exposed persons, she investigated a number of suspected sources, among them different food items.

2.2. Acrylamide and food

Subsequent research from Törnqvist showed, in early 2001, the presence of moderate levels of AA in fried hamburgers, in the range around 10 μg/kg at reasonable cooking temperatures. This was reported in the journal Vår Föda, issued by NFA, but caused no reactions from the scientific community, media or consumers (Törnqvist, 2001).

In the late autumn of 2001, Törnqvist reported to NFA that she had found very high levels, in the mg/kg range, of AA in starch-rich fried foods. The levels made her concerned about possible health effects in consumers. NFA shared her concern and started a survey of the Swedish diet to aid in the assessment of AA exposure via food. A preliminary exposure assessment was finalised in early April 2002.

No information was passed onto other scientists or authorities in Sweden or elsewhere. The major reason for this was to avoid over reactions from the industry, retailers or consumers. Both Törnqvist and NFA had the Hallandsås incidence in fresh memory. The Swedes were believed to remember the dramatic situation and AA was now known to be present in ordinary food, in amounts several orders-of-magnitude higher than the levels found in drinking water in 1997.

However, it was decided to inform representatives from the national food industries in the afternoon of April 23, 2002, when the complete set of data was presented including a crude estimate of the cancer risk, based on animal data, to Swedish consumers. This was done in order to help the companies to inform concerned consumers the following day. A major message at this meeting was that NFA took the situation seriously, that measures had to be taken at a European level, not directly but at a later stage. Since AA was present in a large proportion of the food supply, including potato products, bread, cereals and coffee, it was deemed impossible to make any withdrawals of AA-containing foods. By applying, for example, the estimated risk from AA exposure via food to the WHO approach to regulated genotoxic carcinogens in drinking water, a very large proportion of the food supply would have to be withdrawn from the market (WHO, 1996). This was deemed not proportional to the risk imposed. In addition, AA in food was something that consumers had lived with for centuries. Measures needed to be taken but could wait for a European action initiated by COM.

However, it seems reasonable to assume that if AA had been found in only a limited number of identifiable products, other measures would have been taken, either by NFA or by the food companies themselves, in spite of the fact that AA had not been indicated, by epidemiology, to induce cancer in man.

On April 24 the results were made public by SU and NFA at a joint press conference.

No new formal risk assessment was performed prior to the press conference. A summary of relevant assessments performed by the Environmental Protection Agency in the USA (EPA, 1984, 1993), the European Commission Scientific Committee for Foods (SCF) (EC, 2000) and the IARC (IARC, 1994) was presented at the NFA website together with the exposure assessment based on data produced by NFA itself.

All data available to NFA was presented on the website April 24, 2002 and has since then been continuously updated.

It should be noted that there was no plan for any specific national risk management activities, apart from the risk communication given at the press conference and on the website. It was decided by NFA to hand over the problem to the scientific bodies within EU for further elaboration since Sweden did not have resources to pursue the issue further. At the time there was no operative European Food Safety Agency (EFSA), and SCF, which provided scientific advice to the Community, was tasked by COM, which was not informed prior to the press conference.

3. Risk communication on April 24, 2002

Swedish media reacted, influenced by an unfortunately worded invitation from SU and NFA to the press conference, in a non-proportional way. It was the second biggest press conference since the assassination of the Swedish Prime Minister Olof Palme in 1986. The attention was in no way proportional to the magnitude of the problem, something that later caused problems. The reaction from international media was less intense.

The main messages given at the press conference were

- AA, a genotoxic carcinogen, has been found in a variety of cooked foods.
- Consumers have presumably been exposed to AA for thousands of years. It is positive that we now are aware of this.
- Based on animal data, the perceived cancer risk is big in comparison to other carcinogenic contaminants in foods, but low compared with e.g. smoking.
- Food containing AA will not be withdrawn from the market.
- Industry has been alerted and asked to reduce the levels in their products.
- No new dietary advice will be issued. By following the advice already issued by NFA, the exposure to AA will decrease.

This was probably too many messages given simultaneously. The Swedish media reported mainly on discussions of the value of animal studies in predicting cancer risks to man. NFA was quite hoarsely criticised for overestimating the risks and for making use of the situation to improve its financial situation.

It could be discussed whether this chain of events caused an unnecessary food scare or not and if the proposed SAFE FOODS framework for risk analysis could have helped to reduce consumer anxiety and laid a better foundation for risk management activities.

4. Further development up to mid 2008

4.1. Risk assessment

WHO took an unusually quick initiative and organised a Joint FAO/WHO Consultation in Geneva, June 25–27 2002, only 2 months after the press conference. The Consultation supported earlier assessments referred to by SU and NFA but also highlighted the need for additional data out of a scientific perspective (WHO, 2002). Risk managers or stakeholders were not given the opportunity to formally influence the demands for new data from a management perspective as would have occurred if the SAFE FOODS risk analysis frame had been in place.

A similar event, a Joint Institute for Food Safety and Applied Nutrition (JIFSAN) Workshop, was organised in Chicago on October