Acrylamide Risk Governance in Germany

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Introduction

The risk governance framework of the International Risk Governance Council (IRGC) provides an analytical structure within which to handle risks, from assessment to management. This chapter is a case study of the the events in Germany connected with the discovery of acrylamide in foodstuffs. A central question the case study hoped to answer was whether the framework could help deal with such situations as newly arising hazards from harmful substances in foodstuffs.

Advances in science and technology have led to the emergence of new sources of risk. At the same time, they have offered improved opportunities for identifying existing risks. For instance, modern measurement methods can detect substances in our air, water, and food at concentrations in the parts per billion (ppb) or even parts per trillion (ppt) range. With these improved analytical methods it is very likely that some undesirable compounds, in some cases unintended chemical by-products of production, will be detected in our foods. Since it is hardly feasible to test all foodstuffs for the approximately 100,000 known chemical substances (UBA 2001), it follows that there is some chance that some of them will be detected by chance, and these findings will then reach the public unfiltered. Prompt and careful reactions by scientific and government authorities can prevent the public from being unduly alarmed and such situations from developing into communication crises. What is important in such cases is to find solutions which meet legal health protection requirements and are acceptable to as many parties as possible.

This chapter provides an overview of the acrylamide in food crisis as it unfolded in Germany. It begins with some history on acrylamide, its uses and characteristics, followed by a summary of events which led to its discovery in foodstuffs and the reporting of these finding to the public. The next two sections present first, the institutional structures of consumer protection in Germany and second, the risk governance of acrylamide in Germany. The chapter concludes with an analysis of the events to see whether the risk could have been better handled if the IRGC Framework had been applied. Since the Federal Institute for Risk Assessment (BfR)[1] has recently evaluated the communication of risk in the acrylamide case,[2] only a few observations will be made about this at this point.

[1] The chapter uses a number of abbreviations for the names of several institutions or laws. In some cases there are no official English translations available and the German names had to be translated to create a readable English text – c.f. index of abbreviations and translated names at the end of the chapter.

[2] c.f. Vierboom et al. (2007)

Acrylamide History and Toxicity

Acrylamide was first synthesised in 1949. Since then, production of this toxic substance within the European Union has reached approximately 100,000 tonnes per year. It is used almost exclusively in the production of polyacrylamides. Polyacrylamide is used in sewage treatment, in paper and pulp processing, and in the treatment of minerals, and is an additive to cosmetics and paints (Madle et al. 2003).

Acrylamide was the object of worldwide scientific research even before its discovery in foodstuffs. The first results from animal experiments were published in 1986. The data on the incidence of tumours indicated that no 'safe dose', in the sense of a threshold value, could be assumed (BgVV 2002 b).

However, it is difficult to demonstrate a direct connection between human exposure to a toxin and an increased probability of developing cancer, particularly based on animal experiments alone. Numerous chemicals have been described as carcinogens in animal experiments but to assume the threat of human cancer from this is by no means clear. Particular chemicals often induce cancer in organs which already exhibit an increased incidence of tumours. The increase due to the substance in question can only be estimated relative to the existing risk. Although epidemiological studies are preferable for evaluating the cancer risks, they do not exist for many substances.[3] The possibility that there are chemicals to which only laboratory animals, and not humans, are sensitive cannot be theoretically excluded.

These uncertainties in relating the results of animal experiments to humans are normally dealt with by convention[4] -- that when a substance is found to be carcinogenic in animals it is also treated as carcinogenic in humans, even in the absence of evidence from human studies (Henschler 1993).

If one assumes the existence of a relationship, one must deal with extrapolation from the empirically tested high doses in animals to the hypothetically estimated low doses for humans.[5] The question then arises whether the observations from high dose experiments are also relevant for low doses. The answer depends on whether or not the carcinogen is genotoxic, i.e., able to cause genetic damage. If this is not the case, the majority of scientists assume that a threshold exists, a threshold being a dose below which the risk of cancer is not increased. With genotoxic substances, which include acrylamide, the common convention is to make the conservative assumption that no threshold exists, so that even a minimal dose may lead to a rise in cancer risk (BfR 2002).

The results of scientific analyses of acrylamide have led to the following evaluations by international agencies:

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[3] The first understanding of the causes of cancer came from the observations of occupational medicine, since workers often experience higher exposure levels than the general public. An early milestone was the publication by the English surgeon Percival Pott regarding scrotal skin cancer among chimney sweeps in 1775. Further connections were subsequently revealed, for instance increased bladder cancer among dye workers in 1895, leukaemia due to Benzol in 1941, and lung cancer due to asbestos fibres since the beginning of the 1940s (Henschler 1993).

[4] This assumption essentially represents a precautionary approach in the absence of sufficient scientific evidence – a preference for 'erring on the side of safety'.

[5] In animal experiments, to arrive at statistically significant results, animals must be exposed to very high doses to which humans are not normally exposed.

- The International Agency for Research on Cancer (IARC) rated acrylamide as "probably carcinogenic to humans" (Class 2 A) in 1994 (IARC 1994). This means that the properties of acrylamide determined through animal experiments are estimated to be relevant to and thus transferable to humans (BgVV 2002 b).
- The European Scientific Committee on Food (SCF) evaluated acrylamide in 1991 as a "genotoxic carcinogen". The SCF re-examined this question in 2002 and left its evaluation unchanged, since it believed that the grounds for the decision remained the same (SCF 2002).
- The European Chemicals Bureau conducted an extensive risk assessment of acrylamide within the European Existing Substances Regulation. The final report contains a comprehensive statement of the state of research up to 1995. The report designates acrylamide as "non-threshold carcinogen", and it recommends that human exposure to acrylamide be restricted as much as possible (EC/JRC 2002).

Scientific findings on acrylamide were also gathered in Germany:

- An assessment of the exposure to acrylamide in packing material was conducted at the Max von Pettenkofer Institute of the German Department of Public Health in 1993. The limit of detection for this assessment was one milligram per kilogram (Böhme/Grunow 1993).
- At the 58th Session of the Commission for Cosmetics of the Federal Institute for Consumer Health Protection and Veterinary Medicine on 29 April 1999, the Commission addressed the issue of "genotoxic carcinogens" and demanded "most insistently again that the residual content of monomeric acrylamide in polyacrylamide be minimised as far as possible through an appropriate choice of raw materials" (BgVV 1999, p.2).

Measures to prevent unwanted human exposure to acrylamide had already been included in the recommendations of the World Health Organisation and in German legislation.

- To ensure that no residues remain in drinking water, in 1993 the World Health Organisation defined a maximum permissible value of 0.5 microgram per litre of water. This value is still in force in the current third edition of the Drinking-water Guidelines (WHO 2004). According to Article 6 of the German Drinking Water Ordinance of 21 May 2001, the maximum permissible value of 0.0001 milligram per litre is not to be exceeded (TrinkwV 2001).
- The handling of acrylamide falls under the Ordinance on Prohibited Chemicals (*Chemikalienverbotsverordnung)*, an ordinance to protect people and the environment from hazardous chemicals. Among other requirements, the substance is not to be passed to private end-users (ChemVerbotsV 1993).
- Appendix II of the Ordinance on Hazardous Substances of 26 August 1986, an ordinance which contains provisions for employee protection, also rates acrylamide as a carcinogen. This means that special protective measures are to be observed when handling acrylamide (GefStoffV 1986).

In short, the danger that acrylamide exposure could pose to humans was known, but the problem was believed to be limited to a few applications in which acrylamide was added, directly or indirectly, through human intervention. These situations were effectively regulated by laws and provisions. Acrylamide was certainly not of interest to the general public of Germany.

Events in Sweden up to 24 April 2002

The situation was quite different in Sweden. These events have already been analysed by Löfstedt (2003). The history of the case also plays a role in the German acrylamide case and thus, based largely on Löfstedt's report, is discussed further in this section.

Acrylamide became broadly known in Sweden in 1997 as a result of the "Hallandsås scandal". Hallandsås is a hilly area in Schonen, a region of southwest Sweden. It was here that, in 1992, the Swedish Railway Administration began work on an 8.6-kilometer tunnel which would reduce the journey time between Malmö and Göteborg. Construction quickly fell badly behind schedule. To prevent water leaking into the tunnel, which would further delay progress, the use of an acrylamide-containing sealant, Rhoca-Gil, was resorted to in March 1997.

The first dead fish were found in nearby fish farms in September 1997. Cattle grazing near a stream containing water that had leached from the tunnel later became lame and had to be destroyed. It was rapidly established that large quantities of acrylamide had contaminated the water. The construction site was contaminated both above and under ground. The entire vicinity was deemed to be highly dangerous. This promptly led to all products from the region being taken from the shelves of food stores. The events stoked fears in the Swedish population (Löfstedt 2003, Törnqvist 2005).

Naturally, the media took up the story. Reports appeared about the tunnel workers, who had worked with the sealant without the appropriate safety measures. The Swedish Railway Administration commissioned Margarita Törnqvist, the head of a research team at the Department of Environmental Chemistry at the University of Stockholm[6], to examine the blood of the cattle that had been destroyed. Törnqvist found evidence that the cows had been poisoned by acrylamide. In the tunnel workers' blood, which Törnqvist analysed next, such a high concentration of acrylamide was found that adverse effects on their health were feared. This finding also attracted a great deal of media attention. This combination of circumstances --- acrylamide as the contaminant of an entire district, poisoned cattle, and unacceptable health risks for tunnel workers --- led to the fact that within a few days the majority of the Swedish population knew that acrylamide was a toxic substance.

The investigations later expanded to the investigation of other sources of acrylamide when, in further experiments, Törnqvist also found unexpectedly high levels of acrylamide in the blood of a control group. The research team quickly struck on the idea of looking at food preparation, since the scientific community had long known of the formation of genotoxic chemicals during the roasting and baking of foodstuffs, known as the Maillard Reaction (Widemark 1939). To test this hypothesis, the researchers fed one group of rats normal food and a second group with baked and roasted food. Ten times as much acrylamide was found in the blood of the second group as in the first. The researchers published this result in the journal *Chemical Research in Toxicology*, arriving at the conclusion that:

> These data render it likely that cooking of food is a major source of the background dose of [acrylamide] also in humans. (Tareke et al. 2000, p.1)

This article attracted hardly any media interest. The editor suggested sending out a press release, but Törnqvist refused. She wanted to await further research results and so give recommendations for a reduction of acrylamide concentrations. Otherwise, she feared, unnecessary

[6] Törnqvist's team had developed a method at the beginning of the 1990s with which the blood of Chinese factory workers had been tested for acrylamide.

concern to the population could be caused. Nonetheless, she published another article in the magazine of the Swedish National Food Administration (NFA), in which, among other issues, she discussed how acrylamide levels in hamburgers rose with rising frying temperatures (Tareke/Törnqvist 2001, quoted in Löfstedt 2003). This article did not create much interest either.

Törnqvist was supported in her investigations by a private laboratory, AnalyCen. In the beginning of autumn 2001, some thousands of micrograms of acrylamide could be detected in baked potatoes using a new procedure. These results were discussed with the NFA in October 2001. The NFA's agents, led by Leif Busk, suspected that the issue held a significant potential for crisis and initiated their own experiments at AnalyCen. Törnqvist and the laboratory continued to work on improving their analytical method and were soon able to confirm Törnqvist's original results. Her scientific paper reporting these was rejected by the journal *Nature* in February 2002. At the same time, the NFA agents had confirmed Törnqvist's results with their own experiments and wanted to bring these to the public's attention. Bertil Norbelie, the NFA's director, later defended the decision:

> The Food Administration has to work in the interests of the consumers and this includes going public with the information that we had as we take the view that any secrecy is not defensible. (Norbelie 2002, quoted in Löfstedt 2003, p. 410)

Törnqvist had asked Leif Busk of the NFA at this stage to wait until her paper had undergone the regular peer review process, and Busk had agreed. In Löfstedt's view, "however, at this stage things began spiralling out of control" (2003, p.410), because information had already been leaked from two sources:

(1) NFA employees had begun to inform their European colleagues of the results. Löfstedt gives two reasons for this. Firstly, they wished to spare their colleagues being confronted by the publication of the research results without preparation, and, secondly, there was the possibility of receiving research funds from the European Union. The second argument was decisive; the NFA scientists suspected that, following possibly serious consumer reaction, they should have pointed out they had initiated Europe-wide research activities.

(2) The people in charge at AnalyCen laboratory, without consulting either Törnqvist or the NFA, published a two-page article in their customer magazine about their expertise in the analysis of acrylamide. The laboratory had already received enquiries about this. The despatch of the magazine could not be stopped in time to prevent the leaking of information.

In the middle of April 2002, Törnqvist's article was accepted for publication in the *Journal of Agricultural and Food Chemistry*. In correspondence with the author of this case study in 2006, Törnqvist described the situation thus:

> Yes, the paper was indeed accepted. That meant that several referees had looked at it and have had viewpoints that we had met in a revised manuscript. According to the editor, with whom we checked by email, *the paper was accepted and should be sent for printing.*

At this point, the NFA wanted to take their information to the public. A press conference was called for 11.00 on 24 April. The invitations for this were written jointly by the NFA and the PR department of the University of Sweden and contained the following passage:

> Researchers at Stockholm University have found an element that can cause cancer and which is formed during cooking a wide range of foodstuffs. The National Food Administration has in a pilot study found the substance in many food staples. The levels (of the substance) are high and new research findings will have international importance with regard to risk valuation, food production and consumption. You are therefore invited to receive this information at a press conference arranged by Stockholm University and the National Food Administration (translated from the Swedish, quoted in Löfstedt 2003, p. 411).

This text was issued on the afternoon of 23 April, some 20 hours before the conference. This period was to allow representatives of the national and specialist press to attend. In addition, the NFA held an internal meeting with Swedish food manufacturers beforehand to discuss the research findings. After this meeting the NFA and the University's representatives decided to give out no more information before the press conference.

However, the press's reaction was immediate. Journalists began to harass the individuals involved: Leif Busk of the NFA had 40 calls to his mobile phone within three hours, and his wife and children were also harried with numerous calls. Törnqvist's team was traced in the same way as the publisher of the *Journal of Agricultural and Food Chemistry*. Nonetheless, the journalists did not succeed in discovering which results were to be presented on the following day.

On the morning of 24 April the editor of the *Journal of Agricultural and Food Chemistry* informed Törnqvist that none of the results from her paper could be made public, since this would qualify as a publication and so would prevent publication in the Journal.

150 journalists appeared at the press conference; Sweden had not seen an event of comparable magnitude since the murder of Olaf Palme. In addition, it was also broadcast live on television.

The NFA explained which products and brands possessed the highest acrylamide contents. It is Busk who is quoted here:

> I have been in this field for 30 years and I have never seen anything like this before. The discovery that acrylamide is formed during the preparation of food, and at high levels, is new knowledge. It may now be possible to explain some of the cases of cancer caused by food. (See, for example, reports from BBC News 2002)

Törnqvist, however, did not regard herself as able to present any details from her article, which had a negative effect on her credibility. A Swedish science reporter who made no secret of her irritation with the fact that Törnqvist's article was not available asked whether there were any publication of the results being presented which had undergone a peer review. In retrospect, Törnqvist says:

> I think she wanted to show that she knew that scientific papers should be peer-reviewed. But the paper was peer-reviewed but not published. This was too complicated to explain in this situation. (Personal communication with author, 2006)

The NFA reported that it did not yet have any plans to take measures such as removing particular products from the market, since further research was necessary first. The statement led to the recommendation to eat low-fat products. In the final question-and-answer session, researchers and NFA representatives were asked for their personal recommendations, for instance, what they would advise their own children about eating potato crisps (Löfstedt 2003).

International response to the press conference

The press conference attracted a great deal of attention from the whole western world although immediate reaction was very ambivalent.

The BBC's response was relatively restrained. It was even observed that "the research was deemed so important that scientists took the unusual step of going public with their findings before the details had been officially published in an academic journal". Subsequently, however, some experts' opinions were given, such as that of David Phillips of Cancer Research UK, who described the study's findings as “highly significant” (BBC News 2002).

The New York Times addressed the issue in its editorial of 29 April 2002, arriving at the conclusion that the findings would certainly raise concerns, but that "the Swedes were not so sure of themselves that they took any immediate action to change their own food supply or processes. They simply urged the European Union, other food safety agencies and the food industry to explore the issue" (New York Times 2002). A sharper tone was taken on the following day under the headline "Scientists Cautious on Report on Cancer from Starchy Foods": "The scientists have not published a paper on their small study. Instead, they made their announcement at a news conference last week" (Kolata 2002).

While the WHO had already announced that it would be holding a meeting of experts as soon as possible, the opinion of "many experts" was "that it made no sense to be alarmed over unpublished data on a chemical that was very unlikely to have a measurable impact on cancer rates". The toxicologist Stephen Safe from the A&M University in Texas was quoted as saying: "it’s just dumb, dumb, dumb. There are carcinogens in everything you eat". In addition, it was pointed out that humans were exposed to numerous natural substances which could cause cancer in rodents. The risk of cancer due to acrylamide had yet to be proven. The article ended with the polemic comment that many scientists would be happy to read the Swedish findings if they were published in a reputable scientific journal (Kolata 2002).

Sceptical reactions also appeared in the German and Swedish press. The *Frankfurter Allgemeine Zeitung* referred to Swedish scientists who saw "the danger of cancer for consumers dramatised in an irresponsible manner"(FAZ 2002). This article also pointed out here that the NFA had reported on acrylamide in certain foodstuffs "before the customary publication of research findings in the specialised press". The NFA’s declaration that acrylamide in foodstuffs in Sweden was responsible for "several hundred deaths" per year was challenged by a comment in the Swedish newspaper *Dagens Nyheter*: “the information released is quite insufficient. Without the facts, trust evaporates" (FAZ 2002). The *Frankfurter Rundschau* opened its coverage of 26 April 2002 with the words: "crisps and chips probably do *not*, in the view of researchers, pose the substantial risk of cancer that the Stockholm Food Authority has warned of" (FR 2002).

In Sweden, a discussion of the actions of the NFA and the researchers began immediately after the press conference. Foremost among the criticisms was the accusation that the press conference had simply stoked fears, since no advice was given about how the danger could be reduced. Communications experts even speculated about the motivations of the NFA, specifically that the NFA had sought a way to draw attention to itself or to obtain research funding. Other voices, however, asserted that the greatest error lay in the fact that the media had not responded to Törnqvist's findings earlier.

Just one day later, on 25 April 2002, criticism in the Swedish media was more restrained. Löfstedt (2003) found the reasons for this to be that Swedish politicians had not criticised the NFA and that the WHO had rated the results as so important that they could not have been withheld from the public. On 26 April the WHO issued its own press release which announced that it would be holding a meeting of experts to discuss the significance of the results (WHO 2002).

Four weeks after the press conference, a survey of 250 Swedish households showed that the population was well aware of the fact that crisps and chips contained acrylamide (82% and 63% respectively). This knowledge, however, was not reflected in changes to consumption patterns: just 8 % of those questioned said that they had reduced their intake of crisps. 13 % planned to consume less in the future.

Nonetheless, the events did have economic consequences; the shares of Chips, the largest Swedish manufacturer of crisps, fell 15% on 24 April 2002. Sales of crisps fell 40% in the week following the press conference but recovered steadily thereafter, until in the third week after the press conference they had settled at the level of the previous year (Löfstedt 2003).

The German market for crispbreads fell some 30% in 2002. Whereas the traditional Swedish firm Wasa, which has been part of the Italian company Barilla since 1999, reported a downturn in sales in Germany of 15%, several low-cost producers were faced with much more drastic falls. In Sweden, average sales were down some 5% on the previous year (Kruse 2003, confirmed by the Barilla-Wasa press office).

The surprise the news created internationally also had the consequence that, within a short time, numerous committees of experts had been assembled and research projects launched to learn more about the formation of acrylamide and to discuss the possibilities of reducing the content in foodstuffs. Table 1 lists the conferences and events on acrylamide which have taken place since April 2002 with the European Commission, the WHO and in the USA. This overview is by no means complete, but does clearly demonstrate the many activities undertaken to address the new problem.

Table 1: International expert events concerning acrylamide

Date	Event	Level
25.06.2002	FAO/WHO Consultation	WHO
03.07.2002	Scientific Committee on Food	EC
15.10.2002	EU Commission: Stakeholder Meeting	EC
28.10.2002	JIFSAN[7]/NCFST[8]-Workshop: "Acrylamide in Food: Scientific Issues, Uncertainties and Research Strategies"	USA
16.03.2003	FAO/WHO "Seminar on Acrylamide in Food: Current State of Affairs – Exchange of Views – Update on ongoing research – Identification of Gaps"	WHO
28.03.2003	EFSA-Workshop on Acrylamide Research	EC

[7] Joint Institute for Food Safety and Applied Nutrition, established between the United States Food and Drug Administration (FDA) and the University of Maryland (UM).

[8] National Centre for Food Safety and Technology (NCFST), Chicago, Illinois. A research consortium among the FDA Center for Food Safety and Applied Nutrition (CFSAN), Illinois Institute of Technology (IIT) and the food industry (c.f. http://www.ncfst.iit.edu/main/home.html, accessed 31 May 2006).

28.04.2003	Joint Research Centre (JRC): Analytical methods workshop	EC
21.10.2003	EU Commission Stakeholder Meeting	EC
17.11.2003	EFSA-Workshop on Acrylamide Formation in Food	EC
22.03.2004	JECFA-Seminar	EC
13.04.2004	JIFSAN-Workshop on Acrylamide in Food	USA
08.02.2005	64. JECFA-Meeting in Rome	EC

By 2005, the European Union was already conducting studies in ten areas in connection with acrylamide, for instance on toxicological and epidemiological issues, on methods of analysis, and on the extent of human exposure (EC 2005). The manufacturers of affected foodstuffs were also active; in Sweden, for instance, the manufacturers of crispbreads formed a research association (Kruse 2003). Germany also saw the launch of a research association by producers. Coordinated by their umbrella organisation, the German Federation of Food Law and Food Science (BLL) and provided with a budget of 1.7 million euro, of which 1.6 million came from the Federal Ministry for Economic Affairs and Employment, between 2003 and 2005 issues related to analysis as well as toxicological and technological topics were dealt with (BLL/FEI 2005).[9]

Evaluation of the events in Sweden

The course of events in Sweden was very largely determined by weaknesses in the communications process before and during the press conference. Löfstedt (2003) in his analysis arrives at the following conclusions:

(1) Since the information had already started to leak, there was no alternative to making it officially public. The decision to use the instrument of a press conference was only made following long discussions between the NFA and the University. Their objective was to avoid misunderstanding. The journalists should therefore have the opportunity to pose questions directly, and it was assumed that the researchers would find it easier to explain their complex results in such a context.

No further consideration was given to the fact that the NFA had almost no practice in arranging press conferences, and that Margareta Törnqvist and her team had no training how to deal with the media.

In addition, certain salient questions were not addressed, such as what kind of information the public required at this juncture. Löfstedt put forward the hypothesis that some very simple information would have sufficed, for instance that the NFA was working to verify some preliminary indications of the presence of acrylamide in certain foodstuffs. Holding a press conference was possibly overhasty. Communications experts would have advised a press statement to specialised journals instead.

Whether the public's trust in the NFA fell after these events, as many observers assume, has not been investigated until now.[10]

[9] c.f. also http://www.ilu-ev.de/acrylamid/acrylamid.htm, accessed 31 May 2006.

[10] Löfstedt mentions in his study that Leif Busk of the NFA planned an evaluation of the communications measures. This has not, however, yet been implemented.

(2) There were also long discussions about the wording of the invitation. On this point it is particularly significant that with the NFA and the University of Stockholm, two actors with entirely different interests were involved. While the University was concerned about addressing scientists by emphasising Törnqvist's findings, the NFA favoured striking formulations which would awaken media interest and reach as many consumers as possible. The text was, therefore, the result of a compromise which:

> …gave the worst of both possible worlds with a somewhat sensationalist press invitation with a significant delay leading to information vacuums causing rumour and speculation (Löfstedt 2003, p.420).

This information vacuum was worsened by the refusal of the organisers to move the press conference forward to the evening of 23 April or to answer the enquiries of the media directly. This was why media representatives began to look for other sources of information. Löfstedt's research shows that both organisers considered it too complicated to depart from the procedure once it had been decided on. Both would have moved the press conference forward had they been able to work independently.

The central question concerns the nature of the news to be presented. Was it the release of research findings, or an important piece of information for consumers? The University and the NFA should have resolved this issue before all others.

(3) In the text of the invitation to the press conference, and during the press conference itself, words which function as social amplifiers were used, such as "cancer", "base foodstuffs", and "international concern". Naturally the media picked these words up and made headlines of them, e.g. "Cancer poison found in food" (*Dagens Nyheter*, quoted in Löfstedt 2003, p.420), or "Alarm about cancer poison in common foodstuffs" (*Svenska Dagbladet*, quoted in Löfstedt 2003, p.420). Due to the events in Sweden described above, "acrylamide" was still in the thoughts of journalists and the population as a whole, and functioned as an additional social amplifier.

However, the commotion in the media waned quickly. Instead, the NFA was blamed for fuelling fears and exaggerating risks. Löfstedt names the following reasons for this development:

a) Acrylamide is not mixed into the food, but forms there in natural process. Natural dangers are accepted as facts, in contrast to technological dangers, for which someone can be blamed.

b) The risk appears familiar. It seems safe to assume that, since humanity has used fire, acrylamide has been able to form during roasting. It is not, therefore, a risk whose novelty need concern people.

c) The risk is reckoned to be controllable. If one wishes to reduce the risk, one needs simply to reduce consumption of products with the highest acrylamide content, chiefly crisps and chips. If people see a risk as being controllable, they often regard it as less dramatic. This is also the case for smoking or the consumption of alcohol.

(4) At the press conference particular brand names were disclosed. The NFA was obliged to do this because of the legal situation, or the media could have called on the 'principle of transparency' *(Offentlighetsprincipen)*, under which all government documents are to be made available to public scrutiny. The NFA decided in this case to take a proactive approach which was intended to win the public's trust and to prevent the media making accusations about the withholding of information. Naturally, the NFA was fiercely criticised by the manufacturers for this decision. What was particularly problematic was that only

one test had been conducted for each brand. It has since become known that the acrylamide content can vary widely between different samples of the same brand.

(5) There have been a series of food scares in Europe since the 1990s, of which the most prominent have been BSE, foot and mouth disease, and dioxin in chicken food and hens' eggs. Research has shown that people are not normally able to distinguish these risks with which they are confronted in their daily lives or through media coverage. Single risks are normally present in people's consciousness until they are threatened by a new risk. People who are worried about acrylamide in food at a particular point in time may have forgotten that a few months ago they were concerned about aflatoxin in dried figs. And the issue of acrylamide will probably remain in most people's minds only until such time as the revelation of a novel risk in foodstuffs causes new worries.

It is, in Löfstedt's (2003) opinion, especially problematic if the scientific community is not in agreement in its evaluation of such a circumstance and if the controversy is played out in public. Regarding the questions whether acrylamide caused cancer in humans at all, and to what extent the results of experiments on mice and rats could be applied to humans, heated debates took place between epidemiologists and toxicologists in the Swedish press. Such open disagreements generate a mistrust of science (Löfstedt/Renn 1997).

Sharp (2003) contests this. He sees a contradiction between, on the one hand, promoting transparency and proactive procedures and, on the other hand, permitting selected controversies to take place behind closed doors. He also asks if there is any way in which public disputes between scientists could be directed by a third party.

(6) If the information sources in the Swedish acrylamide case had not been seen as credible, the topic would never have been taken up by the press to the extent that it was. The high level of trust that the NFA and scientists in Sweden enjoyed contributed to an increase in the drama surrounding the events (Löfstedt 2003).

In addition, the question of the peer review also played a significant role. Even in favourable coverage after the press conference it was pointed out that the research findings had not been published in a journal of scientific standing. As late as autumn 2005, this criticism was made in the context of an expert conference in Germany (Wolf 2006). The credibility of the findings therefore suffered badly. However, the topic had been already identified as explosive by employees of the NFA in autumn 2001. An explicit obligation to confidentiality on the parties would probably have generated less pressure to make the findings public at a particular time and allowed time to wait for the publication of Törnqvist's article.

Summary of the characteristics of the acrylamide case: relevance for risk governance

Renn (2003) mentions the following peculiarities of the acrylamide case, which help to define it as a “systemic” risk for society:

- Acrylamide was already known as a constituent of sealant and rated as a carcinogen. There is still no clear and conclusive study linking its presence in food and an increased risk of cancer.
- In Sweden, acrylamide was already known to large portions of the population as a hazardous substance.
- At the time of the discovery neither the extent of exposure was known, nor could a reliable dose-response relationship be specified.

- Practically every person in the world is exposed to acrylamide, since it is generated in the cooking of potatoes and cereals.
- Acrylamide forms in a natural process without any human intervention.

The OECD (2003) describes a risk as systemic when reaction to it entails significant economic, social and even political consequences. Systemic risks require a holistic approach which takes account of this complexity (Renn 2003). The IRGC Framework provides an approach to dealing with cases of systemic risks, because it goes far beyond the simple cause-effect risk analyses and stresses the importance of understanding the interdependencies between the different dimensions of risks, networks of actors, and the public in the governance of risks (IRGC 2005).

The occurrence of acrylamide in foodstuffs possesses other particularities which are fundamental to further challenges to risk governance approaches. The first measurements done in Sweden made it evident that different levels of acrylamide are present not just in different foodstuffs but in identical foodstuffs. Not even the individual crisps in a bag are contaminated to the same extent. That means that the establishment of a threshold value would not solve the problem, but that a solution must be very complex to take account of these various facts. Furthermore, every attempt to lower the quantity of acrylamide by changing the manufacturing method or ingredients also has potential effects on the quality and flavour of a product, and thus also its acceptance with consumers.

The foodstuffs affected also involve foods which are cooked at home, such as roast potatoes and chips. However, the private sphere cannot be influenced by such measures as the establishment of threshold values.

THE INSTITUTIONAL STRUCTURES OF CONSUMER HEALTH PROTECTION IN GERMANY

Before discussing the case of acrylamide in Germany, the structures of consumer health protection will be described, including a first short glance at possible weak points in risk governance (see review in Dressel et al. 2006). As described earlier, the use of acrylamide in Germany in the 1990s was legally regulated in several areas. However, far-reaching changes occurred in the structures of the institutions concerned with the ultimate regulation of acrylamide in Germany between that time and when acrylamide was first discovered in foodstuffs in 2002.[11] Figure 1 depicts the chronological sequence of changes in which the institutions relevant to this discussion appear in grey.

With the restructuring of 1994, the Federal Public Health Department's fields of responsibilities were transferred to three successor organisations, one of which was the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV). The BgVV had been moved from the domain of the Federal Ministry of Health to the then Federal Ministry of Food, Agriculture and Forestry now the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).

[11] c.f. Act on Successor Institutions of the Federal Public Health Department and Act on the Reorganisation of Customers' Health Protection and Food Safety.

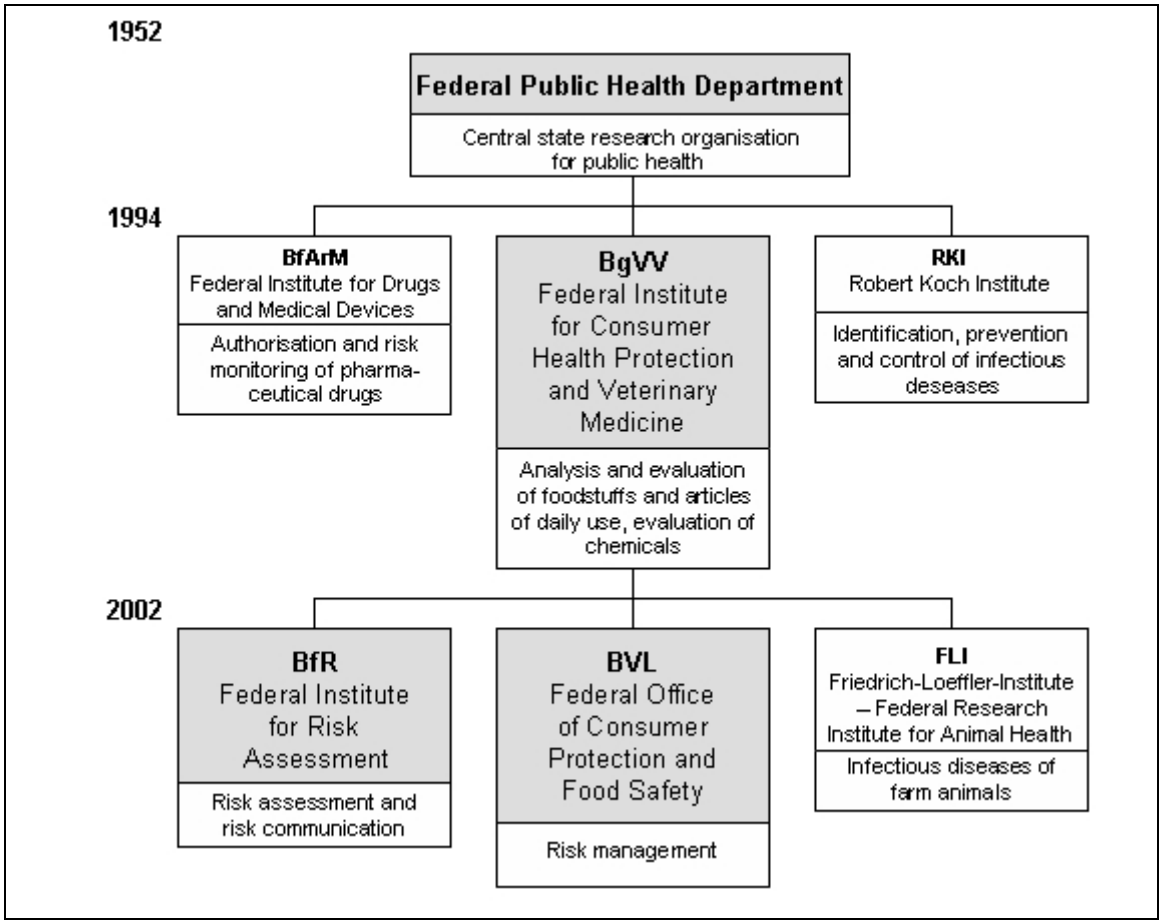

Figure 1: Changes in the institutional structures and main roles in consumer health protection in Germany since 1994

In 2002, a new arrangement was introduced which, amongst other changes, institutionalised the organisational separation of risk assessment and risk communication from risk management.[12] The requirement for a separation of risk assessment and risk management had already received international support in the report of the Codex Alimentarius Commission (Codex Alimentarius 2001). In the aftermath of the BSE crisis, Germany also took up this requirement (von Wedel 2001) and in August 2002 implemented in the Act on the Reorganisation of Customers' Health Protection and Food Safety. On this statutory basis, the duties of consumer health protection were divided between two new authorities, the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL). The separation of the fields of risk assessment and risk management promised more transparency and independence

[12] At European level in relation to food safety according to Chapter 1 article 3 of EC Regulation 178/2002, the following expressions are used as defined:

Risk Assessment: "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation".

Risk Communication: "the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions".

Risk Management: "the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options".

of consumer health protection and was directed towards regaining the trust of the population. In addition, the separation facilitated the cooperation between the European Union, the Federal government and the regional governments in this area (Dressel et al. 2006).

The core duties of the BfR are scientific risk assessment in consumer protection and risk communication. In order that these assessments could take place free of interested parties, the BfR was constituted as a legally capable public corporation (BtDr 14/8747). The BfR is active in the context of regulatory procedures, on its own initiative, at the request of the BVL and the BMELV, as well as in cooperation with EU institutions (Wissenschaftsrat 2006).

The main role of the BVL is to take preventive and protective measures in the fields of food safety and consumer protection in regard to, amongst others, foodstuffs, cosmetics, and other articles of daily use. In addition, it is involved in the design and review of the corresponding monitoring programmes for the regional governments and is the interface for the European early warning system (BtDr 14/8747).

A similar organisational separation has also been implemented in France (Ministère de l'Agriculture 2005), which, like Germany, adopted the structures created at the European level in the wake of the BSE scandal (Dreyer et al. 2006). This approach has not been followed in all the member countries. In the England, these tasks are administered by various departments of the Food Standards Agency.[13] In Sweden, risk assessment and management -- and even legislation -- reside with the NFA.[14]

The chosen organisational form in Germany is not uncontroversial. This is a topic which, because of its complexity, can only be touched on here. However, as early as 2002, criticism of the arrangement was being expressed by Böschen et al. (2002). They suggested that the problems of contemporary societies, by reason of their increasing complexity, can no longer be solved only by scientists providing the knowledge and then handing it to the politicians. Decisive situations are ever more frequently affected by a lack of knowledge. Scientific debate occurs increasingly in public, and descriptions of problems arise as the result of many-layered public-political discourse. Moreover, due to the underlying belief in the objectivity of science, the strict division of duties prevents the search for possible approaches to handling possible differences of opinion productively (Böschen et al. 2002).

Furthermore, Böschen et al. (2002) voiced specific concerns about the fate of risk communication within the institutional structures. A fair representation and consultation of societal interests cannot take place, because the public is seen simply as the addressee of risk communication and not as an independent pole between political administration and business. Risk communication does not take place as a dialogue but as a monologue.

This last criticism is particularly troubling because monologues are not appropriate for bridging the frequent gap between the assessment of a hazard by science and its appraisal by the public. Current research strongly suggests that risk assessments should involve not only quantifiable scientific findings but also societal perceptions and ideals. Furthermore, the OECD sees the education of the population as a basic prerequisite for the management of systemic risks. It is only in this way that broad-based risk prevention can take place in a decentralised and market-based society (OECD 2003).

As part of the planning for the establishment of these new authorities, it had been agreed that the BfR should undergo regular inspection by an external body to ensure the quality of its work

[13] c.f. http://www.food.gov.uk/aboutus/how_we_work/, accessed 31 May 2006.

[14] c.f. http://www.slv.se/templates/SLV_Page.aspx?id=2051, accessed 31 May 2006.

(BMVEL 2001). The Science Council submitted its first report in May 2006. It found a lack of plans in regard to risk communication. The Science Council criticised the fact that the department was overloaded with other work.

In the view of the Science Council, BfR's establishment of an in-house research department fulfilled a major prerequisite for its "high-quality administration" of statutory duties (Wissenschaftsrat 2006, p.7). The quality of the research effort was rated overall as good, in some fields even as very good. However, the lack of strategies for identifying topics for research in anticipation of possible future risks was criticised.

The Science Council has confirmed that the BfR enjoys a good reputation amongst the relevant EU institutions. This reputation is reflected in the chairmanships and other leading roles held by BfR staff on EU committees, panels and working groups to the BfR's management, as well as the adoption of methods developed by the BfR in European standards and guidelines.[15]

Criticism was directed at the way in which the research work of the BfR has been hindered by protracted testing and approval procedures and the long-delayed allocation of research funds. In addition, the Science Council expressed concern that division of responsibilities between the BfR and BVL have not been sufficiently well demarcated. Counterproductive friction has resulted.

The BfR is the only national institution that handles the assessment of risks arising from human and animal foodstuffs, chemicals, and items of daily use, a responsibility that involves testing and monitoring roles. The Science Council does not actually regard these tasks as appropriate for a departmental research institution; however, two reasons favour this current arrangement. Firstly, these permanent roles cannot be executed to the necessary scope and continuity at a university. Secondly, risk assessments performed by a departmental research institution like the BfR are considered to be particularly authoritative. Maintaining control over the administration and quality of these functions raises the trust placed by consumers and business in the outcomes of BfR's assessments (Wissenschaftsrat 2006).

Furthermore, state-sponsored private institutions in Germany do exist which provide information to consumers. This task is not something that must necessarily be administered by the state, but it should be ensured that consumers "can take part in the development of the market as an equal partner"(BMVEL o. J., p.16) and so can increase the personal responsibility that they take. In the acrylamide case, these institutions were chiefly the *aid-Infodienst – Verbraucherschutz, Ernährung, Landwirtschaft – e. V.* (aid), as well as the Federation of German Consumer Organisations (vzbv), the umbrella organisation of the 16 regional states' consumer centres and 23 other consumer-oriented associations.[16]

These remarks have already given a first sketch of the strengths and weaknesses of these structures in Germany, which are also significant in the acrylamide case.

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[15] The first experts' discussion on the acrylamide issue, which took place at the WHO in Geneva from 25 to 27 June 2002, was chaired by Dieter Arnold, the then president of the BgVV (BgVV 2002 e).

[16] *aid-Infodienst* was founded in 1950. It was intended to inform the needy post-war population about correct nutrition (http://www.aid.de/allg/geschichte.php, accessed 31 May 2006). The vzbv has developed from working group of the German Association of Consumer Organisations *(Verbraucherverbände e.V. AgV)*. This was founded in 1953 and conducted the first comparative product test in 1961, now seen as one of the central tasks of consumer protection (http://www.vzbv.de/start/index.php?page=wir&pagelink=geschichte, accessed 31 May 2006).

RISK GOVERNANCE IN THE ACRYLAMIDE CASE IN GERMANY

From IRGC's perspective, risk governance includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken[17]. It describes an integrative approach through which the examination and management of risks can be systematised, regardless of the nature of the risk in question. The framework is divided into four phases: Pre-Assessment, Risk Appraisal, Tolerability and Acceptability Judgement, and Risk Management (IRGC 2005).

In the following sections, the course of events in the German acrylamide case is compared to the individual phases of the Framework. The events are reconstructed with the use of media reports, the results of an Internet search, and interviews with experts. Acrylamide is particularly suitable as a case study for examining the risk governance model, since systematic risks require an integrated approach. The goal of this comparison is to determine whether the Framework can contribute to improved risk governance outcomes.

Pre-Assessment

Even before a society is confronted by a risk, two fundamental questions need to be addressed:

(1) What is understood by the term risk? and,

(2) What indicators are there for the existence of a risk?

The scarcity of resources obliges societies to select particular topics to undergo the process of risk governance. This choice is not always easy, because opinions may vary widely. What counts as a risk to someone may be an act of God to someone else or even an opportunity for a third party (IRGC 2005).

The IRGC governance framework identifies four elements of pre-assessment: problem framing, early warning, screening and scientific conventions. Three are specifically addressed in the context of the German acrylamide case.

Problem Framing

Tversky and Kahneman (1981) demonstrated that how a decision is framed is ethically significant. The psychological model that leads to decisions can be influenced, depending on how the question is formulated. The authors showed that a course of action is more likely to be chosen when it is positively formulated and linked with benefits. The same option is rejected when the costs are named, even though the distribution of costs and benefits are absolutely identical in both cases. For instance, it makes a great difference whether the results of a vaccination is given as "90 out of 100 vaccinated were saved" or "10 out of 100 vaccinated died" (Tversky/Kahneman 1981).

[17] Within the following section a number of phrases and sentences have been taken directly fom the IRGC's White Paper No. 1. In every case the source has been referenced as IRGC (2005) within the paragraph (for easier readability these quotations are not put in quotation marks, however).

Whether a consensus evolves about what requires consideration as a relevant risk depends on the legitimacy of the selection rule. The acceptance of selection rules rests on two conditions: first, all actors need to agree with the underlying goal. These are often legally prescribed, such as prevention of adverse health impacts, purity laws for drinking water, etc. Secondly, they need to agree with the implications which the identified hazard can have on the desired goal (IRGC 2005).

The goal in the present case, the protection of human health from adverse impacts from food, is by no means controversial, but legally established. According to paragraph 1 of the German Food and Feed Code, the purpose of this law is:

> …to ensure the protection of consumers by preventing or defending against hazards to human health in human and animal foodstuffs, cosmetics and articles of daily use (§ 1 LFGB).

The question of the potential consequences from acrylamide in foodstuffs could not be answered in the early stages of the acrylamide case, because everyone had been equally surprised by the Swedish research findings. However, acrylamide had been rated by various institutions around the world as carcinogenic and hazardous to humans. Its presence in drinking water is thus considered undesirable. By extension, it seems likely that a broad consensus would have existed for the restriction of acrylamide in other foodstuffs[18] to negligible or extremely low concentrations.

Early Warning

Löfstedt (2003) had already quoted critics from Sweden who said that the greatest error in the development of the acrylamide case was that no attention had been paid to the scientific publications of Tareke and Törnqvist in 2001. Wiedemann et al. (2002) argues that this error is an indication of the need for the early identification of risks so that problems and gaps in existing knowledge can be addressed in good time.

The international specialist community did not recognise early warning signals, but learned of the new problem at the same time as the general public. Public perception of the following events led to great pressure on authorities and stakeholders to act which certainly frustrated the search for jointly agreed solutions.

Scientific Conventions

As a further element of Pre-Assessment, the IRGC framework suggests agreement on scientific conventions to be used in assessing and evaluating risks. As already partially explained, and as the following discussion will indicate, it would have been helpful in the acrylamide case if these issues, at least, had been decided on:

- the social definition of what is to be regarded as adverse, for example by defining the "No Adverse Effect Level" in food (NOAEL);

[18] Drinking water is a kind of foodstuff (c. f. EC Regulation 178/2002).

- the selection rule determining which potentially negative outcomes should be considered in the risk governance process knowing that an infinite number of potential negative outcomes can be theoretically connected with almost any substance, activity or event;
- the selection of the testing and detection methods;
- the selection of valid and reliable methods for measuring perceptions and concerns;
- the determination of models to extrapolate high dose effects to low dose situations, for example linear, quadra-linear, exponential or other functions or assumptions about thresholds or lack of thresholds in dose-response relationships;
- the extrapolation of the results of animal studies to humans;
- the assumptions made about exposures and definition of target groups.

Decisions on these issues, developed by consensus between experts and the involvement of relevant regulatory institutions, are indispensable for the later step of Risk Appraisal (IRGC 2005). Without agreement on these conventions, discord between scientists ran like a thread through the acrylamide case.

One example of a key disagreement was about the findings of two epidemiological studies, one by Mucci et al., published in the *British Journal of Cancer* in January 2003, and the other by Pelucchi et al., published in the *International Journal of Cancer* in July 2003. The objective of both these studies was to investigate the relationship between the intake of acrylamide and the probability of developing cancer. Neither study detected a statistically significant relationship. The BfR issued full statements in response to both studies, which cannot be discussed in detail here, but which noted numerous failings in both studies. The inadequate size of the population samples alone, for example, made it difficult for either study to demonstrate such a relationship (BfR 2003 a and BfR 2003 b).

The smaller the risk in question, the larger the size of the sample studied must be to provide evidence of the risk. Mucci et al. had 591 participants in their study. According to the BfR, this sample size would have only permitted the detection, with sufficient statistical certainty, a 50% rise in the risk of bladder or kidney cancer (BfR 2003 a). In the risk governance context, the convention that must be agreed upon what weight or credibility to give to epidemiological studies like these that yield 'negative' results.

According to the promotion on their websites, the *British Journal of Cancer* "publishes high quality original papers and reviews that make a significant contribution to increasing understanding of the causes of cancer and to improving the treatment and survival of patients"[19].Like the *International Journal of Cancer,* it undertakes a peer review of every article submitted.[20]

However, by deciding to publish the papers, both journals appeared to disregard the sample size and other problems. The journals could be sure that the studies could be frequently cited and in fact, both studies were reported widely in the mass media (see for example Stern online 2003 a). This had a considerable impact: even today both papers are cited in support of arguments against the risk of cancer associated with human exposure to acrylamide.

This experience, in addition to the controversy surrounding Törnqvist's unpublished research findings, raises the question whether a paper's appearance in an academic journal in fact constitutes a guarantee of sound scientific work. It seems likely that specialist journals also are under

[19] c.f. http://www.nature.com/bjc/index.html, accessed 31 May 2006.

[20] c.f. http://www3.interscience.wiley.com/cgi-bin/jabout/29331/ForAuthors.html, accessed 31 May 2006.

a certain pressure to be able to publish contributions that are relevant to current, and in particular, controversial discussions.

In the early stages of the acrylamide case, an agreement about dealing with disputes between experts could not be reached. However, suggestions for dealing with scientific controversies in general had been proposed by the Helmholtz Society or the Max Planck Institute (c.f. Wiedemann et al. 2002).

A Pre-assesssment, as proposed by the IRGC Framework, was only fulfilled in a limited way for the acrylamide in food crisis, which contributed to difficulties encountered in the risk governance process. An early warning system for the detection of new risks like acrylamide might have given authorities and manufacturers more time to develop their response to the crisis, but it did not exist. The absence of scientific conventions for assessing the seriousness of the risk further hampered risk governance decisions. In effect, however, the presence of acrylamide in foodstuffs was framed as a risk that was undesirable in society, one that ultimately needed to be addressed in some way.

Risk Appraisal

In the IRGC framework, the phase of risk appraisal consists of two components, risk assessment and concern assessment. The aim of this phase is to gather the information that is necessary to assess the size and likelihood of a risk and societal concerns about them in a serious way, crucial steps that must be taken before society can decide whether it wishes ultimately to agree to a risk. The information thus includes the scientific assessment of both the risks (to human health in the case of acrylamide) and the concerns stakeholders may have regarding social and economic implications (IRGC 2005).

Risk Assessment

When a society is confronted by a systemic risk such as acrylamide, complexity, uncertainty and ambiguity have first of all to be clarified. The impacts of these three types of problems for risk assessment and ultimately, risk management, must be made clear (IRGC 2005).

(1) Complexity

The acrylamide problem exhibited substantial complexity. The difficulties of firmly establishing whether acrylamide is carcinogenic have been described earlier. The chain of cause and effect, from exposure to acrylamide to increases in the risk of cancer is not easy to define. There may be a multitude of potential causal agents, interactions between them, as well as a number of specific observed cancer effects many of which may take years to develop.

Complexity can sometimes be resolved if all available knowledge is brought together in what IRGC calls epistemological discourse, for instance,with the help of Delphi interviews (IRGC 2005). No such systematic approach was used to attempt to deal with the complexity of the acrylamide problem, though numerous scientific institutions around the world had begun to research in this area following the Swedish findings.

(2) Uncertainty

In the context of assessing risks, particularly new risks, human knowledge is almost always incomplete and thus contingent on uncertain knowledge and assumptions. The acrylamide case was also dominated by a great deal of uncertainty, in particular the uncertainty arising from the extrapolation of data from animal experiments to humans. At the time that acrylamide problem arose in foodstuffs, the policy convention in place was that substances that were definitely carcinogenic in animal experiments were also treated as carcinogenic in humans. However, as described above, this convention was questioned by some epidemiologists and toxicologists, resulting in considerable media response.

Uncertainty affects risk evaluation and the development of management options. The classic question of 'how safe is safe enough' is replaced by the question of 'how much uncertainty and ignorance are the main actors willing to accept in exchange for some given benefit'. In such cases, risk managers are well advised to include the main stakeholders in the risk management process and ask them to find a consensus on approaches to issues like the extra margin of safety in which they might be willing to accept in exchange for avoiding potentially catastrophic consequences. This type of deliberation, called 'reflective discourse', relies on a collective reflection about balancing the possibilities for over- and under-protection. If too much protection is sought, innovations may be prevented or stalled; if we go for too little protection, society may experience unpleasant surprises. It is recommended that policy makers, representatives of major stakeholder groups, and scientists take part in this type of discourse. The reflective discourse can take different forms: round tables, open forums, negotiated rule-making exercises, mediation or mixed advisory committees including scientists and stakeholders (IRGC 2005).

(3) Ambiguity

The result of a risk assessment is normally evaluated differently by different actors. High complexity and uncertainty favour the emergence of ambiguity. Ambiguity arises when values, priorities, or limitations cannot be agreed upon. Two forms of ambiguity may be distinguished:

a) **interpretative ambiguity** à The result of a risk assessment provokes differing interpretations because there is a lack of clarity whether an effect is adverse or not, e.g., low concentrations of genotoxic substances.

b) **normative ambiguity** à This arises as a consequence of different concepts of what can be regarded as tolerable in terms of e.g. ethics, quality of life parameters, distribution of risks and benefits, and so on. Examples of this would include passive smoking, nuclear power, pre-natal genetic screening.

Both forms of ambiguity are identifiable in the events surrounding acrylamide in Germany. Firstly, as discussed above, no agreement could be found on the issue whether the quantity of acrylamide that a person would normally absorb in their diet should be considered a cause for concern. Secondly, the economic interests of the manufacturers of the affected foodstuffs played a role. The fronts between the different interest groups seem here to have hardened particularly. Since the general public took less part in the debate over the interpretation of toxicological data, it would surely have been sensible to include the issue of the ambiguity in the public discourse.

In problems of high ambiguity, as in the acrylamide case, the IRGC does not see a simple demonstration of open-mindedness about publicly expressed concerns to be sufficient. Such circumstances require an opening of the process of risk evaluation to the participation of the public and new forms of consultation in the form of a participative discourse. These offer affected parties the possibility to exchange arguments, and openly discuss assumptions and ethical values. This form of discourse allows numerous opportu-

nities to resolve conflicts since, for instance, in the course of the discourse common values can be identified, or ways found in which different societal groups can realise their own concepts without interfering with others (IRGC 2005).

The Beginning of the German Acrylamide Case

The problem of complexity, bringing together available knowledge on acrylamide, was easily addressed in Germany. The German authorities were informed of the Swedish findings through the European Union's early warning system on 23 April 2002 (Deutscher Bundestag 2002). The BgVV expressed itself promptly with a press release (BgVV 2002 a). Subsequently, remaining unanswered questions were addressed in a series of official activities, as detailed in Table 2.[21]

Table 2: Official activities in Germany relating to the risk assessment of acrylamide in foodstuffs

14.05.2002	BgVV	1st public expert discussion at BgVV
19.06.2002	BgVV	1st meeting of the acrylamide analysis working group
02.07.2002	BgVV	Statement on FAO/WHO consultation from 25.06. to 27.06.2002
01.08.2002	BgVV	BgVV: Proposal for the introduction of an action value of 1000 Microgram per kilogram foodstuff
August 2002	BgVV	Beginning of proficiency tests
17.09.2002	BgVV	Determination of signal values
01.10.2002	BgVV	Publication of the process for determining acrylamide in solid and pasty foodstuffs
28.11.2002	BfR	Publication of a document on the updated risk assessment of acrylamide in foodstuffs
09.12.2002	BfR	Press statement from BfR: baby foods can also contain acrylamide
16.12.2002	BfR	Results of proficiency tests
27.01.2003	BMVEL	Hearing of the consumer committee of the German parliament on acrylamide in cosmetics
30.01.2003	BfR	Statement on Mucci et al.'s study
10.02.2003	BfR	Publication of results of proficiency tests
15.07.2003	BfR	Results of spot survey of young people on absorption of acrylamide
29.10.2004	BfR	Expert colloquium on research activities (part I)
07.02.2005	BfR	Expert colloquium on research activities (part II)
15.03.2005	BfR	Information on the outcome of the 64th JECFA meeting

A first important step in the acrylamide risk assessment was surely the expert discussion at BgVV on 14 May 2002. Scientists, consumer and business associations, experts from the regional governments, and representatives of the BVL discussed the significance of the Swedish

[21] The multitude of activities undertaken by the BgVV/BfR cannot be discussed in detail at this point. For further information on the BgVV's/BfR's activities in this regard and on acrylamide, please see the Instititute's homepage. All the documents of the BgVV and the BfR discussed in this text are to be found at: http://www.bfr.bund.de.

findings for Germany. The development of validated methods of analysis was seen as a precondition for the determination of the acrylamide contents of products on the German foodstuffs market. Great uncertainty remained regarding the exposure of humans because no current data was available on German eating habits. The experts unanimously supported the risk assessment undertaken by the EU which named acrylamide as a carcinogen. Among other items confirmed as open questions and next steps were that a comparison of laboratories (proficiency test) had to be organised to guarantee uniform measurement, that affected foodstuffs should be investigated in a coordinated fashion, and that human consumption be estimated (BgVV 2002 b).

Simultaneously with the report on the expert discussion, a statement was issued with advice for consumers on how absorption of acrylamide could be lowered by changing eating habits (BgVV 2002 c).

At the first meeting of the acrylamide analysis working group, findings from current research were presented. For instance, data showed that there are foodstuffs with their own potential for the formation of acrylamide, that the highest acrylamide levels are in potato products and crispbreads, and that the lower the amount of water present, the greater the formation of acrylamide (BgVV 2002 d).

An international expert debate on the significance for human health of acrylamide in foodstuffs took place from 25 to 27 June 2002. The organisers of the event were the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). In the meantime, the Swedish findings on the topic had been confirmed by experiments in various countries, including Norway, Switzerland, Great Britain, the USA and Germany.

Provisional exposure estimates suggested that consumers take in less than 1 microgram per kilogram bodyweight per day of the substance over the long term. Experts viewed the question of the genotoxicity and mutagenicity of by acrylamide as crucial. There was as yet no precise assessment of human carcinogenicity available, because data from studies of occupational exposures were, due to the low numbers of cases involved, not appropriate for capturing small changes in cancer risk. However, acrylamide was to be found in higher quantities in foodstuffs than any other carcinogen. The conclusion of the experts was, therefore, to consider acrylamide in foodstuffs as a "major concern" (WHO/FAO 2002, p.1 and p.20). The process of the formation of acrylamide in foodstuffs was still not understood although the methods for its detection were considered valid. Given the incomplete state of the data, no specific recommendations regarding consumption of specific foodstuffs could be given, only tentative advice (WHO/FAO 2002).

The event reinforced the BgVV's stance and approach up to that point that "the very thorough discussion between internationally recognised experts did not reach any conclusions which were substantially divergent from the BgVV's previously held opinion" (BgVV 2002 e, p. 5).

On 1 August 2002, the BgVV issued a statement on the current situation. The Agency stated that a scientifically established conclusion regarding acrylamide in foodstuffs could not be expected in the foreseeable future. Internationally, the only recommendation being made was to keep exposure "as low as reasonably achievable" (ALARA). The BgVV perceived a necessity to improve the situation as fast as possible, and suggested as a first measure the introduction of an "action value" of 1,000 micrograms, i.e., 1 milligram per kilogram foodstuff. With more meaningful data, maximum values for specific foodstuffs could perhaps be established later. In accordance with the current state of knowledge, the action value was applied above all to crisps and other similar snacks, biscuits, and crispbreads (BgVV 2002 f).

In December, the Swiss health authorities issued an estimation regarding the absorption of acrylamide through foodstuffs. The diet of 27 participants had been analysed over two days. A fairly low level of acrylamide intake was ascertained --- just 0.28 micrograms per kilogram body weight per day. A significant result arose from the observation of relative acrylamide absorption from different foodstuffs: 36% of the daily dose came from coffee. It was assumed that this value was so high because potato products were underrepresented in the experiment. Nonetheless the conclusion remained that foodstuffs which contained relatively low levels of acrylamide could make a significant contribution to the total absorbed if consumed in large quantities (BAG 2002).

In December 2002, discussions began between the manufacturers of affected foodstuffs and the authorities at BMVEL (BLL 2003).

A particular hazard from acrylamide for young people was identified, since it was supposed that they would have a higher consumption of crisps and chips (BfR 2002). In July 2003 the results of a study evaluating the exposure of Berlin schoolchildren in the 10^{th} grade of general schools were released. Until then assessments of the exposure to acrylamide had rested largely on data from the national consumption study of 1989 and the National Health Survey of 1998. From these old data, it was concluded that young male adults between 19 and 24 years of age would, on average, take in 50 micrograms of acrylamide per day. An outcome reported from the more recent study was that the average intake was 69 micrograms of acrylamide, or 1.1 micrograms per kilogram bodyweight per day. Among 5% of the schoolchildren, this value was as high as 3.2 micrograms per kilogram bodyweight per day (Mosbach et al. 2003).

On 19 March 2004 the BfR issued a statement on "two years of acrylamide" and gave a list of activities analysing the risk up to that point in time:

- The formation mechanism could be explained to a large extent. Validated analytical methods were available for many foodstuffs.
- A daily intake of 0.5 to 1.0 micrograms per kilogram bodyweight for adults was estimated.
- Through blood tests it could be shown that human exposure actually occurred.
- No indication existed that even low doses of acrylamide could be considered without risk of cancer.
- Experts estimated that an average daily exposure to acrylamide of one microgram per kilogram bodyweight over a lifetime would result in 6 to 100 additional cases of cancer per 10,000 individuals.

Using the state of knowledge current at the time, the content of acrylamide in commercially produced and prepared foodstuffs could be reduced by varying the factors of temperature, time and water content. At the same time, it became clear that the preparation of a product could not be altered beyond certain limits without the product losing its characteristic qualities. Further findings were still to be collected (BfR 2004).

The manufacturers cooperated in a project researching acrylamide. Various analytical, toxicological and technological issues were addressed with the aim of reducing the quantity of acrylamide in foodstuffs. Participants included the German Research Centre for Food Chemistry, the Institute for Food and Environment Research, the German Institute of Food Technology, the Federal Research Centre for Nutrition and Food, and the University of Kaiserlautern. The project's final report was submitted in December 2005 (BLL/FEI 2005).

The unanimous opinion among experts is still that a conclusive quantification of the risk arising from acrylamide in foodstuffs will not become available in the foreseeable future. The risk assessment was quite comprehensively carried out, despite the complexity of the problem. The further development of risk governance approaches took account of the fact that uncertainty is very high in the acrylamide case. Nevertheless, it is striking that the manufacturers were far more involved in the attempt to minimise uncertainty and ambiguity than the other stakeholders, in particular the consumer protection organisations.

Concern Assessment

The IRGC Framework proposes that the concern assessment phase should include: research on concerns about and perceptions of risk by interested societal groups; an understanding of potential economic effects; and the courses of action for addressing them. The rationale for a concern assessment phase is rooted in well-described differences in the way individuals and scientists assess and perceive risks which are described briefly in this section.

A central finding of risk perception research is that the estimation of a hazard by the majority of the population frequently does not correspond with the scientific assessment of the risk.[22] Schütz and Peters (2002) see an explanation of this in the fact that different rules underlie the formation of risk realities for the population, for scientists, and also for the media as the link connecting them.

"Lay people's" perceptions of risk are not based on methodically sophisticated and systematic procedures, but incorporate several qualitative aspects of the risks. For example, risks are judged to be less hazardous if they are seen as being controllable or if they are undertaken voluntarily. Risks are viewed as many times more hazardous when an institution viewed as responsible for imposing the risk can be identified and targeted for recrimination, particularly when they might be viewed as making profit from the situation (Renn/Kastenholz 2000). Furthermore, hazards are held to be less worrying if they have a limited potential to create catastrophes, because the simultaneous death of many people in one place is perceived as significantly more threatening than the deaths of the same number of people over a period of time or in several locations (Jungermann/Slovic 1993). Additional influences include the state of scientific knowledge, the personal effect of the risk, degree of familiarity with the risk, the personal utility of the source of the risk, the balance of risk and utility within society including its possible effects on future generations. But lay people also weigh up probabilities subjectively; for instance, the probability of an event is reckoned to be higher if it can more easily be imagined or if it has already been experienced (Schütz/Peters 2002).

These assumptions also hold true for cancer risks, since the perceptions of the population do not correspond with the scientific assessment of the causes of cancer. This can be illustrated by discussing three examples from the USA in the 1990s. The pesticide Alar, used in the apple industry, was a cause for great concern. The US Environmental Protection Agency estimated that the increase in the risk of cancer to an individual from a lifetime's consumption of apples treated with Alar was 0.00045%. Nonetheless, people developed a great aversion to Alar, and sales of apples fell enormously. In the second case, an article about the relationship between drinking coffee and an increase in the incidence of cancer of the pancreas was publicised. When this finding became known, the consumption of coffee fell for a number of days, but then soon returned to its former level. (The relationship reported could not be verified.) In the third in-

[22] An overview of the current state of risk perception research can be found in Schütz/Wiedemann (2005).

stance, the US Food and Drug Administration planned to withdraw the sweetener saccharin from the market following its classification as a carcinogen. However, protest from the population against this measure was so strong that it was not implemented (Brody 1999).

These examples illustrate that people are indeed prepared consciously to accept some risk of cancer with particularly popular or useful foodstuffs. The opposite reaction in the case of the pesticide Alar may well be explained by the involuntary nature of the risk, that is, that people viewed that the apples were treated with Alar by the producers and that they could only avoid the risk by stopping eating apples. In contrast to coffee, the slighter preference for apples in individuals' diets probably actually resulted in a permanent boycott of apples.

People's views of risks are also influenced by media coverage (Renn/Kastenholz 2000). The topic of acrylamide was a particular object of media interest in 2002. According to a search of the Lexis-Nexis online archive, over 150 media entries on the theme appeared between April and November 2002 (Wiedemann et al. 2002). These reports appeared to lead to least a temporary alteration in consumer behaviour, because sales of crispbreads and potato crisps, both types of product which were at the centre of media coverage along with chips, fell markedly in 2002 and 2003.[23] At the beginning of February 2003, the opinion research institute Polis ascertained that 15% of Federal citizens had changed their eating patterns as a result of media coverage of acrylamide (Stern online 2003 b). In 2003, total sales of savoury snacks had actually risen 2.7% the previous year, although sales of potato crisps specifically were down 4.8%. Instead, more peanuts, pretzel sticks, *Erdnussflips* (extruded specialities), and savoury and cheese biscuits were bought (Handelsmagazin 2004).

Manufacturers and consumer protection organisations are the two groups whose concerns should have been incorporated in a risk appraisal phase for acrylamide. Survey findings show that consumer protection organisations enjoy the highest levels of trust within a population when information about food risks is in question (vzbv 2001, EC 2006). The German acrylamide case was characterised by substantial disagreements between the two parties. Consumer protection organisations claimed that the manufacturers would not do enough against possible health risks for consumers, and felt that they had not been adequately involved in the risk assessment process (vzbv 2002).

The manufacturers initially felt that they had been made solely responsible for the acrylamide problems (e.g., GDCh 2003, confirmed in expert interviews). They signalled their willingness to cooperate on solutions, but emphasised the need for research before the delivery of assessments and criticised the first assessments of the BgVV about human exposure as "unscientific". The introduction of an action value was viewed "very critically", since it did "not contribute to a drastic reduction of acrylamide absorption through foodstuffs" (BLL 2002 b).

The dispute, conducted in public, reached a crisis when, during an information event at the BgVV in August 2002, a manufacturers' association attempted to prohibit the choice of modera-

[23] An interesting point in this context is that sales of crispbreads were apparently already falling in 2002. However, the decline in sales of potato crisps began, according to the statements of market leaders Intersnack, only in November 2002, following a new wave of media coverage on estimations of incidences of death due to acrylamide in foodstuffs. This could, firstly, be because crispbreads tend to be eaten by people who are more interested in health issues and so react more sensitively to such media reports. Alternatively, it could be that there are many people who are more ready to give up crispbreads than potato crisps, just as the Americans gave up apples more quickly than coffee. A further analysis of the figures would be of interest to clarify whether the Germans actually reacted more cautiously than their European neighbours. With potato crisps in particular, it should be recalled that a soccer world cup took place in 2002, so a certain decline in sales might have been expected in 2003, even without acrylamide.

tor for the closing debate. The doctor of chemistry, who had been appointed moderator, was accused of being a professed communist. "There is a strong suspicion that, through the choice of moderator, a clear opposition of the BgVV to the food industry is being engineered." (Baking Goods and Materials Producers' Association, quoted in Schrum/von Aster 2003).

In 2003, after a balance had been drawn up in some media on the occasion of the anniversary of the announcement of the Swedish findings, the scope of media coverage fell markedly. In April 2003 the last press statement on the topic was issued by the BfR.

The discord remained. In 2005, the consumer organisation Foodwatch expressed the opinion that the acrylamide case was an example of "how frivolously commerce and politicians deal with risk substances" (Foodwatch 2005, p.2). The manufacturers, on the other hand, saw the topic's handling by the media as "barely responsible", complained that their largest loss of sales internationally were in Germany, and emphasised the danger that such crises represent for jobs (Wolf 2006)[24].

These episodes/incidents show that no systematic concern assessment was conducted in the German acrylamide case. Instead the controversy between the chief stakeholders, the manufacturers and consumer protection bodies, was conducted in public. The media coverage partly contributed fuel what was already heated debate.

Tolerability and Acceptability Judgement

Judging whether a risk is seen as acceptable or tolerable involves two steps, risk characterisation and risk evaluation. This phase is often the most controversial part of the risk governance process, particularly when, as in the case of acrylamide, the risk in question is accompanied by complexity, uncertainty, and ambiguity. Deciding that a risk is “acceptable” means that no further measures need be taken to reduce it. A “tolerable” risk, in contrast, is one that is viewed as reasonable, but further measures to reduce the risk are deemed necessary. The IRGC framework describes in detail the processes and factors to be considered in evaluating the tolerability or acceptability of a risk (IRGC 2005).

In the German acrylamide case, it is certain that no such systematic and comprehensive judgement of the acceptability and tolerability of the presence of acrylamide in foodstuffs took place. Stakeholders were consulted, and it was attempted by the ministry to conduct a tolerability judgement first with the representatives of the manufacturers. However, no agreement between the participants was reached, so that each group developed its own judgements based on the available information and its own concerns. In its statement of 19 March 2004, the BfR reached the conclusion that with acrylamide it was dealing with a risk that was "to be regarded as significant in comparison with other material risks", and demanded "that the exposure be drastically reduced as rapidly as possible" (BfR 2004, p.1). This decision corresponds to a

[24] An article on p.1 of the *Kölner Express* of 25 November 2002 was seen as particularly lurid: "Frying-Death: More Deaths Than Traffic? It's hiding in chips, crisps, and popcorn - yes, even in Mum's roast potatoes: the secret cancer agent acrylamide. Boffins have now worked out that the chip poison could cause more than 8,000 deaths a year in Germany. Is there anything left we're allowed to eat? After the horror of BSE (mad cow disease), and the trauma of foot and mouth disease the latest findings have stoked more fears. What is this stuff that leaves mealtimes sticking in our throats?" (Renz 2002). Newspapers have to be filled, even on days when there is little news. Then journalists turn to less momentous themes and try to make news of them. The results can then make such an article. Stephan Russ-Mohl, Director of the European Journalism Observatory, is critical: "Even under trying editorial circumstances one should always consider whether one is causing unnecessary fears" (Stute 2006).

judgement of the risk as *tolerable* in IRGC's terminology. In its "Acrylamide Status Report", the BLL described the "problem" as being "taken very seriously by all participants, since acrylamide appeared to be carcinogenic in animal experiments", yet simultaneously emphasised that acrylamide was also formed during the domestic preparation of food, and had been in the foods in question since the discovery of fire (BLL 2003, p.1). This description of the situation tends far more to a judgement of the risk as *acceptable*. It is noticeable that the term acrylamide appears in quotation marks in the title of the document and partially also in the document. The quotation from Kulling in the journal of the Society of German Chemists sounds similar: "the daily consumption of fried foods brings an entirely different health problem to the fore: one-sided, imbalanced nutrition, together with a high energy intake, above all through a large proportion of fats" (Kulling 2002, p.1104).

In contrast, consumer advocates drew on the appraisals of scientists that regarded "acrylamide as far more dangerous than all other chemicals yet found in foodstuffs" (bio verlag 2002). Such statements pushed the acrylamide risk towards one which was no longer tolerable – although no evidence has been found during this research that consumer advocates or other actors wanted to ban affected foodstuffs. However, as shown below, consumer advocates called for the most far-reaching measures for the reduction of the acrylamide levels in foodstuffs. Apart from this, the German Advisory Council on the Environment came to the conclusion that "the intake of acrylamide in food lies beyond the realm of the tolerable" in its environmental survey of 2004 (BtDr 15/3600). However, in the question session of the German Bundestag on 13 November 2002, the then parliamentary secretary to the Federal Minister for Consumer Protection, Nutrition and Agriculture announced that "Let me refer to a similar process: Benzopyrene is produced by barbecueing. This is accepted, because the barbecued food tastes better. Nonetheless, the public has the right to be informed of the risk to health" (Deutscher Bundestag 2002, p.482). This multitude of judgements then accompanied the introduction of measures in risk management with which the problem of acrylamide in foodstuffs should be met in Germany.

Risk Management

When all the phases of the Risk Governance Framework discussed above have been applied and the necessary information processed and collected, risk management is faced with three possible situations:

- **Intolerable:** the risk source (such as a technology or a chemical) needs to be abandoned or replaced or, in cases where that is not possible, for example natural hazards, vulnerabilities and exposure need to be reduced.

- **Tolerable:** the risks need to be reduced or handled in some other way within the limits of reasonable resource investments (ALARA). This can be done by private actors such as corporate risk managers, or public actors such as regulatory agencies, or by public-private partnerships (IRGC 2005). The precautionary principle might also be applied in selecting actions to take.[25]

[25] The European Commission has also endorsed, under certain conditions, the application of the precautionary principle, for instance where a phenomenon, product, or process potentially leads to hazardous consequences, but the risk cannot be defined with sufficient certainty. The recommendation also acknowledges the difficulty of "weighing the rights and freedoms of individuals, companies and associations on one hand with the need to reduce the danger of negative consequences for the environment and the health of people, animals, or plants on the other" (EC 2002, p.1). However, the precautionary principle has attracted criticism because this ap-

- **Acceptable:** the risks are so small, perhaps even regarded as negligible, that any risk reduction effort is unnecessary. However, risk-sharing via insurance and further risk reduction on a voluntary basis both present options for action which can be worth pursuing.

The IRGC framework discusses the risk management approaches that might be considered, as well as appropriate measures for involving relevant stakeholders depending on the type of risks, the results of the assessments, and the extent to which the risks remain complex, uncertain, or ambiguous.

The acrylamide case represents a situation in which the German authorities determined that the risk was at some level tolerable, but was one that needed to be managed carefully. The BgVV, as discussed earlier, at this time still combined the role of risk assessment and risk management in the same organisation. After the WHO and the EU had classified acrylamide as a cause for concern and recommended the fastest possible reduction of exposure, the BgVV regarded setting a limit on acrylamide levels in food as essential. They made the risk management decision to apply the precautionary principle and established an "action value" of 1,000 micrograms per kilogram foodstuff. The level chosen for acrylamide corresponded to the limit for Benzopyrene in the regulations concerning flavourings and cheese (BgVV 2002 f).

The manufacturers' reaction was to reject this. In their view, the level had no toxicological foundation. They saw the possibility of misinterpretation. The BLL reacted with a press release stating that the level had absolutely no effect on the marketability of products (BLL 2002 a).

Following the information event of 29 August 2002 the minimisation concept was presented. According to the BMVEL's press release, the idea had been proposed by the newly established BVL and "was reviewed with the highest foodstuffs monitoring authorities of the regional governments at the beginning of the week" (BMVEL 2002). The minimisation concept comprised the idea that, that foodstuffs be classified into defined commodity groups which would then sampled for acrylamide. In each commodity group, a 'signal value' was established which was defined as the lowest acrylamide level found in the top 10% of foods within a commodity group (in other words, at the 90^{th} percentile of all values). In no case could the signal value be set at a level greater than 1,000 micrograms per kilogram of foodstuff. Signal values, once set, could not be raised (BVL 2005 c). So-called 'minimisation dialogues' were then held with the manufacturers whose products exceeded the signal values in order to introduce measures for the reduction of acrylamide concentrations.

The first calculation of signal values was made in September of 2002. Shortly before the introduction of the minimisation concept, only a very few analytical findings were available: 63 for bread, 42 for crispbreads and 87 results for potato crisps (Galle-Hoffmann 2002). By the publication of the last calculation in October 2005, 10,000 tests had been evaluated. The results of the five published calculations are presented in Table 3.

Table 3 Overview of the signal values for the period 2002-2005

Commodity group	Date of Analysis				
	September 2002	January 2003	November 2003	November 2004	October 2005

proach does not permit risk managers a differentiation by priorities. In addition, what "reasonably" can be taken to mean within the term ALARA is open to question (BfR 2005).

	Acrylamide in micrograms per kilogram of foodstuff				
Shortcrust pastries	800	660	575	575 (760)*	300
Breakfast cereals (Cornflakes and Muesli)	260	260	200	200 (240)*	180
Roast coffee	370	370	370 (520)*	370 (420)*	370 (537)*
Potato crisps	1000 (1500)*	1000 (1200)*	1000 (1470)*	1000 (1029)*	1000 (1333)*
Crispbreads	610	610	610 (1260)*	610 (640)	590
Chips, prepared	770	570	570	540	530
Potato fritter, prepared	1000	1000 (1300)*	1000 (1080)*	1000 (1215)*	1000 (2520)*
Gingerbread and pastries containing gingerbread	1000	1000 (1370)*	1000 (1460)*	1000 (1020)*	1000 (1270)*
Almond biscuit (*Spekulatius*)	1000	710	710 (760)*	560	560 (706)*
Rusks or biscuits for babies and toddlers	n. c.	n. c.	360	360	245
Long-life baked goods for diabetics	n. c.	n. c.	1000 (1740)*	1000 (1010)*	545
Soluble coffee	n. c.	n. c.	1000 (1110)*	1000 (2380)*	1000 (1030)*
Coffee substitute	n. c.	n. c.	1000 (2080)*	1000 (2910)*	1000 (2341)*
* observed value **n.c. = not calculated					

Source: BVL (2005 a)

The aim of the minimisation concept is that the difference between the levels measured in a commodity group be made as narrow as possible, or that the signal value be as near as possible to the average. But the levels do not vary to the desired degree.

In 2003-5 observed levels of acrylamide were at or above the signal value from the preceding year or above the maximum 1,000 micrograms limit in seven to ten commodity groups. Acrylamide levels appeared to decline in five out of the thirteen commodity groups, including chips, shortcrust pastries, baked goods for diabetics, almond biscuits, and children's rusks. However, even in these commodity groups, the trend was not consistent.

The BfR welcomed the minimisation concept but argued that data collection needed to be significantly improved (BfR 2004). It was confirmed in experts' discussions that the process of data collection was unstructured and that there was no control of any changes from the previous year's values; for example, different products were tested from year to year which could account for some of the inconsistencies in results observed. In any case, the monitoring of foodstuffs within the regions was reaching its limits, because the organisations involved also had to deal with other risks associated with foodstuffs.

The BfR reached the conclusion "that a representative quantification of the reduction of the exposure is not possible at present" (BfR 2004) because acrylamide exposure from the domestic preparation of the affected products could not be assessed (BfR 2004). The BVL also held a critical view of the results of the minimisation concept, because "acrylamide levels in foodstuffs have only been fractionally reduced", and called for "a closer relationship" with manufacturing practice (BVL 2005 b).

No official critical evaluations of the minimisation concept from the manufacturers' side could be identified. However, unofficial discussions suggest that it was predominantly viewed as a measure for mollifying consumers. The BfR's appraisal --- that the tests were conducted unsystematically and that thus the results did not reflect reality --- was affirmed. In addition, the fact that foreign manufacturers had not been involved in this process was seen as a problem.

In contrast, the consumer protection organisations complained that the minimisation concept did not go far enough. Foodwatch criticised the fact that the worst levels were taken as benchmarks. To arrive at best practice, Foodwatch argued that it would be more sensible to take lower levels as reference values. Above all, there was a lack of pressure on manufacturers. The test results were to be published to force the manufacturers to take steps to reduce acrylamide levels (Foodwatch 2006 a). Foodwatch gave, as an example, the Dutch firm FZ Organic Food, a manufacturer of organic potato crisps amongst whose products the Tra'fo brand was found to contain extremely high levels of acrylamide. After Foodwatch had made this public, FZ Organic Food had to accept a 30% drop in sales. The company was subsequently able to alter its production and significantly reduce the acrylamide levels in its crisps (Foodwatch 2005).[26] A further central demand of Foodwatch was the labelling of products with a scale which would indicate the "exposure class" of a product (Foodwatch 2006 b). Dissatisfaction with the regulations was clearly expressed (c.f. "Künast bows to the snacks industry", *"Künast kuscht vor Knabberindustrie"*, bio verlag 2003).

The German Food and Feed Code prohibits authorities in Germany to name manufacturers publicly.[27] However, in the near future a law relating to consumer information[28] would be enacted to take account of the food scares of the recent past and strengthen the rights of consumers to information. The current draft, however, still includes grounds for exempting information. This includes cases in which "through the information requested, company or commercial secrets or other information relevant to competition which is comparable to a company or commercial secret in its significance for the company would be made public" (VIG Entwurf). This restriction also attracted strong criticism since this issue is certainly handled in a less restrictive way in other countries, for instance in Sweden with the public principle mentioned above.

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[26] Foodwatch's test results are available on the company's homepage (http://www.fzorganicfood.com, accessed 31 May 2006).

[27] However, there is an exception to the prohibition on naming manufacturers which arises from the consumer information law of the federal state of North Rhine-Westphalia. In Paragraph 4, "right to information", it is stated: "Every natural person has, due to the provisions of this law against the points named in § 2, the right to access to official information available at that point" (IFG NRW). On this legal basis the individual acrylamide test results are indeed available on the internet page of the Ministry of the Environment and Conservation, Agriculture and Consumer protection of North Rhine-Westphalia (c.f. http://www.munlv.nrw.de/sites/arbeitsbereiche/verbraucherschutz/produkte.htm, accessed 31 May 2006). But the findings are presented in a very opaque fashion and provide no practical help to consumers with their purchasing decisions. According to the employee responsible for this at the ministry, however, this is due purely to a lack of finances and personnel. Unfortunately, the number of visits to the site had not been counted. In conversations the assumption was expressed several times that such publications would affect the consumer as confidence-building measures which would hardly alter the long-term purchasing decisions of average consumers. In this context it would have been very interesting to gather evidence for this assumption..

[28] Verbraucherinformationsgesetz (VIG)

This prohibition on divulging the names of manufacturers is not entirely advantageous to them all. A massive image problem was created for the crispbread manufacturer Wasa, whose products were from the beginning shown to contain very low levels of acrylamide. Their sales also declined sharply due to the acrylamide levels found in their competitors' products (Kruse 2003).

The German minimisation concept was praised internationally many times, but not adopted. One reason may be that nobody wanted to give new life to the topic of acrylamide in neighbouring European countries. Most people with whom the topic was discussed reckon that it will also soon be forgotten in Germany.

In Switzerland, the German signal values were even taken as a reason to ban a children's biscuit made by Milupa (nachrichten.ch 2005). In Germany, no attempt has been made to enforce the minimisation concept e.g. withdraw a product from the market due to a high acrylamide level.

This overview of the most important events in risk management in Germany has shown that a solution was found which corresponds to the recommendations of the IRGC. For risks which are evaluated as tolerable, the IRGC suggests a management strategy be considered which is based on the precautionary principle. Since, as the events summarised in this chapter have indicated, this risk could be dealt with as a tolerable one, the minimisation concept was considered to be an appropriate measure for reducing that risk. It provided an opportunity to examine individual exposures to acrylamide, which can differ markedly depending on the foodstuff.

However, for the majority of people with whom the issue was discussed, the minimisation concept was judged to be a failure from the outset, because it was not combined with incentives or sanctions. It was developed by regulatory authorities and the affected industries without input from other stakeholders or evaluation of how it met other important criteria advocated by the IRGC. For example, the minimisation concept did not really provide a valid monitoring programme because of problems with inconsistencies in the sampling program from year to year.

SUMMARY AND CONCLUSION

The purpose of this document has been to examine the case of acrylamide found in foodstuff in Germany within the context of the IRGC Risk Governance Framework. The IRGC framework should improve the societal process of risk governance, especially for systemic risks such as acrylamide. The acrylamide case presented a particular challenge for risk governance as it was a situation in which the emergence and recognition of the potential risk occurred rapidly and caught many unprepared. The news that acrylamide had been discovered in foodstuffs reached the public under unusual circumstances. The way in which scientific information was released to the public contributed to ongoing debates about the quality of the research findings. Although much time has been spent on the investigation of acrylamide, a conclusive assessment of the hazard to humans is not likely to be available for the foreseeable future.

The rapidity with which the crisis developed made it difficult for a full pre-assessment, as advocated by the IRGC, to be completed. Two factors might have helped. No early warning system existed with whose help the risk governance process could have begun under less pressure. The situation was further described by a lack of scientific conventions which could define the appropriate basis for publicly conducted disputes. For sensitive topics like this, it would also

have been appropriate and helpful to have some conventions with which the specialist and popular press might have had to comply without, of course, interfering with the fundamental freedom of the press, but to avoid creating more of a problem. At least the third and crucial factor was met; the factor that acrylamide in foodstuffs presented a type of risk to which society would consider it necessary to apply the the process of risk governance.

The second phase of the framework involves risk appraisal, in which all the available information which society needs to decide whether to take a risk is collected. For the acrylamide case, the risk assessment was conducted largely as the framework suggests. However, the opinions of stakeholders were not considered to the extent recommended. Only a few activities were undertaken to include stakeholder concerns regarding the effects of the risk and the possible risk management options.

For the third phase of the framework, no systematic judgement took place whether the acrylamide risk was to be viewed as acceptable or tolerable on the basis of the knowledge gained. Instead, a number of voices were raised, by direct stakeholders and other public actors, who had developed their own judgements. It is clear from official statements, that government authorities regarded this as a tolerable risk, a risk which needed to be reduced. Manufacturers, however, were inclined to view acrylamide as an acceptable risk, one for which little or no action should be required. The diversity of opinions about the tolerability/acceptability accompanied the introduction of risk management measures.

In the last section of the framework, the risk management phase, the government authorities implemented the minimisation concept, a tool which, could have been perfectly suitable for leading to a reduction of acrylamide levels in foodstuffs. However, since the government relied on voluntary cooperation of the industry, the minimisation concept was not combined with any incentives or sanctions. This half-hearted implementation led to a risk management strategy, that, in reality, would have been only suitable for handling an acceptable risk.

At the same time, the manufacturers in Germany and in Europe made considerable efforts to develop improvements in production methods which corresponded more closely to the management of a tolerable risk.

Whether the manufacturers would have been more proactive in building trust if an early warning system had existed and given them more time to prepare themselves to deal with the problem remains an open question. It has not been possible within this study to confirm whether the manufacturers were made fully responsible for the problem. However, it appears that they could have made far more use of the opportunity to publicise their activities to monitor and reduce acrylamide levels.

Had the IRGC framework been followed, it would have been necessary to establish a consensus between manufacturers and consumer protection groups. However, it is doubtful that inclusion of the public in the debate over the management of acrylamide would have been suitable for the acrylamide problem in Germany. For a while, the public avoided some popular products, perhaps waiting for a sign that a solution had been found or that something had happened. Since nothing did happen, and the manufacturers were not obligated to take any measures, it was certainly no longer clear to the public why they should restrict themselves from food products they desired and so they returned to their former eating patterns.

Although the importance of separating risk assessment from risk management is often stressed in various risk governance frameworks, including IRGC's, the organisational division of risk assessment and risk management in Germany between the BfR and the BVL, respectively does not appear to have played a particularly positive role in the course of the events dis-

cussed. In private conversations, it was lamented that the old BgVV had had greater powers of enforcement and implementation. The BfR could only issue risk assessments but without any enforcement powers, while the BVL had relatively little independence to implement effective risk management measures.

The result of this case study is that if the IRGC framework had been applied it would probably have improved the societal process of risk governance for acrylamide in food in Germany. The framework helped to give a structure to this evaluation of the acrylamide case and to identify clearly the weak points where the process could have been improved, thereby leading to results which would have had greater benefits for society.

INDEX OF ABBREVIATIONS AND TRANSLATED NAMES

	Gesetz über Nachfolgeeinrichtungen des Bundesgesundheitsamtes	Act on Successor Institutions of the Federal Public Health Department
	Gesetz zur Neuorganisation des gesundheitlichen Verbraucherschutzes und der Lebensmittelsicherheit	Act on the Reorganisation of Customers' Health Protection and Food Safety
	Verband der Backmittel- und Backgrundstoffhersteller e. V.	Baking Goods and Materials Producers' Association
	Wissenschaftsrat	Science Council
BfArm	Bundesinstitut für Arzneimittel und Medizinprodukte	Federal Institute for Drugs and Medical Devices
BfEL	Bundesanstalt für Ernährung und Lebensmittel	Federal Research Centre for Nutrition and Food
BfR	Bundesinstitut für Risikobewertung	Federal Institute for Risk Assessment
BGA	Bundesgesundheitsamt	Federal Public Health Department
BgVV	Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin	Federal Institute for Consumer Health Protection and Veterinary Medicine
BLL	Bund für Lebensmittelrecht und Lebensmittelkunde e. V.	German Federation of Food Law and Food Science
BMELF	Bundesministerium für Ernährung, Landwirtschaft und Forsten	Federal Ministry of Food, Agriculture and Forestry (from 20 September 1949 to 12 January 2001)
BMELV	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz	Federal Ministry of Food, Agriculture and Consumer Protection (since 22 November 2005)
BMVEL	Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft	Federal Ministry of Consumer Protection, Food and Agriculture (from 12 January 2001 to 18 October 2005)

BMG	Bundesministerium für Gesundheit	Federal Ministry of Health
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	Federal Office of Consumer Protection and Food Safety
ChemVerbotsV	Chemikalienverbotsverordnung	Ordinance on Prohibited Chemicals
DFAL	Deutsche Forschungsanstalt für Lebensmittelchemie	German Research Centre for Food Chemistry
DIL	Deutsches Institut für Lebensmitteltechnik	German Institute of Food Technology
EFSA	Europäische Behörde für Lebensmittelsicherheit	European Food Safety Authority
FAO	Welternährungsorganisation	Food and Agriculture Organisation
FLI	Friedrich-Loeffler-Institut – Bundesforschungsinstitut für Tiergesundheit	Friedrich-Loeffler-Institute – Federal Research Institute for Animal Health
GDCh	Gesellschaft Deutscher Chemiker	German Chemical Society
GefStoffV	Gefahrstoffverordnung	Ordinance on Hazardous Substances
ILU	Institut für Lebensmittel- und Umweltforschung	Institute for Food and Environment Research
JECFA		Joint FAO/WHO Expert Committee on Food Additives
LFGB	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch	German Food and Feed Code
MUNLV	Ministerium für Umwelt und Naturschutz, Landwirtschaft und Verbraucherschutz NRW	Ministry of the Environment and Conservation, Agriculture and Consumer protection of North Rhine-Westphalia
RKI	Robert-Koch-Institut	Robert Koch Institute
SRU	Sachverständigenrat für Umweltfragen	German Advisory Council on the Environment

TrinkwV	Trinkwasserverordnung	Drinking Water Ordinance
vzbv	Verbraucherzentrale Bundes-verband e. V.	Federation of German Consumer Organisations

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