Federal Institute for Risk Assessment (BfR)

Two Years Acrylamide – A Stocktaking from the Risk Assessment Angle

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Two years have passed since the Swedish National Food Administration drew attention to a health risk that is of importance for large sections of the population: acrylamide (1). The Swedes detected, in some cases, high levels of the "building block" for plastics in numerous foods. Acrylamide is formed during the "browning reaction" when starch-containing foods are fried, oven-baked or deep-fried. In animal experiments the substance triggers cancer and damages the genetic material. A risk cannot be ruled out even in the case of the intake of low amounts. It is highly likely that these health-damaging effects of acrylamide can also occur in man. BfR has described the health risk for the consumer from acrylamide-containing foods compared to other substance risks as important and called for exposure to be drastically reduced as soon as possible.

Since the publication of the Swedish test results a number of measures have been taken on the political, economic and social levels. They aimed to reduce the risks for consumers. After two years BfR examined the efficacy of these measures from the risk assessment angle and drew up a first stocktaking. The Institute comes to the conclusion that the combination of awareness-raising measures in the private and technical sector and technological measures in the industrial sector have led to a reduction of the acrylamide burden in foods. It is not possible to offer quantitative backing for this assessment because of the lack of valid data. In order to quantitatively assess the efficacy of measures to minimise the health risk for consumers and sustainably reduce the risk for consumers, the Institute believes that a series of further measures is necessary. They include, amongst other things, the recording of data on acrylamide contamination of foods and the drawing up of guidelines for good manufacturing practice.

How is acrylamide formed in foods and how can it be detected?

Acrylamide is not added to a food. It is far more a so-called "foodborne toxicant" – a harmful substance created in the food itself in a complex formation mechanism during frying, oven-baking and deep-frying but not during boiling (2,3,4). High levels were measured in starch-containing foods, particularly in potato products like chips and crisps, in roasted cereals, bread, (in particular crispbread and toast), bakery goods, cocoa and coffee (5).

Two mechanisms are mainly under discussion in conjunction with the formation of acrylamide in foods. According to these scenarios, acrylamide can be formed

1. during the Maillard reaction which takes place in all foods containing sugar and amino acids during oven baking and frying as a flavour-giving browning reaction, and/or
2. through the reaction of amino acids with acrolein which is formed from fat during thermolysis.

Model reactions can be used to demonstrate that reducing sugar (glucose, fructose) and the amino acid, asparagine, are major factors in the formation of acrylamide. In this context the carbon chain of acrylamide emerges from asparagine. This is a very good indication that acrylamide is formed during the Maillard reaction.

The reliable analysis of acrylamide in foods and feedstuffs is the foundation for determining the exposure of human beings and for risk assessments. Based on an internationally recognised operating procedure for the analysis of acrylamide in foods, BfR has developed and optimised an analytical method. This is available as a validated method and can be accessed on the Institute's homepage (6).

In order to safeguard the quality of analytics in food control and production, BfR organised a comparative laboratory study (proficiency testing) with international participation. The study showed that reliable study methods were available for many foods after a short time but that the analytics were in need of further improvement for a few complex foods (like for instance cocoa). BfR took up this problem in order to improve the methods by introducing further analytical steps. Based on its experience, the Federal Institute is currently supporting a broadly based comparative study within the European Union (EU) that focuses on coffee and cocoa products. The results available up to now show that it was possible to make further progress in analytics.

Can acrylamide reach food via feedstuffs?

Besides the formation of acrylamide in foods, migration to foods of animal origin (e.g. sausage products, eggs, milk) via acrylamide-containing feedstuffs could contribute to the exposure of the consumer. In principle, feedstuffs consist of similar raw materials to foods. During processing some undergo heating procedures that can lead to the formation of acrylamide. In other cases by-products of acrylamide-containing foods reach the feedstuffs directly. It, therefore, seems realistic to assume a possible acrylamide burden in feedstuffs.

The Federal Institute for Risk Assessment (BfR) has, therefore, identified procedures in the production and/or technical processing of starting products for feedstuffs and mixed feedstuffs. To this end, the Institute collected data on the levels of acrylamide in selected feedstuffs which were then analytically determined. The chemical-analytical studies of a wide range of different starting products and/or mixed feedstuff components mainly produced values in the "not detectable" range of up to 500 microgram (µg) acrylamide per kilogram (kg). In common, single component feedstuffs the acrylamide levels are lower.

This leads on to the question about how much acrylamide passes from feedstuffs to food of animal origin and reaches the consumer. There is still a considerable need for research into this carry-over behaviour of acrylamide. It has been proven that direct carry-over is possible. However, at present, we do not have sufficient insight into the scale on which a carry-over of this kind takes place in tissue (meat, liver), milk and eggs of agricultural livestock – also taking into account the metabolites.

Within the framework of its research activities the Federal Institute for Risk Assessment, together with the former Federal Agency for Milk Research (now Federal Research Agency for Nutrition and Food, BFEL) conducted a provocation study on the carry-over of acrylamide from feedstuffs to cow milk. The results of this study show that a carry-over of this kind, at least in low amounts, is possible.

In a carry-over trial in quails, conducted in the Ludwig-Maximilian University in Munich, the carry-over of acrylamide from feedstuff rations, to which high concentrations of acrylamide had been admixed, was detected in eggs, serum and pectoral muscles.

At present, BfR - in co-operation with the Federal Research Agency for Agriculture in Braunschweig-Völkenrode - is conducting studies on the carry-over of acrylamide from feedstuffs to animal tissue (hens) and eggs. The first results are expected towards the end of the summer.

By way of summary, it can be said that the carry-over of acrylamide from mixed feedstuffs commonly used in practice or commercial grade foods of animal origin is, in principle, possible. However, according to the study results currently available this intake path apparently seems to make only a very minor contribution to the exposure of consumers to acrylamide (7).

How high is the exposure of the population?

The intake of acrylamide from food leads to a long-term burden. Current estimates based on dietary surveys indicate an average daily intake of between 0.5 and 1 µg acrylamide per kg bodyweight in adults. Studies on the binding of acrylamide to the red blood pigment haemoglobin in study participants confirm that there is indeed a burden. Unborn children and breast-fed infants are also exposed to acrylamide (8,9) via the blood of their mothers or breast milk. Smokers have additional exposure to acrylamide.

Some individual groups may have above average exposure to acrylamide from foods. This was also revealed by a BfR study:

In the winter of 2002 BfR collected data on the intake of acrylamide from highly contaminated foods from more than 1,000 15 to 18 year-old pupils in the 10th grade (10). With the help of a questionnaire the of selected foods (11 product groups) was recorded including toast, fried potatoes and nibbles. The consumption data obtained were linked to the current acrylamide exposure data from the notifications of the food surveillance authorities in order to determine, amongst other things, the mean intake amounts of acrylamide for the selected product groups. The study data are not representative for the overall population in the Federal Republic; they do, however, show that the average daily intake of acrylamide is relatively high: namely 1.1 µg per kg bodyweight. If the data are extrapolated to all Berlin pupils in the10th grade, then 5% (1,650) of pupils have a daily intake of more than 3.4 µg acrylamide per kg bodyweight, 1% (330 pupils) even more than 6.9 µg acrylamide per kg bodyweight. Based on these results BfR called for greater efforts to minimise the population's acrylamide intake.

How should we assess the risk potential of acrylamide for human health?

From animal experiments it is known that acrylamide can have various health-damaging effects: it can trigger cancer; it can damage the genetic material(genotoxicity); it can damage the nervous system and impair reproduction and development.

Neurotoxicity as well as reproductive and developmental toxicity are effects with so-called "threshold values": according to the current scientific opinion they only occur above specific acrylamide burdens. The amounts of acrylamide taken up from food are below these threshold values. The neurotoxic effects of acrylamide and its toxic effects on reproduction and development are, therefore, of minor importance for risk assessment within the framework of food safety.

The situation is different in the case of the genotoxic effect. In principle, there is no threshold value assumed for this effect. Any amount, even a minor burden, therefore constitutes a risk. According to the current scientific knowlege there exists a link between the carcinogenic and the genotoxic effects of acrylamide. Therefore, no burden is given for the carcinogenic effect either which is not linked to a risk.

The mutagenic effect of acrylamide was detected both in cell cultures and in animal experiments. The main factor responsible for this impact is apparently a particularly reactive metabolic product, glycidamide. Various studies show that acrylamide is also converted in human beings into the reactive glycidamide.

For methodological reasons high doses must be used in animal experiments on the carcinogenic effect. These doses are far higher than the acrylamide levels to which humans are exposed through food. Hence, there is particular interest in studies on the transferability of findings from animal experiments to human beings. Current studies on the mutagenic effect of acrylamide (11, 12) and the results of a study commissioned by BfR did not supply any indication so far that there is a threshold value for the carcinogenic effect of acrylamide or glycidamide. Hence, it must further be assumed that acrylamide can trigger cancer even in low amounts.

The exact level of the cancer risk through acrylamide for the population cannot be quantified with any certainty. With an assumed daily acrylamide intake of 1 µg per kg bodyweight throughout an entire lifetime conservative risk assessments point to a cancer risk in the range of between 6 and 100 additional cases of cancer per 10,000 individuals (13, 14). This would constitute a comparatively high cancer risk through the intake of acrylamide from food.

What opportunities are there to reduce acrylamide during the production and processing of foods?

Up to now based on theoretical approaches and pilot or production experiments, a number of factors were identified which can be influenced to reduce acrylamide levels. According to the current level of knowledge, the "set screws" for reducing levels in craft and industrial production are mainly the temperature-time regimen in conjunction with water contents in products and the raw materials and formulations used. By means of good co-ordination of these factors, the acrylamide levels can be reduced in many industrial products. This is demonstrated, for instance, by study results of the Institute for Cereal, Potato and Starch Technology from the former Federal Agency for Cereal, Potato and Fat Research (now also the Federal Research Agency for Nutrition and Food, BFEL), individual traceable samples of the state food control offices and data from industry. Furthermore, innovative production processes for instance for crisps are under discussion whose (reproducible) efficacy in conjunction with acrylamide reduction has not yet been confirmed in corresponding studies.

Aside from numerous technological opportunities to reduce acrylamide levels, which can be seized in production, we must accept that the opportunities to influence acrylamide levels are limited. To stay with the same image, the set screws have a dead stop beyond which the product no longer has the typical properties which the consumer expects. Despite every effort we can only ever hope to reduce acrylamide, not to avoid it completely. Two ongoing research projects (a research project financed by the Federal Ministry for Economic Affairs and Industry and the EU research project "HEATOX" (heat-generated food toxicants: identification, characterisation and risk minimisation) are to provide further information on the formation, avoidance, analytics, toxicology and exposure of undesired substances. Besides acrylamide these substances also include further heat-induced substances like for instance 3-monochloropropandiol (3-MCPD) or hydroxymethylfurfural (HMF).

The food trade markets a large number of semi-finished products like for instance chips, potato pancakes or bakery goods which themselves initially only contain low levels of acrylamide. However, they increase during preparation in the home or catering. In the case of these products it is particularly important to keep the ensuing heat exposure during frying, oven baking, roasting or deep-frying as low as possible. The guiding principle is "golden yellow and not browned". The higher the degree of browning, the higher the acrylamide burden. For chips the recommendation is to restrict oil temperature in the chip pan to 175°C and in the oven to 200°C or 180°-190°C in the case of a convection oven (15). In the case of semi-finished products, manufacturers also have the option of reducing acrylamide formation during ensuing processing by, for instance, soaking the processed potatoes and not adding any sugar. Furthermore, manufacturers are called on to adapt their processing recommendations on the product packaging to the above findings. The recommendation of keeping the degree of browning as low as possible applies not only to premade purchased products but also to all dishes prepared in the home or restaurant on a potato or cereal base.

In the two years since the publication of the Swedish results, a wealth of experience has been gained which can lead to a reduction of the contamination of foods with acrylamide. In the opinion of BfR, this experience should be incorporated into "**Guidelines for good manufacturing practice**". The guidelines could initially be worded in a broad way and then gradually adapted or more precisely formulated in line with the growing level of knowledge. In this way it should be possible in future to lay down technologically unavoidable product-specific maximum contents for acrylamide.

Which supraordinate measures and success controls are there for acrylamide minimisation in foods?

The Federal Ministry for Consumer Protection, Food and Agriculture (BMVEL) reacted to the acrylamide problem, amongst other things, by setting up a supraordinate, organisational framework (steering committee, working group on technology, industry discussions, federal/federal states (Bundesländer) discussions) involving industry, consumers, research and public authorities with the goal of identifying and implementing suitable and rapid measures for acrylamide minimisation in foods from the information collected. Against this backdrop, a minimisation concept of the Federal Office of Consumer Protection and Food Safety (BVL) was introduced which is co-ordinated between BMVEL, the federal states (Bundesländer) and industry. The concept envisages the gradual reduction of acrylamide levels. It can be outlined in brief in the following way:

BVL collects the analytical results on acrylamide levels in foods mainly from the official food surveillance of the federal states (Bundesländer). The recorded foods are classified in defined groups of products. From these groups of products those foods are identified which rank amongst the 10% of foods in a product group with the highest levels of contamination. The lowest value from the 10% of foods with the highest contamination of acrylamide in the group of products is the signal value. The competent food surveillance authorities of the federal states (Bundesländer) then hold minimisation discussions with the manufacturers of products that are above the signal value in order to initiate acrylamide reduction measures.

Between September 2002 and November 2003 BVL published three signal value calculations based on approximately 4,200 study results (16). These calculations do not point to any significant reduction in the signal values for most product groups or they indicate a stagnation of values between the second and third calculation period.

Given the acrylamide reduction measures taken by wide groups in industry, the Federal Government and federal states (Bundesländer), which have not led to nationwide but to definite individual cases of success, it seems likely that the current practice of data recording does not sufficiently reflect the actual development. Hence, the nationwide minimisation concept is, in principle, useful and should be continued. At the same time, **data collection should be considerably improved**, particularly with regard to co-ordinated sampling, the number of traceable samples and distinctions between product groups. BVL has already discussed this problem with the federal states (Bundesländer) and taken steps towards improving the situation.

By way of summary it can be said that a representative quantification of the drop in exposure is not possible at present. The same applies, albeit for different reasons, to the situation in the case of food prepared at home. Here, consumers have access to numerous information sources with advice on how to reduce acrylamide levels in food prepared by them (amongst other things on the homepage of the “aid - Information Service Consumer Protection and Food” (17)). The lively interest in information and the feedback are the only indications at present as to whether or not the acrylamide problem and the related risk could be effectively communicated to consumers and whether this has led to changes in their behaviour.

On the EU level expert discussions were conducted under the aegis of the European Commission (EC) and the European Food Safety Authority (EFSA) with representatives from all relevant areas. As a result, guidelines on reducing acrylamide in foods (18) were published (18). A European database is available in which acrylamide levels in foods can be accessed. This database mainly contains data from BVL.

Conclusions

The formation mechanism for acrylamide has not yet been sufficiently investigated. It is probably a mechanism linked to the Maillard reaction, i.e. browning and aroma formation during the heating of foods.

Reliable acrylamide test methods are available today for many foods. The limits of detection could be lowered. For some complex foods (e.g. cocoa) the analytics do, however, require further improvement.

Besides the formation of acrylamide in foods themselves, we must assume a carry-over of acrylamide from mixed feedstuffs commonly used in practice to foods of animal origin. In order to quantify this carry-over and reliably assess its importance for the consumer, further research results are required.

The determined exposure of the population to acrylamide in food is relevant. This applies in particular to risk groups who are particularly exposed because of their dietary habits. According to the current level of scientific knowledge it can be assumed that acrylamide is also carcinogenic in human beings and can have genotoxic effects without there being a threshold for these effects. Hence, any amount of acrylamide must be deemed to be potentially carcinogenic. BfR, therefore, believes it is necessary to undertake further minimisation steps.

A series of factors could be identified which are likely to reduce acrylamide levels during the production or processing of foods. They should be consistently used and, for instance, be incorporated into product-specific guidelines for good manufacturing practice in order to reduce acrylamide levels to values which are indeed technologically unavoidable.

In many areas these measures have already been implemented. A representative quantification of the reduction of exposure is not, however, possible using the data available at present. For a statement of this kind, data recording within the framework of the minimisation concept must be optimised particularly with regard to co-ordinated sampling, the number of traceable samples and distinctions between product groups. BVL and the federal states (Bundesländer) have already entered into corresponding agreements.

At present, the success in communicating the risk and the opportunities for reducing this risk vis a vis consumers can only be presumed but not quantified. The extent to which consumers have in the meantime themselves minimised the acrylamide risk in their homes through suitable food processing measures could only be identified in corresponding surveys.

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