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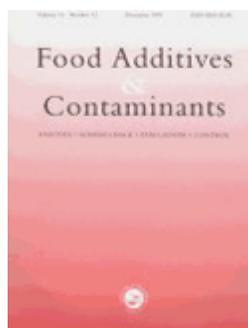
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The German Minimisation Concept for Acrylamide

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Abstract

The German minimisation concept for acrylamide was established as a reaction to the concern caused by the discovery of acrylamide in a wide range of foodstuffs in 2002. It is a pragmatic approach based on a voluntary agreement of all partners involved, governmental organisations as well as the affected industry, with the common aim of a gradual reduction of acrylamide content in food. Now, about four years after its initiation, an evaluation has shown the potential of this concept. For some commodity groups, minimisation of acrylamide content has already been successful, while further minimisation efforts are necessary in other groups to achieve a comprehensive minimisation in all food groups concerned. In contrast to legal regulations, the minimisation concept is a 'soft' risk management instrument. It represents a novel approach, for instance to cope with situations when maximum levels are not available. Such a concept can be considered as a smart solution to bring about preventive measures resulting in health protection. As an innovative risk management tool, it has the potential to tackle the challenges of consumer protection in the future.

Introduction

The problem of acrylamide in food became topical in April 2002 when it was found by scientists of the Swedish National Food Administration in a wide variety of foodstuffs (Swedish National Food Agency 2002). Acrylamide was identified as a product of the heating process – a so called food-borne contaminant. This caused worldwide concern (World Health Organization (WHO) 2002, European Commission 2002). Up to that time, acrylamide was only known as a toxic industrial chemical for technical purposes, primarily in the production of polyacrylamide used for the fabrication of plastic materials and also in the processing of drinking water for instance. This new knowledge about acrylamide meant a big challenge to the authorities responsible for consumer protection because acrylamide has been found carcinogenic and mutagenic in animal tests (Johnson et al. 1986, Friedman et al. 1995, Bull et al. 1984a, b, Robinson et al. 1986). The International Agency for Research on Cancer has also classified acrylamide as a Group 2A carcinogen (International Agency for Research on Cancer (IARC) 1994). Furthermore, a genotoxic mechanism was proven and attributed to glycidamide, the main metabolite formed in mammals (Doerge et al. 2005). However, no comprehensive risk assessment for man is currently available due to a lack of data (Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2005). But JECFA calculated a margin of exposure (MOE) of 300 for the cancer risks caused by acrylamide with mean intake and of 75 with high intake, which is extremely low for a compound that is probably carcinogenic and genotoxic for man (Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2005).

The usual approach to deal with substances which are carcinogenic and genotoxic is the ALARA-principle (as low as reasonably achievable). Another possible management measure to cope with contaminants in food is setting maximum levels. With acrylamide, however, this appeared far from realistic because there were no adequate toxicological data available to deduce such a limit, nor was the technical feasibility given. The mechanism by which acrylamide is formed during the thermal processing of food was largely unknown at that time, and it appeared rather difficult to predict the amount to which acrylamide would actually be formed by a given treatment. It was obvious that the formation of acrylamide during the processing as well as the preparation of food depends on a spectrum of influencing variables, such as raw materials and processing techniques.

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3 In this situation the German minimisation concept for acrylamide was established by the
4 Federal Office of Consumer Protection and Food Safety in August 2002. It was a pragmatic
5 concept based on a voluntary agreement among the Federal Office of Consumer Protection
6 and Food Safety (BVL), the Federal Ministry of Food, Agriculture and Consumer Protection
7 (BMELV), the German federal state authorities and the stakeholders of the affected industry.
8 The mutual aim can be described as the achievement of a gradual reduction of acrylamide
9 content in foodstuffs by avoiding formation of this food borne contaminant as far as possible.
10 This requires the development of processing and preparation techniques which would lower
11 the formation of acrylamide in food without changing the main character of the product. This
12 action followed the ALARA principle: as low as reasonably achievable. So the acrylamide
13 minimisation concept represented an instrument which was expected to accomplish a
14 preventive health protection of consumers, irrespective of the absence of a sufficient risk
15 assessment and maximum levels.
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28 **The Minimisation Concept for Acrylamide**

29 *The signal value*

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31 The core of the minimisation concept is the signal value which ensures the dynamic strategy
32 of this concept. It is calculated for each commodity group. Originally the minimisation concept
33 covered seven commodity groups. Now the number has been expanded to 13. These
34 commodity groups are potentially highly contaminated by acrylamide, posing the highest
35 hazards for the consumers. The signal value is defined as the lowest level of those 10% of
36 products of each commodity group which have the highest acrylamide content. This is
37 illustrated in figure 1. The 20 weights are increasing. The lowest level of the highest 10 %
38 would correspond to the 19th weight in the row. This would be the signal value of a given
39 commodity group.
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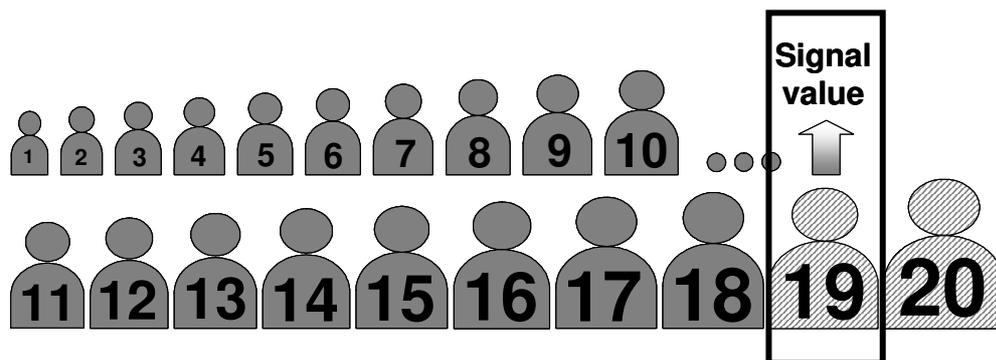


Figure 1: Illustration of the signal value

In addition the signal value has to meet certain conditions. It must be a really existing acrylamide level (not the statistically calculated 90th percentile) in that particular commodity group, it must not exceed 1000 µg/kg, and once it is established, it must not be increased, but has to be maintained or reduced. This definition is necessary to guarantee the dynamics of the concept towards a gradual reduction of acrylamide contents in foodstuffs. Furthermore the signal value acts as a threshold. If the acrylamide content of a product exceeds the current signal value of the corresponding commodity group, a so-called minimisation dialogue will start, ideally followed by appropriate minimisation measures. Therefore, the signal value serves as the bearing instrument and as an indicator of success of minimisation efforts within the relevant assessment period. Nevertheless, the validity of the signal value is limited because of deliberate restrictions within the relevant calculation procedure.

The observer value

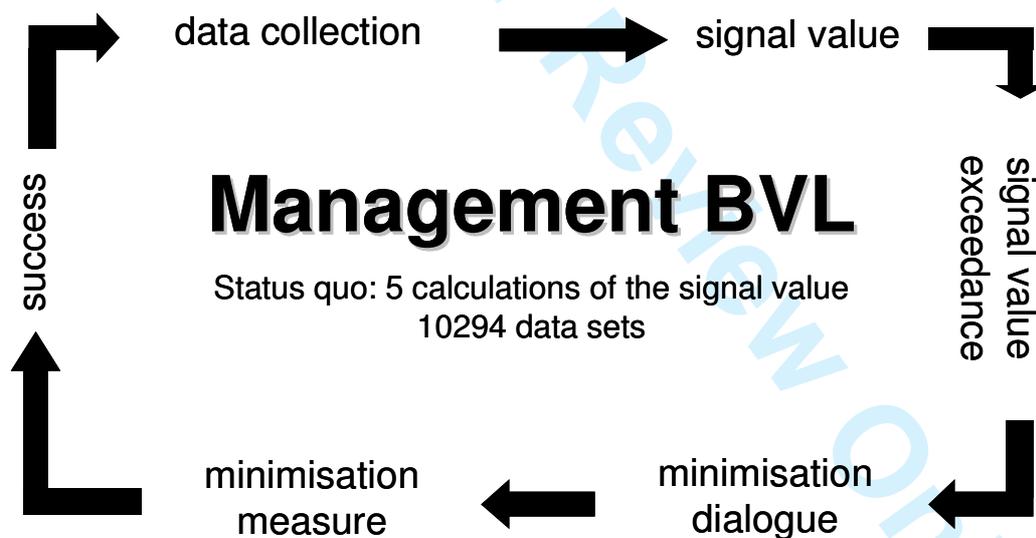
Another important item of the minimisation concept is the observer value. Because of the deliberate limitations of the signal value, it was established to allow a more accurate description of the current minimisation situation. The observer value is calculated basically in the same way as the signal value, but it does not have to meet any condition. That means that the observer value may increase as well as exceed 1000 µg/kg. Thereby it offers the possibility to describe the actual success of minimisation efforts even if the signal value is unchanged. For instance, it can show a decrease from 2380 µg/kg to 1030 µg/kg as is the case for example for the commodity group coffee extract, with the signal value being 1000 µg/kg. Of course it also indicates an increase for example in the case of potato crisps from 1029 µg/kg to 1333 µg/kg, with the signal value being 1000 µg/kg. Accordingly this allows a comprehensive description of the real situation of minimisation.

Additional instruments

Apart from the special instruments of the minimisation concept (the signal value and the observer value), the degree of success as regards the minimisation of acrylamide in foodstuff can also be measured by classical statistical instruments like the mean, the median and the frequency distribution. These values are important complements, because in particular the median and the frequency distribution clearly indicate how many products of a given commodity group have what acrylamide content, and whether many products have acrylamide contents close to the signal value or whether the signal value is caused by extreme values and outliers. The potential of minimisation for a particular commodity group is also reflected in this way. That means, the bigger the difference between the median and the signal value, the bigger is the potential of minimisation in that group of foodstuffs.

The German minimisation concept for acrylamide

A schematic illustration of the German minimisation concept for acrylamide is shown in scheme 1. It works as follows:



Scheme 1: Workflow of the minimisation concept

Data collection:

The official food surveillance authorities of the German federal states take samples of foodstuffs and analyse them for acrylamide. They collect the data and forward them to the Federal Office of Consumer Protection and Food Safety (BVL). These files include information on acrylamide contents, product labelling, producer addresses, batch numbers, best before dates, test methods etc.

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3 *Signal value:*

4 The BVL maintains a database on acrylamide in which 10294 data sets were collected up to
5 March 2006. It calculates the signal value as described under 3.1 based on the data from the
6 previous year (in general from the 1st of September to 31st of August) for all 13 commodity
7 groups once a year. This strategy balances the effects of seasonal fluctuations in acrylamide
8 contents in foods caused by the seasonal variations in the raw materials as well as the
9 seasonal availability of some product groups. Moreover a signal value of 1000 µg/kg is
10 automatically applied to foodstuffs which are not part of any of the 13 commodity groups of
11 the minimisation concept for acrylamide. That means if the BVL gets aware of such a product
12 with an acrylamide content of more than 1000 µg/kg, the minimisation dialogue will start in
13 the same way.
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23 *Signal value exceedance:*

24 The BVL checks all incoming data whether any of the current signal values is exceeded. If a
25 product exceeds the signal value of the respective commodity group, or has an acrylamide
26 content of more than 1000 µg/kg, the BVL will inform the official food surveillance authority of
27 that federal state in which the producer of this product is located.
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33 *Minimisation Dialogue:*

34 The respective federal state authority gets in contact with the particular producer and starts
35 the minimisation dialogue. That is to say they check together with the producer whether
36 ingredients or process parameters could be changed and in which way the acrylamide
37 content of the product could be minimised while its special product properties are
38 maintained.
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44 *Minimisation Measures:*

45 The successful application of the minimisation measures developed will then lead to a
46 reduction of the acrylamide content of that product.
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51 *Success:*

52 The sum of all minimisation dialogues and the application of minimisation measures will lead
53 to a mitigation of acrylamide contents in foodstuffs and therefore to a reduction of signal
54 values in the following year. All in all, this dynamic process results in a gradual reduction of
55 acrylamide in food.
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60 To sum up, the biggest challenge for the success of the minimisation concept is to implement
minimisation measures within the boundaries of nearly unchanged product properties. This

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3 approach takes account of the very sensitive consumer reaction to changes of product
4 quality. A possibility is to ensure that quality criteria like crispness of potato crisps are
5 unchanged after a minimisation of acrylamide contents. Another solution is to inform the
6 consumer about the necessity to change the product quality. A good example for that is the
7 slogan “golden yellow, not carbonized” to advertise the new colour of chips with low
8 acrylamide contents. Both strategies are helpful to obtain consumers’ acceptance of
9 acrylamide-minimised products.
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15 16 17 18 **Assessment of success of the acrylamide minimisation concept**

19 20 21 *Observation of individual products*

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24 Observation of individual products is a special tool within the acrylamide minimisation
25 concept. The aim is to provide evidence about the extent of acrylamide minimisation
26 concerning a single product before and after the implementation of minimisation measures.
27 Thus, observation of single products provides a rationale for the understanding of
28 minimisation processes. Such an example for the successful implementation of minimisation
29 measures is the development in the acrylamide content of diabetics’ cakes. As shown in
30 figure 2, it was possible to achieve not only a gradual mitigation of the acrylamide contents in
31 these cakes but also a strong reduction of the statistical spread of acrylamide values.
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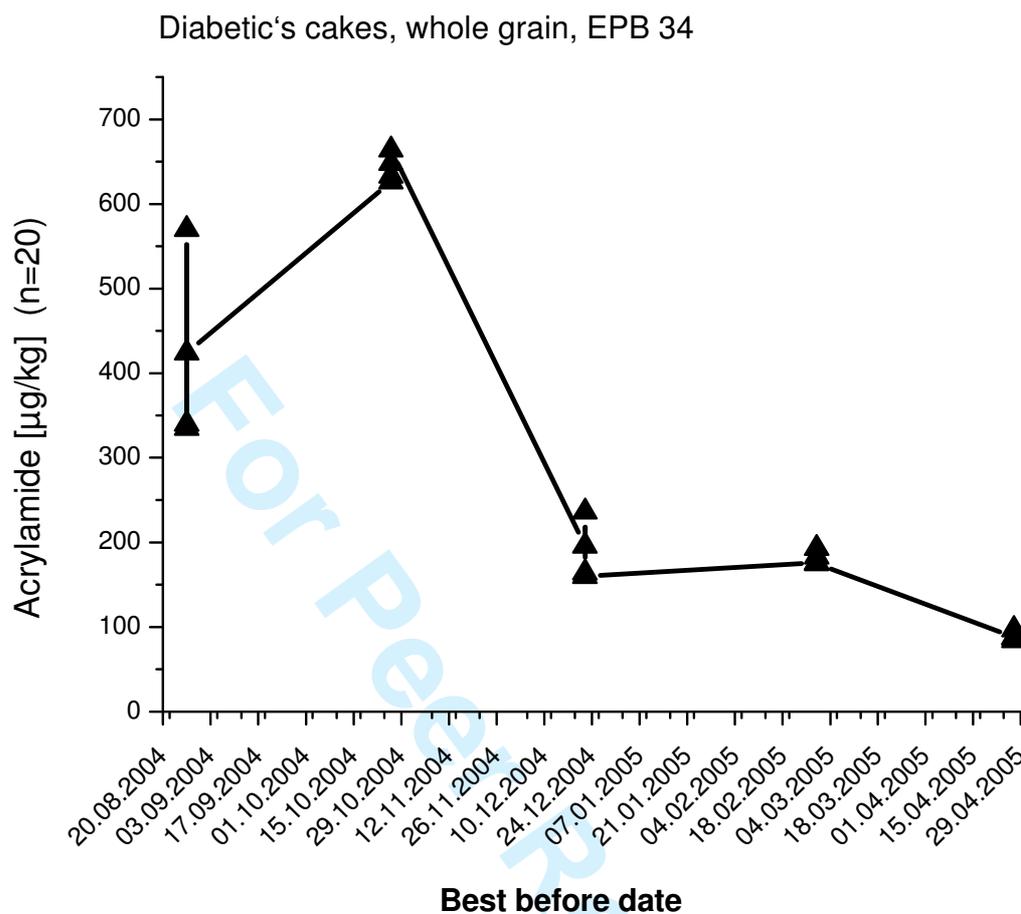


Figure 2: Time course of acrylamide contents of diabetics' cakes, whole grain

Results of the 5th calculation of signal values

Development of signal values and observer values

The assessment of the development of signal and observer values during the assessment period of the 5th calculation, 01 September 2004 – 31 August 2005, is based on classification into three categories:

- Signal value decreased
 - 6 product groups -
- Signal value unchanged (with decreased observer value)
 - 2 product groups -
- Signal value unchanged (with increased observer value)

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3 - 5 product groups -
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6 Detailed data on the results of the 5th calculation of signal values are presented in table 1.
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8 The big differences as regards the number of samples therein demonstrate the pragmatic
9 approach of this concept, since there is no coordination concerning number and kind of
10 products as is the case in a monitoring programme. This is a result of the decision to leave a
11 margin to all suppliers of data. This strategy was necessary within a concept voluntarily
12 agreed among the partners. The wide range between the minimum and maximum levels
13 within one commodity group reflects the broad variety of different products on the market. It
14 also reflects, in particular for products based on potatoes, the change in composition of the
15 raw material potato during a longer period of time, e.g. during storage. However, differences
16 found between products within one food group are driving forces for minimisation efforts,
17 because products with low acrylamide contents demonstrate the possibilities of minimisation.
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29 **Table 1:** Signal values, 5th calculation, valid from 21 October 2005
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Commodity group	Signal value 5 th calculation (µg/kg)	Observer value 5 th calculation (µg/kg)	Number of products	Minimum (acrylamide µg/kg)	Median (acrylamide µg/kg)	Mean (acrylamide µg/kg)	Maximum (acrylamide µg/kg)
Fine bakery ware, short pastry	300	not available	143	5	118	169	1458
Breakfast cereals	180	not available	47	5	50	84	545
Coffee, roasted	370	537	164	101	268	310	935
Potato crisps	1000	1333	159	5	363	652	4215
Crispbread	590	not available	93	5	276	300	1715
Chips, prepared	530	not available	388	5	212	268	2310
Potato fritters, prepared	1000	2520	15	142	675	1065	3072
Gingerbread and bakery ware containing gingerbread	1000	1270	449	5	233	501	6141
Thin almond biscuits	560	706	81	5	230	356	2110
Children's biscuits	245	not available	130	5	81	106	432
Diabetics' cakes and biscuits	545	not available	125	10	186	270	1695
Coffee extract	1000	1030	64	87	857	808	1188
Coffee substitute	1000	2341	19	183	710	1001	2563

The difference between the signal value and the associated median value indicates the potential of minimisation within a commodity group. The commodity group "Coffee extract" shows a difference of less than 150 µg/kg acrylamide between the signal value and the corresponding median. This could reflect either complete absence of minimisation activities, or, more plausibly, an only small minimisation potential (figure 3). In contrast, the food group "Gingerbread" shows a difference of approximately 750 µg/kg acrylamide between the signal value and the corresponding median. This situation allows the interpretation that the minimisation potential in this food group is high. However, a more complex approach regarding the minimisation potential of a food group is the evaluation of the frequency distribution.

Evaluation of the frequency distribution

In addition to the evaluation of development of signal, observer and median values, the evaluation of the frequency distribution provides a further tool for a comprehensive assessment of the success of the minimisation concept. This evaluation is based on all acrylamide contents available for a specific commodity group for the relevant assessment period, thus providing a survey on all acrylamide contents in a given commodity group. When assessing the frequency distribution, a "shift to the left" compared to the normal curve reflects an increase in products with acrylamide concentrations below 300 µg/kg, in some product groups even below 200 µg/kg or 100 µg/kg. This shift can be used in combination with the associated signal and maximum values as an indicator for the minimisation potential of the corresponding food group. As can be seen for the examples "Chips, prepared" (figure 4) and "Diabetics' cakes and biscuits" (figure 5) the decrease of the signal value and the fact that more than 66 resp. 70 percent of all tested products have acrylamide contents of less than 300 µg/kg, allows to state a minimisation success. Moreover, the characteristics of the frequency distribution, the "shift to the left", can be used in combination with the concomitant existence of high acrylamide levels with more than 1000 µg/kg as an indicator for a very high minimisation potential.

2nd category: Signal value unchanged (with decreased observer value)

Coffee extract

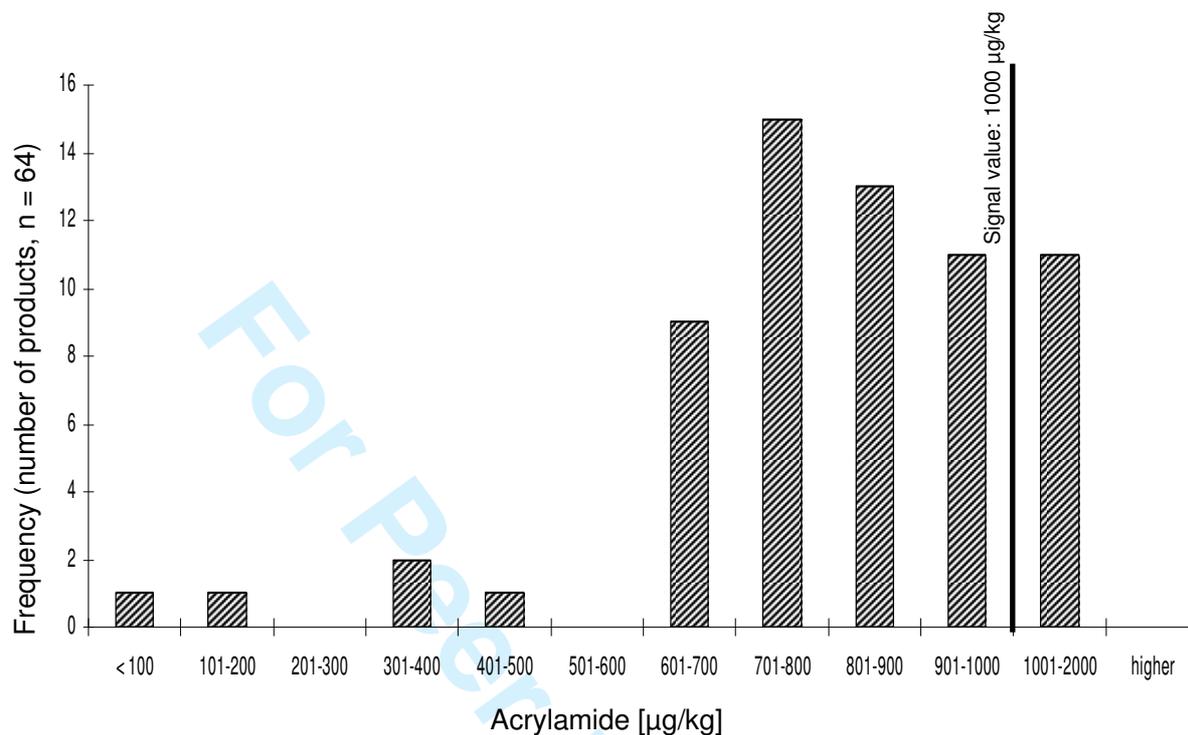


Figure 3: Frequency distribution of coffee extract

1st category: Signal value decreased

Chips, prepared

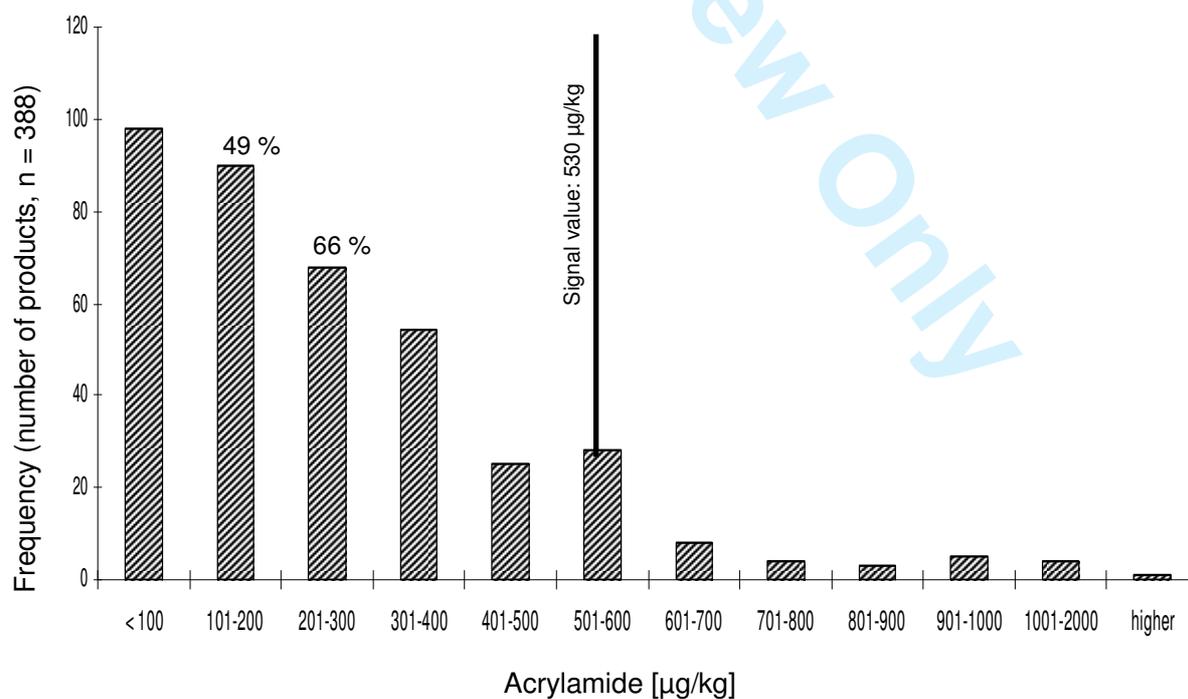


Figure 4: Frequency distribution of chips, prepared

1st category: Signal value decreased

Diabetics' cakes and biscuits

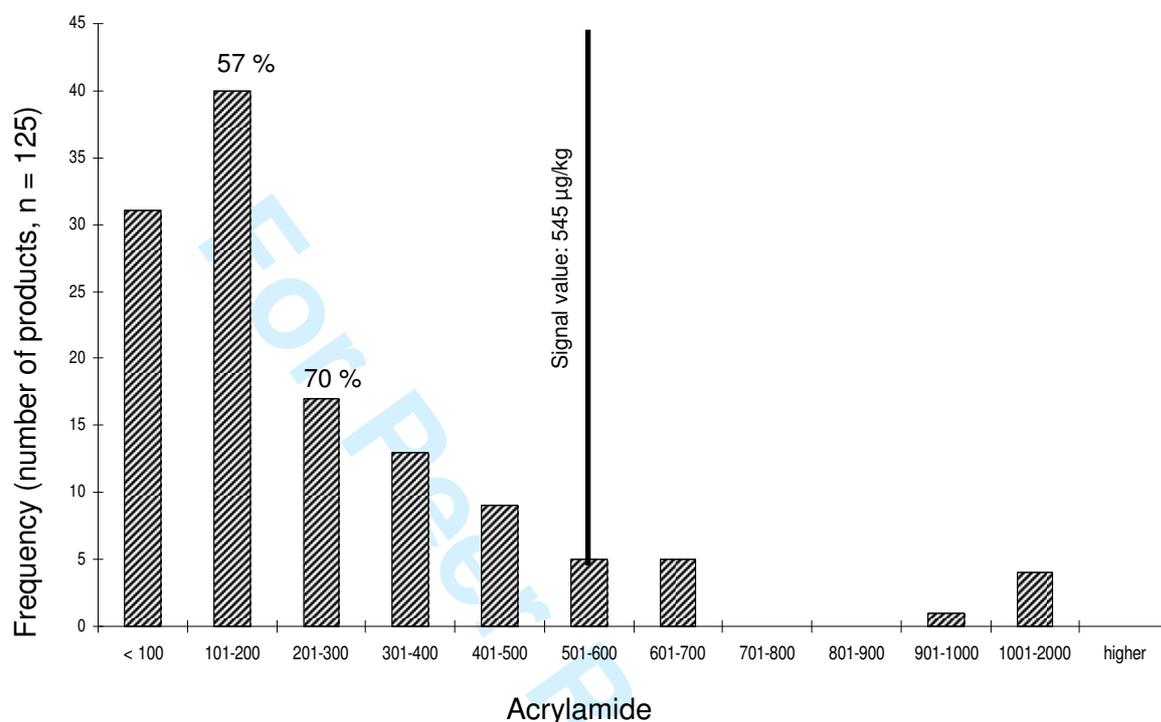


Figure 5: Frequency distribution of diabetics' cakes and biscuits

An overview of all signal and observer values from the 1st to the 5th calculation is shown in table 2.

Table 2: Signal values and observer values, 1st to 5th calculation

Commodity group	Signal (observer) value 1 st calculation 17 Sep 2002 acrylamide (µg/kg)	Signal (observer) value 2 nd calculation 31 Jan 2003 acrylamide (µg/kg)	Signal (observer) value 3 rd calculation 26 Nov 2003 acrylamide (µg/kg)	Signal (observer) value 4 th calculation 17 Nov 2004 acrylamide (µg/kg)	Signal (observer) value 5 th calculation 21 Oct 2005 acrylamide (µg/kg)
Fine bakery ware, short pastry	800	660	575	575 (760)	300
Breakfast cereals	260	260	200	200 (240)	180
Coffee, roasted	370	370	370 (520)	370 (420)	370(537)
Potato crisps	1000 (1500)	1000 (1200)	1000 (1470)	1000 (1029)	1000 (1333)
Crispbread	610	610	610 (1260)	610 (640)*	590
Chips, prepared	770	570	570	540	530
Potato fritters, prepared	1000	1000 (1300)	1000 (1080)	1000 (1215)	1000 (2520)
Gingerbread	1000	1000 (1370)	1000 (1460)	1000 (1020)	

and bakery ware containing gingerbread					1000 (1270)
Thin almond biscuits	1000	710	710 (760)	560	560 (706)
Children's biscuits	n. c.*	n. c.*	360	360	245
Diabetics' cakes and biscuits	n. c.*	n. c.*	1000 (1740)	1000 (1010)	545
Coffee extract	n. c.*	n. c.*	1000 (1110)	1000 (2380)	1000 (1030)
Coffee substitute	n. c.*	n. c.*	1000 (2080)	1000 (2910)	1000 (2341)

* not calculated

As shown in table 2, the signal value of the commodity group "Fine bakery ware, short pastry" was reduced from 800 to 300 µg/kg within the framework of the minimisation concept. The signal value for "Breakfast cereals" decreased from 260 to 180 µg/kg. A slow mitigation appeared to be possible also in the commodity group "Potato crisps". The signal value for "Chips, prepared" decreased from 770 to 530 µg/kg and that for "Thin almond biscuits" from 1000 to 560 µg/kg. In the food group "Diabetics' cakes and biscuits", the signal value was even reduced from 1000 µg/kg with an observer value of 1740 µg/kg to a signal value of 545 µg/kg. On the other hand there seemed to be no changes in the acrylamide contents in all three coffee food groups, the "Crispbread" and the "Gingerbread and bakery ware containing gingerbread" group. This indicates either a very small potential of minimisation in those particular commodity groups or too little minimisation efforts by the industry. So, obviously, besides its success the minimisation concept has also clear limits.

Limits of the minimisation concept

In times of international trade many producers are located in foreign countries and therefore outside the area of competence of the German food surveillance authorities. Small handicraft enterprises and the catering businesses, too, which have neither the know-how nor the possibilities to obtain current scientific information, are difficult to reach because of their greater numbers. The same applies to the home preparation of foodstuff. And finally, as mentioned above, not all commodity groups are accessible for minimisation measures in the same way.

Future prospects of the minimisation concept

So after four years of operating this concept it is necessary to think about modifications, like deleting commodity groups with a very small or almost no minimisation potential, to thereby concentrate the capacity on food groups with a high potential of minimisation or to introduce new food groups which contain potentially less acrylamide but are consumed in larger amounts, like bread. Also you could think of the implementation of Good Manufacturing Practices. Furthermore, a survey of consumption data is in progress in Germany at the moment. Later the German Federal Institute for Risk Assessment will make a risk assessment with consideration of current acrylamide data and consumption survey data. The results may also have some influence on the handling of the minimisation concept.

Acrylamide minimisation concept – a modern risk management tool

The German acrylamide minimisation concept represents an innovative risk management tool. Unfortunately, up to now it is a national approach to tackle a global problem. However, there are many alternative endeavours aiming to minimise acrylamide contents in foodstuffs. For example, the European Commission has issued some information on ways to lower the levels of acrylamide formed in food (European Commission 2003). The Confederation of the Food and Drink Industries of the EU has created the acrylamide “Toolbox”, describing in detail acrylamide formation and providing a set of measures to minimise the formation of acrylamide during manufacturing or processing of food (Confederation of the food and drink industries of the EU (CIAA) 2005).

The experience obtained during four years of operating the acrylamide minimisation concept allows the general recommendation that strategies of gradual minimisation should also be applied with substances other than acrylamide. The acrylamide minimisation concept typifies a pragmatic, flexible solution. Therefore, in cases when a legal limit is not available, this concept has the potential to be the first choice among other strategies for preventive health protection of consumers.

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