

# Federal Institute for Risk Assessment (BfR)

## Semicarbazide in foods

Supplementary opinion of BfR of 15 October 2003

On 31 July 2003 BfR provided information on the occurrence of semicarbazide (SEM) as a contaminant in various foods. This was based on information from the European Food Safety Authority (EFSA). The common feature of these foods was that they were packaged in glass jars or bottles. Initial study results indicated a semicarbazide content of up to 15 µg/kg food. One possible source given for semicarbazide was the blowing agent, azodicarbonamide, used to foam sealing gaskets during the manufacture of lids for bottles and glass jars for foods ([http://www.bfr.bund.de/cms/media.php/70/semicarbazid\\_als\\_kontaminante\\_in\\_glasverpackten\\_lebensmitteln.pdf](http://www.bfr.bund.de/cms/media.php/70/semicarbazid_als_kontaminante_in_glasverpackten_lebensmitteln.pdf))

Against the backdrop of more recent study results, BfR has supplemented its above-mentioned opinion. The results can be summed up as follows:

Contaminants like SEM are generally undesirable in foods. Despite the existing uncertainty about exposure and toxicity, the risk both for adult consumers and infants is currently assessed as being small. BfR does not believe there are any grounds at present for recommending renunciation of the use of baby food in glass jars for infants. However, the industry is urgently called on to develop alternative technologies for the foaming of sealing gaskets which will then reduce or avoid exposure to SEM without abandoning the high standard for the microbiological safety of foods.

### Problem

The question about the potential of SEM to trigger mutations (genotoxicity) is of particular importance when it comes to the health assessment of SEM. Up to now, only a few older toxicological studies were available. This prompted the European Food Safety Authority to commission genotoxicity studies. Initial data and additional analytical results are now available and have been discussed in the various bodies of EFSA. Furthermore, German laboratories from Official Food Control also undertook studies on the occurrence of SEM in lid seals and in foods. Based on the new data the BfR opinion of 31 July 2003 is supplemented as follows:

### Exposure

As a consequence of new studies, it was possible to rule out the formation of SEM – as had been initially suspected – as an artefact during the examination of food samples ([http://www.untersuchungsaeamter-bw.de/stuttgart/seiten/bedarf\\_semicarbazid\\_twistoff.html](http://www.untersuchungsaeamter-bw.de/stuttgart/seiten/bedarf_semicarbazid_twistoff.html)). It is far more the case that foamed sealing gaskets, used in the metal lids of glass packagings, are now thought to be the main source of semicarbazide. According to the results available to EFSA, the range of SEM levels in foods extends from the detection limit up to 25 ppb (microgram per kilogram [µg/kg]). If one takes the highest level of 25 µg/kg and if one assumes that six-month old babies with a body weight of 7.5 kg (this is the consumer group which, on a body weight basis, consumes the largest amount of these foods) takes in a maximum 700 g food packaged in glass jars per day (that's around three jars), then this means in the worst case an exposure of 2.3 µg SEM per kg body weight and day.

BfR is currently examining whether SEM exposure in foods including baby food could also result from sources other than lid seals. There is, at least, in theory the possibility that very low concentrations of SEM could be formed as a degradation product of specific active substances in pesticides. Research up to now has only furnished one possible indication of the active substance triazophos. According to a publication from 1976, SEM was detected after the oral administration of triazophos in rats in a proportion of around 5% as a metabolite in urine. This result could not be confirmed in other studies involving this substance. Based on the documents available to BfR, priority was given moreover to examination of the triazole fungicides; however, up to now no indications of the formation of SEM have been found for active substances from this group. This also applies to tetraconazole discussed in this connection. According to the documents available to BfR, there have been no reports of the occurrence of SEM as a metabolite in plants.

## Health assessment

The first, as yet unpublished results from new studies in cell cultures (*in vitro*) indicate that SEM has a weak mutagenic potential. For the purposes of further clarification, additional genotoxicity studies are conducted, the results of which are submitted to and evaluated by EFSA. Available *in vitro* studies and older animal experiment data do not permit any definitive assessment of genotoxicity or carcinogenicity in man. Since it is not clear either from the animal experiments which organs/tissues SEM reaches, EFSA experts have called for corresponding toxicokinetic studies.

It will not be possible to say how the exposure estimated above is to be reliably assessed from the health angle until the toxicological studies have been concluded. Independently of this, contaminants like SEM are generally undesirable in foods. Despite the existing uncertainty about exposure and toxicity, the risk for both adult consumers and infants is currently assessed as small. The current data situation does not permit any quantitative statements.

## Measures

From the toxicological angle *in vivo* studies, inter alia, must be carried out in order to obtain a definitive assessment of the genotoxic potential of SEM. Only when they are available, will it be possible to undertake a definitive assessment of the genotoxic risk.

Seals manufactured using azodicarbonamide are of special relevance for the safety of baby food. The airtight seal prevents microbiological contamination and protects the nutritional integrity for the shelf life. These requirements concerning microbiological stability and shelf life must be applied in the same way to alternative materials. According to the findings currently available in BfR, when it comes to the packaging of baby food in glass jars with press on/twist off lids, there are at present no alternatives to the sealing gaskets foamed with azodicarbonamide, which meet these stiff requirements.

Industry is urgently called on to develop alternative technologies for the foaming of sealing gaskets which will then reduce or avoid exposure to SEM in foods, particularly in baby foods, without abandoning the high standard for the microbiological safety of foods.

Based on these aspects and also on nutritional-physiological considerations, BfR does not believe that there are currently any grounds for renouncing the use of food packaged in glass jars for infants.