European Food Safety Authority

PRESS RELEASE

EFSA gives update on semicarbazide:
No reason to change current dietary habits including for babies
Precautionary action by industry recommended for baby foods

EFSA released today a risk assessment regarding semicarbazide (SEM) in food based on the most recent evidence made available to its scientific panel. This statement updates preliminary advice issued by EFSA on the possible occurrence of semicarbazide in certain foods packaged in glass jars and bottles. While results are not conclusive at the present time, it has become clear that SEM is present in certain foods in very small quantities. The risk to consumers - if any - is judged by scientific experts to be very small, not only for adults but also for infants. Nevertheless, experts believe it would be prudent to reduce the presence of SEM in baby foods as swiftly as technological progress allows. EFSA therefore recommends that the European Commission put in place a monitoring programme to ensure that industry implement alternative packaging solutions in a timely manner focusing on baby foods as an immediate priority. In the interim, EFSA’s scientific experts advise no change to current dietary habits: consumers may continue to utilise all foods concerned, including baby foods.

On 28th July, EFSA announced that semicarbazide (SEM) may have been found in certain foods packed in glass jars and bottles closed with metal lids sealed with plastic gaskets. The foods concerned included fruit juices, jams and conserves, honey, baby food, pickles and sterilized vegetables, mayonnaise, mustard, sauces, and ketchup. As the toxicity of SEM is not well understood, further investigations into its presence in food and possible effect on human health have been undertaken by EFSA and industry.

Initially, it had been thought that the apparent occurrence of SEM in foods could be explained by its generation through the analytical process itself. However, the latest evidence is understood to show that semicarbazide is produced during the heat treatment of an approved blowing agent (azodicarbonamide) utilized to make sealing gaskets in the lids of glass jars and bottles and that it migrates from the gaskets into foods.

In assessing the risks associated with semicarbazide, experts reviewed: the most recent scientific evidence made available on the toxicology of SEM; the levels found in foods; and estimated intakes of SEM by babies, children and adults. The scientific evidence, including recent research commissioned by EFSA, shows that semicarbazide has weak carcinogenic activity in animals and weak genotoxic activity.
(that is, it can damage DNA, the genetic material in cells). The amounts of semicarbazide present in foods are very low. Although uncertainties about SEM still remain - not only about the extent of human exposure through the diet but also concerning the likelihood of effects in humans - EFSA’s scientific panel concluded that the risk associated with eating foods containing semicarbazide is very small.

Commenting on these conclusions, the Chair of the EFSA Panel, Dr. Sue Barlow explained: “The risk to consumers resulting from the possible presence of semicarbazide in foods – if any – is judged to be very small, not only for adults but also for infants. Although there are uncertainties in the risk assessment due to lack of full data at the present, these relate only to how to assess what is considered to be a very small risk.”

An ad hoc expert group was specifically asked by EFSA to advise further on possible risks to infants given that this is the consumer group for which potential exposure to semicarbazide on a body weight basis is likely to be the highest. In evaluating the possible implications of SEM in baby foods, experts reviewed toxicological aspects alongside microbiological and nutritional considerations. Experts highlighted that although not an obligatory part of infants’ diets, baby foods in jars are widely used for reasons of convenience, quality and nutritional safety. With an excellent record of microbiological safety, they provide strong protection against microbiological and other risks of contamination. While concluding that it would be prudent to reduce exposure to semicarbazide as swiftly as technologically possible, experts stressed that it would be unwise to take any immediate actions on baby foods which could potentially have other detrimental effects on the health of babies. With respect to the possible replacement of current packaging materials and sealing technologies for baby foods currently being investigated by industry, it is critical that careful consideration and evaluation of seal integrity be carried out prior to their introduction.

No immediate action on the part of consumers or retailers is recommended regarding the occurrence of semicarbazide in baby foods and other foods packed in glass jars and bottles.

EFSA does however urge the pursuit of an action programme to reduce the presence of SEM in foods, including the identification of alternative packaging solutions and monitoring of levels of SEM in foods. EFSA also recommends that the Commission put in place a monitoring programme to ensure that the replacement of the current type of sealing gaskets for glass jars by industry progresses as quickly as possible.

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For more background information about the European Food Safety Authority, go to:
http://www.efsa.eu.int/
European Food Safety Authority

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Additional advice on semicarbazide, in particular related to baby food

Ad hoc expert group meeting

9 October 2003
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Ad hoc expert group meeting

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Background

Preliminary advice on the possible occurrence of semicarbazide in certain packaged foods was issued by EFSA on 28 July 2003 (available on the Internet at http://www.efsa.eu.int/pdf/p_afc_doc_01.pdf). The foods concerned are those packaged in glass jars and bottles closed with metal lids sealed with plastic gaskets that are foamed using the blowing agent, azodicarbonamide.

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) considered further data at its meeting on 1 October 2003 and prepared an update on the earlier advice (see Panel statement available at http://www.efsa.eu.int/p_foodadd_en.html).

In the following week, an ad hoc group of experts was convened, including members of EFSA’s AFC Panel, its Panel on Contaminants in the Food Chain and its Panel on Dietetic Products, Nutrition and Allergies. It heard a presentation from the food and packaging industries updating their findings since July. This new information covered industry progress on development of alternative technologies and strategies to reduce or eliminate semicarbazide in foods, further information on the range of concentrations of semicarbazide found so far in foods packaged in glass jars and bottles, and exposure estimates for infants. The ad hoc expert group was specifically asked by EFSA to advise further on possible risks to infants, given that this is the consumer group for which potential exposure to semicarbazide on a body weight basis
is likely to be the highest. The advice of the ad hoc group is given below and includes discussion of microbiological and nutritional aspects of baby foods which need to be considered alongside the toxicological aspects.

**The advice on baby foods**

*Exposure data*

The ad hoc expert group received additional information from industry on the range of concentrations of semicarbazide in foods packed in glass jars and bottles and on consumption of the relevant foods by infants of 4-12 months of age. The number of food samples analysed for semicarbazide is still limited, but confirm that amounts ranging up to 25 ppb have been found in baby foods. The additional information confirms that the preliminary estimate of exposure of infants to semicarbazide, contained in the AFC Panel statement of 1 October 2003, of around 2 microgrammes/kg body weight/day is a reasonable worst case.

*Toxicological aspects*

No additional information on toxicological aspects was presented to the ad hoc expert group since the update provided by the AFC Panel on 1 October 2003. The Panel commented that semicarbazide has weak genotoxic activity *in vitro* and weak carcinogenic activity in female but not male mice, but because of the limited evidence, it is not possible to conclude whether semicarbazide may pose a carcinogenic risk to humans. There is no risk of immediate illness to adults, children or infants from consumption of foods containing semicarbazide. The concern relates to health in the long term because of the possibility that semicarbazide may cause cancer. The risk, if any, is judged to be very small, both for infants and adult
consumers. Although there are uncertainties in the risk assessment due to limitations in the data, these relate only to how to characterise a very small risk. Further details on toxicological aspects can be found in the advice issued by EFSA on 28 July 2003 and in the recent statement of the AFC Panel dated 1 October 2003.

**Microbiological aspects**

Jars of baby food have an excellent microbiological safety record. Additional assurance for the consumer about the integrity of the seal is provided by the incorporation of the ‘pop-up’ button. Current manufacturing practice for baby foods in jars includes controlled heat treatment to ensure that the product is microbiologically safe for the consumer. The airtight seal maintains microbiological stability and ensures a long shelf-life. It prevents contamination with microorganisms, dirt, or insects, during storage and protects the nutritional integrity of the product. If alternative technologies are going to be used to reduce or eliminate semicarbazide from baby foods, it is crucial that the same rigorous microbiological standards are upheld.

The ad hoc expert group was informed that industry is making significant progress on the development of new seal technology. Any future changes to the current gasket would need careful consideration and evaluation of seal integrity before being launched as a replacement for the existing technology.

**Nutritional aspects**

Processed baby foods are products which are carefully regulated with respect to ingredients, low levels of nitrate, pesticide residues and contaminants, and baby foods
in glass jars and bottles make an important nutritional contribution to the diets of many infants. Although not an obligatory part of the diet of infants, they are widely used primarily for reasons of convenience, quality and nutritional safety. If these products were to become suddenly unavailable, or caregivers of infants chose not to use them any longer, it should be borne in mind that the nutritional adequacy of the diets of those infants could be compromised, particularly where caregivers have been relying extensively on these products. There is a possibility that the foods which would be chosen instead might be either not nutritionally equivalent to the foods used before or not suitable for the feeding of infants.

**Conclusions and recommendations**

Semicarbazide is present in certain foods packaged in glass jars and bottles in very low quantities (parts per billion - ppb - or microgrammes/kg of food) due to migration from the plastic gasket which forms the airtight seal in the metal lid. Amounts of up to 25 ppb have been found in baby foods, which give an estimate of intake of around 2 microgrammes/kg body weight/day as a worst case for infants.

There is evidence from animal studies that semicarbazide is a weak carcinogen but it is not possible to conclude whether semicarbazide poses a carcinogenic risk to humans. The risk, if any, is judged to be very small, both for infants and for adult consumers.

Against this background and the microbiological and nutritional issues discussed above, it would be prudent to reduce exposure to semicarbazide as swiftly as technological progress safely allows, and unwise to take any immediate actions on
baby foods which could trigger potentially hazardous consequences of a different nature. In the interim, there is no reason for consumers, including infants, to change their dietary habits because of the possible presence of semicarbazide in certain foods.
Statement of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food

updating the advice available on semicarbazide in packaged foods

Adopted on 1 October 2003
On 28 July 2003, EFSA issued preliminary advice on the possible occurrence of semicarbazide in certain packaged foods (available on the Internet at http://www.efsa.eu.int/pdf/p_afe_doc_01.pdf). The foods concerned are those packaged in glass jars and bottles closed with metal lids sealed with plastic gaskets that are foamed using the chemical blowing agent, azodicarbonamide. The Panel received new information on semicarbazide. The information included oral reports of the progress that has been made on analytical and technological aspects, oral presentation of the results of the genotoxicity studies commissioned by EFSA, a written report of a genotoxicity test conducted by industry, and some preliminary estimates of exposure. On the basis of this new information, the Panel offers the following further advice.

**Analytical aspects**

The current information indicates that semicarbazide detected in foods is not an artefact of the analytical method used to test foods (CIAA, 2003). The method, used so far utilises acid hydrolysis of the sample, derivatisation with 2-nitrobenzaldehyde (2NBA) and determination by LC-MS (liquid chromatography coupled to mass spectrometry) and it measures both free and bound semicarbazide. A new approach suitable for the direct analysis of free semicarbazide has been developed and applied.
This has not yet been validated in an inter-laboratory comparison but it has been used on different samples by three different laboratories. Using this new direct method, free semicarbazide has been found in heated samples of the blowing agent azodicarbonamide, in heated gasket formulations, and in aqueous extracts of gaskets (CIAA, 2003). The levels found are consistent with levels reported using the original analytical method for semicarbazide. On the basis of the available evidence, it can be concluded that free semicarbazide is formed as a consequence of the thermal treatment of azodicarbonamide, it is present in gaskets foamed using azodicarbonamide, and it migrates from these gaskets into foods.

The fate of semicarbazide in the packaged foods is unclear. The direct method of analysis is not yet developed sufficiently to test for free semicarbazide in foods. From basic organic chemistry, semicarbazide is known to react with chemicals such as carbonyl compounds and these functional groups are present in foods. Some or all of the semicarbazide in foods may therefore be bound and not free. It is known, for example, that in animal tissues exposed to nitrofurans antibiotics, where semicarbazide can be detected as one of the breakdown products of nitrofurans, it is not free semicarbazide but bound residues that are present. This binding is reversible, however, and this is the reason for using an acid hydrolysis step in the 2NBA method, in order to free the bound residues. Therefore, it is a reasonable assumption that the 2NBA method of testing foods is a worst case as it should determine both free and reversibly-bound residues of semicarbazide.
Exposure

Concentrations in food

There are few documented data on concentrations of semicarbazide in foods packed in glass jars and bottles. The Panel has been informed that industry intends to set up a database on semicarbazide concentrations in foods but this is not yet available. The foods that have been reported to contain semicarbazide include baby foods, fruit juices, jams and conserves, honey, ketchups and mayonnaise, pickles and sterilized vegetables and sauces. The levels of semicarbazide reported in these foods are variable, in the range non-detectable (less than 1 ppb; parts per billion, microgrammes/kg of food) up to 25 ppb. Baby foods are reported to have the higher concentrations, perhaps because of the higher ratio of gasket area to food mass for these small pack sizes.

Exposure estimates

The Panel has been informed that industry is developing estimates of exposure, based on actual consumption statistics and concentration data across Europe, and that these estimates should become available during October. In the interim, a preliminary estimation of the potential exposure to semicarbazide from food in glass jars and bottles has been made by the Panel. The estimate focused on babies because baby foods seem to contain the highest amounts of semicarbazide and because their food consumption is higher, on a body weight basis, than that of other age groups.

Intake of baby foods increases during weaning when milk is progressively replaced by solid food and then decreases after the first year of life when baby foods are progressively replaced by food not specifically intended for infants. The highest
intake of the affected foods is therefore likely to occur within the first year of life. This is confirmed by limited data from an Italian nationwide food consumption survey (Turrini, 2001). A 6-month-old baby fed only on processed baby foods was therefore taken to represent the worst case in terms of food consumption/kg body weight. On the basis of a limited inspection of food consumption patterns suggested for babies of 6 months, an intake of 700 g of such foods was assumed. Assuming a body weight of 7.5 kg for a baby aged 6 months (CEC, 1993), and taking the highest concentration of semicarbazide reported of 25 ppb, the potential intake of semicarbazide would be 2.3 microgrammes/kg body weight/day. This estimation contains two conservative assumptions. First, exclusive recourse to commercial baby foods packaged in glass jars and bottles, an hypothesis that is not unrealistic. Second, that all the food consumed contains the highest level of semicarbazide reported.

Based on the types of food packaged in glass jars and bottles, in which semicarbazide has been found, it can be concluded that its estimated intake by adults and children on a bodyweight basis will be many times lower than the preliminary estimate of the intake for babies.

**Toxicology**

The main concerns about semicarbazide are its potential genotoxicity and carcinogenicity. The toxicological data available at present remain very limited.

**Genotoxicity**

In the new *in vitro* mutagenicity tests commissioned by EFSA, semicarbazide showed weak mutagenic activity mainly in the absence of a metabolic activating system. Positive results were obtained in Salmonella Typhimurium strains detecting base pair
substitutions (TA1535 and TA100) and in the mouse lymphoma tk forward mutation system (TNO, 2003). The other new study showed weak mutagenic activity only in Salmonella Typhimurium strain TA 1535 in the absence but not in the presence of a metabolic activating system (Industry study, 2003). The available results from an ongoing clastogenicity study in cultured mammalian cells are inconclusive and a second trial is being conducted (TNO, 2003). In vivo, in an earlier study on a series of hydrazine derivatives, the intraperitoneal administration of semicarbazide did not induce DNA damage, as measured by alkaline elution, in liver and lung tissue of mice, whereas positive results were obtained with chemically related genotoxic compounds (Parodi et al., 1981).

From these results it is apparent that semicarbazide is weakly genotoxic in some test systems in vitro. The limited in vivo experimental data available are insufficient to assess whether the activity observed in vitro is also expressed in vivo. Under these circumstances, it would be usual to call for in vivo genotoxicity tests to be conducted. However, the Panel is of the view that such studies, conducted according to standard protocols, may be inconclusive. The Panel considers that a better approach would be to conduct toxicokinetic studies to find out whether semicarbazide, as such, reaches the tissues, and if it does, to focus research efforts on assessing the genotoxic potential in tissues in which it is found.

Carcinogenicity
Semicarbazide appears to be only a weak carcinogen. It did not cause cancer in rats (Weisburger et al., 1981). In mice, increases in tumours that are commonly observed in untreated mice (tumours of the lung and blood vessels) were seen in treated females but not in treated males. The dose at which these tumours were observed was approximately 100mg/kg bodyweight/day given over a lifetime. It is also noted that semicarbazide is one of the weakest carcinogens among several hydrazines that have been tested in mice (IARC, 1974; Parodi et al., 1981; Cheeseman, 1999). Based on this limited experimental evidence, and taking into account the lack of mechanistic information, it is not possible to conclude whether semicarbazide may pose a carcinogenic risk to humans. In view of the weak carcinogenicity in animals and the very low amounts of semicarbazide in foods, if there is any risk it would appear to be very small.

**Conclusions and recommendations**

- It is clear that considerable uncertainties about semicarbazide still remain, not only about the extent of human exposure via foods that have been in contact with foamed gaskets but also concerning possible effects *in vivo*.
- Taking into account the information available to date, on the levels in food, intake and toxicology, the risks to consumers eating products containing semicarbazide is likely to be very small.
- The situation for baby foods requires separate comment. The highest concentrations of semicarbazide have been reported to be in baby foods packaged in glass jars and bottles. Due to their food consumption patterns and small body weight, the highest intakes of semicarbazide are likely to be in infants of 6-12 months consuming such foods regularly. Given the present
uncertainties in the science, the presence of semicarbazide in baby foods is undesirable.

- The Panel is aware that industry is working intensely on technological means to achieve reduction and/or elimination of semicarbazide. The Panel urges, in the light of the continuing uncertainties in the toxicological data, which do not allow a definitive risk assessment to be made, that industry progresses with maximum speed in these efforts to achieve the goal of reduction of semicarbazide in baby foods and ultimately in other foods.

- Concerning baby foods the Panel also noted that glass jars and bottles with secure seals offer very good protection against microbial risks and this should be taken into account in any risk management decisions that may be made.

References


Background information on semicarbazide found in foods packaged in glass jars and bottles

1. Why is EFSA evaluating the safety of semicarbazide?

EFSA was informed by the food industry in July regarding the possible presence of semicarbazide in certain foodstuffs packed in glass jars with metal lids sealed with plastic (PVC) gaskets. As the toxicity of this substance is not well understood, EFSA was asked to advise on the significance of these findings for human health.

2. What is semicarbazide?

Semicarbazide (SEM) belongs to a family of chemicals (hydrazines) which are known to cause cancer in laboratory animals. While semicarbazide has not been extensively tested for toxic effects, it may also be genotoxic (that is, it can damage DNA, the genetic material in cells).

3. Where has semicarbazide been found?

Semicarbazide has recently been detected in food contact materials made using azodicarbonamide, a substance which has been used for over 20 years to make plastic seals for lids on glass jars. It has also been detected in foods packaged in glass jars sealed with these lids.

4. What is azodicarbonamide?

Azodicarbonamide (ADC) is authorised for use in the EU as a blowing agent for plastics in contact with foods. Blowing agents are added to polymers during processing to form minute gas cells throughout the plastic. This is required for the plastic to act effectively as a seal. Such sealing gaskets, found in the metal lids of glass jars, ensure that the food inside is not contaminated by dust, insects or other foreign objects and that it is microbiologically safe.

5. How was SEM discovered in foods?

SEM was found by a private laboratory on the occasion of routine analytical monitoring carried out for food manufacturers.

6. In which foods has SEM been found?
The presence of SEM is not linked to a particular foodstuff but most commonly to a type of packaging which is used world-wide. Metal lids containing sealing gaskets are used for a wide range of products packed in glass jars such as: fruit juices, jams and conserves, honey, baby food, pickles and sterilized vegetables, mayonnaise, mustard, sauces and ketchup.

7. Why are sealing gaskets required?

Gaskets are used to ensure the air tight fit of metal lids on glass jars. The seal protects the food inside the jar from contamination by microbiological hazards, dust, insects or other foreign objects, thus ensuring quality and safe storage of the food prior to opening. The “Push on Twist off” caps utilised for baby foods for instance also provide assurance to consumers that the product is sterile and has not been tampered with.

8. How much SEM has been found in foods?

The foods that have been reported to contain SEM include baby foods, fruit juices, jams and conserves, honey, ketchups and mayonnaise, pickles and sterilised vegetables and sauces. The levels of SEM reported in these foods are variable, ranging from non detectable up to 25 ppb. Baby foods are reported to have the highest concentrations, perhaps because of the higher ratio of gasket area to food mass given the small pack sizes for these foods.

9. Is SEM something new, or has it been around for some time?

SEM is a chemical substance which has been known to chemists for many years. Azodicarbonamide, from which SEM is derived, has been authorised as a blowing agent in the EU for decades. However, the occurrence of SEM in food and food packaging materials is a recent finding, resulting from progress in science and improvements in analytical techniques.

10. What has EFSA done to date?

When informed about the problem in July by industry, EFSA convened an Ad Hoc Expert Group meeting of the EFSA Scientific Panel on Food Additives, Flavourings, Food Processing Aids and Materials in Contact with Food (AFC Panel) on 24 July 2003. An industry delegation was invited to the meeting to present their knowledge regarding the possible occurrence of semicarbazide in foods. At the time the origin of semicarbazide in foods was not clear. The theory was that perhaps certain chemicals used in the formation of the sealing gaskets could be responsible for its presence in foods. However, it was also possible that the presence of semicarbazide was an artefact of the analytical process itself. That is to say that it could have been generated by the analysis for semicarbazide, and that it would therefore not normally be present in foods.

After reviewing the information provided by industry, as well as other scientific information available, the AFC Panel concluded that given the uncertainties regarding both analytical and toxicological aspects, it was not possible to provide a scientifically based risk assessment for semicarbazide at the time. Nevertheless, in keeping with
EFSA’s policy on openness and transparency, a preliminary advice related to the possible occurrence of semicarbazide in foods was drafted and made available to the public on 28 July 2003.

In addition to further research planned by industry, EFSA immediately initiated further studies to address key information requirements necessary for the risk assessment process. Following this, a second meeting of the AFC Panel was convened on 30 September – 1 October in order to review the new scientific evidence that had been made available.

As further issues needed to be considered before issuing EFSA’s risk assessment on semicarbazide in foods, particularly with regards to baby foods, a meeting was held on 9 October in order to bring together a broader range of scientific experts including specialists in microbiology and paediatric nutrition. This meeting included experts from the AFC Panel as well as the Panels on Contaminants in the Food chain and Dietetic Products, Nutrition and Allergies. New data were reviewed at this meeting and the implications of semicarbazide in baby food were discussed taking into account nutritional and microbiological considerations. Following this expert consultation, an update on semicarbazide in foods and its implications for human health was communicated by EFSA to the public on 15 October 2003.

11. What is the state of the evidence today regarding semicarbazide?

As a result of the additional research commissioned since July by EFSA, we have been able to clear some doubts but others still remain. Specifically we now know that semicarbazide is indeed found in certain foods and that it is not simply an artefact of the analytical process. Having said that, there is still no validated method for the analysis of SEM in foods and consideration needs to be given to this issue.

While results of the research commissioned by EFSA show that semicarbazide is weakly genotoxic in some test systems in vitro, considerable uncertainties about SEM still remain, not only about the extent of human exposure through diet but also concerning possible effects in vivo. The risk assessment made public on 15 October is an update and studies aimed at obtaining a more complete assessment of the toxicology of SEM are ongoing, including the evaluation of the possible genotoxicity of semicarbazide.

12. Does SEM present a risk for consumers?

The risk to consumers – if any – is judged by scientific experts to be very small, not only for adults but also for infants. Although there are uncertainties in the risk assessment due to lack of full data at present, these relate only to how to characterise what is considered to be a very small risk. Nevertheless, given the present uncertainties in the science, and the fact that potential exposure to this substance on a body weight basis is likely to be highest for infants, experts believe that it would be prudent to reduce the presence of SEM in baby foods.

15. Is it safe to feed babies foods packed in glass jars?
Scientific experts convened by EFSA to evaluate the specific issue of semicarbazide in baby foods confirmed that there are no reasons for consumers, including infants, to change their dietary habits because of the possible presence of SEM in certain foods. Baby foods packed in glass jars are widely used today by consumers for reasons of convenience, quality and nutritional safety. They also provide strong protection against microbiological risk. Given the present uncertainties in the science, experts concluded that it would be prudent to reduce exposure to semicarbazide as swiftly as technological progress allows. However, experts stressed that it would be unwise to take any immediate actions on baby foods which could potentially have other detrimental effects on the health of babies.

16. **What actions should be undertaken to deal with the risk associated with SEM?**

Actions are already being undertaken to address the potential risks associated with semicarbazide in foods. Further research regarding the origin of SEM in foods, intake and exposure levels as well as toxicology studies are underway. Industry is currently working actively to reduce, and if possible, eliminate SEM from food packaging. The EFSA Panel encourages industry to pursue this work with maximum speed in order to reduce SEM levels, focusing on baby foods as an immediate priority, and ultimately in other foods as well.