



European Food Safety Authority

Note to the Advisory Forum 10 September 2003

Semicarbazide – what happened and lessons learnt from dealing with this matter

Members of the Advisory Forum may wish to be informed about the emerging issue of SEMICARBAZIDE and the way in which collaboration between the Member States, the industry concerned, EFSA staff and members of its Scientific Panel on Food Additives, Flavourings, Processing Aids, and Materials in Contact with Food (AFC panel) enabled a thorough overview of current data to be made and initial findings to be published. The matter is still under review and EFSA is actively seeking further data in order to be able to be in a position to provide more detailed advice to risk managers and stakeholders.

WHAT HAPPENED – A CHRONOLOGY:

- Semicarbazide in non-animal originated food was first discovered by an independent laboratory through routine analysis of nitrofurantoin antibiotics.
- Industry confirmed these findings, and informed the German and Swiss authorities on 26 and 27 June 2003, respectively.
- EFSA was informed by CIAA¹ on 9 July 2003.
- EFSA evaluated this information and scanned other sources for further scientific data.
- EFSA convened an Ad Hoc Expert Group meeting (chair Dr. Sue Barlow) of the EFSA AFC Panel on 24 July 2003. An industry delegation proposed by CIAA was invited to parts of the meeting to present their knowledge on this matter. The Group also considered other information during this meeting and concluded that the existing toxicological data were not sufficient to make a comprehensive risk assessment. However, in the light of the urgency the Expert Group felt that it would be desirable for EFSA and consumers to have some preliminary advice. Therefore, an advice paper on the possible occurrence of semicarbazide in packaged food was drafted.
- Information concerning the issue was also exchanged with the Member States and in particular certain Member States (AT, FR, GR, IE, ES) were provided with further advice from EFSA on specific questions relating to this matter.
- On 28 July 2003 EFSA distributed the final version of the advice paper on semicarbazide to EFSA's Advisory Forum, European Commission, CIAA, and AFC panel members. The paper was placed on the Authority's webpage and EFSA issued a press release. The issue was covered in several papers including UK Daily Mail, UK Times, GR Eftycheria and food specific journals.
- In addition, EFSA initiated immediately genotoxicity studies on semicarbazide with TNO in order to fill the data gap for genotoxicity studies. Once these data are available

¹ Confédération des Industries Agro-Alimentaires de l'UE

(October/November 2003) or if further scientific data on semicarbazide becomes available, the Expert Group will meet again in order to make a more detailed risk assessment.

- After the advice paper was published some other authorities (PT, GR) were provided with further details concerning the information EFSA had on semicarbazide.
- Member States food agency websites also provided information e.g. UK's FSA referred to the EFSA activity on their web page and mentioned the work they have commissioned in this area.

LESSONS LEARNT

- The collaboration between the various stakeholders including the industry, Member States national agencies and EFSA enabled a fast exchange of the scientific and other data to be made and initial findings to be published without delay.
- On emerging issues there is a continuing need for such exchanges of information to ensure that an informed and proportionate response can be made to emerging issues. EFSA would appreciate being kept informed of any national information that becomes available on this and other emerging risks. For its part EFSA will continue to provide information on such matters.
- In this case the Expert Group was able to identify gaps in data and indicate to EFSA what actions were needed in order to fill these. Additional information is now being sought and it is important that EFSA builds its ability to commission short relevant studies when data are lacking on an emerging issue.
- A complicating matter is linked to the implications of the general practice of using semicarbazide as a marker for illegal use of nitrofurans as veterinary drugs. National authorities may want to clarify the various possible sources of semicarbazide in foods.