SCIENTIFIC OPINION

Statement on nitrites in meat products[1]

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food assess the data provided by the Danish authorities, evaluating in particular whether this information, or any other new scientific developments, indicate that there is scientific evidence for a revision of the maximum limits on nitrites in food adopted in Directive 2006/52/EC. The Panel considered that the terms of reference could be answered by considering three issues including 1) whether the data provided by the Danish authorities would support re-evaluation of the ADI for nitrite, 2) whether the current exposure to nitrite from the proposed uses and use levels would exceed the ADI and 3) what nitrite levels would be required to achieve its preservative effects. The Panel concludes that the data provided by the Danish authorities do not provide a basis to revise the ADI of 0.07 mg/kg bw/day for nitrite. The Panel notes that in several European countries the mean exposure at Tier 2 is above the ADI. At Tier 3, the adult high consumers are just above the ADI while for high consumer children exposure is 2.5 times above the ADI, and the higher range of the mean exposure of children is close to the ADI. The Panel concludes, in line with the SCF assessment in 1995 that exposure to preformed nitrosamines in food should be minimized by appropriate technological practices such as lowering the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety. Evaluation of the technological need for the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 is outside the remit of the Panel. However, the Panel notes that this issue has been adequately assessed by others and that the technological need is product specific.

KEY WORDS

Nitrites, food additive.

1 On request European Commission, Question No EFSA-Q-2010-00097, adopted on 11 March 2010.

2 Panel members: F. Aguilar, U.R. Charrondiere, B. Dusemund, P. Galtier, J. Gilbert, D.M. Gott, S. Grilli, R. Gürtler, J. König, C. Lambré, J-C. Larsen, J-C. Leblanc, A. Mortensen, D. Parent-Massin, I. Pratt, I.M.C.M. Rietjens, I. Stankovic, P. Tobback, T. Verguieva, R.A. Woutersen. Two members of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: ans@efsa.europa.eu

Suggested citation: EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Statement on nitrites in meat products. EFSA Journal 2010; 8(5):1538. [12 pp.]. doi:10.2903/j.efsa.2010.1538. Available online: www.efsa.europa.eu

SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food was asked to assess urgently the data provided by the Danish authorities, in particular whether this information, or any other new scientific developments, indicate that there is scientific evidence for a revision of the maximum limits on nitrites in food adopted in Directive 2006/52/EC.

The Panel considered that the terms of reference could be answered by considering three issues including 1) whether the data provided by the Danish authorities would support re-evaluation of the ADI for nitrite, 2) whether the current exposure to nitrite from the proposed uses and use levels would exceed the ADI and 3) what nitrite levels would be required to achieve its preservative effects.

The Panel concludes that the data provided by the Danish authorities do not provide a basis to revise the ADI of 0.07 mg/kg bw/day for nitrite.

The Panel notes that in several European countries the mean exposure at Tier 2 is above the ADI. At Tier 3, the adult high consumers are just above the ADI while for high consumer children exposure is 2.5 times above the ADI, and the higher range of the mean exposure of children is close to the ADI.

The Panel concludes, in line with what has been concluded by the SCF in 1995 that exposure to preformed nitrosamines in food should be minimized by appropriate technological practices such as lowering the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety.

Evaluation of the technological need for the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 is outside the remit of the Panel. However, the Panel notes that this issue has been adequately assessed by others and that the technological need is product specific.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY EUROPEAN COMMISSION

Nitrites exert an important preservative effect in some meat products, in particular by inhibiting the growth of several undesirable micro-organisms, including *Clostridium botulinum*. The use of nitrites may, however, lead to the formation of carcinogenic nitrosamines in meat products. The legislation authorising nitrites, adopted by Directive 2006/52/EC, therefore carefully balances these two risks taking into account the great variety of meat products manufactured and traded throughout the European Union.

The Directive takes into account the opinions of the Scientific Committee on Food and the European Food Safety Authority, which conclude that 50-100 mg nitrite per kg meat may suffice for many products; for other products, especially those with a low salt content and having a prolonged shelf life, the addition of 50-150 mg/kg of nitrite is necessary to inhibit *Clostridium botulinum.*

Following the adoption of the Directive, the Kingdom of Demark made a notification to the European Commission pursuant to Article 95 (4) of the EC Treaty seeking authorisation to maintain national measures that are more stringent than the provisions of an EC harmonised measure in relation to the use of nitrites in meat products.

As a consequence, Commission Decision 2008/448/EC concerning national provisions notified by Denmark on the addition of nitrite to certain meat products approved for a period of two years more stringent national provisions, pending the demonstration by the Danish authorities that the levels laid down in Directive 2006/52/EC would lead to an unacceptable risk.

The Kingdom of Denmark has confirmed its wish to maintain the national provisions and has submitted additional information to support this request. This information includes data on consumption of meat products, imports of meat products, and analysis of nitrite in meat products on the Danish market.

TERMS OF REFERENCE AS PROVIDED BY EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to urgently assess the data provided by the Danish authorities, in particular whether this information, or any other new scientific developments, indicate that there is scientific evidence for a revision of the maximum limits on nitrites adopted in Directive 2006/52/EC.

ASSESSMENT

1. Introduction

The Panel considered that the terms of reference could be answered by evaluating three separate issues which can be summarized as follows:

- The Danish authorities argue that "*the ADI established for the substance does not take account of the formation of nitrosamines which is associated with the use of nitrite in meat products*", and that "*according to scientific assessments, nitrosamines are genotoxic*". The Danish authorities argue that this "*means that it is not possible to establish a limit under which they are not carcinogenic*". To conclude on this issue the Panel decided to re-evaluate the arguments presented in previous evaluations by JECFA, SCF and EFSA and decide if they agree that in spite of the possible formation of nitrosamines the database supports establishment of an ADI of 0.07 mg/kg bw/day.

- The Danish authorities argue that the maximum use levels allowed in Directive 2006/52/EC[3] of 5 July 2006 might result in intakes within the Danish population that would exceed the established ADI. To conclude on this issue the Panel decided to evaluate the exposure assessments provided by the Danish authorities.

- The Danish authorities argue that the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 might not be needed from a technological point of view, because their national provisions on nitrite ensure sufficient protection against food poisoning. The Panel decided that this aspect was outside the remit of the Panel and to refer in this assessment to opinions on this issue provided by others.

2. Derivation of the ADI.

The former SCF and the JECFA both derived ADI's for nitrate and nitrite. The SCF reviewed the toxicological effects of nitrate and nitrite and established an ADI of 3.7 mg/kg bw/day for nitrate in 1990 (SCF, 1992), retained the ADI in 1995 and derived an ADI of 0.06 mg/kg bw/day for nitrite (SCF, 1995). Nitrite was reviewed by JECFA at its sixth, eighth, seventeenth, twentieth, forty-fourth and fiftieth meetings. At its forty-fourth meeting, JECFA (JECFA, 1995) noted that "*several controlled laboratory studies had shown that N-nitroso compounds are formed endogenously when both nitrite and N-nitrosatable compounds are present together at high concentrations; it observed, however, that quantitative data were available only on those N-nitroso compounds that are readily formed endogenously, such as N-nitrosoproline, which is not carcinogenic. As there was no quantitative evidence of the endogenous formation of carcinogenic N-nitroso compounds at the levels of intake of nitrite and nitrosatable precursors achievable in the diet, a quantitative risk assessment of nitrite on the basis of endogenously formed N-nitroso compounds was considered to be inappropriate. The Committee at its forty-fourth meeting therefore based its safety evaluation on studies of toxicity with nitrite. The NOELs in these studies were 5.4 mg/kg bw per day (expressed as nitrite ion) in a 90-day study in rats, in which hypertrophy of the zona glomerulosa* [of the adrenal] *was observed, and 6.7 mg/kg bw per day (expressed as nitrite ion) in a 2-year study, in rats in which effects on the heart and*

[3]Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs.

lungs were observed. On this basis, the Committee allocated an ADI of 0–0.06 mg/kg bw, expressed as nitrite ion, by applying a safety factor of 100".

At the fiftieth meeting, JECFA (JECFA, 2002) reviewed the data that had become available on nitrite since its forty-fourth meeting, including data on the relevance and adverse nature of certain effects, with new information on the mode of action of effects on the adrenals and on toxicokinetics. The JECFA concluded "*that the minimal hypertrophy reflected physiological adaptation to small fluctuations in blood pressure and should not be considered a direct toxic action on the adrenals. This conclusion implies that the safety evaluation should not be derived from the NOEL for minimal hypertrophy of the adrenal zona glomerulosa, used by the JECFA at its forty-fourth meeting, but on NOELs for other end-points. The NOEL of 5.4 mg/kg bw per day (expressed as nitrite ion) was therefore considered to be no longer relevant, as it was based on the indirect effect on the adrenals described above. A NOEL of 6.7 mg/kg bw per day was identified in a 2-year study in rats, in which effects on the heart and lungs were observed at the next higher d*ose".

"*The Committee established an ADI of 0–0.07 mg/kg bw, expressed as nitrite ion, on the basis of the NOEL of 6.7 mg/kg bw per day for effects on the heart and lung in the 2-year study in rats and a safety factor of 100*".

The most recent assessment of nitrate and nitrite in 2002 by the JECFA reconfirmed the ADI of 3.7 mg/kg bw/day for nitrate and set an ADI of 0.07 mg/kg bw/day for nitrite based on a long term National Toxicology Program (NTP) rat study (JECFA, 2002). The ADI was based on heart and lung toxicity in a 2 years study in rats, the NOEL in this study was 10 mg/kg bw/day expressed as sodium salt or 6.7 mg/kg bw/day expressed as anion leading to an ADI of 0.1 mg/kg bw/day expressed as sodium salt or 0.07 mg/kg bw/day expressed as anion (Maekawa *et al.*, 1982).

The ANS Panel also notes that the EFSA Scientific Panel on Contaminants in the Food chain (CONTAM Panel) concluded in its scientific opinion on nitrate in vegetables in 2008 (EFSA, 2008).

> "*No new data were identified that would require a revision of the ADI values of 0-3.7 mg/kg body weight (bw) for nitrate and 0-0.07 mg/kg bw for nitrite as reconfirmed by the Joint FAO/WHO Expert Committee on Food Additives in 2002*."

In preparing the present assessment the ANS Panel carried out an additional literature search covering the period of time from 2008 to present. No new relevant data were identified that would alter the conclusion of the EFSA CONTAM Panel regarding the ADI (EFSA, 2008).

3. Exposure

Dietary exposure to nitrites from the maximum proposed use levels was estimated by the European Union in 2001 following the principles of the stepwise approach, which were used in the report of the Scientific Co-operation (SCOOP) Task 4.2, to estimate additive intakes (EC, 1998). In the Tiered approach, Tier 1 is based on theoretical food consumption data and maximum permitted use levels (MPLs) for additives as permitted by relevant Community legislation. The Second and Third Tiers refer to assessment at the level of individual Member States, combining national data on food consumption with the maximum permitted usage levels for the additive (Tier 2) and with its actual patterns or occurence data in foods (Tier 3). The dietary exposure to nitrites from the maximum proposed use levels was estimated using the Budget method (Tier 1) as outlined in the report of the Scientific Co-operation (SCOOP) Task 4.2, to estimate additives' intakes (EC, 1998). The theoretical maximum daily exposure was 0.31 mg/kg bw/day for children and adults.

Refined exposure estimates were also performed for Tier 2 in this report using maximum proposed use levels with individual food consumption data for children and the adult population. Exposure

estimates for adults and children (3-14 years old) were performed using the detailed individual food consumption data from seven European countries (France, Denmark, the Netherlands, Spain, Italy, UK and Norway). The mean dietary exposure of European children ranged from 0.05 to 0.36 mg nitrite (as nitrite ion)/kg bw/day, and of adults from 0.04 to 0.23 mg/kg bw/day. No high percentile consumer figures were reported.

For Tier 3, the Panel reviewed refined exposure estimates made available from the published literature from Denmark (Leth *et al.*, 2008) and from France (Bemrah *et al.*, 2008 and Menard *et al.*, 2008). These estimates were performed using the detailed individual food consumption data combined with average occurrence data on nitrites in foods, mainly for cured meat products. The mean dietary exposure of European children (aged 3-14 years, two countries) ranged from 0.009 to 0.06 mg/kg bw/day and from 0.11 to 0.17 mg/kg bw/day at the 95th/99th percentile. Estimates reported for the adult population give a mean dietary exposure to nitrites ranging from 0.005 to 0.03 mg/kg bw/day, and from 0.06 to 0.09 mg/kg bw/day at the 95th percentile.

The Panel noted that residual levels reported for cured meat products were based on extensive analytical data realised from several surveys conducted in Denmark between 1995 and 2006 and France between 2000 and 2006. Furthermore the ANS Panel notes that these average residual levels were generally below 60 mg/kg meat product.

Table 1: Summary of anticipated exposure to nitrites in children and the adult population using the Tiered approach (EC, 2001)

	Adult population (>18 years old)	**Children population** (3-14 years old)
	mg/kg bw/day	
Tier 1. Budget method	0.31*	
Tier 2. Maximum permitted use levels for nitrites (from the report of EC 2001 for DK, ES, FR, IT, NL,UK, NO)		
• Mean exposure	0.04-0.23	0.05-0.36
• Exposure 95th or 97.5th percentile	-	-
Tier 3. Average reported nitrite levels**		
• Mean exposure	0.005-0.03	0.009-0.06
• Exposure 95th or 99th percentile***	0.06-0.09	0.11-0.17

* Based on the 25% assumption of food containing the nitrite at the maximum permitted level
** Based on average residual level of nitrite
*** Range of exposures based on 95th percentile for French data and 99th percentile for Danish data

The Panel notes that in several European countries the mean exposure at Tier 2 is above the ADI. At Tier 3, the exposure of adult high consumers is just above the ADI while for high consumer children the exposure is 2.5 times above the ADI, and that the higher range of the mean exposure of children is close to the ADI.

4. Technological need

The ANS Panel considers that the question of the levels of nitrite necessary to provide microbiological safety of meat products is outside of its remit. However, the ANS Panel notes that this issue has been addressed in the 2003 Opinion of the Scientific Panel on Biological Hazards (BIOHAZ Panel) on the request from the Commission related to the effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products (EFSA 2003). The conclusions of this opinion are summarised below:

> *"Several factors contribute to the safety of meat products including: cooking process, salt / brine concentration (aw), storage time and temperature, pH and concentration of nitrite added. Hence, the lowest level of nitrite to have a protective effect against microbiological risks, such as C. botulinum, will be different in different products, depending on other factors including any heat treatment applied, the pH and the water activity /salt concentration. Cured meat products with nitrite have an excellent record of safety with respect to C. botulinum. All laboratory tests indicate that sodium nitrite increases protection against C. botulinum. Research in the 1960s and 1970s failed to identify an alternative to nitrite for cured meat products (NAS, 1982; Widdus and Busta, 1982).*
>
> *The Panel is of the opinion that the in-going amount of nitrite, rather than the residual amount, contributes to the inhibitory activity against C. botulinum. Therefore, control of nitrite in cured meat products should be via the input levels rather than the residual amounts.*
>
> *The Panel agrees with the view of the Scientific Committee on Food (SCF) (expressed in section 3.1.1 of the Opinion of 19 October 1990) that 50 – 100 mg added nitrite (as sodium nitrite) per kg of meat products may suffice for many products. In other products, especially those with a low salt content and having a prolonged shelf-life, addition of between 50-150 mg/kg nitrite is necessary to inhibit the growth of C. botulinum.*
>
> *The Panel agrees with the SCF which recommended in its Opinion of October 1990 that the use of nitrite should only be permitted as a mixture with salt (sodium chloride) to limit the amount of nitrite that can be added and to prevent accidental poisoning through the addition of excessive quantities of nitrite to food. The practicability of using salt containing 0.4 to 0.5% nitrite (as sodium nitrite) has been demonstrated over many years although using salt and nitrite separately has also been shown to be practicable in some countries with no accidental additions of high levels of nitrite over many years.*
>
> *The Panel is of the opinion that the current "indicative in-going amount" of potassium nitrite (E 249) and sodium nitrite (E 250) should be "maximum ingoing amount".*

The ANS Panel has consulted the Secretariat of the BIOHAZ Panel and confirmed that these conclusions remain valid and there are no data which require reconsideration of these conclusions.

In 1995 (SCF, 1995) the Scientific Committee on Food concluded that:

> *"Dietary exposure to N-nitrosocompounds is very low. However, in view of the genotoxic and carcinogenic potential of some of these substances, efforts should continue to reduce dietary exposure. Therefore, the Committee reiterates its previous opinion, that exposure to preformed nitrosamines in food should be minimised by appropriate technological practices such as the lowering of levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure micro biological safety*".

The SCF considered that "*application of HACCP principles to reduce the levels of added preservatives including nitrites and nitrates*" contributed to minimising exposure.

The ANS Panel notes that generally Directive 2006/52/EC sets the maximum levels of nitrite that can be added to meat to have a preservative effect in some meat products. For some traditional products residual levels are specified in this Directive. However, in line with general principles in additives legislation in the European Union and Hazard Analysis and Critical Control Point (HACCP) system principles, for any individual product the amount of an additive added is that necessary to meet its technological function in that product. Thus for food produced in line with these principles nitrite would not need to be added at the maximum levels in legislation.

Furthermore the Panel notes that according to EFSA BIOHAZ Panel the higher levels tend to be required in products with a lower salt content which suggests that other factors would have to be considered if a comprehensive risk benefit analysis were to be undertaken.

5. Discussion

The Panel considered that the terms of reference could be answered by considering three issues, including;

1) whether the data provided by the Danish authorities would support re-evaluation of the ADI for nitrite

2) whether the current exposure to nitrite from the proposed uses and use levels would exceed the ADI

3) what nitrite levels would be required to achieve its preservative effects.

The Panel notes that the data provided by the Danish authorities did not contain new toxicity data on nitrite and in particular on the nature, formation and genotoxicity or carcinogenicity of those *N*-nitroso compounds that are readily formed. The Panel also notes that previous evaluations indicated that "*quantitative data were available only on N-nitroso compounds that are readily formed endogenously, such as N-nitrosoproline, which is not carcinogenic*". Therefore the Panel concludes that the data provided by the Danish authorities do not give reason to revise the ADI of 0.07 mg/kg bw/day for nitrite.

The Panel notes that in several European countries the mean exposure to nitrites at Tier 2 is above the ADI. At Tier 3, the exposure of adult high consumers is just above the ADI while for high consumer children the exposure is 2.5 times above the ADI, and the higher range of the mean exposure of children is close to the ADI.

Evaluation of the technological need for the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 is outside the remit of the Panel. However, the Panel notes that this issue has been adequately assessed by others and that the technological need is product specific.

CONCLUSIONS

The Panel concludes that the data provided by the Danish authorities do not provide a basis to revise the ADI of 0.07 mg/kg bw/day for nitrite.

The Panel notes that in several European countries the mean exposure at Tier 2 is above the ADI. At Tier 3, the exposure of adult high consumers is just above the ADI while for high consumer children the exposure is 2.5 times above the ADI, and the higher range of the mean exposure of children is close to the ADI.

The Panel concludes, in line with what has been concluded by the SCF in 1995 that exposure to preformed nitrosamines in food should be minimized by appropriate technological practices such as lowering the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety.

Evaluation of the technological need for the maximum use levels for nitrite adopted in Directive 2006/52/EC of 5 July 2006 is outside the remit of the Panel. However, the Panel notes that this issue has been adequately assessed by others and that the technological need is product specific.

DOCUMENTATION PROVIDED TO EFSA

Letter from the Danish Permanent Representative to the European Commission 20 November 2009.

REFERENCES

Bemrah, N, Leblanc, JC and Volatier, JL, 2008. Assessment of dietary exposure in the French population to 13 selected food colours, preservatives, antioxidants, stabilizers, emulsifiers and sweeteners. Food additives & contaminants part b-surveillance, 2-14.

EC, 1998. Report on Methodologies for the Monitoring of Food Additive Intake Across the European Union. Final Report Submitted by the Task Coordinator 16 January 1998, Reports of a Working Group on Scientific Cooperation on Questions Relating to Food. Task 4.2. SCOOP/INT/REPORT/2 (Brussels: European Commission Directorate General I11 Industry).

EC, 2001. 542 final. Report from the commission on dietary food additive intake in the European Union. Accessible via: http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0542en01.pdf

EFSA, 2003. The effects of nitrites/nitrates on the microbiological safety of meat products. Scientific Opinion of the Panel on Biological Hazards, 14, 1-31.

EFSA, 2008. Nitrate in vegetables. Scientific Opinion of the Panel on Contaminants in the Food Chain, 689, 1-79.

JECFA, 1995. Joint FAO/WHO Expert Committee on Food Additives, Evaluation of certain food additives and contaminants. Forty-fourth report of the Joint FAO/WHO Experts Committee on Food Additives, WHO Technical Reports series 859. 29-35. Accessible via: http://whqlibdoc.who.int/trs/WHO_TRS_859.pdf

JECFA, 2002. Joint FAO/WHO Expert Committee on Food Additives, Evaluation of certain food additives and contaminants. Fifty-ninth report of the Joint FAO/WHO Experts Committee on Food Additives. WHO Technical Reports series 913. 20-32. Accessible via: http://whqlibdoc.who.int/trs/WHO_TRS_913.pdf

Leth T, Fagt S, Nielsen S, Andersen R, 2008. Nitrite and nitrate in meat products and estimated intake in Denmark from 1998 to 2006. Food additives and contaminants, 1-9.

Maekawa A, Ogiu T, Onodera H, Furuta K, Matsuoka C, Ohno Y, Odashima S, 1982. Carcinogenicity studies of sodium nitrite and sodium nitrate in F-344 rats. Food Chem Toxicol. 1982 Feb;20(1):25-33.

Menard C, Heraud F, Volatier JL and Leblanc JC, 2008. Assessment of dietary exposure of nitrate and nitrite in France. Food additives and contaminants part a-chemistry analysis control exposure & risk assessment, 971-888.

SCF, 1992. Scientific Committee for Food. Opinion on nitrates and nitrites. Reports of the Scientific Committee for Food 26th Series, Opinion expressed on 19 October 1990, 21-28.

SCF, 1995. Scientific Committee for Food. Opinion on nitrates and nitrites. Reports of the Scientific Committee for Food 38th Series, 1-33.

GLOSSARY/ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
BIOHAZ	EFSA Scientific Panel on Biological Hazards
CONTAM	EFSA Scientific Panel on Contaminants in the Food chain
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO/WHO	Food and Agriculture Organization/World Health Organization
HACCP	Hazard Analysis and Critical Control Point
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NOEL	No-Observed-Effect Level
NTP	National Toxicology Program
SCF	Scientific Committee on Food
SCOOP	A scientific cooperation (SCOOP) task involves coordination amongst Member States to provide pooled data from across the EU on particular issues of concern regarding food safety