Contamination of milk by melamine in China

Chairman : Mr Eric Poudelet

All Member States were represented except Czech Republic, Latvia and Republic of Slovenia.

1. Introduction

The Chairman indicated that this meeting was convened at short notice following the contamination in China of milk and milk products by melamine and the need to consider safeguard measures to protect public health.

In the second week of September 2008, the Commission was made aware that high levels of melamine were found in infant milk and other milk products in China. Melamine is a chemical intermediate used in the manufacture of resins and plastics. Melamine, which is high in nitrogen, has been fraudulently added to infant milk and milk to give the appearance of increased protein levels.

The high levels of melamine in infant milk resulted in China in very severe health effects in infants and young children. At least four children have died in China from severe kidney failure due to the melamine added to milk powder, and more than 50,000 infants and young children are currently affected by kidney problems.

The Chairman also indicated that the agenda for the meeting lists a number of items which have to be addressed during the meeting but the order will not necessarily be strictly followed.

2. EU-legislation as regards import into the EU of food and feed from China

Imports of milk and milk products, including milk powder, originating from China have never been allowed into the Community and information available from large industry actors and from competent authorities indicate that no imports of composite milk products intended for the particular nutritional use of infants and young children are taking place from China.

However, certain such composite products, depending of their specific formulation and in particular on the proportion of milk product content, could have been presented for
import without undergoing systematic border checks pursuant to Decision 2007/275/EC concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EC and 97/78/EC.

It can furthermore not be excluded that special import channels for such products exist (intended for instance for Chinese food shops).

Composite product such as chocolate, bonbons, biscuits containing milk or milk products are imported from China into the EU.

3. **EFSA statement**

To assess the risks related to the presence of melamine in composite products containing milk and milk products, such as chocolate, biscuits etc. at the request of the Commission, the European Food Safety Authority (EFSA) issued on 24 September a scientific statement¹, which concludes that the highest risk would be represented by a worst case scenario according to which children with high daily consumption of biscuits and chocolates containing the highest proportion of milk powder (which varies between 16% and more than 20%), with a contamination equal to the highest level found in milk powder from China, could potentially exceed the tolerable daily intake (TDI) of melamine (0.5 mg/kg body weight).

4. **Action level and methods of analysis**

The Commission representative informed the Committee that, in EU legislation, a Specific Migration Limit (SML) for melamine has been established. Indeed, melamine is used in melamine ware/plastics used as food contact materials and can migrate from the food contact material in the food. This SML is derived from the TDI for melamine, i.e. 0.5 mg/kg, whereby it is assumed in a very worst case scenario that a person can be exposed daily to 1 kg of food which has been in contact with food contact material containing melamine. This SML serves as criterion to evaluate if a certain substance may be used in food contact material. Experimental tests are performed with food simulants under worst case conditions in order to verify if the migration is not larger than the SML. In case the migration under these conditions is not higher than the SML, the substance may be authorised for use in food contact materials.

However in reality, migration of melamine from food contact materials is much lower and available studies indicate that migration even under extreme conditions would not be more than a few mg/kg.

Available occurrence data indicate that melamine is only present at low levels in food which has not been unacceptably adulterated by melamine.

Melamine can also be present in food as metabolite of the pesticide cyromazin.

Taking all these facts into account, it was agreed that the level of 2.5 mg/kg is the appropriate level to distinguish between the unavoidable background presence of melamine (from food contact materials, pesticide use…) and unacceptable adulteration.

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This level provides also a large margin of safety according to the EFSA statement on the risks of melamine in food.

Methods of analysis with sufficient sensitivity exist to control the presence of melamine in food at levels of 2.5 mg/kg. The Commission committed to prepare a document describing these methods of analysis and make this document available to the Member States.

It was specified that the action level applies only to melamine and not to the related compounds cyanuric acid, ammeline and ammelide. However for the laboratories which have the capacity to analyse also cyanuric acid, ammeline and ammelide, it was stressed that it is highly recommended to analyse also these substances as this information is of importance for the risk assessment and also for the determination of the treatment of the affected children in China.

5. Measures proposed

The Commission proposed following measures as regards products containing milk and milk products originating in or consigned from China to safeguard public health in the EU.

- prohibition of import into the Community of Chinese composite milk products intended for the particular nutritional use of infants and young children, taking into account that such products represent the primary and, in some cases sole, source of nourishment for infants and young children.

- Member States have to ensure that all composite products (food and feed) containing at least 15% of milk product, originating from China, are systematically tested before import into the Community. All such products which are shown to contain melamine in excess of 2.5 mg/kg product are immediately destroyed. Member States shall also test, as a precaution, composite products whose milk product content cannot be established, but which can be reasonably assumed to contain milk products in significant amounts.

- Member States shall take the necessary measures to ensure that composite products containing milk and milk products originating in or consigned from China which are already placed on the market are subject to an appropriate level of controls.

- unfavourable analytical results shall be reported through the Rapid Alert System for Feed and Food (RASFF) without delay and the favourable results shall be reported on a two-weeks basis.

- Member States shall ensure that any product found to contain melamine in excess of 2.5 mg/kg is destroyed without delay.

- Member States shall ensure that the cost incurred for the control and the costs of official measures taken in case of non-compliance are to be borne by the feed and food business operator.
6. Discussion on the proposed measures

All Member States welcomed the Commission's initiative for a harmonised approach at EU level.

While a number of Member States were in favour of more strict measures (prohibition of import of composite products containing milk and milk products), other Member States were reluctant to perform a 100% check at the border on composite products (chocolate, biscuits…) other than infant formula with more than 15% milk powder because it is considered that such a control is difficult to perform in practice (lack of resource/analytical capacity/non quantitative declaration of ingredients). These Member States indicated that a certification system carried out by the Chinese authorities on all composite products containing milk and milk products (i.e. not limited to the products containing more than 15% of milk products) certifying that the products have been tested and have been found not to contain melamine above 2.5 mg/kg.

The Chair took note of these comments and stated that such a certification could be discussed in the future, after the principle of certification has been agreed with the Chinese authorities.

7. Conclusion

The Chairman announced that the Commission will adopt the envisaged safeguard measures (see point 5) the day after the meeting as interim measures and this in accordance with Article 53 (2) first subparagraph of Regulation (EC) No 178/2002.

As these interim measures are taken by the Commission without prior opinion of the Standing Committee, these measures had to be confirmed or adjusted by the Committee within ten working days after adoption by the Commission. The Chairman indicated that at that occasion the possibility of introduction of a certification system as alternative for the currently presented measures will be considered, after having had discussions on this with the Chinese authorities.

The Committee accepted this approach.

The meeting was closed at 16.00.

Eric Poudelet,
Acting Director (signed)