

HYGIENE MEASURES FOR INFANT NUTRITION AND SUPPLY OF INFANT FOODS IN MATERNITY HOSPITALS

Dears Sir/Madam,

Following a recent circular on 10th June 2002 by Mrs Magda Aelvoet, Public Health Minister, on the subject of the contamination of infant foods by *Enterobacter sakazakii*, it appears that maternity wards have a number of questions from which we would like to formulate concrete recommendations.

The recent cases of contamination of newborns (term and premature) by *Enterobacter sakazakii* have led to greater vigilance in the production and preparation of infant foods, not only in Belgium but also in other Western countries. The FDA (Food and Drug Administration) in the USA sent a circular on this matter to medical bodies in early April.

Contamination by *Enterobacter sakazakii*, which led to the death of a term-newborn baby affected by neonatal meningitis in March 2002, and in 1998 to numerous cases of Necrotising Enterocolitis in 12 newborn babies¹ (of which 2 died), is associated with contaminated baby food.

Milk powders for the preparation of bottles for premature infants are not sterile. The production of milk powders does of course include a heat-treatment step, but as opposed to liquid (milk) foods, they are not subjected to treatments of high enough temperature to sterilise the product. The risk of contamination by potentially pathogenic bacteria is therefore not excluded. Infections resulting from the use of preparations contaminated by the *Enterobacter* family, *Klebsiella* and *Citrobacter* have already been highlighted.

Nosocomial infections by germs present in low quantities in milk powders do not seem to be exclusively due to the presence of these germs in the powder, but also to the procedure followed in the preparation, storage and administration of the milk. The effect can be the transformation, at the time of ingestion, of originally non-sterile products with low inoculum levels into highly contaminated foods.

Bottle centres (Note 1) in maternity wards and hospitals, neonatal units and paediatric wards must comply with the legal standards detailed in the Royal Decree of February 7th, 1997, which deals with the general hygiene of foodstuffs. Those in charge of these services, bottle centres and hospital kitchens are supposed to apply principles of systematic verification at critical points in the preparations ("Hazard Analysis Critical Control Points", article 3 of the Royal Decree of February 7th, 1997 regarding the general hygiene of foodstuffs).

A series of recent surveys show that hygiene standards in bottle centres are insufficiently respected.

The following obligations of the Royal Decree of February 7th, 1997 regarding the general hygiene of foodstuffs should be respected:

- The presence and application of a documented HACCP control system;

- Locking bottle centres whose access is limited to competent staff. Locking the bottle centre is the only way of preventing non-authorised entry (parents and visitors);
- Control of the cold chain from the time of preparation to the time of heating before distribution. Refrigerated installations should be sufficiently powerful and reliable to maintain the recommended temperatures. In the control of the cold chain, the following should be considered:
 - the duration of preparation and ambient temperature
 - duration and temperature of refrigeration
 - duration and temperature of distribution
 - control of the installation of refrigerators and thermometers.
 It should be possible to demonstrate these control elements.

Hygiene recommendations, storage and usage instructions mentioned on the packaging of infant formulas should be categorically respected! Infant food manufacturers state on their products that the bottle can only be prepared at the time of consumption. If this is not possible for exceptional reasons, the bottle can be stored a half-day, or a day maximum in the refrigerator (depending on the brand).

Following the recent cases, manufacturers have confirmed that allowing this exception of storing infant foods in the refrigerator for a limited time would no longer be mentioned in measures of hygiene. **As a consequence, all infant foods can only be prepared at the time of their consumption!** If the hospital does not follow the hygiene recommendations of the manufacturers, it will have to be proven that the preparation procedure used offers the same safety guarantee as direct preparation. In the event of an incident with this type of preparation procedure, the hospital's responsibility can be engaged.

The act of giving ready-prepared bottles when newborns leave the hospital goes against the recommendations made by manufacturers and all basic good hygiene practice principles. Such practices must cease immediately. In acting this way, maternity wards and hospitals give out the wrong message.

Furthermore, it is recommended that bottles, teats and preparation utensils be sterilised after use and cleaning.

According to directive no. 178/2002 of the European parliament and Council on 28th January 2002, setting out the general principles of food legislation, establishing the European Authority on food safety and fixing the procedures regarding the safety of food products, we recommend the implementation of a tracking system for infant foods to include the level of newborn babies. The food product type and batch number should be recorded.

In the event of problems with infant foods or intoxication linked to nutrition, those concerned (paediatricians, head-nurses and executives) should first contact the authorities, the Federal Agency for Food Chain Safety, and the General Inspection of Food Products (02/210.48.33). Attempting to "solve" these problems by a common agreement with food companies does not demonstrate a good sense of responsibilities.

With respect to this, we would like to point out once again that European Legislation (directive 91/321/CEE), transposed to Belgian law, prohibits the free supply of infant food samples to parents. Free gifts of infant foods to hospitals for consumption on the premises and free distribution of infant food samples are only allowed if they are destined to infants who can only be artificially fed.

Only a limited number of medical reasons can justify free artificial feeding of some infants. These medical reasons include: Serious illness of the mother (eg. psychosis, pre-eclampsia, shock), when a mother takes medicine which is not compatible with breastfeeding (eg. cytotoxic, radioactive medicines), a congenital metabolic anomaly in the newborn (eg. galactosemia, phenylketonuria), a very low birth weight (<1500 grams), serious dysmaturity of the newborn, etc. A mother's personal choice not to breastfeed is obviously not considered to be a medical reason for "having to feed the infant artificially".

Furthermore, studies have proved that the distribution of milk powders to mothers (during their stay in hospital) has a negative influence on the duration of breastfeeding. Maternity wards that really want to support breastfeeding should examine their habits, mainly with respect to the distribution of "free samples". Moreover, these practices raise questions about the independence of the hospital and can even cause conflicts of interest.

Given that the success of breastfeeding is directly related to start in life, we recommend that maternity wards and hospitals worldwide install the valid criteria set out by the "Baby Friendly Hospital Initiative".

We would be grateful if you could insist that these legal standards be meticulously respected in all services concerned (maternity wards, paediatric units, hospital hygiene).

The inspectors for the safety of the food chain have received instructions to implement a complete monitoring exercise of bottle centres and of the distribution of infant products in maternity wards.

Yours faithfully,

Delegate administrator,

Dr Piet Vanthemsche.

- NOTE 1: These are "les biberonneries", small kitchens where formula feeds are prepared for newborns.
- Note 2: This is not an officially approved translation into English.