Baby Milk Action/IBFAN Briefing on the impact of commercial research on infant feeding Nov 2005

This paper explores Baby Milk Action and IBFAN's concerns about the commercial sponsorship of medical research and the predominance of research to support product development rather than research in the public interest. It also looks at its affect on the development of the market for formulae containing partially hydrolysed proteins and on policies relating to contamination of infant formulae.

Because the potential for bias – present in all research – is reduced if research is commissioned and funded by a disinterested party rather than one active in the market, IBFAN has been advocating that research on infant and young child feeding which forms the basis for public health policies is free from commercial influence. IBFAN has been calling on the European Commission and other funding bodies to provide 100% funding for research which is essential for informing public health policy on infant feeding. IBFAN believes that this is essential to guarantee optimal levels of protection of health as well as public trust. **This <u>would not</u> prohibit manufacturers carrying out research which they consider to be essential for the improvement of their products and for ensuring their safety**.

Foods for infants and young children have greater potential for increasing the risk of disease and malnutrition than other foods because they replace breastfeeding and can undermine appropriate complementary feeding with safe, indigenous foods. The baby food industry assertion that every new developments in infant food products is necessary and will invariably lead to positive improvements in public health does not stand up to scrutiny.

The latest World Health Assembly Resolution on infant feeding (WHA Res 58.32) provides some safeguards in Para 1(5). This calls on Member States:

> (5*) "to ensure that research on infant and young-child feeding, which may forms the basis for public policies, always contains a declaration relating to conflicts of interest and is subject to independent peer review".*

Formulas with Hydrolysed proteins

The marketing of formulas containing hydrolysed proteins highlights need to protect against bias in research in infant feeding. There are very few long-term studies which examine the outcome for babies fed on these formulae, yet numerous trials undertaken to develop new products.

Of particular concern are the formulas containing partially hydrolysed proteins which carry '***Hypoallergenic'*** and '***HA***' claims. The claims are common in Europe but are not permitted in North America following Nestlé/Carnation's launch of *Good Start HA* in the US in 1988. Several allergic babies suffered from anaphylactic shock as a result. Nine US States and the Food and Drug Administration investigated and forced Nestlé Carnation to stop using 'hypoallergenic' claims which they said were*:"Misleading and deceptive...Those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irreponsible conduct.*"

The work of Dr R.K. Chandra, has for decades underpinned Nestlé's use of health claims on infant formulae. In the last few years Canadian medical journals have called for an investigation into the entire body of research of Dr Chandra after allegations that his research on vitamins is fundamentally flawed. The British Medical Journal refused to print Chandra's work saying the

paper had: ***"All the hallmarks of being entirely invented."*** Chandra has failed to provide his raw data on vitamins, has left Canada and has refused to be interviewed.

In 1993 the European Commission's advisory body, the Scientific Committee for Food (SCF), examined the case of partially hydrolysed proteins but failed to look at the problems which had occurred in the US. Prof Jean Rey, a long-time member of the European Committee on Nutrition (ESPGAN) and the European Scientific Committee for Food (SCF) which advises the EU Commission, has taken funding from Nestlé and Milupa for many years. He left the SCF just before we successfully persuaded the EU Commission to declare the interests of its members in March 2000. In 1993, leading Swedish allergy specialist, Prof Bengt Bjorkstien, challenged Prof Rey about his support for hypoallergenic milks saying:

"The conclusions drawn by the Committee [ESPGAN]...differ substantially from what most American and European researchers suggest, and they are almost identical to those suggested by the company marketing the partially hydrolysed product direct to the public... Why did the Committee not properly address this important controversy but merely uncritically quote a review published in a company sponsored book by an employee of the company?"

www.cbc.ca/stories/2004/06/10/sci-tech/chandra040610
www.biomedcentral.com/news/20040511/02
http://bmj.bmjjournals.com/c
Bjorkstien B. *Comment on Comment on Antigen-reduced infant formula*, Acta Paediatrica, 82:660-2, 1993

Commercially-supported research on thermo-tolerance of *Enterobacter sakazakii.* Is it in the best interest of consumer health and safety?

Research on the thermo-resistance or thermo-tolerance of *Enterobacter sakazakii (Ent. sakazakii)* illustrates the importance for public health and consumer safety of independent scientific research, free from commercial influence.

1997: Independent Research

- A study of the thermo-tolerance or heat–resistance of the pathogen *Ent. sakazakii* in reconstituted dried-infant formula was conducted in Canada by M. Nazarowec-White and J. Farber [1]. The results were published in 1997 in Letters in Applied Microbiology. The authors concluded that: ***"From the data presented here, it appears that Ent. sakazakii is more thermo-tolerant than many other Enterobacteriaceae in dairy products. Ent. sakazakii appeared to be one of the most thermo-tolerant organisms".***

2003: Research conducted by or supported by Nestec

- The Nestlé Research Center, or Nestec Ltd., supported research by P. Breeuwer et al. [2] with the aim to demonstrate that:

  "Ent. sakazakii is not particularly thermo-tolerant but can adapt to osmotic and dry stress".

  Predictably, the outcome of the research study was that: ***"Ent. sakazakii is not particularly thermo-resistant… It is well adapted to survive in dry environments".***

[1] Nazarowec-White M, Farber JM. Thermal resistance of Enterobacter sakazakii in reconstituted dried-infant formula. Letters in Applied Microbiology 1997, **24**, 9-13
[2] Breeuwer P, Lardeau A, Peterz M, Joosten HM. Dessication and heat tolerance of Enterobacter sakazakii. Journal of Applied Microbiology 2003, **95**, 967-973

- Nestec also supported the research for a PhD thesis conducted by Chantal Kandhai[3] . The study was published in the Lancet in January 2004, and examines the process of pasteurization of milk in the factory before spray-drying to produce powdered infant formula. At the outset, the study asserts that: "***Ent. sakazakii does not survive such heat treatment***"..

2004: How Nestlé uses its own research

- The two Nestec studies quoted above allow Nestlé to claim on the company's website[4] that:

  "***Since Ent. sakazakii is heat sensitive and does not survive the heat treatments usually applied in the manufacture of infant formula, its presence in powdered infant formulae is due to post-process contamination from the environment...*** " (emphasis added)
- In this way industry-sponsored research allows manufacturers to create the belief that the contamination of powdered infant formula by pathogens such as *Ent. sakazakii* at factory level is simply not their responsibility.
  - **Is *Ent. sakazakii* "*heat-sensitive*", according to Nestlé?**
    Or is it *heat-resistant*, classified to belong to "*the most thermo-tolerant organisms*", according to the original independent Canadian study?

European Commission and infant feeding research

IBFAN has been calling on the European Commission's Research Directorate General to provide 100% funding for research which is essential for informing public health policy on infant feeding. Below are some comments made to the European Commission concerning the part Commission/part Danone Institute-funded Chopin Project which aims to develop a formula with a new lipid profile.

1. **A clear distinction should be made between research on adults and research on infants.** Special ethical reviews are needed because infants are a vulnerable group that need special protection and do not consent on their own behalf. The research should in any case only be carried out if it cannot be done on an adult population. Have all the necessary animal studies been done in this case?
2. **There should be no coercion to participate in the trial.** The potential for aggressive recruitment is increased when there is a pressure to boost the numbers of artificially fed infants to achieve a statistically significant study. If studies have a commercial component the risk of coercion is increased. It is important that such risks are spelled out clearly in the research protocol and safeguards built in.
3. The request for participation should ideally be done by an independent person.
4. **The provision of free products through any trial should be considered an inducement for parents** to enrol their infants, especially parents living on a low income. In the past free formula has been promised for six months for participation in feeding trials for hydrolyzed formula. Researchers have justified such research on the basis that it is not carried out for the purpose of creating a market for a product.

[3] Kandhai Chantal M, Reij MW, Gorris LGM, Guillaume-Gentil O, van Schothorst M. Occurrence of Enterobacter sakazakii in food production environments and households. The Lancet 2004, **363**, 39-40.
[4] www.nestlé.com "Nestlé position on E. sakazakii"

5. **Steps should be taken to ensure that the European Union logo** on research papers or products is not used in a way that promotes a company or brand and/or confers an image of safety to many mothers.

6. **Who is on the ethics review committee?** Often the people on these committees do not have full information on the implications of the research and often the research proposal is passed by only a few members of the ethics committee, not the full committee.

7. A control must use the best standard of practice.

8. **If a randomized control method is used, then this must be justified** and parents must fully understand the methodology of the research.

9. **For informed consent there must be the fullest possible information given to parents**. This information must include the short and long-term risks of the new formula.

Research should also meet the criteria set out in the *Guidelines on the nutritional assessment of infant formulas*, the report of the Committee on Medical Aspects of Food Policy (COMA) Working Group on the Nutritional Assessment of Infant Formulas. (Report on Health and Social Subjects [47]. 1996. London, The Stationery Office.)

For more information contact: Patti Rundall, Baby Milk Action, 34 Trumpington St, Cambridge, CB2 1QY
www.babymilkaction.org 01223 464420 mob: 07786 523493