Baby Milk Action Comments

Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae

SCF/CS/NUT/IF/65 Final 18 May 2003

Summary Table Comparing Recommendations on the Composition of Infant Formulae from the Scientific Committee on Food Report of 4 April 2003 with Existing Requirements in Commission Directive 91/321/EEC

September 2003

The SCF report can found on the following website:
http://europa.eu.int/comm/food/fs/sc/scf/index_en.html
Outcome of discussions:
http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

Baby Milk Action Comments on the Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (SCF/CS/NUT/IF/65 Final 18 May 2003)

Summary

Baby Milk Action welcomes the majority of the recommendations made in the report, but is wary that some leave the door open to exploitation by the baby food and related industries. Since the Report could have important implications if followed through to existing EU Directives, we would welcome our comments being given serious consideration:

We are pleased that the report:

- recommends a review of existing claims and suggests that many should not be permitted;
- recognises that breastfeeding is the ideal way to feed infants and endorses the 2001 WHA Resolution recommending 6 months exclusive breastfeeding.
- recommends that breastfeeding should be promoted and supported.
- recommends that follow on milks on sale in the EU should packaged very differently to infant formulae (this provision applies only to exports at present)
- acknowledges that existing formulae are not optimum
- recognises the gender perspective,
- concludes that claims for minor transient health complaints (anti-reflux etc) cannot usually be supported

However we regret that the report:

- fails to specifically mention the need for the '*protection*' of breastfeeding and the removal of obstacles such as commercial promotion (apart from the welcome endorsement of WHA Resolution 54.2).
- is weak in relation to follow-on milks in that it fails to acknowledge that follow-on milks are not necessary at all.
- allows *probiotics* to be added to follow-on milks despite the fact that no conclusion is drawn regarding their safety;

- fails to identify the risks of claims in general and leaves the door open with the recommendation that claims about hydrolysates may still be made and that *'mechanisms and criteria should be developed for the communication not only of relevant compositional properties, but possibly also of other effects of infant formulae…"*

- fails to flag up the potential risks of Soya sufficiently and to refer to the conclusions of the British Advisory Committee on Nutrition (SACN) which was that there is no unique or substantive clinical need for Soya infant formulae.

- fails to address the issue of contamination, for example, *Enterobacter Sakazakii*, and proposals for making the product safe or adding informative warnings for parents.

- fails to mention the need for EU controls on the marketing and quality of bottles and teats.

- fails to provide sufficient information regarding the financial interests of members of the Committee to address concerns about undue commercial influence.

The role of Scientific Committee on Food and its 'independence'

One aspect of the report that may be overlooked is the role of the Scientific Committee for Food itself. Although not a risk management body, the SCF has nevertheless had an important impact on the development of European legislation on infant foods and this in turn has had a big impact on infant feeding globally. We believe that several of the weaknesses in EU legislation occurred because the SCF failed to flag up important risks to health, and that this failure occurred because of the influence of the baby feeding industry on SCF members.

In previous years we have met with the Commission to discuss our concerns, prompted questions from the European Parliament and generally brought public attention to the need for greater transparency and independence.

Since the adoption of the new European Commission in September 1999, frequent references are made by the Commission about transparency and the importance of independent scientific advice from an independent scientific body. We are pleased to see that the new European Food Standards Agency now requires its members to make

Annual Declarations of Interest which are available on the Internet. This was not the case with the old SCF. The Commission did send Baby Milk Action copies of the declarations of the members in post in 1998/9, but only after one key member with close links to the baby food industry had left the Committee.

Since 1997 when the 8 scientific committees were moved from DG3 (Industry) to DG24 (Consumer and Development) SCF decisions and minutes have been published speedily on the Internet. However the thorny problem of conflicts of interest was still fudged and delayed and the information available to the public limited. The minutes of the SCF meetings include references to special interests that may be are considered prejudicial to their independence in relation to the items on the agenda but the process still leaves a lot to be desired.

For example, in the minutes of the 137th SCF meeting on 2/3/4 April 2003 three members declare interest in items on the agenda. The specifics of the links are not revealed but all three members were allowed to remain and attend the discussion. One of the members with a declared interest (possibly in the past) is Rapporteur of the report in question another has an interest in Probiotics – one of the controversial items on the agenda. The CVs which are available give no details of the funding referred to, so the public is left to wonder why the conflicts were not considered important. This is a shame.

The report in question contains many important observations and addresses several of the weaknesses in the existing Directives. However, when the conclusions are weak, the reader is inevitably left wondering to what extent they have been influenced by industry. This comment is in no way intended to undermine the excellent work of specific individuals, but to point out an important principle. The problems of such conflicts are outlined well in the report *A Social Science perspective on Gifts from industry to Physicians* (Dana et al, July 9th 2003 Vol 290 No 2, Jama.)

"Social science research…shows that even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias. When individuals have a stake in reaching a particular conclusion, they weigh arguments in a biased fashion that favours a specific conclusion." The Jama report also shows that the disclosure is not necessarily an antidote to bias, *concluding that "Because bias induced by monetary interests is unconscious and unintentional, there is little hope of controlling it when monetary interests exist. The rules governing the British scientific advisory bodies do require members to make public declarations regarding conflicts of interest."*

This has difficult implications for the SCF, since we are aware that many scientists are in receipt of industry funding and are being encouraged, if not forced to forge even closer links with industry. We believe that this problem will only be solved if bodies such as the European Commission rethink their research funding policies, positively encouraging 100% public funding of important research that is in the public interest.

CHAPTER 1: INTRODUCTION

1. 2 The report recognises the benefits of breastfeeding and recommends that efforts continue to *'promote and support breastfeeding in the European Union"* The report fails to mention the need for the 'protection' of breastfeeding - a critically important part of the *International Code of Marketing of Breast-milk Substitutes*. The EC Directive passed in 1991, although making references to the International Code in its opening paragraphs, fails to fully protect breastfeeding because all the protective parts of the International Code and the subsequent World Health Assembly Resolutions are not transposed. There is a paramount need to review the 1991 Directive to better protect infant health from the commercial influences of the breastmilk substitutes and baby feeding bottle industry

1.4.3 We are pleased to see the reference to the 54th WHA Resolution (2001) and the benefits of exclusive breastfeeding for 6 months.

1.6 It is not really true to say that the *"feeding of infant formula and follow on formulae has a history of apparently safe use."* However, we welcome the acknowledgement that the outcomes of artificially fed and breastfed infants are not equal and that existing formulae have not been not optimum. However, this conclusion itself carries risks and should not be used by manufacturers to promote new formulas, giving the impression that all the problems with artificial feeding are resolved with compositional changes. It is also possible that in the next review new problems are registered which need new changes.

A systematic review of studies into the reconstitution of formula feeds in the UK, published this month, concludes that even with the best formula available, babies often do not receive the correct feed. (Renfrew MJ, Ansell P, Macleod KL (2003). Formula feed preparation: helping reduce the risks; a systematic review. *Arch Dis Child* 88:855-8)

Manufacturers have a responsibility to ensure that the products placed on the market meet the highest possible standards at all times, that the labels, warnings and instructions for use are as clear as possible. The public has a right to assume that the composition of

formulas is constantly under review. We would welcome more future studies but would stress that they should be made within an ethical framework with full consent of parents.

1.7 We welcome the observation that only components that serve a nutritional purpose should be used.

1.8 We welcome the observation that the quality of water is important. However, once again this should not be used by companies to promote bottled water, which is expensive and environmentally wasteful.

1.10 We welcome the call for a review of permitted claims. (See comments on Chapter IX below)

CHAPTER 4. Protein

4.2.3.1 Soy-based formulae and follow-on formulae. (Page 42)

In relation to soy-based formula, the report does not refer to the conclusions of the COT and SACN that there is no unique or substantive clinical need for soy formulas. There is no reference to the two reports in the references. The SCF conclusion that soy should be reserved for specific situations only and that cows' milk-based formula should be the standard choice is much weaker. We are surprised by this and consider it to be a very important omission.

Chapter 1X Probiotics

As mentioned in the beginning, it is alarming that one of the members of the Committee declared an interest in Probiotics. The section appears stringent on first reading, but in fact leaves the issue of inclusion of Probiotics wide open, allegedly because the Committee did not have time to form a view. Despite this, the report gives the green light to Probiotics in follow on milks (see comments below) stating:

> "*Follow-on formulae with added bacteria regarded as probiotics have been… for since about three years. The Committee has no reason to object to the addition of bacteria regarded as Probiotics to follow-on formulae, provided the requirements described below are fulfilled"*

"The Committee notes that the available information is still limited, and many studies in young infants have been done in non-European countries and in selected subpopulations of infants that are at increased risk of infectious or atopic diseases."

No mention is made of the Indian Government's decision not to allow imports of formulas and baby cereals containing Probiotics, despite the increased risk of infectious disease in that country.

If the SCF had considered the general issue of claims in more depth, it could have offset some of the potential problems, which will undoubtedly come with Probiotics. These ingredients are already aggressively marketed in Asia, and starting to be promoted in the UK.

Once again, as main safeguard, the Report refers back to scientific evidence from a body such as itself.

> *"The term "Probiotics(s)" should only appear on formula labels if beneficial health effects in recipient infants have been established by adequate clinical trials and the results have been evaluated by an independent scientific body. The Committee considers claims on effects of Probiotics bacteria on modification of the risk for specific health disorders as inappropriate unless such effects have been demonstrated by adequate scientific evidence following the guidance outlined in chapter XI of this report."*

Chapter X Presentation of Infant formulae and Follow-on Formulae

10. 2 Follow-on Milks:

We welcome the report's call for *"the labeling and presentation of infant formulae and follow-on formulae to clearly identify their respective roles as a breast milk substitute and as the liquid part of a diversified diet and should not in any way discourage breast-feeding."*

We warmly welcome the call for the products to be labeled in such a way as to avoid any confusion between infant formula, follow-on formula and foods for special medical purposes. At present this requirement applies only to exports.

It is a shame, given the nature of the report that no reference is made to the lack of

evidence of the clinical need for follow-on milks and the fact that infants can be fed breastmilk or infant formula throughout the first year of life. The report could usefully refer to the World Health Assembly Resolution of 1986 which stated that follow on milk are *'not necessary'*.

The report makes no comment on the fact that the compositional requirements for follow-on milks are much less stringent than they are for infant formula. Indeed the report itself exacerbates this by suggesting the inclusion of Probiotics in follow-on milks. (See comments on Chapter IX)

10. 3 – 10.12 Claims

On first reading these paragraphs seem to propose a welcome radical revision of the EU Directive, eliminating the need for the majority of existing permitted claims. If this recommendation was followed through many of the constraints on EU support for the Codex proposed text (banning health and nutrition claims on all foods for infants and young children) would be eliminated.

However, on the critically important questions regarding claims on Probiotics, long chain fats, hydrolysates, and other ingredients, claims which are infinitely more important in commercial terms, the report is inconclusive and weak.

Since health and nutrition claims seem to be one of the main drivers of the breastmilk substitutes market, it is regrettable that the Report fails to look into these questions more deeply and reach a conclusion about their appropriateness in any context on breastmilk substitutes. The report make no attempt to explore the purpose of nutritional claims or examine how they help consumers make an informed decisions regarding supplemented or unsupplemented products. Nor does it explore whether claims about any specific ingredients would inevitably idealise the products over and above breastfeeding and so have an overall harmful impact on public health.

No reference is made to the advantages of clear QUID labelling and instead the report fudges the issue by stating that: *"Mechanisms and criteria should be developed for the communication not only of relevant compositional qualities, but possibly also of selected other effects of infant formulae and follow-on formulae if they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific review body reviewing such data"*

The procedure regarding who will decide what is scientifically proven is not elaborated. This is urgently needed give the fact that many of the claims currently

on sale in Europe carry claims which have never been seriously checked or backed by adequate research.

10.10 Hypoallergenic claims

We welcome the report's warning against the unwarranted use of the term "*partial hydrolysate"* However we regret the failure of the report to warn of the risks of **any disease risk reduction claims** – supported or unsupported (see comments above) We have written many times about the dangers of hypoallergenic claims and are disturbed that the Committee did not recommend that the claims be stopped completely. Once again we see no reason why the labels of these products should not simply list the ingredients clearly.

10.13 Medical foods

We welcome very much this paragraph, which states:

"The Committee notes that some dietetic products intended for infants with minor and mostly transient health complaints, such as repeated possetting or intestinal discomfort, are currently marketed as Dietary Foods for Special Medical Purposes. Neither the nature of the complaints concerned nor the recently adopted definition of Dietary Foods for Special Medical Purposes (Directive 1999/21/EC) justifies such presentation for the vast majority of these products. The Committee also notes that such presentation has implications for the labelling and marketing practices of these products. The Committee recommends that the scientific basis for the use, potential benefits and compositional aspects of such products should be reviewed.

Further questions: contaminants

It is worrying that the report fails to address the question of contamination from *Enterobacter Sakazakii* This problem occurred within the European Union and is being addressed by Codex and other bodies. It would have been useful to see recommendations from the SCF for example, for labeling warning parents that dried formulae are not sterile.

See IBFAN briefing on health claims.

PR Sept 2003