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Thursday, June 17, 2004

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Dear Robert Madelin

Baby Milk Action Newsletter: Update 34 and the Scientific Committee for Food

Many thanks for your letter of the 29.04.04 and for your nice email message. I am sorry to have taken so long to answer, but your criticism of our article in *Update 34* raises issues which are fundamental to our work and touch on so many different aspects of it that I wanted to make sure I could explain our position fully and coherently.

For over two decades Baby Milk Action and our partners in the International Baby Food Action Network have been highlighting our concerns about the independence of scientific bodies and the influence of such bodies on public health policy setting. The piece in *Update 34* is similar to many other articles and letters we and others have written over the years.¹ It simply highlighted an important difference between the rules of the Scientific Committee for Food (SCF) and the rules of new European Food Safety Authority (EFSA) – a difference which might otherwise have been overlooked. The article promoted EFSA's rules and I can find nothing in it that is incorrect or misleading.

Baby Milk Action is an organisation that cares about the image that is portrayed of the European Community, and we want very much to arrive at a position where the public can have confidence in its procedures. We are sure that the EU has enormous potential for improving infant and young child health and that it can also do much to ensure corporate accountability globally.

In writing the article we had no intention of being unappreciative of the important work that is done by scientific committees such as the SCF. Indeed it is precisely because we are so aware of the importance of medical opinion that we have followed the activities of scientific bodies for so long and have consistently called for the annual declarations of the SCF to be made public, for the EU to give 100% funding for research in the public interest and for public health policies to be based on independently-funded research.

¹ Correspondence with: Commissioner Emma Bonino, 16.4.97; 18.3.99; Horst Reichenbach, DGXXIV, 10.6.97; 3.7.97 Peter Wagstaffe 7.2.97; Bernard Carsin, Commissioner Martin Bangemann 18.3.99; Commissioner David Byrne 27.10.99; Commissioner Erik Liikanen, 20.1.00; Parliamentary Q &A Glenys Kinnock, David Byrne Oct, Dec 99; European Voice: Clamour for action to bolster Union scientists' credibility, 19.1.00, Scientists bow to call for more transparency, 22.3.00, EU Advisors to declare their interests, BMJ 25.3.00.

At the same time we have advocated that our governments and the Commission (which plays such an important role in setting EU legislation) live up to their commitments to protect child rights by ensuring that the EU Directives ² are brought into line with the recommendations of the World Health Assembly, as the European Parliament has requested since 1981.

In response to our queries, we have been assured many times by the Commission that the highest standards are maintained, that the Commission itself holds annual declarations of all Committee members and is aware of potential conflicts of interest. We have been asked to have confidence and trust in the procedures and in the reputation of the scientists. I hope I can explain in this letter why, because of our experience, we have to remain vigilant and questioning.

I regret that because of the limited space available in a four-page publication we could include only a weblink and short summary of our commentary on the *SCF Report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae*.³ This contained a qualifying sentence which might have helped. It said:

"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."

Subject to our already severe space limitations, I would be more than happy to summarise your letter (and/or put a link to it on our website) or to add something along the lines of this last sentence if you thought this was helpful. But first, I hope you will bear with me while I retrace some of the history of the Directives and show how the SCF has been used to weaken them. At the end of the letter I will also add a summary of our discussions with the Commission about Declarations of Interest. I hope this will explain why transparency is so important to our work and how, even now, with the new rules, we fear that best interests of the European public are not being served.

The development of EU legislation on baby foods.

In our discussions with the European Commission during the long campaign to have the EU Directives adopted, the pressure to protect the European baby food market was evident. The European Parliament's demand that the EU should implement the *International Code* was clearly a difficult challenge, and before the Directives were finally adopted in 1991 and 1992, Parliament repeatedly rejected Commission proposals as inadequate. Since the early 80s, the views of the SCF have been used to justify industry positions. For example, in 1985 the Consumer Committee of the EU Parliament questioned the scientific basis for including compositional requirements for follow-on milks ⁴ in the proposed Directives: "*The need of*

⁴ Follow-on milks were invented by companies following the adoption of the *International Code* in a cynical strategy to get round the Code's restrictions. The aggressive promotion of these milks has caused

² COMMISSION DIRECTIVE of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC), COUNCIL DIRECTIVE 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries

³ 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) submitted to the Food Standards Agency. September 2003.

follow-up milks is extremely dubious (page 14) and there is no need whatsoever for a new specially manufactured product."

The European baby food industry (IDACE) responded: "No scientific references are given to support these statements. In the opinion of the paediatric experts of the SCF a standard is necessary. There are many papers which support this scientific opinion.... it should also be noted that FAO/WHO is also developing a Codex standard for follow-up foods."

Thousands of NGOs, parliamentarians and health workers became involved in the campaign and the Directives were significantly strengthened as a result. But many loopholes remained.⁵

One rationale used by the Commission in 1991 for not implementing the WHO requirements in full was that this would pose constitutional problems for several countries. Mr Mathioudakis gave a paper on this at the *Eurodiet* Conference in May 2000. ⁶ We now realise that this argument was not accurate and that advertising restrictions would have been admissible provided they were based on considerations of public welfare and provided the restrictions were in line with the basic principle of proportion.⁷ At the time we took the Commission's word and thought that the amendments we achieved were a breakthrough. At least they allowed Member States, on an individual basis, to ban advertising and to fulfil their obligations under the Code if they wished - something we insisted the EU had no right to prevent. We see now that there was no reason why a complete ban of promotion of all breastmilk substitutes throughout the EU could not have been implemented, and we can only guess at the ill health that could have been prevented.

In subsequent years, although some improvements were made regarding levels of pesticides, many of the gains in relation to marketing were gradually eroded.

In 1995 the Commission issued a discussion paper for Member States about whether new claims should be permitted. The paper clearly showed that health claims have far more to do with

much confusion. Health professionals have warned of the risks to health when these milks are used as breastmilk substitutes and fed to very young babies. The World Health Assembly Resolution (WHA Res 39.28) of 1986 described them as '*not necessary*'. The EU Directives allow unrestricted promotion of follow-on milks.

⁵ Paper analysing the strengths and weaknesses of EU Directives, including a chart showing the legislation adopted in EU Member States. http://www.babymilkaction.org/policy/policy/ndex.html

In his submission to the *Eurodiet* Conference in May 2000, Mr Mathioudakis, speaking for the Commission, argued that the Directives, as adopted in 1991 and 92, represented "the maximum of the WHO Code requirements that could be transposed in Community legislation in line with the statement made during the adoption of the Code. It should be noted that the Community is considered to be very advanced in the implementation of the Code given that there is relative legislation. Other countries have not gone that far. Not all the articles of the Code are fully implemented but this was a conscious choice after lengthy debate with Member States and the European Parliament. For example, one of the provisions of the WHO Code that has not found its way to EU legislation is a total ban on advertising of breastmilk substitutes. Instead advertising is restricted, the reason being that the German Constitution would not allow such a total ban for reasons related to protection of freedom of expression. Is the WG then recommending a revision of the German Constitution ?"

The constitutional relevance of advertising restrictions for Breastmilk Substitutes in Germany, presented to Eurodiet by Andreas Adelberger, AGB, May 2000 Implementation of the International Code of Marketing of Breastmilk Substitutes in CEE countries: Can the countries of Central and Eastern Europe (CEE) adopt the International Code of Marketing of Breastmilk Substitutes and Subsequent Relevant World Health Assembly Resolutions (the Code) as a minimum requirement, without affecting any existing legal commitments or prejudicing eligibility to join the European Union(EU)? Paper commissioned by UNICEF.

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providing benefits for the producer than informing the consumer.⁸ It stated: "Some companies feel that the claim in some cases becomes primarily a tool of information....This [claim] would allow the company to gain a competitive advantage and allow it to recover its investment in research. Companies say that if this was not possible it would inevitably lead to a drying up of research, and loss of benefit for the consumer, lack of motivation, and loss of competitiveness against non-Community companies both with the EU market and the international market. They therefore call into question the existing restrictive legislation in the matter."

Member States decided not to allow the new claims, although somehow, one really bad claim relating to allergies managed to slip through. In 1999 the situation worsened when the *Commission Directive 1999/21/EC on dietary foods for special medical purposes* was adopted, again leaving the door wide open for all manner of claims for an undefined group of specialised foods for infants.⁹ This Directive was severely criticised at the time and its adoption has created problems for Codex, holding back progress on the infant formula standards for several years.

The way forward

The crucial question now is whether improvements in infant and young child health are best made through greater protection and support for breastfeeding or through 'new and improved' breastmilk substitutes. Clearly both these objectives are important. Companies do have a clear responsibility to ensure their products are as safe as possible and scientific committees must keep a close watch on their composition. But how changes are made, what evidence is used to assure safety and how information is communicated are questions that lie at the heart of our concern about bodies such as the SCF and the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN).

In our article we mention Prof Koletzko, the rapporteur of the SCF report, and Chair of ESPGHAN. Prof Koletzko has published a great deal of valuable research on infant feeding over many years. However he has also worked closely with the baby food industry and is currently listed as the contact for Germany on the Chopin Childhood Obesity Programme is important.¹⁰ The Chopin project, part-funded by the Danone Institute and the European Commission's 5th Framework, aims to develop an infant formula with a new lipid profile.^{11 12}

⁸ Claims for infant formulae European Commission DG III paper, 27 March 1995. III/5185/95-EN iii.E.1-BM/cvi

⁹ SMA High Energy is a food for special medical purposes. A promotion for this infant formula to health visitors in Wales, contained 20 health claims, no breastfeeding is best notice and an offer of winning £39 worth of play equipment. April 2004.

¹⁰ If one wants to find out about the interests of SCF members one still has to look in past minutes. There one will see that at the 137th SCF meeting which approved the report (2/3/4 April 2003) three members declare interests in items on the agenda. The specifics of the links are not revealed and the minutes say that Prof Koletzko, "*had been a consultant for a producer infant formula company*," leaving it unclear whether his interests are current or in the past. Another SCF member declared an interest in Probiotics, another controversial item. All three members were allowed to remain and attend the discussion.

¹¹ www.childhood-obesity.org/partners/germany.php, The site states: EU Childhood Obesity web pages are hosted by the international web site of Danone Institutes in order to reduce costs for the development of a new website and thus to use a larger amount of the budget for the creation and dissemination of brochures about this project.

¹² Danone manufactures baby milks and foods and has been found to violate the *International Code*. Monitoring compliance with the International Code of Marketing of Breastmilk Substitutes in west Africa: multisite cross sectional survey in Togo and Burkina Faso, Aguayo, et al.BMJ 2003;326:127 (18 Jan 03)

The first draft of the Commission's proposals for a revision of the EU Directive on infant formula propose that infant formulae may be allowed to carry 5 (possibly more) claims about lipids and other optional ingredients and in its covering note the Commission has used the SCF report to support this.^{13 14}

So while we acknowledge the good work that Prof Kolezko has done in the interests of public health and the important contribution he may have made to many parts of the report, it is hard for us to accept that his independence was not compromised in any way on this particular point.

It is worth noting that baby food market is already said to be expanding by an estimated 12% each year ¹⁵ and despite this, the European Baby food industry, in its comments on the new proposals, have called for permission to make an unlimited number of claims. ¹⁶

As governments within the EU try to cope with the burden of treating non-communicable diseases (diabetes, heart disease, obesity) and look for strategies to prevent such ill health, it is difficult to understand why the Commission should be proposing to include yet more health claims at this time. The Commission has clearly indicated its concern about misleading claims and is well aware that consumers are demanding full and frank information about food. BEUC and the European Public Health Alliance (EPHA) and many other NGOs are calling for a ban on nutrition and health claims on products directed at children.¹⁷ Surely it would make more sense to ensure that the risks of artificial feeding and the benefits of breastfeeding ¹⁸ are fully understood and communicated through clear labelling and adequate warnings, than to focus on

2) Claims related to health effects.

¹⁷ Responses from the European Public Health Alliance, the European Consumers' Organisation (BEUC) and the Baby Milk Action/International Baby Food Action Network, to the EU proposal for a Regulation of the Parliament and the Council on nutrition and health claims – COM (2003) 424 (01)

¹³ Working Document for a proposal for a recast Commission Directive on infant formulae and follow-on formulae. 6 April 2004 SANCO D4/HL/mm/D440180 food law and biotechnology unit (d.4) Health and Consumer Protection Directorate General.

¹⁴ Breaking the Rules stretching the Rules, 2004, Evidence of violations of the International Code of Marketing of breastmilk Substitutes and subsequent Resolutions. International Baby Food Action Network. The report analysed 3000 complaints of industry promotion over the past 2 years, and noted a huge upsurge in health and nutrition claims. 11 out of 16 companies analysed are now using claims. Health claims on any breastmilk substitute idealize the product and are therefore in contravention of Article 9 of the International Code of Marketing of Breastmilk Substitute. They inevitably undermine exclusive and sustained breastfeeding. Claims for processed baby foods for children under 3 years idealise the products and also undermine exclusive breastfeeding and the consumption of healthy indigenous family foods.

IBFAN comments on health claims, http://www.babymilkaction.org/policy/policyindex.html

¹⁵ *Euromonitor*, 2001

IDACE COMMENTS ON EC Working document: Preliminary Draft of a Commission Directive on infant formulae and follow-on formulae(Recast version), dated 5 April 2004. IDACE is concerned about the fact that no procedure has been put in place in order to allow specific nutrition and health claims other than the ones listed in Annex IV. Nutrition and health claims, being true statements/information regarding the compositional and dietary properties of the foods, provide important information to parents. A closed list of nutritional and health claims would impede innovation and progress in infant nutrition. IDACE wishes that a procedure be developed for nutritional and health claims based on the recommendations of the SCE^[6]. As a result IDACE believes that the following 2

claims based on the recommendations of the SCF¹⁶. As a result, IDACE believes that the following 2 types of claims should be allowed¹⁶: 1) Nutrition claims and other statements that provide for simple descriptions related to the

¹⁾ Nutrition claims and other statements that provide for simple descriptions related to the composition of infant formulae,

¹⁸ Risks of formula feeding A brief annotated bibliography INFACT Canada, updated May 2004 <u>http://www.who.int/child-adolescent-health/NUTRITION/infant_exclusive.htm</u> <u>http://www.babyfriendly.org.uk/home.asp</u>,

promotional health and nutrition claims – especially claims which are more often than not supported solely by industry-funded research.

If you accept this analysis, it must follow that the Commission should try to ensure that the EU directives on baby foods are brought into line with WHA recommendations. Already the EU – perhaps helped by your actions while in DG Trade - has expressed its support for the 2001 WHA Resolution 54.2. This has made a big difference at Codex and it is important that this position is maintained and developed since it is still not fully accepted by industry. But there are many other important issues relating to marketing that must be addressed, apart from the optimum length of exclusive breastfeeding.

If the EU were to take such steps now not only would the health gains be substantial, but an important signal would be conveyed about the status of bodies such as the World Health Assembly. This is badly needed.¹⁹ Since the formation of WTO and the increasing pressure to harmonise trade rules, Codex (which unlike the WHA, has a dual objective of consumer protection and ensuring fair trade practices) has assumed much greater importance. Because the EU Directives conflict with WHA recommendations (and if the proposed amendments are adopted will conflict even more) the setting of Codex standards and national laws which protect health is effectively blocked.²⁰

This is relevant to a response you gave to an EPHA question about whether trade agreements should uphold rules such as the *International Code*. In your reply you said:

"Some aspects of this debate relate to corporate responsibility, and trade policy is an important part of the current EU debate on CSR (Corporate Social Responsibility). In addition, it should be a minimum requirement that WTO does not prevent WHO from enforcing its rules and codes. In Europe, we can then control our European companies, but we can't do more than that.²¹

The implementation and enforcement of the *International Code* and WHA Resolutions rests with Member States, and in the case of infant feeding, they are intended as '*minimum requirements*' to be adopted '*in their entirety*' by all countries. The EU is not an exception, and the Commission has an important role to play in ensuring that more is done.

Since 1991 many countries outside the EU have moved ahead to adopt strong legislation which incorporates the *International Code* and subsequent WHA Resolutions. While those within the EU have been held back.²² Through our network we are also aware of several countries wishing to join the EU, whose governments have been led to believe they should

¹⁹ Baby Milk Action submission to the FAO/WHO Electronic Forum on the provision of scientific advice to Codex Alimentarius and member countries. www.fao.org/es/esn/proscad/archive/281103 47.htm

²⁰ Largely because of the compromised position taken by the EU the Codex labelling Committee was not able to proceed with an outright ban on foods for infants and young children in the *Draft Guidelines for the use of Nutrition and health claims*, which the majority of countries clearly wanted. The wording of paragraph 1.4 that will be sent to the CAC at the end of the month is as follows: "*Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.*"

²¹ EPHA website September 2003 <u>http://www.epha.org/a/340?var_recherche=Search+robert+madelin</u> EPHA question to Robert Madelin: *In some cases, codes and rules exist to protect health but they are ignored by the companies that are supposed to abide by them. For example, a WHO code agreed some years ago aims to limit the marketing of powdered baby milk in countries where clean water and sterilisation facilities are lacking. But the corporations producing infant formula have consistently sidestepped this code. Shouldn't trade arrangements uphold these rules?*

²² State of the Code by Country, State of the Code by Company ICDC/IBFAN 2004

not go above EU standards. Companies exploit this misconception and promote their products as if the Directive simply replaces the Code and Resolutions. Sadly the EU Directives are seen as far from 'advanced' and are now more a matter of shame rather than pride.

To sum up. The SCF report - formed under the old rules - is now playing a critically important role in the revision of the EU Directives. The report itself contains many important consumer protection recommendations for improving the EU Directive on infant formula, which we warmly welcome. However, when sections of the report are weak, or where there are omissions and unexplained conclusions, we are left wondering about the extent to which they have been influenced by industry. This is what we tried to express in *Update 34*.

In considering a way forward, I wondered if it would be helpful to open up this discussion for a wider consultation of public interest groups, and to ask EFSA if it could relook at the report in the light of new developments (for example, in relation to contaminants) If you disagree with this analysis, perhaps you would let me know and we will take steps to bring your letter to the attention of our readers.

In the meantime, thank you very much for your patience in reading this long letter. I look forward to your response with interest.

With best wishes Yours sincerely

Patti Rundall, OBE Policy Director

On the following two pages I have included a summary of concerns about the SCF before the establishment of EFSA.

The SCF and EU Directives - before 1997

One of the most influential SCF members in the field of paediatrics prior to the adoption of new rules in 1997, was Prof Jean Rey. On many occasions Prof Rey put forward arguments favourable to industry and some of the weaknesses in the Directive (and Codex standards) can be traced to his advice.

On several occasions I asked Mr Basil Mathioudakis for the Annual Declarations of Prof Rey. Mr Mathioudakis referred me to past minutes and to Prof Rey himself. I telephoned Prof Rey who denied receiving baby food industry money in a personal capacity, but admitted involvement in numerous baby food industry projects in his professional capacity as a Professor of Child Health. He would not say whether this was current. He said that it was sufficient to inform the European Commission.

The SCF minutes were even less helpful. The December 1996 meeting, for example, had a number of items relating to baby foods on agenda, yet under Section 3, Prof Rey declared only an interest in mineral water. He made no mention of his many links to the baby food industry.²³

Prof Rey resigned from the SCF in July 1997, but only after a new amendment to the Infant Formula Directive was adopted. This allowed a controversial disease risk reduction claim relating to partially hydrolysed proteins. An article from leading Swedish allergy specialist, Prof Bengt Bjorksten, in *Acta Paediatica* in 1993 called into question Prof Rey's work on ESPGHAN suggesting an inappropriate commercial influence: "*The conclusions drawn by the Committee regarding what immunilogical characterization should be recommended for antigen-reduced infant formulae 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?*"

1997 onwards

In March 1999 the situation worsened still further when a new Directive on Dietary Foods for Special Medical Purposes ²⁴ was adopted, just as the European Commission resigned. 900 members of the EU-NGDO Liaison Committee passed a Resolution highlighting their worries about the new rules and calling for them to be amended ²⁵. Mike Aaronson, President of the Committee and Director General of Save the Children, regretted the failure of the

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²³ Glenys Kinnock, MEP, question tabled July 1997 requesting full disclosure of members interests and asking, "*is the Commission aware that one prominent member of the committee, who has for many years had close links with the baby food industry, has only so far declared publicly an interest in mineral water*?"

²⁵ Emergency Resolution from the UK National Platform, to the General Assembly of European Development NGOs, meeting in Brussels on 15, 16 and 17 April 1999 (1999/21/EC): Called on the European Commission to amend the Commission Directive for Foods for Special Medical Purposes to *"include controls on marketing and labelling which bring it into line with the International Code and subsequent relevant Resolutions of the World Health Assembly…to ensure that all its policies which affect infant feeding and health are line with the relevant resolutions passed by the World Health Assembly…take co-ordinated action to promote the establishment of truly independent and impartial monitoring mechanisms to review the activities of the baby feeding industry."*

Commission to consult more widely and emphasised the need for the EU to consider the global implications of all its policies. Mr Mathioudakis, who had by this time, moved to DG SANCO, seemed to be once again in charge of all the procedures relating to infant feeding.

Several letters to the Commission, questions in the European Parliament and media articles followed, all calling on the Commission to explain its procedures and publish the Annual Declarations of Interest. Commissioner Liikanen responded in January 2000, promising to send the declarations of current members but said that *"Regarding past members of the SCF no particular obligations concerning this matter were in force."* In March of that year I received paper copies of the declarations of current members from Bernard Carson who said: *"The internal rules of procedure of the scientific committees allow the Members themselves to determine whether their interests can be made public, but, as you will see from the enclosed declarations, all of the Members of the SCF have agreed to public disclosure."* ²⁶

We believed that we really had turned a corner and were pleased to be invited to meet Mr Carsin, Peter Wagstaff and Mr Granero of DG SANCO in April 2000. At the meeting we had a useful discussion about transparency of Scientific Committees in general and the development of EFSA. (See attached notes²⁷.) We learned a lot about the efforts that were being taken to ensure transparency and independence, and the difficulties the Commission faced in dealing with these sensitive matters which, in many countries, are viewed as private matters. Academics in general are fiercely proud of their independence and consider too close an examination of their financial situation as intrusive. We were assured several times that the new procedures were sufficiently rigorous to prevent undue influence. We left the meeting still feeling that too much weight was placed on 'trust' and the reputation of selected candidates, but were pleased that the procedures eventually adopted by the Commission for EFSA, including the downloadable PDF Declarations of Interest, were a significant improvement on the ones relating to the SCF.

²⁶ Letter from IBFANers from 28 countries to Commissioner David Byrne; response from Commissioner Liikanen. Written questions from Glenys Kinnock MEP, Dec 1999; *European Voice* and the *British Medical Journal*.

²⁷ Notes of a Meeting between IBFAN and EU Commission staff about transparency and the Scientific Committees, 27 April 2000, 232 Rue Belliard, Brussels