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Fax No: 1233
Date: July 30, 2003
Cover plus 3 **page**
Chrono:

to:	SPS Notification Authority of the USA USDA/FAS/FSTSD Attn: Carolyn F. Wilson Stop 1027, Room 5545 South Agriculture Building 1400 Independence Avenue, SW Washington, DC 20250	**from:**	Charlotte Hebebrand
fax:	202 690 0677	**ext:**	9515
subject:	EC Comments to the legal text notified by USA in notice G/SPS/N/USA/701		

Dear Sir or Madam,

Please find herewith the EC comments to the draft regulatory text notified in the notice mentioned above.

It would be appreciated very much that any reply to this fax be copied also to the appropriate DG SANCO office in Brussels, as follows:

Mr Henri Belvèze
EC SPS Notification Authority
DG SANCO E 03
Commission européenne
B-1049 Bruxelles, Belgium

Tel: (32 2) 296 2812
Fax: (32 2) 299 8090 / 296 2792
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Gérard Depayre
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30 2003 1 59AM
ON

COMMISSION OF THE EUROPEAN COMMUNITIES
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
E3 - International food, veterinary and phytosanitary questions SANCO

Brussels, 30. 07. 2003
E3/JLP/EBP/un D(2003) 531778

FAX

To:	SPS Notification Authority of USA USDA/FAS/FSTSD Attn: Carolyn F. Wilson. Stop 1027, Room 5545 South Agriculture Building. 1400 Independence Avenue, SW. Washington, D.C. 20250			**Telephone:** +1 (202)720 2239 **Fax:** +1 (202)690 0677
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	S. LECRENIER	ENTR/F01	SC15 1/61	**Fax** 98043
	SANCO SPS	SANCO E03	F101 4/76	**Fax** 98090

Subject: **EC Comments to the legal text notified by the USA in notice G/SPS/N/USA/701**

Message:

Dear Madam or Sir

Please find annexed the EC comments to the draft regulatory text notified in the notice mentioned in subject.

It would be very much appreciated that any reply to this fax be copied too to our EC delegation (See the address above).

P.O.

Henri BELVEZE
EC SPS Notification Authority

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E3 – International food, veterinary and phytosanitary questions

COMMENTS TO THE UNITED STATES NOTIFICATION AUTHORITY[1] CONCERNING THE PROPOSED RULES TO REVISE INFANT FORMULA REGULATIONS NOTIFIED TO THE WTO' SANITARY AND PHYTOSANITARY (SPS) AGREEMENT SECRETARIAT UNDER CODE G/SPS/N/USA/701 AD.1

(PREPARED BY THE EC CONTACT POINT. BRUSSELS, 29/JULY/2003)

In notice G/SPS/N/USA/701/Add.1 4 July 2003, the US Food and Drug Administration (FDA) informs Members States of the WTO Agreement on the Application of Sanitary and Phytosanitary measures (the SPS Agreement) that is extending until 27 August 2003, the comment period for the proposed rule, published in the Federal Register of 9 July 1996 (61 FR 36154), to revise its infant formula regulations in 21 CFR parts 106 and 107.

According to this notice, the proposal would establish requirements for current good manufacturing practice (CGMP) and audits, establish requirements for quality factors, and amend its quality control procedures, notification, and records and reports requirements for infant formula.

In document '*Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Reopening of the Comment Period*' (Federal Register/Vol. 68, No 81), the US Department of Health and Human Services is asking for comments on whether there is a need to include microbiological requirement for *Enterobacter sakazakii*.

The EC Notification Authority thanks the USA for allowing to comment on these important texts and, in response of the request is glad to provide the following comment on this question.

1. While it is obvious that *E. sakazakii* in infant formulae may form a risk for newborn babies, there are not yet comprehensive risk assessments available on this risk. Therefore it is difficult to evaluate which risk management options would be most suitable for preventing this risk. Guidelines for the preparation of the product before the final use would be essential. Microbiological criteria may be one option, but their ability to reduce the human health risk depends on a number of factors, such as the prevalence and contamination level of the bacteria and the sampling plans used.

2. In view of what it is described above, and in order to propose the appropriate legislative initiatives, the European Commission aims to address a question to the European Food Safety Authority (EFSA) regarding the microbiological risks in infant formulae. The EFSA will be asked to assess these risks, including *E. sakazakii*, and to evaluate the efficacy of

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[1] USDA/FAS/FSTSD. Attn: Carolyn F. Wilson. Stop 1027, Room 5545 South Agriculture Building. 1400 Independence Avenue, SW. Washington, D.C. 20250. Telephone: +(202)720 22 39. Telefax: +(202)690 06 77. Email/Internet: ofsts@fas.usda.gov and . wilsonc@fas.usda.gov

different risk management options to control these risks. Based on this scientific advice, the Commission will propose the appropriate actions to be taken.

3. The EC Notification Authority respectfully request the USA provide the following information

   - *Is it available to the USA FDA a risk assessment or a risk profile analysis to support the proposed measures?*

   and if that is the case,

   - *Could the USA FDA submit a copy of these documents to the EC for further evaluation?*

The EC thanks again the USA for its notification and is eager to know the USA replies to the questions in point 3.