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

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COMMENTS TO THE USA CONTACT POINT CONCERNING THE DRAFT NOTIFIED TO THE WTO' SANITARY AND PHYTOSANITARY (SPS) AGREEMENT SECRETARIAT UNDER CODE G/SPS/N/USA/489 AND G/SPS/N/USA/489 AD.1, ALSO NOTIFIED TO TBT UNDER DOCUMENT G/TBT/N/USE/011.

(PREPARED BY THE EC NOTIFICATION AUTHORITY AND ENQUIRY POINT. BRUSSELS, 06 FEBRUARY 6, 2002

Having examined the content of SPS notifications G/SPS/N/USA/489/Add.1 and G/TBT/N/USA/0011 (Annexed to this document) the European Economic Community appreciates the opportunity to be able to provide comments on the legislative initiatives notified thereby.

Background

By notice G/SPS/N/USA/489 Ad.1, the Food and Drug Administration (FDA) informs of that that it has extended until 11 March 2002, the comment period for the proposed rulemaking (ANPRM) for the establishing of import tolerances (notified as G/SPS/N/USA/489) that asked for comments on issues related to the implementation of the import tolerances provision in section 4 of the Animal Drug Availability Act of 1996 (ADAA) that authorizes the FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States.

In this texts, and responding to the call, the EEC is sending comments on both notifications.

[Beginning of EC Comments:]

As is the case in the United States, in the European Community pharmacologically active substances included in animal drugs or veterinary medicinal products intended for the use in food producing animals have to be scientifically assessed with respect to potential harmful residues in foodstuff of animal origin for human consumption. Veterinary medicinal products, which have not been assessed as safe according to requirements laid down in Community law can neither be authorised nor used otherwise for food-production animal species. For those substances for which it has been considered necessary maximum residue limits (tolerances) have been established that are also valid for imported products. Like in the United States it is unlawful to import products to the Community if residues are present in these products that exceed the established limits.

On the other hand we also acknowledge that veterinary medicinal products not authorised in our jurisdiction may be authorised in other countries. This may be the case due to the fact that in other regions different diseases or target species prevail or that companies have chosen not to apply for a marketing authorisation for a specific product in the Community. Non-authorisation in the Community would not *per se* indicate that this

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substance is not safe and that it therefore should be possible to establish tolerances for these substances in order to facilitate trade.

We agree with the opinion that the US government expresses in the above-mentioned notification that any substance used in food-producing animals should fulfil essential human food safety requirements. For the European Community these requirements are established in Council Regulation 2377/90[1]. In the European Community anybody who can provide the necessary data packages can apply for the establishment of maximum residue limits at the European Agency for the Evaluation of Medicinal Products. This evaluation is separate from but a prerequisite for a marketing authorisation/licensing procedure for a veterinary medicinal product in the European Union, to which also members of the European Economic Area are party. Therefore any government, trader, manufacturer, farmers union etc. can apply for establishment of a tolerance (maximum residue limit) valid for the entire Community.

Nevertheless apart from certain possibilities to extrapolate maximum residue limits from one species to another, we find difficult to deviate from these data requirements for particular uses, animal species or products because of the necessity to protect the consumer from potential harmful residues. Moreover, exemptions for imported products are difficult to defend because this would result in a de facto discrimination of domestic production.

The proposals mentioned under **Issue 1 and Issue 2** would be equivalent to the procedure already applicable in the Community (full data package for human food safety requirement needed). We understand that the US would have to introduce an evaluation procedure independent from the licensing procedure. To our understanding analytical methods are part of the date package required.

However as mentioned above the European Community evaluation procedure is already separate from a marketing authorisation procedure and any government, trader, manufacturer, farmers union etc. can apply for a maximum residue limit valid for the entire Community provided that they can supply the necessary data. In our experience only those companies who are interested in marketing a veterinary product in the European Community are willing to invest in the necessary studies. In practice, only the pharmaceutical industry has used the procedure until now.

Issue 3. It would be of value if the intention to establish an import tolerance would be disclosed to the public as early as possible. This is because then it would be possible for other parties to indicate that they would also have an interest in the establishment of such a tolerance and could contribute to the data package if they wished.

[End of EC Comments].

Again, the EEC appreciates the opportunity to comment on the US proposal and we are looking forward to your responses.

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[1] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (*Official Journal L 224, 18/08/1990 P:1-8*)

COMMENTS TO G/SPS/N/USA/489 & G/SPS/N/USA/489 AD.1 ALSO NOTIFIED TO TBT UNDER DOCUMENT G/TBT/N/USE/011

Annex I

WORLD TRADE ORGANIZATION	G/SPS/N/USA/489 16 August 2001
Committee on Sanitary and Phytosanitary Measures	

NOTIFICATION

1.	**Member to Agreement notifying:** UNITED STATES **If applicable, name of local government involved:**
2.	**Agency responsible:** Food and Drug Administration - FDA
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers may be provided in addition, where applicable).** Imported food products of animal origin **Regions or countries likely to be affected, to the extent relevant or practicable:**
4.	**Title and number of pages of the notified document:** Import Tolerances (4 pages)
5.	**Description of content:** The Food and Drug Administration is soliciting comment on issues related to the implementation of the import tolerances provision in section 4 of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerance will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the act) and may be imported into the United States. We plan to propose a regulation for establishing import tolerances. We plan to hold a public meeting on import tolerances during the comment period for this advance notice of proposed rulemaking (ANPRM) and intend to consider the comments made at the meeting and in response to this ANPRM in writing the proposed regulation. We also will work with the Food Safety Inspection Service of the United States Department of Agriculture and other Federal agencies in the development of the proposed regulation.
6.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests**
7.	**An international standard, guideline or recommendation does not exist [X]. If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:**
8.	**Relevant documents and language(s) in which these are available:** 66 FR 42167, 10 August 2001 (available in English)
9.	**Proposed date of adoption:** To be determined
10.	**Proposed date of entry into force:** To be determined

COMMENTS TO G/SPS/N/USA/489 & G/SPS/N/USA/489 AD.1 ALSO NOTIFIED TO TBT UNDER DOCUMENT G/TBT/N/USE/011

11.	**Final date for comments:** 10 December 2001 **Agency or authority designated to handle comments: [ ] National notification authority, [ ] National enquiry point, or address, fax number and E-mail address (if available) of other body:** Food and Drug Administration The full text, which includes instructions for commenting, will be sent upon request to the address in paragraph 12.
12.	**Texts available from: [ ] National notification authority, [ ] National enquiry point or address, fax number and E-mail address (if available) of other body:** United States SPS Enquiry Point/Notification Authority USDA/FAS/FSTSD ATTN: Carolyn F. Wilson Room 5545 South Agriculture Building Stop 1027 1400 Independence Avenue, S.W. Washington, D.C. 20250 Tel: (202) 720-2239 Fax: (202) 690-0677 E-mail Address: ofsts@fas.usda.gov

COMMENTS TO G/SPS/N/USA/489 & G/SPS/N/USA/489 AD.1 ALSO NOTIFIED TO TBT UNDER DOCUMENT G/TBT/N/USE/011

Annex II

WORLD TRADE ORGANIZATION

G/SPS/N/USA/489/Add.1

11 December 2001

Committee on Sanitary and Phytosanitary Measures

Original:

Notification

Addendum

The following communication, dated 7 December 2001, has been received from the United States.

Import Tolerances for Animal Drugs; Extension of Comment Period

The Food and Drug Administration (FDA) is extending to 11 March 2002, the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of 10 August 2001 and was notified as G/SPS/N/USA/489. The ANPRM gave notice that FDA was proposing a regulation for establishing import tolerances. The ANPRM was soliciting comments on issues related to the implementation of the import tolerances provision in section 4 of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerance will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act and may be imported into the United States. FDA is taking action because it has rescheduled the public meeting on the issue and wishes to allow time for the consideration of comments made after the meeting.

Submit written or electronic comments by 11 March 2002.

The addendum, including instructions for commenting, is available from the address below:

United States SPS Enquiry Point/Notification Authority
USDA/FAS/FSTSD
ATTN: Carolyn F. Wilson
Room 5545 South Agriculture Building
Stop 1027
1400 Independence Avenue, S.W.
Washington, D.C. 20250
Tel: (202) 720-2239
Fax: (202) 690-0677
E-mail: ofsts@fas.usda.gov

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