

# Notes for EC Delegates

Not to be forwarded to Codex Secretariat

## CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Washington, D.C., 28 - 31 March 2000

### CX/RVDF 00/2, CX/RVDF 00/6 and ALINORM 99/31 paragraphs 65-70

#### Agenda item 3: Matters Referred from the Codex Alimentarius Commission and Other Codex Committees

##### Draft maximum limits for bovine somatotropin (BST)

##### Background

The Codex Alimentarius Commission in its last meeting decided to hold the MRLs at Step 8 in accordance with the provisions contained in the introductory paragraphs of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts.

In the last meeting of the CCRDVF the Community already objected to the decision to forward the maximum limits for bovine somatotropin (BST) proposed by JECFA to the Codex Alimentarius Commission (ALINORM 99/31 paragraph 70). One of the reasons was that the Codex Committee on General Principles (CC GP) had not finalised its discussions on Other Legitimate Factors. The CC GP in its last meeting before the above-mentioned CAC meeting had discussed the application of "other legitimate factors" in the case of BST but had not been able to reach a conclusion. The CC GP has not finalised its considerations on the role of other legitimate factors in relation to risk analysis. Therefore, the first objection of the Community remains still valid.

The registration and the use of BST is not allowed within the European Community. This ban was imposed to protect animal health and welfare.

BST was last evaluated by the 50<sup>th</sup> JECFA meeting in February 1998. JECFA has agreed on the recommendation of "not specified" maximum residue limit for BST. This means that neither a numerical MRL has been established nor that a method of analysis has been established nor evaluated according to the relevant criteria.

Despite the marketing ban in the European Community, some companies have applied to obtain a decision on the MRL status of BST in accordance with EC Regulation 2377/90. For procedural reasons, the European Community for the time being has to proceed with these applications even if the results would have no effect on the recently confirmed permanent ban on marketing of the BST in the European Community. The risk management decision on this matter, which may involve the application of the precautionary principle, has not been concluded yet.

EC	CX	Committee	Status	Date
Comments	00/02	CC RDVF	Final	20/03/2000

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## European Community Position

The European Community is of the opinion that the establishment by Codex of a non-numerical “MRLs” (which in fact does not represent a maximum residues limit<sup>1</sup>) for BST and for which there is no validated method of analysis available, has no effect as regards international trade and, consequently, it is not necessary.

It should also be kept in mind that the consumers’ expectation is that foods derived from animals should normally be free of dangerous drug residues. However, it has been generally accepted that food-producing animals need to be treated with animal drugs in order to avoid unnecessary suffering of these animals. Consequently, maximum residue limits have been introduced in various countries, whilst Codex Alimentarius in order to balance:

- a) animal health and welfare on one side (by allowing the prevention of diseases and therapeutic treatment of food producing animals), and
- b) effective consumer protection (by avoiding or reducing residues in foods) on the other side

has also made recommendations and established guidelines to that effect.

Furthermore, if there is a public health risk from the use of BST, this appears to be related to the ingestion of insulin-like growth factors and not directly from the ingestion of BST itself. Future scientific work, therefore, to evaluate the public health aspects of BST should now be focused on this aspect.

Consequently, the CC RDVF should consider whether it wants to spend more time on the evaluation of a substance which has no therapeutic or preventive properties and whose use has been proven harmful for animal health and welfare<sup>2</sup> and whose potentially harmful effects on human beings have not yet been fully elucidated

**Therefore the EC proposes that the subject of fixing MRLs for BST should be taken off the agenda of the CC RDVF altogether.**

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<sup>1</sup> Limit = a prescribed maximum or minimum amount, quantity or number according too Webster’s new encyclopaedic dictionary

<sup>2</sup> In dairy cows treated with BST an significant increase in the incidence of several diseases like mastitis, foot and leg and reproductive disorders has been observed.

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