codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/RVDF 03/5 – Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
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PROPOSED DRAFT APPENDIX ON THE PREVENTION AND CONTROL OF VETERINARY DRUGS RESIDUES IN MILK AND MILK PRODUCTS

COMMENTS

Comments have been received from Colombia, France and European Community

COLOMBIA

General Considerations

We consider this a very important document, offering practical guidelines for reducing or minimizing the contamination of milk by veterinary drug residues at farms. Nevertheless, we consider it appropriate to stress the fact that other chemical substances, such as pesticides and other chemical compounds used in animal healthcare and production, may also generate undesirable residues in milk. In this regard, particular care must be taken in adopting good practices for animal feeding and a rational use of all chemical substances used on farms, undertaking a risk assessment to determine the impact they may have on the innocuousness of the milk.

In all cases where the expressions "violating" or "violating residues" appear in the text, in reference to veterinary drug residues, they should be replaced with "prohibited residues" or "residues that do not meet accepted or established levels." In this case, we suggest analyzing the possibility of making reference to categorically prohibited substances, such as, for example, chloranphenicol, and substances permitted as veterinary drugs for which the Codex has established maximum residue limits.

The text below indicates the points in the original text where changes are recommended. The suggested modifications are indicated in ***bold, italics and underlined***.

Specific Points

3.1 Responsibility of the Milk Producer and Veterinarian

8. Very important veterinary drug residue control practices include compliance with the ***instructions*** on the drug labels....

3.2 Responsibility of the *Dairy Industry*

9**.** The industry quality control personnel ***involved in educating*** milk producers in on appropriate handling practices and inspecting raw milk for residues, also share the responsibility for guaranteeing a milk supply free of residues ***of prohibited chemical substances and drugs that do not meet accepted levels.*** Once the milk has left the farm ***to be processed,*** the industry is responsible for the monitoring or inspection programs to determine whether the mixed raw milk is free of residues ***of prohibited chemical substances or drugs residues at concentrations in excess of the tolerated or established levels.***

3.3 Responsibility of the Governmental Authority

12. The authorities ***must*** review the results of the monitoring on the milk, with a particular focus on residues of ***prohibited substances or those that do not meet accepted levels, research the causes of the generation of the inadmissible residues in the milk, and take appropriate measures***

13. ***The governmental authorities must also encourage all parties involved in the production or transformation of milk, as well as the pharmaceutical industry and the industries producing pesticides and other substances used in milk production, to contribute to the development of educational programs for these cattle farmers.***

14. Finally, all parties responsible for the maintenance of a supply complying with the MRLs, including the governmental authorities, must periodically ***evaluate*** their procedures for the control of residues in order to ensure a continuous adequate production.

3.4 Milk Farm Handling Auditing and the Role of HACCP.

15. ***The development of a practical and effective control program for residues on the farm must begin with the identification of those herd handling practices that may contribute to the generation of inadmissible veterinary drug residues or residues of other chemical substances used in animal healthcare and production*****.***

3.5 Principal Characteristics of Residue Control in Milk

16. Maintaining hygienic practices that ensure the cleanliness of the milk production establishment and a clean environment for the milk-producing animals may have a significant effect on ***disease prevention*** in the herd, ***thus minimizing the use of drugs***.

17. ***In order to be effective, the programs must be practical and efficient for the milk producer, who is responsible for the prevention of chemical residues that may put the milk at risk.***

18. ***Special attention must be paid to these elements as well as the general standards of the Good Veterinary Practices.***

20. Since the information on the drug label is designed to prevent the appearance of residues in milk, milk producers must carefully follow the instructions and maintain accurate records of drug use in each animal treated. In cases of prescriptions for purposes other than those approved on the drug label, written records must be kept and signed by the veterinarian, clearly specifying the specific conditions of use and the time of withdrawal for the milk and for the slaughter of the animal. This information may also be placed on the product, but in no case should the product label cover it.

4. Monitoring of Drug Residues in Milk.

22. The prevention of the residues of drugs or other chemical substances in milk is a proactive measure that depends primarily on the procedures, practices and use of the drugs ***on the farm***.

4.1 Function of Residue Monitoring in Milk

24. ***Residue monitoring programs in milk have the function of ensuring compliance with the proper use of the prescribed veterinary drugs and ensuring the innocuousness of the milk supply.***

25. Monitoring programs may also represent an important tool in the control of milk with chemical residues. Since such programs may identify the presence of residues that do not meet accepted levels, they must also [indicate] that the milk should not be consumed or used in the production or processing of products for human consumption. If this is done, the innocuousness of the milk and milk products is preserved.

4.2 Components of a Monitoring Program

27. The concentration of residues in milk diminishes, as does the ability to track the origin of violations, as the total volume of milk increases after its initial collection on the farm (bulk on the farm >tank >silo). The same occurs in the case when milk is found to contain prohibited residues or residues in excess of the established limits: the penalties increase in proportion to the distance from the farm. From a practical point of view, sampling is recommended at the milk farm or in the milk transport tank.

28. ***This would allow for intervention to take place prior to the processing of the milk.***

29. ***With respect to analytical testing, rapid selection tests and validated methods for quantifying and confirming the identity of the detected drugs represents the ideal way to establish a successful monitoring program.***

30*. Currently international organizations have certified rapid selection methods that are commercially available for antimicrobial residues in milk, particularly for beta-lactamic antibiotics.*

Thus reducing the potential for milk with residues of prohibited drugs or other chemical substances reaching consumers.

31. ***Governmental authorities require both qualitative and quantitative data on the identification of residues in milk, since this information is used to enact laws and other regulations.***

Since selection or preliminary tests are not sufficiently quantitative or specific, the availability of validated methods for the confirmation and quantification of the presence of a residue of a drug or other chemical substance is recommended.

4.3 Factors Affecting Residue Monitoring in Milk

38. ***Residues of antibiotics in milk may have a negative effect on milk processing where microorganisms are used.***

40. ***Nevertheless, in all cases, it is essential that the confirmation procedure be validated...***

FRANCE

The French authorities express a general agreement in principle with this document, if one modification is made in the second sentence of paragraph 7 in chapter 3.1, as follows: "*The Dairy veterinarian shares this responsibility in that he performs the diagnoses and prescribes the necessary drugs. He determines the means of administration and the usage conditions of the drugs administered to the animals. In any event, veterinary drugs that may be the origin of residues in milk must have been subject to a prior veterinary prescription; the milk producer and the veterinarian share..."*

EUROPEAN COMMUNITY

The European Community would like to thank the United States of America and the drafting group for the preparation of this *Proposed Draft Appendix on the prevention and control of veterinary drug residues in milk and milk products*. The European Community is generally in agreement with the document that applies the stable to table approach. We particularly welcome that the document confirms that "*veterinary drugs should be used only when necessary and as a complement to, but not a replacement for good management, vaccination and farm hygiene (paragraph 6)*". We propose to generally replace the word "*violative*" by the more generic term

"*non-compliant (with the established standards)*" for clarity. Moreover we have the following comments on specific parts of the text:

Introduction: For completeness the introduction should also mention that residues of in particular antimicrobials might also have a negative impact on the production of for instance cheese.

Heading 3.1: The producers should be called dairy producers and not milk producers, as it is the dairy animals that produce the milk.

Heading 3.2: Likewise it is preferable to refer to the dairy industry all through the document instead of the milk industry.

Paragraph 3: In the last paragraph the word "*violative*" should be replaced by the more generic term "*non-compliant (with the established standards*)" for clarity

Paragraph 7: The second sentence should be replace by: "*The dairy veterinarian of the herd shares this responsibility if he or she carries out the diagnoses and prescribes the necessary medication. He or she determines the way the product is administrated to the animals and the respective conditions of use. In all cases in which veterinary drugs can be the source of residues in milk they should be subject to a respective prescription*."

Paragraph 11: The third sentence in this paragraph should be modified to require government authorities to "*select analytical methods for monitoring and enforcement purposes that meet acceptable performance criteria,...*".

Paragraph 13. The pharmaceutical industry should be able to contribute to the development of educational programmes for dairy producers only if governments can control the programmes. The information can be biased if the commercial interests are dominating. Thus the wording should be changed as follows: *Government authorities should also develop and promote educational programmes for dairy producers, with the co-operation of the concerned parties and the pharmaceutical industry.*

Paragraph 19: The end of the last sentence should read ".. *manufacturer/marketing authorisation holder*". In the proposal to amend the pharmaceutical legislation, the need to have the manufacturer on the label was deleted. In any case this is now only required if the manufacturer is different from the marketing authorisation holder.

Paragraph 20: The end of the last sentence should read "*…appear on the label and be entered in the records*".

Paragraph 33: The significance of the difference between "*healthy animals*" and "*animals judged healthy by a veterinarian for milking purposes if they had been under treatment*" should be explained.