

**EUROPEAN COMMUNITY COMMENTS ON THE
PROPOSED DRAFT REVISED PART I, II, III OF THE CODEX
GUIDELINES FOR THE ESTABLISHMENT OF A
REGULATORY PROGRAM FOR THE CONTROL OF
VETERINARY DRUG RESIDUES IN FOODS
(CX-RVDF 06/16/9)**

*Mixed Competence
European Community Vote*

The European Community and its Member States thank the delegation of Canada and the Netherlands for preparing this document.

We can in general support the development of Codex guidance on sampling and analysis. We have the following remarks.

General:

We would prefer if the term “*non-compliant*” rather than “*adulterated*” could be used in the entire text. This is because “*compliant*” makes reference to an agreed standard such as MRLVDs while adulterated means made impure by adding extraneous, improper, or inferior ingredients.

We would like to reiterate what we have pointed out previously in our remarks on CX-RVDF 04/15/6 for the 15th CCRVDF: it has to be taken into account that consignments of animal products tend to be heterogeneous by nature and will often be made up of commingled product from a variety of animals and sources. Therefore, statistically significant results can only be obtained if disproportionate numbers of samples are taken and analysed. Statistical/non-biased sampling runs therefore counter to the overall goal of using testing only as a verification tool and thus rely more on production control measures to ensure food safety. In consequence all well functioning control systems would produce low non-compliant prevalence and therefore require higher numbers of samples (see table 1). This seems inappropriate.

There is a significant overlap between this document and document CX-RVDF 06/16/10. The Committee should decide which working group should continue to work on sampling procedures to avoid duplication of efforts.

On specific points:

Point 8: It is stated that “*In sampling for residues of an added, regulated substance such as a veterinary drug, it is important to sample as near as possible to where animals raised for food are cared for and slaughtered in herds or flocks. The most meaningful sampling for tissue residues will occur in conjunction with slaughter. For other food products within the scope of this Committee, such as honey, the most meaningful sampling for residues will occur at the time of collection, prior to commingling of samples from different producers*”. This paragraph should be replaced by “*Veterinary drugs are deliberately administered to animals for a specific purpose*”

(e.g. to treat diseases). In consequence sampling should be carried out where the results of subsequent analysis are likely to be most significant. This will in most cases be in conjunction with slaughter of animals or harvest of products (milk, eggs, honey) for food production”.

Point 11: It is stated that “non-biased sampling is designed to provide profile information on the occurrence of residues in specified food producing populations on an annual, national basis. For residue testing, the focus is on gathering information on the prevalence of residue non-compliances; therefore, only compounds with established safe limits such as MRLVDs are usually considered for residue control programmes”. The last part of this sentence after the comma should be deleted because residue programme should also focus on substances that are not permitted due to consumer safety concerns but that represent a temptation for producers due to their efficacy when used in animals (e.g. chloramphenicol, malachite green). This aspect is also discussed in point 12.

Point 15 and Table 1: as the prevalence of the known non-compliance is pivotal to the entire sampling suggested here, it should be explained how this prevalence is to be determined. Indeed it seems the higher the prevalence or history of non-compliances the fewer samples have to be taken according to the content of Point 15 and Table 1. This may be appropriate for a quality control programme of a producer who is aware of all aspect of production before sampling but seems utterly inappropriate for a control programme.

Point 19: It is stated that “Port of entry testing of products derived from food producing animals, poultry, or fish, and honey, imported by member countries of Codex Alimentarius is a means of verifying the effectiveness of the exporting country's residue control programme. Such testing should be statistically based and should reflect both the frequency and the volume of the trade in the product. The purpose of port of entry sampling and testing is not to replace an exporting country's residue control programmes”.

The first sentence implies amongst others that poultry and fish are not food producing animals. It should be rephrased as follows “Port of entry testing of products derived from food producing animals such as meat and honey imported is a means of verifying the effectiveness of the exporting country's residue control programme and not a substitute for this programme”. The second sentence should be replaced by “Such testing should be risk based and reflect both the frequency and the volume of the trade in the product entering the Codex member country”. It is very difficult if not impossible to base such programmes purely on statistics as consignments are often inhomogeneous and deliveries reach the importing countries through different ports of entry.

Point 29: It is stated that “For purposes of control, the MRLVD is applied to the residue concentration found in each Laboratory Sample taken from a Lot. Lot compliance with a Codex MRLVD is achieved when the mean result for analysis of the Laboratory Test Portions does not indicate the presence of a residue which exceeds the MRLVD”. It should be further explained what is meant by “mean result for analysis of the Laboratory Test Portions”.

Point 34: It is stated that “The number of Primary Samples collected will vary depending on the status of the Lot. A Lot may be considered suspect if there is a history of non-compliance with the MRLVD, evidence...”. It is not clear what this “history” refers to: the perceived temptation to use a specific drug incorrectly so that

MRLVD are often exceeded, the history of non-compliance in one country or one geographical area, or the history of non-compliance of a producer?

Point 114: The term “*developing laboratory*” should be replaced by “*laboratories developing methods on a regular basis*” as it might otherwise be misunderstood.

Point 134: It is stated that “*Laboratories should provide their clients on request with information on the measurement uncertainty associated with the quantitative results produced by each quantitative method*”. This document is however on regulatory programmes for the control of veterinary drug residues in foods designed by the competent authority of the respective Codex member. The laboratories involved are in consequence official laboratories and contract laboratories run or employed by the government. The underlying requirement should therefore be formulated differently: “*Governments should require that laboratories ensure that they are at least [95 %] confident of their results*”.