

EUROPEAN COMMUNITY COMMENTS ON
CX-RVDF 04/15/6

Subject: **REQUEST FOR COMMENTS:**
**Codex Guidelines for the Establishment of a Regulatory Programme
for Control of Veterinary Drug Residues in Foods**

The European Community thanks the delegation of New Zealand for preparing this comprehensive document. We can in general support the approach represented by this document, but have nevertheless a number of remarks.

Scope of the document

It is not clear what the precise scope of the document is. In point 6 it is stated that the document is *“intended to provide the overarching principles and guidance on the design and implementation of national and trade related food safety assurance programmes for residual hazards associated with the exposure of animals to veterinary drugs in the production environment.”* The term *“residual hazard”* is however defined on point 9 as *“a biological, chemical or physical agent in or on the food with the potential to cause an adverse health effect as a consequence of food animals being treated with or exposed to chemical compounds in the production system”*. This seems to go further than required for the document. Moreover, point 49 states that *“It is desirable that all formulations of veterinary drugs and pesticides manufactured or imported into the country be required to be recorded on a national register before being able to be used”*.

Considering the mandate of the CCRVDF the hazards in question could be either related to chemical compounds or antimicrobial resistance provoked by their use. However, the definition of *“chemical compound”* (point 9) addresses compounds that fall under the terms of reference of other Codex Committees such as the CCPR (pesticides) and the CCFAC (contaminants). Additionally the terms *“chemicals”*, *“chemical compounds”*, *“agricultural chemicals”* and *“formulations”* are used synonymously throughout the text.

To our appreciation the scope of the document should be related to the mandate of the CCRVDF and therefore be limited to compounds used intentionally in food producing animals. This would include compounds used illegally.

Definitions

With respect to the comments made under *“scope”*, it is important that the document distinguishes more clearly between legal and illegal use. Therefore illegal use/treatment needs to be defined e.g. as *“the use of unauthorised compounds or veterinary drugs/medicinal products or the use of these compounds/products under conditions other than those authorised.”*

The definition of residual hazard should be replaced by *“Hazard”*: *for the purpose of this document is any adverse health effect as a consequence of food animals being*

treated with or exposed to chemical compounds in the production system". This would cover the residues of chemical compounds or antimicrobial resistance provoked by their use.

The definition of *chemical compound* addresses compounds that are in the Codex Alimentarius system covered by other Committees such as the CCPR, CCFAC. It needs to be discussed if the guideline should be applicable outside the mandate of CCRVDF.

The necessity and appropriateness of a definition of *'food animal(s)'* should be reconsidered in particular as the term *'food producing animals'* is used in the definition of veterinary drug.

The term *competent authorities* could be defined more precisely as *"the governmental authority of a country responsible for the programme for control of residues of veterinary drug in foods or any other authority to which that authority has delegated that competence"*. "Country" includes regional economic integration organizations to which a group of countries have transferred relevant competencies¹.

The definition of *"risk based"* should be modified as follows in order to ensure coherence with the definition of risk in the Codex Alimentarius Manual: *"Focussed on and proportionate to an estimate of the probability and severity of an adverse effect occurring in food"*.

A definition of *"withdrawal period"* should be added, e.g.: *"the period between the last administration of the veterinary drug to the animal before tissues/products from the animal can be used in the production of food for human consumption."*

Goals and general principles

Point 10 "v." states that control and verification programmes for residual hazards should be *"be proportionate to the relative human health risk associated with these hazards compared with other food-associated hazards"*. This would seem to require a comparison between different types of hazards, which would be impossible to conduct. We therefore suggest an alternative wording *"be proportionate to balance the human health risk against the measures to eliminate it"*.

Design tools/public linkage, HACCP application

While we can agree to the general idea of applying the HACCP system to design residue control programmes, we would like to stress that point 17 to 20 would need further development and thus demonstrate in more detail how the HACCP system is to be applied to a residue control programme. We would moreover suggest modifying point 16 as follows: *"Risk analysis and HACCP principles may be applied to national control and verification programmes can provide guidance for the design and verification of control programmes to ensure that they are cost effective and effective in respect to human health protection"*.

Public health linkage/ food safety objectives

The term food safety objective (FSO, point 25) should not be used in relation to chemicals risks. FSOs have been developed in relation to the *"Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management"* by the Codex Committee on Food Hygiene (CCFH) to accommodate for the fact that

¹ see CCFAC guideline for the development of equivalence regarding food import and export inspection systems (CAC/GL 34 –1999)

microorganisms have a potential to grow at every stage of the food chain². This is not true for relevant for hazards related to the treatment of food producing animals with chemical compounds.³

We have difficulties in following the logic behind points 24 to 28. The approach described seems to question the procedure to set maximum residue limits (MRLs) on the basis of acceptable daily intakes (ADIs). We would not consider this advisable since the current system has been harmonised internationally for a wide range of compounds (e.g. pesticides, contaminants, food additives, feed additives, veterinary drugs).

We cannot agree to the approach to replace the existing system of using maximum residue limits (MRLs) as control limits by the approach described in points 28 and 83. The latter states that “*recall action is only justified on health grounds if the results indicate an imminent and acute risk to human health.*” This seems to suggest either that in each case a specific scientific risk assessment is carried out or that specific tolerances are to be developed apart from existing MRLs. This approach it will not help to facilitate trade but only make import procedures more complicated. The approach would require an import amount related exposure assessment with respective ‘import MRLs’ to be reconsidered frequently. Moreover, to our understanding the approach boils down to allowing using more chemical compounds if the disease situation in a particular country requires it. This would amongst others indirectly punish those who invest in disease prevention by means other than treatment with chemical compounds, such as better stables and quarantine procedures.

Statistic and sample taking (page 7, point 30 and pages 18 to 20)

In our view the document should not be so concerned with the statistical significance of the results of non-biased sample taking and rather focus on providing feedback to optimise regulatory system. Statistical significance is important for programmes aimed at consumer exposure assessment. Respective programmes can run over years and gather enough data to produce statistically relevant results.

For “*verification programmes*” it has to be taken into account (as stated in point 116) 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. Moreover, the statistical/non-biased sampling runs counter the overall goal of the document to use testing as a verification tool and rely more on production control measures to ensure food safety (see also point 114). Moreover a well functioning control system would produce low non-compliant prevalence and therefore require even higher numbers of samples according to table 1, page 19.

² see ALINORM 04/27/13, paras. 63-90 and Appendix III

³ Therefore in the definition developed by the CCFH the word microbiological needs to be read in the definition of the term as indicated: **Food Safety Objective (FSO):** *The maximum frequency and/or concentration of a (microbiological) hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).* Moreover the CCFH remarked “*that when control measures should be designed so as to achieve a specified level of hazard control, it was too restrictive to give consideration to the establishment of Food Safety Objective only, therefore, it agreed to refer in a generic way to “FSOs and/or related objectives and criteria”.* (Control of Food Hazards (section 5.1, point 30 of ALINORM 04/27/13)

Registration and approval/authorisation of compounds/products

Point 49 considers it “*desirable that all formulations of veterinary drugs and pesticides manufactured or imported into the country be required to be recorded on a national register before being able to be used*”. However, chemicals used illegally are often not imported or produced to be used in animals (e.g. malachite green). The registration procedure as proposed would create a lot of administrative work with probably little to be gained. We therefore suggest replacing the sentence by: “*Countries should identify and approve the pharmacologically active chemical compounds and the legal conditions under which they may be administered to food producing animals and enter these into a public national register.*”

In consequence to the proposed changes in point 49, point 50 should read: “*The basis for inclusion of a chemical compounds into the national register should be a favourable scientific assessment of the benefits and the risks afforded by the use of the chemical compound. For this procedure requirements and criteria should be established, which may include links to the approval or assessments of other competent authorities where use patterns are likely to be similar.*”

Moreover we suggest that points 51 to 53 should be modified as follows:

Point 51: “*The use of chemical compounds not listed in the national register should be appropriately pursued*”.

Point 52: “*Countries should lay down rules on penalties applicable if non-registered chemical compounds are used in food producing animals or found in animal products. They should take all measures necessary to ensure that these rules are implemented and that the penalties provided for are effective, proportionate and dissuasive*”.

Point 53: “*Countries should ensure, e.g. through information and training, that chemical compounds are used in a competent manner by competent users, in order to bring animals to the market that provide safe, wholesome food in a manner that protects public health*”.

On-farm recommendations

Point 59 could be extended to “*Only those veterinary drugs specifically approved for use in lactating animals, laying eggs and honey bees should be used in these animals when milk, eggs or honey, respectively, are collected for human consumption*”.

Point 60 seems to deal with the safety of the person administering chemical compounds to animals and may therefore be out of scope of the document.

Point 62 could be extended and modified as follows: “*Records should be kept of all details of the treatment, e.g. type of chemical compound administered, the nature of the treatment, the date of treatment, the identity of the animals treated, the date of expiry of the withdrawal period. The records should be made available to the competent authority at its request*”.

Point 63 to 66 similar additional advice might be necessary for laying eggs and honey bees and aquaculture fish, molluscs and crustaceans.

Principles and the role of verification programmes

To point 70 the following could be added: *“This confidence should be the basis for issuing official certificates accompanying consignments”*. In point 76 the meaning and significance of *“profiling attributes”* needs to be further explained.

Overlaps with document CX/RVDF 04/15/7 Part II

The remarks under points 85 to 90 need to be checked for overlaps with document CX/RVDF 04/15/7 Part II *“General Considerations on Analytical Methods for Residues Control”* of the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drugs Residues in Foods*.

Analytical results (page 13-14)

Point 92 request that *“analytical results at or above the MRL should not be stated as discrete numbers but as a range of values that the laboratory is confident the true result falls within (the confidence interval). Where the range reported falls both above and below the MRL then it is not possible to definitively conclude the result was non-compliant.”* This suggestion that would only create more uncertainty in particular as in many cases sampling method provides the greatest source of uncertainty. One should rather require that methods are validated to ensure that the results obtained ensure a particular confidence in the result (e.g. 95 percent confidence limit).

In point 94 we suggest to replace *“analysed”* by *“investigated”*, similarly in point 96 the word *“analysis”* should be replaced by *“investigation”*. In point 98 *“recognition”* should be replaced by *“approval”* or *“authorisation”*.

Regularly response to identified non-compliance (page 12-13)

In point 99 should be translated into more plain language e.g. *“Where investigations show that a regulatory programme for the control of veterinary drug residues in food is ineffective, appropriate corrective actions/measures should be taken. The type of actions/measures may depend on the type of chemical compound, the type of animal production or the food concerned and should be proportionate to the hazard and the frequency of its occurrence. The effect of the actions/measures should be assessed by targeted verification.”*