

EUROPEAN COMMUNITY COMMENTS
ON THE PROPOSED DRAFT REVISED GUIDELINES FOR THE
ESTABLISHMENT OF A REGULATORY PROGRAM FOR THE
CONTROL OF VETERINARY DRUG RESIDUES IN FOODS

CX-RVDF 06/16/8

The European Community thanks the delegation of New Zealand for preparing this document. We can in general support the approach represented by this document and are pleased that many of our earlier comments have been taken into account.

General remark: The text should always refer to “*pre-harvest and pre-slaughter*” or “*harvest and slaughter*” rather than to harvest only.

Point 1: It is stated that “*The uncontrolled use of, and/or exposure to, approved and/or non-approved veterinary drugs in food production systems can result in consumers being exposed to amounts of residues in foods at frequencies which could pose a risk to their health*”. We suggest to remove the last part of the sentence “*at frequencies which could pose a risk to their health*” since the risk to consumer cannot always be directly linked to the frequency of exposure.

Point 2: It is stated that “*Modern food production systems should be designed and managed to ensure that the level of exposure to contaminants is sufficiently controlled to prevent consumers of the foods derived from these systems from being exposed to unacceptable amounts of associated hazards at frequencies likely to compromise their health*”. We suggest to remove the last part of the sentence “*at frequencies likely to compromise their health*” since the risk to consumer cannot always be directly linked to the frequency of exposure.

Point 3: We suggest modifying the text as follows: “*The commercial entities involved in the production and marketing of food have the primary responsibility for ensuring food safety. The role of competent authorities is to authorise, restrict or prohibit the use of veterinary drugs and to verify appropriate practices are being applied and sufficient controls are in place within the veterinary drug distribution and food production system as a whole to meet the appropriate level of health protection*”.

Point 9 (Definitions): 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 ‘*food producing animals*’ is also used in point 54.

Point 10: We suggest modifying the text as follows “*Consider the possible risks profiles associated with both approved, non-approved or prohibited veterinary drugs in the production system*”.

Point 23: It is stated that “*Food containing residues above an MRL are not inherently unsafe as long as any calculated acute reference dose is not exceeded*”. The last part of the sentence “*as long as any calculated acute reference dose is not exceeded*” should be deleted. It is not the calculation of a reference dose that makes a product safe.

Point 25: It is stated that *“From a public health point of view, higher MRLs in the exporting country do not pose a particular toxicological health concern as long as the frequency distribution of residues in the exported product, combined with an estimation of the volume of imports relative to the domestic production, allows it to be concluded that it is unlikely that the ADI will be regularly exceeded in the importing country”*. It is not clear what this paragraph is aiming at. It could be suggesting bilateral agreements between importers and exporters on standards different from those agreed in Codex. In this case the issue would fall outside the scope of this document.

We would in this context like to reiterate our respective comment on CX-RVDF 04/15/6 (the document presented under the same title for the last session of the CCRVDF) stressing that we cannot agree to the approach to replace the existing system of using maximum residue limits (MRLs). MRLs are adopted by all Codex Members as risk managers. They thus represent the internationally agreed reference point for action. This is a clear rule.

We cannot agree to an approach under which action following the detection of residues above the MRL is only justified if the results indicate an imminent and acute risk to human health. Such an approach would either require a specific scientific risk assessment in each case to be carried out or that specific tolerances are to be developed apart from existing MRLs. These suggestions it will not facilitate trade but make import procedures only more complicated.

Point 30, 3rd bullet point: The word *“intelligence”* seems redundant and should therefore be deleted.

Point 30, 4th bullet point: Here it should read *“cell count in milk”*.

Point 38: It is stated that *“After the potential types, sources and exposure pathways of chemical inputs into the production system have been identified, it is then necessary to consider what are the circumstances required for each of these to cause an adverse health impact on consumers, as well as the likelihood of such circumstances occurring in the absence of a control”*. This text is not sufficiently clear. We therefore suggest replacing it by the following: *“All sources of residues of veterinary drug should be considered. This requires identification of all potential exposure scenarios and the evaluation of the likelihood that respective circumstances occur. Finally the effect of control measures that may reduce the likelihood of a certain type of exposure should be considered”*.

Point 55: We suggest modifying the text as follows *“Veterinary drugs should only be used off-label in accordance with direct and written veterinary advice such (i.e. diagnosis of the disease and prescription of the veterinary drug). Such advice should be consistent with national and/or international guidance documents and technical information on this issue.”*

Point 56: After *“lactating animals”* the words *“and in egg laying animals”* should be added and after the words *“being milked”* the words *“or in animals whose eggs are collected for human consumption”* should be added. It may also be appropriate to consider bees and honey under this paragraph. In this case should read: *“..., only those veterinary drugs specifically approved for use in lactating animals, laying hens and honeybees should be used in these animals when milk, eggs or honey, respectively, are collected for human consumption”*.

Point 57: This paragraph should be modified as follows: *“Producers should have appropriate on-farm food safety assurance measures in place with respect to the use of and/or exposure to veterinary drugs, including a transparent record keeping system. All workers directly involved with the animals should be familiar with the system used”*.

Point 58: The text in brackets should also refer to egg withholding periods. We take it for granted that term ‘harvest’ covers the collection of honey.

Point 61: We suggest modifying the text as follows *“Discarded milk should not be fed to other animals unless appropriate controls are in place to assure that food for human consumption will not be derived from these animals before any transferred residues have fallen to acceptable levels and/or provided that there is no danger of transferral or generation of antimicrobial resistances”*.

Point 63: We suggest to add a paragraph on other food producing animals after point 63 as “(d)” under the heading *“Additional advice for other food producing animals”* stating that *“For other food producing animals food safety assurance measures comparable to those described for lactating animals in points 60-63 above should be implemented taking into account the unique prospects and limitations of different production systems.”*

Point 74: The significance of the reference to pesticide labels and GAP should be explained. Moreover it is not clear why the reference to quality systems is limited to feed medication.

Point 83: After the last sentence the following should be added: *“Similarly for egg laying animals samples should ideally be taken at the time eggs are collected from the farm”*.

Point 89 requests 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 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).

Point 104: It is stated that *“Where non-compliant results are returned, recalls are not necessary unless an assessment is made that the result indicates a direct risk to human health e.g. where it has been calculated that an acute reference dose is likely to be exceeded. Except in such situations, occasional incidences of results in excess of the relevant MRL should not be considered to constitute an imminent health threat”*. This text is problematic as it is not indicated who is to make such an assessment and for whom. It may be possible for a competent authority to make such an assessment for its own constituency, but it seems unacceptable that such assessment is made for importing countries by an exporting county without the involvement of importing countries.

Point 108: The 1st paragraph should read: *“Trading countries should be encouraged to exchange copies of their control and verification programmes along with the results of the preceding years”*.

Point 112: It is stated that *“It is important that any methodology used is fully validated for the specific matrix analysed and any “regulatory action levels” are set at levels which are determined to pose a significant risk to human health as opposed to just reflecting the level of determination of quantification of the method”*. While we could agree to the general approach behind this statement, its implementation poses significant problems as the issue is often linked to substances where no safe level can be established due to lack of data. The level of determination of quantification of the method is often the only sure reference for evaluation in these cases. This point should therefore be discussed in connection with the Report of the Working Group on Residues of Veterinary Drugs without ADI/MRL (CX/RVDF 06/16/13).

Point 115: It is stated that. *“Except where a higher level of protection has been determined as necessary by an appropriate risk assessment, Codex MRLs, or the MRLs applied in the exporting country should be used as the monitoring tools”* and that *“occasional incidents of non-compliance are found these should not be treated with undue concern unless the type, level or frequency varies substantially from what the exporting country is finding itself”*. These paragraphs provide the impression that in case of doubt the exporting countries rules dictate what action, if any, is taken. We suggest that a solution should be sought in cooperation between importing and exporting county until a more general approach can be agreed within the Codex system.

Point 129: it is stated that *“Where the objective is to verify the overall effectiveness of a system at ensuring the general population’s exposure is less than the ADI then multiple sample units can be combined before analysis, or commingled product sampled and analysed”*. We do not agree to this sampling approach as it may in particular in cases of different residues status between producers hide problems and thus produces a false impression of safety.

Point 139: it is stated that: *“The application of directed or targeted sampling in port of entry sampling programmes is only appropriate where product is known to or suspected of sharing the same exposure profile.”* We do not agree to this statement as a targeted sampling at port of entry is key to risk oriented import control.

Pints 121 – 136: There is a significant overlap between this document and document CX-RVDF 06/16/9. The Committee should decide which working group should continue to work on sampling procedures to avoid duplication of efforts.