codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/RVDF 06/16/8, Add. 1**
March 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Sixteenth Session

Cancun, Quintana Roo, Mexico, 8 -12 May 2006

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

Comments at Step 3 submitted by Australia, Brazil, Canada, European Community, United States, IDF

Australia

Australia thanks New Zealand for the significant progress made on this document. Australia supports its progression, and offers the following comments for consideration:

1. Further clarity is needed in the document to explain the purpose of maximum residue limits (MRLs). The document appears to have the underlying view that MRLs are health standards and that exceeding an MRL invariably presents a health risk. Australia considers that Codex MRLs are established primarily for trade purposes with the proviso that they are protective of the health of consumers.
2. Paragraph 6. Please consider some further explanation of the difference between 'national' and 'trade related' programs.
3. Paragraph 9. Definition of 'veterinary drug' differs to that of the procedural manual. Suggest that the current definition be used. Current definitions may also exist for other terms used here such as 'competent authority' and 'risk based' that would be appropriate for use.
4. Section 5, paragraph i. The paper suggests that one of the aims of a residue control programme is to facilitate trade however, historically, unsafe residues have rarely adversely affected trade. The most probable causes of trade problems are use patterns that are region specific and poor registration authority consideration of residues in crops that are then transferred to animals. It is suggested that point (ii) be modified to: *To facilitate trade by providing verification to the wider registration and residue control system.*
5. Paragraph 10, i, iii, iv, v, x. These points all deal with principles of risk based assessment. Aggregation of these points should be considered.
6. Paragraph 23. The last sentence is potentially confusing. Suggest rewording to: 'Dietary exposure is considered during MRL establishment by the use of conservative dietary intake models that account for potential exposure to the residue in all foods. MRLs are not established at levels that would result in consumer exposure to the residue in excess of the ADI.'

7. 10.5, Reporting of Results, Paragraph 89. The reporting of measurement uncertainty, and how it is to be interpreted has not yet been finalised within the Codex process. It is suggested that this paragraph be removed.

8. Paragraph 107. Not all foods require government to government certification on export/import. This paragraph should be modified to reflect this. Suggest addition of ', where required,' after 'certify'.

9. Paragraph 112. Regulatory action levels are generally set in relation to the standard being addressed rather than at a level deemed to 'pose a significant risk to human health'. It is suggested that the final sentence be removed.

10. Paragraph 116. The meaning of 'direct risk to human health' is not clear. A rewording is suggested, perhaps by removing the word 'direct'.

Brazil

Brazil congratulates the Working Group for the work done and considers that the document is well contextualized, enclosing all the issues recommended at the 15ª CCRVDF meeting (ALINORM 05/28/31, paragraphs 120 and 121). Nevertheless, we would like to make the following specific comments:

Section 4 - Definitions

1. Brazil proposes the elimination of the expression "risk based" from Section 4 – Definitions, and its replacement in the rest of the document for "based on risk", regarding that "risk" is already defined in the Guidelines of Codex Procedures - **15th edition.**

2. Brazil proposes the elimination of the item vi from Section 6 – General Principles, "Clearly identify the objectives of those standards or criteria which are not directly human health protection related.", since it is in disagreement with the purposes of the directive proposal.

Canada

Canada thanks New Zealand for the preparation of this version of the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drugs in Foods. Canada recognizes that there are many considerations in the establishment of a regulatory programme to control residues of veterinary drugs in foods and that it is difficult to condense these elements into a single document.

Canada was pleased to have the opportunity to participate in the electronic working group and provided comments on earlier drafts of the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods. Nevertheless, while Canada considers that this version of the draft guidelines is an improvement, we believe that further redrafting is required.

The redrafting should focus on providing greater clarity and conciseness to make it easier for the information in the document to be applied by member nations. The following are a few examples of some of the areas that need to be revisited during the redrafting process:

- the definitions used in the document must be consistent with the definitions already adopted and in use by Codex (e.g. for veterinary drug and residues of veterinary drugs);
- the modifiers used in expressions like Aappropriate practices@ (paragraph 14), Apredominantly@, Aappropriate controls@, Aappropriate levels@ (paragraph 16), Agenerally@ (paragraphs 21 and 24) are somewhat vague for use in a guideline document.
- the references to "facilitating trade" should be replaced by "ensuring fair practices in the food trade" for consistency with Article I, paragraph (a) of the *Statutes of the Codex Alimentarius Commission*;
- the document should provide guidance on appropriate approaches to address acute as well as chronic health concerns related to the residues of veterinary drugs in foods ; and

- the portions of the text relating to methodology and sampling in Parts I-III, as well as Part IV, 11.0 *Sampling Protocol Design and Planning : Statistical Considerations* should not be included in the redrafted document as another Working Group (led by Canada and the Netherlands) has been assigned to revise that information.
- the word "level' is used with a variety of connotations throughout this document. More specific terms should be used to facilitate clarity.

European Community

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 then 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 <u>or prohibited</u> 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 inn 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 is 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.

United States

The United States thanks New Zealand for their Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods, but the U.S. has major concerns, particularly with the overarching principle of CX/RVDF 06/16/8.

CX/RVDF 06/16/8 is intended to update CAC/GL 16-1993 (Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods). In general, we find the first 8 pages of CAC/GL 16-1993, which describe the overall objectives of the control program, to be well written and straightforward. Specifically, the guideline clearly stresses that the guiding principle for the control of veterinary drug residues should be to ensure that compliance with tolerances/MRLs is maintained (*i.e.,* tolerances/MRLs represent safety standards and a control program should ensure and monitor for compliance).

In our reading, the guiding principle of the revised guideline appears to be a continual and undefined risk analysis of residues above tolerances/MRLs. The U.S. is well aware of the conservatisms that go into the human safety assessment of veterinary drug residues. Those conservatisms are reassuring, given the uncertainties inherent in using laboratory animals as models for man. We are also aware that occasionally edible tissues containing residues above the tolerance or MRL will enter the food supply and that they likely will not result in adverse health effects. Nonetheless, we believe the guiding principle for the control of veterinary drug residues should continue to be to ensure that compliance with tolerances/MRLs is upheld.

CX/RVDF 06/16/8 appears to suggest what might be termed an "existential" application of risk assessment that raises questions about the role of the MRL. It is this aspect of the paper that is troubling to the U.S. CX/RVDF 06/16/8 suggests that the acceptance of a food commodity in trade would depend on a risk estimate regardless of the existence of an MRL violation or that somehow the interpretation of an MRL violation is modulated. This seems to run counter to the idea of having an MRL.

The determination and acceptance of an MRL means that, among other things, a risk assessment has been performed as part of the approval/registration process and, accordingly, the MRL becomes the primary operative benchmark. For trade purposes the important capabilities and reference points are the MRL and the means to accurately detect and measure the drug at the MRL and in the immediate analytical vicinity. Sampling plans and the statistics upon which these plans are based are also significant. These measures offer objective elements for qualifying an exporting country's animal products to enter trade and give the importing country some assurance of the exporting country's compliance with accepted standards.

The U.S. believes that trade in animal products should be based on agreed procedures and benchmarks and not on empirical or "existential" risk assessment procedures which can vary and change according to the elements of the specific residue case (and which would (1) strain resources and (2) dictate very rapid risk assessments to prevent spoilage of perishable commodities). Using the MRL as an indicator for a risk assessment, and not as the primary commodity acceptance benchmark, will, in our opinion, result in more contentiousness in international trade issues. We believe an understanding of the rational application of risk assessment in international trade is needed.

In addition, the U.S. has concerns about (1) the length of time that has passed without appreciable progress having been made on CX/RVDF 06/16/8 and (2) the failure of CX/RVDF 06/16/8 to fully address drug residues in milk and milk products. With respect to item (1) the 13th Session of CCRVDF (December 2001) proposed the drafting of the revised paper, but after 4 years the paper remains at Step 3, with significant issues remaining to be decided. Regarding item (2), the 14th Session of CCRVDF “agreed that a drafting group would prepare a revised version of the Appendix [i.e., Proposed Draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products] for incorporation into the proposed draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods (see Agenda Item 8) by the end of 2003 for circulation, comments and further consideration at its 15th Session.” CX/RVDF 06/16/8 includes only negligible mention of milk. We believe the paper on milk to be of value to CCRVDF and hope it will eventually find its way as an appendix to a guideline on a program for residue control.

Specific Comments:

SECTION 1 - INTRODUCTION

1. Paragraph 5 – Is this paragraph indicating that risk-based control and verification assurance system are all that is required to certify the safety of exported food and that importing countries do not need to re-inspect product? As stated this could appear to place the onus on an importing country to justify why it may refuse entry of exports from a country that claims to have a "risk based" production program. The proper procedure would be for the exporting country to demonstrate to the satisfaction of the importing country that its residue control and production program is the equivalent of that in the importing country.

SECTION 4 - DEFINITIONS

2. Paragraph 9 – Replace “with the potential to” with “at a sufficient level to”.

SECTION 6 – GENERAL PRINCIPLES

3. Paragraph 10i. What specifies-"be risk-based"? This first item should be the identification of the specific hazard and after a consideration of the other ten items in this section, perhaps risk could be assessed.

PART 1: GENERAL CONSIDERATIONS

SECTION 7 – DESIGN TOOLS AND PUBLIC HEALTH LINKAGE

7.2 Public Health Linkage

4. Paragraph 21, second sentence “Where the level associated with the potential for an acute effect is less than that associated with a chronic toxicological effect then *they* will reflect this endpoint and *will be further reduced* by the appropriate safety multiples.” It is **not clear** who “they” are. Nor is it clear what will be further reduced.

5. Paragraph 22 - The term "average consumption of residues over time under the ADI" is used. Clarification is again needed here. Does this mean that occasional intake of toxicological concentrations of residues is acceptable?

PART 2: RECOMMENDATIONS

SECTION 9 – CONTROL POINTS

9.1 Introduction

6 Paragraph 43: Comments on extralabel drug use (para 54, 55, 56) were satisfactorily incorporated, however, the mention of **extralabel drug use in paragraph 43** has caused **concern.** Paragraph 43 states “The shutting off of both the avenues and motivation for extensive off-label use or alternative import and/or manufacture of non-sanctioned veterinary drugs, including non-endorsed alternative distribution and sales networks, are also potentially key control points.” We support the second portion of paragraph 43, the shutting off of non-endorsed alternative distribution and sales networks. We do not believe it is proper to include extralabel drug use, which is legally authorized and regulated in countries, among the non-sanctioned/non-endorsed concerns. Some view paragraph 43 as an agenda to eliminate extralabel drug use. We do not believe that emphasis needs to be given to extralabel drug use in paragraph 43 because there are subsequent paragraphs that address the issue, *e.g.*, paragraph 55 specifically addresses off-label use, and other paragraphs generally include off-label use in the guidance provided by the paragraphs, *e.g.*, section 9.2.

9.2 Regulatory Controls over Veterinary Drugs

7. Paragraph 46 – Replace “should be required” with “are required”.

8. Paragraph 48 – What does “Ideally” mean?

9. Paragraph 49 – What does “as far as possible” mean?

9.3 On-farm Recommendations

10. Paragraph 62 – What does "Ideally" mean?

11. Paragraph 64 – Need to clarify what type of communication (verbal, writing, bill of sale, etc.) should be used inform the purchasers of any food harvesting restriction still in place.

SECTION 10 – VERIFICATION and PART THREE: SECTION 11 – INTERNATIONAL ASSURANCES

12. Paragraphs 74, 95 and 121: References to **pesticides** continue to exist within this document, *i.e.*, paragraphs 74, 95, and 121. We do not think this document should include pesticides within its scope.

13. Paragraph 87 – Whose public health objectives?

14. Paragraph 88 – This item suggests that laboratory results can be disregarded or challenged. This is always a possibility, but the details need to be parsed out in more detail.

15. Paragraph 89 – The entire statement is based on a misunderstanding of uncertainty in analytical measurements.

16. Paragraph 94, 6th bullet refers to "**feed**" in addition to "food." Should it not be limited to "food"?

Part Three: Section 11 – International Assurances

17. Paragraph 106 - "it is the practices and controls in place in the exporting country rather than port of entry testing that best ensures safe food" Both of these practices are necessary to ensure safe food. Therefore, one practice is not better than another practice. The port of entry testing confirms or validates that the practices and controls in place in exporting county are effective. The last sentence, what is mean by "other mechanisms"?

18. Paragraph 107 - Is this paragraph suggesting that port of entry testing is not needed? The paragraph needs clarification.

19. Paragraph 117 – It is not clear what action should be taken during the resolution of the problem when a prohibited substance is found. This needs to be clarified.

20. Paragraph 118 – Need to clarify what is meant by the "level of regulatory reaction by the importing party".

IDF

IDF congratulates the drafting group on the preparation of an excellent paper. The guidelines now reflect risk analysis and integrated control measures. As well, guidance is given in relation to the public health risk of exceeding MRL's. This is very useful.

In addition, it is appreciated that the principles of HACCP are applied and, in line with HACCP, the paper states that the control of veterinary drugs should primarily be based on pre harvest measures. The (post harvest) analysis of residues is explicitly not considered as a control measure but as verification of the control. This emphasis is welcomed by the dairy industry.

General Comments

The objectives of the guide are to provide guidance on national control and verification programmes and on import assurance programmes. One problem encountered is with the name of the document. In the Codex request for comments, the guide is entitled: 'Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods". In the attachment, the guide is titled: Guidelines for: The Design and Implementation of Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals. It is important to understand the intent of the Guidelines – are they for regulatory control purposes or for general control purposes? As they are now written, the Guidelines are about integrated control measures related to food safety. IDF would prefer to see consistency in naming the Guidelines by Codex and believe the title would be better as:

Guidelines for: The Design and Implementation of Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals, or:

Guidelines for the Control of Veterinary Drugs in Foods.

It would also be helpful if a definition of verification was given as this term is used in the guidelines for both regulatory enforcement/surveillance programmes and commercial/private programmes. There also appears to be some confusion about who is responsible for "assuring" food safety (see para 3 – where it talks about commercial entities having primary accountability for ensuring food safety, and para 9 where it defines Competent Authorities as responsible for domestic food safety assurances associated with the use of veterinary drugs). The use of the words "ensuring and assuring" and their different applicability may be the problem. Clarity regarding the term verification should help overcome misunderstandings.

Generally, based on risk assessments, the authority develops legal measures (like MRL's) and undertakes enforcement as risk management tools. The commercial entities on the other hand are responsible for the supply of safe food within the legal framework. They should apply ~~risk analysis~~the HACCP principles (Good practices and HACCP) and quality management principles to adhere to the legal standards (MRL's). These Guidelines should provide a clearer distinction between what are regulatory and what are commercial responsibilities and ensure consistency in assigning these responsibilities. The principle described in paragraph 3 is important, particularly as the guidelines are not just about regulatory controls.

Specific comments

Paragraphs 3-5:

Wholeheartedly support these principles.

Paragraph 9

Residue

A residue is not necessarily a hazard. Suggest changing the first sentence as follows:

*Residue: A compound in the food resulting from animals being treated...*etc.

After the last sentence of this definition, add:

Certain residues may have the potential to cause adverse health effects.

Competent authority

In various other international documents (Codex, WHO, FAO), the term "food safety assurance" is used to mean the set of actions taken by the food operator. For instance, these meanings are repeated again and again all along the FAO/WHO "MRA awareness course" (in press).

In order to avoid any misunderstanding in this regard, ~~I~~it may be better, for activities of competent authorities, to ~~change~~ use the word ~~food safety assurances to~~ food safety enforcement or food safety surveillance rather than food safety assurance.

Paragraph 10

The general principles are an excellent basis for (public) risk management and (commercial) control.

In item ix, validation should be removed as the controls are not validated by audits and sampling (see Codex definitions as well as CCFH guidelines on validation (under development).

Paragraph 34

In the last sentence the words risk management are not used according to the definition. Suggest changing the sentence as follows:

Hazard control is only necessary if there is a relevant risk involved.

Paragraph 38:

Reference to an internationally accepted procedure for (quantitative) risk profiling may be appropriate, otherwise it is very likely that different evaluations of the same situation will result in different risk assessments.

Paragraph 132 - 139

The guidance given on sampling plans for system verification appears to be more suitable for (private/commercial) hazard control programmes than for (public/regulatory) enforcement programmes.