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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/RVDF 04/15/6-Add.1**
Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fifteenth Session

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PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR THE CONTROL OF DRUGS IN FOODS

Comments submitted by: Australia, European Community, United States of America, Consumers International and International Dairy Federation

AUSTRALIA

Australia welcomes the further efforts of New Zealand in drafting the revised guideline; in particular, Australia is supportive of the move toward a risk-based approach for the establishment of a regulatory programme for the control of veterinary drugs in food.

Australia would like to offer the following general comments:

While we acknowledge the draft guideline incorporates general principles that are of use for the control of various hazards in livestock product, the remit of this committee is veterinary drugs, therefore Australia feels the guideline text should focus on residues of veterinary drugs with mention of its general applicability confined to the introduction.

Australia is concerned that the language in the text remains flexible enough to encompass the variety of regulatory systems that operate around the world.

Australia believes that although good progress has been made with this draft, further work is required to make it a useful Codex document. While we are unable to support the draft in its present form, Australia is willing to continue to contribute to the further development and refinement of the document.

Australia also makes these specific comments in relation to the current draft of the guideline:

The title “PROPOSED DRAFT CODEX GUIDELINES FOR: THE DESIGN AND IMPLEMENTATION OF FOOD SAFETY ASSURANCE PROGRAMMES FOR HAZARDS ASSOCIATED WITH THE EXPOSURE OF ANIMALS TO CHEMICAL COMPOUNDS IN THE PRODUCTION ENVIRONMENT” is broader than the remit of the committee and should be reflective of the current scope. Suggest replace CHEMICAL COMPOUNDS by VETERINARY DRUGS.

Introduction

Para 1. “amounts of residual hazards in foods at frequencies” be replaced by “residues of veterinary drugs in foods”

Reasoning: residual hazards is not an accepted definition and not yet defined. Additionally residues of some drugs can elicit an acute response, single meal, and so the use of the term frequencies is not relevant.

Para 2 “from being exposed to unacceptable amounts of associated hazards at frequencies likely to compromise their health” is replaced by “from unacceptable levels of exposure”

Para 4. The application of a risk-based system to all food types should ensure the level of control and verification required is relative to the burden of risk that the food type contributes to society.

Suggest replace “society” by “consumers”.

Para 5. Risk profiles for different hazards may vary by country, region, species and/or production system. The application of a risk-based control and verification assurance system should provide the necessary basis for exporting countries to certify the safety of exported food, and for importing countries to have the confidence to accept such consignments.

As the risk profiles can differ for regions, countries the second sentence does not follow and suggest it is deleted.

Scope

Para. 6. Suggest replace “residual hazard” by “veterinary”.

Para 7. Suggest replace “residual hazard” by “other hazards”.

Objectives

Para 8. “The construct and elements of national control and verification programmes to assure that the residual hazards associated with the use of and/or exposure to chemical compounds are sufficiently controlled so that they are unlikely to have an undue adverse impact on the health of consumers of animal products.”

Suggest replace “residual hazards” by “residues” and replace “chemical compounds” by “veterinary drugs”.

Suggest replace “The elements and operation of import assurance programmes for chemical associated residual hazards” by “The elements and operation of import assurance programmes for residues of veterinary drugs”.

Definitions

Para 9. Suggest delete the definition for residual hazard as it is not a term in common usage in Codex, CCRVDF and is unnecessary in a guidance document focusing on residues of veterinary drugs. However, as the guideline would be a useful reference for the control of residues in livestock of agricultural pesticides and environmental contaminants, it is suggested that the introduction draw the reader’s attention to this fact.

Change “adverse effect” to “adverse health effect”.

General Principles

Para 10. Control and verification programmes for residual hazards associated with chemicals used or present on farms or feeds should:

Replace “residual hazards” with residues and chemicals with veterinary drugs.

iv) In *Consider the possible risks profiles associated with both approved and non-approved chemicals in the production system* replace “chemicals” by “veterinary drugs”.

Section 7. Design Tools and public health linkage

Para 11. In “The production of animal products for human consumption is an integrated process with multiple parties contributing to the control of chemical related residual hazards” replace “chemical related residual hazards” with “residues of veterinary drugs”.

Para 21. In “Agricultural chemicals are regulated in many countries for a variety of reasons” replace “agricultural chemicals” by “veterinary drugs”.

Para 22. Suggest delete, as it is not within the mandate of the Committee to consider biological, physical or chemical residues that are not veterinary drug related.

Para 23. Replace “Residual hazards” with “Residues of veterinary drugs” for both occurrences.

Para. 26 Suggest delete the last sentence, as this is not true of compounds evaluated both by JMPR and JECFA. "Maximum Residue Limits (MRLs) are monitoring tools. Foods containing residues above an MRL are not inherently unsafe. MRLs are concentrations and are food/tissue specific. They are set at levels at least low enough to ensure that even high-level consumers will not consume more than the ADI if they eat large quantities of every food type containing the residue at the MRL for that food type." That is JMPR utilizes a different approach to exposure assessment that involves refinement of the TMDI approach outlined in the last sentence.

Para 27 Suggest is shortened to read "Generally, MRLs reflect the level of residue that should be achievable in the majority of the various edible tissues of treated animals if the veterinary drug is used as per the veterinary drug's label and foods are harvested from the animal production system after the recommended withdrawal period has expired."

Para 28. Veterinary drugs are used for purposes other than disease control, therefore it is suggested that "animal disease" be replaced by "animal disease/pest".

Para 30. Verification programmes should be instigated on a risk basis, therefore it is suggested that the 2nd sentence be modified to "As such they are normally risk based and involve non-biased sampling …..…"

Para 32. "Targeted verification programmes involve the directed sampling of specific suppliers or products considered to pose a greater likelihood of not complying with one of the controls and/or having non-compliant amounts of residual hazard associated" suggest replace "amounts of residual hazard associated" by "residues".

Para 35 Suggest 2nd sentence be modified to "Objectives of surveys may include the *risk based* collection of base-line ….". Suggest that in the last sentence "residual hazard" be replaced by "residue".

Section 8 – Review and ranking of hazards

Para 37 Replace "residual hazards" by "residues."

Para 39. Replace "residual hazards" by "residues."

Para 42. Suggest delete 1st dot point "What type of residual hazard…"

Suggest replace "residual hazard" by "residues" in the remaining dot points.

Section 9 Control Points

NOTE the footnote to the section heading 9.2 Regulatory Controls over Veterinary Drugs and Pesticides states "Pesticides are outside the formal scope of this guide". This should be replaced by "Pesticides, other than those for direct animal treatment, are outside the formal scope of this guide" as various insecticides can fall within the scope of CCRVDF, eg cypermethrin.

Para 44. In this context formulated drugs and pesticides are being addressed. Suggest delete "formulations of" as it is essentially duplication.

Para 46. Use of term "off label" ("extra label" used in many countries) – suggest a definition. This term invariably can be interpreted to mean use of non-sanctioned chemicals (i.e. not registered by relevant authority for example) versus use of sanctioned chemicals contrary to the approved directions for use.

Para 48. It is unclear as to the competent authority referred to. Is it the authority responsible for authorizing marketing of the veterinary drug, the authority certifying the production system? As there may be several authorities involved depending on the regulatory framework employed we suggest using the plural in the sentence "For veterinary drugs and pesticides it is important that the competent authorities tasked with providing assurances have a sufficient level of control over and knowledge of what veterinary drugs are being sold and used within the production systems".

Para 49. Suggest delete "formulations of'".

Para 50. Suggest replace "formulations" with "veterinary drugs and pesticides".

Para 51. Suggest replace "formulations" with "ingredients and veterinary drugs and pesticides not on these lists for use on/in food producing animals." In some countries, veterinarians have the right to formulate animal medicines within a general authority to treat animal conditions and these may not necessarily require specific approval by a central competent authority.

Para 58. Need to define “off-label”. See comments on Para 46.

Para 59 Is it the deliberate intention here to circumscribe a registered veterinarian’s ability to prescribe veterinary drugs? Australia supports veterinarians right to prescribe with the caveat that unregistered drugs should not be used on/in food producing animals. Noting this and the comments below, it is suggested that this para and section 9.3c be expanded to include laying hens,

Para 63. The meaning of this paragraph is not clear. Try “The food control system for milk production should be capable of providing assurances to consumers that milk does not contain unacceptable residues of veterinary drugs likely to give rise to health concerns.”

Para 64-66 Suggest the (1) first sentence of para 66 becomes para 64, (2) the current para 64 is renumbered 65 (3) current para 65 and second sentence of current para 66 is deleted. The desired outcome that milk within a WHP does not enter the vat is captured in the first sentence of para 66. The more prescriptive sentences of para 65 and second sentence of para 66, do not reflect common on- farm practice in Australia. For example, cows within a WHP may not be kept separate, but will certainly be appropriately identified, and cows within a WHP may not be milked after the rest of the herd, but may for example, be milked into a bucket thereby avoiding the milking lines and vat.

Suggest replace “residual hazards” by “residues”.

Para 72. Although this paragraph proposes a performance based risk control approach (which is reasonable), it seems to imply a single control model (which would be unnecessarily restrictive).

Para 77 Suggest replace “residual hazard” by “residues”.

Para 81 Suggest “*residual hazards*” be replaced by “*residues*

Para 86 Point of sampling for milk. Sampling in the Australian milk residue survey is generally taken at the tanker level and may comprise production from more than one farm. The important point in relation to system management is about the ability to trace to farm of origin in the event of a positive test result. Suggest expansion of second sentence to ‘……collected from the farm, or where not practicable that identification systems can readily identify milk from its farm of origin in the event of a positive result’ (or similar).

Para 97 It is assumed that 6th dot point is intended to cover residues in animal products from both direct animal treatments and indirect exposure in feeds. We suggest “animals” is changed to “sources” and “food harvest” is expanded to “food/feed harvest” to be consistent with the rest of the sentence.

Para 101. We suggest the last sentence of this paragraph be changed to “This should be coupled with follow-up verification appropriate to the circumstances to ensure the required corrective actions have been put in place and are being applied.”

Para 103 Should “sector” be replaced with “authority”? The intention of this paragraph is not clear.

Para 106 Second line – remove “in the” after “non compliance”.

Title to table 2, needs explanation of sample size. Suggest insert text from the existing guideline:

“The probability of failing to detect a residue violation and accepting the lot depends upon the directed sampling programmes, sample size and prevalence of the residue violation frequency. Table 2 shows the probability of failing to detect a residue violation using different sample sizes from an "infinite" population with a specified proportion of violations. For example, selecting 5 samples from a large lot in which 10 percent of the units contain violative residues would, on the average, fail to detect a residue violation in 59.0 percent of such lots (i.e., 59.0 percent of the lots would be accepted). Assuming the same conditions as the previous example, but using a sample size of 50, would result in only 0.5 percent of such lots being accepted.”

Q. The draft guideline has omitted parts of GL 16, e.g. sample sizes. Should some of the omitted material be incorporated into the new draft guideline?

EUROPEAN COMMUNITY

English

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 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 competencies[1].

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*".

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

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 microorganisms have a potential to grow at every stage of the food chain[2]. 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.

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[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)

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.

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, <u>laying eggs and honey bees</u> should be used in these animals <u>when milk, eggs or honey, respectively, are collected for human consumption"</u>*.

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 "i*nvestigation*". 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."*

Spanish

La Comunidad Europea agradece a la delegación de Nueva Zelanda la preparación de este amplio documento, con cuyo planteamiento está, en general, de acuerdo, no obstante algunas observaciones que se exponen a continuación.

Ámbito del documento

No queda claro cuál es el ámbito preciso del documento. En el punto 6 se dice que su propósito *«es proporcionar los principios y orientaciones generales sobre el diseño y la implementación de programas de aseguramiento de la inocuidad de alimentos, relacionados tanto con los gobiernos nacionales como con las finalidades del comercio, para los peligros residuales asociados con la exposición de animales a medicamentos veterinarios en el entorno de la producción»*. Sin embargo, en el punto 9 se define el término *«peligro residual»* como *«un agente biológico, químico o físico en o sobre el alimento, que tenga la posibilidad de causar un efecto de salud adverso como una consecuencia del tratamiento de animales productores de alimentos con compuestos químicos o de la exposición a éstos en el sistema de producción»*. Esto parece excesivo para el documento en cuestión. Por otro lado, en el punto 49 se dice que *«sería conveniente que se exigiera que todas las formulaciones de medicamentos veterinarios y plaguicidas fabricadas o importadas en el país fueran registradas en un registro nacional antes de permitir su uso»*.

Teniendo en cuenta el mandato del Comité del Codex sobre Residuos de Medicamentos Veterinarios en los Alimentos (CCRVDF), los peligros en cuestión podrían estar relacionados o bien con los compuestos químicos, o bien con la resistencia a los antibióticos que su uso provoca. Sin embargo, la definición del término *«compuesto químico»* (punto 9) incluye compuestos que entran en el ámbito de competencias de otros comités del Codex como son el CCPR (Comité del Codex sobre Residuos de Plaguicidas) y el CCFAC (Comité del Codex sobre Aditivos Alimentarios y Contaminantes de los Alimentos). Además, los términos *«químicos»*, *«compuestos químicos»*, *«compuestos químicos agrícolas» y «formulaciones»* se emplean a lo largo del texto como sinónimos.

Entendemos que el ámbito del documento debería estar relacionado con el mandato del CCRVDF y, por lo tanto, limitarse a los compuestos que se utilizan intencionadamente en animales productores de alimentos, incluidos los utilizados de forma ilícita.

Definiciones

Con respecto a las observaciones referidas al *«ámbito»*, es importante que el documento haga una distinción más clara entre el uso legal e ilegal. Hay, pues, que definir el uso/tratamiento ilegal, por ejemplo, como sigue: *«el uso de compuestos o medicamentos veterinarios/especialidades farmacéuticas no autorizados, o el uso de estos compuestos/productos en condiciones distintas a las autorizadas»*.

La definición de *«peligro residual»* debería sustituirse por la siguiente definición de *«peligro»*: *«A los efectos del presente documento, todo efecto adverso sobre la salud derivado del tratamiento de los animales productores de alimentos con compuestos químicos, o de su exposición a los mismos, en el sistema de producción»*. Quedarían así incluidos los residuos de compuestos químicos y la resistencia a los antibióticos provocada por su uso.

La definición de *«compuesto químico»* incluye compuestos que, en el sistema del Codex Alimentarius, están cubiertos por otros comités como son el CCPR y el CCFAC. Tiene que discutirse si la guía debería ser aplicable fuera del mandato del CCRVDF.

Debería reconsiderarse la necesidad e idoneidad de una definición del término inglés *«food animal(s)»*, en particular si se tiene en cuenta que en la definición de medicamento veterinario se emplea el término *«food producing animals»*.

El término *«autoridad(es) competente(s)»* podría definirse con más precisión como *«la autoridad gubernamental de un país responsable del programa de control de residuos de medicamentos veterinarios en los alimentos, o cualquier otra autoridad en la que aquella haya delegado tal competencia»*. El término *«país»* incluiría las organizaciones de integración económica regional a las que un grupo de países hubieran transferido las competencias pertinentes[4].

La definición de *«basado en el riesgo»* debería modificarse como sigue, para que sea coherente con la definición de riesgo del Manual del Codex Alimentarius: *«Centrado en una estimación de la probabilidad y gravedad de un efecto adverso en los alimentos, y proporcionado a esta estimación»*.

Debería añadirse una definición de *«periodo de retirada»*, por ejemplo: *«El periodo transcurrido entre la última administración del medicamento veterinario al animal y el momento en que puedan utilizarse sus tejidos/productos para la producción de alimentos destinados al consumo humano»*.

Objetivos y principios generales

De acuerdo con el inciso v del punto 10, los programas de control y verificación para peligros residuales deberían *«ser proporcionales al riesgo relativo de la salud humana asociado con estos peligros en comparación con otros peligros asociados con los alimentos»*. Esto requeriría hacer comparaciones entre diferentes tipos de peligros, lo cual sería imposible. Sugerimos, por tanto, una redacción alternativa: *«ser proporcionados a fin de equilibrar el riesgo para la salud humana con las medidas necesarias para eliminarlo»*.

Herramientas de diseño y conexión con la salud pública; aplicación del sistema HACCP

Si bien estamos de acuerdo con la idea general de aplicar el sistema HACCP para el diseño de programas de control de residuos, querríamos hacer hincapié en que habría que trabajar más los puntos 17 a 20 para ilustrar con más detalle la manera en que ha de aplicarse dicho sistema a un programa de control de residuos. Además, propondríamos modificar el punto 16 como sigue: *«Los principios del análisis de riesgos y del sistema de análisis de peligros y puntos de control crítico (HACCP) pueden aplicarse a los programas nacionales de control y verificación y servir de orientación en el diseño y la verificación de los programas de control, a fin de garantizar su rentabilidad y su eficacia con respecto a la protección de la salud humana»*.

[4] Véanse las Directrices del CCFAC para la Elaboración de Acuerdos de Equivalencia sobre Sistemas de Inspección y Certificación de Importaciones y Exportaciones de Alimentos (CAC/GL 34 –1999).

Conexión con la salud pública/objetivos de inocuidad de los alimentos

No debería utilizarse el término *«objetivo de inocuidad de los alimentos»* (OIA, punto 25) en relación con los riesgos de las sustancias químicas. El Comité del Codex sobre Higiene de los Alimentos (CCFH) ha establecido OIA en relación con el *«Anteproyecto de Principios y Directrices para la Aplicación de la Gestión de Riesgos Microbiológicos»*, a fin de tener en cuenta el hecho de que los microorganismos pueden crecer en cualquier fase de la cadena alimentaria[5]. Esto no es cierto ni pertinente con respecto a los peligros relacionados con el tratamiento de animales productores de alimentos con compuestos químicos[6].

Nos resulta difícil seguir el razonamiento que hay detrás de los puntos 24 a 28. El planteamiento descrito parece cuestionar el procedimiento para fijar límites máximos de residuos (LMR) sobre la base de las ingestas diarias admisibles (IDA). No lo creemos aconsejable, dado que el sistema actual ha sido armonizado internacionalmente para una amplia serie de compuestos (por ejemplo, plaguicidas, agentes contaminantes, aditivos alimentarios, aditivos para piensos o medicamentos veterinarios).

No podemos estar de acuerdo con que se sustituya el sistema actual, consistente en utilizar los límites máximos de residuos (LMR) como límites de control, por el enfoque descrito en los puntos 28 y 83. En este último punto se dice que *«los actos de retiro son solamente justificados tomando la salud como base, si los resultados indican la existencia de un riesgo inminente y agudo para la salud humana»*. Esto parece sugerir o bien que en cada caso se lleva a cabo una determinación científica del riesgo específica, o bien que han de establecerse tolerancias específicas aparte de los LMR existentes. Este planteamiento no ayudará a facilitar el comercio, y no hará más que complicar los procedimientos de importación; exigiría una evaluación de la exposición relacionada con la cantidad importada, y los respectivos LMR aplicables a la importación tendrían que reconsiderarse con frecuencia. Además, entendemos que este planteamiento viene a permitir el uso de un mayor número de compuestos químicos si la situación de un país con respecto a la enfermedad así lo requiere, y esto, entre otras cosas, castigaría indirectamente a aquellos que invierten en la prevención de enfermedades por otros medios distintos al tratamiento con compuestos químicos, como son la mejora de los establos y los procedimientos de cuarentena.

Estadística y muestreo (punto 30 y puntos 123 y siguientes)

En nuestra opinión, el documento no debería preocuparse tanto por la significación estadística de los resultados del muestreo no sesgado y centrarse más bien en el suministro de información para optimizar el sistema reglamentario. La significación estadística es importante para programas dirigidos a evaluar la exposición de los consumidores. Los correspondientes programas pueden estar en marcha durante años y reunir datos suficientes para producir unos resultados estadísticamente significativos.

Con respecto a los *«programas de verificación»*, debe tenerse en cuenta (como queda dicho en el punto 116) que *«las remesas de productos animales tienden a ser heterogéneas por naturaleza y con frecuencia estarán formadas por mezclas de productos de una variedad de animales y fuentes»*. Por lo tanto, sólo pueden obtenerse resultados estadísticamente significativos si se toma y analiza un número desproporcionado de muestras. Además, el muestreo estadístico/no sesgado contradice el objetivo global del documento de utilizar los ensayos como herramienta de verificación y apoyarse más en medidas de control de la producción para garantizar la inocuidad de los alimentos (véase también el punto 114). Por otro lado, un sistema de control que funcionara correctamente daría como resultado una baja prevalencia de incumplimiento y, por lo tanto, exigiría un número aún mayor de muestras conforme a la tabla 1 de la página 22.

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5 Véase ALINORM 04/27/13, apartados 63-90 y apéndice III.

6 Así pues, en la definición elaborada por el CCFH tendría que leerse el término «*microbiológico»* donde se indica a continuación: «***Objetivo de inocuidad de los alimentos (OIA):*** *frecuencia y/o concentración máximas de un peligro (microbiológico) en un alimento en el momento de consumo que proporciona el nivel adecuado de protección (NAP) o contribuye a lograr éste»*. Por otro lado, el CCFH *consideró «que, cuando las medidas de control se deban diseñar para lograr un determinado nivel de control de peligros, sería demasiado restrictivo tener solamente en cuenta el establecimiento de un objetivo de inocuidad de los alimentos (OIA); por lo tanto, el Comité acordó incluir una referencia general a los "OIA y/u objetivos y criterios conexos"»*. (Control de peligros alimentarios, sección 5.1, apartado 30 de ALINORM 04/27/13).

Registro y aprobación/autorización de compuestos/productos

De acuerdo con el punto 49, *«sería conveniente que se exigiera que todas las formulaciones de medicamentos veterinarios y plaguicidas fabricadas o importadas en el país fueran registradas en un registro nacional antes de permitir su uso»*. Sin embargo, las sustancias químicas que se utilizan de forma ilegal a menudo no se importan o producen para su uso en animales (por ejemplo, verde de malaquita). El procedimiento de registro propuesto generaría mucho trabajo administrativo y tendría, probablemente, poco que aportar. Así pues, proponemos sustituir la frase por el siguiente texto: *«Los países deberían identificar y aprobar los compuestos químicos farmacológicamente activos y las condiciones legales en que pueden administrarse a animales productores de alimentos, e introducirlos en un registro público nacional»*.

Consecuentemente con los cambios propuestos en el punto 49, el punto 50 debería rezar así: *«La inclusión de un compuesto químico en el registro nacional debería basarse en una evaluación científica favorable con respecto a los beneficios y los riesgos que su uso entraña. Para este procedimiento deberían establecerse diversos requisitos y criterios, que podrían guardar relación con la aprobación o las evaluaciones de otras autoridades competentes allí donde los patrones de uso pudieran ser similares»*.

Además, proponemos modificar los puntos 51 a 53 como sigue:

Punto 51: *«El uso de compuestos químicos no incluidos en el registro nacional debería ser convenientemente perseguido»*.

Punto 52: *«Los países deberían establecer reglas sobre las sanciones aplicables si se usan en animales productores de alimentos, o se encuentran en productos animales, compuestos químicos no registrados. Asimismo, deberían tomar todas las medidas necesarias para asegurarse de que estas reglas se aplican y de que las sanciones previstas son eficaces, proporcionadas y disuasorias»*.

Punto 53: *«Los países deberían asegurarse — por ejemplo a través de la información y la formación— de que los compuestos químicos son utilizados de forma competente por usuarios competentes, a fin de comercializar animales que proporcionen una alimentación segura y saludable de tal forma que se proteja la salud pública»*.

Recomendaciones para las explotaciones

El punto 59 debería ampliarse del siguiente modo: *«Solamente aquellos medicamentos veterinarios aprobados específicamente para el uso en animales productores de leche, aves ponedoras y abejas melíferas deberían ser utilizados en estos animales cuando se recojan, respectivamente, leche, huevos o miel para el consumo humano»*.

El punto 60 parece que se refiere a la seguridad de la persona que administra los compuestos químicos a los animales y, por lo tanto, puede estar fuera del ámbito del documento.

El punto 62 podría modificarse y ampliarse como sigue: *«Deberían llevarse registros de todos los detalles del tratamiento, por ejemplo el tipo de compuesto químico administrado, la naturaleza y la fecha del tratamiento, la identidad de los animales tratados y la fecha de expiración del periodo de retirada. Tales registros deberían ponerse a disposición de la autoridad competente si así lo solicitara»*.

En los puntos 63 a 66 habría que añadir también la referencia a las aves ponedoras, las abejas melíferas y los peces, moluscos y crustáceos de acuicultura.

Principios y función de los programas de verificación

El punto 70 podría completarse como sigue: *«En esta confianza se basaría la expedición de los certificados oficiales que acompañarían a las partidas»*. En el punto 76 habría que explicar mejor el sentido y la importancia de los *«atributos del perfil»*.

Duplicaciones con el documento CX/RVDF 04/15/7 parte II

Deberían comprobarse las duplicaciones que presentan las observaciones de los puntos 85 a 90 con el documento CX/RVDF 04/15/7 Parte II «*Consideraciones Generales sobre Métodos Analíticos para el Control de Residuos*» de las *Directrices para el Establecimiento de un Programa Reglamentario para el Control de Residuos de Medicamentos Veterinarios en los Alimentos*.

Resultados analíticos (puntos 82 a 103)

En el punto 92 se dice que *«los resultados analíticos que sean iguales o mayores al LMR no deberían ser expresados como números discretos sino como un rango de valores en el que el laboratorio confía que se encuentra el resultado verdadero (el intervalo de confianza). Cuando el rango informado abarca un nivel tanto superior como inferior al LMR, entonces no es posible concluir definitivamente que el resultado se encontraba fuera de cumplimiento»*. Esto no haría sino crear una incertidumbre mayor, sobre todo porque, en muchas ocasiones, el método de muestreo es la mayor fuente de incertidumbre. Antes bien, debería exigirse que los métodos se validen de forma que se garantice que los resultados obtenidos ofrecen una confianza precisa en el resultado (por ejemplo, un límite de confianza del 95 %).

En el punto 94 proponemos que se sustituya *«analizado»* por *«investigado»*, y del mismo modo, en el punto 96, *«este análisis»* por *«esta investigación»*. Asimismo, en el punto 98, el término *«reconocimiento»* debería sustituirse por *«aprobación»* o *«autorización»*.

Respuesta reglamentaria a los incumplimientos detectados (puntos 99 a 108)

El punto 99 debería redactarse en un lenguaje más llano, por ejemplo: *«Si las investigaciones pusieran de manifiesto la ineficacia de un programa reglamentario para el control de los residuos de medicamentos veterinarios en los alimentos, deberían adoptarse las acciones/medidas correctoras apropiadas. El tipo de acciones/medidas puede depender del tipo de compuesto químico, el tipo de producción animal o el alimento de que se trate, y debería ser proporcionado al peligro y la frecuencia con que éste se presenta. Los efectos de las acciones/medidas deberían evaluarse mediante una verificación específica»*.

French

La Communauté européenne remercie la délégation de Nouvelle-Zélande d'avoir préparé ce document complet. D'une manière générale, nous partageons l'approche exposée dans ce document; toutefois, nous avons également un certain nombre de remarques à formuler.

Champ d'application du document

Le champ d'application précis du document n'est pas clair. Il est indiqué au point 6 que le document «*vise à donner les principes généraux et des conseils concernant la conception et la mise en œuvre de programmes nationaux d'assurance de la sécurité alimentaire au niveau commercial pour les dangers résiduels liés à l'exposition des animaux à des médicaments vétérinaires dans l'environnement de production*». Cependant, le terme «*danger résiduel*» est défini au point 9 comme «*un agent biologique, chimique ou physique présent dans ou sur l'aliment et pouvant être préjudiciable à la santé à la suite du traitement ou de l'exposition des animaux destinés à l'alimentation à des composés chimiques dans le système de production*», ce qui semble aller plus loin que ce qui est requis pour le document. De plus, le point 49 indique qu'«*il est souhaitable que toutes les formules de médicaments vétérinaires et de pesticides fabriquées ou importées dans le pays soient inscrites dans un registre national avant de pouvoir être utilisées*».

Compte tenu du mandat du CCRVDF, les dangers en question pourraient être liés soit aux composés chimiques, soit à la résistance aux antimicrobiens résultant de leur utilisation. Cependant, la définition des «*composés chimiques*» (point 9) inclut des composés qui relèvent du mandat d'autres comités du Codex tels que le CCPR (pesticides) et le CCFAC (contaminants). De plus, les termes «*produits chimiques*», «*composés chimiques*», «*produits chimiques agricoles*» et «*formules*» sont utilisés comme synonymes tout au long du texte.

Selon nous, il importe que le champ d'application du document corresponde au mandat du CCRVDF et soit donc limité aux composés utilisés intentionnellement pour les animaux destinés à l'alimentation, y compris les composés utilisés d'une manière illicite.

Définitions

En ce qui concerne les remarques formulées dans la section «*Champ d'application*», il est important que le document distingue plus clairement l'utilisation licite de l'utilisation illicite. C'est pourquoi l'utilisation/le traitement illicite doit être défini, par exemple, comme «*l'utilisation de composés ou de médicaments vétérinaires non autorisés ou l'utilisation de ces composés/produits dans des conditions autres que celles qui sont autorisées*».

La définition du danger résiduel devrait être remplacée par celle-ci: «*Danger: aux fins du présent document, tout effet préjudiciable à la santé à la suite du traitement ou de l'exposition des animaux destinés à l'alimentation à des composés chimiques dans le système de production*». Cette définition couvrirait les résidus de composés chimiques ou la résistance aux antimicrobiens résultant de leur utilisation.

La définition du *composé chimique* inclut des composés qui, dans le système du Codex Alimentarius, sont couverts par d'autres comités tels que le CCPR et le CCFAC. Il y a lieu d'examiner s'il convient que la directive s'applique en dehors du mandat du CCRVDF.

Il importe de reconsidérer la nécessité et le bien-fondé d'une définition des «*food animal(s)*» (*animaux destinés à l'alimentation)*, en particulier parce que le terme de «*food producing animals*» (*animaux destinés à l'alimentation*) est utilisé dans la définition des médicaments vétérinaires.

Le terme d'«*autorités compétentes*» pourrait être défini plus précisément comme «*l'autorité gouvernementale d'un pays responsable du programme de contrôle des résidus de médicaments vétérinaires dans les aliments ou toute autre autorité à laquelle cette autorité a délégué cette compétence*». Le terme de «*pays*» englobe les organisations régionales d'intégration économique auxquelles un groupe de pays a transféré les compétences nécessaires[7].

Il convient de modifier la définition de «*basé sur le risque*» comme suit afin d'assurer la cohérence avec la définition du risque dans le Manuel du Codex Alimentarius: «*Concentré sur et proportionnel à une estimation de la probabilité et de la gravité d'un effet négatif se produisant dans les aliments*».

Une définition du «*délai d'attente*» doit être ajoutée, par exemple: «*délai entre la dernière administration du médicament vétérinaire à l'animal avant que les tissus/produits de l'animal puissent être utilisés dans la production d'aliments destinés à la consommation humaine*».

Objectifs et principes généraux

Le point 10. v. dispose que les programmes de contrôle et de vérification des dangers résiduels devraient «*être proportionnels au risque relatif pour la santé humaine lié à ces dangers par rapport à d'autres dangers liés à des aliments*». Cet énoncé semble induire une comparaison entre différents types de risques, qui serait impossible à établir. C'est pourquoi nous proposons un autre libellé: «*être proportionnels pour trouver un juste équilibre entre le risque pour la santé humaine et les mesures visant à l'éliminer*».

Outils de conception/lien avec la santé publique, application HACCP

Si nous sommes d'accord avec l'idée générale d'appliquer le système HACCP à la conception des programmes de contrôle des résidus, nous souhaitons souligner que les points 17 à 20 devraient être développés davantage pour exposer plus en détail la façon dont le système HACCP doit être appliqué à un programme de contrôle des résidus. En outre, nous proposons de modifier la point 16 comme suit: «*L'application des principes de l'analyse des risques et du système HACCP aux programmes nationaux de contrôle et de vérification peut donner une orientation pour la conception et la vérification des programmes de contrôle en vue de garantir qu'ils sont rentables et efficaces en matière de protection de la santé humaine*».

Lien avec la santé publique/objectifs de sécurité alimentaire

Le terme d'«*objectif de sécurité alimentaire*» (OSA, point 25) ne devrait pas être utilisé en relation avec les risques chimiques.

Les OSA ont été élaborés en relation avec l'«*Avant-projet de principes et lignes directrices pour la conduite de la gestion des risques microbiologiques*» par le Comité du Codex sur l'hygiène alimentaire (CCFH) pour faire face au fait que les micro-organismes sont capables de se développer à chaque étape de la chaîne alimentaire[8]. Ils ne conviennent pas pour les risques liés au traitement des animaux destinés à l'alimentation avec des composés chimiques[9].

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[7] Voir la directive du CCFAC pour l'élaboration d'une équivalence concernant les systèmes d'inspection des importations et des exportations alimentaires (CAC/GL 34 –1999).

[8] Voir ALINORM 04/27/13, paragraphes 63-90 et annexe III.

[9] C'est pourquoi, dans la définition mise au point par le CCFH, le mot «microbiologique» doit être lu dans la définition du terme tel qu'indiqué: ***Objectif de sécurité sanitaire des aliments:*** *fréquence maximale et/ou concentration maximale d'un danger (microbiologique) présenté par un aliment au moment de sa consommation et qui assure ou contribue à*

Nous avons quelque difficulté à suivre la logique qui sous-tend les points 24 à 28. L'approche décrite semble mettre en question la procédure consistant à fixer les limites maximales de résidus (LMR) sur la base des doses journalières admissibles (DJA). Nous considérons que cela ne serait pas souhaitable, étant donné que le système actuel a été harmonisé au plan international pour une large série de composés (par exemple les pesticides, les contaminants, les additifs alimentaires, les médicaments vétérinaires).

Nous ne pouvons approuver la démarche consistant à remplacer le système existant, qui utilise les limites maximales de résidus (LMR) comme limites de contrôle, par l'approche décrite aux points 28 et 83. Ce dernier point précise que «*un rappel n'est justifié en matière de santé que si les résultats indiquent un risque aigu et imminent pour la santé humaine*». Cela semble indiquer soit que, dans chaque cas, une évaluation scientifique spécifique des risques est réalisée, soit que des tolérances spécifiques sont élaborées indépendamment des LMR existantes. Cette approche ne contribuera pas à faciliter les échanges, mais ne fera que rendre les procédures d'importation plus compliquées. L'approche nécessiterait une évaluation de l'exposition liée au volume des importations, avec des «LMR d'importation» respectives qu'il faudrait reconsidérer fréquemment. De plus, selon nous, l'approche revient à permettre d'utiliser plus de composés chimiques si la situation sanitaire d'un pays particulier l'exige. Notamment, cela pénaliserait indirectement ceux qui investissent dans la prévention des maladies par des moyens autres que le traitement avec des composés chimiques, tels que de meilleures étables et des procédures de quarantaine.

Statistiques et prélèvement d'échantillons (page , point 30 et pages 21 à 23)

Nous considérons que le document ne devrait pas se préoccuper tant de la signification statistique des résultats du prélèvement d'échantillons sans erreur, mais se concentrer plutôt sur le retour d'information pour optimiser le système réglementaire. La signification statistique est importante pour les programmes axés sur l'évaluation de l'exposition des consommateurs. Les programmes respectifs peuvent s'étendre sur des années et permettre de collecter suffisamment des données pour produire des résultats statistiquement pertinents.

Pour les «*programmes de vérification*», il y a lieu de prendre en considération (comme indiqué au point 116) le fait que «*les chargements de produits d'origine animale ont tendance à être hétérogènes par nature et seront souvent composés d'un mélange de produits provenant d'un éventail d'animaux et de sources*». Par conséquent, des résultats statistiquement significatifs ne peuvent être obtenus que si des nombres disproportionnés d'échantillons sont prélevés et analysés. De plus, l'échantillonnage statistique/sans erreur va à l'encontre de l'objectif général du document visant à utiliser le contrôle comme outil de vérification et de se fier davantage aux mesures de contrôle de la production pour garantir la sécurité alimentaire.

En outre, un système de contrôle efficace produirait une faible prévalence des infractions et nécessiterait de ce fait des nombres d'échantillons plus élevés encore que ceux indiqués au tableau 1, page 22.

Homologation et autorisation des composés/produits

Le point 49 considère qu'«*il est souhaitable que toutes les formules de médicaments vétérinaires et de pesticides fabriquées ou importées dans le pays soient inscrites dans un registre national avant de pouvoir être utilisées*». Toutefois, les produits chimiques utilisés de manière illicite ne sont généralement pas importés ou produits pour être utilisés chez les animaux (par exemple le vert malachite). Il résulterait de la procédure d'homologation telle que proposée une charge administrative importante avec probablement peu de résultats. C'est pourquoi nous proposons de remplacer la phrase par celle-ci: «*Les pays doivent identifier et approuver les composés chimiques pharmacologiquement actifs et les conditions légales dans lesquelles ils peuvent être administrés aux animaux destinés à l'alimentation et les inscrire dans un registre national public*.»

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assurer le degré approprié de protection de la santé. De plus, le CCFH a reconnu que «*lorsqu'il fallait concevoir des mesures pour atteindre un niveau déterminé de maîtrise des dangers, il était trop restrictif de ne tenir compte que de l'objectif de sécurité sanitaire des aliments. Par conséquent, il est convenu de couvrir les "objectifs de sécurité sanitaire des aliments et/ou objectifs et critères connexes"*». (Maîtrise des dangers alimentaires, section 5.1, point 30 d'ALINORM 04/27/13).

En conséquence des modifications apportées au point 49, le point 50 devrait être libellé comme suit: «*L'inclusion d'un composé chimique dans le registre national doit se fonder sur une évaluation scientifique favorable des bénéfices et des risques liés à l'utilisation du composé chimique. Pour cette procédure, il convient d'établir des exigences et des critères pouvant inclure des liens avec l'approbation ou l'évaluation d'autres autorités compétentes lorsque ces dernières utilisent des modèles qui sont susceptibles d'être similaires*».

De plus, nous proposons que les points 51 à 53 soient modifiés comme suit:

Point 51: «*L'utilisation de composés chimiques non énumérés dans le registre national doit faire l'objet de poursuites appropriées*».

Point 52: «*Les pays fixent des règles quant aux sanctions applicables lorsque des composés chimiques non homologués sont utilisés chez les animaux destinés à l'alimentation ou détectés dans des produits animaux. Ils prennent toutes les mesures requises pour assurer que lesdites règles sont mises en œuvre et que les sanctions prévues sont effectives, proportionnées et dissuasives*».

Point 53: «*Les pays veillent, par exemple au moyen de l'information et de la formation, à ce que les composés chimiques soient utilisés de manière satisfaisante par des utilisateurs compétents, en vue de mettre sur le marché des animaux produisant des aliments sûrs et sains de façon à protéger la santé publique*».

Recommandations au niveau de l'exploitation

Le point 59 pourrait être élargi comme suit: «*Seuls les médicaments vétérinaires spécifiquement agréés pour être utilisés chez des animaux en lactation, <u>des pondeuses d'œufs et des abeilles</u> devraient être utilisés pour ces animaux <u>lorsque respectivement le lait, les œufs ou le miel sont collectés pour la consommation humaine</u>*».

Le point 60 semble traiter de la sécurité de la personne administrant le composé chimique aux animaux et ne relève donc pas du champ d'application du document.

Le point 62 pourrait être élargi et modifié comme suit: «*Il faut conserver des documents contenant tous les détails du traitement, par exemple le type de composé chimique administré, la nature du traitement, la date du traitement, l'identité des animaux traités, la date d'expiration du délai d'attente. Ces documents doivent être mis à la disposition de l'autorité compétente, à sa demande*».

Points 63 à 66: des conseils similaires pourraient être nécessaires pour les pondeuses d'œufs, les abeilles et les poissons, mollusques et crustacés d'aquaculture.

Principes et rôle des programmes de vérification

Au point 70, la phrase suivante pourrait être ajoutée: «*C'est sur cette certitude que doit se fonder la délivrance des certificats officiels accompagnant les chargements*». Au point 76, il conviendrait d'expliciter le sens de l'expression «*caractéristiques d'établissement de profil*».

Recoupements avec le document CX/RVDF 04/15/7 Partie II

Il y a lieu de vérifier les remarques figurant aux points 85 à 90 en raison de recoupements avec le document CX/RVDF 04/15/7 Partie II «*Considérations générales sur les méthodes d'analyse pour le contrôle des résidus*» des *Directives pour la mise en place d'un programme de contrôle réglementaire des résidus de médicaments vétérinaires dans les aliments*.

Résultats des analyses (pages 13-14)

Le point 92 prévoit que «*les résultats d'analyse au niveau de la LMR, ou en dessous de celle-ci, ne devraient pas être énoncés en tant que chiffres discrets mais en tant que fourchette de valeurs dans laquelle le laboratoire a la certitude que se situe le résultat réel (fourchette de certitude). Lorsque la fourchette rapportée se situe au-dessus ou en dessous de la LMR, il n'est alors pas possible de conclure de manière absolue que le résultat était non conforme*». Cette proposition ne ferait que créer plus d'incertitude, en particulier du fait que dans de nombreux cas, la méthode d'échantillonnage fournit la plus grande source d'incertitude. Il faudrait plutôt exiger que les méthodes soient validées pour garantir que les résultats obtenus assurent un degré de certitude spécifique du résultat (par exemple une limite de certitude de 95 %).

Au point 94, nous proposons de remplacer «*analysé*» par «*examiné*»; de même au point 96, le mot «*analyse*» devrait être remplacé par le mot «*examen*». Au point 98, le mot «*reconnaissance*» devrait être remplacé par le mot «*approbation*» ou «*autorisation*».

Réponses réglementaires à des infractions identifiées (pages 16-17)

Le point 99 devrait être transposé dans un langage plus simple, par exemple: «*Lorsque les examens démontrent qu'un programme de contrôle réglementaire des résidus de médicaments vétérinaires dans les aliments est inefficace, des actions/mesures correctives adéquates doivent être appliquées. Le type d'actions/de mesures peut dépendre du type de composé chimique et du type de production animale ou d'aliment concerné et doit être proportionné au risque et à la fréquence de son occurrence. L'effet des actions/mesures doit être évalué par une vérification ciblée*».

UNITED STATES OF AMERICA

The CCRVDF Paper on Guidelines for Establishment of Regulatory Programme for the Control of Drugs in Foods needs substantial work, particularly in the Title, Introduction, Scope, Objectives Sections and in Sections & (Design, Tools and Public Health Linkage) and in Section 11- International Assurances- Part (a). The primary concerns are that the thrust of the paper is wrong in that it provides too much flexibility, particularly for exporting countries, to determine what is a public health hazard and what is not, with regards to residues of veterinary drugs in animal food products. Paragraph 15 is reflective of the problem with the paper. But there are other issues with the paper as well.

The title is cumbersome. The earlier title ("Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods") was fairly specific. The new title unnecessarily stresses hazards and greatly expands the scope of the guidelines.

The use of the term "residual hazard," although defined 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," is questionable. Residual hazard can easily be taken to mean remaining hazard; so the emphasis is on hazards rather than safety and the implication is that hazards remain in food (the definition for residual hazard has no qualification as to withdrawal or discard times which are put in place to ensure edible tissues do not contain residues exceeding the MRL). By having ADIs and MRLs for a drug, we assure food safety when neither of the two is exceeded. The definition as written could be taken to mean hazards are always there, even if the ADI or MRL is not exceeded, something we would wish to avoid implying. The tried-and-true term "residue" would suffice and the paper should indicate that residues above the MRL have the potential to expose consumers to harmful residues (taking this latter general approach would make unnecessary the risk profile and frequency of exposure lines of reasoning that characterize the paper).

We express concern with the discussion indicating that residues of veterinary drugs in food should be considered in a broad context of relative public health risk. If this were to imply a comparison of risks that may occur, for example, from food pathogens in animal food products that may have an acute public health concern, it is unlikely that residues of veterinary drugs in food considered on a life time exposure scenario would become a significant public health concern. Under such a situation, it could result in a minimal response from national authorities for violative residues in foods.

As an observation, the milk paper was to be incorporated into this document. As far as we can understand, the four short paragraphs 63-66 are the most specific regarding milk. This is truly 'condensed' and may not be sufficient for national authorities regulating milk and milk products.

Specific comments

Paragraph 1 and 2: We recommend deleting the word "frequencies" (which, in addition to its use in these paragraphs, is interspersed throughout the entire document). The word may imply that exceeding the ADI is okay from time to time, a theme that is discussed in paragraph 24-28 and a theme we believe is antithetical to establishing an international food safety standard to protect consumers and facilitate fair trade in foods.

Paragraph 8 and 9: We suggest removing the word "undue" from "...undue adverse impact..." in the first bullet of paragraph 8 and "unduly" from "...unduly adversely affected..." in (i) of paragraph 9. The use of the word "undue" may again be tied in with saying it is okay to exceed the ADI occasionally.

Paragraph 26: While the statement "Foods containing residues above an MRL are not inherently unsafe" is arguable, it is misleading without some clarifying statement. The primary purpose of control and verification programs is not to detect unsafe food, it is to detect production systems that are not functioning properly. Throughout this paper, terms such as "inherently unsafe" and "imminent health threat" are used to mitigate the significance of an edible tissue that has a residue exceeding an MRL. This guidance document should focus on residues that exceed international and/or domestic MRLs. Control and verification programs are compliance programs, not safety programs.

We acknowledge that MRLs may be lower than required to achieve the ADI in high level consumers, however, the use of the terms "most MRLs" and "majority of the various edible tissues" imply that exceeding the MRL is not a major event. Again, this document deals with compliance issues and not safety issues. While we may not take serious issue with the statement regarding an occasional residue intake [slightly] exceeding the ADI as not posing a toxicological risk, for the purposes of this paper, that argument is unnecessary. For this paper it would suffice to (1) give the definition of the ADI, (2) note that MRLs are derived with the ADI in mind, (3) state that MRLs have legal and safety implications (that is, residues below the MRL do not pose a concern), and (4) advise that residues above the MRL in edible tissues or animal-derived products may result in consumers being exposed to potentially harmful residues.

Paragraph 28: This paragraph should be deleted. Codex can only set one MRL for a specific veterinary drug residue. This paragraph would imply that an importing country would have to conduct an individual risk assessment every time an MRL was exceeded. The standard becomes the ADI rather than the MRL. A similar implication is made in paragraph 112. The importing country should not have to conduct a risk assessment to see what impact an imported product would have on its population. If the exporting country requires a higher MRL because of different use conditions of a veterinary drug, it is their responsibility to provide information to support the adoption of the higher MRL by Codex.

Regarding paragraphs 57 to 59, some editing of the text is necessary. For example, in paragraph 58, it indicates that veterinary drugs should only be used off-label in accordance with direct and written veterinary service. Such advice should be consistent with national guidance documents on this issue because national guidance is binding while international guidance is not necessarily binding. Paragraph 59 should be deleted because it is unnecessarily limiting for two reasons: 1) where necessary to relieve animal suffering, animals may be treated in an off-label manner and their milk discarded for a withholding time sufficient to preclude an unsafe residue and, 2) drugs used in an off-label manner that have a zero milk withholding interval may be used safely in lactating animals whose milk is used for human consumption.

Paragraph 92: What the paper suggests here (i.e., analytical results should not be stated as discrete numbers but as a range of values that the laboratory is confident the true result falls within) is inconsistent with the U.S. procedures. The paper ought not prescribe specifically how a national program interprets pertinent residue data.

Paragraphs 70-108: This section seems to blur the HACCP relationship of the roles of monitoring and surveillance -, then adds "surveys" and "audits" to the mix (see comments on the definition issues earlier). Verification systems in the HACCP framework are a separate and distinct activity (i.e., to insure that the HACCP system is operating in a state of control. Usually, this refers to the types of activities that national authorities conduct rather than food producers and may include activities other than residue testing, for example). There are some paragraphs later in the document that are probably better placed in this section. There are some redundant paragraphs in the section. The section on audits of pre-harvest control points is probably better placed in Section 9. Parts of section (c) are out of place – some are redundant with Section 9 and some ought to be moved to "Sampling". The U.S. believes that paragraphs regarding import inspections and sampling suggesting that non-compliant (violative) product may not have to be recalled unless there is an imminent health hazard that is neither supportable nor consistent with public health practices and national legislation.

Paragraphs 109 to 136: This entire part seems to slant in favor of an exporting country. It is the responsibility of the exporting country to meet the science-based standards of the importing country. Matters of acceptability and assurances concerning food safety are largely deferred to the exporter. The sense of this entire section needs to be balanced. The U.S. has several concerns regarding this section related to international assurances and public health implications for consumers. The U.S. believes that in order to facilitate trade it is important that an importing country receives assurances from an exporting country that products exported to them meet their level of protection with respect to chemical residues. In this regard, communication and cooperation between relevant competent authorities is important. Trading countries should be encouraged to exchange information about their control and verification programs including rationales for their requirements and test results. Exporting countries have an obligation to meet the importing country's appropriate level of protection, and an exporting country's control and verification system, even if different than that of the importing country's system, they must provide an equivalent level of protection. The intent of the paragraphs regarding ADIs is unclear. If the reference to differing ADIs among member states is intended to apply where there is not an established Codex ADI and recommended MRLs, then additional wording may be appropriate. However, the U.S. suggests deleting the entire paragraph. While targeting quality assurance programs may be useful in providing higher levels of assurance of the safety of specific segments of imported foods, the U.S. prefers that the paragraph(s) are not necessary.

Paragraph 115: "Regulatory action levels" should not be restricted to limits that pose a significant risk to human health. Residue limits should be established well below levels that present a significant risk to human health.

CONSUMERS INTERNATIONAL

Consumers International (CI) commends the New Zealand delegation for its work to draft the Proposed Draft Revised Guidelines (PDRG), and to further incorporate comments. The current version of the PDRG (CX/RVDF 04/15/6) provides a comprehensive framework for addressing human health risk associated with the use of veterinary drugs in food animals. CI recommends that the Proposed Draft Guidelines be modified in relation to the comments below.

General Comments:

CI generally supports the risk-based approach discussed in the PDRG, as well making explicit the anchoring of this risk-based approach within the broader objective of protecting the health of the consumer.

However, CI also urges that regulatory action at times must appropriately be taken in response to a newly recognized risk even before that risk has been completely characterized. Indeed, in some situations, regulatory action may be necessary even when more complete risk characterization is not possible. In other words, the desirability of carrying out a thorough risk assessment should not delay taking action when there is reasonable scientific evidence that a use of a veterinary drug poses a public health risk.

The current draft therefore should be modified to acknowledge the reality that information is not perfectly available to characterize risk and that there are costs to gathering what information is available. The PDRG should also explicitly recognize that there must be a balance between the need to quantify risk and the need to protect public health in the face of uncertainty.

Additionally, the PDRG currently downplays the importance of exceeding MRLs and the need for regulatory response when an MRL is exceeded. CI believes this is misguided for several reasons.

The MRL provides the only internationally recognized upper limit on the presence in foods of drug residues and their metabolites. These MRLs generally are created to address lifetime exposures; in contrast, there is no internationally recognized residue level that addresses the risk from an acute single exposure. At some level above the MRL the residue will become a problem to consumers of those residues. Beyond addressing the problem of acute single exposure, when a MRL is exceeded it usually indicates that a control has failed.

Finally, at various points in the Guideline, certain terms are employed which add little to its clarity, yet are open to overly broad and subjective interpretation. We recommend that use of these kinds of terms in the Guideline be dropped where it is not abundantly clear what those terms mean. We refer the Committee, for example, to the "unduly" in Section 5, paragraph i, and "realistic" in Section 6, paragraph iii.

Specific comments:

Section 1 - Introduction:

Paragraph 1. To make the primacy of the public health/food safety objective more explicit in the Guideline, CI recommends specifically that expression of such – in the last sentence of paragraph 21 – instead should be appended as the final sentence in paragraph 1 of the Introduction.

Similarly, the second statement of General Principles in paragraph 10 should be revised to read, "Be prevention-focused, and serve the primary food safety objective of this Guideline.

Since "residual hazards can also be associated with acute pharmacological effects on consumers or their Gastrointestinal tract microflora, and/or allergic potentials", CI also recommends amending paragraph 1 and 2 to delete references to the "frequencies" of exposure. Acute effects, such as allergic reactions, clearly do not require multiple exposures.

Paragraph 4. A sentence should be added to this paragraph stating that in cases where there is significant scientific evidence of a public health risk from the use of a veterinary drug, the need to fully quantify the risk should not be used to delay taking regulatory action.

Also, use of the term "real health protection gains" is not understood. Resources would not be allocated if risks were not considered to be "real".

Section 4

Definition of residual hazard should be consistent with that offered in paragraph 22. To reflect the more nuanced definitions in paragraphs 22 and 23 (omitting the last sentence of paragraph 23, which is a *non sequitur*), those paragraphs could be moved to replace the current definition of residual hazard in Section 4.

Definition of risk-based. Risk analysis in the ideal case requires large amounts of data on toxicity and exposure that often are not available. This relative lack of data may make it difficult, if not impossible, to obtain a quantitative estimate of risk in advance of knowledge about the severity of an adverse effect in consumers. Current language in the Guideline would seem to suggest that a risk-based approach must include this sort of quantitative estimate. CI recommends changes in this sentence making it clear that risk estimation may be either quantitative or qualitative, and that both may be a reasonable basis for making decisions. Further, we recommend a broader definition more inclusive of qualitative assessments of risk.

On the other hand, if current language is retained "an estimate of the probability and severity of an adverse effect" ought to be changed to "probability or severity".

Section 6 – General Principles

Paragraph v. Omit this paragraph. The point here is not very clear. It seems to call for a determination to be made about the actual human health risk of the hazard in question relative to other unspecified hazards. CI suggests that since the passage doesn't specifically identify the latter, it remains unclear whether such a risk ranking is either possible or appropriate.

Section 7 - Design Tools and Public Health Linkages

Paragraph 22, 23. Consider moving to Section 4, per earlier comments.

Paragraphs 24, 26, and 27. Remove statements downplaying the health importance of exceeding ADIs and MRLs, e.g. last sentence of paragraph 24, etc.

Paragraph 28. Calculating MRLs is difficult enough without the need to incorporate potentially higher residues from exporting countries with higher MRLs. Given the potential for rapid changes in international markets that can occur due to animal disease outbreaks and other production disruptions, it is unrealistic to expect regulatory authorities to make the assessment required in this paragraph. In addition, allowing higher MRLs in imported products may undermine the confidence and trust of consumers and producers in the regulatory program. This could harm international trade and increase the likelihood that producers will use drugs in unapproved ways.

Section 8 – Review and Ranking of Hazards

Paragraph 37. Delete "in the products", as it is inconsistent with the definition of residual hazards in paragraph 22 which makes it clear that the particular hazard in question may not reside in the product itself (i.e. antimicrobial resistance).

Paragraph 38. Delete "along with a relative estimate of the likelihood of this occurring," Calling for relative risk ranking as an essential part of a national control programme presumes an abundance of knowledge and data that in all likelihood do not exist in many situations.

Section 9 – Control Points

Paragraph 54. Replace "an appropriate risk assessment with "appropriate health concerns". Certainly, regulatory action often must be taken in response to newly recognized risks *before* the risk is completely characterized, as is the case with escalating antimicrobial resistance.

Paragraph 58. Add a sentence stating that extra-label veterinary drugs should only be used for non-routine disease treatment or control, and not for routine use including for growth promotion and/or routine disease control, prophylaxis or prevention.

Paragraph 59. Add a sentence stating, "only those veterinary drugs specifically approved for use in laying hens should be used in animals laying eggs for human consumption." Similar to milk, eggs provide another pathway for residues that will not be addressed by drugs approved for meat and poultry.

Section 10. – Verification

Paragraph 103. This paragraph should acknowledge that producers have the responsibility to respond to problems resulting from registration/label issues even if the problem is due to a failure out of their control. Producers still have the responsibility to use drugs in a responsible manner while the responsible sector corrects the problem.

Paragraph 107. Remove the statement downplaying the importance of exceeding MRL.

Section 11. International Assurances

Paragraph 115. Regulatory action should be set at risk levels well below that which is thought to present a significant risk to human health. This general principle is incorporated into risk-based standards in what are generally referred to as "margins of safety". This approach reflects the prevention or public health oriented goal of regulatory action – to act so as to keep the risk to humans *from becoming* significant. It also might be deemed prudent given historical experience with many food contaminants, e.g. dioxins, PCBs, lead, inorganic arsenic. Namely, the science around a particular risk often tends to evolve so that early estimates of that risk are understood *post hoc* to have been understated rather than overblown. In terms of food contaminants, fewer historical examples come to mind of the converse situation, where scientific progress ultimately proves early risk estimates to have been overblown rather than understated.

INTERNATIONAL DAIRY FEDERATION

The IDF would like to congratulate New Zealand and the Working Group consisting of Australia, Belgium, Brazil, Canada, China, Colombia, Costa Rica, France, Switzerland, United Kingdom, United States, European Commission, FAO and OIE, for their excellent job.

The IDF would also like to make both general and detailed comments.

A. General comments:

The IDF fully supports:

- a risk-based "integrated" approach,
- emphasis on prevention as being much more efficient than end-product testing.
- recognition that Good Practice in the Use of Veterinary Drugs may vary between countries depending on the local animal health status, and result in different MRLs for the same drug without necessarily resulting in the ADI being exceeded.

However, the Guidelines are long and contain several repetitions.

A number of definitions, principles and guidelines are not specific to the issue of drug residues and could instead be part of a generic/horizontal document.

The issue of drug (residues) for which no ADI and/or no MRL has been allocated, has not yet been addressed. Yet, this is one of the major barriers to international trade in certain foods (e.g. honey, poultry).

B. Detailed comments

The title of the revised document has been correctly modified to reflect the new scope and objectives.

Section 1 - Introduction: includes basic principles that should appear in a generic/horizontal guideline for the management of food safety.

Section 2 - Scope: The following phrase in para 7 should be clarified: "while outside the formal scope, this guideline..."

Section 3 – Objectives. The first bullet point somehow contradicts para. 3 of the Introduction: the primary responsibility for ensuring food safety remains with the operators of the food chain.

Section 4 – Definitions:

- to be consistent one should refer to "food producing animal" only, not to " food animal" (definition of "Residual hazard").
- Should "competent authorities" be defined for the purpose of these specific Guidelines? The definition "Official inspection systems" established by CCFICS might be used instead.

Part 1: General Considerations

Section 5 – Aims of Residual Hazard Control and Verification Programmes: redundant (see section 3).

Section 6 – General Principles:

- principles i to v are basic and should be part of generic/horizontal guidelines
- principles vii to ix are, in our view, the most relevant.
- meaning of principles vi, x and xi needs to be further specified.

Section 7 – Design Tools and Public Health Linkage:

7.1, Introduction: all statements there should be included as part of a generic/ horizontal guideline for the management of food safety as they are not specific to residues of veterinary drugs.

7.2, Application of Risk Analysis and HACCP-based principles: Verification, i. Analysis of non-compliance, the meaning of "systemic significance" should be clarified.

7.3, "Public Health Linkage": all the paragraphs under this heading, from 21 to 28 should be included in an "explanatory memorandum", or an introduction, as they are general considerations on ADI and MRLs.

7.4, Types of Verification Programmes

Part 2: Recommendations

Section 8 – Review and Ranking of Hazards

8.1, Introduction: again the statements here should be part of either an explanatory memorandum or the main introduction to the Guidelines.

8.2, Types and Types and Sources of Chemicals and Exposure Pathways, and 8.3, Risk Profile Considerations, could be part of generic/horizontal guidelines on the control of (all types of) chemical residues in foods.

Second sentence of para 39 specifically concerns veterinary drugs: while it is clear that suspected potential misuses/abuses should be considered, it must also be made clear that it is simply impossible to establish controls for every possible situation.

This could be done by adding a sentence to this paragraph or in section 9 on Control Points which should also include guidance for the surveillance/monitoring of illegal drugs including both non-sanctioned/ approved and forbidden drugs such as e.g. chloramphenicol (see below comments on Section 11).

Section 9 – Control Points

This section is definitely the "core" of the Guidelines and contains valuable recommendations. A few remarks:

- para 46: term ‘off label’ (‘extra label’ used in many countries) needs to be defined as it is often misinterpreted to mean use of non sanctioned chemicals rather use of sanctioned chemicals contrary to the approved directions for use.

  Remove "potentially" from the last line, as restrictions on off-label use or alternative import and/or manufacture of non-sanctioned drugs are actually key control points.

- para 49: remove "It is desirable that..." and replace it with "All formulations...should be required to be reported..."

- para 54: the Guidelines should specify or give examples of types of drugs that should be sold on prescription only, e.g. antibiotics

- para. 57: how does this apply when no drug has been approved for use in the concerned species, e.g. honeybees?

- para 63: the wording should be improved.

- paras 64, 65 and 66 to be modified as follows: (1) first sentence of para 66 to become para 64, (2) current para 64 to be renumbered 65 (3) current para 65 and second sentence of current para 66 to be deleted (the level of prescriptiveness in them, although the word "ideally" is liberally used, is not consistent with an outcome based approach.)

Section 10 – Verification

10.1 Principles and the Role of Verification Programmes: there are numerous redundancies between this sub-section and previous sections 6 and 7, e.g. between paras 71 and 13, 72 and 10, v., etc.

10.4 Point of Harvest Verification Programmes:

- para 89 should read: " The laboratories ... should have in place ..., should work according to Good Laboratory Practice (GLP), and they should have validated all methodologies used."...

10.5 Analytical Results, (a) Reporting of results:

- In relation with para 92, what to do with analytical results when no ADI and/or no MRL has been allocated ?

10.6, Regulatory responses to identified non-compliances

This sub-section is long and should be shortened for easier reading.

Part 3

Section 11 – International Assurances, (a) Exchange and review of control and verification programmes

- para 110, the sentence should read " the application of ... for exporting countries to certify that the exported food has been produced in accordance with food safety requirements (instead of "to certify the safety of exported food"), and for importing countries... consignments."

(b) Port of entry testing programmes:

- para 114 is redundant (par. 109)

- para 117 in particular is not specific to these Guidelines and should be included with generic/horizontal guidelines.

In accordance with above in comments on Section 8, this section should include guidance for the surveillance/monitoring of illegal drugs, in particular drugs having a "zero tolerance" for residues in foods, e.g. Chloramphenicol and Nitrofurans. The establishment of intervention/reporting limits for the residues of these drugs will help to solve trade-issues resulting only from differences in the analytical capacities of laboratories.

Part 4

Again, this Part is not specific to the issue of drug residues and should be part of generic/horizontal guidelines.

There are a number of redundancies, e.g. between the 3 last bullets of 11.2, Principles, and para 117, the third bullet of 11.2 and para 112.

The meaning of paras 124 and 125 of 11.4, Populations of Interest, needs to be clarified.