codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/RVDF 09/18/6 Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session

Natal, Brazil, 11-15 May 2009

DRAFT GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS

Comments at Step 6 (CL 2007/37-RVDF) submitted by :

European Community, Kenya, Phillippines & Thailand

EUROPEAN COMMUNITY

The European Community (EC) notes that these guidelines were extensively re-worked at the previous CCRVDF session and considers them ripe for the final adoption.

KENYA

We have gone through this document and found it very educative and we had no problem with its advancement to the next step.

PHILLIPPINES

The Philippines reaffirms its support to a simplified and adaptable Regulatory Food Safety Assurance programmes associated with the use of Veterinary Drugs in Food producing animals that could be used by commercial and regulatory entities.

	New/proposed statement	Justification
General principles Section 7: i - viii	Proposes for the inclusion of the statement below as part of the general principles: ix. provide consumers information and education to facilitate sound choice and the proper exercise their rights thereby strengthening consumers' role in evaluating the quality, including safety of the food products.	The best interest of the consumer should be considered in the interpretation and implementation of the national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals. Giving accurate information about the residues on veterinary drugs in foods shall enable the consumers to have an active role as that of government and industry.

	New/proposed statement	Justification
Approach based on risk Paragraph 15 Residues may exert an adverse effect on consumers in a number of ways, such as: (a) chronic toxicological adverse effects; (b)acute pharmacological effects on consumers and on the microflora of the gastrointestinal track of consumers; (c) allergic reactions	Proposes the following statements: (a) ~~(b)~~ acute pharmacological effects on consumers and on the microflora of the gastrointestinal tract~~k~~ of consumers; (b) ~~(a)~~ chronic toxicological adverse effects; (c) development of antibiotic resistance of normal microflora (d) ~~(c)~~ allergic reactions.	For the purpose of synchronization and completeness of the statement. This item was included to emphasize the importance of antibiotic resistance.
Definitions (for the purpose of these guidelines) Production system means the methods or activities used to produce food for human consumption for which the residue control programme of a Competent Authority has been designed.	Production system means the methods or activities used to produce food for human consumption. ~~for which the residue control programme of a Competent Authority has been designed.~~	For brevity
Regulatory Framework Roles 21. Business operators/commercial entities involved in the production, and marketing of food have the primary responsibility for ensuring food safety.	21. Business operators / commercial entities involved in the production, processing and marketing of food have the primary responsibility for ensuring food safety.	Insertion of processing for the purpose of consistency as stated in Gen Principle iv
25. Approval systems should: (b) attempt to take into account the needs of the producers in order to reduce the temptation to use unapproved veterinary drugs or prohibited substances.	(b) ~~attempt to~~ take into account the needs of the producers in order to reduce the temptation to use unapproved veterinary drugs or prohibited substances.	Attempt is a conditional action.
Information on veterinary drugs 30. Information and/or education programmes on suitable use to provide effective treatment while affording protection of consumers should be provided ~~for~~ each approved veterinary product formulation.	The text should read as follows: 30. Information and/or education programmes on suitable use to provide effective treatment while affording protection of consumers should be provided ~~for~~ each approved veterinary product formulation.	Editorial Comment
33. Sale and use conditions may include: (a) Requiring all sales to be subject to a prescription from a veterinarian or other professional with approved competencies; (b) Restricting administration to individuals or professionals with approved competencies;	The text should read as follows: (a) Requiring all sales to be subject to a prescription from a licensed veterinarian ~~.or other professional with approved competencies;~~ (b) Restricting veterinary drug administration to individuals or professionals with approved competencies under the direct or indirect supervision of licensed veterinarian;"	Prescription refers to the written order and instruction to the pharmacist by a duly-licensed veterinarian for the use of a specific veterinary drug and product for a specific species of animal (ref: DA AO 39 S 1991 and DOH AO No III-B). Direct Supervision" means: the supervisor is on the premises in an animal hospital setting or in the same general area in a

	New/proposed statement	Justification
		range setting, the supervisor is quickly and easily available and that the animal has been examined by a veterinarian at such time as good veterinary medical practice requires consistent with the particular delegated animal health care job task. "Indirect Supervision" means that the supervisor is not on the premises, but has given written or oral instructions for treatment of the animal patient, the animal has been examined by a veterinarian at such times as good veterinary medical practice requires, consistent with the particular delegated animal health care task and the animal is not anesthetized as defined in Section 2032. Reference: Compilation of Laws Relating to the Practice of Veterinary medicine, Surgery and Animal Health Technology
34. Efficacy and the necessity of use conditions should be regularly reviewed against the local risk profile. In doing this it should be considered that the non-availability of necessary treatments may encourage use of non-approved veterinary drugs or prohibited substances.	34. Efficacy and the necessity of use conditions should be regularly reviewed against the local risk profile. ~~In doing this it should be considered that the non-availability of necessary treatments may encourage use of non-approved veterinary drugs or prohibited substances.~~	Deleted sentence may compromise food safety.
37. 4th sentence: Veterinary drugs should be used off-label only in accordance with direct and written veterinary advice.	Phrase should read as follows" <u>Off-label use of veterinary drugs should only be done</u> in accordance with direct and written veterinary advice.	Editorial Comment
38. Producers should be encouraged to seek advice of veterinarians or other competent professionals on the application of the correct withdrawal time, where the label direction for use may not be available or may not be clear.	38. Producers should ~~be encouraged to~~ seek advice of <u>licensed</u> veterinarians ~~or other competent professionals~~ on the application of the correct withdrawal time, where the label direction for use may not be available or may not be clear.	Editorial Comment
44. Continuous food safety assurance measures such as record keeping should ensure that products (e.g. milk, eggs, honey) are harvested only if appropriate withdrawal/withholding times have been respected.	44. Continuous food safety assurance measures such as record keeping should ensure that products (e.g. milk, eggs, honey) are harvested only if appropriate withdrawal/withholding times have been followed ~~respected.~~	Editorial Comment
46. Products from animals under harvest restrictions should be obtained in such a way that ensures their product does not mix with that being	46. Products from animals under harvest restrictions should be <u>handled</u> ~~obtained~~ in such a way that ensures their product does not mix with that being harvested for human	Editorial Comment

	New/proposed statement	Justification
harvested for human consumption. Any equipment likely to be contaminated should be adequately cleaned prior to being used on other animals.	consumption. Any equipment likely to be contaminated should be adequately cleaned and disinfected prior to being used on other animals.	
49. Verification programmes should contribute to the: (b) identification of unacceptable production, marketing and/or chains of advice; (d) evaluation of the effectiveness education or risk reduction programmes; (e) evaluation of quality assurance systems;	(b) identification of unacceptable production, processing, marketing and/or chains of advice; (d) evaluation of the effectiveness of education or risk reduction programmes; (e) evaluation of quality assurance management systems;	Editorial Comment
50. Verification programmes should cover, as appropriate, the entire food chain primary production to retail or export.	Verification programmes should cover, as appropriate, the entire food chain from farm to table. ~~primary production to retail or export.~~	Editorial Comment
51. Verification programmes can be classified as follows according to objective and criteria applied to the sample selection: (a) system verification programmes; (b) risk-targeted verification programmes; (c) surveys; (d) port of entry testing programmes.	We would recommend adding: (e) surveillance and monitoring program	Editorial Comment
52. Verification programmes may focus on assessing the (a) effectiveness of a control system; and/or	We would recommend changing to: (a) effectiveness of a food control system; and/or	Editorial Comment
56. Risk profile considerations concerning veterinary drugs include: (b) the class and severity of the adverse human health effect associated with the residue (e.g.chronic toxicity, acute pharmacological, allergic reaction, or microbiological disturbance);	56. Risk profile considerations concerning veterinary drugs include: (b) the class and severity of the adverse human health effect associated with the residue (e.g.chronic toxicity, acute pharmacological, allergic reaction, microbiological disturbance or/ and adverse drug interactions)	Editorial Comment
63. In setting up system verification programmes the following should be considered: (a) systematic examination of the regulatory control system;	(a) systematic examination, surveillance and monitoring, and / or targeted investigation (in case of consumer complaints, outbreaks) by ~~of~~ the regulatory food control system;	Editorial Comment
65. Non-biased sampling programmes should be used in order to find out whether one of the controls within the system needs adjusting. They should not be relied upon for product evaluation.	65. Non-biased sampling programmes should be used to evaluate if the system control needs adjustment, but should not solely be relied upon for product evaluation.	Editorial Comment
68. In setting up risk targeted verification programmes the following should be considered:		Editorial Comment

	New/proposed statement	Justification
(a) previous performance, history of non-compliance;	(a) previous performance, incidence and/or history of non-compliance;	
74. Ideally, samples should be taken before animals and/or products are commingled with animals or product from other suppliers.	74. ~~Ideally,~~ Samples should be taken before animals and/or products are commingled with animals or product from other suppliers.	Standard procedure
77. If sub-units of a consignment are sampled, care should be taken to identify those clearly.	77. If sub-units of a consignment are sampled, care should be taken to identify each specific sample ~~those clearly~~.	For clarity
77. If sub-units of a consignment are sampled, care should be taken to identify those clearly.	77. If sub-units of a consignment are sampled, care should be taken to identify each specific sample ~~those clearly~~.	Editorial Comment
79. In designing a sampling protocol it is essential to define both the purpose of the programme and the population of interest. It is also important to define the criteria to be applied when analysing the results with respect to the need/desirability for any further action, and especially how such criteria and reactions directly relate to the protection of human health.	79. In designing a sampling protocol it is essential to define both the purpose / objective of the programme and the population of interest. It is also important to define the criteria to be applied when analysing the results with respect to the need/desirability for any further ~~action, and especially how such criteria and~~ reactions directly relate to the protection of human health.	To avoid confusion
82. Generally, conclusions will be drawn from the prevalence, or lack thereof, of non-complying results in the units sampled during the production season or calendar year. However, where problems are found during the course of the production season, corrective actions may have already been applied and have started to have a positive effect well before the end of the production season or calendar year. For small populations, or for either low risk or reasonably stable exposure scenarios, several production seasons or calendar years may be used/needed to collect the number of samples statistically determined to give the required confidence.	Generally, conclusions will be drawn from the prevalence, or lack thereof, of non-complying results in the units sampled during the production season or calendar year. ~~However, where problems are found during the course of the production season, corrective actions may have already been applied and have started to have a positive effect well before the end of the production season or calendar year.~~ For small populations, or for either low risk or reasonably stable exposure scenarios, several production seasons or calendar years may be used/needed to collect the number of samples statistically determined to give the required confidence.	Deleted statement is not relevant.
84. The point at which a sample is taken depends on the objective of the specific programme. Where the objective is to verify the effectiveness of controls at the supplier stage, generally samples are taken during at the point of sale/harvest where it is still possible to correlate the unit sampled with a supplier or producer.	The point at which a sample is taken depends on the objective of the specific programme. Where the objective is to verify the effectiveness of controls at the supplier stage, generally samples are taken during ~~at the point of~~ sale/harvest ~~where it is still possible~~ in order to correlate the unit sampled with a supplier or producer	For clarity
88. (a) immediate action, such as product recall, when such action is indicated by a finding in such samples; or	(a) immediate action as indicated by a non-compliant finding such as product recall; or	Editorial Comment
89. A greater degree of assurance is achieved if statistically based system	A greater degree of assurance is achieved if ~~statistically based system~~ verification	Editorial Comment

	New/proposed statement	Justification
verification programmes based on non-biased sampling and risk targeted (e.g. specific suppliers or products) verification programmes are operated in parallel.	programmes such as statistically based system involving ~~based on~~ non-biased sampling and risk targeted (e.g. specific suppliers or products) ~~verification programmes~~ are operated in parallel.	
90. The results of risk targeted verification programmes alone do not allow conclusions on the exposure of the general population with residues of veterinary drugs.	90. The results of risk targeted verification programmes are not sufficient to conclude ~~alone do not allow conclusions on~~ the exposure of the general population with residues of veterinary drugs.	Editorial Comment
94. For port of entry testing programmes the population of interest is all like-product produced under a common control and verification programme.	94. For port of entry testing programmes the population of interest should be the same ~~is all like~~ product produced under a common control and verification programme.	Editorial Comment
100. (b) performance characteristics of the method of analysis (including the confidence interval of the result).	100. (b) performance characteristics of the method of analysis (including the confidence level ~~interval~~ of the result).	Editorial Comment
102. Competent Authorities of importing countries should provide exporting countries regularly with the results of their verification programmes including information to enable trace back.	102. Competent Authorities of importing countries should provide exporting countries regularly with the results of their verification programmes including information for purposes of traceability ~~to enable trace back~~.	Editorial Comment
103. In cases of non-compliance with the food safety parameters, Competent Authorities from the exporting country should conduct a trace back and apply appropriate corrective actions and provide a summary of these to the importing country.	103. In cases of non-compliance with the food safety parameters, Competent Authorities from the exporting country should conduct a trace back then ~~and~~ apply appropriate corrective actions and provide a summary of these to the importing	Editorial Comment
107. Resolution of such problems will require an analysis in the originating country of the source of such residues, the identification of deficiencies within the country's own control and monitoring system, and subsequent application of appropriate additional controls and measures to address the situation.	107. Resolution of such problems will require an analysis ~~in the originating country~~ of the source of ~~such~~ residues in the originating country, the identification of deficiencies within the country's own control and monitoring system, and subsequent application of appropriate additional controls and measures to address the situation.	Editorial Comment
121. Non-compliant product should not be passed as fit for human consumption.	121. Non-compliant product should not be passed as fit for human consumption and should be properly disposed.	Editorial Comment
Regulatory Action	Inclusion of the "Disposal of non compliant product as one of the major item under Regulatory Action that shall include the following mechanisms of disposal ~~system~~ to avoid contaminated meat being ~~for~~ consumed ~~consumption~~: (a) Holding time should at least be equivalent to the declared shelf-life of the products. (c) Unused samples should be disposed according to the approved regulations of concerned authorities.	a. Competent Authority shall ensure that all of the non-compliant products shall be taken out of the food chain. b. All non- compliant products shall be disposed according to the approved regulations by the Controlling Authority.

	New/proposed statement	Justification
Definition page 56	Include the definition of the following: Sample/s refers to one or more sampling units selected or drawn at random without regard to their quality from the population or lot or batch. Sample Size refers to the number of sample units comprising the total sample drawn from a lot or production.	Editorial Comment
170. Final laboratory samples should be prepared as follows:	We recommend the addition of: (d) the container should be properly labeled with the date of sampling	Editorial Comment
Appendix B-Sampling of commodities	Inclusion of the Reporting of test results as on the major item of Appendix B-Sampling of commodities	Editorial Comment
Interaction between the control programme of two Competent Authorities (page 53)	Insert system of resolving conflicting laboratory results between two competent regulatory authorities	Editorial Comment
VII. Class B-Type 08 (Aquatic Animal Products)	Proposes for the specification of <u>cultured</u> aquatic animal products only	Cultured aquatic animal products refers to marine or freshwater plants or animals that are propagated, farmed or cultivate in an aquaculture facility under the supervision and management of an aquaculturist.

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VIII. Class E=Type 18

A – Instruction for collection

Requesting for clarification of unit size of all products under Class E-Type 18 and 19 less than 1 kg.

Line 70 (d) To keep the integrity of the sample adopt applicable international standard in shipping of samples.

THAILAND

- Para 2

To be consistent with the goals of Codex Alimentarius, the second sentence of para 2 should be modified as follows:

"The role of competent authorities is to control the use of veterinary drugs and to verify that appropriate practices are being applied and effective measures are in place within the veterinary drugs distribution and food production systems to provide effective <u>protection of consumers health and facilitate fair trade practice</u>, consistent with the goals of Codex Alimentarius."

Moreover, the underline statement should be used consistently throughout the Draft Guidelines.

-Para 5

Para 5 should be rewritten to reflect clearly that the implementation of this complicated programme which comprises not only sampling and analysis but also validation of analysis will have a significant effect on developing countries and their trade. Developing countries will need technical assistance as well as transition period before they can make full implementation of the Guidelines.

Para 5 should be amended as follows:

"It is recognized that in particular developing countries need <u>a technical assistance including appropriate</u> transition period regarding the full implementation of these Guidelines."

2. Approach based on risk

-Para 15 (a)

To make the statement clearer, para 15 (a) should read as follows:

"(a) *chronic toxicological adverse health effects on consumers"*

Moreover, the underline statement should be used consistently throughout the Draft Guidelines.

-Para 19

We are of the opinion that additional assessment will be necessary only when there is an evidence of risk of consumer health. Moreover, as these Guidelines are related to the national control programme rather than the acceptance of each consignments.".

Therefore, we propose to modify para 19 as follows:

19. The application of a control and verification programme based on risk should provide the necessary basis for exporting countries to certify the safety of exported food, and for importing countries, subject to any additional assessment they deem necessary in case there is the evidence of risk of consumer health, to accept such control programme."

3. Verification programmes

- Para 49

As several contributions in para 49 are not relevant to the topic *Purpose*, it would be more appropriate to place para 49 under the topic *General Design Principles*. The modified para 49 will read as follows:

"*General Design Principles*

49. *Where appropriate*, *verification programmes* should contribute to the:

(a) verification of assumptions made in the registration process;

(b) identification of unacceptable production, marketing and/or chains of advice;"

(c) ……

4. Sample taking

- Para 101

We are of the opinion that, in distributing the laboratory reports on non-compliant results which consist of the description of the method used and the performance characteristics of the method of analysis (including the confidence interval of the results) to all parties affected by the result, other additional scientific data which may be useful to the exporting countries should also be included. Moreover, once the importing countries distribute the laboratory reports on non-compliant results to all related parties, the exporting countries will be directly affected. Therefore, we propose to add a statement to remind the importing countries to confirm the laboratory reports on non-compliant results before distributing them to all parties affected by the results.

We would like to propose to amend para 101 to be as follows:

"*101. Laboratory reports on non-compliant results including additional scientific data upon request should be confirmed prior to distribution to all parties affected by the result (e.g. the owner of the consignment and the certifying competent authority of the exporting country)."*

5. Regulatory action

-Para 121

Regarding the measures in case of non-compliance of the products, we are of the opinion that non-compliant product mentioned in para 121 should be clearly identified as the product presenting a risk to consumer health. In some case, investigation for taking corrective action may be necessary.

Therefore, we would like to amend para 121 to be more practical as follows:

"121. Non-compliant product should not be passed as fit for human consumption. Where the results indicate that there is a direct risk to consumer health, the product should be more investigation in order to take corrective action on control system."

6. Appendix A- Sampling strategies

-Para 135

Under the *topic on Purpose* under *Non-biased sampling*, it should be clearly mentioned that Table1 is designed to be used for non-biased sampling for providing profile information of a control or assurance system.

Para 135 should be amended as follows:

"*135. Table 1 is an example to design non-biased sampling for providing profile information of a control or assurance system for specified animal food population over a defined period."*

7. Appendix B- Sampling of commodities

-Table B

For Table B: milk, eggs, diary products and aquatic animal products, we are of the opinion that the minimum quantity required for laboratory sample of aquatic animal products (Commodity VII. Class B -Type 08) and derived edible products of aquatic animal origin (Commodity VIII. Class E-Type 17) is too large. As inspection of veterinary drug will be carried out on the aquatic animals from aquaculture which are considerably homogeneous, fewer samples should be required as the minimum quantity in the same way as other commodities.

We propose to modify Table B specifically for Commodity VII. Class B -Type 08 and Commodity VIII. Class E-Type 17 to be as follows:

Commodity	Instruction for collection	Minimum quantity required for laboratory sample
VII. Class B - Type 08 (Aquatic animal products)		
A. Packaged fish -fresh, frozen, smoked, cured or shellfish (except oysters)	Collect 1 sample at least 1 kg from 4 increments	500 g
B. Bulk fish 0.5-1.5 kg	Collect 1 sample at least 500 g of edible fish from 4 increments	500 g
C. Bulk fish >1.5 kg	Collect 1000 g of edible fish	500 g
VIII. Class E - Type 17 (Derived Edible Products of Aquatic Animal Origin)		
A. Canned fish and shellfish products (except oysters)	Collect 1 sample of at least 5 cans	500 g
B. Other fish and shellfish products - fish flour and meal	Collect 1 sample of at least 1 kg from 4 increments	500 g