CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 8 (a) **CX/RVDF 12/20/9 Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

PROPOSED DRAFT SAMPLING PLANS FOR RESIDUE CONTROL FOR AQUATIC ANIMAL PRODUCTS AND DERIVED EDIBLE PRODUCTS OF AQUATIC ORIGIN (TABLE C, ANNEX B OF CAC/GL 71-2009)

Comments at Step 3 of Brazil, Chile, Costa Rica, Kenya, Mexico, Philippines and United Kingdom

BRAZIL

General comments

Brazil congratulates the United States for providing the Report of the electronic Working Group on Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin and would like to thank for the opportunity to submit its comments.

Brazil supports the immediate advance of the proposed draft, since Brazil understands that *Codex Alimentarius* actions, as international reference for food safety, should be reinforced and stimulated, ensuring fair practices in food trade. Sampling Plans for Residue Control is a very complex issue and has been widely discussed. Many member countries that are important aquaculture producers contested the original table (12 subsamples), considering the difficulties for transport and the economic losses by the shipment of high value products.

Specific comments

Brazil supports to forward the options 1a. and 2a. for the "Instruction for collection" and that the minimum quantity required for laboratory sample should be 500g for aquatic animal products. These options are consistent with the Table already approved in Annex B of CAC/GL 71-2009 and allow national authorities to use judgment as to the number of units from which to collect samples, taking into consideration the homogeneity of production and the type of fish, crustacean or shellfish.

CHILE

General Comments

Chile joins the eWG recommendation, that upon reaching consensus regarding the proposed language for instructions for sample collection, the Committee should consider the proposed Table for inclusion in the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

Regarding the instructions for Table C sample collection, we support options 1a and 2a, with the specific comments detailed below.

Specific Comments

Comment 1 In the instructions for sample collection, we opt for option 1a and 2a, and in both cases propose to add the phrase "to meet the minimum quantity required for the laboratory sample."

Table C: Aquatic animal products

Commodity	Instructions for collection	Minimum quantity required for laboratory sample
VII. Class B - Type 08 (Aquatic Animal Products)		
Fish, **fish oil, fish meal** and shellfish: Packed and unpacked	1a. Collect appropriate edible tissue from sufficient units randomly selected from each lot ~~to meet laboratory sample size requirements~~ **to meet the minimum quantity required for the laboratory sample.**	500g edible tissue
VII. Class E - Type 17 (Derived Edible Products of Aquatic Animal Origin)		
Canned fish and shellfish products	2a. Collect sufficient units randomly selected from each lot ~~to meet laboratory sample size requirements~~ **to meet the minimum quantity required for the laboratory sample.**	500g edible tissue
Fish oil **Fish meal**	**The sampling procedure for the various types of meal should also consider a specific number of increases per ton; nevertheless, they must be divided into as many separate bags as indicated by the "n" sample and they must also be sent to the laboratory, to meet the minimum quantity required for the laboratory sample.** **For oil stored in barrels, drums or other standard units, the samples should be extracted from "n" randomly selected barrels. A sample of the volume necessary to meet the minimum quantity required for the laboratory sample should be extracted from each of them.**	**1500g of fish meal** **1.5 liters of oil**

Rationale

In derived edible products of aquatic origin, we propose adding the fish oil and fish meal, because they could be used to prepare products for human consumption, and also in the pharmacological industry.

Comment 2

We propose to define aquatic animal products and derived edible products of aquatic origin.

[Also] to clarify the definitions of: laboratory sample, minimum quantity required for laboratory sample, unit, lot for aquatic animal products, lot for edible products of aquatic origin and edible tissue.

Comment 3

Regarding the minimum quantity required for laboratory sample, we support the 500g proposal; nevertheless, the number of samples that should be taken from one production lot must be defined.

COSTA RICA

Costa Rica finds that consistent with our previous decision in this case, we continue to prefer the second option, that is, 1b, because it is clearer.

KENYA

Issues and observations

i. The sampling design is problematic

ii. The instruction for collection of sample size is not too explicit.

iii. The sample size of 500gm does not indicate whether it is of the unit, lot or consignment

Comments

i. The committee while associating itself with the first option for sampling "Collect appropriate edible tissue from sufficient 1 units randomly selected from each lot to meet laboratory sample size requirements." hereby suggests that the sampling method be reviewed.

MEXICO

Regarding subparagraph **a)** we agree that the minimum quantity should be 500g.

Regarding subparagraph **b)** we support using the term "**edible tissue"**; we also suggest specifying the instructions and minimum amount for offal (*head, tail, exoskeleton*) because they are used, in some instances, to prepare stock.

Finally, in subparagraph **d)** we agree that fish meal is not for human consumption, although it should be taken into account that it is used as an additive for animal consumption in concentrate form.

PHILIPPINES

<table>
<tr><th>Proposed</th><th>Recommendation</th><th>Comment</th></tr>
<tr><td>Table C: Aquatic animal products
<table>
<tr><th>Commodity</th><th>Instructions for collection</th><th>Minimum quantity required for laboratory sample</th></tr>
<tr><td>VII. Class B – Type 08 (Aquatic Animal Products)</td><td></td><td></td></tr>
<tr><td>Fish and shellfish – packaged and unpackaged</td><td>Collect appropriate edible tissue from sufficient[1] units[2] randomly selected from each lot to meet minimum laboratory sample size requirements.
~~Or~~
~~Collect appropriate edible tissue from one or more units[2] randomly selected within each lot making up the consignment. The number of units[2] sampled depends on the size of units[2] in the lot.~~</td><td>500g edible tissue</td></tr>
<tr><td>VII. Class E – Type 17 (Derived Edible Products of Aquatic Animal Origin)</td><td></td><td></td></tr>
</table></td><td>Collect appropriate edible tissue from sufficient[1] units[2] randomly selected from each lot to meet minimum laboratory sample size requirements.

Collect sufficient[1] units[2] randomly selected from each lot to meet laboratory sample size requirements</td><td>The instruction for collection selected provides clear understanding on the considerations of sampling like kind of aquatic products to be sampled, consider the requirements of the laboratory, the homogeneity of the unit in each lot and among lots.

The sampling size of 500g edible tissue is just ideal for the reason that we are using screening method and we need to confirm in case of positive results. The amount will also cover re-testing if we found positive to double check and retention sample.</td></tr>
</table>

Canned fish and shellfish products	Collect sufficient[1] units[2] randomly selected from each lot to meet laboratory sample size requirements. ~~Or~~ ~~Collect one or more units[2] selected from each lot making up the consignment.~~	500g edible tissue		
[1]A sufficient number of units should be determined based on the type of fish, crustacean or shellfish, the homogeneity (consistency) of production, and the method of analysis. Sufficient number of units should take into consideration sampling and between lots [2]Unit means a single fish, shell fish, fish portion, package of fish, or can of fish making up a consignment				

UNITED KINGDOM

Executive summary of project VM02174[1]

Background: The Codex Alimentarius Commission has responsibility for establishing standards in international food trade in order to protect consumer health. Its work is served by a range of committees, and in particular the Codex Committee on Residues in Veterinary Drugs in Food (CCRVDF). As recently as 2009, the CCRVDF adopted guidelines for the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drug residues in food. These guidelines had evolved from draft guidelines issued in 2007, with the notable exception that the instructions for collection of the minimum quantities of aquatic animal products had been withdrawn. This was due to concern regarding the rationale behind the instructions for sample collection and the minimum quantities required for analytical laboratory analysis. In light of this it was decided that consideration should be given to the sampling schemes and in particular those associated with aquaculture products with a view to determining their validity and what scope there is for identifying a sampling scheme that was both statistically sound and commercially viable.

There were 7 objectives of the project, all of which were met in full.

1.1 Investigate the statistical recommendations underpinning the CCRVDF draft and adopted guidelines for monitoring veterinary residues in food, and their relationship to the general principles of detecting drug residues in animal products as outlined in EC directive 96/23: Relevant documentation was obtained from the Codex Alimentarius Committee, European Commission and Veterinary Medicines Directorate. The monitoring strategies were compared and statistical rationales examined. Tables listing sample numbers were verified.

1.2 Give consideration to existing and alternative appropriate internationally recognised statistical sampling schemes based on product characteristics and required residue detection limits: Other appropriate sampling schemes were examined, including those used for phytosanitory, illegal drug sampling, and pesticides. This highlighted that pragmatic sampling may have to be employed due to the large number of samples required when using schemes based on probability distributions. In addition, the use of acceptance sampling plans was investigated. These required fewer samples than other schemes but were limited by the setting of an acceptable level of residue in a consignment.

2.1 Establish data on packaging, distribution and importation of aquatic commodities and in particular how aquatic products can be grouped for the purpose of different sampling scheme: Data regarding aquatic commodities were obtained from CEFAS, Marine Scotland, HM Revenue and Customs and RASFF (Rapid Alert System for Food and Feed) EU web portal. UK aquaculture production is dominated by salmon, trout and mussels. While salmon is the major UK aquaculture import, it is prawns/shrimp and catfish that represent products at issue regarding veterinary residues. The majority of produce is transported boxed, either frozen or chilled.

[1] A copy of the full report is available to all at the link below:
http://randd.defra.gov.uk/Document.aspx?Document=9902_VM02174finalreport.pdf

2.2 Understand statutory and non-statutory inspection systems and surveillance schemes for UK produce, prior to exportation and at point-of-importation for key aquatic products from outside the UK.: Data obtained from the VMD was used to examine the statutory and non-statutory schemes operated in the UK. This demonstrated that the statutory scheme, based on EU Directive 96/23/EC, appeared to be an efficient mechanism for monitoring for residues within the UK. The non-statutory scheme related to imports and was intelligence led, targeted sampling. Levels of sampling effort regarding this scheme varied considerably compared to the statutory scheme.

2.3 Identify key aquatic products and current drug residue issues of general interest and the constraints on laboratory testing requirements, including Limit of quantification (LOQ), Limit of detection (LOD), repeatability, reproducibility, test specificity and sensitivity: The VMD and RASFF datasets were examined to identify those residues that were commonly identified in aquaculture commodities. This identified that chloramphenicol and nitrofurans were the residues that were of concern in crustaceans, while dyes could be an issue for fish spp. Laboratory testing measures were examined, and simulations were conducted in the R software language to determine the effect of changing the sensitivity and specificity of analyses when examining farm residue data.

2.4 Explore a range of statistical models using statistical theory and computer simulation techniques to identify whether a meaningful sampling scheme can be identified which could provide a simplified and novel approach to sampling aquaculture commodities and also be sufficiently rigorous to be useful in protecting consumer health: Process control charts were used to analyse the RASFF dataset. This indicated that such an approach could be used to determine when a problem was occurring regarding imports and residues. As Directive 96/23/EC appeared to be successful for the UK, simulations were conducted using this sampling scheme in other aquaculture industries. This indicates that it was only effective where an industry was consolidated into fewer farms with greater output. Where industries are composed of many micro-scale farms, different approaches will be necessary. Simulations were also conducted on consignments entering the EU. These indicated that while sample size was important, given constraints on sample numbers, a large enough sample to justify a defined scheme was unlikely to occur. The simulations also highlighted the importance of taking random samples throughout the consignment, rather than clustered within a consignment.

3.2 Communicate findings: To date the project has produced one peer reviewed paper and one plenary at an international conference. A meeting that communicated and discussed the project with key experts was conducted.

Conclusions and future directions

As globalisation of trade continues, verification that imported produce is safe to eat will continue to be a priority. The most successful mechanisms for ensuring this are through system verification checks operated at the farm level. These should preferably be random checks on individual farms or processing sites, unless there is cause for concern, in which case targeted sampling should be adopted. For large consolidated industries such as EU salmon farming, Directive 96/23/EC appears to provide an acceptable sampling framework for veterinary residues. However, for industries that consist of many small farms, as is associated with crustaceans, such sampling schemes, based on overall tonnage produced may not provide adequate coverage. Therefore, regulatory schemes should be industry specific.

Secondary verification, through the random examination of imports, is unlikely to be successful in protecting the public as only a minority of consignments can be sampled. Analysis of RASFF notifications indicates that that there are spikes in reporting activity regarding residues in imports exceeding MRLs based on geographic origin and species but these change over time when country and industry specific issues are resolved. Process control charts applied to RASFF notifications may be used to identify residue issues as they emerge. It is recommended that targeted sampling should be conducted on imports based on intelligence, RASFF notifications, prior record of the exporter and exporting country.

The outputs of this project may inform the CCRVDF regarding current recommendations for the sampling of aquaculture products. The simulations and analysis conducted support the most recent draft of the CODEX (January 2012) CCRVDF recommendations that a sample should be composed of sufficient units randomly selected from a lot to meet laboratory sample size requirements and the stipulation of a minimum sample requirement that provides scope for additional sampling if required.