CODEX ALIMENTARIUS COMMISSION







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

Agenda Item 7.2

CX/RVDF 16/23/8 September 2016

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

Houston, Texas, United States of America, 17 - 21 October 2016

DISCUSSION PAPER ON THE ESTABLISHMENT OF A RATING SYSTEM TO ESTABLISH PRIORITY FOR CCRVDF WORK

Report of the CCRVDF EWG – applicability and appropriateness of a scoring device on prioritization of emerging issues

A. Background

- 1. CCRVDF22 agreed to establish an EWG led by France, working in English only, with the following Terms of Reference: to prepare a discussion paper exploring the feasibility of adopting a scoring system to establish priorities for the work of the Committee.
- 2. An invitation was sent to all Codex members and a questionnaire was distributed to all of the EWG participants on 7 September 2015. The list of participants is attached as Annex II. Comments from nine Codex member states¹ and one Codex member intergovernmental organization were gathered.
- 3. The questionnaire had three parts: (i) Appropriateness of elaborating a systematic approach for priorization of emerging issues in CCRVDF, (ii) Potential scope for setting up a scoring device for CCRVDF and (iii) Alternatives for elaborating a systematic approach. In this synthesis, we follow the three parts of the questionnaire with the aim to summarize what seemed to be the main messages received from the participants. We also make some proposals to help the elaboration of a scoring system if this initiative had to be followed.

B. Synthesis

Appropriateness of elaborating a systematic approach for priorization of emerging issues in CCRVDF

4. Following an extensive discussion that took place during CCRVDF22, participants were asked about what kind of difficulties this Committee had to face when establishing its framework. All the participants recognized that it can sometimes be challenging to establish if an issue does belong to the mandate of CCRVDF, and therefore, if it has to be addressed in priority. On this question, one respondent also underlined that, if there is an efficient process to establish priorities between veterinary drugs when elaborating MRLs, most of the times, difficulty arise when the Committee has to face an issue more complex than to elaborate MRLs². Some participants also emphasized that this task must be in accordance with the general objective of Codex, which is to ensure both food safety and fair practices in international trade, with a specific care for the needs of developing countries. They noted that, to establish priorities, attention should be paid to the possibility to complete work in a certain timeline, taking into account, for instance, the availability of data or the agreement of all stakeholders about the precise definition of health within the frame of CCRVDF.

¹ Brazil, Chile, European Union, France, Ghana, Japan, New Zealand, Nigeria, Peru, the United States of America.

² This was for instance the case when CCRVDF discussed about the appropriateness to establish risk management recommendations.

CX/RVDF 16/23/8 2

There seems to be a consensus that a formalized approach could improve the Committee efficiency as it would allow to set a pluriannual timetable, as well as it would constitute a trustable memory of decisions made by the Committee. However, the number of topics that CCRVDF has to handle remains manageable, participants insisted that such an approach should remain flexible. A systematic approach could also be used as a basis to help communication between Codex committees or with other international organizations. This communication already exists, but is not always easy to understand for all stakeholders, especially those who don't have enough resources to follow every initiative taken by international forums. Regarding communication, some participants went further and proposed tools designed to make information easier to find for everyone, such as quick incipits, research tools using modern technology, or "Newsletters" giving a regular update of the work done by the different CCRVDF working groups.

Potential scope for setting up a scoring device for CCRVDF

- Most of the participants were of the view that a systematic approach should undergo the following process: (a) Verify that the issue relates to the mandate of Codex, i.e. put the health of the consumers at stake and/or involves fair practices in the food trade; (b) Based on the terms of reference for CCRVDF, determine if the Committee is the relevant Codex committee or is in charge of some significant aspects to address the question; (c) Establish the history of the issue in CCRVDF (has it already been addressed and does it need an update). A participant noted that this process could underline that there are issues that are relevant for Codex but do not belong to any existing committee. When this situation arises, there should be a mechanism for transmitting the issue to the CAC to allow an appropriate case-by-case management. This question, however, might exceed the terms of reference of this EWG.
- As a general comment, it was said that attention should be paid to existing Codex procedures or arenas in order to avoid redundancy. For instance, participants mentioned the existing EWG on the priority list of veterinary drugs to be transmitted to JECFA for (re)evaluation. While recognizing the importance of JECFA in that process, it appears to them that those two tasks should remain distinct as CCRVDF is responsible of the risk management part of risk analysis, to which setting priorities clearly belongs. Underlying that meetings of a future WG on priorization should, to the extent possible, be held together with CCRVDF sessions, with the scope to enable maximum participation, respondents proposed to arrange the meeting of the two WG (i.e. the one on the priority list and the one on priorization between emerging issues) one after the other for logistic facilitation purpose. This could allow keeping JECFA informed about which new issues will have to be addressed, and to ask for its expertise if needed.
- The extent to which a specific approach for emerging issues should be linked to the working group on the priority list and should involve JECFA lead to a wide range of comments. The majority of respondents were of the view that those two tasks should be strictly distinguished, but two participants thought that the existing working group on the priority list was the appropriate one to address prioritization between emerging issues.

Alternatives for elaborating a systematic approach

- Participants expressed various opinions on the type of tool that could be developed to fit those 9. requirements. The majority found a semi-quantitative tool would be the most appropriate one as it would allow for both objectivity and flexibility.
- When asked to determine which criteria would be important to take into account, the participants most cited the health risk an issue can constitute or the extent it impacts international trade, and the improvements a CCRVDF standard could bring to those issues. CCRVDF should verify whether there is an existing document discussing the proposed emerging issue, such as a risk evaluation performed by a national authority indicating existence of a risk for health, and determine how current its content is, before trying to prioritize the emerging issue. One participant underlined that, even if all the proposed criteria³ seemed to be important, it was not always clear if they would be likely to improve or to decrease a potential priority score. All participants were of the opinion that health risk and fair practices in international trade were the most important aspects to take into account when establishing priorities regarding CCRVDF work. Therefore, a systematic approach will have to enhance those aspects. It was also noted that it should not be required to end one project before addressing another one that would be scored with lower priority.

³ The proposed criteria in the initial document were the following ones: Positive impact of new work on public health; Positive impact of new work on international trade; Public Health Risk; Trade Impact; Existence of CCRVDF work on the subject and last revision; Currency of information; Possibility that new data become available; FAO/WHO assistance needed; Negative consequences of non-action on public health; Negative consequences of non-action on trade; Project document/discussion paper available or country committed to prepare one; Work undertaken by other Codex Committee(s) and/or other organization(s); Necessity to have a coherent approach with other international policies.

CX/RVDF 16/23/8 3

C. Proposal

11. CCRVDF members showed interest in the potential utility of a systematic approach dedicated to the prioritization of emerging issues that could be addressed as new works, both during CCRVDF22 and by participating in this EWG. Thus, we tried to elaborate a generic tool that best embedded the comments we received.

- 12. In elaborating a potential new tool, we kept in mind the following requirements:
 - The new tool has to determine if the issue is part of the Codex mandate and if CCRVDF is at least in charge of significant aspects of the issue;
 - It has to remain as neutral as possible in order to improve transparency in setting priorities;
 - It will have to fit within existing procedures, both in order to facilitate large access and participation and to avoid redundancy;
 - It has to be both precise and sufficiently flexible to effectively prioritize CCRVDF's initiatives and proposals for new work;
 - It should be designed to determine which projects would have important consequences in improving health risks management and international trade. It should also help the communication about CCRVDF timeframe with other Codex committees and subsidiary bodies, with other organizations and with the public.
- 13. The proposed tool presented below could be implemented as a test, before CCRVDF decides if it is useful or not, or if it has to be improved. Usually, CCRVDF doesn't have to deal with a high number of emerging issues at the same time. Moreover, questions raised by CCRVDF members often have important technical and scientific aspects that can benefit from the inputs of the JECFA secretariat. For these reasons, it is proposed that issues relevant for prioritization should be examined during the physical working group on the priority list. If assistance from JECFA were needed, it would allow determining if the question could be transmitted to JECFA, taking into account its own framework.

No

CCRVDF is not competent to

examine the issue

Step two: submission of a project document as described in the Procedural Manual, 23rd version, Section II, p. 27

Yes

The issue should undergo the

prioritization rating

Step three: quantitative rating following the matrix below

See Annex I

CX/RVDF 16/23/8 4

Annex I

Proposed quantitative matrix for Step 2

i) Proposed matrix

Criterion	Rating
New information/data/technology Is there new information/data/technology that would justify the need to review the existing code(s), standard(s) or establish a new one?	Yes 20 Intermediate 10 No 0
Positive impact of new work on public health - Whether new work would result in a document/recommendation that could have a positive impact on public health	Yes 20 Intermediate 10 No 0
Public health risk ⁴ raised by the emerging issue	High 20 Medium 14 Low 8
Impact on international trade raised by the emerging issue	High 20 Medium 14 Low 8

ii) Additional criteria

If several emerging issues happen to total the same score, or if further consideration is needed before adding an emerging issue to the CCRVDF agenda, attention should be paid to the following factors:

- (a) The need for WHO/FAO assistance in providing science-based guidelines to help the management of the emerging issue in question and the insurance that this prospective assistance will not cause undue delay to the new work in consideration;
- (b) The need for coordination with other international bodies (including for instance the OIE or the VICH) to correctly manage the issue, avoiding both useless duplication of work and regulation gaps;
- (c) When necessary, advice from the JECFA or other relevant international expertise providers should be gathered to evaluate the feasibility of providing a prospective additional expertise on the matter;
- (d) Finally, in an attempt to promote consensus among CCRVDF members, a qualitative evaluation of the support of undertaking new work should be performed.

⁴ The evaluation of the public health risk, according to the *Definitions of Risk Analysis Terms Related to Food Safety* (Procedural Manual, 23rd version, Section IV – Risk analysis, Definition of risk analysis terms related to food safety, p. 116), will have to encompass both the evaluation of the health effect severity of its probability of occurrence.

CX/RVDF 16/23/8 5

Annex II

List of Participants

Brazil

Suzana BRESSLAU

Official Veterinarian Inspector,

Ministry of Agriculture, Livestock and Food Supply suzana.bresslau@agricultura.gov.br

Chili

Claudio NUNEZ

Profesional Unidad de Acuerdos Internacionales, Servicio Agrícola y Ganadero, Coordinador del Subcomité del Codex en Chile sobre Medicamentos Veterinarios en los Alimentos c.nunez@sag.gob.cl

Roxana Inés Vera MUÑOZ

Coordinadora Unidad de Acuerdos Internacionales del Servicio Agrícola y Ganadero,

Sub-Coordinadora del Subcomité del Codex en Chile sobre Medicamentos Veterinarios en los Alimentos roxana.vera@sag.gob.cl

European Union

Risto HOLMA

DG SANCO, European Commission, Health and Food Safety Directorate-General, Brussels - Belgium 32 22998683

risto.holma@ec.europa.eu; sante-codex@ec.europa.eu

France

Catherine LAMBERT

Deputy Director and Head of European and international affairs, ANMV

8 rue Claude Bourgelat - Parc d'Activités de la Grande Marche - Javené, CS 70611 - 35306 FOUGERES 33 2 99 94 78 87

Catherine.LAMBERT@anses.fr

Anne-Marie JACQUES

ANMV, 8 rue Claude Bourgelat - Parc d'Activités de la Grande Marche - Javené, CS 70611 - 35306 **FOUGERES**

Anne-marie.jacques@anses.fr

Olivier DEBAERE

Deputy Director, Bureau des Instrants et de la Santé Publique en élevage

DGAL- rue de Vaugirard, 75015 Paris olivier.debaere@agriculture.gouv.fr

Mr. Kwame Dei ASAMOAH- OKYERE

Senior Regulatory Officer, Food and Drugs authority kwamedei@hotmail.com

Japan

Mr. Yuji MATSUKURA

Special Assistant to the Director of the Division, Standards and Evaluation Division, Ministry of Health, Labour and Welfare, 1-2-2 Kasumigaseki, Chiyoda-ku 100-8916 Tokyo 81-3-3595-2341 codexj@mhlw.go.jp

Dr. Hajime TOYOFUKU

Professor, Joint Facility of Veterinary Medicine, Yamaguchi University toyofuku@yamaguchi-u.ac.jp

Mr. Tatsuro SEKIYA

Deputy Director, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950 tatsuro_sekiya@nm.maff.go.jp, codex_maff@nm.maff.go.jp

New Zealand

Warren HUGHES

Principal Adviser ACVM Regulation & Assurance Systems Audit, Assurance, & Monitoring Directorate, Regulation & Assurance Branch, Ministry for Primary Industries, Pastoral House, 25 The Terrace, PO Box 2526, Wellington, New Zealand 64-4-894 2560 Warren.Hughes@mpi.govt.nz

Nigeria

Dr. Demola MAJASAN Deputy Director,

codexsecretariat@son.gov.ng

Dr. Mabel Aworh, (DVM, MPH)

Senior Veterinary Officer I/ Epidemiologist Veterinary Drugs/Animal Welfare Branch Quality Assurance and Standards Division Dept. of Veterinary & Pests Control Services, Federal Min. of Agric. & Rural Dev. F.C.D.A, Area 11, Garki, Abuja mabelaworh@yahoo.com

+2348032377831

Peru

Mercedes Lucía Flores CANCINO

Servicio Nacional de Sanidad Agraria (Senasa) Coordinador titular del CCRVDF, Especialista en Inocuidad Agroalimentaria mflores@senasa.gob.pe

United States of America

Dr. Dong YAN

Biologist,

Center for Veterinary Medicine, U.S. Food and Drug Administration, 7500 Standish Place, HFV -151, 20855 Rockville, MD 1 240 402 0825 dong.yan@fda.hhs.gov