UNITED STATES DELEGATION

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

25TH SESSION

25 – 29 JANUARY 2021
CLEVELAND, OH, USA

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
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25-29 January 2021

ADOPTION OF THE AGENDA

AGENDA ITEM No. 1 **CX/RVDF 20/25/1**

Background:

This agenda item provides an opportunity to add to or reorganize the agenda items for the plenary session.

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MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES

AGENDA ITEM No. 2 **CX/RVDF 20/25/2**

Background:

The agenda item is intended to communicate issues arising from the Codex Alimentarius Commission (CAC) and other subsidiary bodies such as Codex Committees or Task Forces. The agenda item includes updates from the CAC on items proposed by the CCRVDF.

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MATTERS ARISING FROM FAO/WHO AND FROM THE 88th MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA88, 2019)

AGENDA ITEM No. 3.1 **CX/RVDF 20/25/3**

Background:

This agenda item is intended to update the Committee on the activities of the FAO and WHO on issues which could impact the CCRVDF. The agenda item also provides an overview of the 88th JECFA meeting (2019).

The 88th JECFA evaluated eight veterinary drugs. The 88th JECFA recommended maximum residue limits (MRLs) for three veterinary drugs and was unable to recommend MRLs for five veterinary drugs. MRL recommendations were made for diflubenzuron in salmon, halquinol in swine, and ivermectin in sheep, pigs, and goats. More data are needed for JECFA to make recommendations for ethion in cattle, flumethrin in cattle, fosfomycin in chicken and pigs, selemectin in salmon, and sisapronil in cattle.

This agenda item also shares information on general considerations of the 88th JECFA (2019) and on the activities of FAO and WHO relevant to the CCRVDF. Some of the general considerations from JECFA88 include an update on the JECFA/JMPR working group, necessary information for use of scientific literature, toxicological profiling of compounds and less-than lifetime dietary exposure assessment, combined exposure to multiple chemicals, and microbiological effects as part of the safety evaluation. JECFA88 also provided comments on the pilot parallel review process for which selamectin was evaluated.

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REPORT OF THE JOINT FAO/WHO EXPERT MEETING ON CARRY-OVER IN FEED AND TRANSFER FROM FEED TO FOOD OF UNAVOIDABLE AND UNINTENDED RESIDUES OF APPROVED VETERINARY DRUGS

AGENDA ITEM No. 3.2 **CX/RVDF 20/25/3-Add.1**

Background:

At CCRVDF22 (2015), some delegations noted that an MRL had been requested for lasalocid in eggs because of risk of cross contamination in feed for laying hens which could result in carry-over in eggs (REP15/RVDF, para 82). An MRL had not been recommended by JECFA because lasalocid sodium is not intended for use in laying hens. The Committee discussed the need to develop a policy to address the issue of carry-over and cross-contamination from medicated feed and to allow for a certain flexibility in the procedure for the establishment of MRLs to address this type of trade issue (REP15/RVDF, para 83).

At CCRVDF23 (2017), the Committee discussed whether the Code of Practice on Good Animal Feeding is sufficient to address carryover of veterinary drugs in feed and determined there was insufficient information on the need to develop specific guidance at the time (REP17/RVDF, para 77). The Committee agreed to request scientific advice from FAO and WHO on possible risk management recommendations to address trade issues while protecting human health.

An FAO/WHO Expert Consultation took place in January 2019 on carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs. The Expert Consultation made several recommendations for addressing the risk of unintended residues in food due to carryover in feed. The recommendations within the scope of the Codex Alimentarius included revision of the Codex Code of Practice on Good Animal Feeding to provide practical guidance addressing the potential for carryover of veterinary drug in feed and establishment of an action level for veterinary drug residues in food for cases where carryover is unavoidable even if the Codex Code of Practice on Good Animal Feeding, Good Manufacturing Practice (GMP), and Hazard Analysis Critical Control Point (HAACP) are followed.

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MATTERS OF INTEREST ARISING FROM THE JOINT FAO/IAEA DIVISION OF NUCLEAR TECHNIQUES IN FOOD RELEVANT TO CCRVDF WORK

AGENDA ITEM No. 3.3 **CX/RVDF 20/25/3-Add.2**

Background:
The Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture Relevant to Codex Work is informational for the Committee.

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REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)

AGENDA ITEM No. 4 **CX/RVDF 20/25/4**

Background:

This agenda item provides information on the recent activities of the World Organization for Animal Health (OIE) and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

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DRAFT MRL FOR FLUMETHRIN (HONEY) AT STEP 7

AGENDA ITEM No. 5 **REP18/RVDF-App. IV**
CL 2020/17-RVDF
& CL 2020/17-RVDF

Background:

The proposed draft MRL for flumethrin in honey was recommended by the 85th JECFA (2017). The recommended MRL was based on twice the limit of quantification of the most reliable analytical method used in the residue studies.

At CCRVDF24 (2018), some members raised concerns that the highly sensitive method that formed the basis for the MRL was expensive and not readily available in developing countries. They noted that the lack of laboratory capacity to measure such low levels could lead to trade problems. The JECFA Secretariat noted that when flumethrin was used according to Good Veterinary Practice, the amount of residue that could be expected in honey is at or below the limit of quantification of current methods and that there was little risk that residues would move from the wax to the honey due to flumethrin's highly lipophilic properties. The CCRVDF24 (2018) agreed to forward a proposal to the Codex Alimentarius Commission (CAC) that an MRL was 'unnecessary' for adoption at Step 5 (allowing for another round of comment and consideration by the Committee). CAC41 (2018) adopted the CCRVDF proposal at Step 5. The draft MRL is out for comment at Step 6 and will be considered by CCRVDF25 (2021) at Step 7.

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PROPOSED DRAFT MRLS FOR DIFLUBENZURON (SALMON-MUSCLE PLUS SKIN IN NATURAL PROPORTION), HALQUINOL (IN SWINE – MUSCLE, SKIN PLUS FAT, LIVER AND KIDNEY), IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AT STEP 4

AGENDA ITEM No. 6.1 **CL 2020/17-RVDF & CX/RVDF 20/25/6**

Background:

The proposed draft MRLs were recommended by JECFA88 (2019). The proposed draft MRLs are for:

- Diflubenzuron in salmon – muscle plus skin in natural proportion
- Halquinol in swine – muscle, skin plus fat, liver and kidney
- Ivermectin in sheep, pigs, and goats – fat, kidney, liver and muscle

The proposed draft MRLs are available for comment at Step 3 and will be discussed by CCRVDF25(2021) at Step 4. The Committee may consider recommending adoption by the next Codex Alimentarius Commission at Step 5 (allowing for another round of comment and consideration by the Committee) or Step 5/8 (final adoption).

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PROPOSED DRAFT MRLS FOR ZILPATEROL HYDROCHLORIDE (CATTLE FAT, KIDNEY, LIVER, MUSCLE) (81ST JECFA) AT STEP 4

AGENDA ITEM No. 6.2 **REP18/RVDF App. III**
CX/RVDF 20/25/7

Background:

Zilpaterol hydrochloride was evaluated at the 78th JECFA (2013) and the 81st JECFA (2015). The 78th JECFA (2013) established an ADI, but requested additional data to recommend MRLs. The sponsor developed and submitted the requested data, which were evaluated by the 81st JECFA. The 81st JECFA (2015) proposed draft MRLs for cattle fat, kidney, liver, and muscle.

CCRVDF23 (2016) agreed to hold the proposed draft MRLs for cattle tissues to allow the sponsor to develop and provide additional data on the bioavailability of incurred residues for re-evaluation by JECFA. The new data developed by the sponsor did not show a difference in bioavailability of zilpaterol hydrochloride residues, but were submitted in full for consideration by the 85th JECFA (2017). The 85th JECFA (2017) evaluated the new data provided and reconfirmed the 81st JECFA's (2015) recommended MRLs.

CCRVDF24 (2018) agreed that JECFA had conducted a robust scientific evaluation and that there were no scientific or public health concerns regarding the proposed draft MRLs for zilpaterol hydrochloride. There was extensive support from Member Countries to advance the proposed draft MRLs to the Codex Alimentarius Commission for adoption at Step 5 (allowing for another round of comment and consideration by the Committee) or Step 5/8 (final adoption). However, some delegations objected to advancing the MRLs based on concerns outside the mandate of the Committee and Codex, including national legislation, animal welfare, and general opposition to "non-therapeutic" uses of animal drugs.

The Chair noted that, while there was consensus on the science, there was no consensus on advancement of the proposed draft MRLs and he proposed to close the debate for the current session of CCRVDF. As the Committee could not reach consensus to advance the MRLs due to

concerns outside the scope of Codex, the proposed draft MRLs for zilpaterol hydrochloride were held at Step 4 and not forwarded to the CAC for consideration.

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DISCUSSION PAPER ON EXTRAPOLATION OF MRLS TO ONE OR MORE SPECIES (INCLUDING A PILOT ON EXTRAPOLATION ON MRLS IDENTIFIED IN PART D OF THE PRIORITY LIST – REP18/RVDF, APP. VI)

AGENDA ITEM No. 7 **CX/RVDF 20/25/8**

Background:

CCRVDF22 (2015) requested JECFA to assess whether, on the basis of data from one or more fish species, it was possible to establish MRLs for finfish, crustaceans or molluscs in general, or for multiple similar groups. In response, the 81st JECFA (2015) requested further information on appropriate groupings of fish species so that representative species could be identified from which MRLs could then be extrapolated to other similar species.

CCRVDF23 (2016) agreed to establish an electronic working group to prepare a discussion paper on the feasibility of establishing MRLs for groups of fish species for veterinary drugs being considered by JECFA/CCRVDF. The electronic working group discussed many factors which could be used to group fish species including temperature, salinity, phylogeny, common physiology, and common behavior.

CCRVDF24 (2018) discussed a proposed step-wise approach to extrapolating MRLs for fish. The Committee agreed to establish a new electronic working group to prepare a discussion paper exploring pragmatic ways for CCRVDF to extrapolate MRLs to more species in its role as a risk manager. This electronic working group would look at extrapolation in fish as well as more broadly. The Committee also identified 10 veterinary drugs in ruminant species and 3 veterinary drugs in fish species for the electronic working group to consider for further extrapolation.

The electronic working group has proposed criteria for extrapolation of existing Codex MRLs in one species to additional species and recommended extrapolation of 12 of the 13 veterinary drugs identified by the CCRVDF24 (2018).

- Amoxicillin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Benzylpenicillin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Tetracyclines MRLs to ruminants in muscle, liver, kidney and milk
- Cyhalothrin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Cypermethrin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Deltamethrin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Moxidectin MRLs to ruminants in muscle, fat, liver and kidney
- Spectinomycin MRLs to ruminants in muscle, fat, liver, kidney and milk
- Levamisole MRLs to ruminants in muscle, fat, liver and kidney
- Tilmicosin MRLs to ruminants in muscle, fat, liver and kidney
- Deltamethrin MRLs to bony fish in muscle
- Flumequine MRLs to bony fish in muscle

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DISCUSSION PAPER ON THE DEVELOPMENT OF A HARMONIZED DEFINITION FOR EDIBLE TISSUES OF ANIMAL ORIGIN (INCLUDING EDIBLE OFFAL)

AGENDA ITEM No. 8 **CX/RVDF 20/25/9**

Background:

CCRVDF22 (2015) requested JECFA recommend MRLs for zilpaterol hydrochloride in offal tissues. The 81st JECFA (2015) noted that there are many definitions for offal which have not been harmonized and requested guidance on a defined list of tissues of interest to CCRVDF. CCRVDF23 (2016) agreed to establish an electronic working group to prepare a discussion paper proposing a definition for edible offal and specifying edible offal tissues of interest in international trade.

CCRVDF24 (2018) considered a broad definition for offal and edible offal proposed by the electronic working group. The Committee agreed that a broad definition could be included in the *Glossary of Terms and Definitions for CCRVDF* but noted that it would be beneficial to harmonize definitions with the Codex Committee on Pesticide Residues (CCPR) which already had a definition for offal. The Committee agreed to establish a new electronic working group to work with the CCPR electronic working group on classification of food and feed to elaborate a definition for edible offal and for any other animal tissues of relevance, for the purposes for harmonization and elaborating MRLs.

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DISCUSSION PAPER ON ADVANTAGES AND DISADVANTAGES OF A PARALLEL APPROACH TO COMPOUND EVALUATION

AGENDA ITEM No. 9 **CX/RVDF 20/25/10**

Background:

CCRVDF24 (2018) discussed approaches that could be considered for the parallel development of MRLs in Codex and by national authorities, while maintaining the scientific integrity and transparency of the JECFA evaluation and Codex process. The Committee agreed to develop a discussion paper led by Canada and supported by Australia, the United States, and the JECFA Secretariat which would look at the advantages and disadvantages of a parallel process for a JECFA evaluation which would take place while a compound was still under evaluation by a national authority for registration.

The Committee and the JECFA Secretariat also agreed to pilot such an approach should a compound become available. JECFA88 (2019) evaluated selamectin in salmon and established an ADI but requested additional information to allow JECFA to complete the evaluation and recommend MRLs.

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DATABASE ON COUNTRIES' NEEDS FOR MRLS

AGENDA ITEM No. 10 **CX/RVDF 20/25/11**

Background:

CCRVDF24 (2018) reviewed the Database on Countries' Needs for MRLs and the high priority needs identified by an electronic working group. Several countries offered to develop dossiers to support JECFA evaluations based on the high priority needs in the Database. The Committee agreed to maintain the Database so that it remains available to members, and highlighted high priority compounds. The Committee also agreed that no further requests for inclusion of additional compounds would be issued.

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PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (REPLIES TO CL 2020/18-RVDF)

AGENDA ITEM No. 11 **CX/RVDF 20/25/12**

Background:

Circular Letter 2020/18-RVDF was issued to collect nominations to the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA. The Circular Letter also requests confirmation of data availability for several other compounds.

One veterinary drug has been nominated at past CCRVDF meetings but will require confirmation of data availability at CCRVDF25:

- Ethoxyquin in shrimp

There are several veterinary drugs which JECFA has begun an evaluation, but has requested additional data in order to recommend MRLs:

- Ethion in cattle tissues
- Flumethrin in cattle tissues
- Fosfomycin in chicken and swine tissues
- Sisapronil in cattle tissues

JECFA88 conducted a pilot parallel review on a new compound, but the evaluation could not be completed. Confirmation of data availability is requested at CCRVDF25:

- Selamectin in salmon tissues

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OTHER BUSINESS AND FUTURE WORK

AGENDA ITEM No. 12

This agenda item is intended for proposals for new work not previously identified in the agenda.

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DATE AND PLACE OF NEXT SESSION

AGENDA ITEM No. 13

The date and place of CCRVDF26 will be identified at a later date.