DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Committee on Residues of Veterinary Drugs in Foods

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S Codex Office is sponsoring a public meeting on April 30, 2020. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) of the Codex Alimentarius Commission (CAC), in San Diego, California, May 25-29, 2020. The U.S. Manager for Codex Alimentarius and the Under Secretary, Office of Trade and Foreign Agricultural Affairs, recognize the importance of providing interested parties the opportunity to obtain background information on the 25th Session of the CCRVDF and to address items on the agenda.

DATES: The public meeting is scheduled for April 30, 2020, from 1:00 p.m. to 3:00 p.m. EST.

ADDRESSES: The public meeting will take place in the United States Department of Agriculture (USDA), Whitten Building, Room 107-A,1400 Independence Avenue SW., Washington, DC 20250. Documents related to the 25th Session of the CCRVDF will be

accessible via the internet at the following address: http://www.codexalimentarius.org/meetings-reports/en. Ms. Brandi Robinson, U.S. Delegate to the 25th Session of the CCRVDF, invites U.S. interested parties to submit their comments electronically to the following email address: Brandi.Robinson@fda.hhs.gov.

Call in number: If you wish to participate in the public meeting for the 25th Session of the CCRVDF by conference call, please register in advance by emailing ken.lowery@usda.gov. Please use the call-in-number: 1-888-844-9904 and participant code: 512 6092

Registration: Attendees may register to attend the public meeting by emailing ken.lowery@usda.gov by April 24, 2020. Early registration is encouraged because it will expedite entry into the building. The meeting will take place in a Federal building. Attendees should bring photo identification and plan for adequate time to pass through the security screening systems. Attendees who are not able to attend the meeting in person, but who wish to participate, may do so by phone, as discussed above.

For further information about the 25th session of CCRVDF, contact Brandi Robinson, International Program Manager, Center for Veterinary Medicine (CVM), Office of New Animal Drug Evaluation, Food and Drug Administration, 7500 Standish Place

HFV-100, Rockville, MD 20855. Phone: (240) 402-0645, Email: Brandi.Robinson@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Ken Lowery, U.S. Codex Office, 1400 Independence Avenue SW., Room 4861, South Building, Washington, DC 20250.Phone:(202) 690-4042, Fax:(202) 720-3157, Email: ken.lowery@usda.gov

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) determines priorities for the consideration of residues of veterinary drugs in foods and recommends Maximum Residue Limits (MRLs) for veterinary drugs. The Committee also develops codes of practice, as may be required, and considers methods of sampling and analysis for the determination of veterinary drug residues in food. A veterinary drug is defined as any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish, or bees, whether

used for therapeutic, prophylactic or diagnostic purposes, or for modification of physiological functions or behavior.

A Codex Maximum Residue Limit (MRL) for residues of veterinary drugs is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be permitted or recognized as acceptable in or on a food. Residues of a veterinary drug include the parent compounds or their metabolites in any edible portion of the animal product and include residues of associated impurities of the veterinary drug concerned. An MRL is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI) or on the basis of a temporary ADI that utilizes an additional safety factor. When establishing an MRL, consideration is also given to residues that occur in food of plant origin or the environment. Furthermore, the MRL may be reduced to be consistent with official recommended or authorized usage, approved by national authorities, of the veterinary drugs under practical conditions.

An ADI is an estimate made by the Joint Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, which can be ingested daily in food over a lifetime without appreciable health risk.

The CCRVDF is hosted by the United States of America, and the meeting is attended by the United States as a member country of the Codex Alimentarius.

Issues to Be Discussed at the Public Meeting

The following items on the Agenda for the 25th Session of the CCRVDF will be discussed during the public meeting:

- Adoption of the Agenda
- Matters referred by CAC and other subsidiary bodies
- Matters of interest arising from FAO/WHO including JECFA88
- 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
- Matters of interest arising from the Joint FAO/International Atomic Energy Agency Division of Nuclear Techniques in Food relevant to CCRVDF work
- Report of World Organization for Animal Health (OIE) activities, including the harmonization of technical requirements for registration of veterinary medicinal products
- Draft MRL for flumethrin (honey) at Step 7
- 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

- Proposed draft MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) (JECFA81 and JECFA85) retained Step 4
- 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)
- Discussion paper on the development of a harmonized definition for edible tissues of animal origin (including edible offal) (coordination between the Codex Committee on Pesticide Residues and CCRVDF)
- Discussion paper on advantages and disadvantages of a parallel approach to compound evaluation
- Database on countries' needs for MRLs
- Priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA
- Other business and future work

Each issue listed will be fully described in documents distributed, or to be distributed by the Secretariat before the Committee meeting. Members of the public may access or request copies of these documents (see ADDRESSES).

Public Meeting

At the April 30, 2020, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Brandi Robinson, U.S. Delegate for the 25th Session of the CCRVDF (see ADDRESSES). Written comments should state that they relate to activities of the 25th Session of the CCRVDF.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this Federal Register publication on-line through the USDA Codex Web page located at: http://www.usda.gov/codex, a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscriptions themselves and have the option to password protect their accounts.

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Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442, Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC, on March 4, 2020.

Mary Lowe,

U.S. Manager for Codex Alimentarius.

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