CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 10 **CRD21**

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

27th Session
21-25 October 2024
Omaha, Nebraska, United States of America

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA
REPLY FROM NEW ZEALAND TO CL 2024/66-RVDF

New Zealand proposes the inclusion of the veterinary drug Bromoform in the priority list for subsequent recommendation to JECFA for evaluation.

The information recommended for consideration in the priority list by CCRVDF has been completed and is attached. Relevant data are anticipated to be available on toxicology, metabolism, pharmacokinetics, and residue depletion studies conducted of the drug in the target species. A comprehensive dossier will be provided for the risk assessment.

Since the registration process of the veterinary product in New Zealand is still ongoing, New Zealand requests that Bromoform be assessed by JECFA as a parallel review.

A Bromoform containing veterinary drug has been submitted for registration in New Zealand and is intended to be submitted in several other countries for use in cattle and other ruminants.

ADMINISTRATIVE INFORMATION

1. Member(s) submitting the request for inclusion: New Zealand

2. Veterinary drug names: Bromoform (methyl tribromide)

3. Trade names: TBC

4. Chemical names and CAS registry number: 75-25.
   IUPAC (International Union of Pure and Applied Chemistry)
   Nomenclature: The IUPAC name for bromoform is tribromomethane. Bromoform is also known by the other names methenyl tribromide and methyl tribromide.
   Molecular formula $CHBr_3$

5. Names and addresses of basic producers: TBC

PURPOSE, SCOPE, AND RATIONALE

6. Identification of the food safety issue (residue hazard):

The food safety issue involves the potential for residues of bromoform to be remain in food products (ruminant tissues) consumed by humans. The level of such residues could pose potential health risks and therefore it is necessary to establish an ADI (Acute Daily Intake), and Maximum Residue Limits (MRLs) to ensure that any residue present in food are within safe levels for human consumption.

Bromoform is a novel veterinary drug that has not yet been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for use in veterinary medicine, and there is currently no established ADI and MRLs for its residues in ruminant tissues.

7. Assessment against the criteria for the inclusion on the priority list:

The New Zealand (MPI) registration procedure will be performed in parallel to the JECFA/CCRVDF review. Currently the risk assessment for food safety dossier is under review at MPI / EPA. It is anticipated that the necessary studies will be completed by July 2025.

Bromoform is intended to be registered in New Zealand and several other countries. Relevant data are anticipated to be available on toxicology, metabolism, pharmacokinetics, and residue depletion studies conducted of the drug in the target species. A comprehensive dossier will be provided for the risk assessment.

RISK PROFILE ELEMENTS

Justification for use: Treatment of ruminants to modify the physiological environment of ruminants so as to reduce the production of methane is important for the continued sustainable production of meat, milk and related products from ruminants. There is a current application for delivery of bromoform via a controlled intraruminal bolus treatment for use in ruminants including the potential use in lactating ruminants.

8. Veterinary use pattern, including information on approved uses if available:

9. Commodities for which Codex MRLs are required: Cattle and Ruminant Liver, kidney, fat, muscle and milk.

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

10. Specific request to risk assessors: Request for establishment of ADI and MRLs for bromoform for Cattle and ruminant muscle, liver, kidney, fat and milk using the parallel review process.

AVAILABLE INFORMATION

11. Countries where the veterinary drugs are registered: Under review by the National Authorities in New Zealand with trials currently underway in several other countries.

12. National/Regional MRLs or any other applicable tolerances: Review of the risk assessment for food safety dossier ongoing in New Zealand (by MPI / EPA).

13. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available:

TIMETABLE

14. Date when data could be submitted to JECFA: July 2025