

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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REPORT OF THE PHYSICAL WORKING GROUP ON CARRYOVER GUIDELINES AND ACTION LEVELS

(Prepared by the Physical Working Group chaired by Canada
and co-chaired by Australia and the United States of America)

INTRODUCTION

1. A Physical Working Group (PWG) meeting chaired by Canada and co-chaired by Australia and the United States of America took place to address the complementary guideline drafted for competent authorities on actions that are to be taken following the detection of a residue of a veterinary drug in food caused by unavoidable and unintentional carryover of veterinary drugs in animal feed where there is no applicable Codex maximum residue limit.

WORK PROCESS: PARTICIPATION AND METHODOLOGY

2. The PWG was attended by various Member countries and observers.
3. The PWG Chairs discussed the last draft of the guideline that was shared as part of CX/RVDF 26/28/9. In line with the terms of reference (TOR) of the PWG, the document contained recommendations for actions to be taken following the detection of a veterinary drug caused by unavoidable and unintentional carryover of veterinary drugs in animal feed where there is no applicable Codex maximum residue limit. Several comments were received on this draft as included in CX/RVDF 26/28/9 Add.1. These edits were considered by the PWG and agreed upon.
4. In addition, there was substantive discussion regarding the title of the guideline.
5. On the basis of these comments, the PWG Chairs prepared a revised guideline, which is attached as an appendices to this report (Appendix I) for consideration by Codex members and observers at CCRVDF28.

SUMMARY OF DISCUSSION

6. The PWG chairs provided an overview of the document and went through the comments received within the EWG and within response to the CL 2026/13-RVDF. The following were the main highlights of the discussion:
 - a. The edits proposed by the Chair and one editorial amendment following a request made by a Member were agreed upon by the PWG.
 - b. One member provided an opinion that the scope of the guideline was limited and did not include all sources of carryover (e.g. carryover resulting from transport, storage and procurement). The Chairs clarified that the committee had previously agreed upon on a definition for unavoidable and unintended veterinary drug carryover in a non-target animal feed, and this definition only referred to carryover caused by feed manufacturing.
 - c. The PWG discussed at great lengths whether the words 'TO BE TAKEN' are appropriate for the title of the guideline. One member expressed their opinion that the phrase 'TO BE TAKEN' was not consistent with the work agreed upon by the Codex Alimentarius Commission (CAC). This member therefore suggested that the phrase be revised to 'THAT COULD BE TAKEN'. One member and an observer indicated their support for maintaining the original title. The Chairs proposed that the phrase 'TO BE TAKEN' could be

replaced with 'FOR'. Three members supported the Chairs proposed revision, while the original dissenting member did not. The Chairs sought advice from the Codex secretariat on what was agreed upon by the CAC. The PWG was informed that the title of the project document for the guideline used the phrase 'TO BE TAKEN', however, other elements of the project document used the phrases 'may be considered' or 'could be taken' with regard to actions taken by competent authorities. Due to time constraints, the Chairs ended the PWG and recommended that the discussion continue in plenary.

CONCLUSIONS

7. The WG completed its task as per its TOR. The outcome is presented in in Appendix I of this document.

PWG RECOMMENDATIONS

8. Codex members and observers are invited to consider the draft guideline as presented in Appendix I.

CHAIRS RECOMMENDATIONS

9. Following the PWG, the Chairs discussed a possible path forward to address the question raised at the PWG regarding the title of the guideline and have included proposed amendments to the title and purpose of the guideline:
 - a. Revise the title to 'GUIDELINES ON RISK BASED ACTIONS TO ~~ADDRESS BE TAKEN BY COMPETENT AUTHORITIES FOLLOWING~~ THE DETECTION OF ~~A~~ RESIDUES OF A VETERINARY DRUG IN FOOD CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED WHERE THERE IS NO APPLICABLE CODEX MRL'
 - b. Revise the purpose to the following: 'These guidelines provide risk-based actions ~~to address to be taken by competent authorities if a the detection of~~ residues of a veterinary drug ~~in a human food commodity of animal origin~~ suspected to be caused by carryover ~~is detected in a human food commodity of animal origin~~. The guidelines should be read in conjunction with 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 (CXG 71-2009).'
10. Codex members and observers are invited to consider the proposed amendments as outlined above.

APPENDIX I

GUIDELINES ON RISK-BASED ACTIONS (TO BE TAKEN/ ~~FOR/COULD BE TAKEN~~) BY COMPETENT AUTHORITIES FOLLOWING THE DETECTION OF A RESIDUE OF A VETERINARY DRUG IN FOOD CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED WHERE THERE IS NO APPLICABLE CODEX MRL

1. INTRODUCTION

Carryover of veterinary drugs in animal feed occurs when veterinary drugs are transferred from feed intended to contain the veterinary drug to feed that is not intended to contain the veterinary drug.¹ Carryover of veterinary drugs in animal feed can occur during feed processing, handling, transportation, delivery or in feeding animals on-farm.¹ When feed affected by carryover is fed to a non-target animal, residues of veterinary drugs can be detected in human food commodities of animal origin for which there are no Codex maximum residue limits (MRLs).

Animal feed manufactures should employ control systems (e.g., flushing, sequencing, or physical clean-out) between batches of animal feed to reduce the incidence of carryover.² Nevertheless, even if the *Code of practice on good animal feeding* (CXC 54-2004), Good Manufacturing Practices (GMP), and Hazard Analysis and Critical Control Point (HACCP) principles are followed, carryover of veterinary drugs in animal feed can occur.¹ This makes the occurrence of carryover in animal feed and any resultant residues in human food commodities of animal origin unavoidable and unintentional. Throughout these guidelines, the term carryover refers to ~~carryover that is~~ unavoidable and unintended unintentional veterinary drug carry-over in a non-target animal feed.

Residues of veterinary drugs in human food commodities caused by carryover are unlikely to be a food safety concern for consumers because the amount of drug that is transferred occurs in low amounts.¹ However, as analytical technologies continue to improve, ~~the detection of~~ residues of veterinary drugs in human food commodities caused by carryover ~~can may be expected to increase detected more frequently, even at very low concentrations~~. Because Codex MRLs might not exist for some human food commodities affected by carryover, “zero-tolerance” approaches have been ~~taken applied in the past some cases~~ even if there is no human food safety concern for the detected residue. This disrupts trade and contributes unnecessarily to food waste. Therefore, a risk-based approach that ensures the health of consumers while facilitating food trade should be used to manage the detection of a residue of a veterinary drug in human food commodities of animal origin caused by carryover.

2. RELEVANT DEFINITIONS

Acceptable daily intake (ADI): An estimate by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg).³

Action level (AL): A concentration of residue resulting from unintended and unavoidable carry-over in a feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on a food, above which action should be taken.⁴

Codex maximum residue limit for veterinary drugs (MRL): The maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It 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. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.³

Good practice in the use of veterinary drugs (GVP): The official recommended or authorized usage including

¹ FAO and WHO. 2019. *Carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs*. Report of the Joint FAO/WHO expert meeting – 8–10 January 2019, FAO Headquarters, Rome, Italy. FAO Animal Production and Health Report No. 13. Rome, Italy.

² *Code of practice on good animal feeding* (CXC 54-2004)

³ *Glossary of terms and definitions* (Residues of veterinary drugs in foods) (CXA 5-1993)

⁴ Annex D, Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods. Codex Alimentarius Procedural Manual.

withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.³

Health-based guidance value (HBGV): A numerical value derived by dividing a point of departure (a no- observed-adverse-effect level, benchmark dose or benchmark dose lower confidence limit) by a composite uncertainty factor to determine a level that can be ingested over a defined time period (e.g. lifetime or 24 h) without appreciable health risk. Related terms: Acceptable daily intake (ADI), Provisional maximum tolerable daily intake (PMTDI), Provisional tolerable monthly intake (PTMI), Provisional tolerable weekly intake (PTWI), Tolerable daily intake (TDI).⁵

Non-target animal: An animal unintentionally exposed to a veterinary drug not authorized or registered for use in that animal species or production class.⁴

Residues of veterinary drugs: Include the parent compounds and/or their metabolites in any edible portion of the animal product and include residues of associated impurities of the veterinary drug concerned.³

Unavoidable and unintended veterinary drug carry-over in a non-target animal feed: The presence of a veterinary drug in a non-target animal feed caused by the previous manufacture of feed using the same equipment after one or more mitigation procedures have been performed (e.g., flushing, sequencing, or physical clean-out).⁴

Veterinary drug: 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.³

3. PURPOSE

These guidelines provide risk-based actions to be taken by competent authorities if a residue of a veterinary drug suspected to be caused by carryover is detected in a human food commodity of animal origin. The guidelines should be read in conjunction with 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* (CXG 71-2009).

4. SCOPE

Residues of veterinary drugs in a human food commodity subject to these guidelines are the following:

- Those detected in a human food commodity where there is no current Codex MRL, and carryover is suspected to be the cause.
- Those from veterinary drugs that have Codex (or JECFA recommended) MRLs in other human food commodities from a target animal class.
- Those from veterinary drugs with a registration, authorization, or approval granted by a competent authority for use in a target animal class.
- Those measured by validated, quantitative analytical methods that are consistent in principle to the methods used when JECFA recommended the MRLs in the other human food commodities from a target animal class.

If a veterinary drug residue is detected in a human food commodity, and the suspected cause is carryover, but ~~there is~~ an applicable Codex MRL exists for that commodity, these guidelines do not apply. In such cases, competent authorities should apply the relevant Codex MRL in these cases.

5. PRINCIPLES

The following principles apply:

- A risk-based approach should be used to manage residues of veterinary drugs in human food commodities suspected to be caused by carryover.
- Codex action levels for veterinary drug residues in human food commodities of animal origin are numeric values ~~that represent a concentration established on the basis of a scientific risk assessment conducted by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), and represent concentrations of veterinary drug residues in food that can may be present because as a result of unavoidable and unintentional~~ carryover.
- ~~Action levels are established based on a scientific risk assessment conducted by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).~~

⁵ EHC 240: Principles for Risk Assessment of Chemicals in Food 2009.

- Residue concentrations at or below a Codex Action Level are acceptable to be in or on food and are not a food safety concern.
- Residue concentrations that are not a human food safety concern are acceptable to be in or on food.
- Unavoidable and unintentional carryover in animal feed ~~may~~ be variable and result in residue concentrations in human food commodities that exceed Codex action levels but are not considered a human food safety concern.
- If there is an established Codex Action Level and/or risk management information presented in Annex 2 of these guidelines, it is reasonable to suspect that detected residues of the associated veterinary drug in the human food commodity from a non-target animal were caused by carryover.
- Action levels and the approach described in these guidelines apply to detected residues in human food commodities of animal origin, and do not apply to animal feed or animal feed commodities.

6. RISK-BASED APPROACH TO MANAGING DETECTION OF RESIDUES OF A VETERINARY DRUG IN A HUMAN FOOD COMMODITY CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER

A risk-based approach should be used to manage residues of veterinary drugs detected in a human food commodity that are within the scope of these guidelines. Such an approach utilizes Codex action levels, when available, and the Risk Management Decision Tool (RMDT) presented in these guidelines.

Section 6.1 contains guidelines to competent authorities on how to manage veterinary drug residues in a human food commodity caused by carryover that have a corresponding action level. If there is not a Codex Action Level or the Codex Action Level is exceeded, competent authorities should refer to the guidelines in section 6.2.

6.1. Application of Codex action levels

Codex action levels ~~are specified~~can be found in the Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CXM 2) ~~or~~and are also available in the Codex Veterinary Drug Residue in Food Online Database. Information on the derivation of action levels ~~and how they are derived can be found~~is provided in Annex D of the *Risk analysis principles applied by CCRVDF*.

If a quantitative measurement of a veterinary drug residue in food is less than or equal to the action level, there is no food safety concern, and no additional action needs to be taken by competent authorities.

If a quantitative measurement of a veterinary drug residue in food exceeds the Codex Action Level, competent authorities should employ the RMDT presented in section 6.2 to assess the food safety risk.

In cases where the residue is detected but not quantified above the limit of quantification⁶, the limit of quantification may be used as a surrogate for the quantitative measurement mentioned above and in section 6.2.

6.2. Application of the Risk Management Decision Tool (RMDT)

The Risk Management Decision Tool enables competent authorities to assess the human food safety risk of a veterinary drug residue in a human food commodity when carryover of the veterinary drug in the animal feed is the suspected cause. The RMDT is a decision tree and is presented in Annex 1.

In general, the RMDT calls for the calculation of a Residue Risk Score (RRS) that places the detected residue value into the context of the JECFA established Health-Based Guidance Value (HBGV) for residues of the veterinary drug. Application of the RRS equation enables competent authorities to conduct a rapid risk assessment of the human food safety of the detected residue. A single RRS equation is unique for a specific veterinary drug and human food commodity known to be affected by carryover. Risk management information and the RRS equation for specific veterinary drugs and human food commodities are presented in Annex 2. A detailed description of the RRS equation and how it is derived is provided in Annex 3.

⁶ For appropriate application of a limit of quantification, see *Guidelines for the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals* (CXG 71-2009)

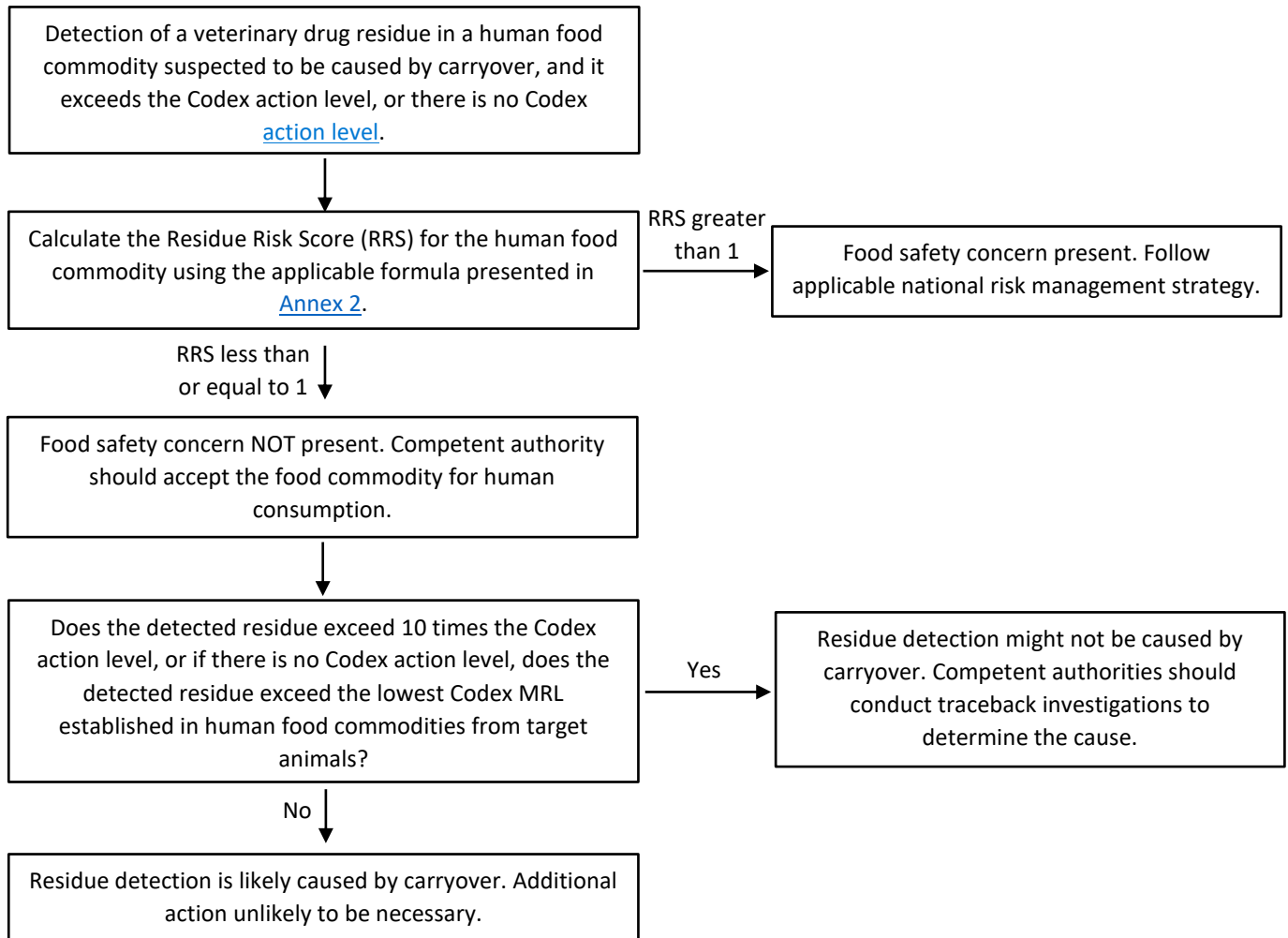
When a quantitative measurement of veterinary drug residue exceeds its action level or when there is not a Codex Action Level, competent authorities should calculate the RRS presented in [Annex 2](#) by inserting the residue concentration they have detected. If the RRS is less than or equal to one, there is no food safety concern, and competent authorities should accept the food commodity for human consumption. If the RRS is greater than one, there is a food safety concern, and competent authorities should follow their applicable national risk management strategy.

The RMDT also provides guidance to competent authorities on whether the detected residue is likely caused by carryover. If there is a Codex Action Level, then an exceedance of 10 times of the action level indicates that carryover might not be the cause because carryover and the resultant residues are expected to occur at low levels. If there is not a Codex Action Level, then an exceedance of the lowest established Codex MRL indicates that carryover might not be the cause of the residue detection because the Codex MRLs are based on a pharmacological dose of the veterinary drug, while carryover occurs at much lower amounts. Although an exceedance of 10 times the action level or exceeding the lowest Codex MRL is not conclusive evidence that carryover is not the cause, these guidelines can prompt competent authorities to initiate traceback investigations to determine the cause if necessary. If traceback investigations reveal another cause, competent authorities should follow their applicable national risk management strategy for unauthorized or unapproved use of a veterinary drug in animal feed.

[Annex 2](#) contains risk management information and the RRS equation for specific veterinary drugs and human food commodities that have been determined by Codex to be susceptible to carryover. However, it is possible for other cases of carryover-related residue detections to exist but not have been considered yet by Codex. If carryover is suspected to be the cause of a residue detection, but applicable risk management information and RRS equation are not presented in [Annex 2](#), competent authorities should consider using the principles described in [Annex 3](#) to derive an appropriate RRS equation to be used in the RMDT.

7. MONITORING AND REVIEW OF DECISIONS TAKEN

If traceback investigations reveal that carryover continuously causes exceedances of a Codex Action Level, competent authorities are encouraged to present their findings to CCRVDF with a view towards possibly revising the Codex Action Level to account for other global scenarios that might not have been considered in the initial assessment due to data limitations. Likewise, if competent authorities determine that carryover is affecting human food commodities and veterinary drugs not discussed in these guidelines, competent authorities are encouraged to present their findings to CCRVDF with a view towards developing an action level, RRS equation, and risk management information. CCRVDF will review and revise the relevant information (e.g., RRS), as necessary, in light of JECFA re-evaluations of veterinary drugs with established RMDT information.

Annex 1. Risk Management Decision Tool (RMDT) for residues of veterinary drugs in foods caused by carryover

Annex 2. Risk management information for use in the Risk Management Decision Tool (RMDT) for compounds and commodities known to be affected by unavoidable and unintentional carryover

NICARBAZIN IN CHICKEN EGGS

Codex has adopted Maximum Residue Limits (MRLs) for nicarbazin in chicken muscle, liver, kidney, and skin with adhering fat. Evidence indicates that unavoidable carryover of nicarbazin can occur in non-target animal feed intended for laying hens despite adherence to Good Veterinary Practices and Good Manufacturing Practices. This can result in residues of nicarbazin in eggs from laying hens. For this reason, competent authorities should ensure that appropriate mitigation steps are taken to reduce the carryover of nicarbazin into feed intended for laying hens. Appropriate mitigation steps can be found in the *Code of practice on good animal feeding* (CXC 54-2004). In cases where the marker residue for nicarbazin (4,4'-dinitrocarbanilide, DNC) is detected in eggs from laying hens, competent authorities should apply the procedures outlined in the Risk Management Decision Tool (RMDT, [Annex 1](#)). The Action Level and Residue Risk Score (RRS) equation for nicarbazin in eggs to be used in the RMDT are presented below.

Commodity: Chicken eggs

Marker Residue: 4,4'-dinitrocarbanilide (DNC)

Action Level: ~~350~~220 µg/kg

Residue Risk Score Equation: $RRS = (\text{DNC Concentration } (\mu\text{g/kg}) \times (7.41 \times 10^{-6})) + 0.23$

LASALOCID IN CHICKEN EGGS

Codex has adopted Maximum Residue Limits (MRLs) for lasalocid in chicken, turkey, quail, and pheasant muscle, liver, kidney, and skin with adhering fat. Evidence indicates that unavoidable carryover of lasalocid can occur in non-target animal feed intended for laying hens despite adherence to Good Veterinary Practices and Good Manufacturing Practices. This can result in residues of lasalocid in eggs from laying hens. For this reason, competent authorities should ensure that appropriate mitigation steps are taken to reduce the carryover of lasalocid into feed intended for laying hens. Appropriate mitigation steps can be found in the *Code of practice on good animal feeding* (CXC 54-2004). In cases where the marker residue for lasalocid (lasalocid A) is detected in eggs from laying hens, competent authorities should apply the procedures outlined in the Risk Management Decision Tool (RMDT, [Annex 1](#)). The Action Level and Residue Risk Score (RRS) equation for lasalocid in eggs to be used in the RMDT are presented below.

Commodity: Chicken eggs

Marker Residue: Lasalocid A

Action Level: ~~150~~100 µg/kg

Residue Risk Score Equation: $RRS = (\text{Lasalocid A Concentration } (\mu\text{g/kg}) \times (8.77 \times 10^{-4})) + 0.67$

Annex 3. Procedures to derive a Residue Risk Score (RRS) equation for residues of veterinary drugs in food caused by unavoidable and unintentional carryover

Introduction

The Residue Risk Score (RRS) is a metric used to determine whether there is a human food safety concern associated with veterinary drug residues in human food commodities caused by carryover of veterinary drugs in animal feed. The RRS value quantifies the human food safety risk in relation to the JECFA established Health-based Guidance Value (HBGV) for residues of the veterinary drug. The general equation is as follows:

$$\text{RRS} = (\text{Detected Marker Residue Concentration } (\mu\text{g/kg}) \times \text{Risk Score Correction Factor}) + \text{GVP Risk Score}$$

The information needed to calculate the RRS (*i.e.*, Risk Score Correction Factor and GVP Risk Score) is established by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) on a case-by-case basis for a specific veterinary drug and human food commodity affected by carryover. After the RRS is developed, the competent authority only needs to apply the RRS equation to the detected residue value. Descriptions of the Risk Score Correction Factor and Good Veterinary Practices (GVP) Risk Score are provided below, including information on their derivation.

Risk Score Correction Factor

The Risk Score Correction Factor is a numerical value that converts the detected residue concentration in the human food commodity to a risk score value, which is a number that quantifies the risk of the detected residue in relation to the JECFA HBGV. The risk score value is the percentage of the HBGV that will be utilized by the detected residue, expressed as decimal. The risk score correction factor is based on the Theoretical Maximum Daily Intake (TMDI) model and consolidates the mathematical steps for the TMDI calculation into a single step for the affected commodity. The risk score correction factor is derived from the following:

- TMDI model consumption factor for the commodity (*i.e.*, 0.3 kg muscle, 0.1 kg liver, 0.05 kg kidney, 0.05 kg fat (skin/fat), 1.5 kg milk, 0.1 kg eggs, 0.02 kg honey)
- TMDI model human body weight (*i.e.*, 60 kg)
- JECFA Health-Based Guidance Value (*e.g.*, ADI or ARfD)
- An estimated marker residue to total residue ratio (M:T) determined by CCRVDF, based on the JECFA-derived M:T ratios associated with the veterinary drug residues in the target animal or other acceptable sources of data.

The final calculation of the Risk Score Correction Factor is as follows:

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{\text{TMDI consumption value (kg)}}{\text{estimated M:T}} \right)}{(\text{HBGV}(\mu\text{g/kg}) \times 60 \text{ kg body weight})}$$

GVP Risk Score

The GVP Risk Score is the percentage of the HBGV utilized when the veterinary drug is used in accordance with GVP in the target animal species, expressed as a decimal. The CCRVDF identifies the appropriate GVP Risk Score based on the JECFA evaluation which recommended the Codex MRLs in the target animal. For example, if JECFA determined that use of the veterinary drug in accordance with GVP results in 53% of the ADI being utilized, then the GVP Risk Score is equal to 0.53.

Examples

Below are examples of how to derive an RRS, using nicarbazin and lasalocid in eggs.

Nicarbazin

TMDI Model Consumption Factor for Eggs: 0.1 kg

CCRVDF-estimated M:T for Eggs⁷: 0.25

Nicarbazin HBGV (ADI): 900 µg/kg bw

Risk Score Correction Factor: 7.41×10^{-6}

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{0.1 \text{ kg}}{0.25}\right)}{(900 \text{ µg/kg} \times 60 \text{ kg body weight})} = 7.41 \times 10^{-6}$$

GVP Risk Score: The 94th meeting of JECFA determined that the maximum estimated ADI utilized by other edible commodities is 23% when nicarbazin is used in accordance with GVP.⁸ Therefore, the GVP Risk Score is 0.23.

Using the Risk Score Correction Factor and GVP Risk Score above, the RRS to be applied to the marker residue for nicarbazin (4,4'-dinitrocarbanilide (DNC)) if detected in chicken eggs is the following:

$$\text{RRS} = (\text{DNC Concentration (µg/kg)} \times (7.41 \times 10^{-6})) + 0.23$$

Lasalocid

TMDI Model Consumption Factor for Eggs: 0.1 kg

CCRVDF-estimated M:T for Eggs⁹: 0.38

Lasalocid HBGV (ADI): 5 µg/kg bw

Risk Score Correction Factor: 8.77×10^{-4}

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{0.1 \text{ kg}}{0.38}\right)}{(5 \text{ µg/kg} \times 60 \text{ kg body weight})} = 8.77 \times 10^{-4}$$

GVP Risk Score: The 81st meeting of JECFA determined that the maximum estimated ADI utilized by other edible commodities is 67% when lasalocid is used in accordance with GVP.¹⁰ Therefore, the GVP Risk Score is 0.67.

Using the Risk Score Correction Factor and GVP Risk Score above, the RRS to be applied to the marker residue for lasalocid (lasalocid A) if detected in chicken eggs is the following:

$$\text{RRS} = (\text{Lasalocid A Concentration (µg/kg)} \times (8.77 \times 10^{-4})) + 0.67$$

⁷ The lowest M:T ratio identified by JECFA in the target animal species was 0.25 (94th Meeting of JECFA).

⁸ Evaluation of certain veterinary drug residues in food. Ninety-fourth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 1041.

⁹ The European Medicines Agency has reported a M:T ratio of 0.38 in chicken eggs (European Medicines Agency, 2006. Lasalocid Sodium (extension to eggs). Summary Report of the Committee for Medicinal Products for Veterinary Use. EMEA/CVMP/46049/2006-FINAL-corr, July 2006.)

¹⁰ Evaluation of certain veterinary drug residues in food. Eighty-first report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 997.