

## INTRODUCTION

1. Hazard prioritization is part of the risk management process within the risk analysis framework.
2. The purpose of prioritizing hazards in feed as described in this document is to contribute to the safety of edible products by optimizing allocation of the resources required for risk assessment and risk management.

## SCOPE

3. This document provides guidance to governments on prioritizing hazards in feed and feed ingredients<sup>1</sup> using the multi-criteria analysis approach. However, it is recognized that other approaches to prioritize hazards might be used.
4. This guidance is applicable to all hazards in the feed of food-producing animals which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in this guidance, as they are not within the scope of the Codex Alimentarius.
5. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered, as it is not within the scope of the Codex Alimentarius.

## DEFINITIONS

6. The following definitions are included to establish a common understanding of the terms used in this guidance.

**Biotransformation product:** Product resulting from the transformation of a chemical or biological agent in the body of the food-producing animal (e.g. via metabolic processes).

**Contaminant:** Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.<sup>2</sup>

**Cross-contamination:** Contamination of a material or product with another material or product, including contamination originating from the previous use of equipment.

**Edible product:** Any tissue or product from a food-producing animal which is intended for human consumption, including for example meat, fish, eggs and milk.

**Feed (Feedingstuff):** Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.<sup>3</sup>

**Feed additive:** Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, that affects the characteristics of feed or animal products. Micro-organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration.<sup>3</sup>

**Feed ingredient:** A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.<sup>3</sup>

**Food:** means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which have been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.<sup>2</sup>

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.<sup>2</sup> In this guidance, it refers to an agent in feed which has the potential to cause an adverse human health effect after transfer into an edible product.

**Medicated feed:** Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.<sup>3</sup>

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<sup>1</sup> Throughout this document the term "feed" refers to both feed and feed ingredients, unless otherwise stated

<sup>2</sup> Codex Alimentarius Commission: Procedural Manual

<sup>3</sup> Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

**Processing Aid:** Any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, food or food ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.<sup>2</sup> (In this guidance this definition applies to feed and feed ingredients).

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.<sup>2</sup> In this guidance, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

**Risk analysis:** A process consisting of three components: risk assessment, risk management and risk communication.<sup>2</sup>

**Risk assessment:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.<sup>2</sup>

**Risk characterization:** The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.<sup>3</sup>

**Risk communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.<sup>2</sup>

**Risk management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.<sup>2</sup>

**Transfer:** Passing of a chemical or biological hazard (including hazardous biotransformation products) from feed of a food-producing animal to an edible product of the animal.

**Undesirable substances:** Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.<sup>3</sup>

## PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

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7. Risk analysis comprises three distinct but closely linked components: risk assessment, risk management, and risk communication.<sup>2</sup>

8. Risk management comprises preliminary risk management activities (including: identification of a food safety problem arising from feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; determination of a risk assessment policy for the conduct of the risk assessment; definition of the output form of the risk assessment; commissioning of the risk assessment; and consideration of the possible results of the risk assessment), evaluation of risk management options, implementation of risk management options, monitoring and review<sup>4</sup>. Prioritization of hazards in feed is part of preliminary risk management activities but can also be undertaken at any point of the risk analysis process.

9. Annex 2 lists references that have been used when developing this document.

10. Details of the steps are described below. An example of the prioritization process based on these steps is given in Annex 1 for illustrative purposes only.

## PRIORITIZATION PROCESS

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11. The prioritization process provides ranking for different combinations of hazard, feed and edible product in a risk analysis framework. A defined prioritization process ensures transparency and repeatability, and facilitates re-evaluation when new data are available without repeating all steps.

12. The prioritization process in this guidance comprises the following steps:

- Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems.
- Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified.
- Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations.
- Step 4. Normalization of these values to make them comparable between criteria.
- Step 5. Weighting of the criteria to reflect their relative importance.
- Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority.
- Step 7. Reporting of the process, methods and results.

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<sup>4</sup> Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

**STEP 1. IDENTIFICATION OF THE HAZARD, THE FEED AND THE EDIBLE PRODUCT POTENTIALLY ASSOCIATED WITH FOOD SAFETY PROBLEMS**

13. In this initial screening step, the risk manager identifies hazard/feed/edible product combinations which are potentially associated with food safety problems, and which may need to be prioritized for risk assessment and risk management. Further guidance on risk assessment of feed is provided in the Guidelines on Application of Risk Assessment for Feed.

14. Useful information on the presence of the hazard in feed and/or edible product may be obtained from existing risk profiles and risk assessments, and from regulatory surveillance programs/data, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food); the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (references in Annex 3); and other reliable rapid alert systems, and industry self-monitoring programs.

15. Information which may be useful includes:

- Descriptions of the hazard, the feed and edible product;
- Description of the food safety problem potentially associated with the hazard/feed/edible product combination;
- Chemical or biological characteristics and toxicology profile of the hazard;
- Levels of hazard in feed and edible products;
- Possible sources of hazard during production, processing, packing, packaging, transport, storage and use;
- Relevant legislation;
- Information on economic impact;
- Information on knowledge gaps.

16. If the data obtained in this step indicate that the association of a specific hazard/feed/edible product combination with a food safety problem is negligible, it may be decided to exclude that combination from further steps. Such screening should use defined exclusion/inclusion decision rules (for example, no occurrence in the area under consideration during a given time-frame).

17. Examples of hazards with potential relevance for human health are given in [http://www.fao.org/ag/againfo/home/en/news\\_archive/2013\\_Feed\\_and\\_food\\_safety.html](http://www.fao.org/ag/againfo/home/en/news_archive/2013_Feed_and_food_safety.html).

**STEP 2. IDENTIFICATION AND DEFINITION OF THE CRITERIA BY WHICH EACH SELECTED HAZARD/FEED/EDIBLE PRODUCT COMBINATION WILL BE QUANTIFIED**

18. The criteria to be used to prioritize the hazard/feed/edible product combinations should be relevant and reflect the purpose of the prioritization.

19. Criteria which could be considered include those related to the extent of occurrence of a hazard in feed and edible product, effects on human health, and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

20. Each criterion should be defined so that there is no ambiguity in interpretation and so that it can be described quantitatively (e.g. number of illnesses, concentration of a hazard). Semi-quantitative descriptions (e.g. low, medium, high) should be clearly explained.

21. Identification and definition of the criteria should be done with the assistance of experts.

**STEP 3. ASSIGNMENT OF CRITERION-BASED VALUES TO THE HAZARD/FEED/EDIBLE PRODUCT COMBINATIONS**

22. For each of the criteria, a value is assigned by experts to the hazard/feed/edible product combinations. Depending on the hazard/feed/edible product combinations and the criteria, different specialized experts may be needed.

**STEP 4. NORMALIZATION OF THESE VALUES TO MAKE THEM COMPARABLE BETWEEN CRITERIA**

23. To permit comparison of values between criteria, they need to be normalized to a common scale with defined levels.

24. The method used for normalizing should be developed by experts and fully documented.

**STEP 5. WEIGHTING OF THE CRITERIA TO REFLECT THEIR RELATIVE IMPORTANCE**

25. Criterion weighting is done independently from the previous steps, typically by risk managers with the support of experts, when required.

26. Each criterion is assigned a weighting which reflects its relative importance. The sum of the weightings is 100%.

**STEP 6. COMBINING THE WEIGHTED NORMALIZED VALUES FOR EACH HAZARD/FEED/EDIBLE PRODUCT COMBINATION TO PRODUCE A SCORE, AND RANKING OF THE SCORES TO OBTAIN THE ORDER OF PRIORITY**

27. For each hazard/feed/edible product combination, the weighted normalized values are combined to obtain a score, e.g.  $(C1*W1)+(C2*W2)+...(Cn*Wn)$ , where C are the normalized criteria values and W are the criteria weights.

28. Ranking of the scores of each of the hazard/feed/edible product combinations yields the prioritized list, which reflects both the normalized criteria values and the weighting of the criteria.

29. It is important to demonstrate the influence of any assumptions used in the ranking process. This could be done for example by using sensitivity analyses (e.g. weighting all criteria equally or weighting which reflects the relative importance of each criterion).

***STEP 7. REPORTING OF THE PROCESS, METHODS AND RESULTS***

30. The prioritization process, methods and results should be documented and reported fully, systematically and transparently. This should include:

- The rationale for the choice of hazard/feed/edible product combinations;
- The rationale for the criteria;
- The rationale for the normalization method;
- The rationale for the weightings;
- An estimate of the sensitivity of the ranking to the normalization method and the weightings, if conducted;
- Identification of all data gaps, assumptions and uncertainties.

**ANNEX 1****EXAMPLE OF THE PRIORITIZATION PROCESS**

The following is a fictitious example, which is intended only to illustrate the steps in the prioritization process. This example uses applicable but not exhaustive criteria and the values used are illustrative. In a real-life situation, details of the process, particularly the criteria definitions, quantification, normalization of the values and weighting of the criteria, must be developed on a case-by-case basis in consultation with experts.

**STEP 1. IDENTIFICATION OF THE HAZARD, THE FEED AND THE EDIBLE PRODUCT POTENTIALLY ASSOCIATED WITH FOOD SAFETY PROBLEMS**

For simplicity, this example uses only three hazard/feed/edible product combinations ("combinations 1, 2 and 3") to demonstrate the prioritization procedure. The process is however primarily intended to be used with a larger number of combinations.

**STEP 2. IDENTIFICATION AND DEFINITION OF THE CRITERIA BY WHICH EACH SELECTED HAZARD/FEED/EDIBLE PRODUCT COMBINATION WILL BE QUANTIFIED**

This example uses four criteria (C1-C4). The descriptions/definitions of these criteria are briefly summarized in Table 1.

**Table 1: Criteria chosen for this example**

Criterion	Description/definition
C1. Occurrence level in feed	% of feed samples exceeding a defined level for the hazard
C2. Transfer from feed to edible product	%, based on measurement or modeling
C3(a) Toxicity of chemical hazard or C3(b) Health effects of biological hazard	(a) Health-based guidance value (e.g. ADI <sup>5</sup> or TDI <sup>6</sup> ) (b) Number of hazard-related illnesses
C4. Impact on feed availability	Replacement feed available (easy, difficult, impossible)

**STEP 3. ASSIGNMENT OF CRITERION-BASED VALUES TO THE HAZARD/FEED/EDIBLE PRODUCT COMBINATIONS**

For each of the criteria C1 to C4, a value is assigned to each hazard/feed/edible product combination, and categorized as shown in Table 2.

**STEP 4. NORMALIZATION OF THESE VALUES TO MAKE THEM COMPARABLE BETWEEN CRITERIA**

An example of normalization is summarized in Table 2. In this example, each criterion value is assigned to one of a range of levels chosen for this example and then normalized to a scale of 0, 0.5, 1.0.

**Table 2: Normalization of values**

Normalized value	0	0.5	1.0
	<i>Low</i>	<i>Medium</i>	<i>High</i>
C1. Occurrence level in feed (% of feed samples exceeding a defined level for the hazard)	<10%	10–25%	>25%
C2. Transfer from feed to edible product (based on measurement or modeling)	<5%	5-50%	>50%
C3(a). Toxicity of chemical hazard (health-based guidance value (e.g. ADI <sup>5</sup> or TDI <sup>6</sup> ))	>1 mg/kg bw/day	1 µg-1 mg/kg bw/day	<1 µg/kg bw/day
C3(b). Health effects of biological hazard (number of hazard-related illnesses per 100'000 of population)	<0.1	0.1-1	>1
C4. Impact on feed availability (replacement feed available)	<i>Replacement easy</i>	<i>Replacement difficult</i>	<i>Replacement impossible</i>

<sup>5</sup> Acceptable Daily Intake (ADI)

<sup>6</sup> Tolerable Daily Intake (TDI)

**STEP 5. WEIGHTING OF THE CRITERIA TO REFLECT THEIR RELATIVE IMPORTANCE**

The weightings chosen for the criteria C1 to C4 in this example are summarized in Table 3.

**Table 3: Criterion weighting chosen for this example**

Criterion	Weighting code	Average weighting decided by experts
C1. Occurrence level in feed	W1	15%
C2. Transfer from feed to edible product	W2	40%
C3. Health hazard ((a) or (b), depending on the hazard*)	W3	30%
C4. Impact on feed availability	W4	15%
<b>Sum</b>		100%

\* C3(a) for chemical hazards, C3(b) for biological hazards

Table 3 shows that the criterion related to transfer from feed to edible product in this example is assigned the greatest weight (40%), followed by health hazard, occurrence level, and impact on feed availability.

**STEP 6. COMBINING THE WEIGHTED NORMALIZED VALUES FOR EACH HAZARD/FEED/EDIBLE PRODUCT COMBINATION TO PRODUCE A SCORE, AND RANKING OF THE SCORES TO OBTAIN THE ORDER OF PRIORITY**

The score for each hazard/feed/edible product combination in this example is calculated using the following equation:

$$\text{Score} = C1*W1 + C2*W2 + C3(a \text{ or } b)*W3 + C4*W4$$

where C are the combination-specific normalized values and W are the criteria weightings.

An example of the calculation of the score for one hazard/feed/edible product combination is shown in Table 4.

**Table 4: Example of scoring of a hazard/feed/edible product combination for Combination 1 (for a chemical hazard)**

Criterion	Value	Normalized value (C)	Criterion Weight (W)	C *W
C1. Occurrence level in feed	<10%	0	15%	0
C2. Transfer from feed to edible product	5-50%	0.5	40%	0.2
C3(a). Health hazard	<1 µg/kg bw /day	1.0	30%	0.3
C4. Impact on feed availability	Low	0	15%	0
<b>Score</b>				<b>0.5</b>

This scoring is performed for each hazard/feed/edible product combination to be prioritized.

Scores and the resulting ranking/prioritization of Combination 1 with two other hypothetical hazard/feed/edible product combinations are summarized in Table 5.

**Table 5: Prioritization of three hazard/feed/edible product combinations based on ranked scores**

Hazard/feed/edible product combination	Score	Ranking / priority
<b>Combination 1</b>	<b>0.5</b>	<b>2</b>
<b>Combination 2</b>	<b>0.475</b>	<b>3</b>
<b>Combination 3</b>	<b>0.75</b>	<b>1</b>

**STEP 7. REPORTING OF THE PROCESS, METHODS AND RESULTS**

The report should include full documentation as described in paragraph 30 of the Guidance.

**ADDITIONAL REFERENCES****Useful sources of information on potential hazard/feed/edible product combinations include:**

WHO Global Environment Monitoring System (GEMS) (WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food). (<http://www.who.int/foodsafety/chem/gems/en/> )

Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (WHO International Food Safety Authorities Network (INFOSAN); ([http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/) ).

Notifications from the European Rapid Alert System for Food and Feed (EU RASFF); (<https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationsList> )

**Some examples of prioritization frameworks, processes and methods are given in:**

Cressey P, Lake R (2003). Ranking Food Safety Risks; A Discussion Document. Institute of Environmental Science & Research Limited, Christchurch Science Centre, New Zealand. Prepared as part of a New Zealand Food Safety Authority contract for scientific services, June 2003.

[http://foodsafety.govt.nz/elibrary/industry/Ranking\\_Food-Science\\_Research.pdf](http://foodsafety.govt.nz/elibrary/industry/Ranking_Food-Science_Research.pdf)

Cressey P, Lake R (2004). Ranking Food Safety Risks; A Prototype Methodology (revised October 2004). Institute of Environmental Science & Research Limited, Christchurch Science Centre, New Zealand. Prepared as part of a New Zealand Food Safety Authority contract for scientific services, October 2004.

([http://www.foodsafety.govt.nz/elibrary/industry/Ranking\\_Food\\_Safety-Science\\_Research.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Ranking_Food_Safety-Science_Research.pdf) )

EFSA (2012). Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the development of a risk ranking framework on biological hazards. EFSA Journal 2012;10(6):2724. [88 pp.] doi:10.2903/j.efsa.2012.2724. Available online:

[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

Eisenführ F, Weber M, Langer T (2010). Rational Decision Making. 1st Edition, 447 pp. Springer Verlag, ISBN 978-3-642-02850-2.

FAO (2012). Multicriteria-Based Ranking For Risk Management Of Foodborne Parasites. Report of a Joint FAO/WHO Expert Meeting, 3-7 September, 2012, FAO Headquarters, Rome, Italy. FAO, 24 October 2012.

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FDA 2011. Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspection of Subject: Egg Farms for Monitoring Compliance with the Egg Safety Rule. U.S. Food and Drug Administration, Department of Health and Human Services, Memorandum, August 9, 2011.

(<http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/EggSafety/UCM267597.pdf>)

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Henson SJ, Caswell JA, Cranfield JAL, Fazil AF, Davidson VJ, Anders SM, Schmidt C (2007). A Multi-Factorial Risk Prioritisation Framework for Food-Borne Pathogens. University of Massachusetts, Amherst MA, Department of Resource Economics. Working Paper No. 2007-8, 21 May 2007.

(<http://people.umass.edu/resec/workingpapers/documents/ResEcWorkingPaper2007-8.pdf> )

Humblet MF, Vandeputte S, Albert A, Gosset C, Kirschvink N, Haubruge E, Fecher-Bourgeois F, Pastoret PP, Saegerman C (2012). Multidisciplinary and evidence-based method for prioritizing diseases of food-producing animals and zoonoses. Emerg Infect Dis 18(4):e1. doi: 10.3201/eid1804.111151

Lake R, Hudson A, Cressey P, Nortje G (2000). Risk Profiles For The Foods New Zealanders Eat: Project F13ra3. Prepared as part of a Ministry of Health contract for scientific services by ESR Risk Profile Project Team, November 2000.

([http://www.foodsafety.govt.nz/elibrary/industry/Risk\\_Profiles-Science\\_Research.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profiles-Science_Research.pdf)

New Zealand Ministry for Primary Industries, Food safety science group. Risk ranking. (<http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-ranking.htm> )

Ng V, Sargeant JM (2010). A stakeholder-informed approach to the identification of criteria for the prioritization of zoonoses in Canada. PLoS One7(1):e29752. doi: 10.1371/journal.pone.0029752

Rowley HV, Peters GM, Lundie S, Moore SJ (2012). Aggregating sustainability indicators: Beyond the weighted sum. J Environ Manage111:24-33. doi: 10.1016/j.jenvman.2012.05.004

Ruzante JM, Davidson VJ, Caswell J, Fazil A, Cranfield JA, Henson SJ, Anders SM, Schmidt C, Farber JM (2010). A multifactorial risk prioritization framework for foodborne pathogens. Risk Anal30(5):724-42. doi: 10.1111/j.1539-6924.2009.01278.x

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<http://www.communities.gov.uk/documents/corporate/pdf/1132618.pdf> )