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Title: Risk Management Framework on the Importation of honey bee packages from the United States	

The purpose of this document (*Risk Management Framework on the Importation of honey bee packages from the United States*) is to provide expectations for any risk mitigation proposals submitted by stakeholders to the Canadian Food Inspection Agency (CFIA) for consideration as part of the risk analysis

Glossary:

List of Acronyms:

- AHB:** Africanized honey bees
- AFB:** American foulbrood
- CFIA:** Canadian Food Inspection Agency
- EFB:** European foulbrood
- SHB:** Small hive beetle
- U.S.:** United States
- USDA – APHIS:** United States Department of Agriculture – Animal & Plant Health Inspection Service
- WOAH:** World Organization for Animal Health
- WTO:** World Trade Organization

The following definitions are taken from the [Terrestrial Code](#) of WOA.

Hazard identification: involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity.

Risk Analysis: the process comprised of hazard identification, risk assessment, risk management and risk communication.

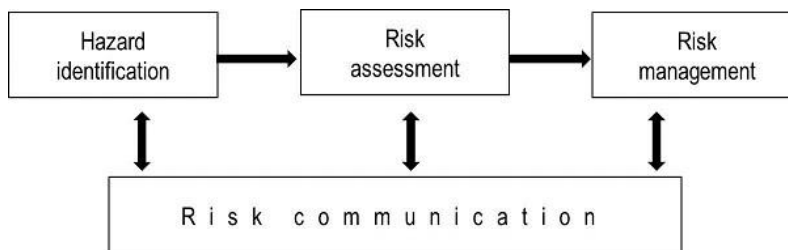


Figure 1 – The four components of the WOA risk analysis process (*Terrestrial Code, Chapter 2.1., Article 2.1.1.*)

Risk Assessment: the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard.

Risk Management: the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Risk Communication: the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties.

Sanitary measure: means a measure, such as those described in various chapters of the *Terrestrial Code*, designed to protect animal or human health or life within the whole territory or a zone of a Member Country from risks arising from the entry, establishment or spread of a hazard.

Veterinary Authority (VA): means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Terrestrial Code*.

1.0 Background

The importation of all honey bees (*Apis mellifera* subspecies) from the United States (U.S.) into Canada were restricted since 1987 as a result of the presence of pests and disease of concern in the U.S. An Import Risk Analysis was completed for importation of honey bees from the U.S. in 2003. Based on that analysis, the importation of individual hand-picked honey bee queens from the U.S. were permitted since 2004. Honey bee packages however still presented a higher risk than queen bees and therefore continued to not be permitted from importation into Canada.

A subsequent risk analysis was conducted in 2014 where a risk assessment concluded that importation of honey bee packages from the U.S. into Canada would lead to unacceptable risks of introduction, establishment and spread of the following hazards: Varroa mites (*Varroa spp.*) resistant to amitraz, American foulbrood (*Paenibacillus larvae*) resistant to oxytetracycline, Small Hive Beetle (*Aethina tumida*) and Africanized honey bees. Following this risk assessment, no proposals for risk mitigation measures that could mitigate the risks identified were submitted by USDA – APHIS to the CFIA. As a result, importation of honey bee packages are not allowed to be imported from the U.S. into Canada at this time.

In 2022, the CFIA put out a call to the public and industry for the submission of any new, science-based information on the status of honey bee health in the U.S. and Canada. In June 2023, a new import risk analysis for honey bee packages from the U.S. was initiated to determine if the importation of approximately 50,000 (24,000-75,000) honey bee packages per year from the continental U.S. could be allowed into Canada. The hazard identification and risk assessment steps were completed in the Fall 2024.

2.0 Summary of the Hazard Identification and Risk Assessment

Hazard Identification Summary (2024)

The CFIA's hazard identification process follows the one proposed in the WOAAH Handbook for Import Risk Analysis of Animals and Animal Products (World Organisation for Animal Health, 2010). The objective of this process is the identification of a biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect. A set of criteria are provided in the Handbook to conduct the hazard identification.

If hazards are identified, the WOAAH *Terrestrial Code* is consulted to determine if sanitary measures exist for each hazard identified. If there are applicable measures, a risk assessment is not necessary in this situation to fulfill World Trade Organization (WTO) obligations. However, if there are no applicable measures in the Code, or if Canada wants to adopt a higher level of protection than the one provided by the measures in the Code, a risk assessment is necessary.

Five hazards were identified in the hazard identification pertaining to importation of honey bee packages from the US: Small hive beetle (SHB), Africanized honey bees (AHB), American foulbrood (AFB), *Varroa* mites and European foulbrood (EFB).

Given that Africanized honey bees are not WOAAH listed and therefore there are no sanitary measures applicable in the *Terrestrial Code*, a risk assessment was required in order determine if the risk was above Canada's acceptable level, and to justify potential import restrictions, should they be needed. While the WOAAH *Terrestrial Code* includes SHB-, AFB-, and *Varroa*-related recommendations for the importation of live honeybees, it was decided to conduct a full risk assessment to better understand the level of risk associated with importing approximately 50,000 packages over a period of one year, particularly given the potential impact of introducing resistant forms of AFB and *Varroa* into Canada. Finally, there is currently a lack of scientific information on resistant forms of EFB in Canada or the United States. Without this information, it is not possible to carry out a risk assessment for EFB, which would be necessary to justify the implementation of import measures that would go beyond what is currently applied for interprovincial movements in Canada.

Risk assessment summary (2024)

The methodology used in this risk assessment is based on the approach recommended in the World Organisation for Animal Health (WOAH) *Terrestrial Animal Health Code* and the *Handbook on*

Import Risk Analysis for Animals and Animal Products (World Organisation for Animal Health, 2010).

The objective of the quantitative risk assessment is to estimate, for each of the hazards identified, the probability of entry, exposure and establishment on at least one recipient hive in Canada as a result of importation of honey bee packages from the US, over a period of one year. Monte Carlo simulations were used to estimate the number of packages imported per year that are infested/infected with each hazard individually, and the number of recipient hives in Canada where each of the following consequence scenarios could take place:

- 1) The hazard is detected and eradicated from the recipient hive during the season of importation; or
- 2) The hazard becomes established in the colony during the season of importation only, but does not survive winter; or
- 3) The hazard survives winter and becomes established year-round.

Depending on the hazard, the model includes a certain number of steps and is run 25,000 times. The model input parameters are probability distributions that represent the values that the variable may take, and the probability of any specific value. These distributions were chosen from available scientific literature and represent the combination of uncertainty and variability. Assumptions were made when parameters were too uncertain and/or too complex to assess or model. These assumptions need to be considered when comparing the risks estimated in this risk assessment with Canada's appropriate level of protection. Finally, a sensitivity analysis was conducted to identify the key variables and uncertain parameters that had the most impact on the model results, using Spearman's rank correlation coefficients.

The likelihood of further spread and the overall national-scale impact of the importation of honey bee packages from the US were assessed qualitatively. For each of the hazard, the final risk estimate is composed of the probability of entry, exposure and establishment, together with the associated qualitative national-scale impact.

Risk Estimate - Small Hive Beetle

The probability of entry, exposure and establishment of SHB on at least one recipient hive in Canada as a result of the importation of between 24,000 and 75,000 honey bee packages from the US for a given year of importation is **100%**. The establishment of SHB would occur on an estimated 1,744 to 4,894 recipient hives distributed among all honey bee producing areas in Canada. This is likely an underestimation given that the model assumes no spread from any of the recipient hives, even though this has a very high likelihood of occurring. Moreover, the number of estimated SHB establishments on recipient hives **is well above the maximum number of new cases having occurred in Canada in a given year.**

The **overall, national-scale impact would be moderate**, with significant effects within the affected provinces and for the Canadian honey bee industry. Costs for ongoing widespread surveillance and control of SHB would be significant. SHBs are difficult to control without significant investments in control programs and surveillance.

Risk Estimate - Africanized honey bee

The probability of entry, exposure and establishment of AHB on at least one recipient hive in Canada as a result of the importation of between 24,000 and 75,000 honey bee packages from the US for a given year of importation is **100%**. It is estimated that AHBs may establish and transmit *A. m. scutellata* genetics on 489 to 1,475 recipient hives distributed among all honey bee producing areas in Canada. This is likely an underestimate given the low to moderate likelihood of further spread, the fact that transmission of *A. m. scutellata* genetics via Africanized drones was not included in the model, and the assumptions related to the absence of migration of the colonies used to produce the package.

The **overall national-scale impact** would be **low** at first (significant effects to a small number of directly affected parties), but may become **moderate over the years**, as the proportion of Africanized genes increases in the Canadian honey bee population. The effects would then be significant within the affected provinces and for the honey bee industry. Costs for ongoing and widespread surveillance and control would be significant. AHBs are difficult to control without significant investments in control programs and surveillance.

Risk Estimate - American foulbrood

The probability of entry, exposure and establishment of rAFB^{OTC} on at least one recipient hive in Canada as a result of the importation of between 24,000 and 75,000 honey bee packages for a given year from the US is **100%**. The establishment of rAFB^{OTC} would occur on an estimated 874 to 2,325 recipient hives distributed among all honey bee producing areas in Canada. This is likely an underestimation given the high likelihood of further spread. Moreover, the number of estimated rAFB^{OTC} establishments on recipient hives **is well above the very few cases having been detected in Canada in a given year**.

The **overall, national-scale impact would be moderate**, with significant effects within the affected provinces, for the Canadian honey bee industry, and potentially to public health. Costs for ongoing and widespread surveillance and control of rAFB^{OTC} would be significant. rAFB^{OTC} are difficult to control without significant investments in time or without the use of antibiotics classified as “High importance” for human health.

Risk Estimate - Varroa mites

The probability of entry, exposure and establishment of rVAR^{am} on at least one recipient hive in Canada as a result of the importation of between 24,000 and 75,000 honey bee packages from the US over a period of a given year is **100%**. The establishment of rVAR^{am} would occur on an estimated 2,195 to 5,948 recipient hives distributed among all honey bee producing areas in Canada. This is likely an underestimation given the high likelihood of further spread. Moreover, the number of estimated rVAR^{am} establishments on recipient hives **is well above the number of cases having been identified in Canada**, where many of the *Varroa* mite populations tested

remain susceptible to amitraz (cases of low efficacy or resistance have been documented in only four provinces in Canada).

The **overall, national-scale impact would be moderate**, with significant effects within the affected provinces and for the Canadian honey bee industry. Costs for adequate beekeepers' training and for the time needed to apply best pest management practices would be significant. rVAR^{am} might be difficult to control without significant changes in pest management recommendations and practices in Canada.

3.0 Risk Management Considerations

According to the WOAHP Terrestrial Animal Health Code's general provisions, the importation of animals and animal products involves a certain level of disease risk to the importing country. This risk may be represented by one or several diseases, infections, or infestations. Additionally, risk increases with increasing volume of commodity imported. The objective of import risk analysis is to provide importing countries with a rational and justifiable scrutiny, based on scientific evidence and risk assessment, of the consequences of the hazards identified associated with the importation of honey bee packages from the U.S.

Risk management is the process of deciding upon and implementing measures to address the risks identified in the risk assessment, to protect animal health whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood of frequency of disease incursions and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.

Risk management components include: (i) the evaluation of risk, (ii) option evaluation, (iii) implementation of measures and (iv) monitoring and review to ensure that risk mitigating measures are achieving the results intended (Figure 2).



Figure 2 – Representation of the different steps of risk management as per WOAHP.

As per the *Terrestrial Code*, “*risk evaluation is the process of comparing the risk estimated in the risk assessment with the reduction in risk expected from the proposed risk management measures*”. In order to achieve this, an acceptable level of risk that provides the target to be reached when evaluating risk mitigation measures must be defined. Under the provisions of the World Trade Organisation – Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPSA - article 3.3), the CFIA can determine its acceptable level of risk / appropriate level of protection (ALOP) to the extent necessary to protect the health of Canada’s domestic animal populations and therefore, may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection determined to be appropriate.

The CFIA defines its ALOP as one where the risks associated with identified hazard, assessed qualitatively (likelihood of occurring) and/or quantitatively (quantity/repetition of import), achieve a negligible risk level (NRL). Considering the results of the risk assessments conducted for each hazard summarized above, all risks estimated are above the NRL.

In managing risk, the transparency of the data collected, analyzed, communicated and decision outcome of the analysis is necessary so that the exporting country and all interested parties are provided with explicit reason for the imposition of import conditions or refusal to import. The process takes into consideration the evaluation of Veterinary Services, zoning, and surveillance systems in place of monitoring of animal health as these are integral inputs for assessing the likelihood of hazards being present in the animal population of the exporting country. In Canada, the CFIA is the Veterinary Authority (VA) and as such, it has the mandate to regulate import of honeybees under the *Health of Animals Act and Regulations*. The VA for the U.S. is USDA-APHIS. In the U.S., legislation exists to regulate the importation of honey bees into the U.S. to contain the spread of undesirable diseases, parasites and species of *Apis* or subspecies of *A. mellifera* (7 U.S.C. § 281–286). USDA-APHIS is responsible, as per the *Terrestrial Code*, for veterinary certification used in international trade.

Defining a Zone:

A “zone” is defined as a part of a country, as determined by the Veterinary Authority on the basis of natural, artificial or legal boundaries, and made public through official channels, containing an animal population or subpopulation with a specific animal health status with respect to an infection or infestation for the purpose of international trade or disease prevention or control.

A “Free zone” is one in which the absence of specific diseases, infections, or infestations in an animal population has been demonstrated by the Veterinary Authority in accordance with the relevant requirements of the *Terrestrial Code*.

Animals belonging to subpopulations of zones should be recognisable as such through a clear epidemiological separation from other animals and all factors presenting risk. The measures taken to ensure the identification of the subpopulation and to establish and maintain its health status

through a biosecurity plan should be documented in detail. These measures should be appropriate to the particular circumstances, and depend on the epidemiology of the disease, environment factors, the health status of the animals in the adjacent areas, applicable biosecurity, and surveillance.

Establishing and maintaining a disease-free status throughout the country should be the ultimate goal for Member Countries. However, given the difficulty of achieving this goal, there may be benefits to a Member Country in establishing and maintaining a subpopulation with a specific health status within its territory for the purposes of international trade or disease prevention or control. Subpopulations may be separated by natural or artificial geographical barriers or by the application of appropriate biosecurity management.

The procedures used to establish and maintain the specific animal health status of a zone depend on the epidemiology of the disease, including the presence and role of vectors, susceptible wildlife and environmental factors, on the animal production systems as well as on the application of biosecurity and sanitary measures, including movement control. Biosecurity and surveillance are essential components of zoning and should be developed through active cooperation between industry and Veterinary Services.

As recommended in the *Terrestrial Code*, “the final authority over the zone or compartment, for the purposes of domestic and international trade, lies with the Veterinary Authority”. Zoning submissions should follow the standards recommended in Chapter 4.4 of the *Terrestrial Code*. The exporting country should be able to demonstrate, through detailed documentation provided to the importing country, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining a zone.

When assessing zoning proposal submitted by the VA of a foreign country, the *Health of Animals Regulations* - Section 7, as referenced below, provides CFIA authority over designation of countries or zones recognized as posing a negligible risk for a disease:

- “**7 (1)** For the purpose of preventing the introduction of a disease into Canada from an animal or thing imported into Canada, the Minister may designate a country or part of a country as being free of a disease or as posing a negligible risk for a disease.

(1.1) The designation shall be in writing and be based on the following criteria respecting the country or part of the country that is the subject of the designation:

- (a) the prevalence of the disease;
- (b) the time since the most recent outbreak of the disease;
- (c) the disease surveillance programs in effect;
- (d) the measures taken to prevent the introduction or spread of the disease;
- (e) the natural barriers to the movement of the disease;
- (f) the zoosanitary infrastructure; and
- (g) any other criteria relevant to the state, extent or propagation of the disease.”

In order for a disease-free zone to be recognized by the CFIA, the foreign VA must submit a request and a dossier for evaluation to the CFIA. The dossier should include detailed information on surveillance programs and biosecurity plans which should encompass movement controls, use of natural, artificial, or legal boundaries, spatial separation of animals, control of fomites, and commercial management and husbandry practices. An on-site evaluation may also be performed and will engage with the VA of the exporting country on this matter. The complete evaluation will consider how the standards described in Chapter 4.4. of the *Terrestrial Code* as well as disease-specific chapters are met, in addition to the requirements in the *Health of Animals Regulations* described above.

At this time, USDA-APHIS has not submitted any requests for the recognition of free zones for any of the hazards identified and assessed in 2024.

4.0 Risk Management Options

The CFIA's ALOP has been established at "Negligible risk level" (NRL), as such, for any risk management proposals to be considered, mitigation measures must clearly and scientifically demonstrate their capability to reduce all hazards risks, and be practical, feasible and effective to meet CFIA's NRL in order to be considered for implementation. Bee health is complex, and it is important that honey bee imports be controlled in such a way that they pose no unacceptable risk to Canada's beekeeping industry.

Expectations of Risk mitigation proposals:

By virtue of a 60-day open to public proposals period, Canadian stakeholders, and the USDA - APHIS are invited to submit to the CFIA any science-based risk mitigation proposals. Canadian beekeepers should provide their proposals via the Canadian Honey Council (CHC) or their provincial association.

Risk mitigation proposals submissions **must consider** the following:

- The expected volume of imports per year (~ 50 000 packages) in addition to the potential harboring of any or all the identified hazards within a package, as determined within the Hazard Identification assessment and Risk Assessment document.
- Risk mitigation proposals must ensure that the likelihood of entry, exposure and establishment of hazards of concern on recipient hives in Canada as a result of the importation of approximately 50 000 packages (over a period of one year) from the US is **negligible**. Given that risks are better managed at the source (origin country) than after importation in an importing country, proposal submissions must focus at providing mitigation measures that reduce the likelihood prior to entry.
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- If zoning is proposed in an option:

- it must clearly be defined by the exporting country and supported by its VA (USDA – APHIS); and,
 - it must be subject to well documented surveillance and control programs that scientifically differentiate the health status of the sub-species within the exporting country; and,
 - a biosecurity plan should be documented in detail.
- Any risk mitigation proposal must be comprehensive and should consider risks at various parts of the supply chain and should include all relevant stakeholders involved in the supply chain.
 - Risk mitigation measures must consider the technical, operational, and economical feasibility to effectively reduce the risks for all hazards identified to CFIA’s negligible level of risk.
 - Proposed mitigation measures must address entirely all identified hazards and demonstrate clearly and scientifically how they reduce all risks impacts to achieve CFIA’s negligible level of risk.

All adequately documented risk mitigation proposal submissions will be assessed by CFIA to ensure that they reduce all identified hazard risks to achieve the CFIA’s NRL and are supported by science.

The consideration of implementation of any measures to mitigate potential risks must uphold the CFIA’s mandate under the *Health of Animals Act and Regulations* to help protect Canadian animal health, which includes the health of the Canadian honey bee population. In line with WOHAI recommendations for international trade, trading partners should exchange information to allow for a bilateral recognition of a country’s zone status.

The CFIA may not consider submissions for mitigation measure that are not supported by science and are unable to be implemented effectively to reduce the potential risk. The CFIA will make the final risk management decision on imports of honeybee packages from the US, after all risk mitigation proposals have been analysed.

5.0 Current Status

Currently, the importation of honey bee packages from the U.S. is not permitted. The import status remains unchanged until all activities associated with the risk analysis are completed and the outcome of the risk analysis is communicated.