

## Issues and gaps in international guidance and national regulatory systems affecting international live insect trade

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## Summary

The distinct histories of exchange of insects and sheer diversity of the insect species shipped, their handling, and the purposes for shipments, have both created and been subject to a complex regulatory landscape. A review of global production, shipping and use experiences from a range of perspectives showed gaps and inconsistencies in international guidance and national implementation for this activity. Private carriers add another layer of uncertainty that is disproportionate to the risks, resulting in variable practices and charges. The issues identified relate to the various objectives and authorities which interface with international movement and trade in live insects. The potential benefits – from pollinator services, biological or genetic control of pests and disease vectors, and the enhancement of international scientific research and innovation – rely on a more evidence-based and efficient approach to trade in insects; this in turn requires an improved and widely accepted risk management landscape for insect trade.

## Keywords

Beneficial insects – Disease vectors – Regulation – Trade facilitation – Biodiversity – Biosecurity

## Introduction – the challenge

Every year, billions of live insects, and other arthropods (mites, ticks, spiders, etc.) are shipped across political boundaries and ecological zones, as outlined throughout this thematic issue of the OIE *Scientific and Technical Review*. Some of the international transfers of insects are non-commercial trade but many of the shipments are for commercial purposes, both of which often contribute to societal priorities that would justify a public good approach to expedite the trade. The potential benefits supported by trade in live insects, outlined in the Introduction of this thematic issue (Mumford & Quinlan [1], this issue) can be

hampered by uncertainty and inefficiency in shipping. The broad and diverse scope for insect trade complicates the regulatory approaches used and even which regulatory authority has responsibility (for example, as discussed by Bellini [2] and Denton *et al.* [3], this issue). A coherent approach to shipping, covering the range of scale, value, purpose and associated risks, would contribute to the efficient and consistent delivery that is crucial to achieve benefits supported by live insect trade. In contrast, inconsistencies or lack of clarity about required documentation and relevant regulation could encourage unauthorised distribution, such as informal trade without proper permits or reporting, which in turn increases associated risks.

This review refers to regulation in a broad sense to mean any codes or best practices, rules, standards, norms, legislation, or routinely applied guidelines that are imposed on the activity – i.e., intentional transport of insects – by a governing authority, or entity delegated the authority, with the power to control or stop the trade (4). This also might include “soft law”, required documentation, and oversight by association with an industry body, for example. While this is a broad use of the term “regulation”, the details of each prevailing approach are elaborated below by topic.

The authors identified several types of problems encountered and associated gaps for at least some parts of insect trade in regulation, guidance and management, shown in **Table I**. Their experiences also highlight that regulation is not the only, or possibly best, approach to resolving some of the current issues.

**INSERT TABLE I HERE**

Existing guidance from intergovernmental bodies that oversee standards on sanitary and phytosanitary issues – International Plant Protection Convention [IPPC], World Organisation for Animal Health [OIE], and Codex Alimentarius – does not comprehensively cover the range of issues associated with international shipments of live insects, nor does guidance from the Convention on Biological Diversity (CBD), discussed further below. This is largely due to the range of issues for

this type of trade and the various objectives of the guidance and legal framework under which it was developed.

Guidance that is specific to a particular use has ensured safe and effective large-scale shipments of live insects for decades. Uses covered include biological control [5]; or for handling of a particular species, strain, or risk profile of insects or other arthropods (e.g., insects for large areawide control programmes [e.g., 6]); or insects moving from research lab to research lab. These examples of guidance, however, are not comprehensive in regard to the issues faced by shippers, carriers, and importers. Also, those successfully shipping using these use-specific guidelines often have greater purchasing influence or official recognition, e.g. as a government programme. In contrast, researchers working with smaller populations, such as laboratory-reared insects or those preparing pilot studies, or in the small or medium enterprise private sector, have reported barriers when trying to ship, even when the insects could be considered lower risk (e.g., if documented as infertile or sterile and thus not able to persist in the environment).

There are cases where small-scale shipment of live insects can cost as much as 100 times or more what it costs for a similar-sized or weight package of other material going on the same route, because the courier has classified the insects as hazardous (Wohlfarter *et al.* [7], this issue). This skews the market in favour of established, and/or larger-scale insect shippers and disproportionately affects research or academic institutes, public entities, or businesses that require small shipments to develop and pursue opportunities for innovation, such as seed colonies for specific genotypes (Simoni [8], this issue). These barriers do not appear to be evidence-based nor proportionate to the actual risks presented, in many cases [9].

The harm from loss or delay of consignments is often beyond financial. Interruption of supplies for field control can have serious consequences in terms of performance [3, 7, and Vila *et al.* [10], this issue]. These smaller scale research shipments can have great value for progressing research, sometimes representing rare or unique samples. Therefore

some form of insurance alone could not cover the losses and issues of liability arise.

Longer-term fair sharing of benefits can contribute to the opportunities for innovation and economic improvement of the source nations as they develop mechanisms linking insect resources to their own enhanced industry and innovation on the one hand, and the incentives required to promote conservation and sustainable use of biological diversity, on the other [11].

This review of the issues and gaps in the regulatory landscape was motivated by the need to address current barriers to shipping in order to facilitate the benefits, rather than particular concerns over any threats from insect trade. Indeed, much of insect trade has proven to be safe, over years if not decades, under the current decision frameworks (e.g., [10], Enkerlin & Pereira [12], Sanchez et al. [13], this issue).

### **Current regulation of insect trade**

Many variations in approaches to regulating insect trade are a matter of historic context. Some relevant international treaties were established much earlier than others. The OIE started as an agreement in 1924 and had established sanitary certificates by the end of that decade [<https://www.oie.int/en/who-we-are/mission/history/>]. The historic involvement of the OIE in bee health is described by Torres *et al.* [14], this issue. The IPPC came into force in 1952, superseding other plant health agreements relating to specific outbreaks, which were in place as far back as the 19<sup>th</sup> century [<https://www.ippc.int/en/history-of-the-ippc>]. The Codex Alimentarius was created in 1962, building on work by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) [<https://www.fao.org/fao-who-codexalimentarius/about-codex/history/en/>]. These three international bodies: OIE, IPPC and Codex, were recognized by the World Trade Organization (WTO) as the reference standard setting bodies for these objectives under its *Agreement on the Application of Sanitary and Phytosanitary Measures*, or SPS, upon its formation in 1995. The Convention on Biological Diversity (CBD) represents more recent global objectives and did not enter into force until 1993

[<https://www.cbd.int/history/>]. **Figure 1** represents the variety of objectives of intergovernmental treaties, international organisations and non-governmental organisations that affect insect trade today.

### **INSERT FIGURE 1 HERE**

Scientific knowledge, societal norms, and resources were at different points for each of these key agreements, although each has mechanisms for updating and adding guidance. In addition, national priorities or constituents may have pushed for resolution at the global level in specific cases, while other sectors were left unaddressed. A case in point is the amendment to the Universal Postal Convention to facilitate the thousands of shipments of *Drosophila* samples each year using mail ([15] and cited by Cook and Parks [16], this issue).

A few countries had a framework for insect trade, such as import of industrial species, before international guidance was available [17]. National regulation generally, however, follows or aims to implement international standards and obligations in matters relating to international trade. In the absence of national regulations specific to insect trade, in the past many countries simply apply regional or international standards [18; 19]. In fact, no comprehensive national regulation of insect trade has been found by the authors. Instead, there is a patchwork of different instruments, both legally binding and voluntary. A recent survey of those involved in live insect trade (described in Oliva *et al.* [20], this issue, although without details on this point) revealed a range of national authorities and institutions that would have a role in oversight of insect trade.

### **Insects with potential impact on plant health**

Movement of insect pests that are potentially harmful to plant health (managed crops and forestry, or natural flora) is covered by the IPPC and its associated guidance, although many of the International Standards for Phytosanitary Measures (ISPMs) refer to the trade of plants or plant products as potential pathways for introduction of pests.

The primary exception is ISPM No. 3 [21], which has been applied for decades to insect trade and employed outside the phytosanitary sector in some cases as well. The Food and Agriculture Organization of the UN (FAO) and the International Plant Protection Convention (IPPC) recognised the challenges in trade of live insects and provided guidance for shipment of biocontrol agents through a Code of Conduct that later became the ISPM No. 3 [19]. The intention was to support the benefits of integrated pest management that is designed to employ fewer chemical pesticides.

#### INSERT BOX 1 HERE

In addition to global guidance, Regional Plant Protection Organizations (RPPOs) and regional trading blocs have developed related and complementary standards, aligning to standards and terminology endorsed by the member countries of the IPPC. In the case of intentional introduction of insects for beneficial purposes relating to plant health, regional standards for the introduction of biological control agents and/or other beneficial organisms generally provide far more detailed guidance than ISPM 3. For example, the standards under the Comité Regional de Sanidad Vegetal del Cono Sur (COSAVE) provide a regional framework, described by Sanchez *et al.* [13], this issue. The North American Plant Protection Organization (NAPPO) also has regional standards regarding the process for certification and for petition for first release of non-indigenous biocontrol agents and non-*Apis* pollinating insects (with *Apis* species covered largely under OIE) [24, 25] and for first release of entomophagous biocontrol agents [26]. In both of these regional examples, member countries are required to implement the standards through national legislation or regulation.

The European and Mediterranean Plant Protection Organization (EPPO) has a suite of standards for evaluation for first import, import into containment [27], required information for dossiers, and risk assessment guidelines. The history of EPPO's involvement with biocontrol guidance and collaboration with the International Organisation for Biological Control (IOBC) and CAB International (CABI) is described by Orlinkski [28]. PM 6/3 on the 'Safe use of

Biological Control' [29] provides extensive details on the invertebrate species widely used in the EPPO region. This listing implies scrutiny by a peer review expert panel on Pest Risk Assessment (PRA), based on existing literature on efficacy, non-target effects, invasion potential, etc. The intention of this annually updated list is to provide National Plant Protection Organisations (NPPOs) and other interested parties with sufficient guidance on the acceptance of species used in the EPPO region, and subsequently make such trade and application more efficient. Lastly PM 6/4 on the 'Decision-support scheme for import and release of biological control agents of plant pests' [30] provides extensive details on the procedures related to weed biocontrol, which may involve the use of beneficial phytophagous insects.

In Europe, corresponding rules for official control measures by the competent authorities and protective measures against their introduction are set by Directive 2000/29/EC [31] and Directive 2008/64/EC [32]. Regulations (EC) No 1107/2009 and (EU) No 528/2012 and Council Regulation (EC) No 708/2007 provide rules concerning the authorisation for the use of certain alien species for particular purposes, such as macro-organisms useful for biocontrol. However, no framework clearly addresses other arthropods that can be vectors of diseases such as mosquitoes, phlebotomids, and ticks).

### **Animal health in relation to insects**

For animal health, at the global level the World Organisation for Animal Health (OIE) is the recognized standard setting body. The OIE provides extensive guidance on the procedures for international movement of vertebrates, particularly livestock, but only covers honeybees (*Apis* spp) as a class of insects. While honeybee health falls within the current mandate of the OIE, and is addressed by dedicated OIE standards, other insects and arthropods are not dealt with, outside their role of vectoring animal diseases, as explained by Torres *et al.* [14], this issue.

Despite the limits of the current scope of the OIE on insects, the authors have found that a number of countries require a sanitary certificate to accompany shipments of live insects to indicate their health status (as

noted by various authors in this issue [7, 8, 10]). The OIE does not provide any guidance on establishing or monitoring insect health from field collection or production systems, even for those vector species and vectored diseases included in the OIE Terrestrial Code (highlighted by Torres *et al.* [14]). The guidance on arthropod surveillance (Chapter 1.5) is aimed at establishing the spatial and temporal distribution, and abundance of vectors of the arthropod-borne listed diseases and emerging diseases in the area of export: the risk assessment process is to determine if there is a likely pathway, rather than to evaluate management measures to prevent introductions via the known pathway of intentional insect trade [33].

An insect vector of a human or animal disease might be imported for research into a country where it is already present without restriction, but if the consignment has vector insects that are infected with the disease being researched, or can transmit one mechanically [34], far more security to ensure isolation and containment is required [35]. It is a different case to declare a non-infected insect population as healthy, however.

It is the opinion of the authors that there is insufficient guidance when the national Veterinary Services of the exporting country are asked to provide documentation on the health status of a specific population or consignment of insects, or for other arthropods. The request, therefore, can be open to interpretation by individuals, private businesses, and official authorities when faced with insect trade, thereby reducing confidence in the certification system [36].

### **Food and feed**

At the international level, use of live insects for food or feed comes under the mandate of the Codex Alimentarius, which historically classes most insects as filth or contamination when present in food and feed products, rather than as a class of food themselves [37, 38, 39]. Therefore, it is not surprising that national regulation of live insects for human or animal consumption is fragmented or still emerging. In Europe, for example, regulatory approaches vary from outright bans to specific guidance on production conditions and food sources allowed

for predatory insects [40, 41]. Although insect trade for food and feed is not the focus of this special issue, Niassy *et al.* [42], this issue, join others to call for Codex Alimentarius to develop guidance for insects as food and feed. This would focus on the impact to end users (consumers and livestock), but also could contribute ideas for a hazard analysis and critical control point (HACCP) approach to maintaining quality and safety through the production process [42].

Risks associated with transport *per se* would generally lie outside of the Codex Alimentarius domain, other than the additional time allowing microbiological contamination, and possibly insects, to grow and develop further during transport.

### **Conservation considerations relating to insect trade**

A wide range of species with various characteristics are being shipped or hand carried after field exploration by entomologists for research purposes. Collection, possession, import, export, and study of live or dead insects may be subject to restrictions relating to conservation of biodiversity, plant, and animal health, as laid out under international agreements. Insect species can be threatened from excessive harvesting in the wild for the purpose of trade, in particular for hobbyists or for use in alternative medicines (as the case presented by Goka [43], this issue, and [44, 45]). There has been limited analysis of such risks, for example by the International Union for Conservation of Nature (IUCN), and thus limited restrictions under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) despite global concern over a general reduction of insect numbers and diversity [46]. Many researchers, conservationists, and regulators [47] have called for a coordinated conservation and recovery plan addressing the decline in natural insect populations and proposed IUCN or the United Nations Environmental Programme (UNEP) to monitor progress.

There is no single intergovernmental treaty or entity that oversees trade in pollinators, either the entire range of species or insect pollinators. As already noted, the OIE recognised the risks from this trade, but has limited its work to date to *Apis* species. Some aspects of trade in pollinators are covered, for example under ISPM 3 [21], since the

clarification of its expanded scope in the revision in 2005 (see **Box 1**). The pollinator industry has been considered as a source for introduction of parasites and pathogens that are damaging the health of domestic and wild populations of pollinators for some time [48, 49, 50], which highlights the need for some form of health certification relating to the founding stock and production process prior to export. This also suggests that Veterinary Services or other designated insect health experts should conduct importation risk assessments at the national level. Yet ideally, this risk assessment should also consider the risk to biodiversity through invasion and plant health in the same process [43, 51, and Temmermans & Smagghe, this issue, 52]. Such an initiative will require thoughtful development.

The CBD approaches the issues around insect trade primarily from the perspective of protecting biodiversity in the environment. The CBD does not set standards nor provide oversight in their implementation, but instead coordinates development of guidance on related issues [53, 54, 55]. It does address issues arising from the use of genetic resources, however, through the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD*.

Currently, compliance with requirements aimed at protecting biodiversity and fair sharing of benefits from access to biocontrol agents, for example, does not have a well-defined process in the majority of cases [56, 57]. To date, efforts to support access and sharing of benefits for the biocontrol agent collection and research – a largely non or low profit activity – has led to requirements for various types of documents, under different regulations, subject to a wide diversity of government agencies, and depending on the field of use and origin, with variation between countries even in the same region [58].

The complexity of overlapping authorities preventing the introduction and spread of invasive species can be seen with the example of forest pests: a recent review [59] includes an analysis of international instruments that directly or indirectly affect the management of potential pests to prevent invasion. Many of the recommendations for

integrating the numerous sources of guidance to apply to one sector would hold true for preventing insects moving in trade from becoming an invasive species for the importing territory.

Even if a shipper is following ISPM 3, the dispute mechanism established under the IPPC could not be used for cases related to impacts of insect trade outside of plant health, but in theory the World Trade Organization's Sanitary and Phytosanitary Committee could possibly consider cases on a broader scale. It is unlikely that a country would use such a time consuming and politically charged forum to resolve any issues related to insect trade, however; it is more likely that contract law would be relied upon for ensuring delivery of live insects as required.

### **Specific rules for genetically modified insects**

The export, transport, and import of transgenic insects are subject to requirements that are often additional to those noted above, although national frameworks may operate through biosafety committees that are comprised of representation of the same authorities already noted [60]. The international treaty of most relevance is the Cartagena Protocol on Biosafety to the CBD [61]. This lays out a global framework for notification of shipments of genetically modified organisms, including insects [62], for release in the importing country thereby allowing national authorities to manage risks and concerns in a timely manner. As with other international guidance, the guidance is to be interpreted in regional or national legislation and regulations. One of the earlier examples was NAPPO's guidance on the importation of transgenic arthropods [63], which is since archived due to change in authorities in two of the member countries. The Directive 2001/18/EC of the European Parliament and of the Council (and its consolidated version dated 2021) sets out the regime applicable to genetically modified organisms for the EU. Guidance specific to genetically modified insects generally focus on the modification, however, rather than filling a gap for overall management of insect trade.

The concepts of biosafety from proper packaging and containment are critical to transport of GM insects, as well as other categories

considered to present a risk. **Box 2** considers what risk management is appropriate for preventing exposure to the environment and possibly to workers as well, if considered necessary.

#### **INSERT BOX 2 HERE**

Underlying this separate agreement is the idea that products from modern biotechnology are inherently different from those modified in other ways, such as by traditional breeding, introduced symbiosis, or in other ways; this assumption does not appear to be supported by the years of experience since its ratification, primarily with genetically modified crops. There is a sense, as well, that by restricting these frameworks to the understanding of genetic modification concurrent to the period of development of these instruments, rather than a scope that covers any novel traits, novel uses (such as [52], this issue), or production methods, that national legislation and regulations have already fallen behind the trends in use of altered insect populations.

#### **Commercial issues, quality, and usefulness issues for insect trade**

In addition to protection goals, insect trade is subject to requirements regarding fraud, protection of intellectual property, and other commercial requirements, which may be managed under contractual arrangements governed under international business law, memorandums of understanding, material transfer agreements or other means. These commercial issues associated with identity, ownership and some of the uses of live insect trade are not addressed here.

Another aspect of shipping any living product is maintaining quality to ensure that the insects serve the purpose behind the shipments in the first place. This means that some shipments also are managed under “fit for purpose” standards, relying on guidance about shipment of particular types of live insects in order to ensure utility upon arrival. This type of guidance has been developed by a number of intergovernmental and private organisations. The FAO/IAEA produced guidelines for packing, shipping, holding, and release of sterile Tephritid fruit flies [6], and for packaging and shipping sterile tsetse

flies [68, 69]. A detailed manual for quality control of Tephritid fruit flies is also available [70]. Guidance for mosquito programmes is also under development and addresses some aspects of safety and risk, but also discusses quality measures. All of these guidelines mention quality control, meeting phytosanitary requirements, and meeting export and import country documentation requirements. The potential role of sanitary (Veterinary Health) certificates is not noted in any of these guidelines.

### **Guidance from the transport sector**

Much of the trade in live insects is via air freight. Environmental conditions of shipments are optimised for insect survival and quality (such as described for biocontrol agents by Vila et al. [10], this issue), as they move from a production site or wild harvest, through domestic and international transport, to the ultimate destination after clearing the usual border checks. These conditions aimed at maintaining the utility of the shipments, of course, also contribute to other types of risks by keeping the insects viable.

Therefore, the final aspect to the current regulatory landscape is the guidelines, norms, and standards applied to any type of commercial transport (see for example Simoni [8], this issue). The airline and freight courier industries refer to the International Civil Aviation Organization (ICAO) of the United Nations and the private International Air Transport Association (IATA) to guide them on handling potentially hazardous materials.

The IATA has cooperated with the biocontrol industry to provide specific details for packaging of mites and insects in the latest guidance [10]. A new shipping label that could rapidly inform those in contact with the consignment of the identity, risk status, and any handling requirements for the contents and need for timely delivery has been proposed [7].

Globally harmonised classification and labelling of environmentally hazardous living organisms have been under consideration at the United Nations Economic and Social Council Sub-Committee of Experts on

Transport of Dangerous Goods [65]. A classification system that aligns with key principles such as evidence-based risk assessment and takes into account any modifications or treatments of the population being shipped (such as inability to survive outside of the packaging for the life stage being shipped; inability to produce viable offspring if able to survive, etc.) would avoid additional restrictions for trade that is already demonstrated to be safe based on high volumes shipped with no incidents, for example.

Ideas for improved coordination appear below, with further discussion in Quinlan *et al.* [71], this issue.

### **Gaps or inconsistencies in regulation of insect trade**

**Table II** presents a list of aspects that require more consistent guidance, based on earlier discussions convened by Imperial College London (as reported in [72]). The list of possible documentation in ISPM 3 includes most of these points [21]. While these aspects seem to be universally necessary when considering international trade, a simple “one size fits all” guide is not feasible. Guidance should consider the types of insects or other arthropods that are being shipped, the life stage (egg; larvae, pupae, or nymph; adult), specific requirements such as documentation, packaging or delivery, and reporting criteria needed to better facilitate achieving the benefits from this trade while mitigating any risks.

#### **INSERT TABLE II HERE**

Given the current variations in carrier policies, some additional steps in the guidance to support risk-based classification of shipments could save considerable costs and enable the pursuit of important benefits. Consistent classification of shipments, based on the risks and risk mitigation strategies, would facilitate data reporting, collection, and analysis. If animal health certificates are required, clear guidance on the appropriate information required for such a form would standardise the practice.

## Conclusions

Every year there is a number of shipments transporting a variety of species and strains, and representing a broad range of interests in trade of live insects. There is every reason to expect increases in trade in live insects and insect-based food and feed [e.g., 73, 74]. Presently, trade occurs under a variety of regulations and oversight. This paper aims to highlight the importance of guidance and the need for evidence-based risk assessment and management to ensure safe international trade of insect while minimising unjustified trade barriers and simple inefficiencies in shipping. It also argues for arthropod-specific guidance, rather than working from the paradigm of insects as a subset of all animals. Where guidance exists, high level agreement on the integration of various authorities or the hierarchy of authorities is needed. Enhanced transparency in this guidance will support suppliers, users, shippers, and regulators.

In light of the current gaps and inconsistencies in guidance for shipping live insects and other arthropods – within the sector but also in comparison to other time sensitive trade – the authors propose further discussion among stakeholders to agree on pragmatic solutions. Discussions should include international organisations with mandates relating to ways in which the insect trade affects both health protection and conservation, and economic and innovation objectives, including but not limited to: OIE, IPPC, CBD, IAEA and FAO; national bodies involved in regulation of insects and their trade, as well as those potentially using or advancing benefits based on trade and exchange of insects; recognized advisors and facilitators of these benefits, such as CAB International; associations or guidance bodies for the shipping sector in general, including ICAO and IATA; and research and academic bodies with objectives affected by this international trade.

Coordination should be aimed at promoting a more transparent and pragmatic process for live shipments, which will lead to rationally avoiding both potential risks and scientifically unjustified barriers. New initiatives must avoid imposing additional requirements for trade already moving effectively, such as several large volume sectors (e.g.,

for sterile insect technique [12, 74]). A harmonised risk-based approach may also provide a more suitable platform than existing regulations or guidance for consideration of future innovations or emerging risks, and the most appropriate risk management options for these, as the trade in live insects grows and changes [75].

The range of issues reinforces the authors' view that discussions around rationalising regulation of or guidance for insect trade will need to be broad and flexible. We believe that basing decisions about shipping on evidence of risk and proportional management, where needed, is the best way to support the benefits supported by live insect trade – through research, industrial outputs, and field programmes relying on safe delivery of insects, when and where needed.

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**Table I**

**Issues from gaps in regulation, guidance or management for insect trade and possible solutions**

Problem	Possible solution
Live insects not accepted for shipment by individual representative when company policy (or national regulations) would indicate acceptance of consignment	<ul style="list-style-type: none"> <li>• Advance notification and acceptance of contract terms</li> <li>• Guidance from trade and transport associations (e.g., IATA)</li> </ul>

	<ul style="list-style-type: none"> <li>• Educational materials aimed at transport sector</li> </ul>
Insects in transit could escape and cause harm or be a perceived risk to environmental/plant, human, or animal health during transit or in receiving country	<ul style="list-style-type: none"> <li>• Packaging standards</li> <li>• Tracking procedures</li> <li>• Disposal procedures, labelling and documentation indicating specific live organism hazard</li> </ul>
Uncertainty for carrier over acceptance of shipments in receiving countries due to specific risk, unclear requirements, or inadequate documentation	<ul style="list-style-type: none"> <li>• Accessible documentation of approval for species, source, use, import route, certification of identity and quality, documentation, inspection</li> <li>• Prior notification of shipment to receiving country</li> <li>• Documentation specifications</li> <li>• Insurance for costs incurred through rejection, disposal</li> </ul>
Delays caused by Customs clearance, biosecurity inspection or other factors outside the control of the carrier	<ul style="list-style-type: none"> <li>• Educational materials aimed at border authorities</li> <li>• Prior notification of shipment to receiving country</li> </ul>
Potential liability of the carrier to the shipper or recipient for loss or damage to quality of live insects due to handling or delay	<ul style="list-style-type: none"> <li>• Handling protocols for live material to cover insects, specifying responsibilities of each party</li> <li>• Contract terms</li> <li>• Insurance</li> </ul>
Imported insects delivered successfully could cause environmental or human, animal health risk after delivery in the intended receiving country, either through intended use or escape	<ul style="list-style-type: none"> <li>• Import risk assessment by receiving country</li> <li>• Accessible documentation of approval for species, source, use, import route, certification of identity and quality, documentation, inspection</li> </ul>

**Table II****Aspects of shipping live insects to be considered in coordinated guidance**

- Procedures for assessing risk, particularly for inactive life stages (eggs, pupae) or for strains modified in ways that alter risk
- Characterisation of relevant health or other risks related to specific shipments (species, diseases, origin, and destination, conditions in transit)
- Review of production and handling procedures as a proxy for health certification of individual shipments
- The minimal required content/procedures to carry out health certification, if required, and appropriate expertise and qualifications to do so
- Design and audit processes for certified production systems
- System of notifications to shippers, inspectors, and recipients
- Standardized approach to specification of approximate numbers, volume, or weight of insects
- Documentation (labels, permits, handling instructions)
- Importer/Exporter authority coordination and recognition
- Shipper/Courier rules and acceptance of live cargo
- Packaging requirements (security, viability, inspection access, temperature and humidity monitoring *en route*)
- Routing permits (through specified official inspection ports and for ports of transit)
- Transit point requirements
- Liability related to survival of shipped insects given diverse and uncertain routes
- Emergency destruction procedures

**Box 1****The role of ISPM 3 in international live insect trade**

ISPM No. 3 is unique in its status as an international standard for the trade of live insects. The intention of the ISPM is described as to facilitate safe export, shipment, import, and release of organisms that would include live insects for beneficial purposes. It allows sovereignty in decisions regarding import of biological control agents yet has facilitated such trade in a number of countries, even when a national or regional regulatory framework was not in place [18,19]. By virtue of the scope of the IPPC, the ISPM was developed for agricultural use of biocontrol agents, which results in the national authority for evaluation often being located in agriculture ministries, although coordinating with environmental or other relevant authorities [13]. The clear description of roles and responsibilities of the exporting and importing authorities has been cited as an important part of the ISPM when it comes to implementation [19].

The current version of the ISPM, revised in 2005, extends to other beneficial insects: “biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products” [21; although not clearly stated, this covers insect pollinators, not mammals] and emphasises the risk as determined using other ISPMs for this purpose, rather than focusing on “exotic” or endemicity status, as in the earlier versions [22]. Despite that shift towards risk-based decisions, ISPM 3 specifically excludes living modified organisms (genetically modified) from its scope.

Further, while ISPM 3 addresses a number of issues in live insect trade, it does not provide details for pre-shipment or production procedures to maintain healthy stock, nor certification or audit of the production process as a means for reducing the risk of contaminants to the trade, although it requires that “no contamination or infestation of this organism, or that interbreeding with local genotypes of the same species does not result in new phytosanitary risks”. Collection of insects from the wild and other issues relating to conservation are only outlined in terms of impact on non-target organisms.

The standard has been cited for purposes of public or animal health when other guidance is lacking (as noted in this issue [2]). ISPM 3 itself notes that expertise in issues arising from other international fora, including human health, should be considered. The ISPM 12 regarding phytosanitary certificates [23], however, says that no statements regarding animal health, or other non-phytosanitary issues, should appear on this official document, but rather notes to connect other statements to the certificate (e.g., relating to CITES) can be included. Therefore, it would seem that while phytosanitary certificates are often used in shipments of live insects, the best mechanism and document for validating health of insects, insect populations or insect production facilities remains unclear to many parties.

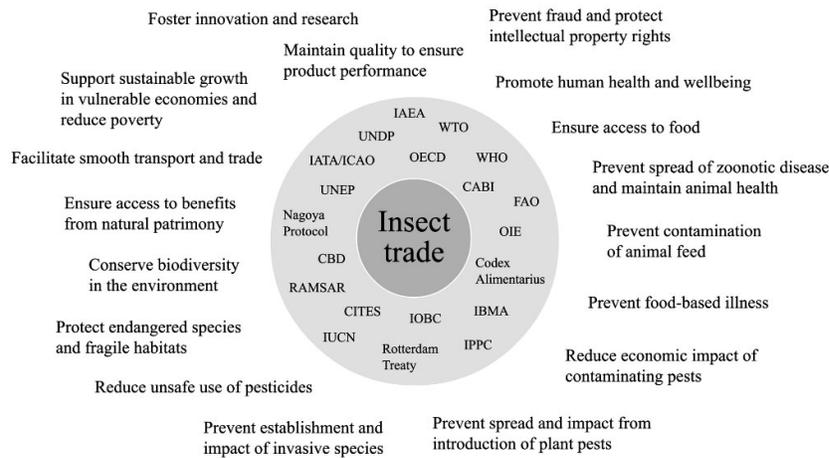
This leads to the conclusion that ISPM 3 must be considered for any future guidance on live insect trade, but by itself leaves gaps in coverage. Close coordination on guidance that cites this ISPM is recommended. Manuals or guidelines supporting ISPM 3, as originally envisioned (19), could be one mechanism for integrating practices that consider the various objectives interfacing with live insect trade (e.g., as shown in Figure 1). Such manuals would likely hold no legal status but could act as a much-needed roadmap for those involved in the trade.

**Box 2****Cases when risk management based on biosafety measures can be evaluated generically**

The key risks during the transport stage relate to maintaining the “usefulness” of the insects and avoiding their escape. If containment of the insects is secure throughout transport, then concerns around exposure of the environment or workers and around the integrity of the shipment and identity of the insects being shipped, become irrelevant. Packaging that is universally recognised for achieving containment can reduce the probability of escape and associated risks to a negligible level. Adding clear instructions about the proper actions to take if the consignment is lost or delayed past the point of utility further ensures that the risk of escape is managed. Special handling is already required for insects that are genetically modified or potential vectors, particularly if infected for research purposes [64].

In addition to evaluating the packaging, carriers, importers or inspectors may want information about the security of the facilities providing and receiving the live insects. Beeckman & Rüdelsheim [65] review the regulations associated with biosafety in relation to facilities and labs. Hayes & Quinlan [66] note some characteristics relevant to insects, as does the Arthropod Containment Guidelines, such as potential mobility, and propose levels of containment by classification [35]. These consensus guidelines now include insects with gene drives as well [67], in other words insects with higher risk profiles.

None of these precautions guarantee that the quality of insects will be maintained, but the safety concerns are covered by proper containment. Biosafety and delivery on time under prescribed conditions should be the primary concerns of carriers, but they are likely to also look for reassurance that the documentation is in order so that delays at Customs in the importing country can be avoided.



**Fig. 1**

**Global agreements and organisations that affect insect trade, and their overlapping or competing objectives.**

CABI *CAB International*; CBD *Convention on Biological Diversity*; CITES *Convention on International Trade in Endangered Species of Wild Fauna and Flora*; FAO *Food and Agriculture Organization*; IAEA *International Atomic Energy Agency*; IATA *International Air Transport Association*; ICAO *International Civil Aviation Organization*; IBMA *International Biocontrol Manufactures Association*; IPPC *International Plant Protection Convention*; IOBC *International Organisation for Biological Control*; IUCN *International Union for Conservation of Nature*; Nagoya Protocol *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD*; OECD *Organisation for Economic Co-operation and Development*; OIE *World Organisation for Animal Health*; Ramsar *Convention on Wetlands of International Importance especially as Waterfowl Habitat*; Rotterdam Convention *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*; UNDP *United Nations Development Programme*; UNEP *United Nations Environmental Programme*; WHO *World Health Organization*; WTO *World Trade Organization*.