Movement of Biological Materials

Guidance document

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Belgian
Biosafety
Professionals

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Please note that in suite of the Brexit (31 January 2020), the United Kingdom is no longer part of the European Union. Hence Great Britain (Scotland, England, and Wales) must be considered as third country. By exception, Northern Ireland will still comply to the EU rules until January 1st, 2025.

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Elisabeth Heylen, on behalf of the BBP Steering Team

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1 Introduction to the guidance document

1.1 Introduction

This guidance document serves as a practical guide and will help you to 'move' biological materials in a legally correct manner. With 'movement' of biological materials we mean the shipment, transport, import and/or export of such materials from one facility to another. The scope of this guidance document is limited to the movement of biological materials for use in research and development (R&D). It does not cover the movement of biological materials with a market authorization that will be used in commercial applications.

It is also important to highlight that this guidance document will not cover all possible types of biological material. It covers living organisms such as microorganisms, cells, invertebrates, plants and animals, as well as materials such as natural or synthetic DNA and RNA (from oligo's to complete genomes), proteins and peptides. The living organisms may be genetically modified or not, and the nucleic acids and proteins may or may not be of a recombinant nature. All such materials are being shipped from one facility to another all over the world continuously. It is important that this is being done correctly to avoid regulatory infringements, to avoid that valuable materials are being destroyed or delayed at customs because of incorrect labelling or a missing document, and to ensure that shipper, carrier, consignee, the public and the environment are protected from exposure to potential hazards.

Depending on the type of material, shipment of that material may trigger one, but more often, different types of legislation. All have their consequences for the paperwork to be done and for the way the material needs to be packed and labelled. It is a complex matter and certain types of regulatory triggers may easily be missed. With this guidance document, BBP aims to provide a broad overview of the different pieces of legislation that will impact the way you need to move your biological materials. The document will provide the necessary practical guidance. It serves to show the 'regulatory forest', and at the same time make all 'individual trees' clearly visible, so you will be able to navigate through it.

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1.2 Definitions

Movement of biological materials	The shipment, transport, import and/or export of biological materials from one facility to another
Biological materials	Living organisms, such as microorganisms, invertebrates, plants and animals, cell cultures of any origin Materials such as samples or biopsies from living organisms, natural or synthetic DNA and RNA (from oligo's to complete genomes), proteins and peptides
Import	Transfer of materials from outside the European Union (EU) into the EU (for the purpose of this guidance document, into Belgium). Please note that in suite of the Brexit (31 January 2020), the United Kingdom is no longer part of the European Union. Hence Great Britain (Scotland, England and Wales) must be considered as third country. By exception, Northern Ireland will still comply to the EU rules until January 1st, 2025.
Export	Transfer of materials from inside the EU (for the purpose of this guidance document, from inside Belgium) to a country outside of the EU. Please note that in suite of the Brexit (31 January 2020), the United Kingdom is no longer part of the European Union. Hence Great Britain (Scotland, England and Wales) must be considered as third country. By exception, Northern Ireland will still comply to the EU rules until January 1st, 2025.

Re-export	Export of material that has previously been imported, and which in the meantime has not been transformed.
Third country	Country outside the European Union.

1.3 How this guidance document works

In Chapter 2 of this guidance document, you will find so-called 'regulation triggering tables' per category of biological materials. In each table you will find the types of regulation that **may** apply to shipment of your material (depending on the type of material, one or more regulations can apply). In Chapter 3 of this guidance document, for each type of legislation an instruction card with relevant information is provided. The card specifies the goal and the general requirements of the legislation, but also provides practical information on its consequences in terms of the necessary paperwork and on how to package and label your material. Below, some examples are given to further illustrate how the guidance document works.

Example 1: Import of a CHO cell line

CHO cells are Chinese hamster ovary cells. Below, you find a table with a list of legislations that may be triggered by the movement of animals and related materials. In a **first step** you must determine which of these legislations apply to the CHO cell line. In this particular case, the cell line is not genetically modified, is not stemming from an endangered species, and is not an animal by-product[1], even though the cell line is produced from an animal. However, if the culture medium in which the cell line is transported contains calf serum, which is very likely, this will trigger the animal by-product legislation (see Chapter 3.4). Furthermore, the cell line does not contain an animal pest, is not a genetic resource and does not present a material that can be dually used. It even does not trigger the legislation for transport of dangerous goods, as the cell line is neither infectious nor genetically modified. The result of this analysis is presented in the table below. In any case, you will have to take into account that the shipment needs to go through customs clearance (see Chapter 3.12).

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[1] Animal cell cultures are not an animal by-product, because they are considered to still be living entities. If you would take a biopsy and produce a cell culture from the biopsy, then the biopsy would be an animal by-product, but the cell culture would not be.

Table example 1: Animals and related materials

(See also Table 2.1 'Animals and related materials' in Part 2 of the Guidance document)

Possibly relevant legislation	Live animals	Animal bodily parts	Animal bodily excreta	Animal derived cells / cell lines
				CHO cell line
GMO/LMO	□	□	□	□
CITES - endangered species	□	□	n.a.	□
Animal By-Products	n.a.	□	□	☑
Quarantine animal pests and diseases	□	□	□	n.a.
Transport of live animals	□	n.a.	n.a.	n.a.
Access & Benefit Sharing (Nagoya)	□	□	n.a.	□
Dual Use	n.a.	n.a.	n.a.	□
Transport of dangerous goods	□	□	□	□
Transport of non-dangerous goods	□	□	□	☑
Customs/Tax	□	□	□	☑

n.a.: not applicable

If you do not immediately know whether a certain type of legislation applies, then you can consult the instruction card that describes this legislation to determine this.

In a **second step**, after having 'ticked the boxes', you go to the instruction cards of the legislation(s) that your material triggers to find information about the necessary paperwork, as well as the packaging and labelling requirements for the material. All instruction cards contain concrete contact information of the relevant competent authorities, or directions on where to find this contact information.

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Example 2: Import of a HEK293T cell line

This case looks very similar to Example 1, except that this cell line has been genetically modified to introduce the SV40 Large T antigen gene and that it stems from human origin. Since the cell line has been genetically modified, it now also triggers the legislation on GMOs (see Chapter 3.1), and of transport of dangerous goods (see Chapter 3.10). Also, since it originates from humans, the biobanking legislation is triggered. The result of the regulatory analysis for the HEK293T is shown below.

Table example 2: Material from human origin

(See also Table 2.3 'Material from human origin' in Part 2 of the Guidance document)

Possibly relevant legislation	Human bodily materials	Human bodily excreta	Human-derived cells / cell lines
			HEK293T cell line
GMO/LMO	n.a.	n.a.	☑
Animal By-Products	□	□	☑
Access & Benefit Sharing (Nagoya)	n.a.	□	n.a.
Biobanking	☑	☑	☑
Dual Use	n.a.	n.a.	□
Transport of dangerous goods	□	□	☑
Transport of non-dangerous goods	□	□	□
Customs/Tax	□	□	☑

n.a.: not applicable

Example 3: Import of a non-human primate (NHP) cell line

Also this case is almost identical to Example 1, except that the cell line triggers the CITES legislation (see Chapter 3.3) because it stems from a protected animal species. The result of the regulatory analysis is shown below.

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Table example 3: Animals and related materials
(See also Table 2.1 'Animals and related materials' in Part 2 of the Guidance document)

Possibly relevant legislation	Live animals	Animal bodily parts	Animal bodily excreta	Animal derived cells / cell lines
				NHP cell line
GMO/LMO	□	□	□	□
CITES - endangered species	□	□	n.a.	☑
Animal By-Products	n.a.	□	□	☑
Quarantine animal pests and diseases	□	□	□	n.a.
Transport of live animals	□	n.a.	n.a.	n.a.
Access & Benefit Sharing (Nagoya)	□	□	n.a.	□
Dual Use	n.a.	n.a.	n.a.	□
Transport of dangerous goods	□	□	□	□
Transport of non-dangerous goods	□	□	□	☑
Customs/Tax	□	□	□	☑

n.a.: not applicable

Example 4: Export of a genetically modified mouse

A genetically modified mouse triggers the legislation for GMO/LMO (see Chapter 3.1), as well as for transport of dangerous goods (see Chapter 3.10). Additionally, it will trigger legislation related to the transport of live animals (see Chapter 3.6), which aims at ensuring the welfare of animals during transport, as well as protecting public and animal health as animals are a potential source of infectious agents.

Table example 4: Animals and related materials
(See also Table 2.1 'Animals and related materials' in Part 2 of the Guidance document)

Possibly relevant legislation	Live animals	Animal bodily parts	Animal bodily excreta	Animal derived cells / cell lines
	GM mouse			
GMO/LMO	☑	□	□	□
CITES - endangered species	□	□	n.a.	□
Animal By-Products	n.a.	□	□	□
Quarantine animal pests and diseases	□	□	□	n.a.
Transport of live animals	☑	n.a.	n.a.	n.a.
Access & Benefit Sharing (Nagoya)	□	□	n.a.	□
Dual Use	n.a.	n.a.	n.a.	□
Transport of dangerous goods	☑	□	□	□
Transport of non-dangerous goods	□	□	□	□
Customs/Tax	☑	□	□	□

n.a.: not applicable

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Example 5: Export of genetically modified rice seeds for a field trial in Africa

In this particular case you trigger the GMO legislation (see Chapter 3.1), more particular the 'Cartagena Protocol on Biosafety' (= LMO regulatory framework). Moreover, the legislation on transport of dangerous goods (see Chapter 3.10) is triggered because the rice seeds are genetically modified. Tax legislation may be triggered when it concerns commercial products with a value above a certain monetary value. For the exact values, the customs/tax department of the country of import is to be consulted. The result of the regulatory analysis is shown below.

Table example 5: Plants and related materials
(See also Table 2.2 'n.a.: not applicable

Plants and related materials' in Part 2 of the Guidance document)

Possibly relevant legislation	Propagatable plant materials	Non-propagatable plant materials	Plant-derived cell lines
	GM rice seeds		
GMO/LMO	☑	□	□
CITES - endangered species	□	□	□
Access & Benefit Sharing (Nagoya)	□	□	□
Dual Use	□	n.a.	n.a.
Phytosanitary	☑	□	n.a.
Transport of dangerous goods	☑	□	□
Transport of non-dangerous goods	□	□	□
Customs/Tax	☑	□	□

n.a.: not applicable

Example 6: Import of a non-pathogenic bacterium recently isolated from a spring in Iceland

As the recently isolated bacterium is a 'genetic resource', it will trigger the Nagoya Protocol on access and benefit sharing (see Chapter 3.7). As the bacterium is non-pathogenic, the legislation on the transport of dangerous goods will not be triggered. However, if there would a suspicion that the bacterium is pathogenic, or this cannot be ruled out, then the legislation on transport of dangerous goods will be triggered (see Chapter 3.10). If ABPs (such as casein, tryptone, peptone) are present in the microbial culture medium then the legislation on Animal By-products will be triggered (see chapter 3.4).

Table example 6: Microorganisms (cultures)
(See also Table 2.6 '
Microorganisms (cultures)' in Part 2 of the Guidance document)

Possibly relevant legislation	Microorganisms
	Bacterial isolate from a spring in Iceland
GMO/LMO	☐
Animal By-products	
Quarantine animal pest & diseases	☐
Access & Benefit Sharing (Nagoya)	☑
Dual Use	☐
Phytosanitary	☐
Transport of dangerous goods	☐
Transport of non-dangerous goods	☑
Customs/Tax	☑

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2 Regulation triggering tables

2.1 Animals and related materials

Possibly relevant legislation	Live animals	Animal bodily parts [2]	Animal bodily excreta [3]	Animal-derived cells / cell lines
GMO/LMO	□	□	□	□
CITES - endangered species	□	□	n.a.	□
Animal By-Products	n.a.	□	□	□
Quarantine animal pests and diseases	□	□	□	n.a.
Transport of live animals	□	n.a.	□	n.a.
Access and Benefit Sharing (Nagoya)	□	□	n.a.	□
Dual Use	n.a.	n.a.	n.a.	□
Transport of dangerous goods	□	□	□	□
Transport of non-dangerous goods	□	□	□	□
Customs/Tax	□	□	□	□

n.a.: not applicable

2.2 Plants and related materials

Possibly relevant legislation	Propagatable plant materials [4]	Non-propagatable plant materials [5]	Plant-derived cells / cell lines
GMO/LMO	□	□	□
CITES - endangered species	□	□	□
Access and Benefit Sharing (Nagoya)	□	□	□
Dual Use	□	n.a.	n.a.
Phytosanitary	□	□	□
Transport of dangerous goods	□	□	□
Transport of non-dangerous goods	□	□	□
Customs/Tax	□	□	□

n.a.: not applicable

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[2] Includes organs, tissues, cells, blood, serum, plasma, sperm, ovum

[3] Urine, faeces, milk, sweat, saliva and other bodily materials that can be obtained without invasive procedures

[4] Includes whole plants, seeds, pollen, reproductive plant parts, callus. What is to be considered a reproductive plant part differs from plant species to plant species, taking into account the circumstances needed for survival and propagation of the material. If it is for planting or for further propagation, even in *in vitro* lab circumstances, then select Propagatable plant materials.

[5] Includes leaves and all other non-reproductive plant parts

2.3 Material from human origin

Possibly relevant legislation	Human bodily materials [6]	Human bodily excreta [7]	Human-derived cells / cell lines [8]
GMO/LMO	n.a.	n.a.	□
Animal By-Products	□	□	□
Access and Benefit Sharing (Nagoya)[9]	n.a.	□	n.a.
Biobanking	□	□	□
Dual Use	n.a.	n.a.	□
Transport of dangerous goods	□	□	□
Transport of non-dangerous goods	□	□	□
Customs/Tax	□	□	□

n.a.: not applicable

2.4 Invertebrates

Possibly relevant legislation	Arthropods	Nematodes
GMO/LMO	□	□
CITES - endangered species	□	n.a.
Animal By-Products	□	□
Quarantine animal pests and diseases	□	n.a.
Transport of live animals	□	□
Access and Benefit Sharing (Nagoya)	□	□
Phytosanitary	□	□
Transport of dangerous goods	□	□
Transport of non-dangerous goods	□	□
Customs/Tax	□	□

n.a.: not applicable

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[6] Includes tissues, cells, blood, serum, plasma, sperm, ovum

[7] Urine, faeces, milk, sweat, saliva and other bodily materials that can be obtained without invasive procedures

[8] The medium in which the human material is transported can contain animal by-products (e.g. calf serum)

[9] The ABS Regulation is applicable in the case microbiota are isolated from human bodily excreta (e.g. faeces) and genetic and biochemical composition of strains and the function of genes is studied with the aim to use these strains in probiotics. Also see Regulation Triggering Table 2.6 (Microorganisms).

2.5 Soil

Possibly relevant legislation	Soil [10]
Phytosanitary	☐
Access and Benefit Sharing (Nagoya)	☐
Transport of non-dangerous goods	☐
Customs/Tax	☐

2.6 Microorganisms (cultures)

Possibly relevant legislation	Microorganisms [11]
GMO/LMO	☐
Animal By-Products	☐
Quarantine animal pest and diseases	☐
Access and Benefit Sharing (Nagoya)	☐
Dual Use	☐
Phytosanitary	☐
Transport of dangerous goods	☐
Transport of non-dangerous goods	☐
Customs/Tax	☐

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2.7 Proteins en peptides

Possibly relevant legislation	Proteins / Peptides
Animal by-products	☐
Dual Use	☐
Transport of dangerous goods [12]	☐
Transport of non-dangerous goods	☐
Customs/Tax	☐

[10] Transport regulations apply not for the soil (including sediments and growing media associated with plants for planting) itself, but for the (micro)organisms it may carry

[11] Bacteria, archea, yeast, fungi and fungi-like, viruses and viroids, *Mycoplasma*

[12] The regulation on the transport of dangerous goods applies when the protein is a toxin (e.g. Shiga toxin) or when the protein is pathogenic (e.g. prions)

2.8 DNA / RNA

Possibly relevant legislation	DNA / RNA
Access and Benefit Sharing (Nagoya)	☐
Dual Use	☐
Transport of non-dangerous goods	☐
Customs/Tax	☐

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3 Legislation instruction cards

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3.1 GMO / LMO

Goal of the regulatory framework

The general goal of the regulatory frameworks for genetically modified organisms (GMOs) and living modified organisms (LMOs) is to protect human health and the environment from possible risks associated with activities involving GMOs/LMOs. The regulatory frameworks formulate requirements for the contained use, deliberate release for experimental or commercial purposes, as well as the transboundary movement, transit, handling and use of GMOs/LMOs. This has been documented at European level in EU legislation and at global level via de Cartagena Protocol on Biosafety (CPB) (1).

The Cartagena Protocol on Biosafety was developed with the goal to stimulate the development of GMO regulatory frameworks in countries where there was no legislation yet, and to harmonize the procedures for the transboundary movement of LMOs. The CPB is part of the Convention on Biological Diversity (2), which has the goal to protect biodiversity and stimulate its sustainable use.

Scope

A **GMO** is defined as an organism in which "the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". An **LMO** is defined as any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids and that possesses a novel combination of genetic material obtained through the use of modern biotechnology [13].

Contained use and deliberate release for experimental and commercial purposes of GMOs is covered in EU (3) and Belgian (4)(5)(6)(7) GMO legislations. What constitutes a GMO subject to the requirements of this legislations is further detailed in Annexes I and II to EU directives 2001/18/EC (8) and 2009/41/EC (3). Organisms made using conventional mutagenesis, that is, mutagenesis techniques that existed and were used prior to 2001, are GMOs that are exempted from the provisions of the EU GMO legislation.

The EU GMO legislation does not apply to:

- Transport of GMOs by road, rail, inland waterway, sea or air
- Storage, culture, transport, destruction, disposal or use of genetically modified microorganisms (GMMs) which have been placed on the market in accordance with Directive 2001/18/EC (8) or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in that Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.
- Dead material derived from a GM organism (e.g. freeze dried ground leaf material from GM plants). However, in non-EU countries (e.g. US, China) different rules may apply.

Transboundary movement, transit, handling and use of LMOs is covered by the CPB and applies to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The CPB requirements only apply in countries that are a Party to the Protocol. A full list of parties to the Protocol is available at http://bch.cbd.int/protocol/parties/.

The concepts of GMO and LMO are similar but lead to significant differences in what is regarded a regulated article under the GMO legislation in different jurisdictions. In the EU, organisms made using targeted mutagenesis (genome editing by means of for instance type 1 site-directed nucleases) are not exempted from the GMO legislation. In jurisdictions that base their GMO legislation on the LMO definition such organisms are not a GMO because they are considered not to possess a novel combination of genetic material. The targeted mutations could also have arisen spontaneously or result from the application of conventional breeding techniques. This is for instance the case in

[13] Application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

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countries like Argentina and Brazil, but also in countries like Australia and Japan these organisms are not considered a GMO. In the USA these types of organisms are not subject to the USDA APHIS regulations. This means that specific categories of genome edited organisms can become a GMO or lose the qualification of being a GMO when they leave one jurisdiction and enter the other. For import, transit, or export of such organisms the following applies: if in either the country of import, transit, or export the organism is considered a GMO, then the shipment of that organism should follow the requirements that apply to the shipment of a GMO. In Belgium, the contained use legislation does not only apply to GMOs. It also applies to activities with non-genetically modified pathogens (including human pathogens, plant pathogens, and animal pathogens). Activities include culturing, storing, transporting, destroying, disposing of or using the organisms in any other way, and for which specific containment measures are to limit their contact with the general population and the environment in order to maintain an elevated safety level. Importantly, diagnostic activities that do not intend to grow the pathogens, are not in scope [14].

General requirements

In the context of movement of biological materials, one of the most relevant requirements is that you need to have an authorization to be able to lawfully receive, store and use the GMO at your premises. Depending on the aim of use, different authorizations are required (see below). For all deliberate release activities (with the exception of some clinical trials that are dealt with under the contained use legislation), a scientific assessment of the application is performed by the Biosafety Advisory Council, resulting in an advice to the relevant competent authority.

When users, once authorized, aim to transport GMOs, specific requirements will have to be followed. The type of requirements will depend on e.g. the type of material to be transported, the destination of the material and the intended use of the material (see below).

Import into the European Union

For the import of a GMO in the context of R&D, no import license is required, but it is necessary to have a contained use permit in order to be able to lawfully receive the GMO at your premises for storage and use in the context of contained use [15]. Getting an authorization for contained use activities involves a two-step licensing process with the local and/or regional authority: a general environmental permit that basically certifies the facilities, and a biosafety authorization that covers the specific activities (the biosafety dossier).

Moreover, if you want to import a GMO from a Party to the CPB outside the EU for use in contained facilities, the CPB requires that the accompanying documentation clearly identifies them as a GMO and specifies any requirements for their safe handling, storage, transport and use, as well as the contact point for further information, including the name and address of the consignee.

If you import a GMO with the intention to deliberately release it into the environment for experimental purposes, you also need to have a specific permit for this type of use. The reception and storage of that material can in that case be covered by the deliberate release permit. An experimental release can for instance be a clinical trial with a genetically modified live vaccine, or a field trial with a genetically modified crop.

Export from the European Union

For the export of GMO in the context of R&D, it is not necessary to obtain an export license from any Belgian Federal or regional authority, but most countries outside Europe require that the importer obtains an import license from their competent authorities. For this, cooperation between the exporter and importer is necessary and, as an exporter, you have a duty of care to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

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[14] https://www.bioveiligheid.be/content/ingeperkt-gebruik-toepassing-van-de-wetgeving-op-pathogene-micro-organismen; https://www.biosecurite.be/content/utilisation-confinee-application-de-la-legislation-dans-le-cas-des-micro-organismes

[15] The same is true for the import of a non-genetically modified pathogens. What is stated in this instruction card for the contained use of GMOs, similarly applies to the contained use of non-genetically modified pathogens.

If you want to export a GMO for the first time to a Party to the CPB outside the EU with the intention to deliberately introduce it into the environment, you need to have an advanced informed agreement (AIA) of that Party according to procedures laid down in their legislation. The modality of the AIA will depend on the legislation/procedures in the country of import. Every new event is considered a new GMO for which the AIA requirement applies. The notification sent to the competent authority of the Party of import, which serves to obtain the agreement, needs to contain as a minimum the information specified in annex I to EU Regulation 1946/2003 [9]. A copy of the acknowledgement of receipt and the decision by the country of import need to be sent to the competent authority of the country of export and to the European Commission.

Even though important countries like the USA, Canada, Australia and Argentina are not a Party to the Cartagena Protocol, they do have certain requirements if you would want to move GMOs into those countries. In the USA for instance, you need to have an import permit from the Biotechnology Regulatory Services for the import of GMOs that have not been deregulated in the USA. Canada and Australia have similar import requirements for GMOs in which also immediately any phytosanitary issues are dealt with. In Argentina such requirements exist for GM plants.

For (contact) information of the competent authorities of the countries to which you want to ship your GMOs, you can consult the CBP webpages at https://bch.cbd.int/database/compiled-national-contacts#ALL.

Transactions within the European Union

For movement within the European Union, whether for use in containment or for an environmental release, no specific import or export permits are necessary. The receiving party only needs to have the necessary permits in place in order to be able to lawfully receive the material.

Transport requirements

GMOs should be packed and labelled as required by the international legislation for transport of dangerous goods by road, rail, inland waterway, sea or air. For detailed instructions it is referred to the card(s) relevant for the type of material and/ or to the Instruction Cards Dangerous goods as well as Customs / Tax.

As required by the CPB, the accompanying documentation should clearly identify the material as GMO and specify any requirements for their safe handling, storage, transport and use, as well as the contact point for further information, including the name and address of the consignee. This can be achieved by incorporating this information into existing documentation accompanying the GMO (no need for a stand-alone document).

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Competent authorities and contact details

For the contained use of GMOs, limited to the biosafety dossier:
Flanders competent authorities
Departement Omgeving
Afdeling Gebiedsontwikkeling, omgevingsplanning en -projecten (GOP)
Graaf de Ferrarisgebouw
Koning Albert II-Laan 20 bus 8
BE-1000 Brussel
Contact: Veerle Janssens – CC: Veronique Rombaut
Phone: 02 553 7997
Email: GOP.omgeving@vlaanderen.be / erkenningen.omgeving@vlaanderen.be

Brussels competent authorities
Bruxelles Environnement / Leefmilieu Brussel
Div. Autorisations et partenariats / Afd. Vergunningen en partnerschappen
Site de Tour & Taxis
Avenue du Port 86C / 3000
1000 Bruxelles
Phone: 02 775 75 75
Email: permit@environnement.brussels / permit@leefmilieu.brussels
Website: http://www.environnement.brussels/

Walloon competent authorities
Service Public de Wallonie
Direction Générale Opérationnelle « Agriculture, Ressources naturelles et de l'Environnement » (DGARNE)
Département des Permis et Autorisations
Avenue Prince de Liège 15
BE-5100 Namur
Phone: 081 33 61 29
Website: http://environnement.wallonie.be

For all three regions the biosafety dossiers are administered and handled by the Section Biosafety & Biotechnology (SBB) of Sciensano. All biosafety dossiers need to be submitted to the SBB as well:
Sciensano -SBB, Contained Use
Rue Juliette Wytsmanstraat 14
BE-1050 Brussel
Phone: 02 642 52 93
Email: contained.use@sciensano.be
Website: www.biosafety.be

For the deliberate release of (veterinary) medicinal GMOs into the environment (clinical trials):
FAGG-AFMPS
Division R&D
Galileelaan 5/03
BE-1210 BRUSSEL
Email: ct.rd@fagg.be

For the deliberate release of all other GMOs into the environment:
Federal Public Service (FPS) Health, Food Chain Safety and Environment
Directorate General Health, Animal, Plant and Food
Eurostation II
Victor Horta plein 40, bus 10
BE-1060 Brussel
Contact: Mathieu Capouet
Phone: 02 524 73 26
Email: mathieu.capouet@health.fgov.be
Website: http://www.ogm-ggo.be/

For export with the goal to deliberately release the GMO into the environment of the receiving country:
Federal Public Service (FPS) Health, Food Chain Safety and Environment
Directorate General Environment
Multilateral & Strategic Affairs
Place Victor Horta 40, box 10
Bloc II – 2nd floor
BE-1060 Brussels, Belgium
Contact: Stephanie Langerock
Phone: 02 524 92 96
Email: stephanie.langerock@health.fgov.be

Contact point for the European Commission for export of GMOs that will be deliberately released into the environment of the receiving country:
European Commission
Directorate General for Health and Food Safety
BE-1049 Brussels
Phone: 02 299 11 11
Email / Notification address: Sanco-notifications-cartagena-protocol@ec.europa.eu

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References

(1) Cartagena Protocol on Biosafety (https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf)

(2) Convention on Biological Diversity (https://www.cbd.int/convention/text/)

(3) EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms

(4) Besluit van de Vlaamse regering van 6 februari 2004 tot wijziging van het besluit van de Vlaamse regering van 6 februari 1991 houdende vaststelling van het Vlaams reglement betreffende de milieuvergunning, en van het besluit van de Vlaamse regering van 1 juni 1995 houdende algemene en sectorale bepalingen inzake milieuhygiëne

(5) Arrêté du Gouvernement wallon de 4 juillet 2002 déterminant les conditions sectorielles relatives aux utilisations confinées d'organismes génétiquement modifiés ou pathogènes.

(6) Besluit van de Brusselse Hoofdstedelijke Regering van 8 november 2001 betreffende het ingeperkt gebruik van genetisch gemodificeerde en/of pathogene organismen en betreffende de indeling van de betrokken installaties

(7) Royal Decree of 21 February 2005 concerning the deliberate release into the environment and placing on the market of GMOs or of products that contain GMOs

(8) EU Directive 2001/18 on the deliberate release into the environment of genetically modified organisms

(9) EU Regulation 1946/2003 on transboundary movements of genetically modified organisms

Summary

Requirements for GMO/LMO*		
Transaction within the EU	**Import from third country to EU**	**Export from EU to third country**
No import or export permit	No import permit	Requirements depending on the importing country
Appropriate permit to be able to lawfully receive and store the material (receiver)	Appropriate permit to be able to lawfully receive and store the material (receiver)	For export with the intention to deliberately release the LMO into the environment: (1) an advanced informed agreement must be acquired (2) a copy of the acknowledgement of receipt and the decision must be sent to the Belgian competent authorities and the EC
Labelling clearly indicating type and characteristics of material, including any instructions for safe handling	Labelling clearly indicating type and characteristics of material, including any instructions for safe handling	Labelling clearly indicating type and characteristics of material, including any instructions for safe handling

*Under specific circumstances, derogations may apply

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3.2 Human Body Material - Biobanking

Goal of the regulatory framework

A Biobank is a structure which, for the purposes of scientific research, obtains, treats, stores and makes available human body material (HBM) as well as data pertaining to the HBM and its donor. Performing one of the above activities with HBM for scientific research is sufficient to consider a structure as a Biobank.

The Biobank legislation refers to the law of 19 December 2008 (1) on the acquisition and use of HBM for the purpose of human medical applications or scientific research, and the Royal Decree (RD) of 9 January 2018 (2) on Biobanks which entered into effect on May 1, 2019. The Biobank legislation underwent some modifications: the Law of 30 October 2018(3) included stool samples while the Law of 23 February 2022(4) proposes a lighter regime for 'artificialized' HBM (i.e. cell lines) and 'extracted' material (i.e. RNA, DNA) on the condition that the material is not used for intrinsic genetic research. The general goal of this regulatory framework is to protect donor and donor's rights and to prevent unethical collection and use of HBM in scientific research.

Scope

The regulatory framework applies to the donation, procurement, collection, testing, transformation, preservation, storage, distribution, import and use of HBM and prepared products from HBM for scientific research. **HBM refers to** any biological material originating from humans, including human tissues and cells, gametes, embryos, foetuses, as well as the substances extracted therefrom, whatever their degree of processing/transformation (DNA, RNA, proteins, ...), including (commercial) cell lines and stool.

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General requirements

In order to protect donor and donor's rights and to prevent fraudulent collection and use of HBM, Biobanks must comply with several requirements. These include:

- Notifying the Federal Agency for Medicines and Health Products (FAMHP) for their activities;
- Maintaining a register of HBM;
- Entering into detailed agreements in relation to the sourcing and supply of HBM;
- Appointing a medical doctor, or a pharmacist as responsible for the management of the Biobank;
- Ensuring the traceability of the HBM;
- Obtaining a positive opinion from an ethics committee (of choice) in relation to their objectives and activities.
- Also end-users of HBM must comply with several legal requirements. These include:
- The need to have a contract with a notified biobank** for the use of the HBM in research;
- Ensuring the traceability of the HBM;
- The obligation to report any 'incidental findings', which means that incidental findings that present important information about the (future) health status of the donor need to be reported to the Biobank.

In the context of movement of HBM, specific requirements will have to be followed. The main aim of the requirements is to ensure traceability of the material. For transport, the prevailing transport regulations must be followed.

Import into Belgium

The Biobank legislation covered in this sub-chapter is specific to Belgium and is not based on EU legislation. The requirements for import and export do not only apply to import and export involving third countries that are not part of the EU. These requirements also apply to import and export

involving EU countries. Therefore, in contrast to the other sub-chapters in this guidance document import and export means import to and export from Belgium to any country.

No specific import permits are required. However, when receiving HBM from foreign parties, the import of the HBM should go via a notified Biobank. An end-user is not allowed to import the HBM directly. This does not mean that the HBM needs to physically pass via the Biobank, but the material should at least be registered in the Biobank. In order to lawfully register the HBM in the Biobank, at least the following minimal dataset should be available:

- Type of HBM, number of samples, amount.
- Origin of the HBM (contact details hospital, physician, biobank, commercial supplier …)
- Informed Consent Form (ICF), if applicable
- Status of the HBM: anonymous or pseudonymous (coded)
- Optimally, for HBM collected abroad additional data and guarantees should be provided:
- A collection protocol approved by an ethics committee outside Belgium (or "institutional review board") and a model informed consent form (ICF) for the specific sample;
- The necessary guarantees that the HBM has been collected in accordance with the legislation in force in the country of origin and in accordance with international standards of ethics and protection of privacy and personal data;

There is a list of notified biobanks on the website of FAGG-AFMPS (https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf) that can be contacted to assist in the import of the HBM. Each of those Biobanks will have their own procedures and forms for this.

Export from Belgium

No specific export permits are required. However, when exporting HBM to third parties outside Belgium, this export must go via a notified Biobank. End-users of HBM are not allowed to export HBM to third parties outside Belgium directly. The Biobank needs to have the minimal dataset as indicated above under import.

Transport requirements

For transport, the prevailing transport regulations must be followed.

The HBM must be packaged and transported in function of the type of HBM; transport conditions should be as such that the quality of the HBM can be guaranteed. The containers containing the HBM should be shock-resistant and designed as such to prevent contamination of those charged with packaging and transport of the HBM, and to maintain appropriate temperature levels. For long distance transport it is desirable to add a device for temperature control to the container.

Packaging and shipping of (dangerous) human material, must be described in a procedure and must comply with IATA/ADR, and other relevant regulations. Hazardous HBM should be packed and labelled as required by the international legislation for transport of dangerous goods by road, rail, inland waterway, sea or air. For detailed instructions consult the instruction card(s) relevant for the type of material and/ or to the instruction cards Dangerous goods as well as Customs / Tax.

Competent authorities and contact details

Federal Agency for Medicines and Health Products…:
Avenue Galiléé 5/03
1210 Brussels
Contact: Nick Van Gelder
Phone: 02 528 4000
Email: nick.vangelder@fagg-afmps.be
mch-mlm@fagg-afmps.be,
biobanks@fagg.be

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References

[1] Law of 19 December 2008 concerning the procurement and use of human body material for medicinal application on human beings or for scientific research (B.S. 30/12/2008).

[2] Royal decree of 9 January 20018 concerning biobanks (B.S. 05/02/2018)

[3] Law of 30/10/2018 - wijziging van de wet van 19 december 2008 inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek (B.S. 28/12/2018).

[4] Law of 23/02/2022 - Wet houdende bepalingen betreffende menselijk lichaamsmateriaal en embryo's en gameten (B.S. 08/03/2022)

**list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf

Summary

Requirements for HBM	
Import from any country into Belgium	**Export from Belgium to any other country**
No import permit	No export permit
Import must go via a notified Biobank	Export must go via a notified Biobank
Labelling clearly indicating type and characteristics of material, including any instructions for safe handling	Labelling clearly indicating type and characteristics of material, including any instructions for safe handling

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3.3 CITES - endangered species

Goal of the regulatory framework

Protect and sustain certain species of wild fauna and flora by strictly regulating their international trade.

Scope

In order to protect and sustain certain species of wild fauna and flora, their international trade is subject to strict regulation. This has been documented in the Convention on International Trade in Endangered Species of Wild Fauna and Flora, known as CITES [(1)]. CITES is implemented in Europe by the EU Wildlife Trade Regulations [(2)], notably Council Regulation (EC) No 338/97 and associated regulations.

Your organism is subject to the EU Wildlife Trade Regulations when it is enclosed in Council Regulation (EC) No 338/97 Annexes A, B, C or D [(3)], whereby Annexes A, B and C equal the Annexes I, II and III, respectively, of the worldwide Convention on International Trade in Endangered Species of Wild Fauna and Flora [(1)]. In brief, the most endangered species, threatened with extinction, are listed in Annex A. Annexes B and C describe species that are less threatened. Annex B also contains species for which introduction of live specimens into the natural habitat of the European Union would constitute an ecological threat to wild species of fauna and flora indigenous to the Union. Annex D, referred to as the "monitoring list", includes species that might be eligible for listing in one of the other Annexes and for which import levels should therefore be monitored.

General requirements

If you want to import or export an animal or plant specimen [16] subject to the EU Wildlife Trade Regulations, you need specific permits and/or certificates. The type of permit and/or certificate you need will depend on the Annex on which your animal or plant specimen is listed.

Commercial activities with species of wild origin listed in Annex A are prohibited. Commercial activities with species listed in Annex B are possible provided that the trade does not endanger the survival of the wild population. Circumstances in which exemptions can be granted are mentioned in EU Wildlife Trade Regulations. For all exemptions, relevant certificates need to be issued by a competent authority of the Member State in which the specimens are located, and this on a case-by-case basis.

Import into the European Union

If you want to import an animal or plant specimen listed in Annex A or B into the European Union, an import permit has to be applied for in the country of destination. An import permit can only be issued if relevant certificates and other documentary evidence are provided e.g. showing that the trade will not have any harmful effect on the conservation of the species, and that the specimen has been obtained in accordance with the legislation on the protection of the species concerned. Such documentation normally includes a copy of the export permit or re-export certificate, issued by the country where the specimen is located (see below).

The import permit, together with the relevant certificates and documentary evidence, has to be presented at the border customs office at the point of introduction into the European Union.

If you want to import an animal or plant specimen listed in Annex C or D into the European Union, an import notification has to be completed by the importer and submitted to customs at the time of import.

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[16] Specimen: any animal or plant, whether alive or dead, of the species listed in Annexes A to D, any part or derivative thereof, whether or not contained in other goods, as well as any other goods which appear from an accompanying document, the packaging or a mark or label, or from any other circumstances, to be or to contain parts or derivatives of animals or plants of those species, unless such parts or derivatives are specifically exempted from provisions of the CITES Regulation or the Annex in which the species concerned is listed.

For species listed in Annex C, the notification requires relevant documentary evidence showing that the specimens have been obtained in accordance with the legislation on the protection of the species concerned. Such documentation normally includes a copy of the export permit or re-export certificate, issued by the country where the specimen is located (see below).

The registered import notification and, if relevant the documentary evidence, has to be presented at the border customs office at the point of introduction into the European Union. The import notification for species listed in Annex C has to be accompanied by an export permit, a re-export certificate or any other certificate of origin, issued by the (re-) exporting country where the specimens are located.

Applications for import permits or certificates as well as submission of an import notification are directed to the Belgian CITES department of the Federal Public Service - Health, Food Chain Safety and Environment. Online procedures are available via the CITES database at https://www.health.belgium.be/en/animals-and-plants/plants/what-cites (Online system for your CITES documents applications). Registration is required.

Export from the European Union

If you want to export an animal or plant specimen listed in Annex A, B or C from the European Union, an export permit has to be applied for in the exporting country where the specimen is located. Similarly, in case of re-export, a re-export certificate has to be applied. Export permits or certificates can only be issued if relevant documentary evidence is provided e.g. showing that the trade will not have any harmful effect on the conservation of the species, and that the specimens have been obtained in accordance with the legislation on the protection of the species concerned.

The export permit or re-export certificate, together with the relevant documentary evidence, has to be presented at the border customs office at which the export formalities are completed. An export permit or re-export certificate is linked to an import permit, issued by the country of destination.

No export permit or a re-export certificate is required for species listed in Annex D.

Applications for certificates are directed to the Belgian CITES department, as described for import.

Transactions within the European Union

For transactions with species listed in Annex A within the European Union, only a certificate for commercial use is required. Moreover, for movement of live specimens that are not captive-bred of a species listed in Annex A, prior authorization from a competent authority of the Member State in which the specimen is located is required.

For species listed in Annex B, C or D, no certificate is required. However, for species listed in Annex B, the person responsible for moving the specimen must have proof of the legal origin of the specimen. Such proof can consist of e.g. the previously issued import permit, an invoice and/or a declaration of origin.

Applications for the required certificates are directed to the Belgian CITES department, as described for import.

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Transport requirements

The EU Wildlife Trade Regulations covers a wide variety of specimens, ranging from live animals and plants, to specific parts of them (e.g. cell cultures). Consequently, packaging, labelling and documentation (apart from the documentation referred to in the sections above) will depend on the type of specimen to be transported.

For detailed instructions it is referred to the card(s) relevant for the type of specimen and/ or to the Instruction Cards Dangerous goods as well as Customs / Tax.

Derogations

Under specific circumstances, derogations may apply for import, export and/or re-export. Such circumstances include, but are not limited to:

- Transit through the European Union with a destination outside the European Union
- Certain specimens which are personal or household effects
- Non-commercial loans, donations and exchanges between scientists and scientific institutions

Specific requirements and procedures that have to be fulfilled in case of derogations are described in detail in the EU Wildlife Trade Regulations. For more information, please consult the competent authorities.

Competent authorities and contact details

Belgian CITES Department
Federal Public Service - Health, Food Chain Safety and Environment
Victor Hortaplein 40 / 10
1060 Brussel
Phone: 02 524 97 97 (contact center)
Email: cites@health.fgov.be

References

(1) https://cites.org/eng/disc/text.php
(2) http://ec.europa.eu/environment/cites/legislation_en.htm
(3)https://www.speciesplus.net/, https://checklist.cites.org/#/en, http://ec.europa.eu/environment/cites/species_en.htm (including link to detailed Annex A - D)

Summary

Species listed in Annex	Requirements for *		
	Import to the EU	Export or re-export from the EU	Transactions within the EU
A	Import permit	Export permit or re-export certificate	Certificate for commercial use
B	Import permit	Export permit or re-export certificate	Proof of legal origin of the specimen
C	Import notification	Export permit or re-export certificate	None
D	Import notification	None	None

* Under specific circumstances, derogations may apply for import, export and/or re-export
EU: European Union

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3.4 Animal by-products

Goal of the regulatory framework

Lay down health rules for animal by-products and derived products not intended for human consumption.

Scope

Animal by-products (ABP) are defined as entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos, and semen. Animals are defined as to include both vertebrate and invertebrate animals, which means that also insects are included. Derived products are products obtained from one or more treatments, transformations or steps of processing of animal by-products. ABP and derived products not intended for human consumption are a potential source of risks to public and animal health. Consequently, their use, transport and disposal are strictly regulated at EU level. This has been documented in Regulation 1069/2009 (1) and the implementing Commission Regulation 142/2011 (2).

The ABP regulation covers a wide range of products with varying risks. Category 1 covers the materials with the highest risk. Category 3 covers the materials with the lowest risk. In view of the scope of this guidance document, only requirements for ABP and derived products intended for diagnostic, research and educational purposes [17] are discussed. Examples of ABP and derived products intended for diagnostic, research and educational purposes are:

- Category 1 - Animals that die during an animal experiment (3); Animals slaughtered within the purpose of an animal experiment; Polyclonal antibodies of animals from outside the EU;
- Category 2 - Manure and contents of the gastrointestinal tract; oocytes, embryo's and sperm not destined for breeding purposes; dead-in-shell poulty;
- Category 3 - Blood collected from animals that do not show any signs of disease communicable through blood to humans or animals; serum produced for use in biotechnology and research (e.g. fetal calf serum or fetal bovine serum as a supplement to basal growth medium in cell culture applications).

Cell cultures (established lineages) and purified antibodies are exempt from the ABP legislation, unless stabilizers or other components derived from ABP are present. If ABPs are present in cell cultures, the whole may be classified as category 2 (or 1). Primary cells are not exempt. Also microbial culture media may contain ABP such as pepton, casein or tryptone.

In order to enable their optimal use, special rules apply for ABPs and derived products intended for diagnostic, research and educational purposes. Under all circumstances, these special rules should ensure the control of risks to public and animal health. Under no circumstances, these special rules can apply for samples of (pathogenic) agents for which special veterinary and zootechnical rules are provided in the European legislation (4). National provisions, as referred to in Regulation 1069/2009, on the use, transport and disposal of ABP and derived products intended for diagnostic, research and educational purposes have been implemented in the Belgian legislation via the Royal Decree of May 4, 2015 (5).

General requirements

Before starting activities (including transport), users of ABP and derived products intended for diagnostic and research purposes are required to notify their activities to the competent authorities by letter, fax, or email. The competent authorities will subsequently register the users (6).

[17] Animal by-products (ABP) and derived products intended for examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities. Such material cannot be placed on the market or used for other purposes. For those cases, other rules will apply.

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When users, once registered, aim to transport ABP or derived products intended for diagnostic, research and educational purposes, specific requirements will have to be followed. The type of requirements will depend on e.g. the type of material to be transported, the destination of the material and the intended use of the material (see below).

Import into the European Union

If you want to import ABP or derived products intended for diagnostics, research and educational purposes into the European Union, approval from the competent authorities is required. Therefore, an import permit has to be applied for. It is important to read this permit and its requirements carefully and to ensure full compliance to these requirements.

The import permit will also specify if veterinary inspection is required. If veterinary inspection is required, the import first needs to be notified at least one working day in advance to the competent authorities via the IMSOC/TRACES NT system . However, registration via TRACES NT is not required, only when the point of entry into the EU is in the same country as the receiver and when no veterinary inspection is needed (e.g. samples of animal tissue conserved in formaldehyde; the obligation to veterinary inspection will be specified in the import permit). Also, a health certificate may be needed for import into the European Union, e.g. for unprocessed manure. More information on the need for a health certificate can be requested from the competent authorities (see further under 'competent authorities and contact details'). For the import permit issued by FAVV/AFSCA, a fee of approx. 54 euros will be charged; for veterinary inspection, a fee of 83 euros will be charged . Entry into the European Union occurs via an official border control post (BCP) .

Please note that when ABP and derived products intended for diagnostics and research purposes contain OIE listed animal pathogens (prior knowledge), additional permits form FAVV/AFSCA may be required (see chapter 3.5). For some critical sample types (e.g. serum samples from Ethiopian cattle), without prior knowledge of pathogen presence, samples may be referred to a reference laboratory to verify absence of such pathogens.

Upon entry into the European Union, ABP and derived products intended for diagnostic and research purposes have to be transported directly to their final destination, without passing by an intermediate operator. If samples are imported in Belgium for subsequent transactions to another member state, the rules for introduction into that member state need to be communicated upfront to the competent authorities of Belgium.

The user is required to maintain a register documenting e.g. receipt of ABP and derived products, type of samples, origin of samples, disposal methods and disposal dates. After their use, all ABP and derived products intended for diagnostic and research purposes are to be destroyed, archived or returned to the place of origin .

Applications for import permits and health certificates are directed to the "Federaal Agentschap voor de Veiligheid van de Voedselketen" (FAVV) via a standard application form as provided by the FAVV ("Aanvraagformulier voor het bekomen van een machtiging voor de invoer uit 3de landen van voor onderzoek en diagnose bestemde monsters van dierlijke oorsprong" or "Formulaire de demande d'obtention d'une autorisation d'importation, depuis des pays tiers, d'échantillons de recherche et de diagnostic d'origine animale").

Dispatch [18] from the European Union

If you want to dispatch ABP or derived products intended for diagnostic, research and educational purposes from the European Union, different rules may apply depending on the importing country. Please consult the FAVV-AFSCA for more details.

Transactions within the European Union

[18] As ABP or derived products intended for diagnostic, research and educational purposes cannot be sold, they can, strictly speaking, not be exported but are rather dispatched (send to a particular place for a particular purpose).

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When transporting ABP within the EU, there may be a need for an authorization from the Member State of destination and a TRACES NT notification for category 1 and 2 material. Also, for certain materials, a health certificate may be needed. Please contact the Federal Agency for Food Chain Safety for more details on when an authorization and/or a health certificate is required (see Competent authorities and contact details).

From the perspective of the ABP regulation, registered users are allowed to transport ABP or derived products intended for diagnostic, research and educational purposes themselves within the European Union. However, also other regulatory frameworks have to be taken into account to determine final transport requirements (e.g. Dangerous goods).

As mentioned above, the user is required to maintain a register documenting e.g. receipt of ABP and derived products, type of samples, origin of samples, disposal methods and disposal dates.

Transport requirements

The ABP regulation covers a wide variety of specimens. Consequently, packaging, labelling and documentation (apart from the documentation referred to in the sections above) will depend on the type of specimen to be transported.

For detailed instructions it is referred to the card(s) relevant for the type of specimen and/ or to the Instruction Cards Dangerous goods as well as Customs / Tax.

In any case, it shall be ensured that during their transport ABP and derived products intended for diagnostic, research and educational purposes are accompanied by a commercial document describing (i) material and animal species of origin, (ii) ABP category, (iii) quantity of material, (iv) place of origin and destination of material, (v) name and address of consignor, and (vi) name and address of consignee and/or user. A template for a commercial document ('Handelsdocument voor de traceerbaarheid van dierlijke bijproducten bestemd voor technische doeleinden, taxidermie, onderwijs of onderzoek' / 'Document commercial de tracabilité de sous-produits animaux destines a des usages techniques, a la taxidermie, a l'enseignement ou a la recherche') can be found on the website of or requested for at the Federal Agency for Food Chain Safety.

Depending on the level of risk to public and animal health arising from certain derived products, ABP and derived products intended for diagnostic, research and educational purposes may have to be accompanied by a health certificate. More information on the need for a health certificate can be requested at the competent authorities.

Derogations

Once a product is categorized as an ABP or derived product not intended for human consumption, this decision is irreversible, and the product is subject to the ABP regulation. Under certain circumstances, however, specific requirements and/or procedures may apply. Such includes, but is not limited to:

In certain situations, notification of the authorities prior to working with ABP is not required. Such situations include but are not limited to working with ABP for strictly educational activities whereby less than 20 kg / week of category 3 material is used.

For certain products regulated under other Community legislation (e.g. medicinal products for veterinary or human use) an end point in the manufacturing chain can be determined after which the products should be exempt from controls under the ABP regulation.

Users that apply, transport and/or dispose ABP or derived products for strictly educational purposes only, may receive additional derogations by their competent authorities.

Cell cultures (established lineages), monoclonal antibodies and purified polyclonal antibodies originating from within the EU, are exempt of the ABP legislation, unless stabilizers or other components derived from ABP are present. Primary cells are not exempt.

Specific requirements and procedures that have to be fulfilled in case of derogations are described in detail in the ABP regulation. For more information, please consult the competent authorities.

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Competent authorities and contact details

Notification for activities with ABP or derived products intended for diagnostic, research and educational purposes:

Federal Public Service (FPS) Health, Food Chain Safety and Environment
Directorate General Health, Animal, Plant and Food – Dienst Inspectie
Galileelaan, 5/2
1210 Brussel
Phone: 02 524 97 97 (contact center)

Import permits and health certificates:

Federaal Agentschap voor de Veiligheid van de Voedselketen (Federal Agency for the safety of the food chain)
Administratief Centrum Kruidtuin
Food Safety Center
Kruidtuinlaan 55
1000 Brussel
Phone: 02 211 86 05
Email: import@favv-afsca.be

Questions and dossiers related to export to third countries / shipment to other member states:

Federaal Agentschap voor de Veiligheid van de Voedselketen (Federal Agency for the safety of the food chain)
Cel Notificaties & Certificering
Administratief Centrum Kruidtuin
Food Safety Center
Kruidtuinlaan 55
1000 Brussel
Phone: 02 211 82 11
Email: export@favv-afsca.be

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References

(1) Regulation (EC) No. 1069/2009, laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

(2) Commission Regulation No. 142/2011, implementing Regulation (EC) No 1069/2009 and implementing Council Directive 97/78/EC

(3) Directive 2010/63/EU, on the protection of animals used for scientific purposes

(4) Directive 92/118/EEG, laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

(5) Royal Decree 4/05/2015 - KB betreffende dierlijke bijproducten bestemd voor onderzoek, onderwijs, het voederen van nietvoedselproducerende dieren en voor de vervaardiging en het in de handel brengen van sommige afgeleide producten

(6) http://www.afsca.be/dierlijkebijproducten/erkendeoperatoren/ Section X 'Geregistreerde gebruikers van dierlijke bijproducten en afgeleide producten voor specifieke doeleinden' or http://www.afsca.be/sousproduitsanimaux/operateursagrees/ Section X 'Utilisateurs enregistrés des sous-produits animaux et produits dérivés pour des fins spécifique').

Summary

Requirements for *		
Transaction within the EU	**Import from third country to EU**	**Export from EU to third country**
No import permit Health certificate (depending on the risk and the amount of the material **)	Import permit Health certificate (depending on the risk and the amount of the material **)	Requirements depending on the importing country

*: Under specific circumstances, derogations may apply

**: No health certificate is required for samples below 2 liters when being used in a registered laboratory. Please contact the Federal Agency for Food Chain Safety for more details on when an authorization and/or health certificate are not / are required

EU: European Union

3.5 Quarantine animal pests and diseases

Goal of the regulatory framework

To protect human and animal health and the environment from risks posed by animal pests and diseases and, in particular, protect animal production from diseases that could cause serious economic damage.

Scope

The framework covers information exchange on outbreaks of quarantine animal pests and diseases, and the setting of conditions for import, export and use of quarantine animal pests and diseases.

Your organism is a quarantine animal pest or disease when it is part of the OIE-listed diseases. The OIE (World Organization for Animal Health) updates its lists on a regular basis and the list can be found on www.oie.int under 'Animal Health in the World'.

General requirements

Before starting any activities with causative agents of an OIE-listed animal pest or disease (including transport), users are required to obtain an authorization (contained use license for non-genetically modified pathogens, see Chapter 3.1 GMO / LMO) to be able to lawfully receive, store and use the organisms at their premises.

If you subsequently want to import or export the agent, you need specific permits or licenses. However, depending on the agent, there may be restrictions on import and use, as explained in more detail in the section 'Import into the European Union'.

Import into the European Union

If you want to import a causative agent of an animal pest or disease that is mentioned on the OIE list, but was not mentioned before in the OIE "list A" diseases [19], you have to apply for an import license. A template of the application form can be found at the website of FAVV-AFSCA. The application form has to be submitted to FAVV-AFSCA (see Competent authorities and contact details).

Upon deliverance of the import license, FAVV-AFSCA may impose conditions on the (contained) use of the agent, in coordination with the Section Biosafety & Biotechnology (SBB) of Sciensano.

For causative agents of an animal pest or disease that are mentioned on the OIE list, and were also mentioned before in the OIE "list A" diseases, only the Belgian National Reference Laboratory for infectious animal diseases (Sciensano) is allowed to import such agents. Other laboratories are not allowed to do so.

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Export from the European Union

If you want to export the causative agent of an OIE-listed animal pest or disease, you need to have an import license from the country of destination. You need to contact the Veterinary Authority of the country of destination and follow their instructions and forms. You can find the responsible Veterinary Authorities through the www.oie.int website by browsing to '*About us'*, then '*Our members*' and subsequently '*Delegates*'. Alternatively, you can contact FAVV-AFSCA (see below).

Please note that the agent of an OIE-listed animal pest or disease may also be considered as a dual use item and may require a permit for export to third countries. Please see chapter 3.8 for more detail on dual use.

[19] Former OIE list A agents are: foot and mouth disease, swine vesicular disease, peste des petits ruminants, lumpy skin disease, bluetongue, African horse sickness, classical swine fever, Newcastle disease, vesicular stomatitis, rinderpest, contagious bovine pleuropneumonia, Rift Valley fever, sheep and goat pox, African swine fever, highly pathogenic avian influenza

Also note that even when importing from third countries a culture of an animal pathogen (non-OIE listed disease agent) with no ABPs in the culture medium, you still need an FAVV/AFSCA import permit (Common Health Entry Document for animal Products or CHED-P, the same document that is required for importing ABP). This arises from Regulation (EU) 2021/632[20].

Transactions within the European Union

The Belgian reference laboratory (Sciensano) does not require additional permissions to send or receive animal pathogens, however national requirements in other Member States vary. Samples containing list A animal pathogens can be exchanged between Belgian reference laboratories[21]. Any transfer of list A pathogens must be prearranged and solicited between sender and receiver, which includes an undertaking to not export the materials from the EU in compliance with dual use regulations. Non-reference laboratories and all other institutions need to have permission from FAVV-AFSCA to have such material transported from an EU Member State into Belgium.

Transport requirements

Causative agents of quarantine animal pests and diseases fit the definition of Dangerous Goods according to the international transport regulations, and should therefore be packed and labelled as described in the Instruction Cards Dangerous goods as well as Customs / Tax.

Derogations

Under specific circumstances, derogations may apply for import and export of causative agents of quarantine animal pests and diseases. For example, animal by-products that *may* contain former OIE "list A" agents, *may* be used by other laboratories than the National Reference Laboratory, in case it concerns experiments that do not seek to culture the agents (e.g. pcr-analysis).

Mostly, additional terms of use are required under these circumstances. Such include but are not limited to:

- Validated treatment (e.g. heat, radiation) of samples prior to import to minimise the risk of inadvertent introduction of a pathogen via the imported material
- Testing of samples by the National Reference Laboratories to confirm presence / absence of certain agents before transporting the material to the user

On each of these exceptions, FAVV-AFSCA decides on a case-by-case basis taking the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin into account.

Competent authorities and contact details

Import:
Administratief Centrum Kruidtuin
Food Safety Center
Kruidtuinlaan 55
1000 Brussel
Phone: 02 211 86 05
Email: import@favv-afsca.be

Export:

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[20] COMMISSION IMPLEMENTING REGULATION (EU) 2021/632 of 13 April 2021laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU)2019/2007 and Commission Decision 2007/275/EC

[21] Overview of Belgian reference laboratories: https://nrchm.wiv-isp.be/nl/ref_centra_labo/default.aspx

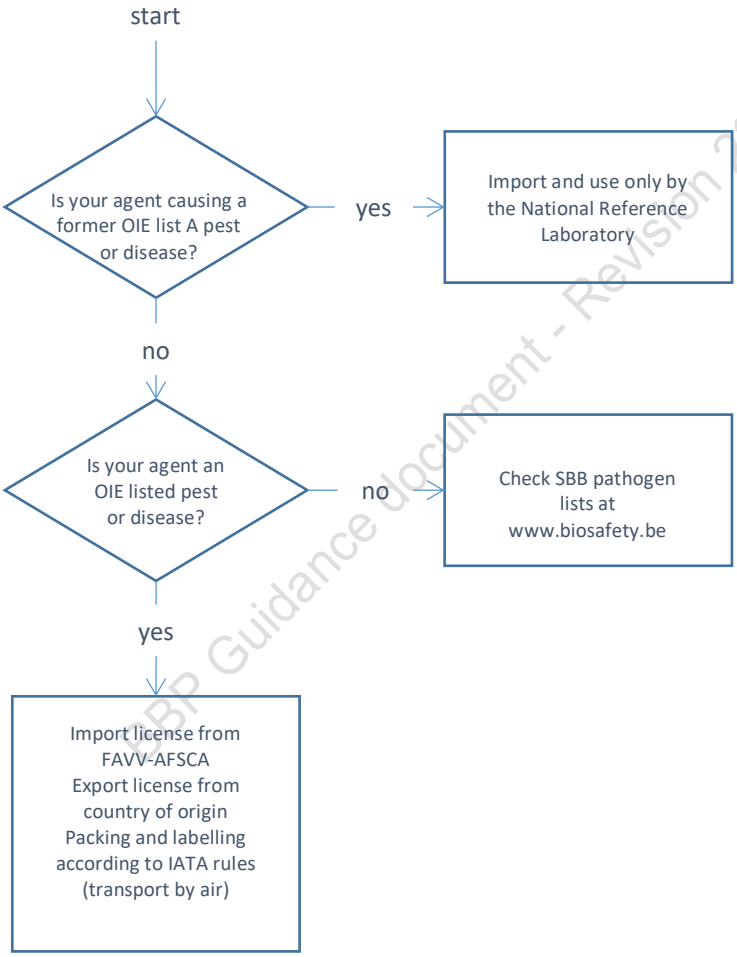
See www.oie.int and browse to '*About us*', then '*Our members*' and subsequently '*Delegates*', or contact the FAVV-AFSCA department responsible for import and export

References

The European legislation is extremely complex with currently very many different acts that cover individual or several quarantine animal pests and diseases. The European Parliament and the Council adopted the Regulation (EU) 2016/429 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0429-20191214) on transmissible animal diseases ("Animal Health Law") in March 2016. It is applicable from 21 April 2021.

Royal Decree 19/03/2004 - KB tot vaststelling van de veterinairrechtelijke en de gezondheidsvoorschriften voor het handelsverkeer en de invoer van bepaalde producten bestemd voor menselijke consumptie en tot wijziging van het koninklijk besluit van 31 december 1992 betreffende de veterinaire en zoötechnische controles die van toepassing zijn op het intracommunautaire handelsverkeer van sommige levende dieren en producten en tot wijziging van het koninklijk besluit van 31 december 1992 betreffende de veterinaire controles voor dieren en bepaalde producten van dierlijke oorsprong ingevoerd uit derde landen.

Summary



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3.6 Live animals

Goal of the regulatory framework

Lay down welfare as well as public and animal health rules for the transport of live animals.

Scope

The scope of the legislation covering transport of live animals is twofold. First, it aims to ensure the welfare of animals during transport. Requirements to ensure welfare during transport not only apply for vertebrate animals [(1) (2) (7)], but are also clearly described for invertebrate animals in the IATA Live Animal Regulation [(7)]. Secondly, as many animals are a potential source of risks to public and animal health, regulations also aim to trace all steps in the transport process by setting up rules for documentation and inspection [(3) (4)]. Specifically, an online "TRAde Control and Expert System" (TRACES NT) has been set up by the European Union, which allows tracking and tracing of all movements of live animals imported into and traded within the European Union (http://ec.europa.eu/food/animal/diseases/traces/index_en.htm).

In view of the scope of this manual, this card will mainly address those topics relevant for transport of live animals intended for research purposes.

General requirements

Before starting research activities with vertebrate animals that entail some form of suffering, an authorization to work with vertebrate animals has to be provided by the competent authorities for animal welfare. Therefore, a standard application form has to be submitted as described in Annex 2 of the animal welfare legislation [(5)]. Upon approval, the user receives an authorization number (LA number). Only authorized users are allowed to work with live animals for research purposes. Additional approval is required if the user also wants to breed or commercially supply animals (as described in Annex 3 of the animal welfare legislation [(5)]). Laboratory animals are usually kept in confined establishments. Within the circuit of confined establishments animals may be exchanged with reduced movement requirements [(9)].

When authorized users aim to import, export or otherwise transport live animals, additional authorizations and/or certificates are needed. The type of authorization and/or certificate you need, will depend e.g. on the animal species you want to transport [(6)], the country of origin and destination, the mode of transport and the purpose of use of the animal (commercial or non-commercial). In general, transport of animals used for experimental purposes is seen as a commercial transport.

Import into the European Union

All imports of live **vertebrate animals** into the European Union need to be notified to the competent authorities via an official border control post (BCP)[22] before entry into the European Union. Such notification is done via TRACES NT by means of a Common Health Entry Document type A (CHED-A). For import of live animals, notification must be done at least one working day before the expected arrival of the animals on European Union territory. Entry in the EU of animals is only permitted when originating from a country (zone) listed in [(8)] with specific conditions and animal health guarantees, Derogations apply when insects are intended to be used for scientific or diagnostic purposes.

Further import requirements depend on whether animals belong to a 'harmonized' or 'non-harmonized' species. For harmonized animal species, the EU has set general import and health requirements that apply to all member states. Such harmonized principles help to prevent the entry

[22] When shipping via air, it is important to verify whether the courier has a point of entry at Zaventem. If inspection is required, this is done at the inspection centre at the border control post. The inspection centre for non-human consumption is DNATA building 703 (Machelen). At Zaventem, only inspection of documents is performed.

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of animals with infectious diseases within the EU. Harmonized animal species are e.g. ruminants, swine and horses, as well as pets (dogs, cats, ferrets) in case of non-commercial movements. For non-harmonized animal species (e.g. bees, apes, rabbits, zoo animals, and pets for commercial import) requirements apply as set by the national governments.

If you want to import a harmonized animal into the European Union, no import authorization has to be applied for. However, transport does require an official veterinary certificate issued by a veterinarian of the competent authority in the country of origin.

If you want to import a non-harmonized animal into the European Union, an import authorization must be applied for at the competent authorities in the country of destination. The authorization outlines the specific requirements for the import. Apart from the import authorization, also an official veterinary certificate as described above is required.

Additional requirements may apply depending on the animal species to be imported (http://ec.europa.eu/food/animal/liveanimals/index_en.htm).

The import authorization, together with the relevant certificates and documentary evidence on the health status of the animals, must be presented at an official BIP at the point of entry into the Union. At the official BIP (i) a documentary, (ii) an identity and (iii) a physical (clinical) check will be performed to confirm that the shipment is suitable for introduction into the European Union as a whole or, if applicable, into specific member states only.

Once the shipment is approved, the person responsible for the load receives a completed, signed and stamped CHED-A and a certified copy of the official veterinary certificate by the veterinarian at the official BIP.

Applications for import permits and health certificates are directed to the “Federaal Agentschap voor de Veiligheid van de Voedselketen” (FAVV) of the Federal Public Service - Health, Food Chain Safety and Environment via a standard application form as provided by the FAVV (“Aanvraagformulier voor de invoermachtiging van dieren” or “Formulaire de demande d’une autorisation d’importation d’animaux”).

For the import of **invertebrate animals** including eggs (for instance insects like *Drosophila melanogaster*) for use in scientific research, it is not necessary to have an official health certificate signed by an official veterinarian. However, upfront notification of the shipment in TRACES NT still is required. The import permit, together with a commercial document and a sanitary declaration that the animals are free of pathogens and that “the animals were examined on the day of packing and found suitable for transport”, suffice. The commercial document must at least include the following information:

- country of origin,
- name and address of the sender and of the company of origin,
- name and address of the consignee and of the delivery address,
- place of loading,
- characteristics of the means of transport,
- species (scientific name), category and number of animals,
- identification of the shipment.

In contrast to an official health certificate, such a sanitary declaration can be drafted by the shipper and does not have to be drafted by the competent authorities. The application must also clearly state that it concerns the import of invertebrates for scientific research. Every item must go through customs.

Export from the European Union

If you want to export live animals from the European Union, different rules may apply depending on the importing country. For existing export agreements and for country-specific export rules, please consult the FAVV-AFSCA for more details. In case an official veterinary certificate is required, it can be applied for via TRACES NT and will be delivered by FAVV. Inspection of animals by an official veterinarian is to be performed within 48 hours prior to departure.

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Transactions within the European Union

For transactions with live animals within the European Union, no import authorization is needed. However, transport does require an official veterinary certificate for certain animal species, such as horses, ruminants and dogs. An application for a veterinary certificate can be done via TRACES NT and will be delivered by FAVV. Inspection of animals by an official veterinarian is to be performed within 48 hours prior to departure.

For animal species not requiring an official veterinary certificate by FAVV, at least documentation certifying that the animals show no signs of disease and that no sanitary restrictions apply to the holding of origin, should be available (e.g. “Certificate of origin” for laboratory mice and rats).

Transport requirements

The regulations on the transport of live animals cover a wide variety of animal species. Consequently, packaging (i.e. caging), labelling and documentation (apart from the documentation referred to in the sections above) will depend on the type of specimen to be transported. Moreover, it will depend on the mode of transport (e.g. road, air, water). For detailed instructions it is referred to the “Live Animals Regulations” (LAR) of IATA (including guidelines for air and non-air transport for vertebrate as well as invertebrate animals) [7]. European Regulation (EG) 1/2005 [1] and related documents describe how animals must be protected during transport.

Genetically modified live animals which, in accordance with the current state of scientific knowledge, have no known pathogenic effect on humans, animals and plants and are carried in receptacles that are suitable for safely preventing both the escape of the animals and unauthorized access to them, are not subject to the provisions of ADR. The provisions specified by the International Air Transport Association (IATA) for air transport “Live Animals Regulations, LAR” can be drawn on as guidelines for suitable receptacles for the transport of live animals.

In any case, for road transport of live vertebrate animals, specific documentation has to be present in the vehicle, including:

- Document describing the origin of the animals, the time and place of departure, the place of arrival and the expected duration of the journey
- Transporter authorization (transport > 65 km)
- Certificate of approval for the means of transport (compulsory for all transports of farm animals, compulsory for long distance transports of other animal species)
- Certificate of competence for the driver (compulsory for all transports of farm animals, obtained after passing an exam)
- Journey log (compulsory for international transports of more than 8 hours of unregistered horses, cattle, small ruminants and pigs). The journey log includes a plan of the trip and has to be submitted to the local “Provinciale Controle Eenheid” (PCE) of FAVV at least 48 hours prior to the transport.

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Derogations

Under specific circumstances, derogations may apply for transport of live animals. Such includes but is not limited to the following:

- Live animals **cannot** be used to transport an infectious substance, unless it cannot be consigned by any other means. If a live animal has been intentionally infected and is known or suspected to contain an infectious substance, it shall only be transported under terms and conditions approved by the competent authority.
- An EU passport and documentation on correct rabies vaccination is required for transport of cats, dogs and ferrets. Transport requirements may differ when the animals will be used for scientific purposes.

Specific requirements and procedures that have to be fulfilled in case of derogations are described in detail in the regulation. For more information, please consult the competent authorities.

Competent authorities and contact details

Import permits:

Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV)
Federal Public Service - Health, Food Chain Safety and Environment
Administratief Centrum Kruidtuin
Food Safety Center
Kruidtuinlaan 55
1000 Brussel
Phone: 02 211 82 11
Email: import@favv-afsca.be

Specific email address for general & specific research related questions:
researchcontactpoint@favv-afsca.be

"Provinciale Controle Eenheden" (PCE):

http://www.favv.be/pce/

Animal welfare:

Flanders competent authorities
Departement Omgeving
Dienst Dierenwelzijn
Koning Albert II-laan 20, bus 8
1000 Brussel
Email: dierenwelzijn@vlaanderen.be

Brussels competent authorities:

Bruxelles Environnement / Leefmilieu Brussel
Thurn & Taxis-site
Avenue du Port 86C/3000 / Havenlaan 86/C/3000
1000 Bruxelles / Brussel
Email: info@environnement.brussels

Walloon competent authorities:

Service Public de Wallonie
Unité Bien-être animal
Avenue Prince de Liège 7
5100 Namur (Jambes)
Email: ubea.dgarne@spw.wallonie.be

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References

(1) Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations

(2) Royal Degree of 14/02/2007 - Koninklijk besluit betreffende het commercieel vervoer van dieren andere dan landbouwhuisdieren 02/2014

(3) Council Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

(4) Commission Implementing Regulation (EU) 2019/2130 establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts

(5) Royal Degree of 29/05/2013 - Koninklijk besluit betreffende de bescherming van proefdieren

(6) Commission Implementing Regulation (EU) 2021/632 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts

(7) http://www.iata.org/publications/store/Pages/live-animals-regulations.aspx

(8) Commission Implementing Regulation (EU) 2021/404 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council

(9) Council Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

(10) Regulation (EU) 2020/692 supplementing Regulation (EU) 2016/429 as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin

Summary

Animal species	Requirements for *		
	Import to the EU	**Export from the EU**	**Transactions within the EU**
Harmonized	Official health certificate (country of origin) Common Health Entry Document type A (CHED-A)	Requirements depending on the importing country	Official veterinary certificate (country of origin) (for specific enlisted animal species) or Documentation certifying the health status of the animals (for other animal species)
Non-harmonized	Import authorization Official veterinary certificate (country of origin) Common Health Entry Document type A (CHED-A)	Requirements depending on the importing country	Official veterinary certificate (country of origin) (for specific enlisted animal species) or Documentation certifying the health status of the animals (for other animal species)

*Under specific circumstances, derogations may apply

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3.7 Access and Benefit Sharing (Nagoya)

Goal of the regulatory framework

A multi-country agreement providing a framework for access to genetic resources and traditional knowledge associated with the genetic resources, for sharing benefits relating to their utilization and for monitoring compliance with these provisions.

Scope

The Convention of Biological Diversity (CBD) (1) provides that States have the sovereign right to exploit their own resources pursuant to their own environmental policies. Furthermore, one of the objectives of the CBD is the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

The Access and Benefit Sharing (ABS) aspects are further elaborated in the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity" (2). The Nagoya Protocol entered into force on 12 October 2014. Compliance with the Nagoya Protocol is verified by the Competent Authorities in the country of use. In the EU this is regulated in Regulation (EU) No 511/2014 (3). It is complemented by implementing regulation and guidance documents.

Given the recognition of sovereign rights, each country can establish legislation to regulate the procedure to get access to genetic resources (GR) sourced on their territory and to traditional knowledge (TK) associated with the genetic resources. This can range from no obligation (free access and use) to a complete system of Prior Informed Consent (PIC) and a contractual agreement specifying Mutually Agreed Terms (MAT).

It is essential to understand the limits of the agreed use and implement the obligations of the terms. This may include restrictions to transferring the material to other parties for the same or for other uses. The Regulation specifies stages at which the user needs to make a Due Diligence Declaration i.e. 1) Funding of Research and 2) Final Stage of Development.

It is a complex regulatory area, partly because of the different ways by which countries regulate ABS. Some aspects will gradually be clarified and settled. In general, the following definitions can guide users in understanding applicability:

- "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology;
- "Genetic resources" means genetic material of actual or potential value;
- "Genetic material" [23] means any material of plant, animal, microbial or other origin containing functional units of heredity;
- "User" means a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources;
- "Biotechnology" any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;
- "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Another aspect is the retroactivity of the obligations. The entry into force of the Nagoya Protocol sets a clear starting point. However, some countries had ABS legislation established before this date and others are implementing legislation with retroactive application. As such a case-by-case evaluation is the only way to fulfill due diligence. In general, the following rule of thumb can be used:

[23] At the time this guidance document was prepared, synthetic genetic material and sequence information do not constitute a genetic resource, but this may be subject to change in the future.

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- For Access and Benefit Sharing: as indicated in the legislation in the country where the GR is/was accessed;
- For Compliance (in an EU country): only for material accessed (1) after the entry into force of the Nagoya Protocol, *i.e.* 12 October 2014, (2) if the country of origin is a Party to the Protocol, and (3) if said country has ABS measures into force.

General requirements

Whenever an organization sources genetic resources and/or traditional knowledge, it should be checked if the necessary access obligations in the country of origin have been covered. If not, a PIC and or MAT may need to be obtained. Material can only be transferred to a third party if properly covered in a PIC and/or MAT. If impossible to obtain, then the use of the genetic resources may need to be discontinued.

The user must ensure that the use is restricted to what is specified in the PIC and that all conditions specified in the MAT are respected.

In case a user based in the EU reaches one of the stages defined in the EU regulation and all the compliance conditions (see Scope) are met, then a Due Diligence Declaration must be made to the Competent Authority of the Member State. The CA transfers information to the ABS Clearing house and to the Commission.

Import into the European Union

Any access of a genetic resource should be conducted in compliance with the ABS regime in the provider country. If required, a PIC and/or MAT should be obtained.

Import as such does not trigger a specific requirement.

Export from the European Union

Any transfer of a genetic resource should be conducted in compliance with the ABS regime in the provider country. Proper documentation should be transferred. If a specific stage is reached (see Scope), a Due Diligence Declaration should be made to the national Competent Authority.

Export as such does not trigger a specific requirement.

Transactions within the European Union

Any access and transfer of a genetic resource within a EU country or from/to another EU country should be conducted in compliance with the ABS regime in the provider country. If required, a PIC and/or MAT should be obtained.

Import as such does not trigger a specific requirement.

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Transport requirements

The Nagoya protocol is applicable to a wide variety of materials. Consequently, packaging, labelling and documentation (apart from the documentation referred to in the sections above) will depend on the type of material to be transported.

For detailed instructions it is referred to the card(s) relevant for the type of specimen and/ or to the Instruction Cards Dangerous goods as well as Customs / Tax.

In any case, when handing over genetic resources, ABS documentation should be transmitted in order to ensure compliance.

Derogations

Under specific circumstances, derogations may apply on the Nagoya protocol. Such includes but is not limited to the following:

- Human genetic resources are not subject to the protocol. However, the ABS Regulation is applicable in the case microbiota are isolated from human bodily excreta (e.g. faeces) and genetic and biochemical composition of strains and the function of genes is studied with the aim to use these strains in probiotics.
- Compliance for Plant Genetic Resources for Food and Agriculture (PGRFA) is assumed under another framework, i.e. Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
- Compliance for genetic resources related to the pandemic influenza preparedned is assumed under another framework, i.e. the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIPF) from the World Health Assembly.

For more information, please consult the competent authorities.

Competent authorities and contact details

In Belgium there are four different competent authorities: (1) the Flanders region for the Flanders territory, (2) the Walloon region for the Walloon territory, (3) the Brussels Capital Region for the Brussels capital territory, and (4) the Federal authorities for the territory of the North Sea and the Federal research institutes.

Federal level

Ms. Salima Kempenaer
General Directorate (DG5) Environment Federal Public Service (FPS) Health, Food Chain Security and Environment DG5 Environment
Place Victor Horta 40 bte 10, Bloc 11
1060 Brussels Belgium

Brussels competent authorities

Brussels Environment
Site Tour & Taxis
Avenue du Port 86C / 3000 Havenlaan
1000 Brussels
Phone: +32 (0)2 / 775.75.75

Flanders competent authorities

Agentschap voor Natuur en Bos
Herman Teirlinckgebouw – Havenlaan 88 bus 75
1000 Brussels, Belgium
Phone: +32 2 553 02 80
Email: nagoya@vlaanderen.be
Website: Agentschap Natuur en Bos

Walloon competent authorities

Direction Générale opérationnelle de l'Agriculture, des Ressources naturelles et de l'Environnement
Avenue Prince de Liège 15, 5100 Namur (Jambes), Belgium
Phone: (+32) 081/649617
Email: damien.winandy@spw.wallonie.be
Website: http://www.wallonie.be/fr/guide/guide-services/16088

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References

(1) Convention on Biological Diversity (https://www.cbd.int/convention/text/)

(2) Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (https://www.cbd.int/abs/text/default.shtml)

(3) Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union was adopted on 16 April 2014

Summary

Material	Requirements for *		
	Import to the EU	**Export from the EU**	**Transactions within the EU**
Genetic Resource (within the meaning of the Nagoya Protocol)	Obtain information on origin (provider country) of the genetic resource Ensure coverage by PIC and/or MAT (if required) Observe scope of utilization Due Diligence Declaration when reaching a checkpoint during utilization**	Provide information on origin (provider country) of the genetic resource Verify coverage by PIC and/or MAT (if required) Due Diligence Declaration when reaching a checkpoint **	Obtain/provide information on origin (provider country) of the genetic resource Ensure/verify coverage by PIC and/or MAT Observe scope of utilization Due Diligence Declaration when reaching a checkpoint **

*: Under specific circumstances, derogations may apply
**: Checkpoints include (1) Funding of Research and 2) Final Stage of Development
PIC: Prior Informed Consent
MAT: Mutually Agreed Terms
EU: European Union

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3.8 Dual Use

Goal of the regulatory framework

Set up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Scope

Dual-use items are goods (including software and technology) normally used for civilian purposes, but which may have military applications, or may contribute to the proliferation of Weapons of Mass Destruction (WMD). In brief, the items in question are or may be intended, in their entirety or in part, for use in connection with the development, production, handling, operation, maintenance, storage, detection, identification or dissemination of chemical, biological or nuclear weapons or other nuclear explosive devices or the development, production, maintenance or storage of missiles capable of delivering such weapons.

Due to their nature, the export, transfer, brokering and transit of dual-use items are strictly regulated at EU level. This has been documented in the dual-use Regulation 2021/82[((1)].

Your organism is regarded a dual-use item when it is enclosed in the EU control list of dual-use items (Annex I of the dual-use regulation), that is regularly updated. Within the EU control list, biological material falls under category 1 - 'Special materials and related equipment'. More specifically it is categorized as either:

- 1C351 (human and animal pathogens, zoonoses and toxins[24])
- 1C353 (genetic elements and GMO)
- 1C354 (plant pathogens).

General requirements

If you want to export an item subject to the dual-use regulation, you need specific permits. The type of permit will depend on e.g. the type of material you want to transport, the destination of the material and the intended use of the material. Not all types of permits described in the dual-use regulation can be granted for export of biological items (1C351 - 1C354).

Export and/or transit of items that are not listed on Annex I of the dual-use regulation may also require a permit or may be forbidden ('catch-all procedure'). Such can be the case when export is scheduled to a country subject to an arms embargo or when the items in question are or may be intended, in their entirety or in part, for a military end-use. Moreover, goods that are not dual use can be put under license by international sanctions [(2)]. Please consult the competent authorities for more details.

In case material does not require a permit, it can still be subject to customs control at the Belgian border [25]. Customs control may request proof that no permit is required for the material, which can be delivered by means of a release letter.

Import into the European Union

The dual-use regulation only covers export (and transit) of dual-use items, but does not concern import of such items. Nevertheless, Members States have the possibility to adopt via national legislation special provisions on import of dual-use items. Currently, this is not the case for Belgium.

Export from the European Union

[24] Toxins in the form of deliberately isolated preparations or mixtures, no matter how produced, other than toxins present as contaminants of other materials such as pathological specimens, crops, foodstuffs or seed stocks of microorganisms.

[25] Many products are flagged at customs control based in tariff codes (HS Nomenclature). Only a minority of the flagged items actually fall under dual use items.

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If you want to export biological material listed on Annex I of the dual-use regulation from the European Union to a third country, you have to apply for an individual export permit. An individual export permit is valid for one end-user in one third country. Request forms for the export permit have to be accompanied by an (international) import certificate or end-use certificate for dual-use items, depending on the country of destination. The end-use certificate needs to be validated by a competent authority in the country of destination (i.e. a local Chamber of Commerce or a Belgian Embassy). If the end-use certificate is not validated, then the certification procedure is initiated by the licensing office (see Competent authorities and contact details).

The export permit, once assigned, is valid throughout the entire European Union. The export permit has to be presented at the border customs office at which the export formalities are completed.

Export permits are valid for three years and can be extended for another three years for the remaining value and amount of materials. Export permits need to be returned to the competent authorities once the validity date has expired, or sooner, in case the value and amount of materials for which the permit was granted has been exported.

Exporters of dual-use items have to keep a detailed register or records of their exports [26]. Such registers or records shall include in particular commercial documents such as invoices, manifests and/or transport documents containing sufficient information to allow identification of the description of the dual-use items, the quantity of the dual-use items, the name and address of the exporter and of the consignee and, where known, the end-use and end-user of the dual-use items.

Application forms for export permits or end-use certificates as well as more information on the application procedures can be found on the website of the competent authorities or can be requested via their contacts (see Competent authorities and contact details).

It is highlighted that in suite of the Brexit (31 January 2020), the United Kingdom is no longer part of the European Union. Hence Great Britain (Scotland, England, and Wales) must be considered as third country. Therefore, it is strongly advised to check the modalities and end date of any existing permit for export to the United Kingdom.

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Transactions within the European Union

For transactions of biological material listed on Annex I of the dual-use regulation within the European Union, no restrictions apply, and no permits are needed, unless your material is listed on Annex IV of the dual-use regulation. Annex IV lists highly sensitive items (for example ricine and saxitoxine in category 1C351). For these items, an export permit is needed even if export is restricted to other EU Member States (see requirements for export).

For transactions within the Benelux, no export permit is needed.

Transport requirements

The dual-use regulation is applicable to a wide variety of materials. Consequently, packaging, labelling and documentation (apart from the documentation referred to in the sections above) will depend on the type of material to be transported.

For detailed instructions it is referred to the card(s) relevant for the type of specimen and/ or to the Instruction Cards Dangerous goods as well as Customs / Tax.

Derogations

Under specific circumstances, derogations may apply for the export of dual-use items. Such circumstances include, but are not limited to:

[26] In general, export details have to be kept for a minimum of three years after export. For Flanders, details have to be kept for seven years after export.

- Global export authorization granted to one specific exporter in respect of a type or category of dual-use item which may be valid for exports to one or more specified end users and/or in one or more specified third countries

Specific requirements and procedures that have to be fulfilled in case of derogations are described in detail in the dual-use regulation. For more information, please consult the competent authorities.

Competent authorities and contact details

Flanders competent authorities:

Department Kanselarij & Buitenlandse zaken
Dienst Controle Strategische Goederen
Herman Teirlinckgebouw
Havenlaan 88 bus 80
1000 Brussel
(: 02 553 71 24 / 02 553 48 80
Email: csg@vlaanderen.be
website: http://www.vlaanderen.be/csg; https://www.fdfa.be/nl/digitaal-loket (digital counter for permit requests)

Brussels competent authorities:

Brussels International Directorate
Licencing Unit
20, Kruidtuinlaan/Boulevard du Jardin Botanique
1035 Brussels
Phone: 02 800 37 27
Email: calu@sprb.brussels, du-arms@sprb.brussels

Walloon competent authorities:

S.P.W.
Direction Générale Opérationnelle de l'Economie, de l'Emploi et de la Recherche
Direction des Licences d'Armes
14, Chaussée de Louvain
5000 Namur
Phone: 081 64 97 55, 081 64 95 06
Email: samuel.vlaminck@spw.wallonie.be, pascale.alberte.dumont@spw.wallonie.be
Website: http://economie.wallonie.be/Licences_armes/Accueil.html

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References

[1]Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Unionregime for the control of exports, brokering, technical assistance, transit and transfer of dual- use items (recast) Translation into the Flemish legislation: Besluit van de Vlaamse Regering van 14 maart 2014 tot regeling van de uitvoer, doorvoer en overbrenging van producten voor tweeërlei gebruik en het verlenen van technische bijstand (http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&table_name=wet&cn=2014031421)

[2] http://ec.europa.eu/dgs/fpi/what-we-do/sanctions_en.htm

Other useful links:

Direction des Licences d'Armes et des Biens à Double usage – SPW – 11 juin 2021 (Walloon Region & Brussels Capital Region).

See: https://economie.wallonie.be/Licences_armes/News/Nouveau%20R%C3%A8glement%20double%20usage.docx

VLIR (2017) Guidelines for researchers on dual use and misuse of research.

See: https://vlir.be/wp-content/uploads/2019/10/2017VLIR003_FolderOnderzoek_EN_DEF_20180212.pdf

Summary

Material listed in Annex **	Import to the EU	Export from the EU to non-EU countries***	Export from the EU to countries under embargo/sanction	Transactions within the EU	Transactions within the Benelux
I	Not applicable	Export permit	Export forbidden	None	None
IV	Not applicable	Export forbidden	Export forbidden	Individual permit	None

* Under specific circumstances, derogations may apply

** Export and/or transit of items that are not listed on Annex I of the dual-use regulation may require a permit or may be forbidden ('catch-all procedure'). Such can be the case when export is scheduled to a country subject to an arms embargo of the EU, the VN or the OVSE, or when the product is, in its entirety or in part, intended for a military end use

*** For Australia, Canada, Japan, New Zealand, Norway, Liechtenstein, Switzerland, US and Great Britain (Scotland, England and Wales) specific rules apply. For export of items listed in Annex IIg a permit is required. For all other items a simplified registration procedure applies.

EU: European Union

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3.9 Phytosanitary

Goal of the regulatory framework

Provide measures for controlling and managing plant pests in the EU depending on the risk they represent from an economic, environmental, social, and agricultural point of view, and according to their impact on the quality of production.

Note: The plant health regulatory framework was completely overhauled in 2016 and introduced a number of changes, including but not limited to:

- **Outermost regions of Member States referred to in Article 355 (1) of the Treaty of Europe (TFEU), except for Madeira and the Azores, are excluded from the scope and are considered as part of third countries.**
- **A 'pre-export certificate' to exchange information is used among Member States when a plant or plant product moves through more than one Member State before it is exported to a third country (previously covered by an Intra-EU Phytosanitary Communication Document – IPCD). Note: other documents such as 'phytosanitary certificate', 'phytosanitary certificate for re-export', and 'plant passport' continue to be used.**

Scope

The Regulation (EU) 2016/2031[(1)] on protective measures against pests of plants focuses on four key areas: (i) plant pests, (ii) the import of plants in the EU, (iii) the movement of plants or plant products within the EU and (iv) the obligations and responsibilities for professional operators. Commission Implementing Regulation (EU) 2019/2072[(2)] establishes uniform conditions to implement Regulation (EU) 2016/2031 and is regularly updated[(2)].

(i) **Pests are classified into different categories** and regulated depending on their quarantine status or whether they affect the quality of plant reproductive material. They are listed in **Implementing Regulation (EU) 2019/2072** as '**Union quarantine pests**' (Annex II), '**Protected zone quarantine pests**' (Annex III) and '**Union regulated non-quarantine pests**' or RNQP (Annex IV). '**Priority pests**' are those quarantine pests whose potential economic, environmental or social impact are the most severe for the Union territory and are listed in Commission Delegated Regulation (EU) 2019/1702[(11)].

(ii) The phytosanitary requirements for import into the EU (including Belgium) are specified in the Annexes of **Implementing Regulation (EU) 2019/2072**:

- Annex VI specifies the import prohibitions
- Annex VII lists specific phytosanitary import requirements which plants and plant products imported into the EU shall comply with
- Annex IX specifies import prohibitions for specific protected zones
- Annex X lists the special requirements for import in specific protected zones
- Annex XI specifies the list of plants, plant products and other objects subject to phytosanitary certificates (and those for which such certificates are not required for their introduction into the Union territory). But also see:
  - (EU) 2018/2019 [(12)], Annex II: for pineapple, banana, date, doerian and coconut no phytosanitary certificate is required.
  - (EU) 2016/2031 [(1)], article 2: for the import of e.g. dried leaves for destructive molecular analysis no phytosanitary certificate is required (since it does not concern living material or untreated material; the risk of introduction and spread of harmfull organisms has been eliminated by drying of the material and the material will be detructed after analysis).

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- Annex XII lists the plants, plant products and other objects for which a phytosanitary certificate is required for their introduction into a protected zone from certain third countries of origin or dispatch
- In addition, the regulation also lists 'high-risk plants, plant products or other objects' for which the introduction into the EU territory is provisionnally prohibited until a full risk assessment has been carried out. These are listed in Commission Implementing Regulation (EU) 2018/2019 (12).

(iii) The phytosanitary requirements for **movement of plants or plant products within the EU** (including Belgium) are also listed in the Annexes of **Implementing Regulation (EU) 2019/2072**:

- Annex IX specifies import prohibitions for specific protected zones
- Annex X lists the special requirements for import in specific protected zones
- Annex VIII lists the special requirements for movement within the Union territory
- Annex XIII lists plants, plant products and other objects for which a plant passport is required for their movement within the EU. In addition, if mentioned in Annex VIII or Annex X, then also a plant passport is required, unless they are subject to the exceptions listed in Article 6(3).
- Annex XIV lists plants, plant products and other objects for which a plant passport with the designation 'PZ' is required for introduction into, and movement within certain protected zones
- Article 13 lists the specific derogations for the obligations for plant passports.

(iv) The obligations and responsibilities for professional operators:

- Be registered by the competent authorities.
- Notification of any pest encountered during control.
- Take immediate precautionary measures to prevent the pest spreading and withdraw any plants, plant products and other objects under their control in which the pest may be present, from the market.
- Ensure the traceability of certain plants, plant products and other objects they receive from and transfer to other professional operators.

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Note: Outermost regions of Member States referred to in Article 355 (1) of the Treaty of Europe (TFEU), except for Madeira and the Azores, are excluded from the scope of this regulation and are considered as part of third countries.

For official testing, scientific or educational purposes, trials, varietal selection or breeding, it is allowed to import, transport and handle (ZP) quarantine pests when a specific set of conditions has been met. These conditions are specified in **Commission Delegated Regulation (EU) 2019/829** (3) and are not applicable for trial and scientific activities with RNQP. A guidance document (Procedure 2009/75/PCCB[27]) has been issued by FAVV/AFSCA.

General requirements

Only authorized companies and institutes are allowed to request official permissions ('Letter of Authority' - LoA) and import, transport or handle so-called 'specified pests and plants, plant products and other objects'. These are the following:

- Union quarantine pests, listed pursuant to Article 5 of Regulation (EU) 2016/2031;
- pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;
- protected zone quarantine pests, listed pursuant to Article 32(3) of that Regulation;

[27] https://www.favv-afsca.be/plantaardigeproductie/invoercontroles/_documents/20220310_200975PCCB_NL_v4.pdf (nl), https://www.favv-afsca.be/productionvegetale/controleimportation/_documents/20220310_200975PCCB_FR_v4.pdf (fr)

- plants, plant products or other objects subjected to measures adopted pursuant to Article 30(1), and listed pursuant to Articles 40(2) and (3), 41(2) and (3), 42(2) and (3), 49(1), 53(2) and (3), and 54(2) and (3) of Regulation (EU) 2016/2031;
- any specified pests, plants, plant products or other objects requiring an authorisation within the meaning of Regulation (EU) 2016/2031.

In order to become authorized, a company or institute needs to submit a dossier to FAVV-AFSCA [(4)]. FAVV-AFSCA will evaluate the dossier and will grant the authorization when all requirements are met. Often these authorized facilities are referred to as 'confinement facilities', but it is important to keep in mind that they are only allowed to receive the material for which they are authorized and not any other regulated materials.

Import into the European Union

Different import requirements are applicable depending on the type of material:

For materials requiring a 'Letter of Authority' for import and transport:

- Only authorized companies and institutes can request a 'Letter of Authority' at FAVV-AFSCA [(5)].
- In the case of specified material originating in the Union, the letter of authority shall conform to the format set out in Part A of Annex II **Commission Delegated Regulation (EU) 2019/829**. It shall be officially endorsed by the Member State of origin, for movement of the respective specified material under quarantine or confinement conditions.
- In the case of specified material originating in third countries, the letter of authority shall conform to the format set out in Part B of Annex II **Commission Delegated Regulation (EU) 2019/829**. It shall be officially endorsed by the third country of origin for introduction of the respective specified material under quarantine or confinement conditions.
- In the case of multiple introductions into, or movements within, the Union, of a specific type of specified material, one single letter of authority may be issued by the competent authority at the moment of the first sending and covering all those introductions or movements. Box 10 should indicate that the letter of authority covers multiple introductions into, or movements within, the Union of that specified material. Maximum validity is one year from the date of issuance.

For materials requiring a phytosanitary certificate:

- The certificate must be issued by the competent plant health authority of the country of origin. The original phytosanitary certificate must accompany the consignment.
- The products entering with a phytosanitary certificate are subject to at least a documentary and identity phytosanitary check at the first point of entry[28] in the EU in a Border Control Post [(6)]. To mediate this, a pre-notification needs to be done in IMSOC/TRACES NT [(7)] one working day prior to the physical arrival of the consignment into the Union (art. 56 of Regulation 2017/625). (Note: whereas Belgium requires pre-notification in IMSOC/TRACES NT for each item listed on Annex XI Part A or B, or Annex XII of Implementing Regulation (EU) 2019/2072, certain EU member states do not require such pre-notification in TRACES-NT if they are only listed on Annex XI Part B, and only when the consigment would be selected for physical phytosanitary check, the Border Control Post would require an entry to be made in IMSOC/TRACES NT; this should be carried out on at least 1% of these consignments according to Implementing Regulation (EU) 2019/66) [(13)].
- If all checks are favorable, the products are cleared and a CHED-PP (with status "validated") is issued in IMSOC/TRACES NT. When the result of the checks is non-compliant (e.g.

[28] When shipping via air, it is important to verify whether the courier has a point of entry at Zaventem. If inspection is required, this is done at the inspection centre at the border control post. The inspection centre for non-human consumption is DNATA building 703 (Machelen). At Zaventem, only inspection of documents is performed.

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presence of quarantine organisms, missing or invalid phytosanitary certificate, document inconsistencies etc.), the products will be sent back to country of origin or destroyed.

- In certain cases, only the documentary check is done at the Border Control Post, and the consignment is authorised to move to a approved Control Point where identity and physical checks will be performed. In such case, a CHED-PP will be issued with status "Authorised for transfer" [8].

After import, a plant passport may be required for further transport within and between EU Member States (see "Transactions within the European Union").

It is important to mention that plant pathogens that are not listed as a (protected zone) quarantine pests (or specified pests requiring an authorisation within the meaning of Regulation (EU) 2016/2031), do not fall under the above-mentioned phytosanitary requirements. However, in order to lawfully receive, store and/or perform research with such plant pathogens, as well as the ones listed on the annexes, a contained use permit is mandatory (see also **Chapter 3.1** GMO / LMO).

Export from the European Union

When exporting plants and plant products, the competent Plant Health Authority of the receiving country needs to be contacted for the specific requirements regarding local phytosanitary regulation and/or import permit requirements. On the FAVV-AFSCA website you can find information and information sources for the phytosanitary requirements of third countries [9]. In many cases this will include the requirement for a **phytosanitary certificate**.

Note:

- For plants or plant products that were originally imported into the EU with a phytosanitary certificate, and need to be exported out of the EU again, a phytosanitary certificate for re-export is required. The original phytosanitary certificate needs to be available at the time of inspection.
- If you are transporting plants and plant products through another EU Member State with the objective of exporting them to a third country, you must use a pre-export certificate for the intra-EU transport. It confirms to the other Member State's national authority for plant protection that the merchandise has gone through a phytosanitary inspection and lists the harmful organisms that were tested. It needs to mention the country of final destination, as well as the necessary declarations to prove that the material complies with the phytosanitary requirements of the country of final destination. The pre-export certificate needs to be available at the time of inspection in the Member State that will issue the phytosanitary certificate prior to export from the EU.

If a phytosanitary certificate, a phytosanitary certificate for re-export or pre-export certificate is required, you can request it via the FAVV-AFSCA or the regional authorities, depending on the type of material:

- FAVV-AFSCA:
  - propagating material of ornamental plants and other plants for planting for ornamental purposes;
  - propagating material of fruit crops, with the exception of specialized fruit tree nurseries and producers of rootstock and grafting material and fruit crops where the competent entity of the Region carries out official certifications within the framework of the trade guidelines;
  - forestry propagating material.
  - Exports to Russian Federation → Follow procedure PCCB/S4/1604537 [10]
- Regional authorities:
  - certified seed potatoes;
  - certified seeds and standard seeds of vegetables;
  - fruit crop propagating material for specialized fruit tree nurseries and producers of rootstocks and inoculums where the competent entity of the Region carries out official certifications within the framework of the trade guidelines;
  - vegetable crop propagating and planting material;
  - vegetative propagation material of vines.

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→ Contact the regional authority for concrete instructions

An additional inspection of the products or an inspection at the place of production (growing) may be required. In certain cases, multiple inspections during the growing season or analysis reports from accredited labs that certify absence of particular pests of diseases may be needed for a phytosanitary certificate or pre-export certificate to be issued.

Transactions within the European Union

All plants, plant products and other objects listed on Annex XIII and Annex XIV of **Implementing Regulation (EU) 2019/2072 (except for the derogations listed in Article 13**) require a plant passport for transport within and between Member States. A company or institute needs to be authorized and inspected to be able to issue such plant passports. Authorization and inspection are either done by FAVV-AFSCA or the regional authorities, depending on the type of material:

- FAVV-AFSCA:
  - propagating material of ornamental plants and other plants for planting for ornamental purposes;
  - propagating material of fruit crops, with the exception of specialized fruit tree nurseries and producers of rootstock and grafting material and fruit crops where the competent entity of the Region carries out official certifications within the framework of the trade guidelines;
  - forestry propagating material.
  - mandatory pre-cultivation soil samples in all sectors

  The process for requesting authorization and inspection is explained in detail at the FAVV-AFSCA website:
  - https://www.favv-afsca.be/professionelen/plantaardigeproductie/wetgeving/verordeningeu/#d1 (Dutch)
  - https://www.favv-afsca.be/professionnels/productionvegetale/legislation/reglementue/ (French)

- Regional authorities:
  - certified seed potatoes;
  - certified seeds and standard seeds of vegetables;
  - fruit crop propagating material for specialized fruit tree nurseries and producers of rootstocks and inoculums where the competent entity of the Region carries out official certifications within the framework of the trade guidelines;
  - vegetable crop propagating and planting material;
  - vegetative propagation material of vines.

  Contact the regional authority for concrete instructions. A plant passport is only valid for transport within and between Member States.

Specific exceptions on the need for plant passports include the following:

- for movement of plants, plant products and other objects in frontier zones, destined for export (i.e. phytosanitary transit), if LoA for the material available, or in travellers' luggage
- for direct supply to final users (except in case of online commerce)
- movements of plants, plant products and other objects within and between the premises of the same registered operator which are in close proximity to each other

If you are transporting plants and plant products through another EU Member State with the objective of exporting them to a third country, you must use a pre-export certificate for the intra-EU transport. More information regarding the requirements and use for pre-export certificates is included under "Export from the European Union".

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Transport requirements

Plant pathogens, plants and plant materials are classified as non-dangerous biological goods as long as they are non-GMO. For transport requirements, consult Chapter 3.11.

In case plant pathogens, plants or plant products are transported that require a phytosanitary certificate, plant passport or Letter of Authority, the physical document needs to be attached to the shipment. Furthermore, for import customs documents (pro-forma and packing list) are also required (see Chapter 3.12 Customs / Tax).

Derogations

Under specific circumstances, derogations may apply for the transport of plants and plant products. Such derogations are listed in http://www.favv-afsca.be/plantaardigeproductie/invoercontroles/ >> Uitzondering (Dutch) and http://www.favv-afsca.be/productionvegetale/controleimportation/ >> Dérogation (French). For more information, please consult the competent authorities.

Competent authorities and contact details

Competent Authority

Federal Public Service (FPS) Health, Food Chain Safety and Environment
Directorate General Animal, Plant and Food
Victor Hortaplein 40 – bus 10
1060 Brussels
Phone: 02 524 97 97
Website: https://www.health.belgium.be/

Executive department - Federal

Federal Agency for the Safety of the Food Chain (FAVV/AFSCA)
AC Botanique – Food Safety Center
Kruidtuinlaan 55
1000 Brussels
Phone: 02 211 82 11
Website: http://www.favv-afsca.be
Email: import@favv-afsca.be

Executive departments - Regional

Vlaamse Overheid
Departement Landbouw en Visserij
Koning Albert II-laan 35 bus 40
1030 Brussels
Phone: 02 552 77 05
Email: kwaliteit.plant@lv.vlaanderen.be
Website: https://lv.vlaanderen.be/nl/plant/plantaardig-teeltmateriaal

Service Public Wallonie Agriculture, Ressources naturelles et Environnement
Direction de la Qualité et du Bien-être animal
Îlot St-Luc, Chaussée de Louvain 14
5000 Namur
Phone: 081 64 96 08
Website: https://agriculture.wallonie.be/vegetaux

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References

(1) Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC

(2) Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing

Regulation (EU) 2018/2019. Always check the latest consolidated version at EUR-Lex - 32019R2072 - EN - EUR-Lex (europa.eu).

(3) Commission Delegated Regulation (EU) 2019/829 of 14 March 2019 supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding

(4) Procedure 2009/75/PCCB §5.1 of FAVV-AFSCA

(5) Procedure 2009/75/PCCB §5.2 of FAVV-AFSCA

(6) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

A list of the Border Control Posts and Approved Control Posts is available at the website of FAVV (http://www.afsca.be/plantaardigeproductie/invoer/default.asp or http://www.afsca.be/productionvegetale/importation/)

(7) TRACES-NT CHED-PP Manual: https://webgate.ec.europa.eu/cfcas3/tracesnt-webhelp/Content/L_CHED-PP/Intro.htm

(8) Import from third countries (https://www.favv-afsca.be/professionelen/invoer/ or https://www.favv-afsca.be/professionnels/importation/)

(9) https://www.favv-afsca.be/professionelen/export/planten/ or https://www.favv-afsca.be/professionnels/exportation/vegetaux/

(10) Circulaire relative à la délivrance de certificats phytosanitaires à l'exportation et à la réexportation (PCCB/S4/1604537) or Omzendbrief betreffende fytosanitaire certificaten voor uitvoer en wederuitvoer (PCCB/S4/1604537)

(11) Commission Delegated Regulation (EU) 2019/1702 of 1 August 2019 supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council by establishing the list of priority pests

(12) Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation

(13) Commission Implementing Regulation (EU) 2019/66 of 16 January 2019 on rules on uniform practical arrangements for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules on protective measures against pests of plants applicable to those goods

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3.10 Dangerous goods

Goal of the regulatory framework

Protect shipper, carrier, the public and the environment against the risks inherent to the transport of dangerous goods by laying down strict requirements for packaging, labelling and documentation.

Scope

Dangerous goods are substances capable of posing a significant risk to health, safety and/or environment. Consequently, their transport is strictly regulated in the international Dangerous Goods Regulatory (DGR) framework [(1)].

The DGR framework covers a wide range of dangerous goods. These are classified into 9 classes, whereby each class is assigned a UN number and a proper shipping name according to its hazard and composition. Each class has its specific requirements for sub-classification of goods, for packaging, marking and labelling, as well as for proper documentation needed to transport dangerous materials in a safe way.

The framework also covers a variety of transport modes, such as air [(2)], road [(3)], and water [(4)]. In view of the modes of transport, it is highlighted that quantity limitations are applicable when shipping biological materials by air. More details can be found in Annex I. In some cases, special provisions need to be taken into account when shipping biological materials by air or by road. These are additional requirements on top on the standard requirements. A list of the most relevant special provisions can be found in Annex I as well. Under no circumstances is transport of dangerous goods by mail allowed.

States and Operators may submit variations to the DGR framework, e.g. restricting the transport, or the conditions of transport for substances. It is advised to contact your courier prior to shipment in order to ensure that all State and Operator requirements are met.

NOTE: In view of the scope of this chapter, only requirements for the transport of biological dangerous goods are discussed (Class 6 - Toxic and infectious substances and Class 9 - miscellaneous). In case your package also contains substances belonging to one of the other DGR classes, such as chemicals, explosive or flammable compounds, the transport must also comply with the corresponding requirements (including packaging, labelling and documentation.

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General requirements

Below, a general overview is provided of the requirements to be fulfilled in terms of classification, identification, packaging, marking, labelling and documentation.

I. Classification

If you want to transport a dangerous biological good, you first have to further classify your material according to the DGR. A schematic classification tree can be consulted in Annex II - Classification tree for dangerous goods. For more detailed information on classification, it is referred to https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf.

In view of the classification in Class 6, the following is noted:

- If your material is not on the Category A list, a risk assessment needs to be performed to exclude that the material falls under Category A

- A correct classification of infectious substances of Category A is the competence of a dangerous goods IATA-certified person, which is an additional required certification for an ADR-certified safety advisor [29].
- Plant pathogens do not fall in Class 6 according to the dangerous goods regulations and, therefore, are not regulated as dangerous goods (see Instruction Card Dangerous goods).
- If your material is both infectious and a GMO, then you only need to comply with the requirements of Class 6.2.
- Please note that some countries like China, Japan and Russia decided to use a different risk classification system, where risk group 4 is foreseen for harmless organisms, whereas risk group 1 is foreseen for organisms associated with the higest risk. Check the correct risk classification[30] when planning receipt of organisms from these countries.

II. Identification

Dangerous goods must be properly identified by a UN specification number, shipping name, hazard class, and hazard label, if relevant. For transport of biological material, following codes and names are most relevant:

UN no.	Proper Shipping Name	Class	Hazard label
3172	Toxins, extracted from living sources (liquid)	6.1	Poison or Toxic
3462	Toxins, extracted from living sources (solid)	6.1	Poison or Toxic
2814	Infectious substance, affecting humans (liquid)	6.2	Infectious substance
2814	Infectious substance, affecting humans (solid)	6.2	Infectious substance
2900	Infectious substance, affecting animals (liquid)	6.2	Infectious substance
2900	Infectious substance, affecting animals (solid)	6.2	Infectious substance
3373	Biological substance, Category B	6.2	None
3245	GMO	9	None
1845	Dry ice or carbon dioxide, solid	9	Miscellaneous
1977	Nitrogen, refrigerated liquid	2.2	Non-flammable gas & Cryogenic liquid

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III. Packaging

Dangerous goods must be packed in good quality packages complying with the packaging requirements for the material to be transported. The shipper is responsible for all aspects of the packaging of dangerous goods, i.e.:

- Comply with packaging requirements. For biological material, following codes and names are most relevant:
  - Infectious substances Cat A (UN 2814, UN 2900): Packing Instruction PI620 / P620
  - Infectious substances Cat B (UN 3373): PI650 / P650

[29] IATA certification can only be obtained by passing an exam at an IATA-certified training school. For people involved in preparation of shipments, it is important to ensure a proper understanding of the dangerous goods regulations. Dangerous goods training is therefore recommended which, at least, covers general awareness and packing / classification of biological specimens. The IATA-certified person has the final responsibility to approve the shipment.

[30] For the Belgian classification of microorganisms issued by SBB/Sciensano please see: https://www.biosafety.be/content/tools-belgian-classification-micro-organisms-based-their-biological-risks

  - Genetically Modified Organisms (GMO) (UN 3245): PI959 / P904
  - Toxin, extracted from living organisms (liquid) (UN3172): PI652 (PGI), PI654 (PGII), PI655 (PGIII) / P001
  - Toxin, extracted from living organisms (solid) (UN3462): PI666 (PGI), PI669 (PGII), PI670 (PGIII) / P002
  - Dry ice as refrigerant (UN 1845): PI954
  - Liquid nitrogen as refrigerant (UN 1977): PI202
- Follow the manufacturers' packaging instructions
- Ensure that the relevant maximum quantities are not exceeded
- Ensure that the responsibilities for packing are fulfilled when the package is presented to the carrier for shipping

When more than one package is to be send with the same packing requirements, an "overpack" can be used. This is an enclosure used by a single shipper to contain one or more packages in order to form one handling unit for convenience of handling and storage. Not UN certified (no testing required). Wording 'overpack' is to be used (also 'All packed in one' exists = package that allows for dry ice including in the UN box, not frequently used as the amount of dry ice that can be included in the closed box is mostly not enough for a shipment)

IV. Marking and labelling

Labels and markings on a package are an essential source of information to communicate to all parties involved in the transportation process. It is the shippers' responsibility to mark and label the package, including an overpack if relevant, in compliance with the DGR framework.

An overview of relevant labels is provided below. The requirements apply to the transport of biological materials by air. However, with some minor variations the marking and labelling requirements also apply to shipments by road.

Hazard labels

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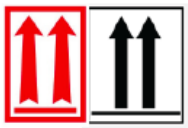
Infectious substance class 6.2	Infectious substance of CAT. A	
Biological substance of Category B		
Genetically Modified Organisms (GMO)		
Toxin, extracted from living organisms		
Miscellaneous Dangerous Goods class 9	When carbon dioxide (dry ice) is used as refrigerant	
Non-flammable, Non-toxic gas class 2	When liquefied nitrogen is used as refrigerant (in combination with package orientation label)	

Handling labels

Cargo Aircraft Only	For packages containing dangerous goods that are permitted only on cargo aircraft		NOTE: if the permitted quantity for passenger and aircraft are identical this label must not be used
Cryogenic Liquid	For packages containing liquid nitrogen		NOTE: this label is not required when a dry shipper is applied
Package orientation label	For Packages containing infectious substances and GMO in liquid form		NOTE: at least at 2 opposite sides

When the package dimensions are adequate, labels must all be located on the same side of the package near the “Proper Shipping Name” marking and close to the shipper or consignee address.

If one or more packages are packed in an overpack, all markings and labels must be repeated on the overpack, except for the UN specification marking . Moreover, the word “OVERPACK” must be indicated.

When different items (classes) of dangerous goods, requiring different hazard and handling labels, are packed in the same package, they must be affixed adjacent to each other.

V. Documentation

Shipments of dangerous goods need to be accompanied by a “dangerous goods transport document” as described in the UN Model regulations. The shipper is responsible for completing the “dangerous goods transport document”. Depending on the means of transport, a different type of document may be needed.

Air:

- Shipper’s Declaration for Dangerous Doods (DGD) (in certain cases as illustrated in the detailed transport requirements, see below)
- Airway Bill (AWB)

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples of documentation, see also Chapter 3.12 Customs / Tax - Documentation and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

Detailed transport requirements

Detailed instructions on identification, packaging, marking, labelling and documentation for different types of biological material are described in:

- Transport requirements for toxins, isolated from living organisms
- Transport requirements for infectious substances Category A
- Transport requirements for infectious substances Category B
- Transport requirements for human or animal specimen
- Transport requirements for genetically modified organisms

A live animal that has been intentionally infected and is known or suspected to contain an infectious substance cannot be transported, unless the infectious substance cannot be consigned by any other means. In the latter case, the animal can only be transported under the terms and conditions approved by the appropriate national authority.

For each of the above-mentioned categories of material, it has to be taken into account that if refrigerants such as dry ice and/or liquid nitrogen are present in the packages, also the requirements described in Transport requirements when using carbon dioxide and/or Transport requirements when using liquid nitrogen have to be fulfilled.

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Competent authorities and contact details

Service Public de Wallonie
Direction Générale Agriculture, Ressources naturelles et Environnement (DGO 3)
Avenue Prince de Liège 15
B-5100 Namur (Jambes)
Phone: +32 (0)81 33 66 60)
Email: adr.adn@spw.wallonie.be

Departement Mobiliteit en Openbare Werken
Afdeling toegepast Mobiliteitsbeleid
Graaf de Ferraris-gebouw
Koning Albert II-laan 20 bus 2
B-1000 Brussel
Phone: +32 (0)2 553 71 24
Email: via contactpunt (https://www.mow-contact.be/?url=contactpunt/index.html)

Le Service public régional de Bruxelles
Bruxelles Mobilité
Place Saint-Lazare, 2
B-1035 Bruxelles
Phone: 0800 94 001 (green number)
Email: mobilite@sprb.brussels

References

(1) 19th revision of UN Model Regulation for the Transportation of Dangerous Goods http://www.unece.org/trans/danger/publi/unrec/rev19/19files_e.html
(2) Translation to IATA Dangerous Goods Regulations (not available online) http://www.iata.org/publications/Pages/standards-manuals.aspx
(3) European agreement concerning the international carriage of dangerous goods by road
https://unece.org/transportdangerous-goods/adr-2021-files
(4) See guidelines for transport by air

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Transport requirements for toxins, isolated from living organisms

I. Classification

Toxic substances are substances of which it is known by experience or regarding which it is presumed from experiments on animals, that in relatively small quantities they are able by a single action or by action of short duration, to cause damage to human health or death. They are classified as class 6.1.

A biological material is presumed to be toxic to humans when it falls within any one of the following categories:

1. Oral Toxicity: a liquid with an LD50 for acute oral toxicity of not more than 500 mg/kg or a solid with an LD50 for acute oral toxicity of not more than 200 mg/kg.
2. Dermal Toxicity: a material with an LD50 for acute dermal toxicity of not more than 1000 mg/kg.
3. Inhalation Toxicity: a dust or mist with an LC50 for acute toxicity on inhalation of not more than 10 mg/l, or a material with a saturated vapor concentration in air at 20 °C of more than one-fifth of the LC50 for acute toxicity on inhalation of vapors and with an LC50 for acute toxicity on inhalation of vapors of not more than 5000 ml/m³

The packing group (PG) then further classifies the level of danger according to PG I, PG II or PG III. In brief:

Group	Oral toxicity LD50 (mg/kg)	Dermal toxicity LD50 (mg/kg)	Inhalation toxicity LC50 (mg/l)
I	≤ 5	≤ 40	≤ 0.5
II	≥ 5 but ≤ 50	≥ 40 but ≤ 200	≥ 0.5 but ≤ 2
III	solids: ≥ 50 but ≤ 200 liquids: ≥ 50 but ≤ 500	≥ 200 but ≤ 1000	≥ 2 but ≤ 10

This chapter will specifically address toxins, isolated from living organisms.

II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
3172	Toxins, extracted from living sources (liquid)	6.1	Poison or Toxic
3462	Toxins, extracted from living sources (solid)	6.1	Poison or Toxic

III. Packaging

Package instructions differ depending on the packing group the material is assigned to:			
UN no.	**Packing Group (PG)**	**IATA instructions**	**ADR instructions**
3172	I	PI652	P001
	II	PI654	P001
	III	PI655	P001
3462	I	PI666	P002
	II	PI669	P002
	III	PI670	P002

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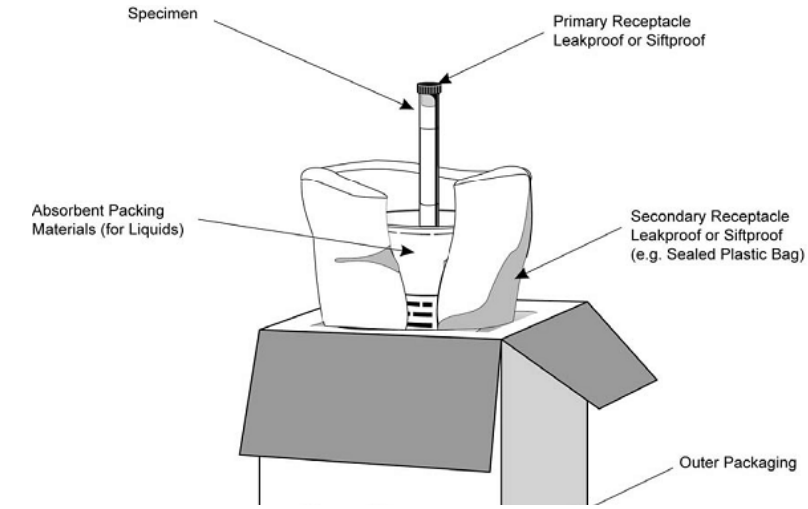
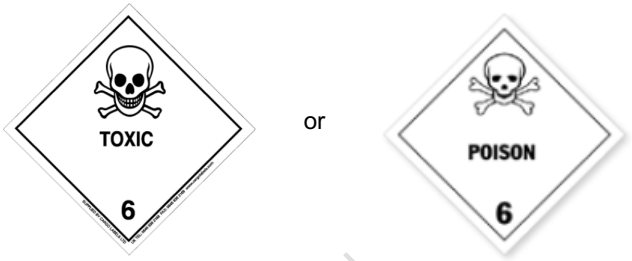


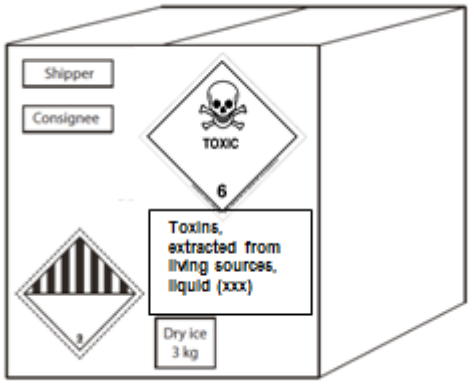
IV. Marking and labelling

Following marking and labelling is required for transport of toxic materials:

PG I (all quantities), PG II (≥ 100 ml / ≥ 500g), PG III (≥ 5 l / ≥ 5kg)

- Proper shipping name (see above) including the technical name of the toxin
- Shippers' name and address
- Receivers' name and address
- Labels:





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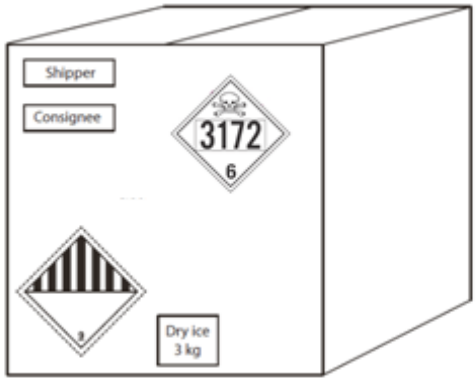
PG II (< 100 ml / < 500g), PG III (< 5 l / < 5kg)

- UN number (3172 for liquids; 3462 for solids)
- Shippers' name and address
- Receivers' name and address
- Labels:

or



V. Documentation

Following documentation is required for transport of toxins, isolated from living organisms:

Air:

- Airway Bill (AWB)

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Transport requirements for infectious substances Category A

I. Classification

Category A samples are classified in Class 6.2 - Infectious substances. Category A samples contain an infectious substance as listed in Table 3.6.D of the DGR (https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf), which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in healthy human and animals.

If your material is not listed in Table 3.6.D of the DGR, a risk assessment needs to be performed to definitely exclude it from Category A.

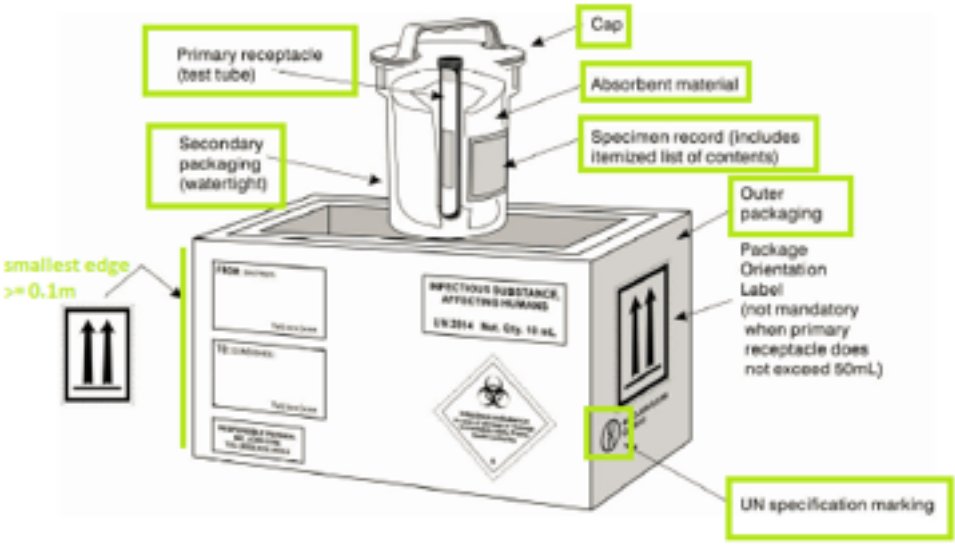
II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
2814	Infectious substance, affecting humans * (liquid)	6.2	Infectious substance
2814	Infectious substance, affecting humans * (solid)	6.2	Infectious substance
2900	Infectious substance, affecting animals * (liquid)	6.2	Infectious substance
2900	Infectious substance, affecting animals * (solid)	6.2	Infectious substance

III. Packaging

Infectious substances of Category A must be packed according to Packing Instruction PI620 (IATA) / P620 (ADR)

Please note that quantities are limited to 50 ml. This quantity limit does not apply to body parts, organs or whole bodies (exemption A81).

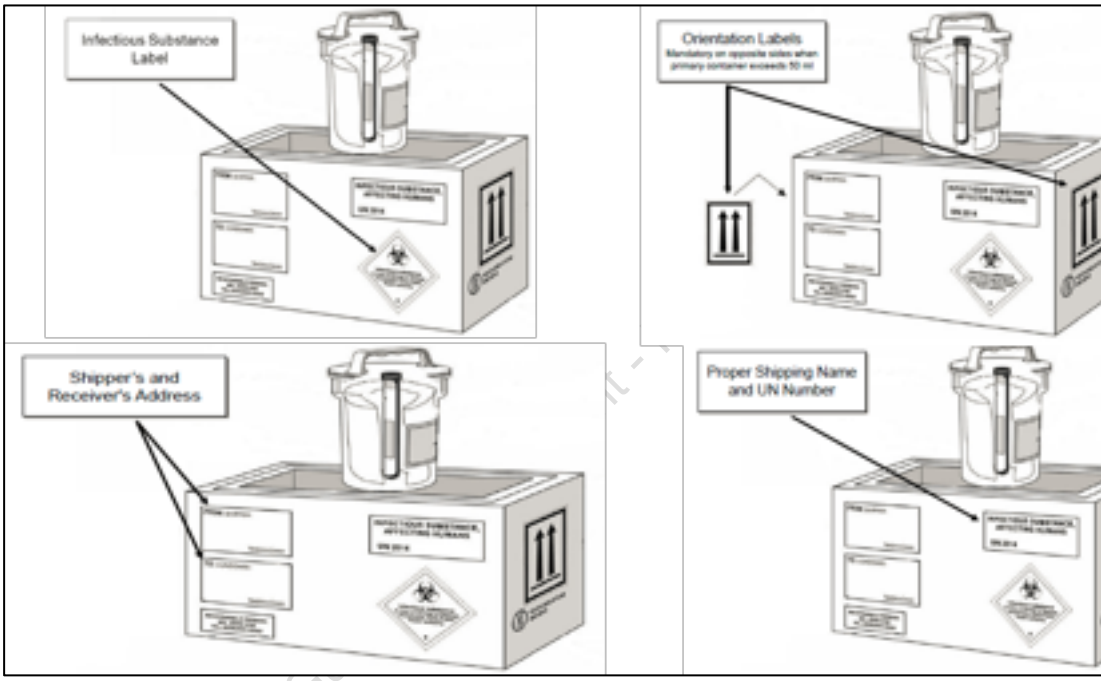


IV. Marking and labelling

Following marking and labelling is required for transport of infectious substances of Category A:

- UN number (including the letters ‘UN’), proper shipping name and NET quantity (correctly written i.e. small ‘m’ and capital ‘L’); UN and proper shipping name on the same site
- Shippers’ name, address and telephone number
- Receivers’ name, address and telephone number (on the same site as the shipper’s data)
- Name and telephone number of responsible person (who is available 24/7 until the shipment arrives)
- Labels:

(when volume exceeds 50 ml)



V. Documentation

Following documentation is required for transport of infectious substances of Category A:

Air:

- Shipper’s Declaration for Dangerous Doods (DGD) in EN, FR or ES language - amount of copies depending on number of stops
- Airway Bill (AWB)

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Transport requirements for infectious substances Category B

I. Classification

Category B samples are classified in Class 6.2 – Toxins and infectious substances. They contain an infectious substance which does not meet the criteria for inclusion in Category A.

Exemptions are:

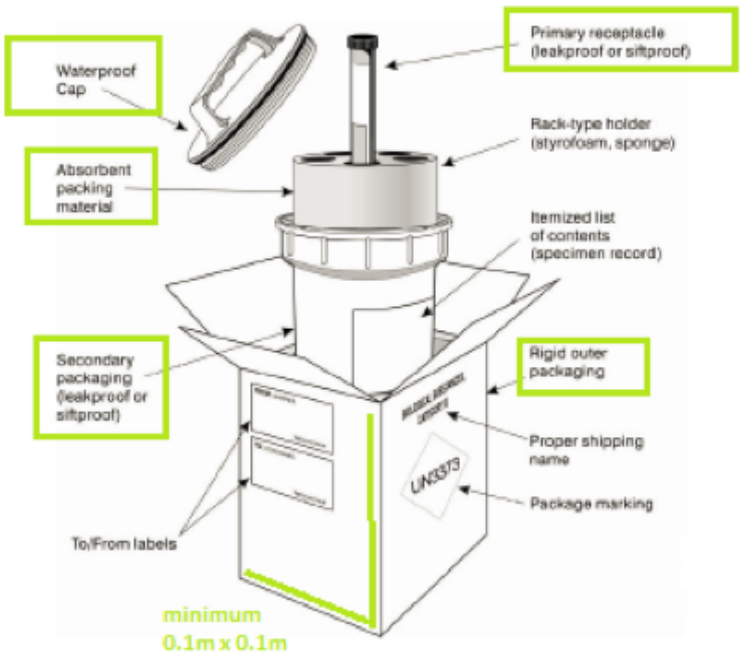
- Substances that do not contain infectious substances or that are unlikely to cause disease in humans or animals,
- Substances containing microorganisms that are non-pathogenic to humans or animals,
- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk,
- Environmental samples (including food and water samples) that are not considered to pose a significant risk of infection,
- Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests,
- Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation,
- Plant pathogens.

II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
3373	Biological substance, Category B	6.2	None

III. Packaging

Infectious substances of Category B must be packed according to Packing Instruction PI650 (IATA) / P650 (ADR)



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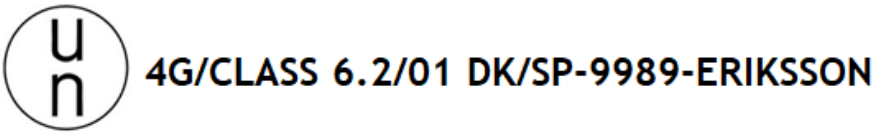
Packaging UN-specific marking: Example for marking packagings for infectious substances:



UN: United nations symbol

4G: the code designating the type of packaging (e.g. 4:box; G:fibreboard)

CLASS6.2 the text “CLASS 6.2

01 last two digits of the year of manufacture of the packaging

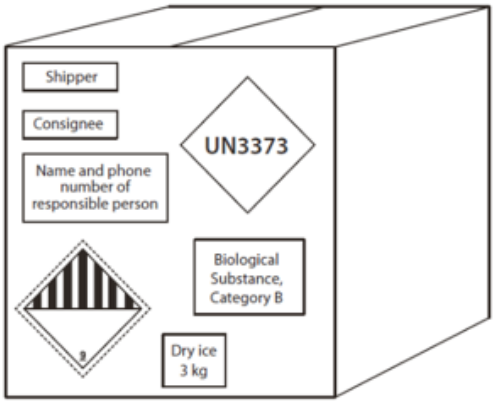
DK State authorizing allocation of the mark

SP-9989-Eriksson: the name of the manufacturer or other identification of the packaging specified by the competent authority

IV. Marking and labelling

Following marking and labelling is required for transport of infectious substances of Category B:

- UN number, proper shipping name (on the same site of the box)
- Shippers’ name and address
- Receivers’ name and address
- Name and telephone number of responsible person
- Labels:



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In case the package is too small [31] to contain all labels, details of shipper and receiver must be at one side of the package, the other required labels can be at the other side of the package.

V. Documentation

Following documentation is required for transport of infectious substances of Category B:

Air:

- Airway Bill (AWB)

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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[31] Smallest external dimension of the outer packaging must not be less than 100 mm

Transport requirements for human or animal specimen

I. Classification

Human or animal specimens are human or animal materials, collected directly from humans or animals, including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluid swabs, as well as body parts. They are being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention. If there is any reason to suspect or if it is known that the specimen contains a pathogen, it is classified in Class 6.2 – Toxins and infectious substances, class UN 2814, UN 2900 or UN 3373 as appropriate (see below). Only in case there is a minimal likelihood that pathogens are present, regulations have been amended to make certain patient specimens exempt from Dangerous Goods requirements.

II. Identification

As appropriate:

UN no.	Proper Shipping Name	Class	Hazard label
2814	Infectious substance, affecting humans * (liquid)	6.2	Infectious substance
2814	Infectious substance, affecting humans * (solid)	6.2	Infectious substance
2900	Infectious substance, affecting animals * (liquid)	6.2	Infectious substance
2900	Infectious substance, affecting animals * (solid)	6.2	Infectious substance
3373	Biological substance, Category B	6.2	None

Only in case there is a minimal likelihood that pathogens are present, regulations have been amended to make certain patient specimens exempt from Dangerous Goods requirements. These exemptions apply to both air and ground transportation. No UN number is then assigned to the materials, but the package should contain the proper shipping name: “Exempt human specimen” or “Exempt animal specimen”. In such case, the material may also be shipped by regular mail.

In determining whether a patient specimen has a minimal likelihood that pathogens are present and, consequently, is exempt from Dangerous Goods requirements, an element of professional judgment is required. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

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III. Packaging

According to their classification, patient specimen must be packed according to:

- Transport requirements for infectious substances Category A
- Transport requirements for infectious substances Category B

Only in case there is a minimal likelihood that pathogens are present (see II – Identification), packaging can be done as described in Chapter 3.11 Non-dangerous goods, including plants and plant pathogens).

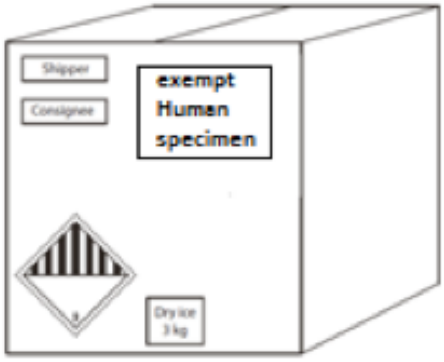
IV. Marking and labelling

According to their classification, patient specimen must be packed according to:

- Transport requirements for infectious substances Category A
- Transport requirements for infectious substances Category B

Only in case there is a minimal likelihood that pathogens are present (see II – Identification), following marking and labelling is to be used:

- Proper shipping name
- Shippers' name and address
- Receivers' name and address
- Labels: /



V. Documentation

Following documentation is required for transport of patient specimen:

Air:

- Airway Bill (AWB)
- Although no specific requirements are requested to be mentioned on the AWB, it is recommended that substances shipped under provisions for exempt human or animal specimen mention "Exempt Specimen" in the "Nature and Quantity of Goods" section.

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Transport requirements for genetically modified organisms

I. Classification

For the purpose of transport, genetically modified organisms (GMO) or microorganisms (GMMO) have been defined as microorganisms and organisms (1) in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally, and (2) capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction.

Unless they meet the definition of toxic or infectious substances, GMO / GMMO are assigned to Class 9 – Miscellaneous dangerous goods.

GMO / GMMO are not subject to ADR when authorized for use by the competent authorities of the countries of origin, transit and destination.

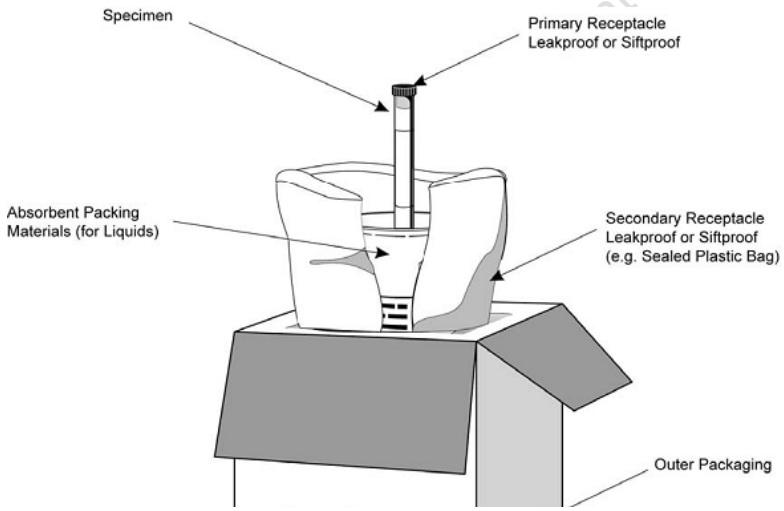
Genetically modified live animals which, in accordance with the current state of scientific knowledge, have no pathogenic effect on humans, animals and plants and are carried in receptacles that ate suitable for safely preventing both the escape of the animals and unauthorized access to them, are not subject to the provisions of ADR. The provisions specified by the IATA Live Animal Regulation can be drawn as guidelines for suitable receptacles for the transport of live animals.

II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
3245	GMO	9	None

III. Packaging

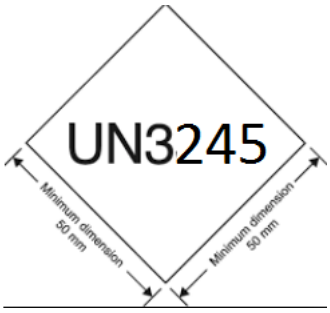
GMO / GMMO must be packed according to Packing Instruction PI959 (IATA) / P904 (ADR)



IV. Marking and labelling

Following marking and labelling is required for transport of GMO / GMMO:

- UN number
- Shippers' name and address
- Receivers' name and address
- Labels:



GMO / GMMO are not subject to any other requirements of ADR when packed and marked in accordance with packing instruction P904.

V. Documentation

Following documentation is required for transport of GMO / GMMO:

Air:

- Airway Bill (AWB)

Road:

- Convention Relative au Contrat de Transport (CMR)

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Transport requirements when using carbon dioxide (dry ice)

I. Classification

When using dry ice (CO_2) as refrigerant in a package to maintain viability, stabilizing or preventing or neutralizing the hazards of the biological substances, samples are classified in Class 9 - Miscellaneous.

II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
1845	Dry ice / carbon dioxide solid For road transport an additional descriptive text “As Coolant” must be mentioned after the proper shipping name	9	Miscellaneous

III. Packaging

Samples with dry ice as refrigerant must be packed according to Packing Instruction PI954 (or according to the ADR special provision 5.5.3). That means that the package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package.

If dry ice is used in an unpacked form, it shall not come into contact with the metal structure of a vehicle. Measures shall be taken to provide adequate insulation between the dry ice and metal containers by providing minimum 30 mm separation.

IV. Marking and labelling

Following marking and labelling is required for samples with dry ice as refrigerant:

- UN number, proper shipping name (when combined with other material (e.g. cat. B), then all UN numbers and shipping names have to be located on the same side of the package)
- For road transport an additional descriptive text “As Coolant” must be mentioned after the proper shipping name
- NET weight of the solid carbon dioxide (on the outside of each package, and total NET weight on the overpack when relevant)
- Receivers’ name, address and telephone number
- Labels:

(for road transport)

V. Documentation

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Following documentation is required when transporting dry ice:

Air:

- Airway Bill (AWB) mentioning the presence of dry ice as refrigerant

Road:

- Convention Relative au Contrat de Transport (CMR)
- Additionally, the CMR must mention UN number, proper shipping name and the addition ‘as coolant’ for road transport, number of packages and net weight of dry ice in each package in the “Nature and Quantity of Goods” section.

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Transport requirements when using liquid nitrogen

I. Classification

When using liquid nitrogen as refrigerant in a package to maintain viability, stabilizing or preventing or neutralizing the hazards of the biological substances, samples are classified in Class 2.2.

II. Identification

UN no.	Proper Shipping Name	Class	Hazard label
1977	Nitrogen, Refrigerated Liquid For road transport an additional descriptive text "As Coolant" must be mentioned after the proper shipping name	2.2	Non-flammable gas & Cryogenic liquid

III. Packaging

Samples with liquid nitrogen as refrigerant must be packed according to Packing Instruction PI202 (IATA) / P202 (ADR). That means that the primary receptacle must be in plastic capable of withstanding very low temperatures, and not in glass. Moreover, the primary receptacle must maintain its containment integrity at the temperature of the refrigerant used, as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost. The secondary receptacle must also withstand very low temperatures and, in most cases, will need to be fitted over individual primary receptacles.

It is noted that:

- When using a dry shipper system, no liquid is present and consequently the requirements described in this chapter are not applicable.

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IV. Marking and labelling

Following marking and labelling is required for samples with liquid nitrogen as refrigerant:

- UN number, proper shipping name when combined with other material (e.g. cat. B), then all UN numbers and shipping names have to be located on the same side of the package)
- For road transport an additional descriptive text "As Coolant" must be mentioned after the proper shipping name
- NET weight of the liquid nitrogen (on the outside of each package, and total NET weight on the overpack when relevant)
- Receivers' name, address and telephone number
- Labels:

(for road transport)

V. Documentation

Following documentation is required when transporting liquid nitrogen:

Air:

- Airway Bill (AWB) mentioning the presence of liquid nitrogen as refrigerant

Road:

- Convention Relative au Contrat de Transport (CMR)
- Additionally, the CMR must mention UN number, proper shipping name and the addition ‘as coolant’ for road transport, number of packages and net weight of liquid nitrogen in each package in the “Nature and Quantity of Goods” section.

For more detailed information and examples see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

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Annex I - List of dangerous goods (non-exhaustive list)

						IATA					ADR	
						Passenger and Cargo Aircraft		Cargo Aircraft only				
UN	Proper Shipping Name	Class	Hazard Label	EQ	PG	Packing INS	Max. NET QNTY / Package	Packing INS	Max. NET QNTY / Package	Special Provision	Packing INS	Special Provision
A	B	C	D	E	F	G	H	I	J	K	L	M
2814	Infectious substance, affecting humans * (Liquid)	6.2	Inf. Sub.	E0	-	PI 620	50 mL	PI 620	4 L	A84 A140	P620	318
2814	Infectious substance, affecting humans * (Solid)	6.2	Inf. Sub.	E0	-	PI 620	50 g	PI 620	4 kg	A84 A140	P620	318
2900	Infectious substance, affecting animals * (Liquid)	6.2	Inf. Sub.	E0	-	PI 620	50 mL	PI 620	4 L	A84 A140	P620	318
2900	Infectious substance, affecting animals * (Solid)	6.2	Inf. Sub.	E0	-	PI 620	50 g	PI 620	4 kg	A84 A140	P620	318
3373	Biological substance, Category B	6.2	None	E0	-	PI 650	4 kg / 4 L	PI 650	4 kg / 4 L		P650	319
3245	GMO	9	None	E0	-	PI 959	No Limit	PI 959	No Limit	A47	P904	219 637
1845	Dry ice / carbon dioxide solid	9	Misc.	E0	-	PI 954	200 kg	PI 954	200 kg	A48 A805	Not regulated	5.5.3
1977	Nitrogen, refrigerated liquid	2.2	Non-flammable gas & Cryogenic liquid	E1		PI 202	50 kg	PI 202	500 kg	A152	P202	5.5.3

Explanation of the columns

Column A	UN number
Column B	Proper Shipping Name + descriptive text (*) addition of technical name required
Column C	Class or Division of the article
Column D	Hazard label(s) to be applied to the outside of each package and overpack
Column E	Excepted quantity code from E_O-E_5 E_O = not allowed under excepted quantities
Column F	Packing Groups I, II, III
Column G	Packing instruction for the transport of the biological material on a passenger and cargo aircraft
Column H	Maximum net quantity allowed in each package except if the letter G (Gross Weight) is mentioned NOTE: It is forbidden to take biological substances in the personal luggage
Column I	Packing instruction for the transport of the biological material on a Cargo Aircraft Only (CAO)
Column J	Maximum net quantity allowed in each package for transport on a Cargo Aircraft Only (CAO) except if the letter G (Gross Weight) is mentioned
Column K	Special provisions for air transport
Column L	Packing instruction in accordance with ADR

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Column M	Special provisions for ADR (see below)

Special provisions (as referred to in Column M)

A81	The quantity limits do not apply to body parts, organs or whole bodies NOTE: Blood, urine and other body fluids are not considered “body parts” for the purposes of this special provision
A140 (ADR 318)	For the purposes of documentation, the proper shipping name must be supplemented with the technical name. Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assigned to UN 2814 or UN 2900, the words” suspected category A infectious substance” must be shown, in parentheses, following the proper shipping name on the Shipper’s Declaration for Dangerous goods, but not on the outer package.
A47 (ADR 219)	GMO packed and marked in accordance with PI 959 (ADR P904), are not subject to any requirements. If GMO meet the definition of a toxic substance or an infectious substance and the criteria for inclusion in class 6.1 or 6.2, the requirements for transporting toxic substances apply.
A48	Packaging tests are not considered necessary
A805	Notwithstanding the requirements to package UN 1845 in accordance with packaging instruction 954, Carbon Dioxide, solid (dry ice) may be placed directly within an overpack that meets the requirements of packaging instruction 954 to cool other dangerous goods. The other dangerous goods must be packed in accordance with the relevant packaging instruction.
ADR319	Substances packed and packages marked in accordance with packaging instruction P650 of ADR are not subject to any other requirement
ADR637	GMO which are not dangerous for humans and animals, but which could alter animals, plants, microbiological substances and ecosystems in such a way as cannot occur naturally. GMO are not subject to the requirements of ADR when authorized for use by the competent authorities of the country of origin, transit or destination. Live (in)vertebrate animals should not be used to carry these substances classified under this UN number unless the substance can be carried in no other way For the carriage of easily perishable substances under this UN number appropriate information shall be given. (E.g. “Cool at +4°C” or “carry in frozen state” or “Do nor freeze”)
A152	Insulated packagings, conforming to the requirements of PI 202, containing refrigerated liquid nitrogen fully absorbed in a porous material are not subject to these regulations provided the design of the insulated packaging would not allow the build-up of pressure within the container and would not permit the release of any refrigerated liquid nitrogen irrespective of the orientation of the insulated packaging. The words “not restricted” and the special provision number A152 must be provided on the air waybill.
ADR5.5.3	Packaged goods requiring cooling shall be capable of withstanding very low temperatures and shall not be affected or significantly weakened by the coolant. Packages shall be designed and constructed to permit the release of gas to prevent a build-up of pressure that could rupture the package. If dry ice is used in an unpacked form, it shall not into contact with the metal structure of a vehicle. Measure shall be taken to provide adequate insulation between the dry ice and metal container by providing minimum 30mm separation.

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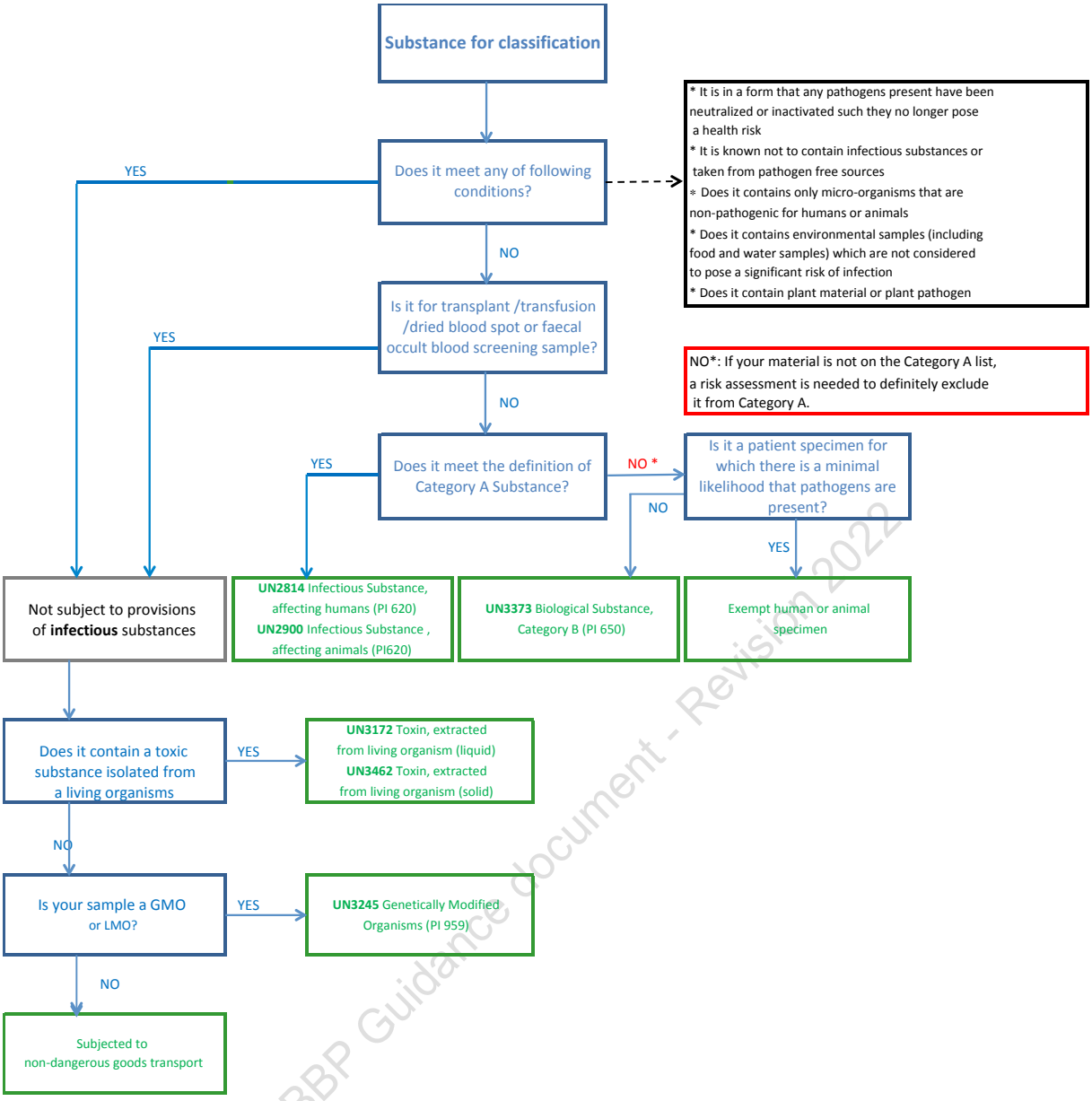
Annex II - Classification tree for dangerous goods



NOTE: In case your package also contains substances belonging to one of the other DGR classes, such as chemicals, explosive or flammable compounds, the transport must also comply with the corresponding requirements for those classes (including packaging, labelling and documentation).

3.11 Non-dangerous goods, including plants and plant pathogens

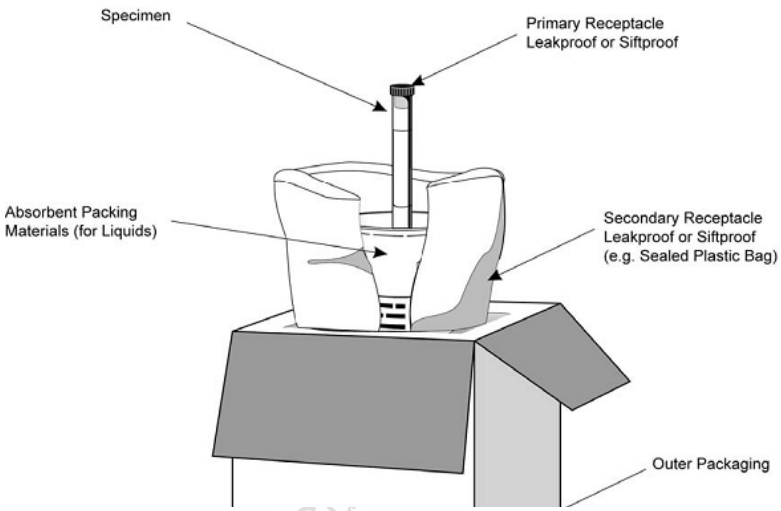
Requirements for the transport of non-dangerous goods

Non-dangerous biological goods are non-infectious biological materials and plant material, including plant pathogens, on the condition that they are not GMO/LMO. In case of doubt whether your item is a dangerous good or a non-dangerous good, please consult Annex II - Classification tree for dangerous goods.

The goal of the transport requirements for non-dangerous goods is to minimize the risks that may be associated with the transport of the goods, thereby protecting shipper, carrier, the public and the environment. The transport requirements mainly aim at a safe triple packaging of the goods. A brief overview is provided below:

Non-dangerous goods are not identified by means of a UN specification number. They must be packed in good quality packages consisting of:

- one or more specimen container(s)
- absorbent material
- protecting container
- box or mailing bag



The shipper is responsible for all aspects of the packaging of the goods, i.e. he or she has to ensure that the package is strong enough to withstand the transport, that the manufacturers' packaging instructions are followed and that the package is properly presented to the carrier for shipping.

When more than one package is to be send with the same packing requirements, an "overpack" can be used. This is an enclosure used by a single shipper to contain one or more packages in order to form one handling unit for convenience of handling and storage.

It has to be taken into account that, in case refrigerants such as dry ice and/or liquid nitrogen are present in the packages, also the requirements described in Transport requirements when using carbon dioxide and/or Transport requirements when using liquid nitrogen have to be fulfilled.

Minimal marking and labelling requirements include the receivers' name and address.

Documentation that needs to accompany the shipments of non-dangerous goods include:

Air:

- Airway Bill (AWB)

- The AWB must be completed in English and signed in triplicate by the shipper. One signed copy is to be retained by the shipper (file for a minimum of 3 months), the other two signed copies must be handed over to the carrier.

Road:

- Convention Relative au Contrat de Transport (CMR)
- The CMR must be completed in the official language of the receiving country and, if that language is not English, French or German, the CMR must also contain a description in one of these three languages.

For more detailed information and examples of documentation, see also Chapter 3.12 Customs / Tax and Chapter 3.13 Examples of links or documents relevant for movement of biological material.

Depending on the plant species / type of plant material, a phytosanitary certificate or plant passport may be required for the importation, transit and domestic movement of plant materials (see Chapter 3.9 Phytosanitary).

In case of questions or more information about the transport of non-dangerous goods, see Competent authorities and contact details for the transport of dangerous goods.

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3.12 Customs / Tax

Goal of the regulatory framework

The regulatory framework aims to list all necessary requirements, in particular documentation, needed for the custom clearance process related to customs and tax requirements.

Scope

The custom clearance and tax requirements are put in place for trade activities. However, in many countries a custom clearance process is also mandatory when biological samples are imported or exported for research purposes. The customs department is the government designated authority to implement such custom clearance policies.

Customs clearance involves:

- Preparation and submission of documents required to facilitate export from or import into the country
- Accompanying cargo during customs examination
- Assessment
- Payment of duty
- Taking delivery of cargo and related documentation from customs after clearance

Customs clearance may be facilitated by a so-called customs clearance agent or broker. This is a licensed agency or operator who is authorized to file the necessary documents on behalf of the importer and co-ordinate the clearance activity. When shipping via an airline, it is mandatory to operate via a licensed and authorized broker [32].

The main aim of this instruction card is to provide an overview of the minimum required documentation that needs to be presented during border control. The information is based on EU [(1)(2)(3)] and national [(4)(5)] legislation.

General requirements

In order to determine which requirements are applicable for a certain cargo in terms of custom clearance and tax assessment, goods have to be classified. Classification is done based on international classification systems. Classification subsequently determines a range of documentation requirements.

Moreover, any individual legal identity (i.e. sole trader, partnership, company or individual) needs an Economic Operator Registration and Identification (EORI) number. The number is assigned by a local Member State. It will be used to identify the shipments across all EU countries [33].

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I. Classification

For classification of cargo, a Harmonized Commodity Description and Coding System, also known as the Harmonized System (HS) has been set up. It is an internationally standardized system of names and numbers (6-digit HS codes, www.hscode.org) to classify traded products and to ensure their uniform classification. Worldwide, almost all countries use HS codes to determine tariff classification and corresponding duty rates. The Harmonized System is maintained by the World Customs Organization (WCO, www.wcoomd.org, http://www.tariffnumber.com). The international HS codes is extended by an additional and country-specific 4 numbers.

[32] Most of the courier companies are authorized, but it is recommended to be check prior to each transport

[33] The EORI number is a unique operator identification number that is valid and recognized by customs throughout the European Union (https://financien.belgium.be/nl/douane_accijnzen/ondernemingen/financi%C3%ABn-eori/eori (NL), https://finances.belgium.be/fr/douanes_accises/entreprises/finances-eori/eori (FR))

In order to facilitate the customs clearance process for biological materials for research purposes, the HS code has to be indicated on the accompanying documentation during transport, together with the statement that the 'declared value' of the material has 'no commercial value'.

Except HS codes, also Tariff Codes are used. Tariff codes are product-specific codes which are also maintained by the WCO. Tariff codes exist for almost every product involved in global commerce. A complete tariff code is no less than six digits and can be up to ten (i.e. HS code with further subdivisions, http://www.tariffnumber.com). The more digits in a tariff code string, the more specific the identification of the product it relates to.

When goods are declared to customs in the European Union, the goods must additionally be classified according to the Combined Nomenclature (CN) as described in the Combined Nomenclature Regulation (1). The CN is comprised of the Harmonized System (HS) nomenclature with further Community subdivisions. Each CN subdivision has an eight-digit code number, the CN code, followed by a description [34]. The first six digits refer to the HS-headings, the following two digits represent the CN subheadings [35]. A search tool is available on the Access2Markets website from the European Commission DG Trade: https://trade.ec.europa.eu/access-to-markets/en/home.

II. Documentation

Classification subsequently determines the type of documentation needed for customs clearance and tax assessment. Below, an overview is provided of the most relevant documents. Examples of the documents are presented in Chapter 3.13 Examples of links or documents relevant for movement of biological material.

Commercial invoice

The commercial invoice is a record or evidence of the transaction between the exporter and the importer. Once the goods are available, the exporter issues a commercial invoice to the importer in order to charge him / her for the goods. The commercial invoice is always required for customs clearance.

Although some entries specific to the export-import trade are added, it is similar to an ordinary sales invoice. The minimum data generally included are the following:

- Contact details for exporter and importer (name and address)
- Date of issue
- Invoice number
- Description of the goods (name, quality, etc.)
- Species name(s): scientific and common name e.g. *Brassica napus*, oilseed
- Clear description of the samples: e.g. Dried leaf samples, liquid DNA, lyophilized DNA, viable seed ("sample" is not sufficient)
- Quantity of goods and Unit of measure: e.g. xx mg, ml, kg, units etc. (Note: when working with units, clarify what a unit is e.g. 1 unit = 1 eppendorf tube containing 2 leaf discs)
- Unit value (e.g. X EUR/unit or X EUR/kg)
- Total item value
- "Intended use" of the samples: e.g. for laboratory use, for tissue culture growth, …

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[34] An updated version of the Annex I to the Combined Nomenclature Regulation (1) is published as a Commission Regulation every year in the L-series of the Official Journal of the European Communities (as well as on CD-ROM). Such updates take into account any changes that have been agreed at international level, as well as other changes that may be required to reflect the evolution of e.g. commercial policy, technology or statistical requirements. Imported and exported goods have to be declared stating under which subheading of the nomenclature they fall.

[35] Example: HS Chapter 18 - Cocoa and Cocoa Preparations (2 digits), HS Heading 1806 - Chocolate and other food preparations containing cocoa (4 digits), HS Subheading 1806 10 - Cocoa powder, containing added sugar or sweetening matter (6 digits), CN Subheading 1806 10 15 - Cocoa powder containing no sucrose or less than 5% by weight of sucrose (8 digits)

- In case of research samples, clearly mention “SAMPLES FOR RESEARCH PURPOSE ONLY, NOT FOR SALE, NOT FOR FOOD” that import is not for commercial purposes. If only ‘samples’ are mentioned, the shipment may be considered a commercial transaction and a C30 document [36] can be asked to confirm correct pricing of the imported goods. Also note that under specific conditions, samples for resaerch purposes can be exempted from import duties and VAT[37].
- Total invoice value and currency of payment – Note: this needs to match the sum of the different total item values.**The total invoice value can never be 0 euro**[38].
- The terms of payment (method and date of payment, discounts, etc.)
- The terms of delivery according to the appropriate Incoterm [39]
- Means of transport
- HS, GN Code or tarrif code

A full and clear description of the material to be shipped is key for a swift treatment by customs. A correct HS, GN or tarrif code on the invoice allows customs to decide, on a technical basis, whether the shipment must be inspected by customs or not.

No specific format is required. The commercial invoice is to be prepared by the exporter according to standard business practice [40] and it must be submitted as an original, along with at least one copy. In general, there is no need for the invoice to be signed. However, in practice both the original and the copy of the commercial invoice are often signed. The commercial invoice may be prepared in any language. However, a translation into English is recommended. Each invoice needs to have a unique number, related to a single shipment.

Proforma invoice / Export invoice

A proforma invoice or export invoice shows a description of the goods to be sold, their quantity and price (**the invoice value cannot be 0 euro**). In contrast to the commercial invoice, it is not a VAT invoice and cannot be used to reclaim VAT. Consequently, the proforma or export invoice does not form part of the accounting records.

No specific format is required. The invoice is to be prepared by the exporter and it must be submitted in the original, along with at least one copy. In general, there is no need for the invoice to be signed. However, in practice both the original and the copy of the Proforma or Export invoice are often signed. The invoice may be prepared in any language. However, a translation into English is recommended.

Road Waybill (CMR)

The Road Waybill or CMR is a document containing the details of the international transportation of goods by road [(6)]. It enables the consignor to have the goods at his disposal during transportation by road. It must be issued in quadruplicate and signed by the consignor and the carrier. A first copy is intended for the consignor, the second remains in the possession of the carrier. A third copy accompanies the goods and is delivered to the consignee. The fourth copy must be signed and

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[36] A C30 document can be issued via da.toelatingen.vilvoorde@minfin.fed.be

[37] Circulaire 2020/C/147 betreffende de Definitieve Vrijstellingen – Goederen die worden ingevoerd met het oog op onderzoek, analysen of proefnemingen / Circulaire 2020/C/147 concernant les franchises définitives - Marchandises importées pour examens, analyses ou essais (https://eservices.minfin.fgov.be/myminfin-web/pages/public/fisconet/search/nl/37b80465-e7a9-4fde-8870-d5f88036ef56)

[38] For value estimation, see: The USDA Economic Research Service: http://www.ers.usda.gov/data-products/commodity-costs-and-returns.aspx (information on dollars per planted acre, yield, and price), or the Global Economy Database (Global Economy.com) (provides data for 200 countries and is updated yearly; the average commodity prices are provided over a period of time as well as on a monthly basis).

[39] Incoterms® rules - ICC - International Chamber of Commerce: https://iccwbo.org/resources-for-business/incoterms-rules/

[40] The original invoice, as well as the other transport documents described in this chapter, are subject to the VAT regulation and have to be archived for 7 years.

stamped by the consignee and then returned to the consignor. Usually, a CMR is issued for each vehicle.

The CMR is not a document of title [41] and is non-negotiable. It must be completed in the official language of the receiving country and, if that language is not English, French or German, the CMR must also contain a description in one of these three languages.

Air Waybill (AWB)

The Air Waybill or AWB is a freight bill which serves as a proof of the transport contract between the consignor and the carrier's company during carriage of goods by air. It is issued by the carrier and falls under the provisions of the Warsaw Convention (7) and the Montreal Convention (8). A single AWB may be used for multiple shipments of goods. It consists of three originals and several extra copies. A first original is intended for the consignor, the second remains in the possession of the carrier. A third copy accompanies the goods and is delivered to the consignee. The additional copies may be required at the airport of departure or destination, for the delivery and/or in some cases, for further freight carriers.

The AWB must be completed in the official language of the receiving country and, if that language is not English, French or German, the AWB must also contain a description in one of these three languages.

When shipping research samples, it is important to specify the storage conditions of the samples under 'handling information'.

A specific type of AWB, called the IATA Standard Air Waybill, is used by all carriers belonging to the International Air Transport Association (IATA). It embodies standard conditions associated with those set out in the Warsaw and Montreal Conventions.

Rail Waybill (CIM)

The Rail Waybill or CIM is a document serving as a proof of the transport contract between the consignor and the carrier's company during carriage of goods by rail (9). The CIM is issued by the carrier in five copies. The first and original document accompanies the goods, the second is kept by the consignor. The three remaining copies are kept by the carrier for internal purposes.

The CIM must be completed in the official language of the receiving country and, if that language is not English, French or German, the CIM must also contain a description in one of these three languages .

Bill of Lading (B/L)

A Bill of Lading or B/L is a document serving as a proof of the transport contract between the consignor and the carrier's company during carriage of goods by waterway. The B/L is described in a number of regulations (10) (11).

The B/L is issued by the agent of a sea carrier. It provides written evidence regarding receipt of the goods, the conditions on which transportation is made, and the engagement to deliver the goods at the prescribed port of destination to the lawful holder of the bill of lading. As such, it is also a receipt for merchandise. The B/L is signed in fourfold by the captain, the agent, or the owner of a vessel.

Packing list (P/L)

The packing list or P/L is an inventory of the incoming cargo. It generally includes the following:

- Contact details of exporter, importer and transport company

[41] Formal commercial document (such as bill of sale, certificate of title, title deed) or shipping document (such as a bill of lading, dock receipt, warehouse receipt) that confers and/or proves ownership. A document of title enables its holder (possessor) to receive, retain, sell, or otherwise dispose of the document and the goods or property listed therein.

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- Date of issue
- Number of commercial or proforma/export invoice
- Type of packaging (drum, crate, carton, box, barrel, bag, etc.)
- Number of packages
- Content of each package (description of the goods and number of items per package)
- Net weight, gross weight and measurement of the packages

The list is used by the shipper or forwarding agent to determine the total shipment weight and volume, as well as to determine whether the correct cargo is being shipped. In addition, local and/or foreign customs may use the list to check the cargo.

Packing lists come in fairly standard forms and can be obtained from the freight forwarder. No specific format is required. It is not uncommon that the P/L is combined with the commercial or proforma invoice. In that case it is called "(Commercial) Invoice/Packing List" and simply contains more packing information than normally required [42].

In general, there is no need for the P/L to be signed. However, in practice, both the original and the copy of the packing list are often signed. The packing list may be prepared in any language, although a translation into English is recommended The packing list has to be attached to the outside of a package in a waterproof envelope or plastic sheath marked "Packing list enclosed".

Certificate of Origin (CoO)

The Certificate of Origin or CoO is a document stating the country from where the product originates. It is an international trade document attesting that goods in a particular export shipment are wholly obtained, produced, manufactured or processed in a particular country.

CoOs are needed when customers or the customs authorities of the importing country [43] explicitly ask for them. The CoO is to be applied for at the responsible Chamber of Commerce within the region where the exporter has his registered office (online application via https://www.digichambers.be/logon2.aspx).

The main type of CoOs issued are the co-called “Non-Preferential CoOs” or “Ordinary CoOs”. These certify that the country of origin of a particular product does not qualify for any preferential treatment. An EUR1 document, also known as a "Preferential CoO", “Movement Certificate” or EUR-MED document, on the other hand, enables importers in certain countries, who have specific trade agreements with the EU, to import goods at a reduced or nil rate of import duty. The EUR1 certificate is delivered by the Customs authorities (Preferentiële oorsprong | FOD Economie (fgov.be) or Origine préférentielle | SPF Economie (fgov.be)).

Import into the European Union

When importing biological materials for research purposes into the European Union, either by air, ship, road or multi modal transport, the cargo to be imported is to be deposited by the courier company, transportation agency or the freight forwarder into the customs designated bonded warehouse [44] for customs clearance.

For Custom Clearance, following documentation is minimally required:

- Commercial invoice or Proforma invoice of supplier
- Packing List

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[42] A combined invoice/packing list makes sense as the (commercial) invoice already contains most of the packing and packaging information. By adding some additional details to the invoice, it can equal the P/L.

[43] It is the importing country that determines if a CoO is required, irrespective of the commercial value. Within the EU, a CoO is required only when the commercial value is more than 6000 €. If the value of the material is less than 6000 €, the CoO is not required, expect if the material is supposed to be re-exported to a non-EU country. CoOs are also required by customs in the importing country to determine tariff rates.

[44] A customs bonded warehouse is a sealed storage area where imported goods are stored under customs supervision.

- Bill of Lading (transport via waterway), Air Waybill (transport by air), or CMR (transport by road)
- Certificate of Origin / EUR1
- License, permit or authorization to import (depending on the type of material to be imported)
- Export permit (depending on the type of material to be imported)

Other types of documentation may be specified e.g. by the buyer, by the courier, by financial institutions, by legal contract terms, or as per importing country regulations. Please contact the competent authorities for more details.

As of 1 July 2021, the VAT de minimis threshold of 22 EUR is no longer be applied and VAT is being charged on all goods entering the EU. The result is that any shipment entering the EU needs to pass Customs, where, based on the description of the good and the GN (also known as HS code) code, the assessment is made if additional controls and/or inspections are needed, and goods are sent to the inspecting authority, prior to any further clearance action. If you want to consult which additional controls and/or inspections are needed for a specific GN code, you can check this upfront in the TARBEL Tariff Browser[45]. Give in the (first part of) GN code and click on 'Browse Nomenclature tree'. In there, select the commodity you're interested in, and on the next page, you'll be able to consult the non-tariff and tariff measures, as well as taxes applicable on the commodity. The details of the conditions can be seen when clicking on the letter 'C'.

Export from the European Union

When exporting biological materials for research purposes, documentation as described for import is minimally required. However, requirements may vary depending on the importing country. Please check with the contacts at the importing country in order to verify or contact the Belgian competent authorities.

Transactions within the European Union

When transporting material within the European Union, at least an invoice (commercial or proforma), a packing list and, depending on the mode of transport, a CMR, AWB or CIM are required. Other types of documentation may be asked for, as mentioned above in the chapter 'Import'.

Transport requirements

The main requirements for customs clearance and tax assessment relate to documentation, as described above. However, since the tax and customs regulation is applicable to a wide variety of materials, it is additionally referred to packaging, labelling and documentation instructions described in the card(s) relevant for the type of specimen and/ or to the Instruction Card Dangerous goods.

Competent authorities and contact details

Certificate of Origin
Federation of Belgian Chambers of Commerce 46
Belliardstraat 2 – 7th Floor
B-1040 Brussels
Belgium
Website: https://www.digichambers.be/en/Home

EUR.1 Certificate
FOD Financiën
Centrale Administratie der douane en accijnzen

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[45] https://eservices.minfin.fgov.be/extTariffBrowser/Browser?lang=EN

[46] In most EU countries (incl. Belgium), the Chambers of Commerce are the key agent in the delivery of certificates of origin. The Chambers of Commerce are authorized by the Federal Ministry of Economy. In some countries, this privilege may also be extended to other bodies such as Ministries or Customs Authorities.

Dienst douaneprocedures (Directie 9)
North Galaxy - Toren A - 21e verdieping
Koning Albert II-laan 33, bus 37
1030 Brussel
Belgium
Email: info.douane@minfin.fed.be

References

(1) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff

(2) EU Tax legislation via: http://ec.europa.eu/taxation_customs/common/legislation/legislation/taxation/index_en.htm

(3) EU Customs legislation via: http://ec.europa.eu/taxation_customs/common/legislation/legislation/customs/index_en.htm

(4) Koninklijk Besluit van 30 maart 1936 houdende reglementering van de afgifte van oorsprongsattesten (BS 07.04.1936)

(5) Ministerieel Besluit van 14 september 2000 tot uitvoering van het Koninklijk Besluit van 30 maart 1936 houdende reglementering van de afgifte van oorsprongsattesten

(6) Convention on the Contract for the International Carriage of Goods by Road (CMR), https://treaties.un.org/doc/Treaties/1961/07/19610702%2001-56%20AM/Ch_XI_B_11.pdf

(7) Convention for the Unification of Certain Rules relating to International Carriage by Air, 12 October 1929

(8) Convention for the Unification of Certain Rules for International Carriage by Air, opened for Signature at Montreal on 28 May 1999, http://www.iata.org/policy/Documents/MC99_en.pdf

(9) Convention concerning International Carriage by Rail (COTIF), http://www.cit-rail.org/en/rail-transport-law/cotif/

(10) Wet van 13 juni 2014 tot uitvoering en controle van de toepassing van het Verdrag betreffende maritieme arbeid 2006

(11) International Convention for the Unification of Certain Rules of Law relating to Bills of Lading ("Hague Rules"), and Protocol of Signature, Brussels, 25 August 1924

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3.13 Examples of links or documents relevant for movement of biological material

All links and documents provided below are **examples** that may be relevant for your movement. BBP is not responsible for any regulatory compliance issues resulting from either the correct or the incorrect application of example documents.

3.13.1 Overview of relevant links and documents

CH	Legislation		NL	FR
1	GMO/LMO	Contained use permit application	https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-flemish-region (Flanders)	https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-wallonia (Wallonia) https://www.biosafety.be/content/contained-use-gmos-andor-pathogens-notification-procedure-brussels-capital-region (Brussels Capital Region)
1	GMO/LMO	Deliberate release permit application	Koninklijk besluit van 21 februari 2005 tot reglementering van de doelbewuste introductie in het leefmilieu evenals van het in de handel brengen van genetisch gemodificeerde organismen of van producten die er bevatten (Annex II)	Arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant (Annex II)
2	Biobanking	Obligation to register all human body material in a notified Belgian Biobank (list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf)	Wet van 19 december 2008 inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek. Koninklijk besluit van 9 januari betreffende de biobanken. Compendium Biobanken (https://www.afmps.be/sites/default/files/content/compendium_20072018.pdf)	La loi du 19 décembre 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique. Arrêté royal du 9 janvier 2018 relatif aux biobanques. Compendium Biobanques (https://www.afmps.be/sites/default/files/content/compendium_20072018.pdf
3	CITES	Permit application forms, certificates	http://www.health.belgium.be/nl/dieren-en-planten/dieren/wat-cites	http://www.health.belgium.be/fr/animaux-et-vegetaux/animaux/quest-ce-que-la-cites

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CH	Legislation		NL	FR
4	ABP (R&D)	Application form to obtain a registration to work with ABP for R&D	http://www.health.belgium.be/nl/aanvraagformulier-voor-een-registratie-een-erkenning-door-de-fod-volksgezondheid-toepassing-van	http://www.health.belgium.be/fr/formulaire-de-demande-denregistrement-ou-dagrement-par-le-spf-sante-publique-en-application-du
4	ABP (R&D)	Application form for import (animal by-products)	http://www.favv-afsca.fgov.be/dierlijkebijproducten/documentatie/_documents/2011-04-22_instructieinvoermonstersonderzoekendiagnose_NL_ext1.pdf	http://www.afsca.be/productionvegetale/circulaires/_documents/2011-04-22_instructieinvoermonstersonderzoekendiagnose_FR_ext1.pdf
4	ABP (R&D)	Commercial document	https://www.favv-afsca.be/plantaardigeproductie/omzendbrieven/_documents/2019-04-05_aanvraagformulierNL.pdf	https://www.favv-afsca.be/productionvegetale/circulaires/_documents/2019-04-05_aanvraagformulierFR.pdf
5	Quarantine animal pest and diseases	Application form for import (products of animal origin)	http://www.afsca.be/exportderdelanden/omzendbrieven/_documents/973640_JVS_invoermachtiging_NL_bijlage_2B.pdf	
6	Live animals	Application form to obtain an authorization to work with vertebrate animals	Koninklijk besluit van 29 mei 2013 betreffende de bescherming van proefdieren (http://www.ejustice.just.fgov.be/doc/rech_n.htm) https://www.vlaanderen.be/natuur-en-milieu/dieren-en-dierenwelzijn/proefdieren (Flanders)	Arrêté royal de 29 mai 2013 relatif à la protection des animaux d'expérience (http://www.ejustice.just.fgov.be/doc/rech_n.htm) https://leefmilieu.brussels/themas/dierenwelzijn/dier proeven-een-strikt-omlijnde-praktijk (Brussels Capital Region)
6	Live animals	Common Health Entry Document (CHED-A)	Intro - CHED-A (europa.eu)	
6	Live animals	Official veterinary certificate	Depending on the country of origin (for requirements, see Commission Regulation (EU) No 206/2010, http://eur-lex.europa.eu/eli/reg/2010/206/oj	
6	Live animals	Application form for import (live animals)	http://www.favv.be/exportderdelanden/omzendbrieven/_documents/973640_JVS_invoermachtiging_NL_bijlage_2A.pdf	http://www.afsca.be/exportationpaystiers/circulaires/_documents/973640_JVS_autorisations_import_FR_ext_2A.pdf
7	Nagoya	/	https://www.health.belgium.be/en/animals-and-plants/biodiversity/genetic-resources/nagoya-protocol	
8	Dual use	Permits and certificates	https://www.fdfa.be/nl/digitaal-loket (Flanders)	http://economie.wallonie.be/Licences_armes/2U/Types_licences.html (Walloon)

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CH	Legislation		NL	FR
9	Phytosanitary	Forms, certificates	http://www.favv.be/exportderdelanden/planten/	http://www.favv.be/exportationpaystiers/vegetaux/
10	Dangerous goods	DGD	Shipper declaration for dangerous goods	
11	Non-dangerous goods	/	/	
12	Tax and customs	Commercial invoice	Commercial invoice	
12	Tax and customs	Proforma invoice	Proforma invoice	
12	Tax and customs	CMR	Road Waybill (CMR)	
12	Tax and customs	AWB	Air Waybill (AWB)	
12	Tax and customs	CIM	Rail Waybill (CIM)	
12	Tax and customs	B/L	Bill of Lading (B/L)	
12	Tax and customs	P/L	Packing list (P/L)	
12	Tax and customs	CoO	Non-Preferential Certificate of Origin (CoO)	
12	Tax and customs	EUR1	EUR1 document	

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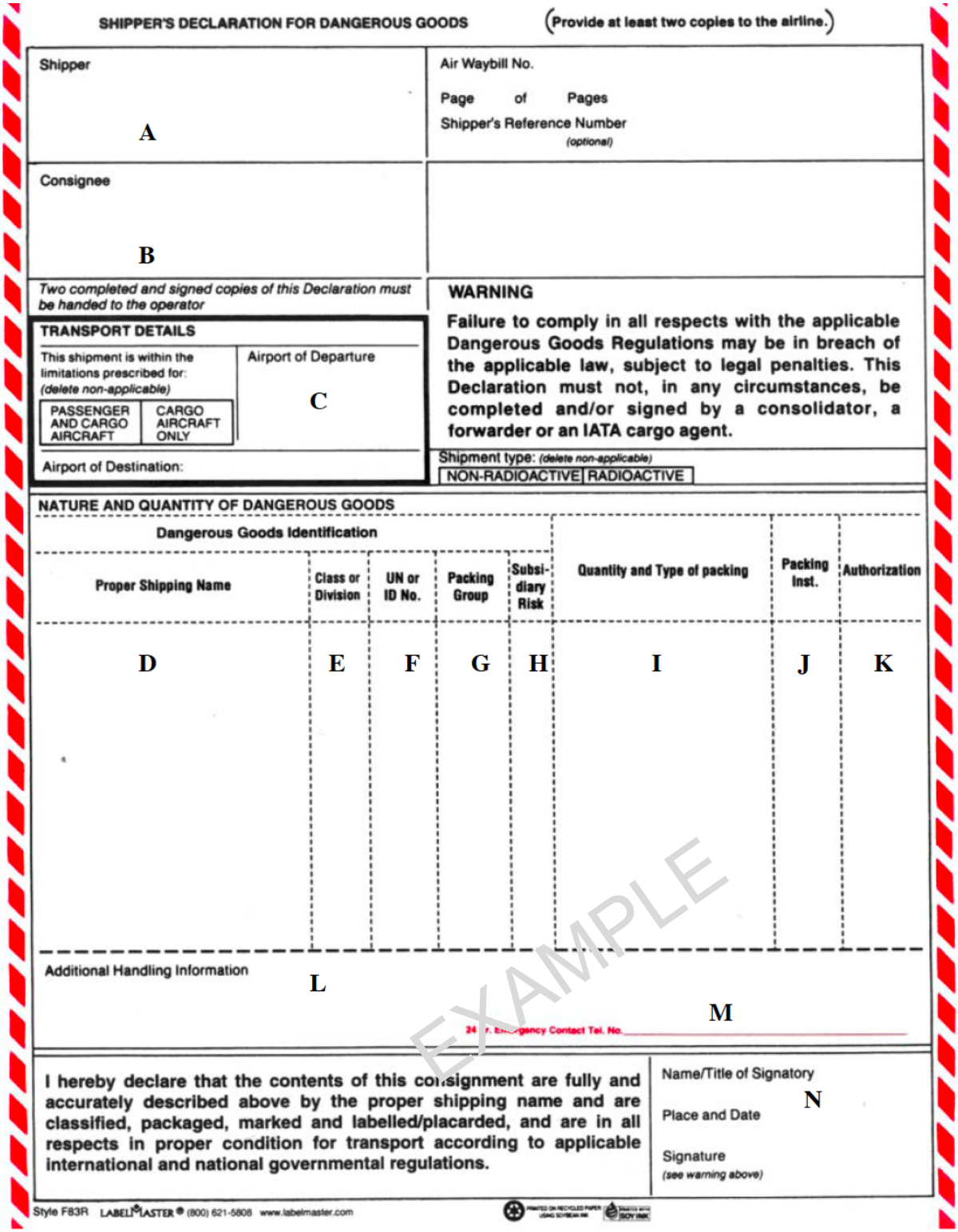
3.13.2 Shipper declaration for dangerous goods



SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline.)

Shipper

A

Air Waybill No.

Page of Pages

Shipper's Reference Number *(optional)*

Consignee

B

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*

PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure

C

Airport of Destination:

Shipment type: *(delete non-applicable)*

NON-RADIOACTIVE | RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
D	E	F	G	H	I	J	K

Additional Handling Information

L

M

24 hr. Emergency Contact Tel. No.

EXAMPLE

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory

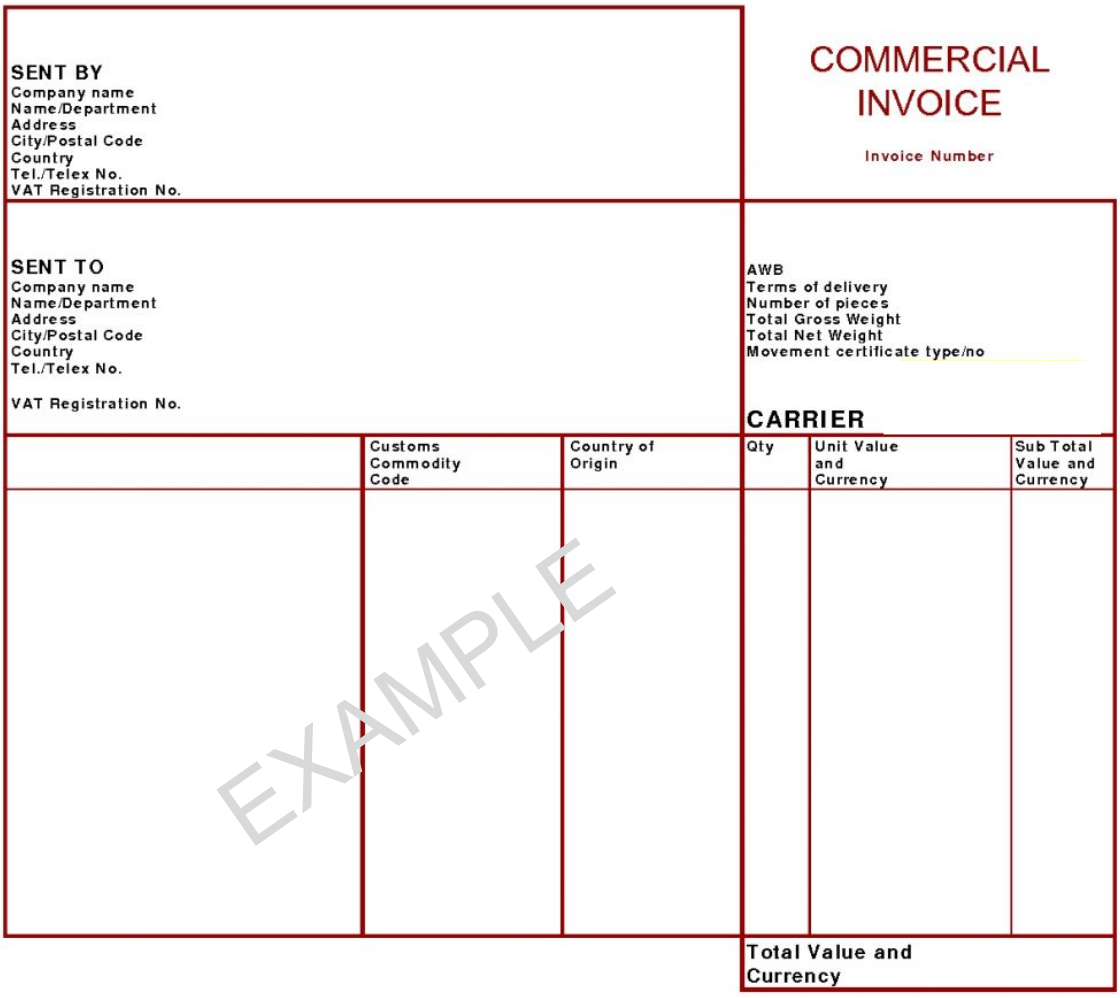
N

Place and Date

Signature *(see warning above)*

Style F83R LABELMASTER® (800) 621-5808 www.labelmaster.com

3.13.3 Commercial invoice



SENT BY
Company name
Name/Department
Address
City/Postal Code
Country
Tel./Telex No.
VAT Registration No.

COMMERCIAL INVOICE

Invoice Number

SENT TO
Company name
Name/Department
Address
City/Postal Code
Country
Tel./Telex No.

VAT Registration No.

AWB
Terms of delivery
Number of pieces
Total Gross Weight
Total Net Weight
Movement certificate type/no

CARRIER

	Customs Commodity Code	Country of Origin	Qty	Unit Value and Currency	Sub Total Value and Currency

EXAMPLE

Total Value and Currency

REASON FOR EXPORT

I declare that the above information is true and correct to the best of my knowledge
Date

Signature _____
Name

The exporter of the products covered by this document declares that, except where otherwise clearly indicated, these products are of preferential origin and the country of origin of the goods is

Place and date
Signature _____

3.13.4 Proforma invoice

SENT BY	PROFORMA INVOICE
Copmany Name	
Address	
City	Invoice Number
Postal Code	
Country	AWB Number
Tel	
VAT Registraton No	

SENT TO	
Company Name	Terms of delivery: DDU
Address	Number of pieces: 1
City	Total Gross Weight:
Postal Code	Total Net Weight:
Country	
Tel / E-mail	CARRIER
VAT Registration No	

Material Descriptions	Customs Commodity Code	Country of Origin	QTY	Unit Value $	Sub Total$
					0
			Total Value $	0	

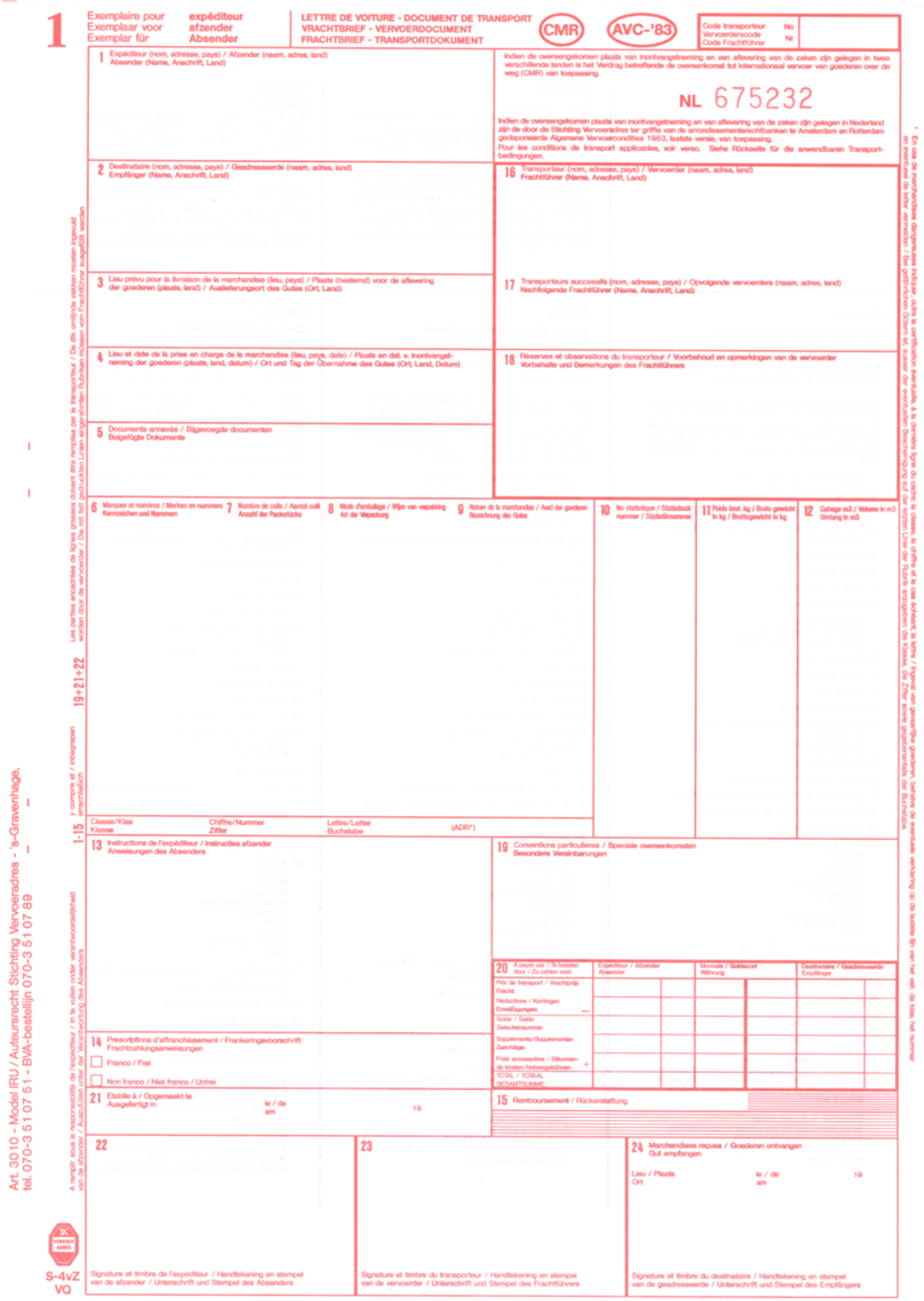
EXAMPLE

REASON FOR EXPORT:

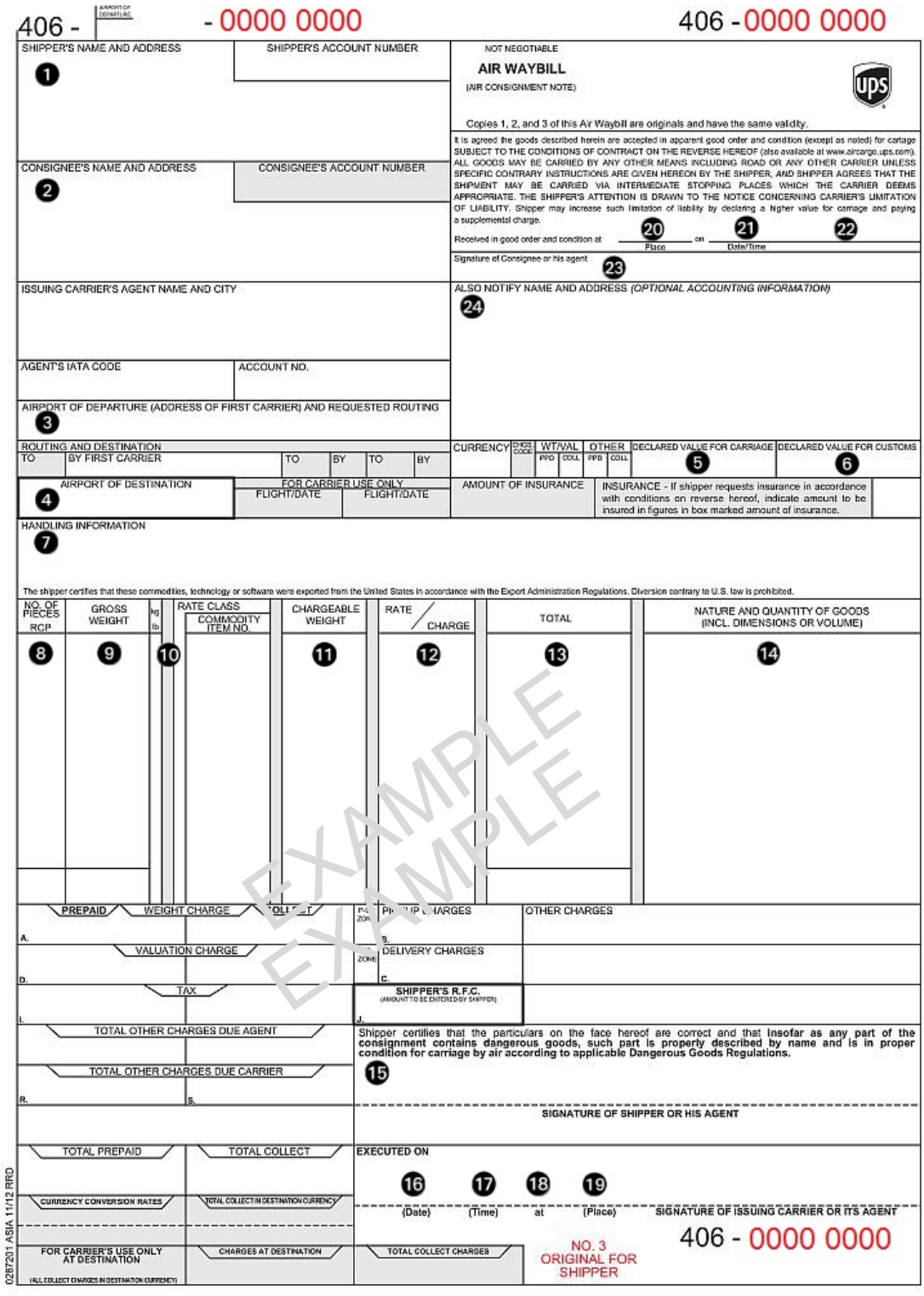
I declare that the above information is true and correct to the best of my knowledge.

Name:	Signature	Date

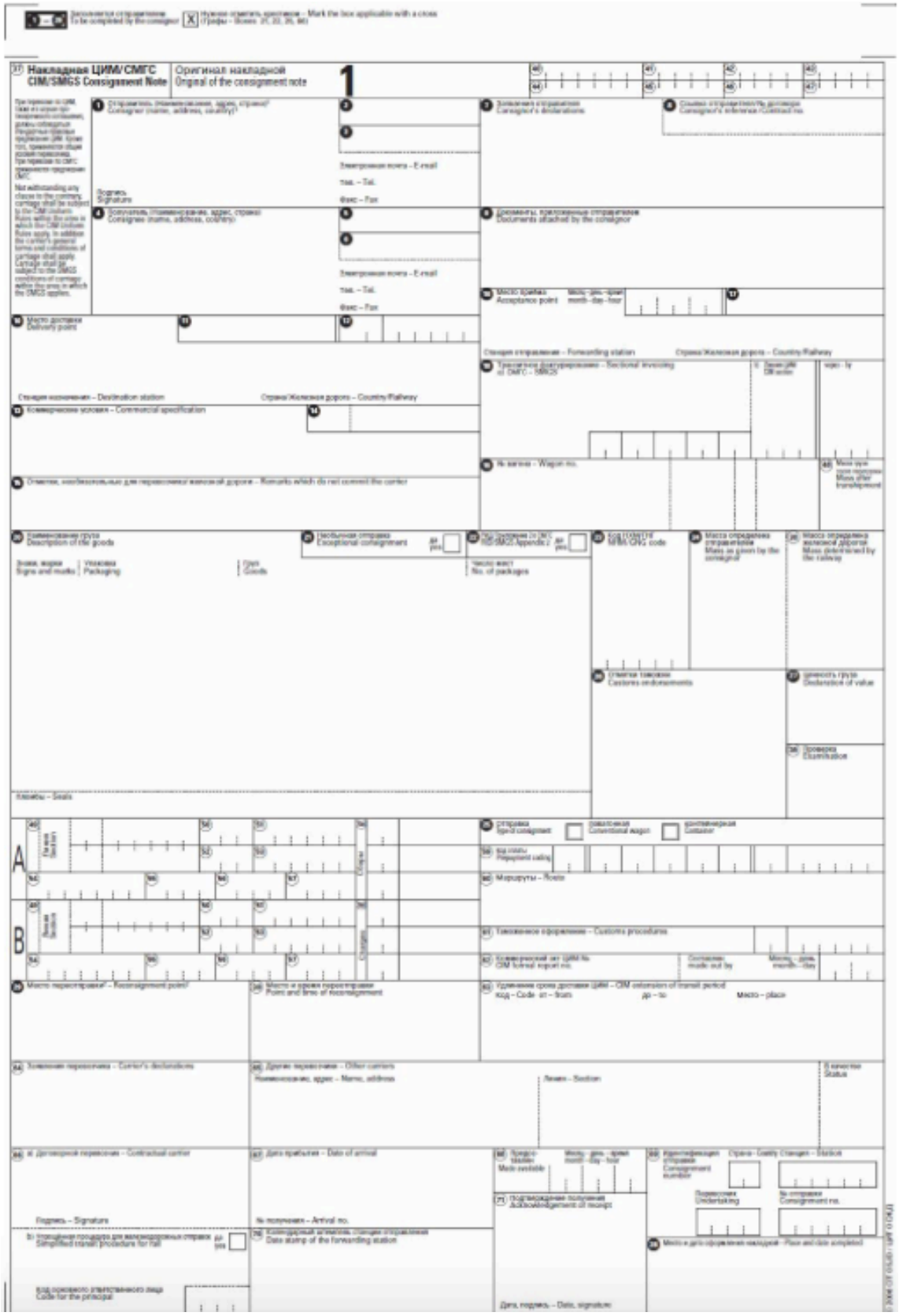
3.13.5 Road Waybill (CMR)



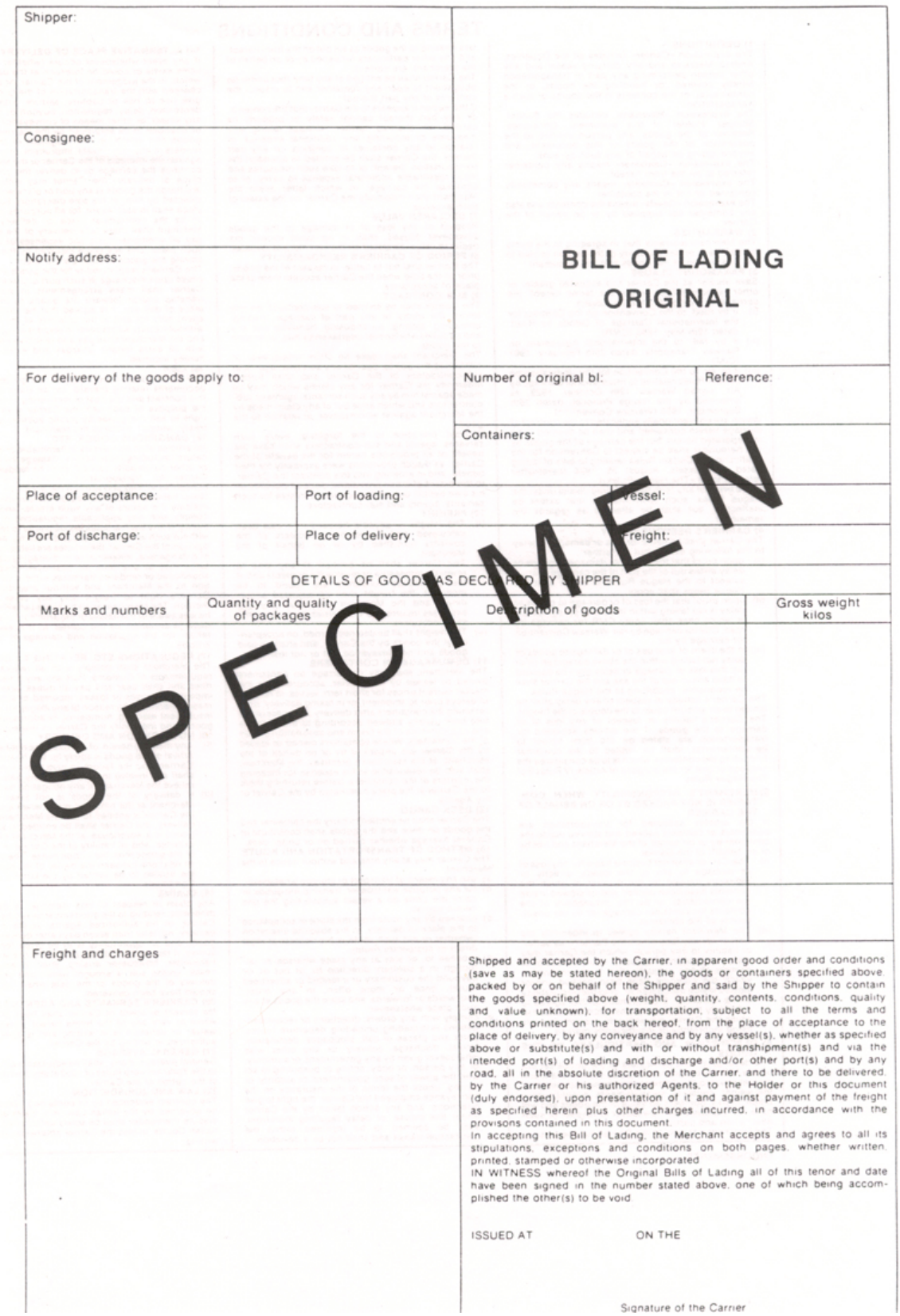
3.13.6 Air Waybill (AWB)



3.13.7 Rail Waybill (CIM)



3.13.8 Bill of Lading (B/L)



Shipper:

Consignee:

Notify address:

BILL OF LADING
ORIGINAL

For delivery of the goods apply to:

Number of original bl:

Reference:

Containers:

Place of acceptance:

Port of loading:

Vessel:

Port of discharge:

Place of delivery:

Freight:

DETAILS OF GOODS AS DECLARED BY SHIPPER

Marks and numbers	Quantity and quality of packages	Description of goods	Gross weight kilos

Freight and charges

Shipped and accepted by the Carrier, in apparent good order and conditions (save as may be stated hereon), the goods or containers specified above, packed by or on behalf of the Shipper and said by the Shipper to contain the goods specified above (weight, quantity, contents, conditions, quality and value unknown), for transportation, subject to all the terms and conditions printed on the back hereof, from the place of acceptance to the place of delivery, by any conveyance and by any vessel(s), whether as specified above or substitute(s) and with or without transhipment(s) and via the intended port(s) of loading and discharge and/or other port(s) and by any road, all in the absolute discretion of the Carrier, and there to be delivered, by the Carrier or his authorized Agents, to the Holder or this document (duly endorsed), upon presentation of it and against payment of the freight as specified herein plus other charges incurred, in accordance with the provisons contained in this document.
In accepting this Bill of Lading, the Merchant accepts and agrees to all its stipulations, exceptions and conditions on both pages, whether written, printed, stamped or otherwise incorporated.
IN WITNESS whereof the Original Bills of Lading all of this tenor and date have been signed in the number stated above, one of which being accomplished the other(s) to be void.

ISSUED AT ON THE

Signature of the Carrier

SPECIMEN

3.13.9 Packing list (P/L)

Company Name

Company Address
Phone: 555-555-5555555
Fax: 123-112-123456
Website: www.website.com
Email: abc@example.com

Packing List

Sent To: _____

Sent From: _____

Date: _____ Account No: _____

Shipping Date: _____ Shipping Co: _____

Department Name: _____

Product Description	Total Quantity:	Shipping No:	Total Weight:	Product No:

Special Info:

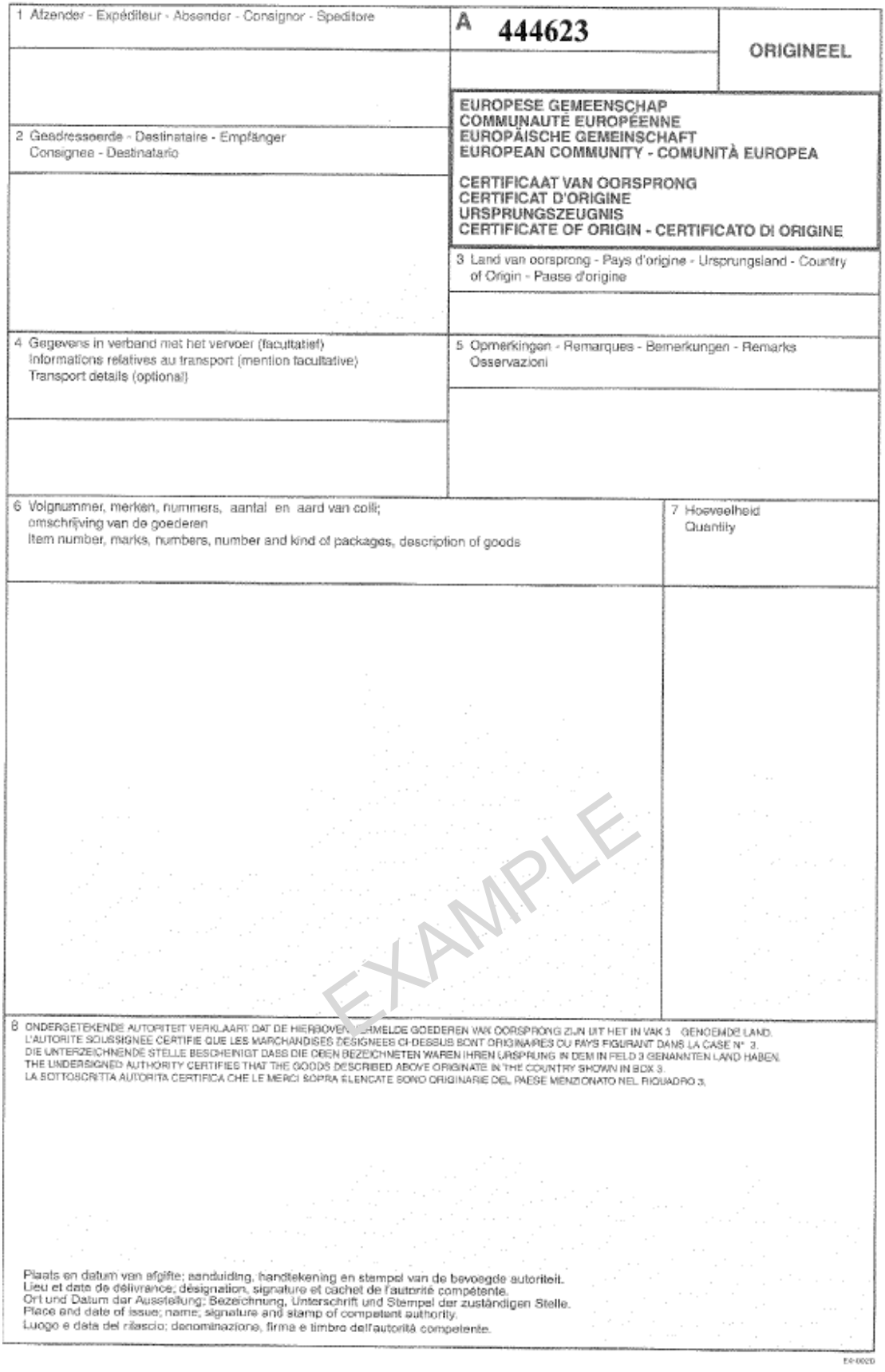
_____
_____
_____

_____
Authorized Signatures

EXAMPLE

Packing List Template

3.13.10 Non-Preferential Certificate of Origin (CoO)



1 Afzender - Expéditeur - Absender - Consignor - Speditore

A 444623

ORIGINEEL

EUROPESE GEMEENSCHAP
COMMUNAUTÉ EUROPÉENNE
EUROPÄISCHE GEMEINSCHAFT
EUROPEAN COMMUNITY - COMUNITÀ EUROPEA

CERTIFICAAT VAN OORSPRONG
CERTIFICAT D'ORIGINE
URSPRUNGSZEUGNIS
CERTIFICATE OF ORIGIN - CERTIFICATO DI ORIGINE

2 Geadresseerde - Destinataire - Empfänger
Consignee - Destinatario

3 Land van oorsprong - Pays d'origine - Ursprungsland - Country of Origin - Paese d'origine

4 Gegevens in verband met het vervoer (facultatief)
Informations relatives au transport (mention facultative)
Transport details (optional)

5 Opmerkingen - Remarques - Bemerkungen - Remarks
Osservazioni

6 Volgnummer, merken, nummers, aantal en aard van colli;
omschrijving van de goederen
Item number, marks, numbers, number and kind of packages, description of goods

7 Hoeveelheid
Quantity

EXAMPLE

8 ONDERGETEKENDE AUTORITEIT VERKLAART DAT DE HIERBOVEN VERMELDE GOEDEREN VAN OORSPRONG ZIJN UIT HET IN VAK 3 GENOEMDE LAND.
L'AUTORITE SOUSSIGNEE CERTIFIE QUE LES MARCHANDISES DESIGNEES CI-DESSUS SONT ORIGINAIRES DU PAYS FIGURANT DANS LA CASE N° 3.
DIE UNTERZEICHNENDE STELLE BESCHEINIGT DASS DIE OBEN BEZEICHNETEN WAREN IHREN URSPRUNG IN DEM IN FELD 3 GENANNTEN LAND HABEN.
THE UNDERSIGNED AUTHORITY CERTIFIES THAT THE GOODS DESCRIBED ABOVE ORIGINATE IN THE COUNTRY SHOWN IN BOX 3.
LA SOTTOSCRITTA AUTORITÀ CERTIFICA CHE LE MERCI SOPRA ELENCATE SONO ORIGINARIE DEL PAESE MENZIONATO NEL RIQUADRO 3.

Plaats en datum van afgifte; aanduiding, handtekening en stempel van de bevoegde autoriteit.
Lieu et date de délivrance; désignation, signature et cachet de l'autorité compétente.
Ort und Datum der Ausstellung; Bezeichnung, Unterschrift und Stempel der zuständigen Stelle.
Place and date of issue; name, signature and stamp of competent authority.
Luogo e data del rilascio; denominazione, firma e timbro dell'autorità competente.

EX-002D

3.13.11 EUR1 document

MOVEMENT CERTIFICATE

1. **Exporter** (Name, full address, country)	**EUR.1** No A 000.000 See notes overleaf before completing this form.
	2. **Certificate used in preferential trade between** ..... **And** ..... (Insert appropriate countries, groups of countries or territories)
3. **Consignee** (Name, full address, country) (Optional)	4. **Country, group of countries or territories in which the products are considered as originating** / 5. **Country, group of countries or territories of destination**
6. **Transport details** (Optional)	7. **Remarks**
8. **Item number; Marks and numbers; Number and kind of packages[99]; Description of goods**	9. **Gross mass (kg) or other measure (litres, m^3., etc.)** / 10. **Invoices** (Optional)
11. **COMPETENT PUBLIC OR CUSTOMS AUTHORITY ENDORSEMENT***	12. **DECLARATION BY THE EXPORTER**
Declaration certified Export document[60] Form .....No ..... Of ..... Competent public authority or customs office..... Issuing country or territory ..... Stamp .... Place and date .... (Signature)	I, the undersigned, declare that the goods described above meet the conditions required for the issue of this certificate. Place and date .... (Signature)

EXAMPLE

4 Cases for movement of biological material

Case number 1.1: Import of a HEK EBNA cell line in large quantities (100 mL) from USA to Belgium. The cell line is designed to produce a protein-conotoxin complex. The cell culture is in freezing medium RPMI containing 20% Fetal Bovine serum and 10% DMSO and is shipped on dry ice

Type of material and subgroup: Material from human origin

Possibly relevant legislation		
GMO/LMO	☑	GM cell line
CITES – endangered species	☐	
Animal By-Products	☑	Fetal bovine serum
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Biobanking	☑	HEK is a human derived cell line
Dual Use	☑	Conotoxin listed on 1C351
Phytosanitary	☐	
Transport of dangerous goods	☑	Category B biological material, dry ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in USA *)		
GMO / LMO	Relevant permit to work with GMO			
Animal by-products	Notification of competent authority for use of ABP in research and diagnosis Import permit Commercial document			
Biobanking	The cell line needs to be registered by the recipient in a biobank that is notified in Belgium**			
Dual Use	/			
Transport of dangerous goods			As cell line is able to produce large quantities of toxin present on the dual use list, the material is classified as 6.2 - Biological substance of category B (takes priority over class 9 - UN3245 (GMO)) Class 9 - UN 1845 (dry ice)	<u>Packaging</u>: • PI650 (Category B material) <u>Labelling:</u> • UN number, proper shipping name • Shippers' name and address • Receivers' name and address • Name and telephone number of responsible person • Labels <u>Packaging</u>:

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in USA *)		
				• PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package Labelling: • UN number, proper shipping name • NET weight of the solid carbon dioxide • Receivers' name, address and telephone number • Specific labels for dry ice
Customs/Tax		Commercial or proforma invoice AWB (mentioning dry ice as refrigerant and Biological substance of category B) Packing list		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

** list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf

Case number 1.2: Import from the Netherlands to Belgium of a blood sample from a person possibly infected with avian influenza. The sample is transported at room temperature and will be used for diagnostic purposes.

Type of material and subgroup: Material from human origin

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Biobanking	☑	Blood sample of human origin
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Category B biological material
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in the Netherlands *)		
Biobanking	The blood sample needs to be registered by the recipient in a biobank that is notified in Belgium**		Class 6.2 - UN 3373	Packaging: • PI650 (Category B material) Labelling: • UN number, proper shipping name • Shippers' name and address • Receivers' name and address • Name and telephone number of responsible person • Labels
Transport of dangerous goods				
Customs/Tax		Commercial or proforma invoice CMR (mentioning Biological substance of category B) Packing list		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

** list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf

Case number 1.3: Export of human induced pluripotent stem cells via lentiviral transduction to Australia in culture. The medium in which the stem cells are transported contains fetal calf serum

Type of material and subgroup: Material from human origin

Possibly relevant legislation		
GMO/LMO	☑	GM cells
CITES – endangered species	☐	
Animal By-Products	☑	Fetal Bovine Serum
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Biobanking	☑	Stem cells of human origin
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	GMO
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Australia *)	Exporter (in Belgium)		
GMO / LMO	Relevant permit to work with GMO Import permit	Relevant permit to work with GMO		
Animal by-products		Commercial document		
Biobanking		The exporter needs to register the stem cells in a- biobank that is notified in Belgium** and the biobank needs to facilitate the export		
Transport of dangerous goods			Class 9 - UN 3245 (GMO)	<u>Packaging</u>: • PI959 <u>Labelling:</u> • UN number • Shippers' name and address • Receivers' name and address • Labels
Customs/Tax		Commercial or proforma invoice AWB (mentioning UN 3245 GMO) Packing list		

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* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

** list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf

Case number 1.4: Transport of vaginal swabs from healthy young women in view of a population screening/study on the vaginal microbiome in Belgium during the COVID-19 pandemics. Upon sampling, swabs are stored in a buffer which inactivates potentially present viral pathogens. The presence of SARS-CoV-2 in vaginal swabs is unlikely (literature indicates very low presence of SARS-CoV-2 receptors in vaginal tissue)

Type of material and subgroup: Material from human origin

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Biobanking	☑	If the presence of human cells on the swabs cannot be excluded, compliance to Biobank legislation is required
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	Only in case there is a minimal likelihood that pathogens are present
Customs/Tax	☐	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer	Exporter		
Biobanking	The samples need to be registered by the recipient in a biobank that is notified in Belgium**	/		
Transport of non-dangerous goods	/	/	None Can be shipped by regular post	Packaging: • Safe triple packaging Labelling: • Exempt human specimen • Receivers' name and address

*Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

** list of notified biobanks: https://www.afmps.be/sites/default/files/content/INSP/MLM-MCH/ListBiobanks_20210915.pdf

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Case number 2.1: Export of genetically modified mice to Chili. Genetic modification involves the knock-out of interleukin (IL) 1

Type of material and subgroup: Animals and related material

Possibly relevant legislation		
GMO/LMO	☑	GM mice
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☑	Non-harmonized species
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Chili *)	Exporter (in Belgium)		
GMO / LMO		Relevant permit to work with GMO	Live animals	According to IATA Live Animal Regulation
Transport of live animals	Different rules may apply depending on the importing country (https://www.favv-afsca.be/professionelen/export/levendedieren/, or contact the competent authorities for more details)	In case an official veterinary certificate is required, it can be applied for via TRACES NT and will be delivered by FAVV Inspection of animals by an official veterinarian is to be performed within 48 hours prior to departure		
Customs/Tax		Commercial invoice ** AWB Packing list		
Other		Authorization to work with animals in view of animal welfare		

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* Required documentation will depend on the regulatory framework in the importing country (e.g. authorization to work with animals in view of animal welfare, requirements in view of Nagoya protocol). Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

** In general, transport of animals used for experimental purposes is seen as a commercial transport

Case number 2.2: Import of healthy ferrets from the USA

Type of material and subgroup: Animals and related material

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☑	Harmonized species
Access & Benefit Sharing (Nagoya)	☐	USA is not party to the Nagoya protocol
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in USA *)		
Transport of live animals	EU passport	Notification of competent authorities via official border control post (BCP) before entry into the European Union (via TRACES NT by means of a Common Health Entry Document (CHED-A), at least one working day before the expected arrival of the animals on European Union territory) Official veterinary certificate issued by a veterinarian in the country of origin Documentation on correct rabies vaccination	Live animals	According to IATA Live Animal Regulation
Access and Benefit Sharing		None: US is no party to the Nagoya protocol		
Customs/Tax		Commercial invoice ** AWB Packing list		
Other	Authorization to work with animals in view of animal welfare	Authorization to work with animals in view of animal welfare		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

**In general, transport of animals used for experimental purposes is seen as a commercial transport

Case number 2.3: Import of tissue samples and a cell culture of the *Ara macao* from Surinam. Material is transported on dry ice, cell culture medium contains fetal calf serum for stabilization purposes

Type of material and subgroup: Animals and related material

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☑	Annex A
Animal By-Products	☑	Fetal Calf Serum, tissue samples
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Dry Ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Surinam *)		
CITES - endangered species	Import permit	Export permit		
Animal By-Products	Notification of competent authority for use of ABP in research and diagnosis Import authorization Commercial document	None		
Access and Benefit Sharing (Nagoya)	None	If required: Prior Informed Consent (PIC) Contractual agreement specifying Mutually Agreed Terms (MAT)		
Transport of dangerous goods	None	None	Class 9 - UN 1845 (dry ice)	<u>Packaging</u>: • PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package <u>Labelling:</u> • UN number, proper shipping name • NET weight of the solid carbon dioxide • Receivers' name and address • Specific labels for dry ice

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Surinam *)		
Customs/Tax		Pro forma (or commercial) invoice AWB (mentioning dry ice as refrigerant) Packing list		

* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations

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Case number 2.4: Export of a tissue sample of a rhesus macaque to the UK. Material is transported on dry ice

Type of material and subgroup: Animals and related material

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☑	Annex B
Animal By-Products	☑	Tissue samples
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Dry Ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in UK *)	Exporter (in Belgium)		
CITES - endangered species	Import permit	Export permit or re-export certificate		
Animal By-Products	Different rules may apply depending on the importing country (consult http://www.favv-afsca.fgov.be/exportderdelanden/dierlijkeoorsprongnietgeschikt/ or contact the competent authorities)	Commercial document		
Transport of dangerous goods	None	None	Class 6.2 - UN 3373 (in case of unknown health status) Class 9 - UN 1845 (dry ice)	Packaging: • PI650 (Category B material) Labelling: • UN number, proper shipping name • Shippers' name and address • Receivers' name and address • Name and telephone number of responsible person • Labels Packaging: • PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in UK *)	Exporter (in Belgium)		
				Labelling: • UN number, proper shipping name • NET weight of the solid carbon dioxide • Receivers' name and address • Specific labels for dry ice
Customs/Tax		Pro forma (or commercial) invoice AWB (mentioning dry ice as refrigerant) Packing list		

* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

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Case number 2.5: Transport of samples collected from dead wild animals by a professional (e.g. ranger, veterinarian) for diagnostic purposes within Belgium (cause of death unknown)

Type of material and subgroup: Animals and related material

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☑	Depending on the wildlife species
Animal By-Products	☑	Tissue samples
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Depending on the anamnesis either category A or B
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Receiver (in Belgium)	Sender (in Belgium)		
CITES - endangered species	None	Certificate for commercial use (if Annex A) Proof of legal origin (Annex B)		
Animal By-Products	Notification of competent authority for use of ABP in research and diagnosis Commercial document	If veterinarian, then he/she does not require to notify the authorities in order to register him/herself for use of ABP for R&D		
Transport of dangerous goods	None	None	Class 6.2 - UN 2900	Packaging: • PI620 (Category A material) Labelling: • UN number, proper shipping name • Shippers' name, address and telephone number • Receivers' name, address and telephone number • Name and telephone number of responsible person (who is available 24/7 until the shipment arrives) • Labels
			Class 6.2 - UN 3373	Packaging: • PI650 (Category B material) Labelling: • UN number, proper shipping name • Shippers' name and address

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Receiver (in Belgium)	Sender (in Belgium)		
				• Receivers' name and address • Name and telephone number of responsible person • Labels
Customs/Tax		Packing list		

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Case number 2.6: Import of live sheep (*Ovis aries*) from a non-confined farm in New-Zealand

Type of material and subgroup: Animals and related material

Possibly relevant legislation	
GMO/LMO	☐
CITES – endangered species	☐
Animal By-Products	☐
Quarantine animal pests & diseases	☐
Transport of live animals	☑
Access & Benefit Sharing (Nagoya)	☐
Dual Use	☐
Phytosanitary	☐
Transport of dangerous goods	☐
Transport of non-dangerous goods	☐
Customs/Tax	☑

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in New Zealand)		
Live animals	-Import authorization from FASFC -Prior to transport, the shipment must be notified to the Border Control Post.	-Animal health certificate [1] OV/CAP-X, OV/CAP-Y	Live animals	• According to IATA Live Animal Regulation
Customs/Tax		Commercial invoice AWB Packing list		

[1]The animal health certificate has been issued within a period of 10 days before the date of arrival of the consignment at the Border Control Post; however, in the case of sea transport, that period may be extended by an additional period corresponding to the duration of the sea transport.

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Case number 2.7: Import of live carp from Indonesia

Type of material and subgroup: Animals and related material

Possibly relevant legislation	
GMO/LMO	☐
CITES – endangered species	☐
Animal By-Products	☐
Quarantine animal pests & diseases	☐
Transport of live animals	☑
Access & Benefit Sharing (Nagoya)	☑
Dual Use	☐
Phytosanitary	☐
Transport of dangerous goods	☐
Transport of non-dangerous goods	☐
Customs/Tax	☑

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Indonesia)		
Live animals	-Import authorization from FASFC -Prior to transport, the shipment must be notified to the Border Control Post.	-Animal health certificate [1] AQUA-ENTRY-ESTAB/RELEASE/OTHER	Live animals	• According to IATA Live Animal Regulation
Access and Benefit Sharing (Nagoya)		Indonesia is party to the Nagoya Protocol; however, no ABS procedure is in place		
Customs/Tax		Commercial invoice AWB Packing list		

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Case number 5.5: Import of live GMO mouse from US

Type of material and subgroup: Animals and related material

Possibly relevant legislation	
GMO/LMO	☑
CITES – endangered species	☐
Animal By-Products	☐
Quarantine animal pests & diseases	☐
Transport of live animals	☑
Access & Benefit Sharing (Nagoya)	☐
Dual Use	☐
Phytosanitary	☐
Transport of dangerous goods	☐
Transport of non-dangerous goods	☐
Customs/Tax	☑

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in US)		
GMO/LMO	Authorization		Live animals	• According to IATA Live Animal Regulation
Live animals	-Import authorization from FASFC -Prior to transport, the shipment must be notified to the Border Control Post.	-Animal health certificate		
Customs/Tax		Commercial invoice AWB Packing list		

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Case number 3.1: Import of *Agave parviflora* from Brazil, rooted in soil

Type of material and subgroup: Plants and related material

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☑	*Agave parviflora* is listed in Annex A of Council Regulation (EC) No 338/97
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals		
Access & Benefit Sharing (Nagoya)	☑	Plants are a genetic resource *
Dual Use	☐	
Phytosanitary	☑	Soil (i.e growing medium) attached to plants is listed in 2019/2072(EU) Annex VII, Part 1 (Always check the latest consolidated version at EUR-Lex - 32019R2072 - EN - EUR-Lex (europa.eu))
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	Plants are non-dangerous goods
Customs/Tax	☑	

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* Plants are genetic resources, but you only trigger the Nagoya Protocol when you access them after 12 October 2014, and you 'utilize' them; that is: "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether Brazil is a Party to the Nagoya Protocol. Brazil is a Party to the protocol since 2021 and it has strict Access and Benefit Sharing regulation in place.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Brazil**)		
CITES	Import permit			
Access and Benefit Sharing (Nagoya)		When required for Brazil: • Prior Informed Consent (PIC) • Contractual agreement specifying Mutually Agreed Terms (MAT)		
Phytosanitary	Pre-notification in TRACES-NT	Official statement that: **consignment complies** with Commission. Implementing Regulation **2019/2072**, Annex VII, Part 1 (Always check the latest consolidated version at EUR-Lex - 32019R2072 - EN - EUR-Lex (europa.eu)). Details on the actual requirements below the table *** Note: this official statement can be in the form of a phytosanitary certificate with additional declarations.		
Transport of non-dangerous goods	None	None		Non-dangerous goods are not identified by means of a UN specification number <u>Packaging:</u>

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Brazil**)		
				• No specific packaging instructions (except good quality packages according to a triple packaging system) Labelling: • Shippers' name and address • Receivers' name and address
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

*** Official statement that:

a) the growing medium, at the time of planting of the associated plants:

(i) was free from soil and organic matter and had not been previously used for growing plants or for any other agricultural purposes,
or
(ii) was composed entirely of peat or fibre of Cocos nucifera L. and had not been previously used for growing plants or for any other agricultural purposes,
or
(iii) was subjected to effective fumigation or heat treatment to ensure freedom from pests and which is indicated on the phytosanitary certificate referred to in Article 71 of Regulation (EU) No 2016/2031, under the rubric 'Additional declaration',
or
(iv) was subjected to effective systems approach to ensure freedom from pests and which is indicated on the phytosanitary certificate referred to in Article 71 of Regulation (EU) No 2016/2031, under the rubric 'Additional declaration
and
in all the cases mentioned in points (i) to (iv) was stored and maintained under appropriate conditions to keep it free from quarantine pests

b) since planting:

(i) appropriate measures have been taken to ensure that the growing medium has been kept free from Union quarantine pests, including at least:
- physical isolation of the growing medium from soil and other possible sources of contamination, hygiene measures,
- using water free from Union quarantine pests;

or
(ii) within two weeks prior to export the growing medium including, where appropriate, soil has been completely removed by washing using water free from Union quarantine pests. Replanting may be performed in the growing medium that meets the requirements laid down in point (a). Appropriate conditions shall be maintained to keep freedom from Union quarantine pests, as provided for in point (b).

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Case number 3.3: Export of GM maize seeds to Brazil for use in laboratory research

Type of material and subgroup: Plants and related materials

Possibly relevant legislation		
GMO/LMO	☑	GM maize
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☑	Maize seeds
Transport of dangerous goods	☑	GMO
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Brazil *)	Exporter (in Belgium)		
GMO / LMO	Import permit	Relevant permit to work with GMO Copy of the import permit (AIA is not required for contained use)		
Phytosanitary		Phytosanitary certificate		
Transport of dangerous goods			Class 9 - UN 3245 (GMO)	<u>Packaging</u>: • PI959 <u>Labelling:</u> • UN number • Shippers' name and address • Receivers' name and address • Labels
Customs/Tax		Commercial or proforma invoice AWB (mentioning UN 3245 GMO) Packing list		

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* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

Case number 3.4: Export of (GM) plant material (seeds, leaf material, roots, …) to China for use in laboratory research

Type of material and subgroup: Plants and related materials

Possibly relevant legislation		
GMO/LMO	☑	Applicable depending on the specific case
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☑	Plant material
Transport of dangerous goods	☑	In case of GMO
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in China)	Exporter (in Belgium)		
GMO / LMO	Import permit*	Relevant permit to work with GMO Copy of the import permit (AIA is not required for contained use)		
Phytosanitary		Phytosanitary certificate, if required by the Chinese authorities		
Transport of dangerous goods			Class 9 - UN 3245 (if GMO)	<u>Packaging</u>: • PI959 <u>Labelling:</u> • UN number • Shippers' name and address • Receivers' name and address • Labels
Customs/Tax		Commercial or proforma invoice AWB (mentioning UN 3245 GMO) Packing list		

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* Import permit needs to be obtained by the recipient organization from the local Chinese customs service. That import permit is necessary in order for the FAVV to deliver the necessary documentation that should accompany the material, such as a phytosanitary certificate.

Case number 4.1: Export of a culture of verotoxic *E. coli* to an EU member state

Type of material and subgroup: Microorganisms

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	No ABP (such as casein, tryptone, peptone) present in the microbial culture medium
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☑	Verotoxic *E. coli* listed as 1C351
Phytosanitary	☐	
Transport of dangerous goods	☑	Category A material
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in a EU member state *)	Exporter (in Belgium)		
Dual use		Export license	Class 6.2 - UN 2814	Packaging: • PI620 (Category A material) Labelling: • UN number, proper shipping name • Shippers' name, address and telephone number • Receivers' name, address and telephone number • Name and telephone number of responsible person (who is available 24/7 until the shipment arrives) • Labels
Transport of dangerous goods		Shipper's Declaration for Dangerous Goods		
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

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Case number 4.2: Importing cultures of HIV and HBV from China into Belgium

Type of material and subgroup: Microorganisms

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	No ABP (such as casein, tryptone, peptone) present in the microbial culture medium
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	Genetic resource *
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Cultures of HIV and HBV are category A
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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*HIV and HCV are genetic resources, but the Nagoya Protocol is only triggered when you access them after 12 October 2014, and you 'utilize' them; that is: "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether China is a Party to the Nagoya Protocol and has legislation that covers the access to these genetic resources. If so, you need to comply with that legislation, and send in 'due-diligence' declarations to the competent authorities.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in China**)		
GMO / LMO	Relevant permit to work with pathogens			
Access and Benefit Sharing (Nagoya)		None: China currently does not have ABS legislation that would cover the access to HIV or HBV cultures	Class 6.2 - UN 2814	Packaging: • PI620 (Category A material) Labelling: • UN number, proper shipping name • Shippers' name, address and telephone number • Receivers' name, address and telephone number • Name and telephone number of responsible person (who is available 24/7 until the shipment arrives) • Labels
Transport of dangerous goods	None	Shipper's Declaration for Dangerous Goods		
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

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** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 4.3: Export of disarmed GM *Agrobacterium tumefaciens* [47] to the USA for laboratory use. Transport is performed at 4 °C using cool packs

Type of material and subgroup: Microorganisms

Possibly relevant legislation		
GMO/LMO	☑	GM bacteria
CITES – endangered species	☐	
Animal By-Products	☐	No ABP (such as casein, tryptone, peptone) present in the microbial culture medium
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	GMO
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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[47] Updated scientific name *Rhizobium radiobacter*, synonym *Agrobacterium radiobacter*

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in USA *)	Exporter (in Belgium)		
GMO / LMO	Import permit (Biotechnology Regulatory Services or BRS permit)	Relevant permit to work with GMO Copy of the import permit Copy of acknowledgement letter		
Transport of dangerous goods			Class 9 - UN 3245 (GMO)	<u>Packaging</u>: • PI959 • Also check the BRS permit or packaging guidelines 7 CFR 340.7 <u>Labelling:</u> • UN number • Blue-White label (cfr. BRS permit) • Shippers' name and address • Receivers' name and address • Labels
Customs/Tax		Commercial or proforma invoice AWB (mentioning UN 3245 GMO) Packing list		

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* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

Case number 4.4: Import of yeast strains isolated in 2012 from a spontaneous fermentation in Malaysia

Type of material and subgroup: Microorganisms

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	No ABP (such as casein, tryptone, peptone) present in the microbial culture medium
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource *
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	The yeast is neither pathogenic nor genetically modified
Customs/Tax	☑	

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*Even though the yeast has been taken from the wild in 2012, the import in 2016 constitutes 'access' and therefore may trigger the Nagoya protocol which entered into force on 12 October 2014. You trigger the Nagoya Protocol when you "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether Malaysia is a Party to the Nagoya Protocol and has legislation that covers the access to these genetic resources. If so, you need to comply with that legislation, and send in 'due-diligence' declarations to the competent authorities.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Malaysia**)		
Access and Benefit Sharing (Nagoya)		None: Malaysia is not a Party to the Nagoya Protocol		
Transport of non-dangerous goods	None	None		Non-dangerous goods are not identified by means of a UN specification number <u>Packaging:</u> • No specific packaging instructions (except good quality packages according to a triple packaging system) <u>Labelling:</u> • Shippers' name and address • Receivers' name and address
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

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Case number 4.5: Import of Aujeszky's disease virus (SHV-1) from Russia. The virus is shipped by means of a cell culture of PK15 cells that was inoculated one day before shipment at a low multiplicity of infection (m.o.i).

Type of material and subgroup: Microorganisms

Possibly relevant legislation		
GMO/LMO	☑	Pathogens within contained use legislation
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☑	OIE-listed disease (2016)
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource *
Dual Use	☑	Virus listed as 1C351
Phytosanitary	☐	
Transport of dangerous goods	☑	Category A, dry ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Russia *)		
GMO / LMO	Relevant permit to work with pathogens			
Quarantine animal pests and diseases	Import license			
Access and Benefit Sharing (Nagoya)	None	If required: Prior Informed Consent (PIC) Contractual agreement specifying Mutually Agreed Terms (MAT)		
Dual use		Export license		
Transport of dangerous goods	None	Shipper's Declaration for Dangerous Doods	Class 6.2 - UN 2900	<u>Packaging</u>: • PI620 (Category A material) <u>Labelling:</u> • UN nr, proper shipping name • Shippers' name, address and telephone number • Receivers' name, address and telephone number • Name, tel number of responsible person (who is available 24/7 until the shipment arrives) • Labels
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 5.1: Import of dead insects that are sampled in hospitals in Rwanda

Type of material and subgroup: Invertebrates

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	Depending on the type of insects that are sampled *
Animal By-Products	☑	Dead insects
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource **
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	Dead insects
Customs/Tax	☑	

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*In this particular example it is unlikely that samples include CITES protected insects (certain butterflies)

**Insects are genetic resources, but the Nagoya Protocol is only triggered when you access them after 12 October 2014, and you 'utilize' them; that is: "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether Rwanda is a Party to the Nagoya Protocol (which it is) and has legislation that covers the access to these genetic resources (which it hasn't yet). If so, you need to comply with that legislation, and send in 'due-diligence' declarations to the competent authorities.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Rwanda***)		
Animal By-Products	Import authorization from FAVV			
Access and Benefit Sharing (Nagoya)		None yet: Rwanda does not have ABS legislation yet that applies to these insects		
Transport of non-dangerous goods	None	None		Non-dangerous goods are not identified by means of a UN specification number Packaging: • No specific packaging instructions (except good quality packages according to a triple packaging requirements) Labelling: • Shippers' name and address • Receivers' name and address
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

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*** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 5.2: Import of live *Drosophila melanogaster* from a *Drosophila* stock center in the USA

Type of material and subgroup: Invertebrates

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☑	Insects are live invertebrate animals *
Access & Benefit Sharing (Nagoya)	☑	Genetic resource **
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

*The legislation on import and transport of live animals also applies to invertebrate animals, and therefore also applies to insects such as *Drosophila*.
**Even though insects are a genetic resource, in this particular case the Nagoya Protocol on Access and Benefit-Sharing is not triggered for two reasons: (1) The US is not a Party to the protocol, and (2) the Drosophila in the stock center will not have been taken from the wild recently (after 12 October 2014).

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in the US ***)		
Live animals	Import authorization from the FAVV Prior to transport, the shipment must be notified to the Border Control Post. The shipment must be offered for inspection by personnel of the Border Control Post.	Sanitary declaration	Live animals	According to IATA Live Animal Regulation
Access and Benefit Sharing (Nagoya)		None: the US is not a party to the protocol and the *Drosophila* has not been taken from the wild recently		
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

*** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

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Case number 6.1: Import of soil samples from Iceland

Type of material and subgroup: Soil

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource *
Dual Use	☐	
Phytosanitary	☐	Soil is included in 2019/2072(EU) Annex VI (Always check the latest consolidated version at EUR-Lex - 32019R2072 - EN - EUR-Lex (europa.eu)).
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	
Customs/Tax	☑	

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*Soil is a genetic resource, but the Nagoya Protocol is only triggered when you access them after 12 October 2014, and you 'utilize' them; that is: "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether Iceland is a Party to the Nagoya Protocol and has legislation that covers the access to these genetic resources. If so, you need to comply with that legislation, and send in 'due-diligence' declarations to the competent authorities.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Iceland**)		
Access and Benefit Sharing (Nagoya)	None: Iceland currently does not have ABS legislation			
Phytosanitary	Letter of Authority	Countersigning of the Letter of Authority by NPPO		
Transport of non-dangerous goods	None	None		Non-dangerous goods are not identified by means of a UN specification number <u>Packaging:</u> • No specific packaging instructions (except good quality packages according to a triple packaging requirements) <u>Labelling:</u> • Shippers' name and address • Receivers' name and address
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

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** Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 6.2: Import of sediments from a lake in Chile

Type of material and subgroup: Soil

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☑	Genetic resource * (sediments)
Dual Use	☐	
Phytosanitary	☐	Soil is included in 2019/2072(EU) Annex VI (Always check the latest consolidated version at EUR-Lex - 32019R2072 - EN - EUR-Lex (europa.eu)).
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	
Customs/Tax	☑	

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*Sediment is a genetic resource, but the Nagoya Protocol is only triggered when you access them after 12 October 2014, and you 'utilize' them; that is: "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of modern biotechnology". If that is the case, you need to check whether Chile is a Party to the Nagoya Protocol and has legislation that covers the access to these genetic resources. If so, you need to comply with that legislation, and send in 'due-diligence' declarations to the competent authorities.

Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in Chili**)		
Access and Benefit Sharing (Nagoya)		None: Chile currently does not have ABS legislation		
Phytosanitary	Letter of Authority	Countersigning of the Letter of Authority by NPPO		
Transport of non-dangerous goods	None	None		Non-dangerous goods are not identified by means of a UN specification number Packaging: • No specific packaging instructions (except good quality packages according to a triple packaging requirements) Labelling: • Shippers' name and address • Receivers' name and address
Customs/Tax		Pro forma (or commercial) invoice AWB Packing list		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 7.1: Import of recombinant synthetic DNA on dry ice

Type of material and subgroup: DNA / RNA

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Dry ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required *(e.g. permits, notifications, certificates, pro-forma invoice, …)*		IATA classification	Packaging and labelling
	Importer (in Belgium)	**Exporter** (in Bulgaria *)		
Transport of dangerous goods			Class 9 - UN 1845 (dry ice)	Packaging: • PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package Labelling: • UN number, proper shipping name • NET weight of the solid carbon dioxide • Receivers' name and address • Specific labels for dry ice
Customs/Tax		Pro forma (or commercial) invoice AWB (mentioning dry ice as refrigerant) Packing list		

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* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

Case number 8.1: Export of shiga toxin dissolved in a physiological salt solution to New Zealand on dry ice. The shiga toxin has been purified from a laboratory strain of *E. coli*

Type of material and subgroup: Proteins and peptides

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☑	Shiga toxin listed on 1C351
Phytosanitary	☐	
Transport of dangerous goods	☑	Shiga toxin (LD50 0.25mg/kg), dry ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in New Zealand *)	Exporter (in Belgium)		
Dual Use	Import certificate or end-use certificate for dual use goods	Individual export permit	Class 6.1 - UN3172, liquid PG I / Class 9 - UN 1845 (dry ice)	Packaging: • PI652 / PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package Labelling: • UN number for both classes • Proper shipping name for both classes, as well as the technical name of the toxin (shiga toxin) • Shippers' name and address • Receivers' name and address • Labels for both classes • NET weight of the solid carbon dioxide
Transport of dangerous goods				
Customs/Tax		Commercial or proforma invoice AWB (mentioning dry ice as refrigerant and UN3172 Toxin, extracted from living organisms, liquid (shiga toxin)) Packing list		

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* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.

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Case number 8.2: Import of mouse (c57bl/6) polyclonal antibodies (5 x 1 ml) from the USA at room temperature

Type of material and subgroup: Proteins and peptides

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☑	Non-purified polyclonal antibodies
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☐	
Transport of non-dangerous goods	☑	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Belgium)	Exporter (in USA *)		
Animal By-Products	Notification of competent authority for use of ABP in research and diagnosis Import authorization Commercial document		None	Packaging: • Triple packaging including absorbant material Labelling: • Receivers' name and address
Transport of non-dangerous goods	TRACES NT pre-notification			
Customs/Tax		Commercial or proforma invoice AWB Packing list Safety declaration		

* Required documentation will depend on the regulatory framework in the exporting country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the exporter what is required, to make sure that materials are not shipped without all necessary authorizations.

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Case number 8.3: Export of a purified monoclonal antibody to Germany on dry ice by means of road transport. The production system of this antibody is a mouse hybridoma

Type of material and subgroup: Proteins and peptides

Possibly relevant legislation		
GMO/LMO	☐	
CITES – endangered species	☐	
Animal By-Products	☐	Monoclonal antibodies are no animal by-products
Quarantine animal pests & diseases	☐	
Transport of live animals	☐	
Access & Benefit Sharing (Nagoya)	☐	
Dual Use	☐	
Phytosanitary	☐	
Transport of dangerous goods	☑	Dry ice
Transport of non-dangerous goods	☐	
Customs/Tax	☑	

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Possibly relevant legislation	Documentation required (e.g. permits, notifications, certificates, pro-forma invoice, …)		IATA classification	Packaging and labelling
	Importer (in Germany *)	Exporter (in Belgium)		
Transport of dangerous goods			Class 9 - UN 1845 (dry ice)	Packaging: • PI954 (dry ice) Package must be designed and constructed as such that it permits the release of carbon dioxide and prevents a build-up of pressure that could rupture the package Labelling: • UN number, proper shipping name • "As Coolant" (road transport) after the proper shipping name • NET weight of the solid carbon dioxide • Receivers' name and address • Specific labels for dry ice
Customs/Tax		Pro forma (or commercial) invoice CMR (mentioning dry ice as refrigerant) Packing list		

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* Required documentation will depend on the regulatory framework in the importing country. Indicated are documents / authorizations that may be applicable. It is recommended to check up front with the importer what is required, to make sure that you do not ship materials for which not all necessary authorizations have been obtained by the importer.