Intermediate Products

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Intermediate products legislation

Regulation (EU) 142/2011

- **Definition of intermediate products:** Annex I, point 35
- **General rules:** Article 23
- **Specific rules:** Annex XII, including registration of plants, transport requirements after BCP
- **Model Importers declaration:** Annex XV

Definition of intermediate products-

Annex I point 35:

Intermediate product means a **derived product**:

*"**(a)** which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, **in vitro diagnostic** medical devices for medical and veterinary purposes, **laboratory reagents** or cosmetic products as follows:*

(i) as material in a manufacturing process or in the final production of a finished product;

(ii) in validation or verification during a manufacturing process; or

(iii) in quality control of a finished product"

i.e Intended for medical / veterinary uses, lab reagents, cosmetics

Definition (continued)

(b) *"whose **design, transformation and manufacturing stages have been sufficiently completed** in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a)"*

i.e. Already processed

Definition (continued)

(c) *"which however requires **some further manufacturing or transformation, such as mixing, coating, assembling or packaging** to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products"*

i.e. Requires some further work before final use

In summary:

- **Intended for medical / veterinary uses, lab reagents, cosmetics**
- **Already processed**
- **Requires some further work before final use**

If it doesn't meet these requirements then it is not an intermediate product

Raw material that can be used

Annex XII, point 1(a)

Intermediate products may derive from the following materials:

- **Category 3 materials** (*excluding materials referred to in Reg. (EC) 1069/2009 article 10 (c), (n), (o) and (p))*
- Products generated by the animals referred to in Reg. (EC) 1069/2009 article 10, point (i), (l) and (m) *(i.e. aquatic animals, invertebrates, rodents, lagomorphs)*
- Mixtures of the above

Raw material *(continued)*

Annex XII, point 1(b)

In addition, the following materials may also be used for intermediate products destined for the production of:

- medical devices and in vitro diagnostic medical devices
- laboratory reagents
- * active implantable medical devices (* See next slide)
- * medicinal products and veterinary medicinal products

- Materials (as previous slide) which may have originated from animals submitted to **illegal treatment** as defined in Article 1(2)(d) of Directive 96/22/EC
- **Category 2** material referred to in article 9 (f),(h) Reg.(EC) 1069/2009
- Mixtures of the materials referred to above

Raw material *(continued)*

Annex XII, point 1(g), (c)

For these products:

* active implantable medical devices
* medicinal products and veterinary medicinal products

The materials mentioned in previous slide may be used only where:

(g) the importer demonstrates to the competent authority that the materials:

(i) do not carry any risk of transmission of a disease communicable to humans or animals; or

(ii) are transported under conditions which prevent the transmission

(c) the competent authority considers the use of such materials justified for the protection of public or animal health

Import conditions

1. Intermediate products, imported into or in transit through the Union shall comply with the conditions controlling potential risks to public and animal health referred to in Annex XII of Reg.(EU) 142/2011

Specific import conditions

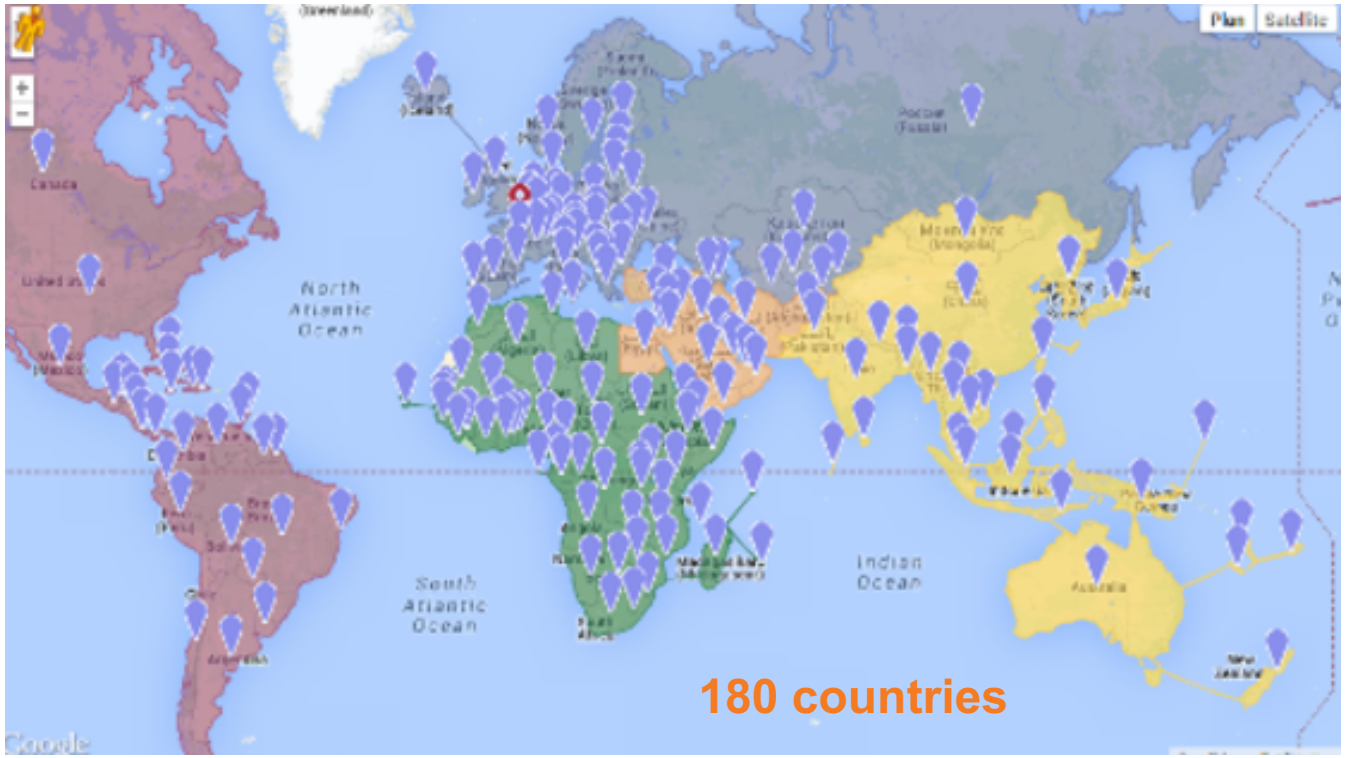
1. Authorized country (Annex XII, point 1(d))
2. Approved manufacturing plant (Annex XII, point 1(e)). *(Criteria for approval by competent authority of third country detailed in Annex XII point 2)*
3. Importer's declaration (Annex XII, point 1(f))
4. Official Border Controls, CHED (Annex XII, point 3)
5. Direct to registered or approved establishment (Annex XII, point 3)

There are also rules for transits

Specific import conditions *(continued)*

1. Country of origin

Must come from a third country listed as a member of the World Organisation for Animal Health (OIE)



Specific import conditions *(continued)*

2. Establishments in third countries

https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerActivity_en.htm

Animal by-products

- Section I : Slaughterhouses
- Section II : Dairy plants
- Section III : Other facility for the collection or handling of animal by-products (i.e. unprocessed/untreated materials)
- Section IV : Processing plants
- Section V : Petfood plants (Including plants manufacturing dogchews and flavouring innards)
- Section VI : Game trophies plants
- Section VII : Plants or establishments manufacturing intermediate products
- Section VIII : Fertiliser and soil improvers
- Section IX : Storage of derived products
- Section X : Blood and blood products, excluding of equidae, for technical purposes other than feed for animals

Specific import conditions *(continued)*

COUNTRY
SECTION

Brazil
Plants or establishments manufacturing intermediate products

Validity date from
24/08/2019
Date of publication
24/08/2019

00102

Example EU list of approved intermediate plants in third countries

List in force

Approval number	Name	City	Regions	Activities	Remark	Date of request
1	BRF S.A	Concordia	Santa Catarina	CAT3		26/05/2011
1001	BRF S. A.	Rio Verde	Goias	CAT3		26/05/2011
103	BRF S. A.	Serafina Correa	Rio Grande do Sul	CAT3		26/05/2011
104	BRF S. A.	Chapeco	Santa Catarina	CAT3		26/05/2011
1058	COFIBAM INDÚSTRIA E COMÉRCIO DE FIOS E CABOS LTDA	Araçatuba	São Paulo	CAT3		28/07/2011
1125	JBS S/A	Guaicara	São Paulo	CAT3		17/03/2015
1155	JBS AVES LTDA	Nova Veneza	Santa Catarina	CAT3		26/05/2011
1184	ALIMENTOS ESTRELA LTDA	Sao Luiz Gonzaga	Rio Grande do Sul	CAT3		26/05/2011
11904	PENTAPHARM DO BRASIL COMÉRCIO E EXPORTAÇÃO LTDA	Uberlandia	Minas Gerais	CAT3		04/06/2012
1507	VENSA COMERCIO E INDUSTRIA DE PRODUTOS DE ALIMENTACAO ANIMAL LTDA	São Paulo		CAT3		26/05/2011
1636	SOROQUALITY BIOTECNOLOGIA EIRELI	Aparecida De Goiânia	Goias	CAT3		08/08/2018
1661	Companhia Minuano de Alimentos	Lajeado	Rio Grande do Sul	CAT3		26/05/2011
1726	BELA VISTA PRODUTOS ENZIMÁTICOS INDÚSTRIA E COMÉRCIO LTDA	Concordia	Santa Catarina	CAT3		05/12/2011
1751	MARFRIG GLOBAL FOODS S. A.	Tangará Da Serra	Mato Grosso	CAT3		26/05/2011

Specific import conditions *(continued)*

3. Importers Declaration

Importer's declaration required (Annex XII point 1(f))

Specimen: (Annex XV, **Chapter 20**)

CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through (2) *the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products*

COUNTRY: **Veterinary certificate to EU**

I.1. Consignor Name Address Tel.	I.2. Certificate reference No	I.2.a.	
	I.3. Central competent authority		
	I.4. Local competent authority		
I.5 Consignee	I.6 Person responsible for the load in EU		

Part I : Details of dispatched consignment

I.5. Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.
I.7. Country of origin / ISO code / I.8. Region of origin / Code	I.9. Country of destination / ISO code / I.10. Region of destination / Code
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postcode
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.

Model importers declaration

I.18. Description of commodity	I.19. Commodity code (HS code)
	I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging

COUNTRY

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

II. Health information	II.a. Certificate reference No	II.b.

Part II: Certification

DECLARATION

I, the undersigned, declare that the intermediate product referred to above is intended to be imported by me into or to be transited through the European Union and satisfies the definition of an intermediate product provided for in point 35 of Annex I to Commission Regulation (EU) No 142/2011 ([1a]), and in particular that:

(1) it is intended for the manufacture of:

([2]) *either* [- medicinal products,]

([2]) *and/or* [- veterinary medicinal products,]

([2]) *and/or* [- medical devices for medical and veterinary purposes,]

([2]) *and/or* [- active implantable medical devices,]

([2]) *and/or* [- in vitro diagnostic medical devices for medical and veterinary purposes,]

([2]) *and/or* [- laboratory reagents,]

([2]) *and/or* [- cosmetic products;]

(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires further manufacturing or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service as a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, an active implantable medical devices, an in vitro diagnostic medical device for medical and veterinary purposes or a cosmetic product in accordance with the European Union legislation ([1b]) applicable to those products or as a laboratory reagent;

(3) it has been derived from:

([2]) *either* [- material which may have originated from animals submitted to an illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC ([2a]) or in Article 2(b) of Council Directive 96/23/EC ([2b]);]

Model importers declaration

↓ continues with long list of possible raw materials ↓

(4) its outer packaging is labelled 'FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / ACTIVE IMPLANTABLE MEDICAL DEVICES / IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / LABORATORY REAGENTS / COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the European Union for any other use;

(5) the consignment will be transported directly to the place of destination in the European Union as indicated under point I.12 of this declaration, that is:

(2) *either* [an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009],

(2) *or* [an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they may only be dispatched to an establishment or plant referred to in the preceding indent of this point.]

Model importer's declaration

The importer

Name (in capital letters): Address:

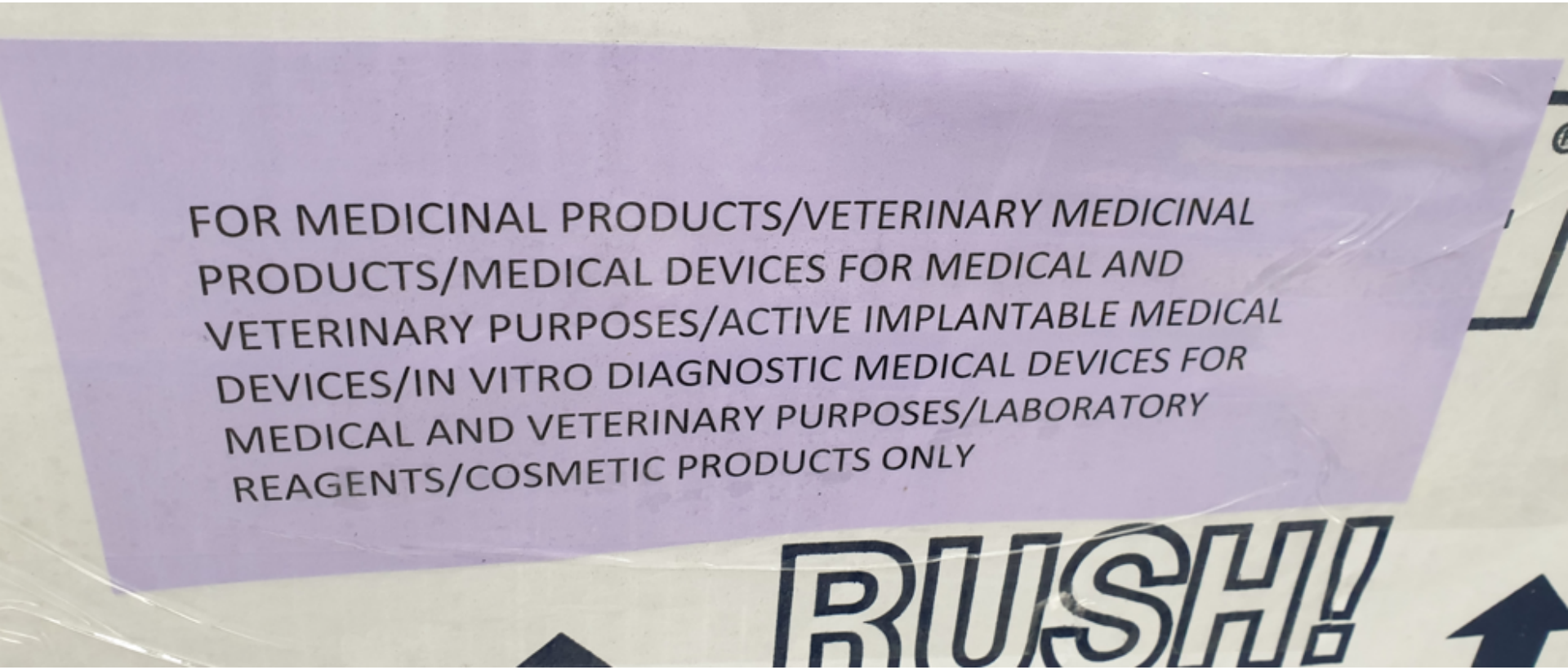
Date: Signature:

4. Official Border Controls – Identity check

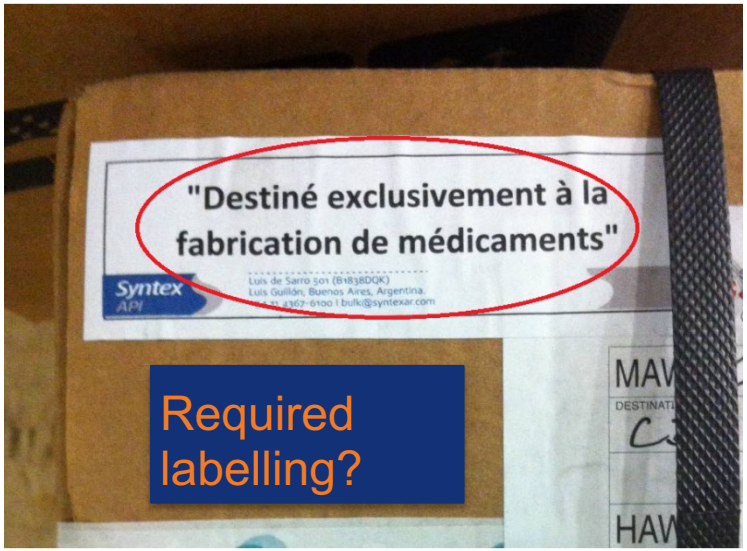
4. Identity check *(continued)*

Labelling requirements

(ref point II.4 of health certificate):



4. Identity check *(continued)*



"FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICAL DEVICES FOR MEDICAL & VETERINARY PURPOSES / ACTIVE IMPLANTABLE MEDICAL DEVICES / IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / LABORATORY REAGENTS / COSMETIC PRODUCTS ONLY"

Destination establishment

Registered establishment or ABP store

Annex XII, point 3:

3. The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:

   (a) a registered establishment or plant for the production of laboratory reagents, medical devices and *in vitro* diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;

   (b) an establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they must only be dispatched to an establishment or plant referred to in (a) of this point for the uses referred to in (a).

Destination establishment - EU Member States

https://ec.europa.eu/food/safety/animal-by-products/approved-establishments_en

EU countries, EEA countries: List of approved ABP establishments

EU site per Member State and per sector (frequently updated)

- Establishments list per country EN
- Establishments list per sector EN

List of EU countries' approved establishments in the Animal by-Product field

Austria (AT)	Belgium (BE) FR / NL / EN
Bulgaria (BG)	Croatia (HR)
Cyprus (CY) EN	Czech Republic (CZ)
Denmark (DA)	Estonia (EE) EN
Finland (FI)	France (FR)
Germany (DE)	Greece (EL)

Destination establishments: e.g. Poland

Intermediate products destinations are usually listed in Section XIII but may be Section IX):

Destination establishment

Intermediate products which have been transported to an establishment or plant referred to in point 3 of Annex XII **fall outside the scope of the ABP regulations** provided that the destination establishment meets the following requirements:

Destination establishment *(continued)*

a) the establishment or plant has adequate facilities for the receipt of the intermediate products, which prevent the transmission of diseases communicable to humans or animals;

b) the intermediate products do not pose any risk of transmission of diseases communicable to humans or animals

c) the establishment or plant keeps records on the amount of materials received, their category, if applicable, and the establishment, plant or operator to whom they have supplied their products; and

d) unused intermediate products or other surplus materials from the establishment or plant, such as expired products, are disposed of in accordance with Regulation (EC) No 1069/2009.

Destination establishment *(continued)*

3. The operator or owner of the establishment or plant of **destination** of intermediate products or his representative shall use and/or dispatch the intermediate products *exclusively for use in manufacturing:*

- medicinal product,
- veterinary medicinal product,
- medical devices for medical and vet purposes,
- active implantable medical devices,
- in vitro diagnostic medical devices for medical and veterinary purposes,
- laboratory reagent
- cosmetic products

Notification to competent authority

Reg (EU) 142/2011 Annex XII point 5:

"The official veterinarian at the border inspection post concerned shall inform the authority in charge of the establishment or plant at the place of destination of the consignment by means of the TRACES system".

Auditing of destination establishments

Reg (EU) 142/2011 Annex XII point 8:

"The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Regulation".