

WELMEC

European Cooperation in Legal Metrology

Compliance of Imported e-marked Prepackages



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European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to packers, Importers and the Competent Departments responsible for ensuring the prepackages meet the specified requirements.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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Foreword

WELMEC Working Group 6 was set up to discuss, and propose solutions for, the problems associated with the trading of e-marked prepacked products (hereafter called 'prepackages') between Member States¹. It was decided by the WELMEC Committee² to provide guidance for Competent Departments³ and economic operators to ensure that imported prepackages comply with legal requirements. This guide is to address all the issues found in the imported prepackages project carried out by WELMEC WG6 in 2011. The intention of this guide is to achieve a uniform level of enforcement and ensure that all prepackages, whether packed in, or imported into, the Community (hereafter called 'Union'⁴) meet the applicable metrological requirements.

This guide is part of a series of guides published by WELMEC, which are primarily intended to provide guidance to all those concerned with the application of Directive 76/211/EEC for prepacked products. These guides are intended to lead to a uniform interpretation and enforcement of this directive and assist in the removal of barriers to trade.

Documents agreed by WELMEC are published on their website at <http://www.welmec.org/latest/guides.html>

For further information and advice on prepackages, please contact your national Competent Department whose contact details can be found at www.welmec.org.

¹ Where in this guide the term 'Member State' is used this means a country of the European Economic Area (EEA), Turkey or Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

² WELMEC Committee meeting May 2011.

³ The 'Competent Department' is the term used in Directive 76/211/EEC for a body that is responsible for ensuring that prepackages meet the legal requirements. It is for each Member State to appoint a Competent Department.

⁴ The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

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1 Introduction

- 1.1 Directive 76/211/EEC¹ (hereafter called the 'Directive') states "In the case of imports from non-EEC countries, the Importer may instead of measuring and checking provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility."
- 1.2 The European Commission has provided its view on the application of the Directive relating to imports in 2005. One of the conclusions was that guidance should be developed to reflect the specific situation of Importers².
- 1.3 The Regulation (EC) 765/2008 (hereafter called the 'Regulation') setting out requirements for accreditation and market surveillance relating to the marketing of products³ requires that market surveillance be applied where there are Union harmonised requirements. It requires⁴ that national market surveillance infrastructures and programmes shall ensure that effective measures can be taken in relation to any product category subject to Union harmonised legislation. This includes 'e'-marked prepackages (hereafter called 'prepackages') and '3'-marked measuring container bottles⁵.
- 1.4 The Regulation also requires⁶ that where in a Member State more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate. In the light of this, this guide intends to give guidance to all relevant authorities. The contact details of the Competent Departments responsible for ensuring prepackages comply with the requirements of the Directive are available on the WELMEC website⁷.
- 1.5 The responsibilities specified in the Regulation also include that authorities "... shall carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are released for free circulation." This implies that to ensure there are no barriers to trade and to create a fair trading environment, all prepackages, whether imported or packed in the Union⁸, shall⁹ be subject to the same level of compliance checks.

¹ Directive 76/211/EEC, Annex I.4.

² Report public consultation: Metrological Requirements for Prepackaged Products, 24 August 2005, paragraph 16.

³ Regulation (EC) 765/2008, Chapter III covers the market surveillance framework.

⁴ Regulation (EC) 765/2008, Article 6, paragraph 3.

⁵ Directive 75/107/EEC, relating to bottles used as measuring containers.

⁶ Regulation (EC) 765/2008, Article 27, paragraph 2.

⁷ <http://www.welmec.org/working-group-area/working-group-6/members-email-addresses/>

⁸ The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

⁹ Regulation (EC) 765/2008, Article 27, paragraph 1.

2 Scope

2.1 This guide aims to give guidance for all authorities responsible for ensuring that prepackages that are released¹ to the Union² market meet the European legal metrology requirements.

These authorities include but are not limited to:

- external border control,
- Competent Departments, and
- authorities responsible for carrying out market control on prepackages³.

2.2 This guide may also benefit those organisations that:

- intend to, or do import prepackages from outside Europe (third countries) into Member States,
- intend to, or do export prepackages to Europe,
- intend to, or do distribute or sell imported prepackages to other distributors, to retailers or to consumers, and
- provide evidence to Importers about prepackages and/or of packers outside Europe.

Please note that:

- complying with this guide does not preclude authorities to carry out checks and surveillance activities in order to ensure compliance with the Directive, and
- other legislation may apply to prepackages imported into the Union that may contain other requirements that:
 - o are not covered by, and/or
 - o may be more specific than the Directive.

2.3 This guide is structured so that there is a chapter for each stakeholder outlining the legal obligations and expectations. The flowchart on the next page will direct stakeholders to the chapter relevant to their activity.

¹ Releasing to the market shall mean delivering to a Distributer/Retailer, to a Person arranging for the packing to be done or to a consumer.

² The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

³ See WELMEC Guide 6.7: Guidance for Market Control on Prepackages For Competent Departments.



Figure 1: Flowchart that directs stakeholders to the chapter relevant to their activity.

3 Packer outside Europe

3.1 Definition

The 'Packer outside Europe' means a packer¹ located outside the Union² and who distributes prepackages:

- to a European Importer³, or
- to one or more Agents of the Importer residing in one or more Member States⁴,

that bear a mark or inscription that identifies:

- the Person⁵ arranging for the packing to be done⁶, or
- the Importer established in a Member State.

Note 1: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive, not the Packer outside Europe.

Note 2: When the Packer outside Europe provides results of measurements or of samples to the European Importer, he may also be an 'Evidence provider' and chapter 11 is also applicable.

3.2 Obligations

The Packer outside Europe shall:

- ensure that the labelling requirements are met (see Annex 1) and that the three quantity requirements are met (see Annex 2),
- if the Importer so requires, provide adequate evidence to the Importer so that the Importer possesses all the necessary guarantees enabling him to assume responsibility. See Annex 5,
- ensure that each batch is identifiable, and
- if the Importer assumes responsibility based on evidence that the Packer outside Europe provide, the relationship between that evidence and the batch shall be related based on this batch identification.

3.3 Ensuring compliance

To ensure compliance with the Directive, the Packer outside Europe shall provide records to the Importer of prepackages sold to him, in particular:

- identification of batch(es),
- copy of the label, and
- number of prepackages sold.

¹ A packer is a person who places product in packing material that bears a nominal quantity, an e-mark and an identification of the Importer or the Person arranging for the packing to be done.

² The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

³ See chapter 6: Importer.

⁴ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁵ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

⁶ See chapter 4: Person arranging for the packing to be done.

4 Person arranging for the packing to be done

4.1 Definition

The 'Person arranging for the packing to be done' means a person¹ who sells imported prepackages that bear his name, mark or inscription that he obtains from an Importer² or the Agent of the Importer³ and who resides in one or more Member States⁴.

Note 1: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive, not the Person arranging for the packing to be done.

The Person arranging for the packing to be done is only mentioned in Annex I.3.2 of the Directive as one of the three marks or inscriptions that shall appear on the label⁵. In the first paragraph of Annex I.4 in the Directive only the packer or Importer have responsibilities⁶. The Person arranging for the packing to be done is not mentioned anywhere else in the Directive and therefore has no responsibilities in ensuring that prepackages meet the requirements of the Directive.

Note 2: Someone who receives prepackages directly from (the Packer) outside Europe, is either the Importer or the Agent of the Importer, even if the prepackages bear the name, mark or inscription of himself, or of the Packer outside Europe.

Note 3: This guide covers prepackages imported from third countries⁷ and therefore this chapter is not applicable to a Person arranging for the packing to be done who obtains prepackages that bear his name, mark or inscription from a packer⁸ that resides in a Member State.

4.2 Obligations

The Person arranging for the packing to be done shall:

- provide to Competent Departments⁹ and Related Authorities¹⁰, the name and address of the Importer of the prepackages that he sells based on a specimen of the packing material of a single prepackage or on records, and
- allow Competent Departments to perform checks¹¹ to ensure that the prepackages comply with the provisions of the Directive and for the purpose of verifying that prepackages meet the requirements of the Directive.

¹ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

² See chapter 6: Importer.

³ See chapter 7: Agent of the Importer.

⁴ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁵ Directive 76/211/EEC, Annex I.3.2: "All prepackages made up in accordance with this Directive shall bear on the package ... a mark or inscription ... to identify the packer or the Person arranging for the packing to be done or the Importer ...".

⁶ Directive 76/211/EEC, Annex I, 4: "The packer importer shall be responsible for ensuring that prepackages meet the requirements of this Directive."

⁷ A third country is a country that is not a Member State.

⁸ A packer is a person who places product in packing material that bears a nominal quantity, an e-mark and an identification of the Importer or the Person arranging for the packing to be done.

⁹ See chapter 8: Competent Department.

¹⁰ See chapter 9: Related Authority.

¹¹ As specified in Directive 76/211/EEC, Annex I.4 and I.5.

4.3 Ensuring compliance

To ensure compliance with the Directive, the Person arranging for the packing to be done shall keep records of prepackages bought and sold, in particular:

- number of prepackages bought and sold,
- identification of batch(es),
- copy of the label, and
- name and address of the Importer or the Agent of the Importer.

5 Distributer/Retailer

5.1 Definition

The 'Distributer/Retailer' means a person¹ who is part of the marketing process² of prepackages in the Union³, other than the Importer⁴, an Importers agent⁵ or the Person arranging for the packing to be done⁶, who buys prepackages from an Importer or wholesaler with the intention of selling them to wholesalers and/or retailers and/or consumers.

Note 1: The Distributer/Retailer that sells prepackages that bear his name, mark or inscription is the Person arranging for the packing to be done and chapter 4 applies.

Note 2: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive, not the Distributer/Retailer.

5.2 Obligations

The Distributer/retailer shall, based on records and/or a specimen of the packing material of a single prepackage, assist Competent Departments⁷ and Related Authorities⁸ by providing them with the:

- name and address of the person he obtained the prepackages from,
- the name and address of the Importer (if he has this information available), and
- if he does not sell to consumers, the name and address of the (legal) person he has sold prepackages to.

Furthermore, the Distributer/Retailer shall allow Competent Departments to perform checks⁹ to ensure that the prepackages comply with the provisions of the Directive and for the purpose of verifying that prepackages meet the requirements of the Directive.

5.3 Ensuring compliance

To ensure compliance with the Directive, the Distributer/Retailer shall keep records of prepackages bought and sold, in particular:

- number of prepackages bought and sold,
- identification of batch(es),
- copy of the label,
- name and address of supplier, and
-
- in case of sale to other distributor, wholesaler or retailer: name and address of wholesaler or retailer.

¹ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

² The term 'marketing process' means the chain of distribution of prepackages starting with the Importer and ending with sale to the consumer by the Retailer.

³ The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

⁴ See chapter 6: Importer.

⁵ See chapter 7: Agent of the Importer.

⁶ See chapter 4: Person arranging for the packing to be done.

⁷ See chapter 8: Competent Department.

⁸ See chapter 9: Related Authority.

⁹ As specified in Directive 76/211/EEC, Annex I.4 and I.5.

6 Importer

6.1 Definition

The 'Importer'¹ shall mean any person² established within a Member State³ who releases⁴ prepackages packed in a third country⁵ to the Union⁶ market.

Note 1: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive.

Note 2: The Importer is the person who decides whether prepackages meet the requirements, before placing the prepackages on the market.

The term 'decides' includes (but is not limited to):

- written or oral instruction, order or allowance to release to the market,
- act of releasement to the market,
- fail to prevent releasing to the market without explicit decision, and
- subcontracting the releasement the market to an agent⁷ (see note 3).

Note 3: In the case that the Importer relies on evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility, the Importer may subcontract the releasing to the market to one or more of his agents that reside in one or more Member State(s).

6.2 Examples

A fulfilment house is deemed to be the Importer, as he is not the packer established in the Union.

A fulfilment house may also be the 'Person arranging for the packing to be done'⁸ in case his marks or inscriptions appear on the label.

¹ Derived from Decision Nr. 768/2008/EC, Article R1.5.

² The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

³ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁴ Releasing to the market shall mean delivering to a Distributer/Retailer, to a Person arranging for the packing to be done or to a consumer.

⁵ A third country is a country that is not a Member State.

⁶ The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

⁷ See chapter 7: Agent of the Importer.

⁸ See chapter 4: Person arranging for the packing to be done.

6.3 Obligations

The Importer shall either:

- a) carry out checks on each batch of imported prepackages in accordance with procedures recognised by the Competent Department¹ of the Member State in which he is established², using a legal measuring instrument suitable for effecting the necessary operations to ensure that the prepackages meet all the labelling and quantity requirements. See Annexes 1 and 2 and WELMEC Guide 6.4³,
- b) decide whether the imported prepackages meet the requirements based upon all the necessary guarantees enabling him to assume responsibility for each batch of prepackages imported. This must be done before the prepackages are released to the market (see Annex 3), or
- c) a combination of both a) and b).

Furthermore, the Importer shall:

- provide information regarding prepackages that will be imported to the Competent Department of the Member State he is established in as required by national provisions. A minimum would be to notify the Competent Department of the Member State prior to the first importation so that the Competent Department is able to meet its obligations and carry out reference tests as required by the Directive on the Importer's premises,
- keep records of prepackages that have been imported, bought and sold,
- provide assistance to Competent Departments⁴ and/or Related Authorities⁵ of Member States where one or more of the Importers Agents⁶ are established in, and
- allow Competent Departments to perform checks⁷ to ensure that the prepackages comply with the provisions of the Directive and for the purpose of verifying that prepackages meet the requirements of the Directive.

¹ See chapter 8: Competent Department.

² If provided for by national legislation.

³ WELMEC Guide 6.4: Guide for Packers and Importers of e-marked prepacked products.

⁴ See chapter 8: Competent Department.

⁵ See chapter 9: Related Authority.

⁶ See chapter 7: Agent of the Importer.

⁷ As specified in Directive 76/211/EEC, Annex I.4 and Annex I.5.

6.4 Ensuring compliance

To ensure compliance with the Directive, the Importer shall have details of prepackages that will be imported, in particular:

- a copy of the label,
- description of the product,
- number of prepackages to be imported,
- the name and address of the packer in the third country,
- the identification of batch(es), and
- the location of batches of prepackages that will be imported. This may include the location of agents that reside in one or more Member State(s).

Furthermore, the Importer shall keep records of prepackages bought and sold, in particular:

- those containing:
 - a) the results of the checks of 6.3a, in order to certify that these checks have been properly and accurately carried out, and/or
 - b) the evidence that the Importer was in the possession of all the necessary guarantees enabling him to assume responsibility for each batch of imported prepackages at the time of decision-making as referred to in 6.3b (see Annex 5),
- the decision that the Importer took based on the above records,
- the location of batches of prepackages that have been and will be imported. This may include the location of agents that reside in one or more Member State(s),
- the number of prepackages bought and sold,
- the identification of batch(es),
- a copy of the label,
- the name and address of the packer in the third country, and
- in case of sale to another distributor, wholesaler or retailer: name and address of distributor, wholesaler or retailer.

7 Agent of the Importer

7.1 Definition

The 'Agent of the Importer' shall mean any person¹ established within a Member State² who releases³ prepackages packed in a third country⁴ to the Union⁵ market under the responsibility of an Importer⁶.

Note 1: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive, not the Agent of the Importer.

Note 2: The Agent of the Importer also becomes an 'Evidence provider'⁷ if he carries out sample checks from batches of prepackages produced by a packer in a third country on behalf of the Importer.

Note 3: It is the Importer who decides whether prepackages meet the requirements, before he allows his Agent to release the prepackages to the market.

7.2 Obligations

The Agent of the Importer shall:

- provide the name and address of the Importer who is responsible for the prepackages that the Agent of the Importer releases to the Union market to the Competent Department⁸ and Related Authorities⁹ in the Member State where the Agent is established in, and
- allow Competent Departments to perform checks¹⁰ to ensure that the prepackages comply with the provisions of the Directive and for the purpose of verifying that prepackages meet the requirements of the Directive.

¹ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

² 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

³ Releasing to the market shall mean delivering to a Distributer/Retailer, to a Person arranging for the packing to be done or to a consumer.

⁴ A third country is a country that is not a Member State.

⁵ The 'Union' shall mean the countries of the European Economic Area (EEA), Turkey and Switzerland and any other country that the EU has a formal agreement with that covers prepackages.

⁶ See chapter 6: Importer.

⁷ See chapter 10: Evidence provider.

⁸ See chapter 8: Competent Department.

⁹ See chapter 9: Related Authority.

¹⁰ As specified in Directive 76/211/EEC, Annex I.4 and Annex I.5.

7.3 Ensuring compliance

To ensure compliance with the Directive, the Agent of the Importer shall keep records of prepackages received and delivered, in particular:

- the location of batches of prepackages that have been and will be received and delivered,
- the number of prepackages received and delivered,
- the identification of batch(es),
- a copy of the label, and
- the name and address of the Importer responsible for the prepackages.

Furthermore, the Agent of the Importer shall provide information regarding prepackages that he will receive on behalf of the Importer to the Competent Department of the Member State he is established in as required by national provisions. A minimum would be to notify the Competent Department of the Member State prior to the first time of receiving prepackages so that the Competent Department is able to meet its obligations and carry out reference tests as required by the Directive on the Agent of the Importers premises.

8 Competent Department

8.1 Definition

'Competent Department' are the authorities¹ responsible for ensuring² that Importers meet the requirements of the Directive.

Note 1: There may be more than one Competent Department in a Member State³.

Note 2: The legal power of a Competent Department is limited to the Member State in which the Competent Department is located.

Note 3: (Parts of) the tasks of the Competent Department may be carried out by other organisations under the responsibility of the Competent Department or whos responsibility is laid down in legislation.

Note 4: If prepackages arrive physicyly at an Agent of the Importer located in another Member State than where the Importer is located, it is the Competent Department of the Member State where the Agent of the Importer is located that is responsible for carrying out the reference test.

The non-compliance should be referred back to the Competent Department where the Importer is located⁴ who will:

- a) acknowledge receipt of the referral,
- b) investigate the non-compliance in a timely manner,
- c) give a progress report every 4 weeks, and
- d) report back at the end the findings, and should a non-compliance have been found, confirm the corrective and preventative action that has been taken together with the agreed timescale.

¹ An authority is a public institution with legal personality, component of the State structure, on or below the level of central government and accountable to citizens.

² Recognize procedures (Directive 76/211/EEC, Annex I.4), carry out the reference test on the packer's premises on the premises of the Importer (Directive 76/211/EEC, Annex I.5) and carry out other checks (Directive 76/211/EEC, Annex 1.6).

³ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁴ See also WELMEC Guide 6.0: Introduction to WELMEC documents on prepackages, chapter 2.

8.2 Obligations

The Competent Department recognise the procedures¹ of Importers² who carry out checks on each batch of imported prepackages (as referred to in 6.3.a) and do not assume their responsibility based upon necessary guarantees enabling the Importer to assume responsibility (as referred to in 6.3.b).

Furthermore, the Competent Department perform checks on the premises of the Importer or of his agent³ to ensure that the prepackages comply with the provisions of the Directive⁴ (reference test).

The Competent Department can carry out any checks at any stage in the marketing process, in particular for the purpose of verifying that prepackages meet the requirements of the Directive⁵ (See WELMEC Guide 6.7⁶).

8.3 Ensuring compliance

To ensure compliance with the Directive, the Competent Department work with other Competent Departments and with Related Authorities⁷ to:

- share intelligence, and/or
- plan and carry out activities to ensure compliance with the requirements of the Directive.

Furthermore, the Competent Department respond to information provided to them by Competent Departments in other Member States, Related Authorities or consumers regarding prepackages in the marketplace and take appropriate proportionate action to ensure compliance (see Annex 3).

¹ If provided for by national legislation.

² See chapter 6: Importer.

³ See chapter 7: Agent of the Importer.

⁴ As specified in Directive 76/211/EEC, Annex I.4.

⁵ As specified in Directive 76/211/EEC, Annex I.5.

⁶ WELMEC Guide 6.7: Guidance for Market Control on Prepackages For Competent Departments.

⁷ See chapter 9: Related Authority.

9 Related Authority

9.1 Definition

A 'Related Authority' is a public institution with legal personality, component of the State structure, on or below the level of central government and accountable to citizens other than the Competent Department¹ of a Member State² responsible for carrying out enforcement activities on its territory.

Note 1: (Parts of) the tasks of the Related Authority may be carried out by other organisations under the responsibility of that authority.

Note 2: The activities are (but are not limited to): customs, metrology, product safety, and food safety.

9.2 Obligations

The Related Authority shall work with Competent Departments to:

- share intelligence, and/or
- plan and carry out activities that facilitate Competent Departments ensuring compliance with the requirements of the Directive.

Furthermore, the Related Authority shall enter into a formal agreement with the Competent Department as recommended in "Guidelines for import controls in the area of product safety and compliance"³ produced by the European Commission for Customs.

9.3 Ensuring compliance

To ensure compliance with the Directive, the Related Authority shall pass on to the Competent Department a copy of the label from a prepackage which bears an 'e'-mark.

Furthermore, the Related Authority shall pass on to the Competent Department, in particular, copy of any non-compliant labelling, including any batch code and details of Importer and the storage (warehouse) facilities where prepackages can be inspected and tested. Non-compliant labelling includes:

- a) the wrong shaped 'e',
- b) 'e' being less than 3 mm high,
- c) quantity declaration being too small, and
- d) illegal symbols for weight and volume, that is any that are not g, kg, ml, mL, cl, cL, l and L. See Annex 1 for the requirements.

See Annex 4 for a flow chart for proportionate actions.

¹ See chapter 8: Competent Department.

² 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

³ https://ec.europa.eu/taxation_customs/publications/taxation-customs-documents/binding-tariff-information_en

10 Certification Organisation

10.1 Definition

A Certification Organisation is a person¹ who assesses the procedures that a Packer outside Europe² uses:

- to ensure that the prepackages meet the requirements at the moment of importation in one or more Member States³, and
- that make up the evidence that enables the Importer⁴ to assume responsibility.

Note 1: Competent Departments⁵ qualify as Certification Organisations.

Other organisations that carry out relevant (parts of the) tasks of the Competent Department under the responsibility of the Competent Department or whos responsibility is laid down in legislation⁶, also qualify as a Certification Organisation.

Note 2: Another person qualifies as a Certification Organisation after it has been established that the person is independent, credible and capable, where:

- 'established' means an investigation by a Competent Department of the Member State where the Importer is located that covers independence, credibility and capability, where a decision made by another Competent Department can be taken into account, if available,
- an 'independent' person is disinterested from the Packer outside Europe, the Importer, the Agent of the Importer⁷, the Distributer/Retailer⁸ and the Person arranging for the packing to be done⁹,
- a 'credible' person is:
 - o accredited by an accreditation body in a Member State against ISO 17021 or an equivalent standard, or
 - o peer-to-peer assessed by a Competent Department in a Member State against ISO 17021 or an equivalent standard and of which the decision has been made available to Competent Departments in other Member States,
- a 'capable' person judges filling and measuring/checking procedures of a sufficient number of packers as or on behalf of a governmental authority against criteria laid down in chapter 4 of WELMEC Guide 6.6¹⁰ or equivalent.

¹ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

² See chapter 3: Packer outside Europe.

³ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁴ See chapter 6: Importer.

⁵ See chapter 8: Competent Department.

⁶ See chapter 8: Competent Department, note 3.

⁷ See chapter 7: Agent of the Importer.

⁸ See chapter 5: Distributer/Retailer.

⁹ See chapter 4: Person arranging for the packing to be done.

¹⁰ WELMEC Guide 6.6: Guide for recognition of procedures.

10.2 Obligations

The Certification Organisation shall perform audits and surveillance in accordance with the requirements of ISO 17021 or an equivalent standard.

Furthermore, the Certification Organisation shall describe the packer's procedures covering the subjects of chapter 4 of WELMEC Guide 6.6¹.

10.3 Ensuring compliance

To ensure compliance with the Directive, the Certification Organisation shall provide to the Importer:

- a description of the packer's procedures covering the subjects of chapter 4 of WELMEC Guide 6.6¹,
- reports of audits and surveillances of the procedures of packers outside Europe, and
- a copy of accreditation certificate, including scope, standard and date of validity or of evidence of peer-to-peer assessments by a Competent Department in a Member State.

¹ WELMEC Guide 6.6: Guide for recognition of procedures.

11 Evidence provider

11.1 Definition

An 'Evidence provider' is any person¹ that on behalf of the Importer² carries out measurements or checks on batches of prepackages filled by a Packer outside Europe³ that enable the Importer to assume his responsibility (see chapter 6.3b).

Note 1: It is the Importer who is legally responsible that the prepackages meet the requirements of the Directive, not the Evidence provider.

Note 2: An Evidence provider can be:

- a) a person of which a Competent Department of the Member State, where the Importer is located, has established that the person is independent, credible and capable, where:
 - 'established' means an investigation by a Competent Department of the Member State where the Importer is located that covers independence, credibility and capability and of which the decision has been made available to Competent Departments in other Member States,
 - an 'independent' person is disinterested from the Packer outside Europe, the Importer, the Agent of the Importer⁴, the Distributer/Retailer⁵ and the Person arranging for the packing to be done⁶,
 - a 'credible' person is:
 - o accredited by an accreditation body in a Member State⁷ against ISO 17020, ISO 17025 or an equivalent standard, or
 - o peer-to-peer assessed by a Competent Department⁸ in a Member State and of which the results have been made available for Competent Departments in other Member States
 - a 'capable' person:
 - o has 'inspection of prepackages' or 'testing of prepackages' in its scope, or
 - o performs a significant number of reference tests of prepackages as a governmental authority.
- b) The packer in a third country⁹, in which case his procedures have to be assessed by a Certification Organisation¹⁰.
- c) The Agent of the Importer. The results of checks by the Agent of the Importer are a sufficient guarantee that enable the Importer to assume his responsibility (see chapter 6.3b) if these checks are carried out in accordance with procedures recognised by the Competent Department of the Member State where the Agent of the Importer is established.

¹ The term 'person' means any natural person or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

² See chapter 6: Importer.

³ See chapter 3: Packer outside Europe.

⁴ See chapter 7: Agent of the Importer.

⁵ See chapter 5: Distributer/Retailer.

⁶ See chapter 4: Person arranging for the packing to be done.

⁷ 'Member State' means a country of the European Economic Area (EEA), Turkey or Switzerland or any other country that the EU has a formal agreement with that covers prepackages.

⁸ See chapter 8: Competent Department.

⁹ A third country is a country that is not a Member State.

¹⁰ See chapter 10: Certification Organisation.

11.2 Obligations

The Evidence provider shall carry out checks on prepackages that enable the Importer to assume his responsibility.

Furthermore, the Evidence provider shall prove the (continued) ability to perform such checks.

11.3 Ensuring compliance

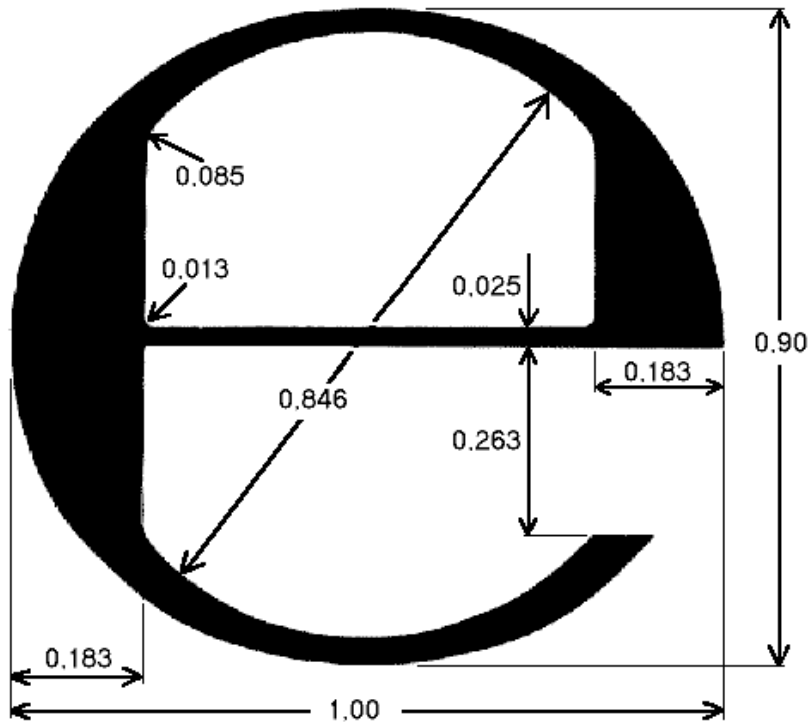
To ensure compliance with the Directive, the Evidence provider shall provide the Importer with the results of measurements or checks. See Annex A.5.1.

Furthermore, the Evidence provider shall provide the Importer with a proof of credibility. See Annex A.5.2.

Annex 1 – Labelling requirements for prepackages

A.1.1 The ‘e’-mark

The ‘e’-mark shall be a minimum of 3 mm high, placed in the same field of vision as the indication of the nominal quantity, and be of the form as shown below.



A.1.2 Nominal quantity

The nominal quantity (nominal weight or volume) shall be expressed in the SI units of kilograms, grams, litres, centilitres or millilitres.

If the unit of measurement is not spelt out in full, then the only permissible symbols are:

- kg or g, and
- l, L, cl, cL, ml or mL.

The nominal quantity must be in figures, not written out in text. Example: “1 kg” is acceptable but “one kg” is not acceptable.

Approximate indications like “ca. 200 g” are not allowed.

The figures must be at least the following minimum heights:

Nominal quantity g or ml	Minimum heights of figures mm
$5 < Q_n \leq 50$	2
$50 < Q_n \leq 200$	3
$200 < Q_n \leq 1\ 000$	4
$1\ 000 < Q_n \leq 10\ 000$	6

Markings in imperial (UK and US) units shall be in letters and figures of dimensions not larger than those of the corresponding markings in SI units.

A.1.3 Identity of the Person arranging for the packing to be done or the Importer

A mark or inscription enabling the Competent Departments to identify¹:

- a) the Person arranging for the packing to be done, or
- b) the Importer established in the Union.

The identity markings on the prepackage shall identify a Person arranging for the packing to be done (for whom the prepackages have been imported or packed for) or the Importer.

Where the markings on prepackages do not identify the Importer in a Member State, it is the responsibility of the person whose name and address or mark appears on the prepackage to identify the Importer in a Member State to the Competent Department.

¹ On 27 November 2013 Daniel Hanekuyk provided the opinion of the DG-ENTR lawyer on whether the person identified on the label of a prepackage must reside in the EEA, Switzerland or Turkey: "at least one name and address or mark of the Packer, the Person arranging the packing to be done or the Importer established in the EU must appear. Addresses referring to Packers outside EU have no legal relevance. The person identified, and their address, shall be within a Member State."

Annex 2 – Quantity requirements for prepackages

Prepackages covered by the Directive shall be made up in such a way that batches¹ of completed prepackages satisfy the following requirements.

A.2.1 Average actual quantity

“the actual contents shall not be less, on average, than the nominal quantity²”

The prepackages shall pass the reference test of the Directive or a test whose effectiveness is comparable to that reference test. The reference test shall be carried out by the Competent Department and shall be performed on a sample drawn from a batch of imported prepackages which consist of up to 10 000 prepackages.

A.2.2 TU1-limit

“the proportion of prepackages having a negative error greater than the tolerable negative error laid down ... shall be sufficiently small for batches of prepackages to satisfy the requirements of the tests specified in Annex II.³”

The ‘tolerable negative error’ (TNE) for each nominal quantity is specified in paragraph 2.4 of Annex I of the Directive. The quantity, which is one tolerable negative error below the nominal quantity, is sometimes referred to as ‘TU1’ or ‘T1’.

A ‘defective’ prepackage is one whose quantity of product is below TU1 or T1. ‘Sufficiently small’ is not defined in the Directive although the reference test is based on an AQL (acceptable quality level) of 2.5%. Because statistical methods of testing are used, there is still a risk of failing a batch even if the amount of TU1 is less than 2.5%.

A.2.3 TU2-limit

“no package having a negative error greater than twice the tolerable negative error given in the table in 2.4 may bear the EEC sign ...⁴”

The quantity which is two tolerable negative errors below the nominal quantity is sometimes referred to as ‘TU2’ or ‘T2’.

A.2.4 Other checks

The Competent Departments can carry out any checks at any stage in the marketing process, in particular for the purpose of verifying that prepackages meet the requirements of the Directive.

¹ A batch shall comprise all the prepackages of the same nominal quantity, the same type and the same production run, packed in the same place.

² Directive 76/211/EEC, Annex I.1, 1.1.

³ Directive 76/211/EEC, Annex I.1, 1.2.

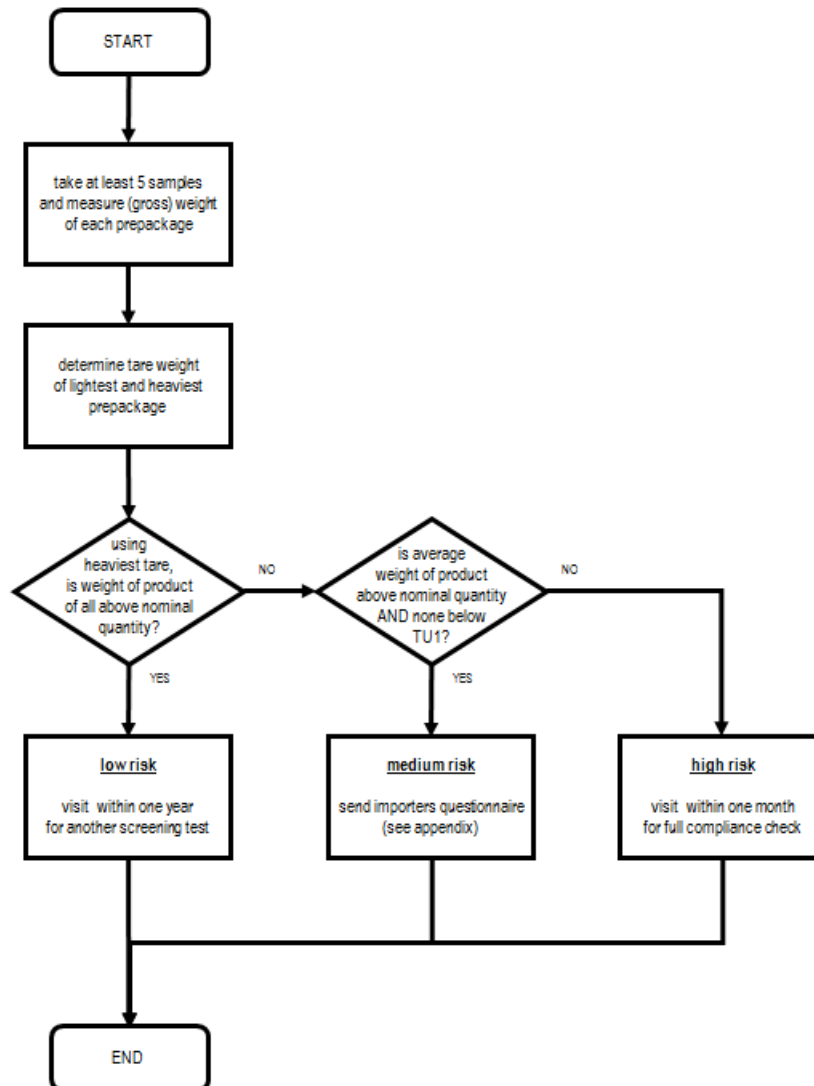
⁴ Directive 76/211/EEC, Annex I.1, 1.3.

Annex 3 – Competent Departments’ proportionate actions

Competent Departments have the responsibility to ensure compliance of all ‘e’-marked prepackages, and this needs to be effectively and efficiently. The flow charts in this annex provide a method of risk-based actions to carry out their obligations.

A.3.1 Market Control

Where prepackages from an unknown source are found anywhere in the marketplace, and it is possible to carry out quantity checks on the prepackages, the following screen test will ensure consistency of enforcement using a risk-based approach.

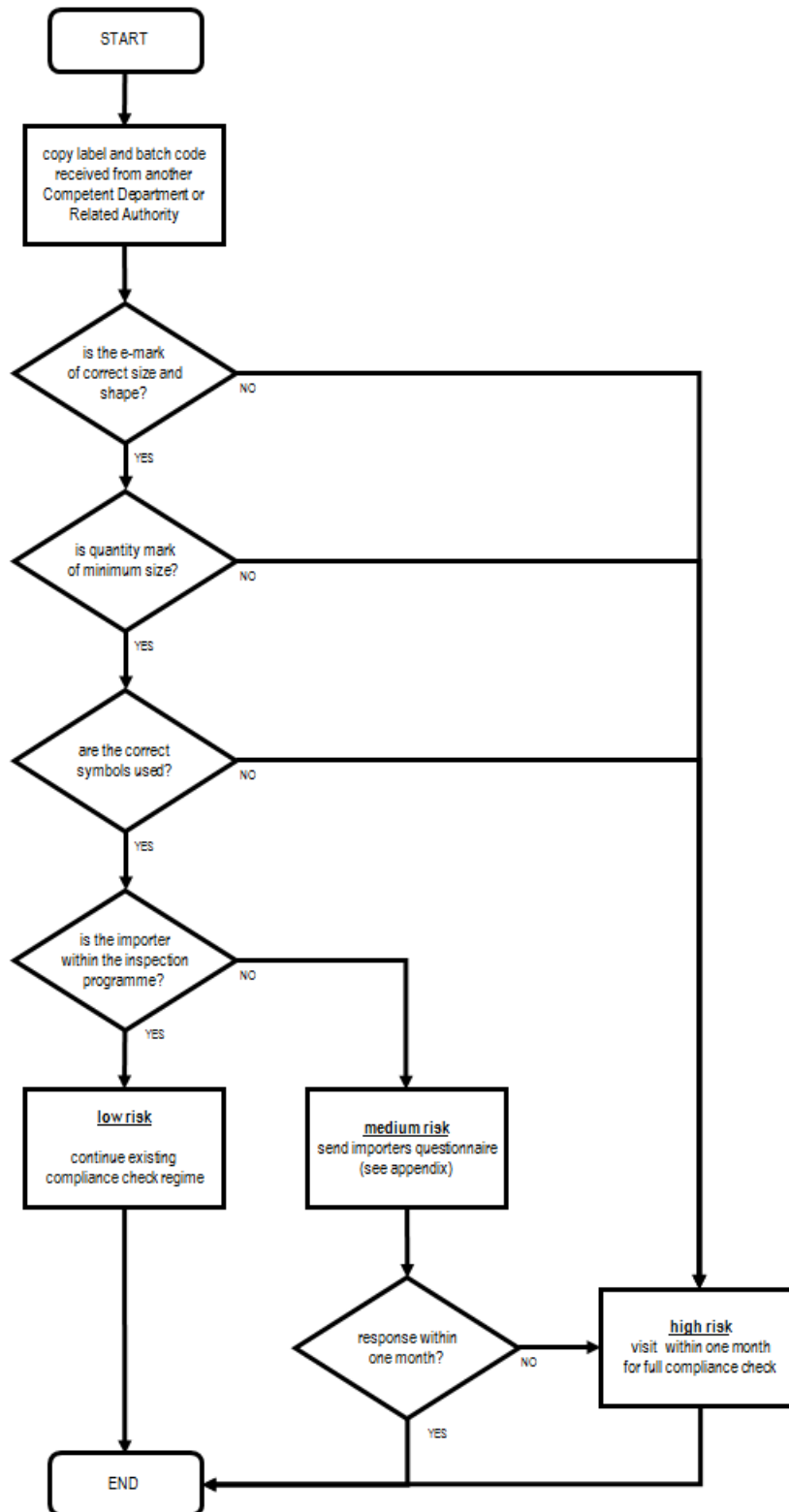


A.3.2 Action based on information

Where a Competent Department receives information regarding imported prepackages from another Competent Department or a Related Authority, the following provides guidance on proportionate actions to take.

Where the Related Authority informs the Competent Department of prepackages with non-compliant labels, the Competent Department has the responsibility of ensuring non-compliant prepackages are not released to the marketplace. The Competent Department needs to decide on whether to release the batch based on objective evidence.

One avenue is for the Competent Department to carry out a reference test on the impounded batch of prepackages.
 Where the Competent Department receives information of imported prepackages which are correctly labelled, the following flowchart will ensure consistency of enforcement using a risk-based approach.



Appendix – Imported Prepackages Questionnaire

Name & address of person:

Product name & quantity:

Batch identity: (insert)

Imported on: (date)

1. Are you the person who imported the prepackages into the EEA?

YES / NO

If NO, what are the contact details of the Importer?

.....
.....

2. If YES, what is the address of the warehouse:

.....

3. How do you fulfil your legal metrology responsibilities?

a) Carry out physical quantity checks on batches YES / NO

b) Rely on documentation YES / NO

4. If documentation, which of the following is used:

a) Actual production quantity control records YES / NO

b) Declaration that is packing to a minimum YES / NO

c) A statement from the metrology service YES / NO

d) Other, please state

.....

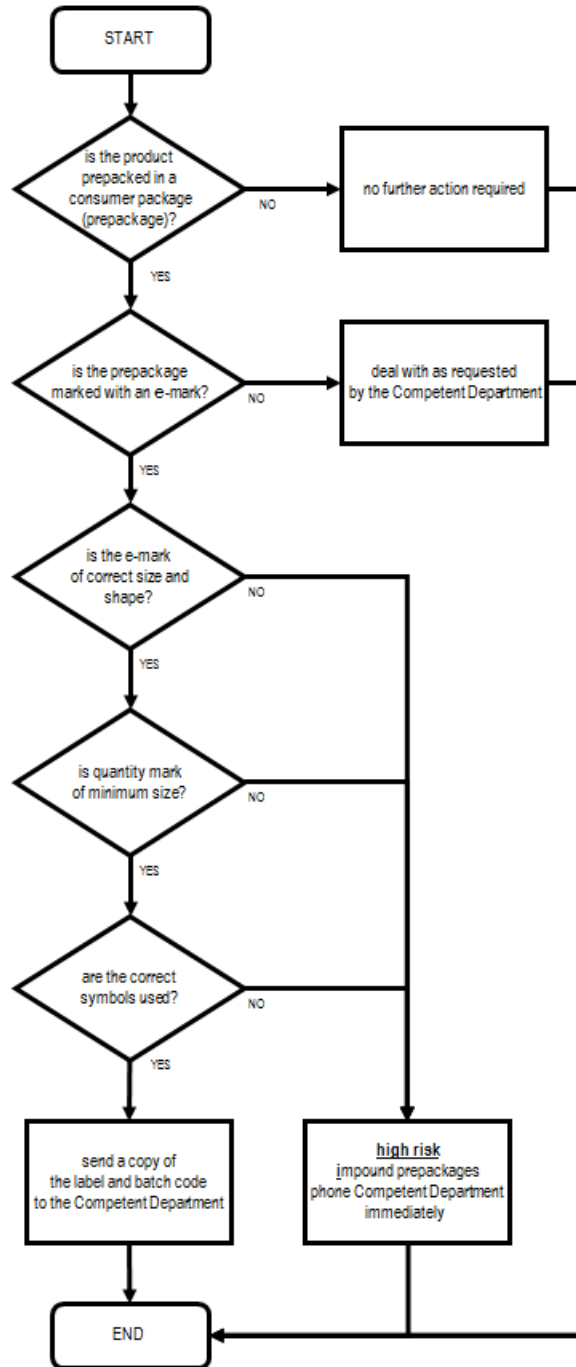
5. Please send copy of the documents (check results or documentation) relating to the import of the batch of product identified above.

Note: The guarantees and the documents used by the Importer to ensure his responsibility need to be understandable by the Competent Department.

Thank you for your time in completing the above, please post or e-mail back to sender.

Annex 4 – Related Authority Information Exchange

Following the flow chart below will effectively and efficiently monitor the importation of prepackages.



Annex 5 – Evidence for Importers

Evidence that enable the Importer to assume his responsibility consists of:

- the results of measurements or checks (see A.5.1), and
- proof of credibility of the person who performed the checks (see A.5.2).

In any case it is the Importer that decides whether each batch of imported prepackages meet the requirements of the Directive based upon the above evidence. This must be done before the prepackages are released to the market.

A.5.1 Results of measurements or checks

The results of measurements or checks consist of:

- batch size, batch identification, copy or photo of label,
- information of accuracy of measuring equipment used: photo of dataplate(s),
- collection of measuring results:
 - packing material: sample size, 100% (in case of individual tare) or none (in case of net-weighing),
 - density (in case of declaration in unit of volume), and
 - prepackages: sample size or 100% (in case of use of checkweigher/multihead),
- measuring results:
 - weight of packing material,
 - density of product (in case of declaration in unit of volume), and
 - prepackages:
 - in case of sampling: individual results, average and standard deviation, and
 - in case of checkweigher/multihead: average and standard deviation,
- calculations performed with measuring results (formulae),
- acceptance and rejection criteria for:
 - average quantity of product of prepackages in the batch,
 - number and/or percentage of prepackages with actual quantity of product less than TU1, and
 - number of prepackages with actual quantity of product less than TU2.

The procedures of a Packer outside Europe that comply with the requirements of chapter 4 of WELMEC Guide 6.6¹ provide for the above evidence.

¹ WELMEC Guide 6.6: Guide for recognition of procedures.

A.5.2 Proof of credibility of the person who performed the checks

The proof of credibility that the Importer must use depends on the person that provided the evidence for:

A.5.2.1 Checks by an independent, credible and qualified body

A copy of:

- the accreditation certificate, including scope, standard and date of validity, or
- results of peer-to-peer assessments by a Competent Department in a Member State.

A.5.2.2 Checks by the packer in the third country

- a description of the packer's procedures covering the subjects of chapter 4 of WELMEC Guide 6.6¹, and
- reports of initial audits and yearly surveillances by the Certification Organisation of the procedures of the Packer outside Europe, and
- a copy of:
 - o the accreditation certificate of the Certification Organisation, including scope, standard and date of validity, or
 - o evidence of peer-to-peer assessments by a Competent Department in a Member State of the Certification Organisation, including scope, standard and date of validity.

A.5.2.3 Checks by the Agent of the Importer

- a description of the procedures of the packer in the third country covering the subjects of chapter 4 in WELMEC Guide 6.6¹, and
- evidence that these procedures have been recognised by the Competent Department in the Member State where the agent is located in.

¹ WELMEC Guide 6.6: Guide for recognition of procedures.