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WELMEC

Informative Document

Multipacks

Prepared by
Working Group 6 Prepackages

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Background

WELMEC Working Group 6 was set up to discuss, and propose solutions for, the problems associated with the trading of ℮-marked prepacked products (hereafter called 'prepackages') between Member States[1]. The intention of this document is to inform about collective prepackages, whether packed in, or imported into, the Union'[2] meet the applicable metrological requirements.

WELMEC publishes guides, 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.

This document is not one of these guides. The information in this document provided is of a pure information nature only.

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

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1 Where in this document 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 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.

Contents

1 Introduction

Why this document is written

Several pieces of legislation that cover certain types of prepacked product have requirements for the labelling of multipacks.

For this document we looked at: food for human consumption, medical products for humans, animal feed, animal medicine and cosmetics. We found nothing for chemicals and aerosols (yet).

These requirements are not consistent with each other. This leads to labels that include too many of all sorts of declarations, which all can be checked by authorities and therefore must all be correct.

quantity declarations found on a box with ice creams declared in mass and volume

This document gives guidance and advice to packers on which quantities (not) to declare on the multipack. We have included the e-mark.

It would be preferable to show real examples of both good and bad labels to illustrate the guidance, but it would be unreasonable to ask packers to share these.

Disclaimer

Of course, following this guidance and advice does not preclude the Courts to interpret the legislation otherwise. In the end, it is and remains the responsibility of the packer to meet the requirements in legislation.

The annex contains a list of legislation and standards at the time of publication. It is strongly recommended to check if that list is still accurate when you read this: it may be outdated.

Some assumptions

It is assumed that:
- you know what the labelling requirements for the quantity of product in prepackages are for your type of product
- you know what the e-mark requires from you
- you understand the terminology used in prepackaging (and if not, see WELMEC 6.1)

The e-marking legislation could be interpreted as that there is only one nominal quantity to which the e-mark applies. This implies that other quantity declarations are considered voluntarily and subject to general rules for fair trade practices or consumer protection. This interpretation does not take into account:
- differences in the unit to use (see article 3 and 4 of 76/211/EEC), so one quantity declaration is the nominal quantity in one Member State and another one is the nominal quantity in another Member State
- that Member States may have other metrological requirements for prepackages that are not e-marked, this would lead to two sets of requirements if only one declaration is considered the nominal quantity

To apply to all interpretations, this document assumes that an e-mark applies to all declarations of product quantity on a prepackage.

Structure of this document

Chapter 3 lays down definitions applied to and interpreted in relation to multipacks. Terms that have a definition in chapter 3 are written in italics.

Chapter 4 contains flow diagrams that visualise legal requirements for multipacks food for human consumption, medical products for humans, animal feed and cosmetics. Chapter 5 provides some guidance for packers of multipacks that contain prepacked items of all types of product[1]. Chapter 6 gives a short summary of the main definitions and requirements and chapter 7 provides a list of questions and answers.

Readers guidance

We use the following icons:


good idea


not recommended


warning, this may get you in trouble


refers to product-specific requirement


Insights and wisdoms


examples are in blue

[1] these types of product include foods and non-foods

2 Scope

2.1 This document covers multipacks.

A multipack contains:
- product combined with one or more prepacked item(s) filled with product

example: prepacked salad with little bags of sauce, cheese, and croutons that the user can open and add to the salad by himself

- two or more prepacked items containing product

This document covers multipacks that meet the requirements of Directive 76/211/EEC. These bear the e-mark on their label.

The prepacked items inside the multipack:
- may or may not meet the requirements of Directive 76/211/EEC
- may or may not be intended for individual sale to the consumer or individual use by the end-user

2.2 This document may benefit all economic operators such as:
- persons who make up multipacks,
- packers and importers of prepacked items,
- enforcement authorities and
- persons that intend to, or do distribute or sell multipacks to other distributors, to retailers or to consumers

and the competent authorities.

3 Definitions and terms

This chapter introduces the definitions of '*multipack*' that contain one or more '*prepacked items*'.

The prepacked items can either be '*prepackages*' if they meet the requirements of Directive 76/211/EEC or '*non-e-marked prepacked items*' if they do not.

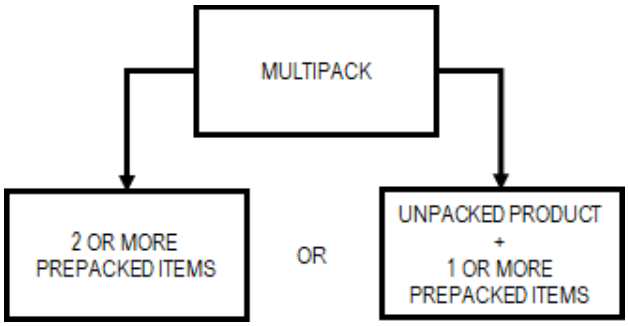
3.1 Multipack

multipack – a *prepackage* that contains:

- 2 or more *prepackages*; or
- 2 or more *non-e-marked prepacked items*; or
- 1 or more *prepackages* and 1 or more *non-e-marked prepacked items*; or
- product that is not separately packed; and
  a. 1 or more *prepackages*
  b. 1 or more *non-e-marked prepacked items*
  c. the combination of a. and b.

Example: meal salad, meal kit.

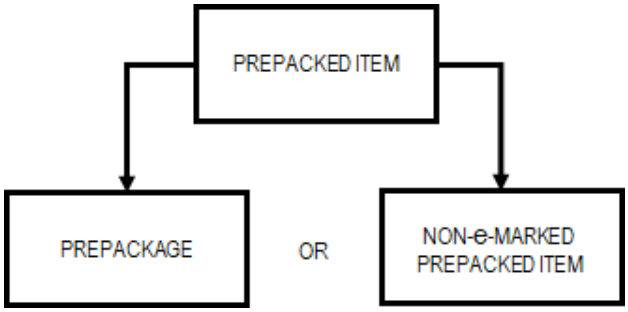
Note 1: a multipack is also called: a collection, collective package or joint presentation.



Transport packaging is a *multipack* that is not intended as unit of sale destined for the ultimate consumer/end user and merely used to ship, store, and handle two or more *prepacked item*s. The authorities may give other priorities to enforcement on transport packing.

3.2 Prepacked item

prepacked item – either a *prepackage* or a *non-e-marked prepacked item* that is inside a *multipack*.



A portionpack is a *prepacked item* that contains one portion of product.

Example: sachets of sauce, little bottles of shampoo.

3.3 Prepackage

prepackage – combination of a product and the packing material in which it was put,
- without the purchaser present at the time of packing when the actual quantity of product was determined, and
- whose *nominal quantity* of product has a predetermined value, and
- whether the packing material encloses the product completely or only partially but in any case in such a way that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification

(WELMEC 6.1 Definitions of terms, 2.1)

Note 1: for the purpose of this document, the term '*prepackage*' is used for a *prepackage* that is made up in accordance with the Directive 76/211/EEC. Such *prepackage* bears[1]:
- the *nominal quantity*;
- a mark or inscription to identify the packer or the person arranging for the packing to be done or the importer ('*identification mark*');
- a small 'e'[2] in the same field of vision as the *nominal quantity*.

The e-mark is often required by persons further down the distribution chain.

Note 2: there is a legal ruling[3] that certain *portionpacks* of honey supplied by a mass caterer to the ultimate consumer/end user are 'pre-packed foodstuff'.

There is good reason to also apply this ruling to *portionpacks* that contain other products.

If such *portionpacks* are made up in accordance with the Directive 76/211/EEC, they shall bear the indications of note 1.

Note 3: a *prepackage* may or may not be intended as a unit of sale/use destined for the ultimate consumer/end user

Example: prepacked ingredients in a meal salad or meal kit are no unit of sale, not even when they are made up in accordance with Directive 76/211/EEC and bear the indications of note 1.

[1] For complete text, see article 3 of Annex I of Directive 76/211/EEC
[2] This 'e' shall have the form shown in the drawing contained in section 3 of Annex II to Directive 71/316/EEC.
[3] Case C-113/15 of 22/09/2016, see annex 1.4.

3.4 Non-e-marked prepacked item

non-e-marked prepacked item – a prepacked item inside a *multipack* that is not a *prepackage*.

Note 1: the labelling of a *non-e-marked prepacked item* lacks one, more or all of the following: *nominal quantity*, *identification mark*, e-mark.

Note 2: national metrology requirements of the Member State apply to *non-e-marked prepacked item*s.

Note 3: when the *multipack* bears the e-mark and also bears the *nominal quantity* of a *prepacked item* inside the *multipack*, the *prepacked item* inside shall meet the requirements of the Directive 76/211/EEC, including labelling requirements of note 1 of chapter 3.3 (the *prepacked item* inside effectively becomes a '*prepackage*').

3.5 Principal display panel

Many pieces of legislation that cover prepacked product require that important indications must be printed on that part of the packing material that is designed to be visible for the consumer/buyer 'under normal conditions of presentation'[1].

Most countries in the world call that part of the prepackage the *principal display panel*.

principal display panel – part of a *prepackage* that is designed to be visible under normal conditions of display for sale.

(OIML R79-e15, chapter 2 Terminology.10)

Note 1: There could be more than one *principal display panel*.

Note 2: Generally, the *principal display panel* bears the name of the product. Most legislation also require the *nominal quantity* on the *principal display panel*.

In many legislations, other/voluntary labelling should be placed away from the principal display panel (ie. on another side of the packing material).

The Directive 76/211/EEC has no such requirement.

Note 3: the quantity of the product to which other/voluntary labelling refers must meet the requirements, regardless of its location on the packing material.

[1] 'normal conditions of presentation' is the terminology used in article 3 of Annex I of 76/211/EEC

3.6 Identification mark and the responsible person

The responsible person is the person who has the responsibility to ensure that the *prepackages* meet the requirements.

When a *prepackage* is e-marked, the *responsible person* is the packer or the importer. If the responsible person is not marked, the person arranging for the packing to be done shall be marked. He should be able to identify the *responsible person*, based on the packing material.

identification mark – a mark or inscription on the *prepackage* that enables the authorities to identify the *responsible person*, or the person arranging for the packing to be done.

Note 1: an identification mark may be a registered trade mark.

The packer who fills prepackages for another packer (who places them in a multipack or adds them to their prepackages), shall apply an identification mark, nominal quantity and the e-mark to the prepackages that he fills for the other packer.

The packer who places these prepackages in a multipack or adds them to his prepackages shall also apply an identification mark to the multipack or his prepackages.

These identification marks may be identical, with one identifying the responsible person and the other identifying the person arranging for the packing to be done.

3.7 Total quantity and nominal quantity

The nominal quantity of product – the quantity of product in a *prepackage* declared on the label by the packer.

(WELMEC 6.1 Definitions of terms, 3.1)

For the purpose of this document, the *nominal quantity* of a *multipack* is referred to as total nominal quantity.

Note 1: If the multipack consists solely of *prepackages*, then the *total nominal quantity* is equal to the sum of the *nominal quantities* of all *prepackages* inside the multipack.

Note 2: if the nominal quantities of the prepackages inside the multipack are expressed in the same unit (mass or volume)[1], the total nominal quantity shall be expressed in that unit.

Note 3: If the nominal quantities are expressed in different units (mass and volume)[1], the total nominal quantity shall be expressed in a unit of mass (g or kg)[2].

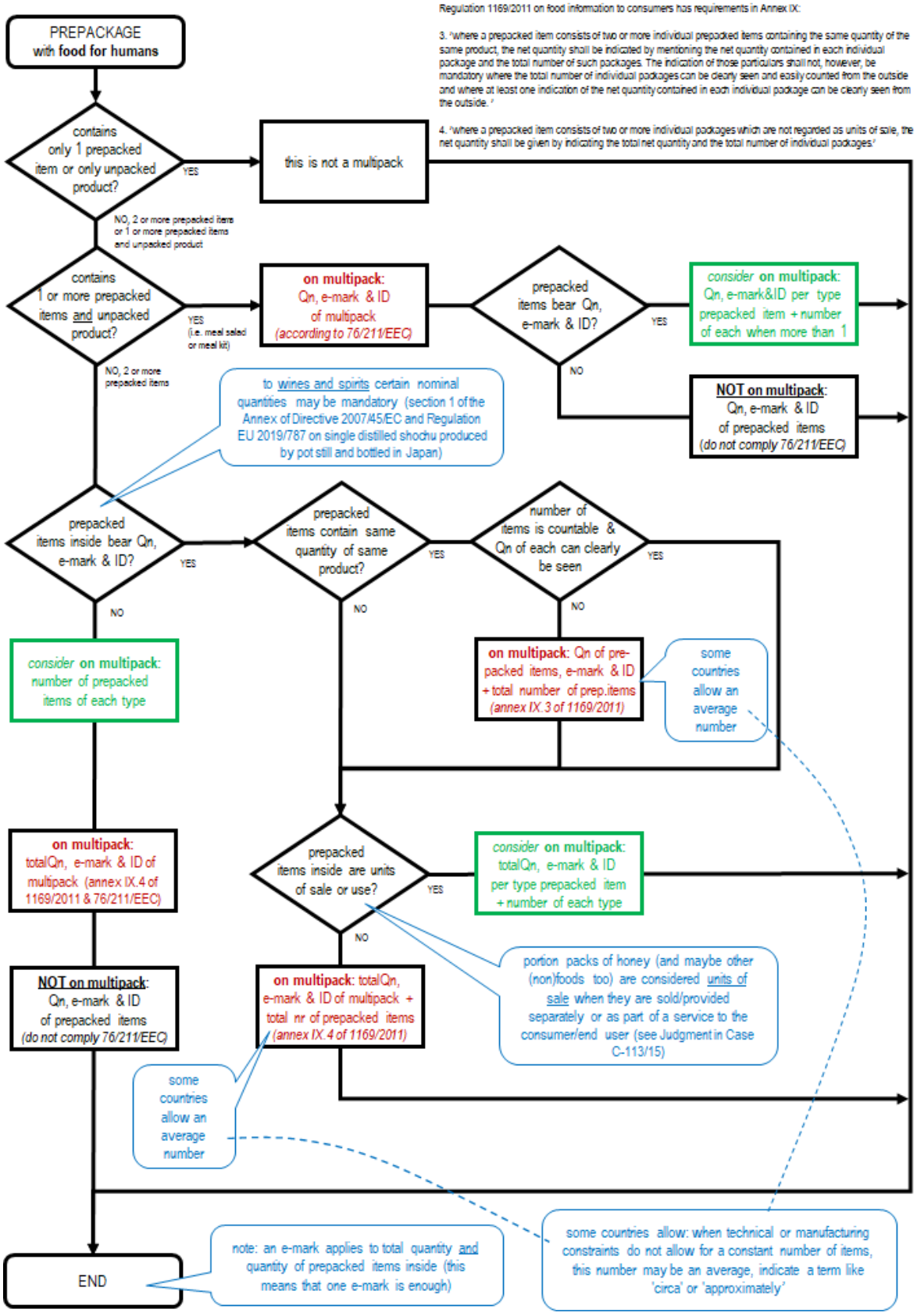
[1] mass: in g or kg, volume: ml, cl or L
[2] Analogous to what is stated in Article 4.2 of 76/211/EEC

4 Requirements from legislation

In the flow diagrams of this chapter, text in red means: legal requirement, in green means: optional and in blue helps to decide or to consider.

4.1 Food labelling and 76/211/EEC

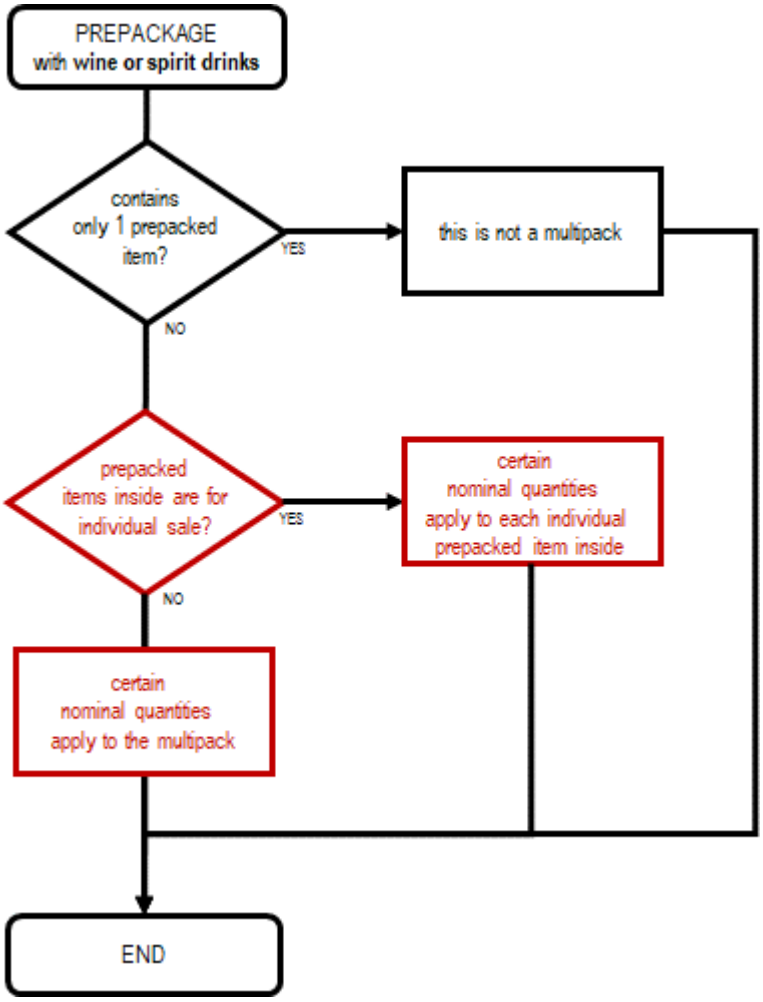
How to combine no. 3 and no. 4 of Annex IX of Regulation 1169/2011 and Directive 76/211/EEC.



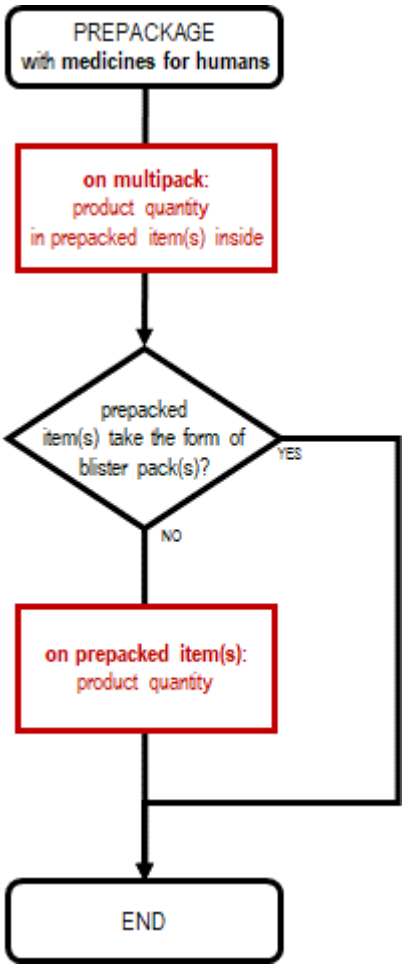
4.2 Directive 2007/45/EC on nominal quantities for prepacked products and 76/211/EEC

Directive 2007/45/EC on nominal quantities for prepacked products, has requirements in article 5 for 'multipacks and prepackages made up of individual packages which are not intended to be sold individually'

'… where two or more individual prepackages make up a multipack, the nominal quantities listed in section 1 of the Annex shall apply to each individual prepackage. Where a prepackage is made up of two or more individual packages which are not intended to be sold individually, the nominal quantities listed in section 1 of the Annex shall apply to the prepackage.'



4.3 Directive 2001/83/EC on medicine for humans and 76/211/EEC



Article 54 of Directive 2001/83/EC.
The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:
(c) ... the contents by weight, by volume or by number of doses of the product;

Article 55 of Directive 2001/83/EC
The particulars laid down in Article 54 shall appear on immediate packagings other than those referred to in paragraphs 2 and 3.

2. *The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62.*
   - *the name of the medicinal product as laid down in point (a) of Article 54,*
   - *the name of the holder of the authorization for placing the product on the market,*
   - *the expiry date,*
   - *the batch number.*
3. *The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed:*
   - *the name of the medicinal product as laid down in point (a) of Article 54 and, if necessary, the route of administration,*
   - *the method of administration,*
   - *the expiry date,*
   - *the batch number,*
   - *the contents by weight, by volume or by unit.*

Questions and answers version 15 on medical products for human use – quality, safety and innovation state the following (relevant for this document):

1.19. Question: In case of a bundle of several single packs sold as one unit, should the anti-tampering device and unique identifier be placed on the bundle packaging or on each single pack?

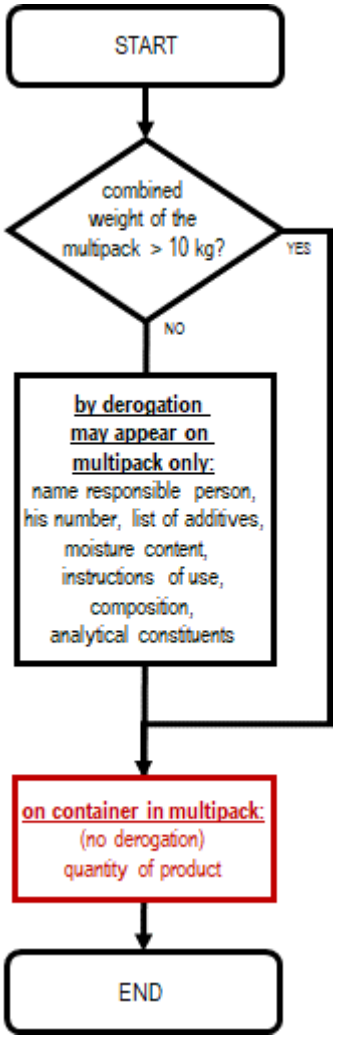
Answer: …. If, …, the product presentation is described as a "multi-pack", the outer packaging as that of the bundle and the single packs as not for individual sale (the text 'can't be sold separately' or equivalent is present on the packs), then …. The outer packaging must include, …, all applicable labelling requirements as laid down in Article 54 of Directive 2001/83/EC.

4.4 Regulation 767/2009 on animal feed and 76/211/EEC

Regulation 767/2009 on animal feed gives exceptions for labelling rules for multipacks with a (gross?) weight of 10 kg and less:

Article 21, Derogations
7. For quantities of pet food sold in packages with several containers, the particulars referred to in Article 15(b), (c), (f) and (g) and Article 17(1)(b), (c), (e) and (f) may be given only on the outer packaging instead of on each container, provided that the combined total weight of the package does not exceed 10 kg.

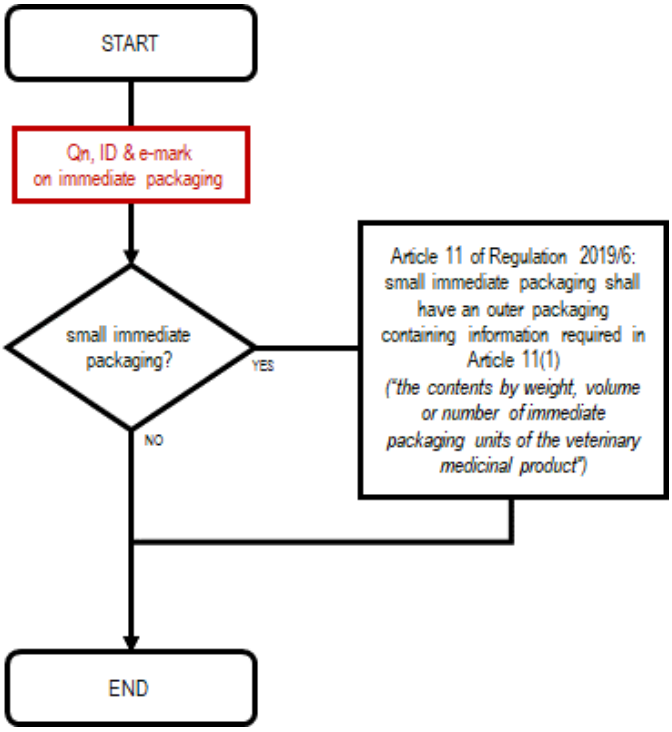
The quantity of product is not a derogation as meant in this article 21. This means that the quantity of product shall always be declared on the individual (pre)packed item.



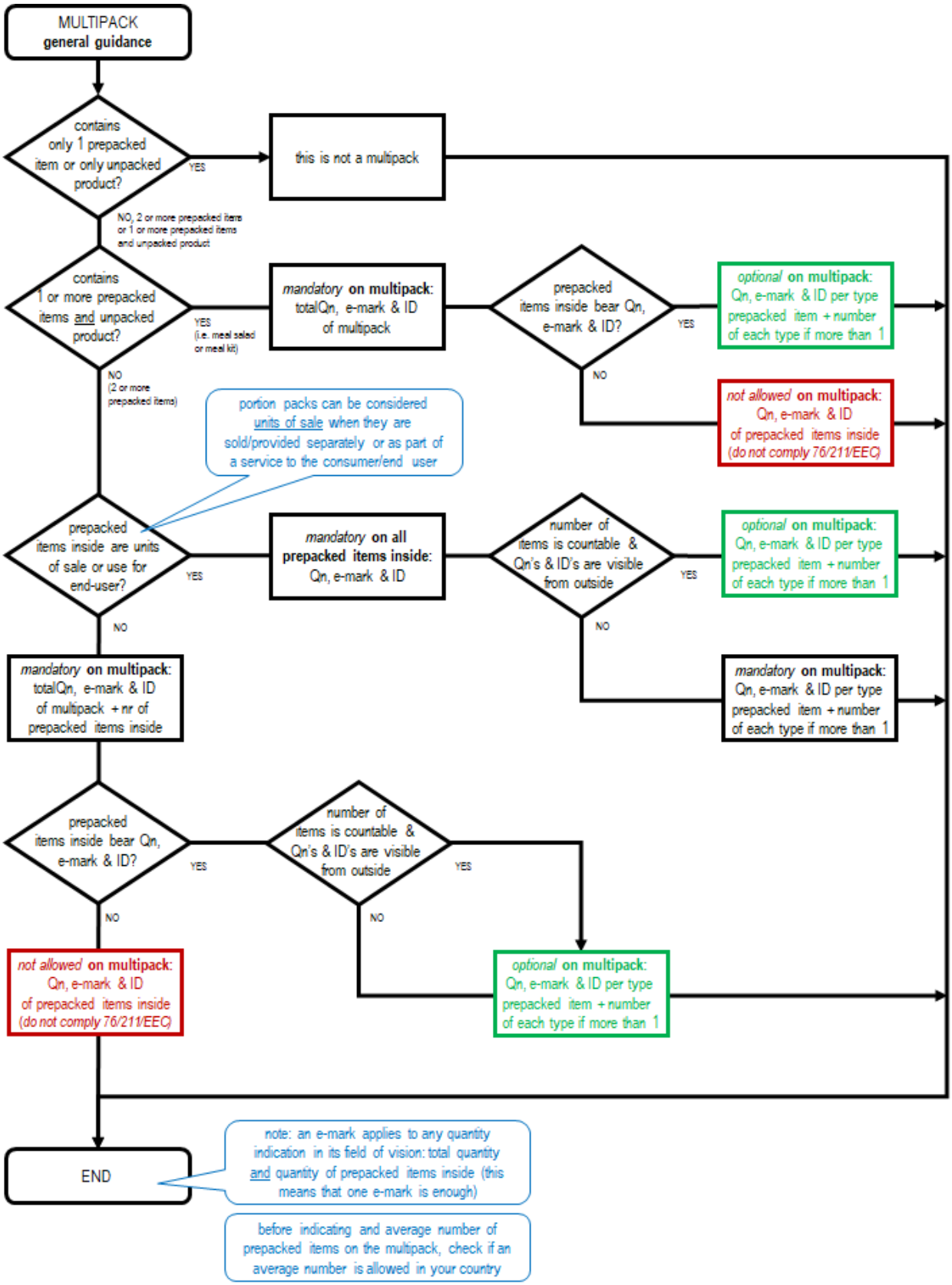
4.5 Regulation 2019/6 on animal medicine and 76/211/EEC

Article 11 Labelling of the outer packaging of veterinary medicinal products
1. The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than:
(a) …
(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
2. …
3. …
4. …

Article 12 Labelling of small immediate packaging units of veterinary medicinal products
1. By way of derogation from Article 10, immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain the following information and shall contain no information other than:
(a) …
(b) …
(c) …
(d) …
2. The immediate packaging units referred to in paragraph 1 of this Article shall have an outer packaging containing information required in Article 11(1), …



5 Guidance for packers of multipacks



1. If a prepackage contains only one prepacked item or only unpacked product, it is not a multipack.
2. If a prepackage contains one or more prepacked items and unpacked product (like a meal salad or a meal kit), it is mandatory to declare the total nominal quantity, the e-mark and the identification mark.
    a. If the prepackaged items inside the multipack bear the nominal quantity, the e-mark and the identification mark, it is optional to also repeat them[1] on the outside of the multipack.
    b. If the prepackaged items inside the multipack do not bear one or more of the nominal quantity, the e-mark and the identification mark, it is not allowed to declare them[1] on the outside of the multipack. Prepacked items without one or more of the nominal quantity, the e-mark and the identification mark do not comply with the e-marking Directive.
3. If the prepacked items inside a multipack are units of sale to the consumer or units of use for the end-user[2], it is mandatory to declare the nominal quantity, the e-mark and the identification mark on these prepacked items.
    a. If the number of prepacked items inside the multipack is easily countable and the nominal quantities and identification marks are visible from the outside, it is optional to also repeat them[1] on the outside of the multipack.
    b. If the number of prepacked items inside the multipack is not easily countable and/or the nominal quantities and identification marks are not visible from the outside, it is mandatory to declare the nominal quantity, the e-mark and the identification mark of the prepacked items inside and the number of each type (if more than one type), on the outside of the multipack.
4. If the prepacked items inside a multipack are not units of sale to the consumer or units of use for the end-user, it is mandatory to declare on the multipack the total nominal quantity, the e-mark and the identification mark on the multipack and the number of prepacked items inside.
    a. If the prepacked items inside a multipack bear their nominal quantities, the e-mark and the identification mark, it is allowed to repeat them[1] on the outside of the multipack, regardless if the number of prepacked items inside the multipack is easily countable and the nominal quantities and identification marks are visible from the outside.
    b. If the prepackaged items inside the multipack do not bear one or more of the nominal quantity, the e-mark and the identification mark, it is not allowed to declare them[1] on the outside of the multipack. Prepacked items without one or more of the nominal quantity, the e-mark and the identification mark do not comply with the e-marking Directive.

In all cases, the e-mark applies to any quantity indication in its field of vision: total nominal quantity and nominal quantity of prepacked items inside.

Before declaring an ‘average’ number of items, check if that is allowed in your country.

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[1] Them means the nominal quantity, the e-mark and the identification mark of the prepacked items inside

[2] One can argue that portion packs provided to a consumer or end-user for free or as part of a service are ‘units of sale to the consumer or units of use for the end-user’ and therefore must bear nominal quantity, the e-mark and the identification mark. Examples are: bottles of shampoo in a hotel, (peanut) butter or honey as part of a meal (on a portion pack of honey a legal ruling exists)

6 The extremely short summary

1. A multipack contains:
    a. not separately packed product combined with one or more prepacked items, or
    b. two or more prepacked items containing product

2. Prepacked items inside a multipack:
    a. may or may not meet the requirements of Directive 76/211/EEC
    b. may or may not be a unit of sale destined for the ultimate consumer/end user

3. An e-mark on a multipack applies to:
    a. any mandatory (nominal) quantity of product
    b. to non-mandatory quantity claims
    note that non-mandatory quantity claims may be mandatory in other Member States
    c. the nominal quantity of the prepacked items inside, if these are on the multipack
    d. the (total) nominal quantity of the multipack, if that is on the multipack

4. Only declare what is mandatory. Your measuring and checking procedures have to guarantee all nominal quantities that you declare.

5. A non-e-marked item (a prepacked item inside a multipack that is not a prepackage) does not become a prepackage when its nominal quantity, identification and e-mark are placed on the (outside of the) multipack.

6. You do not have to repeat on the multipack whatever is visible/countable from the outside.

7. If you are filling prepackaged items for another packer (who repacks them into a multipack or adds them to their prepackages), apply the nominal quantity, e-mark, and your identification mark to the prepackages that you fill.

7 Best practice - questions and answers

7.1 Optional/voluntary quantity indications do not have to comply, do they?

Wrong! Packers must place quantity indications on a label for a reason: to help customers to make decisions when buying their product.

Extra optional/voluntary quantity indications are there to help even better. That is why they shall comply too![1]

7.2 Is it allowed to declare the mandatory labelling of non-e-marked prepacked items on the multipack and not on the non-e-marked prepacked item itself?

No. A non-e-marked prepacked (inside or outside a multipack) is not compliant with the e-marking Directive without the mandatory labelling.

7.3 To what quantity declaration does the e-mark apply?

The e-mark, placed in the same field of vision as the nominal quantity, is a guarantee that the prepackage meets the requirements of the e-marking Directive. Therefore, a(ny) e-mark that is placed in the same field of vision of nominal quantities (and the total quantity, if present), is a guarantee that they meet the requirements of the Directive or Unfair Commercial Practices legislation.

7.4 What do inspectors check?

Inspectors can check any mandatory and voluntary quantity declaration.

Inspectors can check the procedures that packers must have in place when prepackages are e-marked. These procedures apply to any quantity placed in the same field of vision as the e-mark.

7.5 What to declare if items in the multipack are not prepacked?

Unpacked items in a prepackage (i.e. pieces of fruit) do not make up a multipack, but a prepackage. The nominal quantity of product, the e-mark and the identification mark of the packer must be declared. Other (maybe national) legislation applies to the quantity declaration of the items.

7.6 Declaration of quantity on multipacks is complicated. Do you have some simple rules?

See the flow diagram of chapter 5 and the extremely short summary (chapter 6).

If you have a question about your particular situation, contact the Competent Department in your Member State.

[1] See ‘some assumptions’ of chapter 1.

Annex 1: list of relevant (interpretation of) legislation, judgments, standards, and recommendations

1.1 Directive 76/211/EEC[1] on prepackages with an e-mark has no special requirements for multipacks.

1.2 Directive 2007/45/EC on nominal quantities for prepacked products, has requirements in article 5 for '*multipacks and prepackages made up of individual packages which are not intended to be sold individually*'.

1. '*… where two or more individual prepackages make up a multipack, the nominal quantities listed in section 1 of the Annex shall apply to each individual prepackage.*
2. *Where a prepackage is made up of two or more individual packages which are not intended to be sold individually, the nominal quantities listed in section 1 of the Annex shall apply to the prepackage.*'

1.3 Regulation 1169/2011 on food information to consumers has requirements in Annex IX:

3. '*where a prepacked item consists of two or more individual prepacked items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. The indication of those particulars shall not, however, be mandatory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside. '*

4. '*where a prepacked item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.*'

1.4 Judgment of the court in Case C-113/15 of 22/09/2016[2]

When supplied by a mass caterer, a portionpack is regarded as a unit of sale destined for the ultimate consumer: "*Each of the individual portions ... presented in the form of portion-cups ... and packed in cartons supplied to mass caterers constitutes a 'pre-packaged foodstuff' where the mass caterers sell those portions separately or offer them for sale to the ultimate consumer as part of pre-prepared meals for an all-inclusive price.*"

In relation to the above, the article 16.2 of regulation 1169/2011 on food information to consumers is relevant: '*In the case of packaging or containers the largest surface of which has an area of less than 10 cm^2 only the particulars listed in points (a), (c), (e) and (f) of Article 9(1) shall be mandatory on the package or on the label.*'

(a) the name of the food;
(c) …
(e) the net quantity of the food;
(f) …

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1 Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (76/211/EEC)

2 The ruling was about portionpacks of honey. There is reason to assume that this ruling also applies to portionpacks with other products.

1.5 The Q&A application 1169/2011 on food information to consumers - 2.12.1
"*where, following good manufacturing practices, the precise indication of the total number of individual (pre)packages is not possible because of technical (no piece count control) or other manufacturing constraints, this number can exceptionally refer to the average number. The term 'approximately' or similar wording/abbreviations could also be used*".
is superseded by 2018/C196/01 of 2018, without the above interpretation.

Note: Germany does not allow the reference to the average number. The policy of other countries is unknown.

1.6 Questions and answers version 15 on **medical products for human use** – quality, safety and innovation state the following (relevant for this document):

1.19. Question: In case of a bundle of several single packs sold as one unit, should the anti-tampering device and unique identifier be placed on the bundle packaging or on each single pack?

Answer: …. If, …, the product presentation is described as a "multi-pack", the outer packaging as that of the bundle and the single packs as not for individual sale (the text 'can't be sold separately' or equivalent is present on the packs), then …. The outer packaging must include, …, all applicable labelling requirements as laid down in Article 54 of Directive 2001/83/EC.

1.7 Article 55 of Directive 2001/83/EC relating to **medicinal products for human use** states:

3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed:
…
- the contents by weight, by volume or by unit.

1.8 Regulation 1223/2009 on **cosmetic products** mentions the following in Article 19, Labelling:

1. …, cosmetic products shall… bear the following information …:
(a) …
(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

1.9 Regulation 767/2009 on **animal feed** gives exceptions for labelling rules for multipacks with a (gross?) weight of 10 kg and less:

Article 21, Derogations
7. For quantities of pet food sold in packages with several containers, the particulars referred to in Article 15(b), (c), (f) and (g) and Article 17(1)(b), (c), (e) and (f) may be given only on the outer packaging instead of on each container, provided that the combined total weight of the package does not exceed 10 kg.

The quantity of product is not a derogation als meant in this article 21. This means that the quantity of product shall always be declared on the individual (pre)packed item.

1.10 Regulation 2019/6 on **animal medicine**

Article 11 Labelling of the outer packaging of veterinary medicinal products
1. The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than:
(a) …
(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
2. …
3. …
4. …

Article 12 Labelling of small immediate packaging units of veterinary medicinal products
1. By way of derogation from Article 10, immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain the following information and shall contain no information other than:
(a) …
(b) …
(c) …
(d) …
2. The immediate packaging units referred to in paragraph 1 of this Article shall have an outer packaging containing information required in Article 11(1), …

1.11 OIML recommendation 79 (2015) *Labeling requirements for prepackages* and OIML R87 (2016) *Quantity of product in prepackages* have no requirements for multipacks.