

NORDIC CRITERIA FOR MORE SUSTAINABLE PACKAGING

For healthcare products

Version 2, August 2023

Capital Region of Denmark, Region of Southern Denmark, Central Denmark Region, North Denmark Region, Region Zealand and Amgros

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1 Introduction

The Nordic Criteria for More Sustainable Packaging for Healthcare Products aim to reduce climate and environmental impacts of packaging in the healthcare sector. The document contains a library of criteria for packaging that can be used in the tender process.

The criteria have been developed in collaboration between stakeholders responsible for public green procurement in the health sector in Norway, Sweden, Denmark, Iceland and the Faroe Islands. The criteria have been circulated for consultation in the relevant industry organisations in Norway and Denmark as well as in the framework of Medtech Europe, the European industry association.

By joining forces in the development and the implementation of these sustainability criteria for packaging, we send a strong signal to the market and set a clear direction for suppliers. The criteria should support a cost-effective change towards *more* climate and environmentally sustainable packaging for healthcare products.

The purpose of the criteria is to assist the relevant responsible persons for public sector tenders, e.g., category managers, public procurement officers or tender consultants in defining packaging-specific criteria relevant to the specific procurement. Health sector suppliers in the Nordics may find it useful to familiarise themselves with the criteria as a way to prepare for potential supplier requirements.

The document includes a guide to the tender consultant on how to use the criteria (section 2) and a library of criteria (section 4) which can be implemented in the tender documents as appropriate. A number of appendices include additional information. The appendices are intended to be a work of references where tender consultants may find further technical information about the use of the criteria.

The first library of criteria was published in August 2022 and applied in a number of calls for tenders. Based on the experiences, the criteria and the guides have been revised. The Library of criteria in itself and the criteria within

have not been changed. Mostly, the changes is reflected in more in-depth explanations of and guides on how to use the criteria in practice. The main content of the revision consists of:

- > The addition of chapter 2, which provides a more thorough introduction to the purpose and delimitation of the criteria, and provides a common understanding of what the library of criteria can be used for.
- > The guide includes a more thorough explanation of how to use the criteria.
- > The addition and improvement of a number of appendices and ancillary documents that can be used when preparing calls for tenders and assessing tenders.

2 More sustainable packaging for healthcare products

This chapter introduces two main topics:

- > How to understand and delimit packaging for healthcare products, and
- > What is the purpose of the library of criteria, and how to understand the concept of sustainability.

2.1 What is packaging for healthcare products?

The health sector uses products and associated packaging that is either sterile, clean or ordinary. To stipulate relevant requirements for packaging for healthcare products and to communicate sustainability requirements for packaging between the contracting entity and the tenderer, a common frame of understanding for packaging for healthcare products is needed.

The Nordic Criteria for More Sustainable Packaging for Healthcare Products build on the general terminology for packaging, in accordance with the European Parliament and Council Directive 94/62/EC of 20 December 1994, article 3, paragraph 1:

*"(a) sales packaging or **primary packaging**, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;*

*(b) grouped packaging or **secondary packaging**, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics;*

*(c) transport packaging or **tertiary packaging**, i.e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers;"*

The Directive is described further in Appendix G.

In general, **sterile packaging** consists of three layers, as described above. However, the functioning of the primary packaging for a sterile medical product is more complex than is the case with, e.g., a bag of potatoes. First and foremost, the purpose of the primary packaging is to ensure that the sterile product remains sterile until it is used. The packaging must allow for sterilisation through the packaging by means of various sterilisation methods, and it must be

possible to open it with and without gloves so as to ensure that the product remains sterile.

Consequently, sterile primary packaging is technologically and material-wise complex. The requirements for sterile packaging and package systems for terminal sterilised medical equipment are stated in DS/EN 11607-1:2020, parts I and II. Annex D of the standard describes, in very overall terms, 'environmental considerations' as a topic of increasing importance. But the standard does not further specify how to handle 'environmental considerations' for sterile packaging.

Packaging for **clean** (non-sterile) products is typically less complex. Clean packaging usually has two layers of packaging; the primary packaging layer protecting the product, and the outer packaging protecting the product and the primary packaging.

There may be national guidelines for how to describe packaging for healthcare products. Appendix C contains an overview of the terminology for sterile and non-sterile packaging that is used in the Danish Regions' contract appendix 5, which is linked to the general definition of packaging used in the European Packaging and Packaging Waste Directive.

Section C.1 of the appendix includes examples of types of packaging that may be used to start a market dialogue. The examples are intended to support the dialogue with tenderers, ensuring that all parties understand what the packaging is made of. *Also see the template 'Power point skabelon og eksempler på emballageniveauer'.*

2.2 What is more sustainable packaging according to the joint Nordic criteria?

The overall purpose of using these criteria is to lower the climate and environmental impact of packaging, e.g., greenhouse gas emissions.

Nonetheless, it is very complex to calculate the total climate and environmental impact of packaging. The climate and environmental impact of packaging depends on its life cycle: choice and extraction of raw materials; consumption of raw materials, water and energy consumption in connection with production; emission to water and air in connection with production; transportation; storage; utilisation; type and quantity of materials; recyclability; and disposal.

The Nordic Criteria for More Sustainable Packaging were developed as a tool for tender processes that may contribute to reducing the climate and environmental impact of packaging. The sustainability criteria for packaging were neither developed nor able to cover all aspects of the life cycle of a specific packaging. Using sustainability criteria may ensure that packaging with a smaller climate and environmental impact is in demand.

The sustainability criteria only deal with a number of selected sustainability topics. The topics were chosen based on the European Packaging and Packaging Waste Directive 94/62/EC and the latest revision (EU)2018/852, meaning that the criteria contribute to operationalising the European Packaging and Packaging Waste Directive. See further in Appendix G - Introduction to the European Packaging and Packaging Waste Directive (European Parliament and Council Directive 94/62/EC), and the latest revision of EU Directive 2018/852.

The criteria are divided into the following *three sustainability topics* and elaborated on below:

- > Reduce material consumption
- > Design for recycling
- > Recycled or sustainably sourced materials content.

Reducing material consumption is usually the most effective measure when it comes to developing more environmentally friendly packaging. It reduces resource consumption and waste volumes. Furthermore, this sustainability topic offers economic advantages to producers.

Designing **packaging for sorting and recycling** also contributes to reducing the total resource consumption, since the recycled materials can be used for new products.

By **requesting recycled and bio-based materials**, the call for tenders contributes to reducing the dependency on fossil resources. Furthermore, bio-based materials also support the development of a bio-based economy. The challenge of bio-based materials, especially plastics, is that they may potentially come from raw materials that could have been used for foods (e.g., maize) or be grown in areas that could have been used for food production. Consequently, it is important to pay attention to the origin of the biomass used to produce bio-based materials. In turn, it is crucial to ensure that the requested bio-based materials meet relevant standards.

Based on the chosen sustainability topics, the criteria may contribute to, in a systematic and provable manner, requesting *more* sustainable packaging in tender documents. To be reasonably accurate, the criteria place great emphasis on the quality of the documentation.

The criteria were developed to support the European Packaging and Packaging Waste Directive. That is also the source of the logic that is integrated into the criteria, in terms of choosing and prioritising what is relatively more sustainable than other materials.

The choice of materials should be included when assessing which material is relatively more sustainable than other materials. The hierarchy of materials shown in Figure 1 can be used to indicate the range of the environmental impact. The higher the packaging is located in the hierarchy, the lower its environmental impact. As such, the hierarchy of materials can provide an

overview of whether there is room for improvement in terms of choice of material.

The hierarchy of materials does not include information about the specific weight or the degree of recyclability. Therefore, the decision on which measures to take to reduce the environmental impact should not be based on the hierarchy of materials alone. The degree of recyclability and the specific weight of the different packaging materials should also be included in the assessment.

Also see Appendix G about the European Packaging and Packaging Waste Directive.

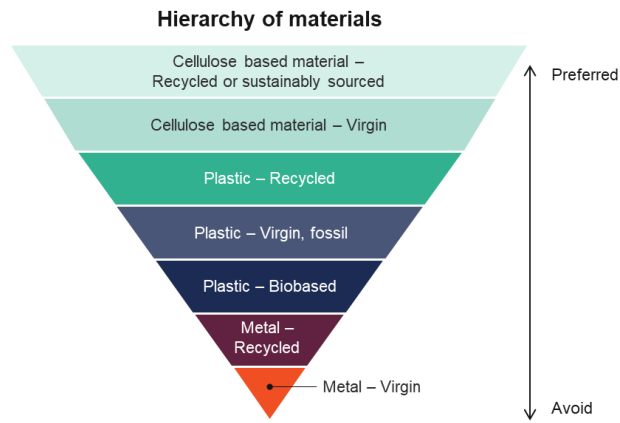


Figure 1 Hierarchy of materials for choosing which materials are preferable to others. Note biogenic plastic here represent bioplastics from first and partly secondary raw materials.

3 Guide to the use of the criteria

This document includes:

- > a library of criteria, which is included in chapter 4
- > a glossary and abbreviations, which are included in Appendix A and Appendix B
- > elaborations on definitions, standards, directives and ancillary tools for the tender process, which are included in Appendix C to Appendix G.

3.1 Structure of library of criteria

For each of the three sustainability topics, a library of criteria is presented. The criteria include the main materials that are traditionally used for packaging, i.e., plastics, cardboard and metals.

The criteria are divided into three levels according to their potential climate and environmental impact:

- > **Basic criteria** are designed to provide a starting point for efforts to achieved more sustainable packaging.
- > **Advanced criteria** are designed to accomplish higher levels of climate and environmental performance supporting higher climate, environmental and innovation goals.
- > **Spearhead criteria** are designed for excellent climate and environmental performance.

The criteria are expected to be relevant to up to 80 per cent of all packaging. It is necessary that the feasibility of all criteria be tested through early market dialogue in the pre-tendering process. This will enable the adaption of the criteria to be in line with the market maturity of the individual product segment.

Appendix E contains an in depth guidance with suggestions of subjects for the market dialogue, based on current experience and a reference to an Excel sheet that can be used in the market dialogue to create an overview of the maturity of a specific pool of suppliers in terms of the sustainability criteria for packaging.

Following the market dialogue, criteria must be chosen within each sustainability topic and the level (basic, advanced or spearhead) determined in light of the specific call for tenders and the market maturity.

In some cases, aspects may challenge the use of the criteria due to, e.g., specific requirements for product packaging, such as sterile packaging, or requirements for storage etc. The use of the criteria should therefore be implemented accordingly.

The criteria are designed to be copied and applied directly; however, it may prove useful to adjust the text to the specific tender documents. The early market dialogue and the results of any consultation may determine whether a criterion should be used as a minimum criterion or a competition criterion in the specific tender process.

It is expected that the market will develop. As it does, the criteria will move up the ladder, i.e., advanced criteria are expected to be basic criteria in the coming years and spearhead criteria to be advanced criteria at some point. However, to push the market, it is important to use the criteria as often and as broadly as possible when purchasing products for the health sector.

The use of the criteria must not compromise requirements related to patient safety, product approval procedures or criteria in standards (e.g., ISO 11607 standard series, the Directive 93/42/EEC on Medical Devices, the Directive 90/385/EEC on Active Implantable Medical Devices, Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Regulation (EU) 2017/745 on Medical Devices, Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices).

3.2 Use of the criteria

This section explains when and how you can work with sustainability requirements for packaging in a typical tender process. Tender processes may differ in planning, so this section is based on a generic and simplified tender process that usually consists of the following phases:

- > Phase 1: Preparation
- > Phase 2: Tender phase - (the publication marks the start of the tender phase)
- > Phase 3: Contract period (following contract signage)

3.2.1 Phase 1 – Preparation

The preparation includes all activities carried out before the call for tenders is ready for publication, and is the most important phase in terms of building sufficient knowledge about the specific packaging so as to include relevant requirements in the tender documents.

- > Clarify the potential for setting climate and environmentally related sustainability criteria for packaging in the tender documents.
- > Analyse the current consumption pattern regarding volume and packaging material to select and target products with the highest packaging consumption. The climate and environmental effect of using the packaging criteria is normally largest for the high-volume products.

- > If relevant, clarify the internal possibilities for sorting the packaging at end of life.
- > Conduct market analysis and market dialogue to map the market maturity in terms of what criteria it can meet and at what level. If relevant, use Appendix E – Market analysis.
- > Assess, already in the market dialogue, whether there is mutual clarity of which packaging layers and materials the packaging consists of. If relevant, use Appendix C.1 or see *'Power point skabelon og eksempler på emballageniveauer'*, which describes a number of examples of packaging as basis for the dialogue.
- > It may be a good idea in the market dialogue to seek information about whether the packaging comes from a producer or a distributor since that may affect each tenderer's knowledge level and, in turn, their possibility of responding to the tender documents in an effective and true manner.
- > Choose at least one criterion in each of the three sustainability topics. Set an ambition level for the actual call for tenders and identify the relevant criteria to include in the tender documents based on the market dialogue. The ambition level is increased by 1) using the higher level of criteria, 2) using the criteria as minimum criteria and 3) weighting climate and environmental competition criteria high in the tender process. Be sure to clarify how to evaluate fulfilment of sustainability criteria for packaging.
- > Consider if it is possible to include dialogue about development and improvement during the contract period.

3.2.2 Phase 2 – Tender phase

The tender phase starts with the publication of the call for tenders. In this phase, focus is on:

1. answering any questions regarding the criteria following publication, while complying with the principles of tender law
2. evaluating the tender process.

3.2.3 Phase 3 – Contract period

In the contract period, parties may be invited to dialogues about results, processes and the results of any agreed development activities, for instance once a year, and follow up on compliance with the stated criteria. If the supplier is required to make improvements or work with specific plans during the contract period, this must be followed up on – the contract must state how and how often you want to follow up on such measures.

4 Library of criteria

The criteria are divided into three sections according to their sustainability purpose:

1. Reduce material consumption
2. Design for recycling
3. Recycled or sustainably sourced materials content.

If the criteria compromise current safety, legal, regulatory or standard requirements for a specific product, they must be adjusted to avoid compromising safety, legal, regulatory or standard requirements.

4.1 Reduce material consumption

The aim of the following criteria is to reduce and minimise materials used for packaging and promote more sustainable choices of materials. There are four ways to do this. Only choose one of either criterion 1.1, 1.2 or 1.3 to avoid evaluating the same type of information in different ways. In the market dialogue, clarify whether 1.4 (metal in packaging) is relevant for the products in the specific call for tenders.

4.1.1 Criterion 1.1.: Reduce material consumption

The advantage of using this criterion is that reference is made to an international standard that is relatively well-known. Evaluating on the criterion is simple. The standard is described in brief in Appendix F.

No.	Level	Criteria	Documentation
1.1 <i>Reduce material</i>	Basic	Competition criterion It is considered positive that, at contract start, the proposed packaging has been minimised in terms of weight and volume in accordance with the ten performance criteria in EN 13428 or similar during the contract period.	Completion of Annex A in EN 13428, stating which of the ten performance criteria are met.
	Advanced	Minimum criterion At contract start, the proposed packaging must be minimised in terms of weight and volume in accordance with the ten performance criteria in EN 13428 or similar.	Declaration of conformity with EN 13428.
	Spearhead	-	-

4.1.2 Criterion 1.2. Weight and material information

The advantage of using this criterion is that the answer provides a good data basis for, e.g., calculating the total weight of a specific packaging. This information may be useful, especially if you work on reducing waste volumes. The combination of data on weight and material also provides a good data basis for calculating the CO₂ e emissions of the specific volume of packaging.

No.	Level	Criteria	Documentation
1.2 Weight and material information	Basic	Minimum criterion State the specific weight in grams and the types of material used for all packaging (primary secondary, tertiary) in the bill of quantities. The winning tenderer must submit data sheets for the five highest-volume products in the bill of quantities.	<i>The weight in grams and types of material used for all packaging (primary, secondary, tertiary) are stated in the bill of quantities. As for plastics (LDPE, HDPE, LLDPE, PP, PET etc.), the main type must be stated in grams and in percentage of recycled or bio-based content.</i>
	Advanced	Minimum criterion State the specific weight and the types of material used for all packaging (primary secondary, tertiary). The winning tenderer must submit data sheets for every product in the bill of quantities.	<i>The weight in grams and types of material used for all packaging (primary, secondary, tertiary) are stated in the bill of quantities. As for plastics (LDPE, HDPE, LLDPE, PP, PET etc.), the main type must be stated in grams and in percentage of recycled or bio-based content.</i>
	Spearhead	-	-

4.1.3 Criterion 1.3 Reduce the climate and environmental impact of packaging by means of a scoring model

The advantage of using this criterion is that the supplier can provide data in a simple and uniform manner that is comparable across suppliers. The scoring model calculates the total climate and environmental impact of the specific packaging as one single score.

The scoring model is designed to automatically favour use of the most sustainable materials. The scoring model consists of a spreadsheet complete with a user guide, as well as an elaborative description of method, which transparently accounts for the decisions that the scoring model is built on. See Appendix D for an introduction to the scoring model and the actual scoring model in the Excel file 'Environmental factor scoring calculation'.

No.	Level	Criteria	Documentation
1.3 Reduce the climate and environmental impact of packaging	Basic	<p>Competition criterion</p> <p>State the score calculated based on the packaging scoring model.</p> <p>The higher the score, the more points are given in the evaluation of the tender.</p>	<p><i>Filled-in calculation from the scoring model.</i></p> <p><i>No further documentation is required.</i></p> <p><i>The contracting authority reserves the right to test the result based on the specified weight and types of material stated in the bills of quantities.</i></p>
	Advanced	-	-
	Spearhead	-	-

Kommentert [TK1]: Var den ikke blevet vendt om?

4.1.4 Criterion 1.4: Minimise metal use

The advantage of using this criterion is that it can be used to phase out packaging with metal, e.g., aluminium such as aluminium film on the inside of plastic bags, to prevent inexpedient substitution that increases the consumption of aluminium packaging. The criteria permit nails and staples as well as metal layers serving as barriers, e.g., small barrier capsules in bottles with liquid content.

No.	Level	Criteria	Documentation
1.4 <i>Minimise metal use</i>	Basic	Minimum criterion No metal can be utilised in secondary or tertiary packaging, with the exception of nails in pallets and staples in cardboard boxes.	<i>Declaration of conformity</i>
	Advanced	Minimum criterion No metal can be utilised in secondary or tertiary packaging, with the exception of nails in pallets and staples in cardboard boxes. No metal can be utilised in primary packaging, with the exception of metal layers serving as barriers that are thinner than 5 µm and placed on the inside or middle layer of flexible plastic packaging.	<i>Declaration of conformity</i>
	Spearhead	-	-

4.2 Design for recycling of plastics

The purpose of stipulating requirements for increased recyclability of plastic packaging is to support – also in the health sector – the widest possible use of recyclable types of plastic for packaging.

Often, plastic packaging for the health sector is of high-quality materials. Consequently, there is every reason to plan for recycling of as much plastic packaging from the health sector as possible by means of appropriate sorting of waste.

Throughout most of the EU/EEA, producer's responsibility has already been established as well as recycling schemes for fibre-based packaging such as cardboard and paper. Recycling schemes also exist for a number of types of plastic that are often used for packaging, such as PE (LDPE, HDPE, LLDPE), PP and PET.

Nevertheless, since plastic packaging for the health sector must meet special functional requirements, e.g., in sterile packaging, these types of packaging also include quite a few special types of plastic that prevent effective recycling, such as combinations of PA+PP+EVOH or PE+PET.

One particular challenge to recycling of plastic packaging in the health sector is adhesive labels made of a different material than the main component of the packaging, e.g., paper labels. Paper labels reduce the quality of the recycled plastic considerably as well as reduce the financial profitability considerably in the recycling process.

Four criteria are proposed, aiming to increase the recyclability of plastic. The four criteria supplement each other and can therefore all be used in the same call for tenders.

4.2.1 Criterion 2.1. Limit variety in plastic types

All three levels of this criterion are stated as minimum requirements. Therefore, it is important, through dialogue with the suppliers, that a sufficient number of suppliers are able to meet the requirements. The criterion may be considered a positive list of permitted materials.

No.	Level	Criteria	Documentation
2.1 <i>Limit variety in plastic types</i>	Basic	Minimum criterion If the tertiary packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the tertiary packaging is not plastic, this criterion does not apply.	<i>Declaration of conformity which states that the specific packaging meets the criterion.</i>
	Advanced	Minimum criterion If the tertiary and/or the secondary packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the tertiary and/or secondary packaging is not plastic, this criterion does not apply.	<i>Declaration of conformity which states that the specific packaging meets the criterion.</i>
	Spearhead	Minimum criterion If the packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the packaging is not plastic, this criterion does not apply.	<i>Declaration of conformity which states that the specific packaging meets the criterion.</i>

4.2.2 Criterion 2.2. Increase the recyclability by excluding non-recyclable types of plastic

This criterion may be considered a negative list of materials that cannot be recycled and thus are unwanted.

	Level	Criteria	Documentation
2.2 Increase recyclability	Basic	<p>Minimum criterion</p> <p>The plastic packaging cannot be made of:</p> <ul style="list-style-type: none"> > Styrene polymers (PS, EPS, XPS) > Regenerated cellulose (e.g., cellophane) > Oxo- or biodegradable polymers. <p>Secondary and tertiary packaging cannot be made of:</p> <ul style="list-style-type: none"> > PVC > Composite and/or packaging combining different materials, (e.g., cardboard with plastic window). <p>If the packaging is not plastic, this requirement does not apply.</p>	<i>Provide a technical data sheet which describes the material composition of the packaging.</i>
	Advanced	<p>Minimum criterion</p> <p>The plastic packaging cannot be made of:</p> <ul style="list-style-type: none"> > Styrene polymers (PS, EPS, XPS) > Regenerated cellulose (e.g., cellophane) > Oxo- or biodegradable polymers. > PVC <p>Primary, secondary and tertiary packaging cannot be made of:</p> <ul style="list-style-type: none"> > Composite and/or packaging combining different materials, (e.g., cardboard with plastic window). <p>If the packaging is not plastic, this requirement does not apply.</p>	<i>Provide a technical data sheet which describes the material composition of the packaging.</i>

	<p>Spearhead</p>	<p>Minimum criterion</p> <p>Bio-based plastic must be PE (LDPE, HDPE, LLDPE), PP, PET and have a certified chain of suppliers (e.g., RSB, Bonsucro or the like) or come from secondary/tertiary resources.</p> <p>The plastic packaging cannot be made of:</p> <ul style="list-style-type: none"> > Styrene polymers (PS, EPS, XPS) > Regenerated cellulose (e.g., cellophane) > Oxo- or biodegradable polymers. > PVC <p>Primary, secondary and tertiary packaging cannot be made of:</p> <ul style="list-style-type: none"> > Composite and/or packaging combining different materials, (e.g., cardboard with plastic window). <p>If the packaging is not plastic, this requirement does not apply.</p>	<p><i>Provide a technical data sheet which describes the material composition of the packaging.</i></p>
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4.2.3 Criterion 2.3. Documentation of the recyclability of plastics.

The advantage of using the suggested method for documenting recyclability is that the recyclability of a specific plastic packaging can be documented.

The documentation tool consists of a third-party-driven European online tool that provides easy access to a free assessment of the recyclability of a plastic packaging. The assessment uses a letter to indicate the recyclability of a plastic packaging, just like the energy label letters. The letters can easily be converted into a score.

Using this method presumes that the tenderer is deeply familiar with the packaging and its components, since the tenderer is otherwise not able to enter accurate data in the tool.

At contract signing, the winning supplier(s) shall be requested to provide an actual certification of the recyclability of their packaging.

Moreover, RecyClass also provides reasons for the achieved score stating the recyclability of the specific packaging, thereby indicating any potential for improvement to the tenderer.

So far, RecyClass has proven a successful tool, also for packaging for medical equipment even though the tool was not designed for that industry.

No.	Level	Criteria	Documentation
2.3 <i>Document recyclability</i>	Basic	-	-
	Advanced	<p>Competition criterion</p> <p>It is considered positive to which extent the recyclability of the plastic packaging is documented by means of a free self-assessment by RecyClass or a similar certification scheme. The higher the score (class), the more points are given in the evaluation of the tender.</p> <p>The winning tenderer must present an actual certification, at no cost to the contracting authority.</p> <p>If the packaging is made of cardboard, paper or a similar fibre-based material, the maximum number of points are granted.</p>	<i>State certification of class from RecyClass or the like (e.g., Cyclos-HTP).</i>
	Spearhead	<p>Minimum criterion</p> <p>If the packaging is plastic, the recyclability of plastic packaging(s) must be documented by means of certification by RecyClass or a similar certification scheme. Plastic packaging must, as a minimum, meet the requirements for Class B in RecyClass or similar level in other certification system.</p> <p>If the packaging is not plastic, this requirement does not apply.</p>	<i>Present certification by RecyClass documenting class A or B or a similar level (e.g., Cyclos-HTP) in a similar certification scheme.</i>

4.2.4 Criterion 2.4. Labels that do not harm the recyclability of plastic packaging

Due to a high level of safety, there are vast requirements for documentation, often directly on products, in the health sector, and therefore for labels. For certain types of products, the label is required to tolerate being submerged in hot water for up to 48 hours. That makes special demands on the label and the adhesive used. For products subject to these durability requirements, it is recommended not to use requirements for labels.

However, compliance with safety requirements means that many types of labels made of paper and associated adhesive actually reduces the recyclability of plastic, since paper mixed in the plastic mass reduces recyclability from both a quality and economic perspective. Therefore, removing paper labels on plastic packaging is a key action area in relation to the recyclability of plastic packaging, whenever that is possible without compromising requirements for safety and documentation.

No.	Level	Criteria	Documentation
2.4 Avoid labels that harm recyclability	Basic	Competition criterion It is considered positive to what extent labels on plastic packaging comply with the following options: <ul style="list-style-type: none"> > It must be possible to wash off labels at temperatures below 60 °C and be water soluble/releasable. > Labels must be made of the same material as the packaging. > If the packaging is PET, the label must be PP or PE (LDPE, HDPE, LLDPE) and not cover more than 40 per cent of the surface. > If the packaging does not feature a label, the maximum number of points are granted.	<i>State which option the packaging complies with.</i>
	Advanced	Minimum criterion Labels on plastic packaging must comply with <i>at least</i> one of the following options: <ul style="list-style-type: none"> > It must be possible to wash off labels at temperatures below 60 °C and be water soluble/releasable. > Labels must be made of the same material as the packaging. > If the packaging is PET, the label must be PP or PE (LDPE, HDPE, LLDPE) and not cover more than 40 per cent of the surface. > If the packaging does not feature a label, this criterion does not apply.	<i>State which option the packaging complies with.</i>
	Spearhead	Competition criterion It is considered positive that labels on plastic packaging wash off at temperatures below 60 °C and are water soluble. If the packaging does not feature a label, the maximum number of points are granted.	-

4.3 Recycled or sustainably sourced materials content

The aim of the following criteria is to promote the use of recycled materials and sustainably sourced materials. By requiring that packaging contains a certain percentage of recycled materials, the total climate and environmental impact is reduced since no energy or materials are used on procuring virgin materials.

However, the use of recycled materials presumes that the materials are clean and, e.g., do not contain any unwanted and harmful substances that may accumulate in the environment and people through the recycling process.

The two suggested criteria apply to plastic- and fibre-based packaging, respectively. The total packaging may contain both plastic- and fibre-based packaging (e.g., the primary packaging may be a plastic bag, and the secondary packaging may be a cardboard box). Therefore, both criteria may be used in tender documents, just targeting different packaging materials.

4.3.1 Criterion 3.1. Reduce the climate and environmental impact of plastic packaging

The criterion aims to reduce the climate and environmental impact of plastic packaging by requesting recycled resources and sustainably sourced materials.

By having recycled plastic make up a certain percentage of the packaging, you go from virgin fossil-based materials to materials that do not put any pressure on non-renewable materials.

By having bio-based plastic make up a certain percentage, you go from fossil-based materials to renewable materials. For this to become a true advantage, the bio-based plastic is presumed to come from certified sources and be either 2nd or 3rd generation bioplastic. In reality, this means that the bio-based plastic materials are not made of materials that could have been used for food. Instead the plastic is made of by-products from food production or waste, such as sugar canes or bio-waste.

No.	Level	Criteria	Documentation
3.1	Basic	-	-
Reduce the environmental impact of plastic packaging	Advanced	<p>Minimum criterion</p> <p>If the tertiary packaging includes plastic:</p> <ul style="list-style-type: none"> > At least 50 per cent of the plastic content of the tertiary packaging is made of from 	<p><i>No documentation is required in the tender.</i></p> <p><i>Prior to contact signing, documentation must be presented. The documentation must be provided in</i></p>

		<p>recycled plastic or bio-based plastic¹</p> <p>Bio-based must be PE (LDPE, HDPE, LLDPE), PP, PET and have a certified chain of suppliers (e.g., RSB, Bonsucro or the like) or be 2nd or 3rd generation bio-plastic.</p> <p>If the tertiary packaging is not plastic, this criterion does not apply.</p>	<p><i>accordance with ASTM D6866, EN16785-1 or similar for bio-based content and/or EN15343, ISO 22095 or similar for recycled content.</i></p>
	<p>Spearhead</p>	<p>Minimum criterion</p> <p>If the tertiary and/or secondary packaging includes plastic:</p> <ul style="list-style-type: none"> > At least 50 per cent of the plastic content of the secondary and the tertiary packaging is made of from recycled plastic or biobased plastic¹ <p>Bio-based must be PE (LDPE, HDPE, LLDPE), PP, PET and have a certified chain of suppliers (e.g., RSB, Bonsucro or the like) or be 2nd or 3rd generation bio-plastic.</p> <p>If the tertiary and/or secondary packaging is not plastic, this criterion does not apply.</p>	<p><i>No documentation is required in the tender.</i></p> <p><i>Prior to contact signing, documentation must be presented. The documentation must be provided in accordance with ASTM D6866, EN16785-1 or similar for bio-based content and/or EN15343, ISO 22095 or similar for recycled content.</i></p>

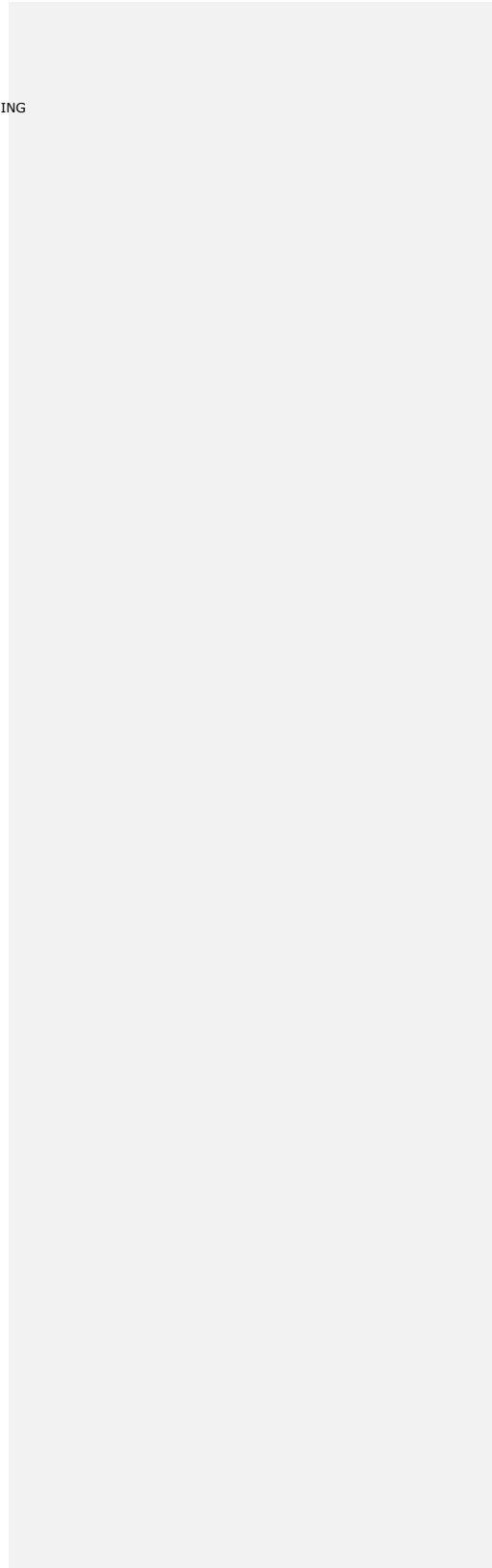
4.3.2 Criterion 3.2. Reduce the climate and environmental impact of fibre-based materials

By requesting fibre-based packaging (e.g., cardboard or paper) that contains a certain percentage of recycled fibres, the climate and environmental impact is reduced since fewer virgin materials are extracted.

By requesting fibre-based packaging made entirely or partly by FSC- or PEFC-certified wood and fibre products, it is ensured that the fibres come from forests managed sustainably in relation to both the environment and people.

No.	Level	Criteria	Documentation
3.2 Avoid deforestation from the use of unsustainable cardboard	Basic	Minimum criterion If the tertiary and/or secondary packaging is fibre-based: <ul style="list-style-type: none"> > At least 50 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. > If the tertiary and/or secondary packaging is not fibre-based, this criterion does not apply. 	Declaration of conformity. Certification under relevant scheme must be stated on either the packaging or the delivery note/invoice.
	Advanced	Minimum criterion If the tertiary and/or secondary packaging and/or manual/leaflet is fibre-based: <ul style="list-style-type: none"> > At least 90 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. > If the tertiary and/or secondary packaging and/or manual/leaflet is not fibre-based, this criterion does not apply. 	Declaration of conformity. Certification under relevant scheme must be stated on either the packaging or the delivery note/invoice.
	Spearhead	Minimum criterion If the packaging and/or manual/leaflet is fibre-based: <ul style="list-style-type: none"> > At least 90 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. > If the packaging and/or manual/leaflet is not fibre- 	Declaration of conformity Certification under relevant scheme must be stated on either the packaging or the delivery note/invoice.

		based, this criterion does not apply.	
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Appendix A Glossary

The glossary is split by topic:

- > Packaging
- > Reuse and recycling
- > Plastics
- > Fibre-based materials
- > Others.

Packaging	
Packaging	According to the European Packaging and Packaging Waste Directive (EUROPEAN PARLIAMENT AND COUNCIL. DIRECTIVE 94/62/EC of 20 December 1994, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0062&from=da Appendix G), "'packaging' shall mean all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. 'Non-returnable' items used for the same purposes shall also be considered to constitute packaging." Packaging consists of primary, secondary, and tertiary packaging.
Primary packaging	"sales packaging or primary packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase" (European Parliament and Council Directive 94/62/EC of 20 December 1994, article 3, paragraph 1). See further in Appendix C – about levels of packaging.
Secondary packaging	"grouped packaging or secondary packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics" (European Parliament and Council Directive 94/62/EC of 20 December 1994, article 3, paragraph 1). See further in Appendix C – about levels of packaging.
Tertiary packaging	"transport packaging or tertiary packaging, i.e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers;" (European Parliament and Council Directive 94/62/EC of 20 December 1994, article 3, paragraph 1). See further in Appendix C – about levels of packaging.

Kommentert [TK2]: Jeg har tidligere fundet en nyere og opdateret udgave af direktivet fra 2018. Ville det ikke være hensigtsmæssigt at henvise til det i stedet for?

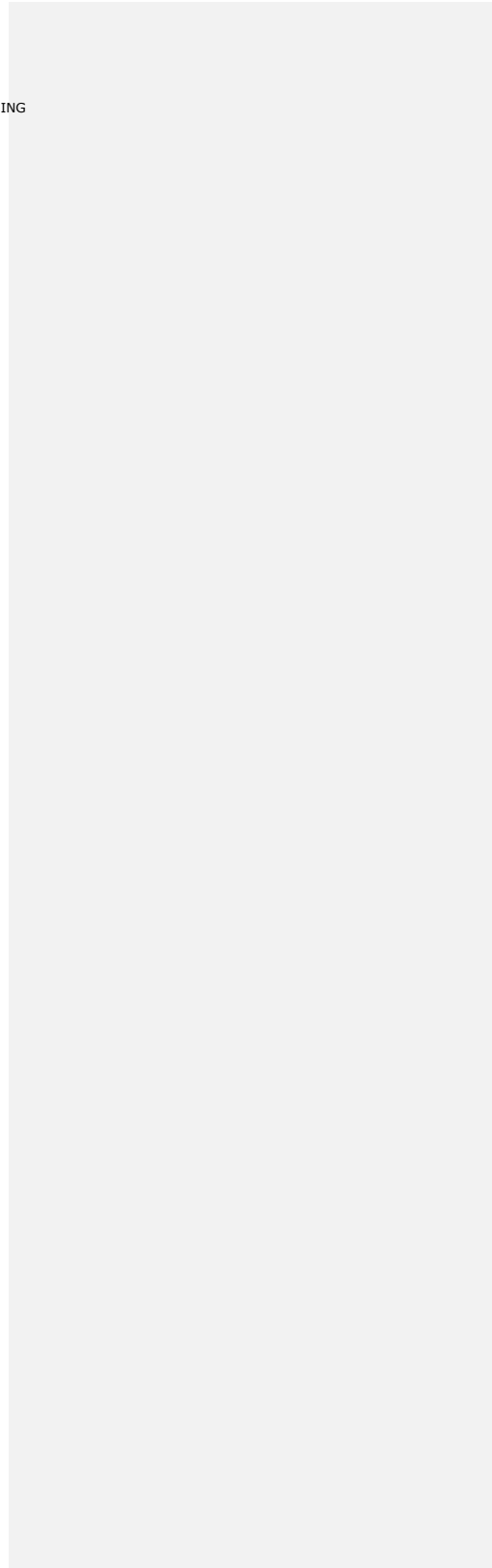
Reuse and recycling	
Reuse	"'Reuse' shall mean any operation by which packaging, which has been conceived and designed to accomplish within its life cycle a minimum number of trips or rotations, is refilled or used for the same purpose for which it was conceived, with or without the support of auxiliary products present on the market enabling the packaging to be refilled; such reused packaging will become packaging waste when no longer subject to reuse" (EUROPEAN PARLIAMENT AND COUNCIL. DIRECTIVE 94/62/EC of 20 December 1994, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0062&from=da Appendix G).
Recycling	"'Recycling' shall mean the reprocessing in a production process of the waste materials for the original purpose or for other purposes including organic recycling but excluding energy recovery" (EUROPEAN PARLIAMENT AND COUNCIL. DIRECTIVE 94/62/EC of 20 December 1994, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0062&from=da Appendix G).
Recyclability	'Recyclability' is the ability of a material to reacquire the properties that it had in its virgin state, where virgin state refers to the material in its purest form before being processed or shaped for a specific use.
Open and closed recycling loops	'Closed-loop recycling' shall mean that the quality of the materials being recycled are kept at a similar level by cycling materials into the same application, whereas, an 'open-loop recycling' shall mean that the materials being recycled are degraded in quality and/or material properties, and require applications with lower demands (Ellen MacArthur Foundation, 2014, https://www.ellenmacarthurfoundation.org/assets/downloads/EllenMacArthurFoundation_TheNewPlasticsEconomy_20-1-16.pdf).
Disposal phase (incl. sorting and preparing for recycling)	The 'end of life' phase of a material or product, whether that is landfilling, incinerating, recycling or reusing.
Circular economy	'Circular economy' shall mean "an industrial system that is restorative and regenerative by design. It rests on three main principles: preserving and enhancing natural capital, optimising resource yields, and fostering system effectiveness" (Ellen MacArthur Foundation, 2014,

	https://www.ellenmacarthurfoundation.org/assets/downloads/EllenMacArthurFoundation_TheNewPlasticsEconomy_20-1-16.pdf).
Multilayer packaging, and Packaging combining different materials	<p>Multilayer packaging/packaging combining different materials consists of two or more materials, e.g., cardboard with a plastic window, or packaging with one side made of paper and the other made of plastic. It may be possible to manually separate some of these types of packaging consisting of several materials; however, since manual separation is not possible at hospitals, this type of packaging is typically unwanted.</p> <p>Packaging that can be separated in the recycling process is not considered multilayer packaging or packaging combining different materials. Among other things, that goes for labels and tape on cardboard boxes. Small labels and/or tape on packaging do not make packaging multilayer packaging.</p>
Composite materials/packaging	Composite materials consist of two or more materials melted together without the possibility to mechanically separate them. E.g., reinforced packaging for sharp objects with nylon (PA) to ensure the products protection. They differ from the above (multilayer packaging and packaging combining different materials) in that the materials have been melted together and cannot be manually separated from each other. This type of packaging is typically not recyclable. Multilayer plastic packaging/composite plastic packaging is recyclable when the polymers are technically compatible, e.g., PE and PP.
Non-recyclable composite/packaging	Non-recyclable composite are materials that will not separate before or in the recycling process.
Plastics	
Plastics/polymers	A polymer is a chemical compound that contains a chain of repeating molecular units. A plastic material is a polymer, typically modified with additives, which can be moulded or shaped by pressure and temperature. See abbreviations below for different polymers and additives (e.g., to enhance barrier properties). See more on plastics and recycling hereof, e.g., in https://plastikviden.dk/media/212448/study-about-plastic-sorting-and-recycling.pdf
Bioplastic (bio-based and biodegradable)	<p>A term that covers bio-based plastics, biodegradable plastics and plastics that is both bio-based and biodegradable. For further information, see, e.g.: https://www2.mst.dk/Udgiv/publications/2020/02/978-87-7038-165-9.pdf</p> <p>Bio-based plastics are plastics with building blocks that are derived partly or wholly from plant-based feedstocks.</p>

	Bio-based plastic is categorised as first, second and third generation, depending on the origin of the bio-based feedstocks. First-generation bioplastic is made of edible feedstocks, second-generation bioplastic is made of agricultural and forestry residual products (non-food biomass), and third-generation bioplastic is made of bio-based waste products, e.g., used cooking oil).
Compostable plastics	Plastic that biodegrades in industrial composting facilities and is compliant with the standard EN 13432 (Packaging – Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging).
Monomers	If plastic consists of a monomer, the packaging only contains one type of plastic.
Biodegradable (biodegradation)	The breakdown of an organic chemical compound by micro-organisms into carbon dioxide, methane (in the absence of oxygen), water and mineral salts of any other elements present (mineralisation) and new biomass.
Mechanical recycling of plastics	Plastic waste is sorted and reprocessed by mechanical means (shredding, melting, granulation) into pellets, flakes, powders or granulates. Only thermoplastics goes through mechanical recycling. This is the most common form of recycling.
Chemical recycling of plastics	It is defined as techniques used to break down plastic polymers into their constituent monomers, which in turn can be used again in refineries, or petrochemical and chemical production. There are different types of chemical processes; examples are pyrolysis, hydrolysis, hydrocracking and gasification. In Europe, chemical recycling only recycles a small, but increasing share of packaging and post-consumer plastic waste. Also known as feedstock recycling.
Biological recycling of plastics	Biodegradable plastics that enters industrial composting facilities is said to be biologically recycled.
Technologically recyclable	'Technically recyclable' means that it is possible for a given material to be collected, sorted and transported to a recycling facility, and to be recycled into a 'new' product. That a material is technically recyclable only takes into consideration whether the material can be recycled, and not whether there is a demand for it on the market.
RecyClass	RecyClass is a tool where you in through a number of steps can check the level of recyclability of your package. There is also advice on improving your package's design and the possibility to get your package certified. Behind RecyClass is a collaboration across the value chain. See more at: https://recyclclass.eu/

Cyclos HTP	Cyclos HTP is a German institute that certifies packaging and other goods as recyclable. See more at: https://www.cyclos-htp.de/
Fibre-based materials	
Fibre-based materials	Fibre-based materials are considered to be wood-based. This includes paper, carton, cardboard, wood and other cellulose materials.
Regenerated cellulose	A class of materials manufactured by the conversion of natural cellulose to a soluble cellulosic derivative and subsequent regeneration, typically forming either a fibre (e.g., rayon) or a film (e.g., cellophane).
FSC	<p>Forest Stewardship Council (FSC) forest management certification confirms that the forest is being managed in a way that preserves biological diversity and benefits the lives of local people and workers, while ensuring it sustains economic viability.</p> <p>There are several FSC certificates, including FSC 100% (all wood-based materials used in the product/packaging come from responsibly managed, FSC-certified forests) and FSC MIX (all wood-based materials used in the product/packaging are one of the following: materials from FSC-certified forests, FSC-controlled wood and recycled materials).</p>
PEFC	Programme for the Endorsement of Forest Certification (PEFC) is a forest management certification like FSC. PEFC works to promote sustainable forest management. The difference between PEFC and FSC is how the organisations are structured as well as the certification and control requirements.
Other abbreviations	
AB distributor	The good is sent from a distributor.
AB factory	The good is sent from a manufacturer.
RSB standards	<p>The Roundtable on Sustainable Biomaterials (RSB) is a global, multi-stakeholder independent organisation that drives the development of a bio-based and circular economy on a global scale through sustainability solutions, certification and collaborative partnerships.</p> <p>The RSB standard is a method of sustainability validation of bio-based and recycled resources. The RSB Standard is anchored in 12 sustainability principles, and their underlying criteria, to ensure that the key environmental and social issues surrounding</p>

	the use of fuels and products made from bio-based and advanced feedstocks are addressed.
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Appendix B Plastic abbreviations

		Polym er	Additive
ABS	Acrylonitrile butadiene styrene	x	
A- PET	Amorphous polyethylene terephthalate	x	
ASA	Acrylonitrile styrene acrylate	x	
C- PET	Crystalline polyethylene terephthalate	x	
EPS	Expanded polystyrene (foam)	x	
EVO H	Ethylene vinyl alcohol		x
HD PE	High density polyethylene	x	
HIP S	High impact polystyrene	x	
LDP E	Low density polyethylene, aka PELD	x	
PA	Polyamide, aka nylon	x	
PC	Polycarbonates	x	
PE	Polyethylene	x	
PET	Polyethylene terephthalate	x	
PET G	Glycol-modified polyethylene terephthalate	x	
PLA	Polylactic acid	X	
PO	Polyolefins	x	
PP	Polypropylene	x	

		Polym er	Additive
PS	Polystyrene	x	
PVC	Polyvinyl chloride	x	
PVd C	Polyvinylidene chloride		x
R- PET	Recycled polyethylene terephthalate	x	
XPS	Extruded polystyrene (foam)	x	

Appendix C Levels of packaging/Danish national guidelines (contract appendix 5)

Below table shows the link between the terminologies used in contract appendix 5, the Danish national infection hygiene guidelines and the EU Packaging Directive.

According to the Danish national infection hygiene guidelines, which are described in the Danish Regions' joint contract appendix 5, the three levels of packaging for sterile packaging are referred to as N1, N2 and N3, respectively, cf. below. Packaging for clean (non-sterile products) is referred to as inner and outer packaging.

Sterile products	Clean (non-sterile) products	EU Packaging Directive
<p>The definition of 'inner packaging' is not used for sterile products since they always contain a primary and secondary packaging. The primary and secondary packaging should always be considered clean and should be handled as such.</p>	<p>Inner packaging (N1 and/or N2)</p> <p>Inner packaging for non-sterile products may consist of both primary and secondary packaging, or one of the two.</p> <p>Inner packaging aims to protect the product and protect it against contamination in case the transport packaging is opened. It is designed to be stored in rooms without contamination and must be handled by means of clean procedures.</p>	
<p>N1: Primary packaging</p> <p>The primary prepacking (individual packaging) is designed to maintain the sterility of the product. In the primary packaging, the products must be packed per product unit, i.e., one piece of the specific product per primary packaging. It must be possible to open the primary packaging in an easy and safe manner with or without gloves in order to ensure the product remains sterile. It must be possible to remove the product from the primary packaging while maintaining its sterility.</p>	<p>N1: Inner packaging (primary packaging)</p> <p>The primary prepacking (individual packaging) for non-sterile products is the inner packaging layer. In the primary packaging, the products must be packed per product unit, i.e., one piece of the specific product per inner packaging. The primary packaging for clean products is the inner packaging layer and must be handled by means of clean procedures.</p>	<p>Primary packaging</p> <p>Sales packaging or primary packaging, i.e., packaging designed to constitute, at the point of sales, a sales unit for the end user or consumer;</p>

<p>N2: Secondary packaging</p> <p>Secondary prepacking (departmental packaging) is designed to protect the primary packaging and protect it against contamination in case the transport packaging is opened. It is designed to be stored in rooms without contamination.</p>	<p>N2: Inner packaging (secondary packaging)</p> <p>Secondary prepacking (departmental packaging) is a collection of a number of units, regardless of that is how it will be used eventually, or whether it is used to store products in, e.g., in case of grouped packaging (departmental prepacking/twin pack).</p>	<p>Secondary packaging</p> <p>Grouped packaging or secondary packaging, i.e., packaging designed to constitute, at the point of sales, a collection of a specific number of sales units, whether it is sold as such to the end user or consumer, or whether it is only used to fill shelves at the point of sales; It can be removed from good without changing the properties of the good.</p>
<p>N3: Tertiary packaging (transport packaging)</p> <p>This layer is considered transport packaging. Transport packaging is the outer layer of packaging in which the product is distributed from the supplier/manufacturer to the customer. The transport packaging protects products against dust, dirt, impact and an insubstantial volume of moisture during transport. Thereby, the transport packaging is unclean and is removed before the product arrives at a clean area where it is stored.</p>	<p>N3: Outer packaging (transport packaging)</p> <p>This layer is considered transport packaging. The outer packaging is the outer layer of packaging in which the product is distributed from the supplier/manufacturer to the customer. The transport packaging protects products against dust, dirt, impact and an insubstantial volume of moisture during transport. Thereby, the transport packaging is unclean and is removed before the product arrives at a clean area where it is stored.</p>	<p>Transport packaging</p> <p>Transport packaging or tertiary packaging, i.e., packaging designed to ease handling and transport of a number of sales units or grouped packaging, to prevent damage caused by physical handling or transport. Transport packaging does not include road, rail, ship and air freight containers.</p>

C.1 Examples of levels of packaging

Below are a number of examples of how to interpret levels of packaging for sterile, non-sterile (clean) and unclassified products.

It is recommended to prepare specific examples of levels of packaging (reflecting the specific tender process) for suppliers to use when preparing for tender documents. The purpose is to give suppliers a better understanding of the levels of packaging related to the specific tender process.

See the template in Appendix C 'Power point skabelon og eksempler på emballageniveauer', which includes a number of examples of levels of packaging of different products and can be used as template and adjusted to the specific tender process.

C.1.1 Sterile product: Syringe with sterile water

Kommentert [TK3]: Tekst og skabelon er ikke oversat

Steril sprøjte
med sterilt vand

N1 – PRIMÆR EMBALLAGE – INDER-EMBALLAGE (I)
N2 – SEKUNDÆR EMBALLAGE – INDER-EMBALLAGE (I)
N3 – TERTIÆR EMBALLAGE – YDER-EMBALLAGE (Y)
PRODUKT – IKKE EMBALLAGE

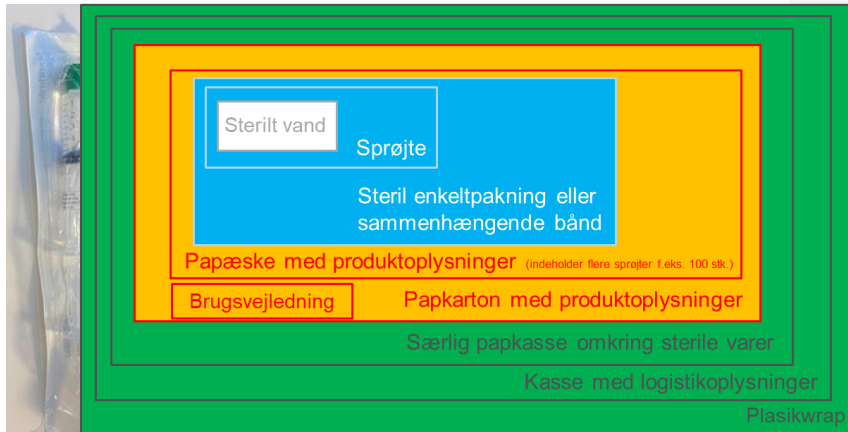


Figure 1 Example of levels of packaging for a sterile product. The example is from the tender of the irrigation fluid contract. Left: Photo of product - sterile syringe with irrigation fluid.

C.1.2 Non-sterile product: Bags of irrigation fluid

Kommentert [TK4]: Tekst og skabelon er ikke oversat

Poser med skyllevæske

N1 – PRIMÆR EMBALLAGE
N2 – SEKUNDÆR EMBALLAGE
N3 – TERTIÆR EMBALLAGE
PRODUKT – IKKE EMBALLAGE



Figure 2 Example of levels of packaging for a non-sterile (clean) product. The example is from the tender of the irrigation fluid contract. Left: Photo of product - bag of irrigation fluid.

C.1.3 Unclassified product: Tea in tea bag.

Kommentert [TK5]: Tekst og skabelon er ikke oversat

Te i tepose

N1 – PRIMÆR EMBALLAGE
N2 – SEKUNDÆR EMBALLAGE
N3 – TERTIÆR EMBALLAGE
PRODUKT – IKKE EMBALLAGE

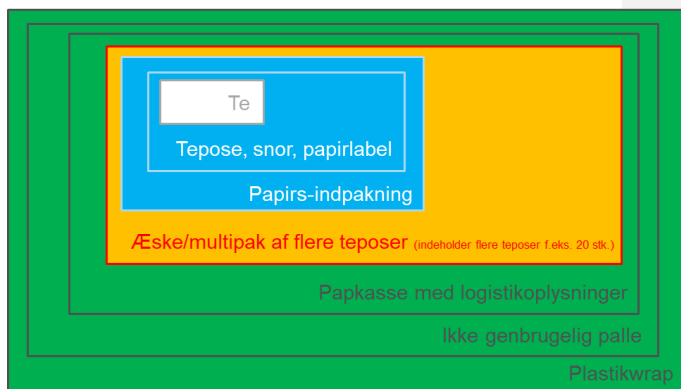


Figure 3 Example of levels of packaging for an unclassified product. Left: Photo of product - tea in tea bag.

Appendix D Scoring model

D.1 Introduction

With a view to encouraging suppliers (defined as contract holders) to choose packaging with as small climate and environmental consequences as possible, a specific criterion may be applied (criterion 1.3). The criterion is applied by having the supplier fill in the scoring model, which then calculates a score. The score is recommended to be used as a competition criterion in the tender material. The supplier must use the scoring model themselves to calculate a score.

The scoring model may be used for all levels of packaging or exclusively for assessing one or two of the levels of packaging. For instance, for just the tertiary and secondary packaging, if the primary packaging is identical for all suppliers due to, e.g., quality requirements. The scoring model is an Excel file: *'Environmental factor scoring calculation'*.

The scoring model is based on a life cycle assessment, which consists of a screening of various categories of materials. Together with the weight of the materials, the scoring model lets you compare the total climate and environmental consequences of the packaging production, starting with the extraction and production of the material (excluding, though, production of the packaging).

The scoring model gives an overall environmental score that can be used directly in tender processes, allowing for the assessment of tenders without including an environmental expert in the tender process. The factors are indicative and will not necessarily match the results of a life cycle assessment of a specific packaging product.

D.2 Selection of products for the scoring model

If more than five products are included in the tender material, it is recommended to only fill in the scoring model for a number of selected products. See appendix E.1.3.

D.3 User guide

Specify the weight, materials as well as other information about all packaging elements, including accompanying user guide and/or leaflet. Based on the information, the scoring model calculates a score for all the packaging elements for the specific product. The score is calculated based on integrated index values for the different types of materials that you can choose between in the model. A complete guide on how to fill in the scoring model is available in the 'Introduction' tab in the scoring model. You can see an example of how to fill in the scoring model in the 'Example description' tab - 'Example - Scoring model'.

If the tenderer takes back the packaging in order to reuse it or if the packaging is being part of an established standardized take-back scheme as, e.g., EUR-pallets, the packaging is given a weight of 0 g in the model.

The higher the score, the more positive assessment of the packaging.

Kommentert [TK6]: Har vi ikke vendt modellen om igen?

D.4 Materials included in the scoring model

The scoring model includes metal, plastics and cellulose-based material in the different categories in a virgin and recycled version, and for plastic also a bio-based version (based on first-generation and, in part, second-generation - for more information, see below the table).

The tender material should state what the supplier should do if they have a material that is not covered by the scoring model.

Table 1 Definitions and information about the types of materials available in the scoring model

Material	Specification	Explanation
Metals Including metal foil. The most common material is assessed to be aluminium, hence the factors are mainly based hereon.	Virgin	Virgin metals are fully produced from primary raw material sources.
	Recycled	100% recycled content.
Plastics Including plastic laminates and plastic non-reusable plastic pallets. The most common material is assessed to be LDPE, hence the factors are mainly based hereon.	Virgin	Virgin plastic is produced from fossil fuels. PS, EPS and XPS are excluded following the tender criteria.
	Recycled	Mechanically recycled plastic is defined as products/packaging with 100% recycled plastic.
	Bio-based	Bio-based plastic is defined as bio-based, but not oxo- or biodegradable polymers. The focus is on bio-based materials from first-generation (biomass of food quality, e.g., vegetable oil) and partly second-generation (non-food biomass, e.g., residual forestry and agricultural products) plastics, i.e., representative of the current market. Third-generation bioplastic (biomass from waste products, e.g., used cooking oil) is therefore excluded.

Cellulose-based material For instance, cardboard and paper including non-reusable wooden pallets and other either adhered or attached paper, e.g., manuals/leaflets. The most common material is assessed to be cardboard, hence the factors are mainly based hereon.	Virgin	Virgin fibres are produced from 100% new fibres.
	Recycled or sustainably sourced	100% recycled/sustainably sourced fibres. Cellulose fibres are to a lesser extent included. Sustainably sourced fibres are, e.g., FSC- or PFEC-certified fibres.

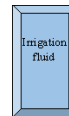
D.5 Bio-based plastic

Since the scoring model was prepared in the autumn of 2021, the market for bioplastics has developed rapidly. In the scoring model, bio-based plastic is, as described, primarily based on first-generation bioplastic. Consequently, if suppliers can deliver second-generation or third-generation bioplastic, it is not fair to use the bioplastic score in the current form of the scoring model. A new scoring model is being prepared.

Please note that oxo- and biodegradable materials are not permitted, cf. criterion 2.2. If you do not want suppliers to use first-generation bioplastic, this can be stated in this criterion.

D.5.1 Example of completed scoring model

An order of 1,000 plastic bags of irrigation fluid is delivered in cardboard boxes, each one lined with a plastic bag. Each cardboard lined with a plastic bag contains 10 plastic bags of irrigation fluid. Each box also includes a user guide. The order is delivered on a reusable EUR pallet. On delivery, the boxes on the pallet are wrapped in single-use plastic foil.

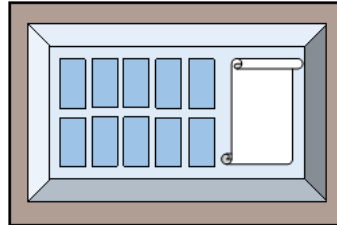


Primary packaging N1

The bags of irrigation fluid (*1,000 unit(s) included in the order*) are made of virgin plastic (*weight: 10 g per plastic bag*) and constitute the primary packaging.

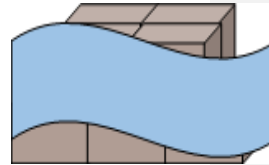
Secondary packaging N2

10 plastic bags of irrigation fluid are gathered in a plastic bag made of recycled plastic (*weight: 50 g per plastic bag*), placed in a cardboard box made of recycled cellulose-based material (*weight: 150 g per cardboard box*). There are 100 cardboard boxes with plastic bags on a EUR pallet. Each of the 100 cardboard boxes include a user guide (*weight: 100 g*). The user guide is made of 60% recycled paper (*60 g*) and 40 % virgin paper (*40 g*). The plastic bag, the cardboard box and the user guide constitute the secondary packaging.



Tertiary Packaging N3

The 100 cardboard boxes are placed in transport cardboard boxes, ten in each. In total, there are ten transport cardboard boxes made of recycled cellulose-based material (*weight: 250 g per transport cardboard box*) on a pallet. The 10 transport cardboard boxes are wrapped in plastic foil made of virgin fossil plastic (*weight: 500 g*). The transport cardboard box and the plastic foil constitute the tertiary packaging (the transport packaging).



The reusable EUR pallet is included in the model with a weight of 0 g.

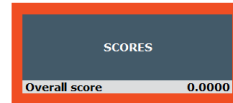
For this example, the scoring model is used as shown in Figure 4.

EXAMPLE - SCORING MODEL							
Input				Results			
Delivery form (e.g., a pallet or a box)	Reusable pallet	<i>This field is not used directly in the calculation. It is to be used to indicate the type of delivery form used in the calculation. The field is obligatory to fill out if the calculation is performed in the software and the user manual (see Annex 2).</i>					
Number of product units in a delivery (units)	1,000	<i>This field is obligatory to fill out if the calculation is performed in the software and the user manual (see Annex 2).</i>					
Packaging element description	Packaging layer	Material (see sheet "Definitions" for further explanation)	Number of packaging units in the delivery (in the tertiary packaging)	Weight per packaging unit (gram)	Total weight of each packaging element per delivered product (gram)	Factor	Calculated score
Plastic bag with irrigation fluid	Primary packaging (N1)	Plastic, Virgin fossil-based	1,000 unit(s)	10 g	10.0000 g	8	0.0800
Plastic bag containing 10 bags with irrigation fluid	Secondary packaging (N2)	Plastic, Recycled	100 unit(s)	50 g	5.0000 g	10	0.0500
User manual with product information - 60% recycled paper content	Secondary packaging (N2)	Cellulose based material, Recycled or sustainably sourced	100 unit(s)	60 g	6.0000 g	20	0.1200
User manual with product information - 40% virgin paper content	Secondary packaging (N2)	Cellulose based material, Virgin	100 unit(s)	40 g	4.0000 g	13	0.0520
Cardboard box with product information	Secondary packaging (N2)	Cellulose based material, Recycled or sustainably sourced	100 unit(s)	150 g	15.0000 g	20	0.3
Cardboard box for transportation	Tertiary packaging (N3)	Cellulose based material, Virgin	10 unit(s)	250 g	2.5000 g	13	0.0325
Plastic wrap used to hold and protect the secondary packaging during transport	Tertiary packaging (N3)	Plastic, Virgin fossil-based	1 unit(s)	500 g	0.5000 g	8	0.004
Reusable EUR-pallet	Tertiary packaging (N3)	Reused item	1 unit(s)	0 g	0.0000 g		
SCORES							
Overall score							0.6385
Primary packaging (N1)							0.0800
Secondary packaging (N2)							0.5220
Tertiary packaging (N3)							0.0365
Scoring factors							
Material							Factor

Figure 4 Example of calculation using the scoring model

Total score

The final score is indicated per product. The underlying calculations in the model multiply the number of each packaging elements by the weight of the specific packaging element and divide by the number of products in the order. The final score (stated in cell M10) is the score used in the tender process.



SCORES	
Overall score	0.0000

Appendix E Market analysis

The market dialogue can be used to identify relevant sustainability criteria at a suitable level, and decide whether each criterion should be a minimum or a competition criterion. Hereby, the level of ambition for the tender process is determined based on what suppliers are able to deliver. Moreover, a market dialogue is a useful way of understanding the levels of packaging in the specific tender process and making sure that suppliers understand the definitions of the levels of packaging.

It is important to give suppliers enough time to gather information/documentation for the market dialogue. A consultation period of at least two months is suggested (longer in the summer as the summer break is taken at different times across Europe).

The market dialogue is recommended to be a combination of written communication as well as oral dialogue with suppliers to make sure that you obtain the requested product-related information.

In the following, a number of topics exemplify what may be useful to discuss with suppliers in the market dialogue.

E.1 Selection of sustainability criteria and setting of level of ambition

It is recommended to use the market dialogue to study what criteria suppliers may meet and at what level. This can be used to select relevant criteria at a suitable level.

One way of gathering this information is shown in the template "*Markedsdialog – Excel skabelon - leverandørtilbage melding til udvælgelse af kriterier*", which is a fictive example of how to select criteria based on feedback from suppliers in the market dialogue (either by having the bid manager fill it in during the actual market dialogue, or by written feedback from suppliers). The library of criteria is forwarded/announced to suppliers in the Excel template, and suppliers/bid managers use the colour code red, yellow and green to indicate how hard/easy it is for them to meet the requirements applicable to the different levels. This is done for all criteria for all levels (basic, advanced and frontrunner).

This allows tender consultants to set the right level for the criteria that are selected for the tender process, and determine whether the criteria should be minimum or competition criteria. The library of criteria is a gross list and the level of ambition is indicative. The level of ambition for the specific call for tenders is determined based on the market dialogue, by the tender process manager.

E.2 Process of collecting knowledge for selection of criteria

The following is an example of how the process of selecting sustainability criteria may be. The example is based on a specific call for tenders where the market dialogue contributed positively to the preparation of tender documents. Prior to a physical meeting, suppliers had received "*Nordic criteria for more sustainable packaging*" containing the library of criteria.

Suppliers were asked to answer the following questions:

- > Which criteria they were/were not able to meet – and at which level (basic, advanced and frontrunner). The suppliers were asked to fill in "*Markedsdialog – Excel skabelon – leverandørtilbage melding til udvælgelse af kriterier*".
- > Whether any criteria were unclear, lacking further elaboration.
- > Whether any of the criteria were irrelevant.

Despite a well-prepared market dialogue, it is our experience that not all suppliers are able to clearly state which criteria they would be able to meet at which level. Experience from specific market dialogues has shown that it is important to inquire about suppliers' answers and to see the packaging (physically or images of it).

E.3 Selection of products for evaluation

In the case of a tender process involving several products, a number of products should be selected to which the sustainability criteria are applied. This to ease the work for suppliers and tender consultants. It is suggested to use the market dialogue to look into which products have the largest volume of packaging. For instance, the products that should be prioritised in the contract may be chosen based on which products:

- > account for the largest total volume,
- > have the most layers of packaging, or
- > where a modified packaging will have the largest environmental impact (e.g., products with unnecessary large packaging and/or metal packaging).

The selection parameters should be determined in the bill of quantities.

Appendix F Packaging minimisation (standard DS/EN 13428)

The following sections describe how the supplier documents that the weight and volume of the packaging have been reduced.

One of the purposes of the criteria for more sustainable packaging is to reduce material consumption. The suppliers can use the principles of the DS/EN 13428 standard to document that the company has reduced the weight and volume of the packaging based on ten performance criteria. These are described in Annex A of the standard.

It is important that the performance (functionality and safety) of the packaging as well as the customer's acceptance remain unchanged or sufficient. The supplier must assess all ten performance criteria when working systematically on minimising packaging weight and/or volume. The supplier must do this to ensure that all potentials for minimisation are considered and to identify critical aspects of packaging performance. The latter is important to ensure that the packaging maintains sufficient functionality and safety.

The ten performance criteria are:

- > Product protection
- > Packaging manufacturing process
- > Packing/filling process
- > Logistics
- > Product presentation and marketing
- > User/consumer acceptance
- > Information
- > Safety
- > Legislation
- > Other issues.

Appendix G Introduction to the European Packaging and Packaging Waste Directive (European Parliament and Council Directive 94/62/EC), and the latest revision of EU Directive 2018/852

This appendix gives a brief introduction to Directive 94/62/EC on packaging and packaging waste with the latest revision of Directive (EU) 2018/852.

G.1.1 Purpose of directive

- > To harmonize the management of packaging and packaging waste and to improve the quality of the environment by preventing and reducing the environmental impact of packaging and packaging waste
- > To prevent the production of packaging waste
- > To promote the reuse, recovery and other forms of recycling of packaging waste as opposed to final disposal of such waste, thereby contributing to the transition to a circular economy.

The Directive covers all packaging placed on the market in the European Union (EU) and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used.

G.1.2 Recycling targets

No later than on 31 December 2025, at least 65 percentage by weight of all packaging must be recycled.

No later than on 31 December 2030, at least 70 percentage by weight of all packaging must be recycled.

G.1.3 Essential requirements

EU Member States must ensure that all packaging placed on the market meets all essential requirements stated in Annex II of the Directive:

- > The packaging volume and weight must be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer.
- > Packaging must be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimised.

- > Packaging must be designed to permit its reuse or recovery, and this may include design for material or organic recovery as well as design for recovery of energy.

G.1.4 Next revision

The European Commission proposes to change the current Directive into a regulation, i.e., with direct legal effect in the Member States. It is proposed to include packaging in the Market Surveillance Regulation to ensure compliance with sustainability criteria. The proposed regulation is expected to raise the level of protection, focusing on the following main issues:

- > Packaging prevention and packaging waste reduction
- > Promotion of reusable and refillable packaging

Increased and improved recycling of packaging waste, including requirements for recycled plastic in new packaging, labelling, compostability as well as requirements for deposit and take-back schemes.

G.1.5 Assessment of the impact of the proposed regulation on packaging for the health sector

Packaging for the health sector will be covered by the regulation; however, product contact packaging, i.e., primary packaging, will be exempt from the requirement to use recycled materials.

Pharmaceutical packaging is given an extended deadline until 2035 to meet the requirement for recyclable packaging.

The requirement to design for recycling means, among other things, that packaging will be given a total score, either A, B, C or D, depending on how well the packaging is designed for recycling. This requirement is already implemented in the joint Nordic packaging requirements.

Similarly, a definition of when packaging may be considered compostable is expected to be introduced, as well as a pan-European labelling scheme.

In general, the regulation will support the long-term strategy behind the joint Nordic packaging requirements for the healthcare sector.