Specific requirements for by-products from the Oil & Fat Industry

GMP+ BA 7
Version EN: 1 January 2022

GMP+ Feed Certification scheme
### History of the document

<table>
<thead>
<tr>
<th>Revision no. / Date of approval</th>
<th>Amendment</th>
<th>Concerns</th>
<th>Final implementation date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 / 04-2018</td>
<td>New document</td>
<td>-</td>
<td>01-09-2018</td>
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<td></td>
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<tr>
<td>1.0 / 03-2019</td>
<td>- Crude fatty acids from splitting and pure distilled fatty acids from splitting can, under strict conditions, fall out of scope of GMP+ BA7</td>
<td>Annex 1</td>
<td>01-04-2019</td>
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<tr>
<td></td>
<td>- Several flowcharts are corrected / updated</td>
<td>Annex 2</td>
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<td>Annex 1</td>
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<tr>
<td></td>
<td>13.6.4 Salts of fatty acids</td>
<td></td>
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<tr>
<td>1.2 / 11-2020</td>
<td>Several products produced with/ derived from fatty acids from splitting can, under strict conditions, fall out of scope of GMP+ BA7</td>
<td>Annex 1</td>
<td>15-12-2020</td>
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<tr>
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<td>Editorial change</td>
<td>3.1</td>
<td>01-01-2023</td>
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<td></td>
<td>'Melting point’ is deleted as parameters to be analysed for oil and fat by-products</td>
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1. **Introduction**

1.1. **General**

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a ‘license to sell’ in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, to traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

1.2. **Structure of the GMP+ Feed Certification scheme**

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:
### GMP+ Feed Certification scheme

**A – documents**
- General requirements for participation in the GMP+ FC scheme

**B – documents**
- Normative documents, appendices and country notes
  - Feed Safety Assurance
  - Feed Responsibility Assurance

**C – documents**
- Certification requirements of the GMP+ FC scheme

**D – documents**
- Guidelines to help companies with the implementation of the GMP+ requirements

All these documents are available via the website of GMP+ International (www.gmpplus.org).

This document is referred to as GMP+ BA7 *Specific requirements for by-products from the Oil and Fat Industry* and is part of the GMP+ FSA module.
2. General Requirements

2.1. Introduction

By-products from the oils and fats industry are often used in all kind of feed. As part of the harmonisation of key elements in their standards, GMP+ International, OVOCOM, AIC and QS have decided to define together a minimum set of safety control measures and conditions, to be applied by a company who produces or trades one of the above mentioned by-products.

The purpose is – beside creating a level playing field - to increase feed safety when using the by-products coming from the oils and fats industry (a.o. by-products coming from milling / crushing and refinery). This should contribute to more confidence in the products and ensure even more that only safe products are supplied in the feed chain.

2.2. Basic principle

Basic principle is that these by-products need to come out of a closed ('assured') chain. In the framework of GMP+ feed safety assurance and GMP+ certification, this means:

For the GMP+ certified producer:
A producer of by-products from the oil and fat industry needs to assure the feed safety in compliance with the relevant GMP+ standards, and be certified as such.

As additional part of this certification, this GMP+-certified producer should specifically demonstrate there is compliance with the relevant additional requirements, which are laid down in chapter 3 of this appendix.
Specific sourcing requirements have been laid down for a soap stock splitter.

For the GMP+ certified trader:
A trader/importer of these by-products must - within the framework of his GMP+ certification - purchase from the above mentioned certified producers (or equivalent). This trader must also, demonstrate compliance with the relevant additional requirements, which are laid down in chapter 3 of this appendix.

Note:
- The specified requirements focus mainly on sourcing, producing, labelling and monitoring, and are – as stated above - applicable for both producers and traders of the specified by-products.

For a compound feed company
The producer of compound feed which is to be delivered to a farmer does not need to apply this appendix. For fat blender relevant parts of this appendix applies. Think of labelling and transfer of information.

---

a The best is to apply the GMP+ B2-standard
b The best is to apply the GMP+ B3-standard.
## 2.3. Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIC</td>
<td>Agricultural Industries Confederation</td>
</tr>
<tr>
<td>EFISC</td>
<td>European Feed and Food Ingredient Safety Certification</td>
</tr>
<tr>
<td>First generation GMQ oil</td>
<td>E.g. rapeseed oil, sunflower oil, soya oil, palm oil. This term refers to GMQ oils and fats used as raw materials for soap stock splitting. These soap stocks origin from refineries that have used GMQ oil for refining.</td>
</tr>
<tr>
<td>FOSFA</td>
<td>Federation of Oils, Seeds and Fats Associations</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically Modified Organism</td>
</tr>
<tr>
<td>GMQ</td>
<td>Good Merchantable Quality “Merchantable quality”: goods of any kind which are the subject of a contract for a consumer sale are not of merchantable quality if they are not as fit for the purpose or purposes for which goods of that kind are commonly bought as is reasonable to expect having regard to their price, to any description applied to them by the seller and to all other circumstances.</td>
</tr>
<tr>
<td>GROFOR</td>
<td>German Association of Wholesale Traders in Oils, Fats and Oil Raw Materials</td>
</tr>
<tr>
<td>MONG</td>
<td>Matter Organic Non-Glycerol MONG is a residue from glycerin, meaning the vegetable fat-like residues (e.g. triglycerides and fatty acids) from the refining of vegetable glycerin. MONG also contains glycerin, salts and water. So basically everything that is not glycerol / glycerin. This is usually a small percentage that is still in the raw glycerin (defined as 100 less the sum of the percentages of glycerol, ash and water). With further processing of the glycerin, MONG is removed and is thus a byproduct of the glycerin refining.</td>
</tr>
<tr>
<td>Multi feedstock</td>
<td>Multiple, different raw materials, which are used for the manufacture of a (final or intermediate) product. In the context of this document it concerns different raw materials whose origin may be difficult to trace, for example UCOs and animal fats.</td>
</tr>
<tr>
<td>NOFOTA</td>
<td>Netherlands Oils Fats Oilseeds Trade Association</td>
</tr>
<tr>
<td>OVOCOM</td>
<td>Belgian consultation platform intended for the feed sector, manages the Feed Chain Alliance Standard</td>
</tr>
<tr>
<td>PAH</td>
<td>Polycyclic Aromatic Hydrocarbons</td>
</tr>
<tr>
<td>PCB</td>
<td>Polychlorinated biphenyl</td>
</tr>
<tr>
<td>POME</td>
<td>Palm Oil Mill Effluent</td>
</tr>
<tr>
<td>QS</td>
<td>QS Qualität und Sicherheit, manages the QS scheme</td>
</tr>
<tr>
<td>UCO</td>
<td>Used Cooking Oils</td>
</tr>
</tbody>
</table>
### 3. Specific requirements

#### 3.1. Specific requirements for oil and fat by-products

<table>
<thead>
<tr>
<th>Topic</th>
<th>Requirement/condition</th>
<th>Explanation/guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope &amp; application</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What feed products are we talking about?</td>
<td>Any product derived directly or indirectly from crude or recovered oils and fats by oleochemical or biodiesel processing or distillation, chemical or physical refining, other than: - refined oils, - products derived from refined oils - feed additives; to be used in feed</td>
<td>These conditions apply to: - By-products of vegetable oils/fats - Products from the oleochemical industry, which are laid down in Regulation (EU) No 68/2013 (the Catalogue of feed materials), including amendments to this regulation. These conditions do not apply to: - Crude oil (examples: crude degummed oil, crude palm oil etc.) - By-products of fats/oils from animal origin - Products mentioned in the so-called Feed Materials Register</td>
</tr>
<tr>
<td>As per Annex I of this document</td>
<td>In Annex 1 examples of products are listed which are in or out of the scope of this appendix.</td>
<td></td>
</tr>
<tr>
<td>(source: Regulation (EU) 2015/1905)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Annex 2 provides an overview of processes of refining of oils, downstream processing of oils and biodiesel production process. These are general descriptions of the processes and may in some details deviate from the processes as laid down in FSP. Products falling under scope of this appendix are highlighted.

‘To be used in feed’: it does not matter under which specification/status the product is purchased. If destination is feed, this appendix applies.
## Specific requirements for by-products from the Oil & Fat Industry - BA 7

<table>
<thead>
<tr>
<th>Topic</th>
<th>Requirement/condition</th>
<th>Explanation/guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>From which origin?</strong></td>
<td>Any origin, except when produced by an EU based and registered food company</td>
<td>If the producer is based in the EU and registered as an EU food operator and the by-product comes out of a process covered under the EU food registration, this appendix does not apply. The regular scheme requirements apply.</td>
</tr>
<tr>
<td><strong>Who must apply this appendix?</strong></td>
<td>Any participant which is involved in the production and trade of the oil and fat by-products, which fall under the scope of this appendix</td>
<td>The producer of compound feed which is to be delivered to a farmer does not need to apply this appendix. For a fat blender this appendix applies. See section 2.2. For traders this basically means that they must forward product information and analyses results which are requested by this appendix.</td>
</tr>
<tr>
<td><strong>Requirements for producers and traders</strong></td>
<td><strong>Shipment, supervision and sampling</strong>&lt;br&gt;When shipped by sea vessel or barge&lt;br&gt;- Shipment to be carried out under a well-known, in the international trade accepted contract (FOSFA, NOFOTA, GROFOR) to assure&lt;br&gt;  - Independent supervision&lt;br&gt;  - Sampling per lot&lt;br&gt;  - Safe previous cargoes and technical equipment&lt;br&gt;</td>
<td>This assures that shipment is supervised by an independent accredited cargo superintendent&lt;br&gt;A lot is an expression which is particularly used when shipping by boat or vessel. A lot can be divided on several holds. A lot is often documented by a Bill of Lading.&lt;br&gt;A batch is more used to indicate a certain volume of product originating from a production process.&lt;br&gt;Safe previous cargoes and technical equipment as per FOSFA requirements.</td>
</tr>
<tr>
<td></td>
<td>When shipped by vehicles (tank/container):&lt;br&gt;- sampling of each truck</td>
<td>Individual samples must be labelled, sealed and stored correctly.&lt;br&gt;Batches (‘truckloads’) may be stored together in a tank, which must be tested before delivery. Positive release before delivery.</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td>Batch by batch</td>
<td>100% positive release. Batches/lots need to be tested before used in feed. Producer of the by-product is responsible unless agreed (in contract or another official document) to transfer this responsibility for testing to his customer. They must also agree that results are shared. Representative test results need to accompany any delivered batch, also to customers.</td>
</tr>
<tr>
<td>Topic</td>
<td>Requirement/condition</td>
<td>Explanation/guidance</td>
</tr>
<tr>
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<tr>
<td>-</td>
<td>Carried out at a laboratory with complies with the GMP+ requirements</td>
<td>Please, notify your laboratory that spiking should be added directly on the sample before sample extraction, confirmation single spikes should be carried out on unexpected residues. Accreditation must include the specific parameter and matrix.</td>
</tr>
</tbody>
</table>
| Parameters to be analysed | - Fatty Acid profile  
- Moisture and impurities  
- Free Fatty Acid  
- Melting point  
- Dioxins, dioxin-like PCBs, non-Dioxin-like PCBs  
- Pesticides  
- Heavy metals (Arsenic, Cadmium, Mercury, Lead and Nickel)  
- Mineral oil  
- PAH's | Results must fit to the profile of the product and the producer. Levels must not exceed the limits as laid down in GMP+ BA1 and Directive 2002/32/EC  
| Labelling | Product name (including botanical origin) and number according to Reg. (EU) No 66/2013, as amended, must be declared (see Annex 1 to this appendix) | Labelling requirements applies for all origins, EU and non-EU.  
Note: Although not addressed in every scheme as a feed safety issue, the GMO labelling must also comply with EU legislation. |
| -     | When it concerns composite product, names and numbers of all ingredients must be mentioned. | Specification of oils and fats products including the catalogue numbers and the botanical origin. |
| Transfer of information | Information, which is generated as a result of application of this appendix, must be unambiguous and must accompany every batch / shipment to demonstrate that requirements have been met. |
### Specific requirements for soap stock splitters

<table>
<thead>
<tr>
<th>Specific purchase requirement for soap stock splitters</th>
<th>Requirement/condition</th>
<th>Explanation/guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sourcing of raw materials for soap stock splitters (acidulators)</strong></td>
<td>Clear contracts with specification of incoming raw materials</td>
<td>A clear contract is a commercial contract with clarity about the contractual parties involved and it should contain all relevant specifications of the incoming raw materials. The soap stock splitters are to be considered as a starting point in the assured chain.</td>
</tr>
</tbody>
</table>

**Raw materials to be used:**
- Wet gums out of processing food/feed grade oil (GMQ)
- Soap stock out of first generation GMQ vegetable oil (chemical refinery).
- Soap stocks from neutralisation process (derived from GMQ oil to be used in biodiesel production).

This is from GMQ crude vegetable oil which quality is also used to process refined oils for human consumption.

Note that the oil which is used in biodiesel production is only partly refined, meaning only neutralized. Bleaching and deodorization is normally not part of the biodiesel process.

**Raw materials not be used (negative list):**
- By-products from biodiesel production (e.g. MONG)
- Soap stocks out of multi feedstock biodiesel. Multi feedstock means non-GMQ vegetable oil. In this case besides oils/fats from vegetable origin, also fats/oils from animal origin or Used Cooking Oils are used to produce the biodiesel
- Tank bottoms
- Regained oil from bleaching earth
- Deodistilates
- Skimming fats from water treatment processing (e.g. POME)
- Fats from animal origin

This negative list should be literally stated in the purchase contract of the soap stock splitter and the suppliers of the raw materials to the soap stock splitter.
### Annex 1: Product name and number according to Reg. (EU) No 68/2013

<table>
<thead>
<tr>
<th>Within the scope of annex</th>
<th>Number</th>
<th>Name</th>
<th>Description</th>
<th>Examples of products falling under this number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>1.2.13</td>
<td>Crude maize germ oil</td>
<td>Product obtained from maize germ</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.6.13</td>
<td>Rice bran oil</td>
<td>Oil extracted from stabilised rice bran</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2.20.1</td>
<td>Vegetable oil and fat (2)</td>
<td>Oil and fat obtained from plants (excluding castor oil from the ricinus plant), it may be degummed, refined and/or hydrogenated.</td>
<td>Castor oil, CAS no. 8001-79-4, EC no. 232-293-8; Palm oil stearin fraction; Rape seed stearin fraction; Sunflower stearin fraction</td>
</tr>
<tr>
<td>No</td>
<td>2.20.2</td>
<td>Used food factory vegetable oils</td>
<td>Vegetable oils having been used by food business operators in accordance with Regulation (EC) No 852/2004 for cooking purposes and which have not been in contact with meat, animal fats, fish or aquatic animals.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2.21.1</td>
<td>Crude lecithins</td>
<td>Product obtained during degumming of crude oil from oilseeds and oil fruits with water. Citric acid, phosphoric acid, sodium hydroxide or enzymes may be added during degumming of the crude oil.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2.22.3</td>
<td>Hemp oil</td>
<td>Oil obtained by pressing of hemp plants and seeds</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>7.1.4</td>
<td>Algal oil (1)</td>
<td>Oil obtained by extraction from algae. May contain up to 0,1 % antifoaming agents.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>9.2.1</td>
<td>Animal fat</td>
<td>Product composed of fat from land animals, including invertebrates other than species pathogenic to humans and animals in all their life stages. If extracted with solvents, may contain up to 0,1 % hexane.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10.4.6</td>
<td>Fish oil</td>
<td>Oil obtained from fish or parts of fish followed by centrifugation to remove water (may include species specific details e.g. cod liver oil).</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10.4.7</td>
<td>Fish oil, hydrogenated</td>
<td>Oil obtained from hydrogenation of fish oil</td>
<td></td>
</tr>
<tr>
<td>Within the scope of annex</td>
<td>Number</td>
<td>Name</td>
<td>Description</td>
<td>Examples of products falling under this number</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------</td>
<td>------</td>
<td>-------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Yes</td>
<td>13.6.1</td>
<td>Acid oils from chemical refining (^{(3)})</td>
<td>Product obtained during the deacidification of oils and fats of vegetable origin by means of alkali, followed by an acidulation with subsequent separation of the aqueous phase, containing free fatty acids, oils or fats and natural components of seeds, fruits tissues such as mono- and diglycerides, crude lecithin and fibres.</td>
<td></td>
</tr>
<tr>
<td>Yes(^{d})</td>
<td>13.6.2</td>
<td>Fatty acids esterified with glycerol (^{(4)})</td>
<td>Glycerides obtained by esterification of fatty acids with glycerol. May contain up to 50 ppm Nickel from hydrogenation.</td>
<td></td>
</tr>
<tr>
<td>Yes(^{d})</td>
<td>13.6.3</td>
<td>Mono di and tri glycerides of fatty acids (^{(4)})</td>
<td>Product consisting of mixtures of mono-, di- and triesters of glycerol with fatty acids. They may contain small amounts of free fatty acids and glycerol. May contain up to 50 ppm Nickel from hydrogenation.</td>
<td></td>
</tr>
<tr>
<td>Yes(^{d})</td>
<td>13.6.4</td>
<td>Salts of fatty acids (^{(4)})</td>
<td>Product obtained by reaction of fatty acids with at least four carbon atoms with calcium, magnesium, sodium or potassium hydroxides, oxides or salts. May contain up to 50 ppm Nickel from hydrogenation. Analysis should be done on the fat component (e.g. PFAD) or on the end-product.</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13.6.5</td>
<td>Fatty acid distillates from physical refining (^{(3)})</td>
<td>Product obtained during the deacidification of oils and fats of vegetable origin by means of distillation containing free fatty acids, oils or fats and natural components of seeds, fruits tissues such as mono- and diglycerides, sterols and tocopherols.</td>
<td></td>
</tr>
<tr>
<td>Yes(^{c})</td>
<td>13.6.6</td>
<td>Crude fatty acids from splitting (^{(3)})</td>
<td>Product obtained by oil/fat splitting. By definition it consists of crude fatty acids (C_6-C_{24}), aliphatic, linear, monocarboxylic, saturated and unsaturated. May contain up to 50 ppm Nickel from hydrogenation.</td>
<td></td>
</tr>
</tbody>
</table>

\(^{c}\) The products 13.6.6 and 13.6.7 are out of scope of GMP+ BA7 only in case the feedstock used to produce these products is vegetable oil falling under the Catalogue of feed materials number 2.20.1. When other products are used as the feedstock (e.g. by-products as defined in GMP+ BA7), 13.6.6 and 13.6.7 are within scope of GMP+ BA7.
Within the scope of annex | Number | Name | Description | Examples of products falling under this number
--- | --- | --- | --- | ---
Yes | 13.6.7 | Pure distilled fatty acids from splitting (3) | Product obtained by the distillation of crude fatty acids from oil/fat splitting potentially plus hydrogenation. By definition it consists of pure distilled fatty acids C$_6$-C$_{24}$, aliphatic, linear, monocarboxylic, saturated and unsaturated. May contain up to 50 ppm Nickel from hydrogenation. | Ricin oleic acid (syn. Castor oil acid), CAS no.141-22-0, EC no. 205-470-2; Icosa-5,8,11,14-tetraenoic acid (syn. Arachidonic acid), CAS no. 506-32-1, EC no. 208-033-4; Hexanoic acid (syn. Caproic acid) of vegetable origin, CAS no.142-62-1, EC no. 205-550-7; Octanoic acid (syn. Caprylic acid) of vegetable origin, CAS no.124-07-2, EC no. 204-677-5; Oleic acid (syn. octadec-9-enoic acid) of vegetable origin, CAS no. 112-80-1, EC no. 204-007-1; Linoleic acid (syn. 9,12-Octadecadienoic acid), CAS no. 60-33-3, EC no. 200-470-9; Linolenic acid (syn. (9Z,12Z,15Z)-9,12,15-Octadecatrienoic acid), CAS no. 463-40-1, EC no. 207-334-8; Stearic acid (syn. octadecanoic acid) of vegetable origin, CAS no. 57-11-4, EC no. 200-313-4

No | 13.6.8 | Soap stocks (3) | Product obtained during the deacidification of vegetable oils and fats by means of aqueous calcium, magnesium, sodium or potassium hydroxide solution, containing salts of fatty acids, oils or fats and natural components of seeds, fruits or animal tissues such as mono- and diglycerides, crude lecithin and fibres. |
<table>
<thead>
<tr>
<th>Within the scope of annex</th>
<th>Number</th>
<th>Name</th>
<th>Description</th>
<th>Examples of products falling under this number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes&lt;sup&gt;d&lt;/sup&gt;</td>
<td>13.6.9</td>
<td>Mono- and diglycerides of fatty acids esterified with organic acids&lt;sup&gt;(4)(5)&lt;/sup&gt;</td>
<td>Mono- and diglycerides of fatty acids with at least four carbon atoms esterified with organic acids.</td>
<td></td>
</tr>
<tr>
<td>Yes&lt;sup&gt;d&lt;/sup&gt;</td>
<td>13.6.10</td>
<td>Sucrose esters of fatty acids&lt;sup&gt;(4)&lt;/sup&gt;</td>
<td>Esters of saccharose and fatty acids.</td>
<td></td>
</tr>
<tr>
<td>Yes&lt;sup&gt;d&lt;/sup&gt;</td>
<td>13.6.11</td>
<td>Sucroglycerides of fatty acids&lt;sup&gt;(4)&lt;/sup&gt;</td>
<td>Mixture of esters of saccharose and mono and diglycerides of fatty acids.</td>
<td></td>
</tr>
</tbody>
</table>
| No                      | 13.8.1  | Glycerine, crude [Glycerol, crude]                                   | By-product obtained from:  
- the oleochemical process of oil/fat splitting to obtain fatty acids and sweet water, followed by concentration of the sweet water to get crude glycerol or by transesterification (may contain up to 0.5 % methanol) of natural oils/fats to obtain fatty acid methyl esters and sweet water, followed by concentration of the sweet water to get crude glycerol;  
- the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin. Mineral and organic salts might remain in the glycerine (up to 7.5 %).  
May contain up to 0.5 % Methanol and up to 4 % of Matter Organic Non Glycerol (MONG) comprising of Fatty Acid Methyl Esters, Fatty Acid Ethyl Esters, Free Fatty Acids and Glycerides; |                                               |

<sup>d</sup> This product is out of scope of GMP+ BA7 in case it is only produced with/ derived from 13.6.6 or 13.6.7 obtained by splitting of vegetable oil falling under the Catalogue of feed materials number 2.20.1. In all other cases, this product is within scope of GMP+ BA7.
<table>
<thead>
<tr>
<th>Within the scope of annex</th>
<th>Number</th>
<th>Name</th>
<th>Description</th>
<th>Examples of products falling under this number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>13.8.2</td>
<td>Glycerine [Glycerol]</td>
<td>Product obtained from:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- the oleochemical process of (a) oil/fat splitting followed by concentration of sweet waters and refining by distillation (see part B, glossary of processes, entry 20) or ion-exchange process; (b) transesterification of natural oils/fats to obtain fatty acid methyl esters and crude sweet water, followed by concentration of the sweet water to get crude glycerol and refining by distillation or ion-exchange process;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin with subsequent refining of the glycerine. Minimum Glycerol content: 99 % of dry matter;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- saponification of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps, followed by refining of crude Glycerol and distillation. May contain up to 50 ppm Nickel from hydrogenation.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13.11.1</td>
<td>Propylene glycol; [1,2-propanediol]; [propane-1,2-diol]</td>
<td>Organic compound (a diol or double alcohol) with formula C₃H₈O₂. It is a viscous liquid with a faintly sweet taste, hygroscopic and miscible with water, acetone, and chloroform. May contain up to 0.3 % di-propylene glycol.</td>
<td></td>
</tr>
<tr>
<td>Within the scope of annex</td>
<td>Number</td>
<td>Name</td>
<td>Description</td>
<td>Examples of products falling under this number</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------</td>
<td>------</td>
<td>-------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Yes</td>
<td>13.11.2</td>
<td>Mono-esters of propylene glycol and fatty acids (4)</td>
<td>Mono-esters of propylene glycol and fatty acids, alone or in mixtures with di-ester</td>
<td></td>
</tr>
</tbody>
</table>

(1) The name shall be supplemented by the species.
(2) The name shall be supplemented by the plant species.
(3) The name shall be supplemented by the indication of the botanical or animal origin.
(4) The name shall be amended or supplemented to specify the fatty acids used.
(5) The name shall be amended or supplemented to specify the organic acid.
Annex 2: Overview of processes of refining of oils, downstream processing of oils and biodiesel production process (source: FSP and EFISC)

Flow chart chemical refining

- From distillation / stripping
- From prepressing

**Crude Oil**
- Crude lecithins (wet gums) (2.20.1)
- Degumming
  - Crude degummed oil (2.20.1)
  - Drying
    - Soap stocks (13.6.8)
    - Drying
      - Lecithin
        - Salts of fatty acid (13.6.4)
        - Neutralisation
          - Alkali solution
            - Active coal (optional)
            - Bleaching earth
            - Desolventising & toasting
              - Used bleaching earth
                - Solvent extraction
                  - Filter aid
                    - Winterisation
                      - Filter aid
                        - Deodorisation
                          - Refined Oil (2.20.1)
                          - Deodistillate

**Acids**
- From prepressing
  - Acid oil (13.6.1)**
  - Splitting
    - Salts of fatty acid (13.6.4)
    - Neutralisation
      - Alkali solution
        - Active coal (optional)
        - Bleaching earth
        - Desolventising & toasting
          - Used bleaching earth
            - Splitting
              - Soap stocks (13.6.8)
              - Drying
                - Lecithin
                  - Salts of fatty acid (13.6.4)
                  - Neutralisation
                    - Alkali solution
                      - Active coal (optional)
                      - Bleaching earth
                      - Desolventising & toasting
                        - Used bleaching earth
                          - Solvent extraction
                            - Filter aid
                              - Winterisation
                                - Filter aid
                                  - Deodorisation
                                    - Refined Oil (2.20.1)
                                    - Deodistillate

a. Typical flow chart; the order of the process steps may vary amongst production plants
b. Used bleaching earth with active coal is not fed back to meal at integrated crushing and refining and is disposed of outside of the feed chain
c. The number refers to that in the Catalogue of Feed Materials - Commission Regulation 68/2013
Specific requirements for by-products from the Oil & Fat Industry - BA 7

Flow chart physical refining

- Crude Oil
  - Degumming
    - Crude degummed oil (2.20.1)
      - Bleaching
        - Winterisation (optional)
          - Distillation
            - Fatty acid distillate (13.6.5)
            - Refined oil (2.20.1)

- Desolventising & toasting
  - Used bleaching earth
    - Filter aid (optional)
      - Solvent extraction

- Desolventising & toasting
  - Crude lecithins (wet)

- Desolventising & toasting
  - Used bleaching earth

- Acids
  - Active coal (optional)
    - Bleaching earth
      - Filter aid

- Used bleaching earth with active coal is not fed back to meal at integrated crushing and refining and is disposed of outside of the feed chain

*Typical flow chart; the order of the process steps may vary amongst production plants

1Used bleaching earth with active coal is not fed back to meal at integrated crushing and refining and is disposed of outside of the feed chain
Specific requirements for by-products from the Oil & Fat Industry

Flowchart Oil Industry

Physical refinery

1. Oil, physically refined
2. Transesterification

3. Separation process

4. Crude Methyl Ester

5. Distillation Fractionation

6. Methyl Ester fraction

7. Hydrolysis

8. Distillation and phase separation

9. Pure distilled fatty acids from splitting (13.6.7)

( ): Codes conform the Catalogue of feed materials or Feed Material Register
Specific requirements for by-products from the Oil & Fat Industry

Flow chart downstream processing

Crude, Refined or Processed oil (2.20.1)

- Hydrogenation
  - Hydrogenated oil (2.20.1)

- Interesterification
  - Interesterified oil (2.20.1)

- Splitting + fractionation
  - Fatty acids from splitting (13.6.6, 13.6.7)
  - Glycerine (13.8.1, 13.8.2)

- Fractionation
  - Olein (2.20.1)
  - Stearin (2.20.1)

Flow chart downstream processing continues to refining (potentially)

Oleochemical production processes

By-products from the oil & fat industry (within scope of GMP+ BA.7)

- Splitting
  - Glycerine crude (13.8.1)

- Crude fatty acids from splitting (13.6.6)

- Hydrogenation / fractionation / distillation

- Pure distilled fatty acids from splitting (13.6.7)
Biodiesel production process

Incoming crude and/or refined Vegetable oil

Esterification

Trans-esterification

Neutralization, Water washing, Phase separation

Removal of methanol, water by evaporation

Finished Biodiesel

Acid Water

Glycerol

Acidulation and MONG Separation

Water

Methanol/Water Removal/Separation

Glycerine

Dehydration

Deodorisation

Breaching/purification

Refrined Glycerin (13.8.2)

Crude Glycerin (13.8.1)

Storage

Transport

Free Fatty Acids

Option A

Option B

Some preceding processing steps could take place. See FEDHOL sector document

Note: FFA not sold for feed, only used for technical purposes
Flowchart Mono- and diglycerides of rape seed fatty acids esterified with organic acids
Flowchart Mono- and diglycerides of rape seed fatty acids esterified with organic acids

A

3.4 Filtration

Filter aid / foreign bodies

3.5 Spray cooling

3.6 Mixing (homogenization)

3.7 Sieving

Mono- and diglycerides of rape seed fatty acids esterified with organic acids

3.8 Temporary storage

Packaging material

3.9 Packaging

3.10 Metal detection

Metal particles (Product reject)

4. Storage

5. Transport

End of process
Specific requirements for by-products from the Oil & Fat Industry - BA 7

Flowchart Mono-, di- and triglycerides of vegetable fatty acids

Start process

1. Reception

2. Storage

3.1 Sieving

3.2 Pre-heating (indirect)

3.3 Reaction

3.4 Distillation

Glycerin, refined from the oleochemical process (13.080)

Raw materials* (13.6.7; 2.20.1)

Steam

Physical foreign bodies

Di and Triglycerides

A

* Raw materials used:
  - Pure distilled fatty acids from splitting (13.6.7)
  - Vegetable oil / fat, hardened (hydrogenated) refined (2.20.1)

Into GMP+ chain, only the feed materials already included in the FSP product list (with its risk assessment available) as well as food grade raw materials can be used as raw materials (note that technical grade raw materials are excluded).

Note: The name must be amended or supplemented to specify the fatty acids used as well as the botanical origin.

(): Codes conform to the Catalogue of feed materials or Feed Material Register
Specific requirements for by-products from the Oil & Fat Industry - BA 7

Flowchart Mono-, di- and triglycerides of vegetable fatty acids

A

3.5 Refining

3.6 Filtration

3.7 Cooling

Filteraid (Cellulose and Clay) → Spent Filter aid

Mono-, di- and triglycerides of vegetable fatty acids (13.6.3)

4. Storage

Packaging material → 5.1 Packaging

5.2 Metal detection → Metal particles

6. Storage

7. Transport

End of process*

* Monitoring frequency of end product depends on the raw material used (positive release for dioxins). See GMP+ BA4.

(): Codes conform to the Catalogue of feed materials or Feed Material Register
Specific requirements for by-products from the Oil & Fat Industry

**Flowchart Oil Industry**

**Chemical refinery**

- **B** Oil, crude
  - Caustic soda
  - Water
  - **10.1 Saponification** free fatty acids
    - **10.2 Centrifuge** soap stocks (13.6.8)
    - Bleaching earth and possibly active carbon
    - **10.3 Bleach** Oil, neutralized, bleached
      - **10.4 Centrifuge** Acid oils from chemical refining (13.6.1)
      - Sulphuric acid or hydrochloric acid
    - **10.4 Deodorize** Deodistillates (untreated)
      - **10.5 Validated treatment** (to remove contaminants), e.g. fractionation by means of distillation and treatment with active carbon
        - Oil, refined (2.20.1)
        - Deodistillates (treated)

* These treated deodistillates can only be marketed under positive release for dioxin.
Specific requirements for by-products from the Oil & Fat Industry - BA 7

Flowchart Oil Industry

Splitting

2.20.1 Crude oil / Refined oil

12.1 Split (high T and pressure)

12.2 Cool

12.3 Deacidify

Crude fatty acids from Splitting (13.6.6)

12.4 Wash (optional)

12.5 Dry (indirect) (optional)

12.6 Fractionated distillation

Pure distilled fatty acids from splitting (13.6.7)

6

D

Processing glycerol

'sweet' water (10-20% glycerol)

7

Fatty acids, undistilled

2.20.1 Crude oil / Refined oil

Water

28/31
Flowchart Saturated fatty acids (C3 to C10 and C12) esterified with glycerol

1. Reception Raw materials
   - Saturated fatty acids (from C3:0 to C11:0, also C12:0) *
   - Glycerol (Vegetal origin)

2. Storage

3.1. Indirect (pre)heating

3.2. Reaction (synthesis)
   - Thermal fluid / Steam (Stainless steel vessel)
   - Activated carbon
   - Sodium hydroxide (Caustic soda)

3.3. Cooling

3.4. Intermediate storage

3.5.1. Bleaching / Deodorization
   - Bleaching earth
   - Sodium hydroxide (Caustic soda)

3.5.2. Filtration
   - Filter aid (cellulose / Diatomaceous earth)
   - Spent activated carbon / Filter aid / Bleaching earth
   - Sodium hydroxide (Caustic soda)

3.6. Intermediate storage

3.7. Distillation (Indirect heating) (removal of reaction water) / Deodorization

3.8. Cooling

B

A

3.9. Waste water

* C3 - Propionic acid obtained from synthetic process
C4 - Butyric acid obtained from synthetic process
C5 - Valeric acid obtained from synthetic process
C6 - Caproic acid obtained from coconut oil
C7 - Enantionic acid obtained from sunflower oil
C8 - Caprylic acid obtained from Palm fatty acids or coconut oil
C9 - Pelargonic acid acid obtained from sunflower oil
C10 - Capric acid obtained from Palm fatty acids or coconut oil
C12 - Lauric acid obtained from Palm kern oil or coconut oil
Flowchart Saturated fatty acids (C3 to C10 and C12) esterified with glycerol

- **A**
  - 3.9 Distillation (Remove excess of acid)
  - Saturated fatty acids (C3 to C10 and C12)

- **B**
  - IBC's / Drum barrel
  - 4. Packaging
  - 5. Storage
  - 6. Transport
  - End of process

Intermediate storage
GMP+ International
Braillelaan 9
2289 CL Rijswijk
The Netherlands
t. +31 (0)70 – 307 41 20 (Office)
   +31 (0)70 – 307 41 44 (Help Desk)
e. info@gmpplus.org

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