



Novel Food Regulation

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**Phycomorph European Guidelines for a
Sustainable Seaweeds Aquaculture - Pegasus
26 February 2019**

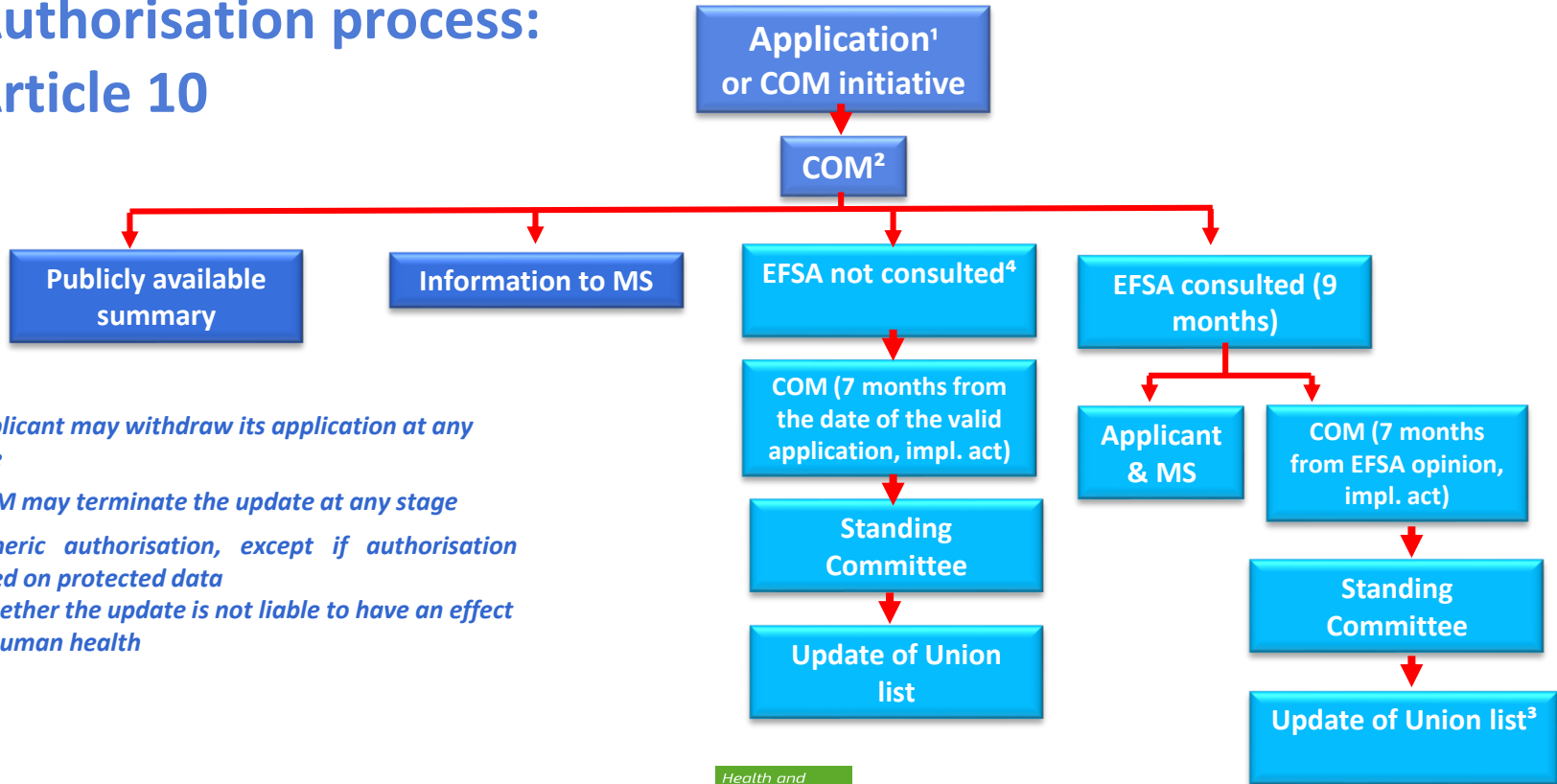
*Health and
Food Safety*

The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission



European Commission

Authorisation process: Article 10



¹Applicant may withdraw its application at any time

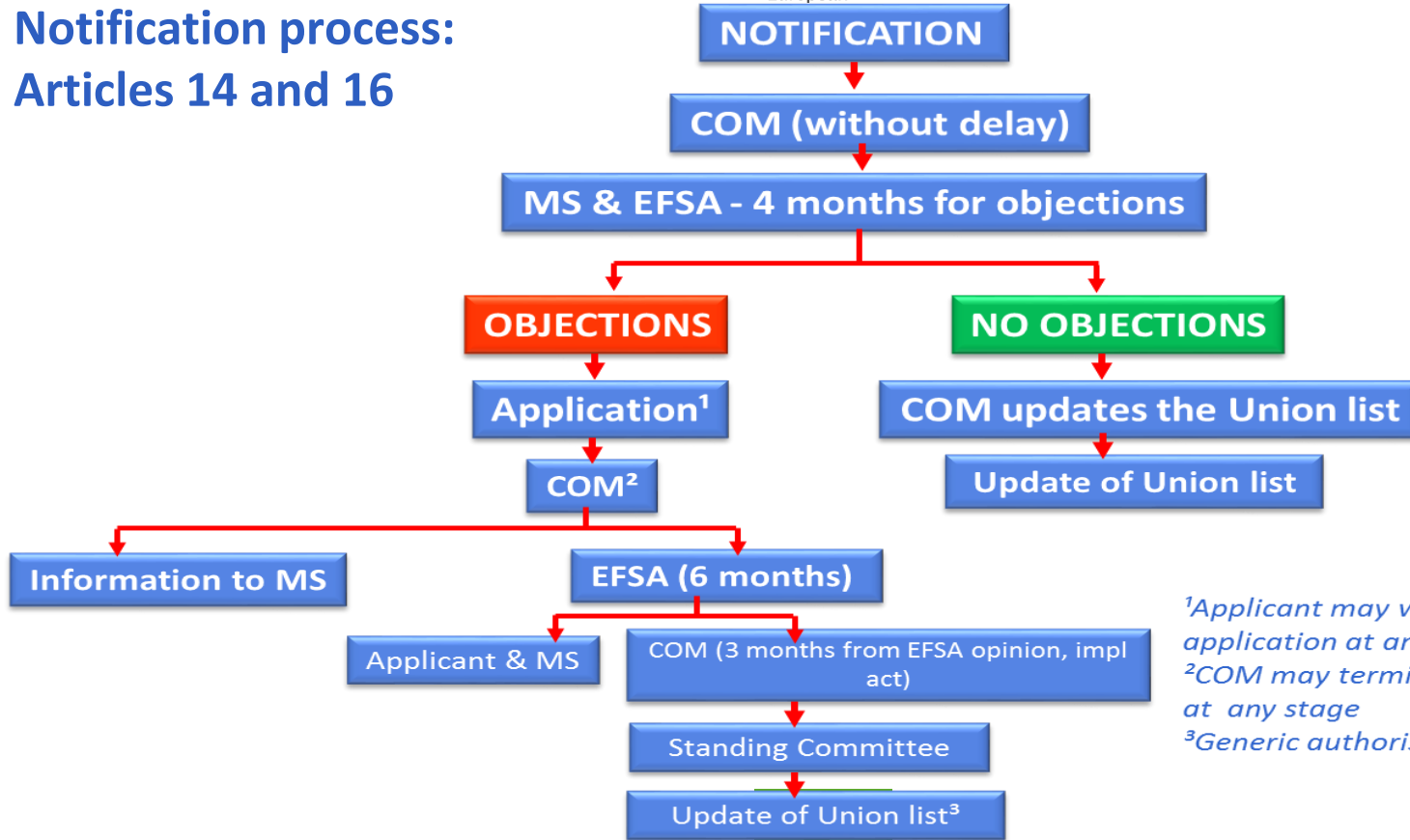
²COM may terminate the update at any stage

³Generic authorisation, except if authorisation based on protected data

⁴Whether the update is not liable to have an effect on human health



Notification process: Articles 14 and 16



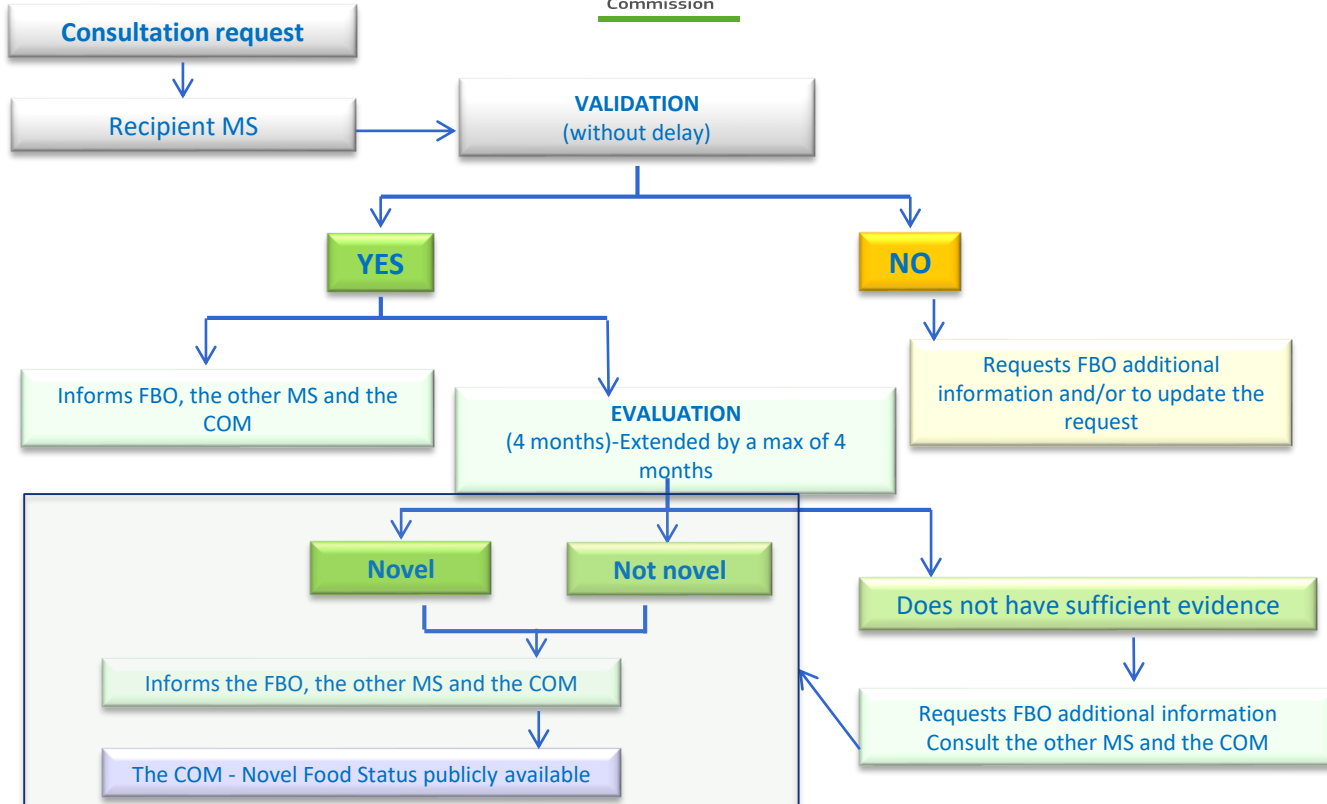
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²COM may terminate the update at any stage

³Generic authorisation



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Algae and extracts from algae listed in the Union list

- *Algal oil from the microalgae Ulkenia sp.*
- *Astaxanthin-rich oleoresin from Haematococcus pluvialis algae*
- *Odontella aurita microalgae*
- *Schizochytrium sp. oil rich in DHA and EPA*
- *Schizochytrium sp. (ATCC PTA-9695) oil*
- *Schizochytrium sp. Oil*
- *Schizochytrium sp. (T18) oil*
- *Dried Tetraselmis chuii microalgae*
- *Fucoidan extract from the seaweed Fucus vesiculosus*
- *Fucoidan extract from the seaweed Undaria pinnatifida*
- *Ecklonia cava phlorotannins*

Novel food catalogue



Seaweeds

Ecklonia bicyclis
Fucus vesiculosus
Palmaria palmata
Hizikia fusiforme
Chondrus crispus
Laminaria digitata
Laminaria japonica, Saccharina japonica
Porphyra tenera

Seaweeds

Ascophylum nodosum
Ulva lactuca
Himanthalia elongata
Fucus serratus
Sacharina latissima, Laminaria sacharina.
Undaria pinnatifida
Gracilaria verrucosa
Enteromorpha sp.
Alaria sculenta

Codium sp. No information

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Ecklonia cava phlorotannins'	<i>Specified food category</i>	<i>Maximum levels</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ecklonia cava Phlorotannins'.</p> <p>Food supplements containing <i>Ecklonia cava</i> phlorotannins shall bear the following statement:</p> <ul style="list-style-type: none"> (a) This food supplement should not be consumed by children/adolescents under the age of twelve/fourteen/eighteen (*) years. (b) This food supplement should not be consumed by persons with thyroid disease or by persons who are aware of or have been identified as being at risk of developing thyroid disease. (c) This food supplement should not be consumed if other food supplements containing iodine are also consumed. (*) Depending on the age group the food supplement is intended for.' 	
	Food Supplements as defined in Directive 2002/46/EC intended for the general population, excluding children under the age of 12 years	163 mg/day for adolescents from 12 to 14 years of age; 230 mg/day for adolescents above 14 years of age; 263 mg/day for adults.		

Authorised Novel Food	Specification
<p>'Ecklonia cava phlorotannins</p>	<p>Description/Definition: <i>Ecklonia cava</i> phlorotannins are obtained via alcohol extraction from the edible marine alga <i>Ecklonia cava</i>. The extract is a dark brown powder, rich in phlorotannins, polyphenolic compounds found as secondary metabolites in certain brown algae species.</p> <p>Characteristics/Composition Phlorotannin content: 90 ± 5 % Antioxidant activity: > 85 % Moisture: < 5 % Ash: < 5 %</p> <p>Microbiological criteria: Total viable cell count: < 3 000 CFU/g</p>

Authorised Novel Food	Specification
	<p>Mould/yeast: < 300 CFU/g Coliforms: Negative to test <i>Salmonella</i> spp.: Negative to test <i>Staphylococcus aureus</i>: Negative to test</p> <p>Heavy metals and Halogens: Lead: < 3,0 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 3,0 mg/kg Arsenic: < 25,0 mg/kg Inorganic Arsenic: < 0,5 mg/kg Iodine: 150,0-650,0 mg/kg CFU: Colony Forming Units'</p>

Monitoring recommendation for seaweed

Commission Recommendation (EU) 2018/464

- Occurrence data for arsenic, cadmium, iodine, lead and mercury should be gathered to support a dietary assessment.*
- Monitoring to be performed during the years 2018, 2019 and 2020*
- List of seaweed species provided based on consumption habits*

E-submission



1. System designed to allow applicants to submit novel foods applications and/or traditional foods notifications from third countries online. <https://webgate.ec.europa.eu/fscap>
2. All applicants must submit applications/notifications through that system.
3. All info at https://ec.europa.eu/food/safety/novel_food/e-submission_en
4. The user guide available in all EU languages.



European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/safety/novel_food_en

Functional mailbox: SANTE-NOVELFOODS@ec.europa.eu