

THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

Novel food: astaxanthin-rich oleoresin from algae

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EU approves change in specifications for astaxanthin-rich oleoresin from Haematococcus pluvialis algae

Commission Implementing Regulation (EU) <u>2024/1026</u> of 8 April 2024 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae

Update

The European Commission has approved a change in the specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae.

What is changing?

This Regulation authorises lower minimum specification limits for protein and astaxanthin (ATX) monoesters, and increased maximum specification limits for relative amounts of ATX diesters and 9-cis stereoisomers in total ATX (see Table 1).

Why?

EFSA (2023) concluded that the proposed changes in the specifications are safe at the acceptable daily intake (ADI) of ATX from food supplements at 0.2 mg/kg body weight.

Timeline

The new specifications apply from 29 April 2024.

Recommended Actions

Exporters of food supplements containing this substance must ensure that the new specifications set out in Table 1 are respected.





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Background

Astaxanthin is a carotenoid produced from *H. pluvialis* algae, first authorised for use in food supplements for the general population by Regulation (EU) 2017/2470.

Implementing Regulation <u>2021/1377</u> limited its conditions of use to adults and adolescents older than 14 years based on an opinion of <u>EFSA (2020)</u>.

Implementing Regulation (EU) <u>2023/1581</u> authorised its use in food supplements intended for children 3–10 years old and adolescents 10–14 years old, provided that the intake of ATX from food supplements would not exceed an ADI of 0.2 mg/kg body weight per day.

For further information on the novel food authorisation process, see Novel foods explained.

Resources

EFSA (2023) <u>Safety of a change in specifications of the novel food oleoresin from Haematococcus pluvialis containing astaxanthin pursuant to Regulation (EU) 2015/2283</u>. EFSA Journal, 21(11): 5993.

EFSA (2020) <u>Safety of astaxanthin for its use as a novel food in food supplements</u>. EFSA Journal, 18(2): 8338.

Implementing Regulation (EU) 2017/2470 establishing the list of novel foods

Implementing Regulation (EU) <u>2021/1377</u> authorising the change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae

Implementing Regulation (EU) <u>2023/1581</u> as regards the conditions of use of the novel food 'astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae'

Sources

Implementing Regulation (EU) <u>2024/1026</u> as regards the specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae

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Table & Figures

Table 1 Specification limits for protein and astaxanthin (ATX) in oleoresin from <i>Haematococcus pluvialis</i> algae		
Specification	% Weight / weight of (total) carotenoids	
	Old (range)	New (range)
ATX monoesters	79.8-91.5%	66.7-91.5%
ATX diesters	0.16-19.0%	0.16-32.5%
ATX 9-cis stereoisomer	0.3–17.3%	0.3-30.0%
Protein content	0.3-4.4%	0.0-4.4%
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Source: Implementing Regulation (EU) 2024/1026

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