



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach
The Director



I would like to thank you for your email of 24 March 2021¹, in which you communicate, amongst others, your considerations regarding a possible implementation of the new provisions under Regulation (EU) 2018/848², Annex II, Part III, point 3.1.3.2(b), concerning the requirements for the areas suitable for organic production of bivalve molluscs and other species that are not fed by man but instead feed on natural plankton.

To sum up your position, you believe that molluscs growing in class B areas that, before being placed on the market for human consumption, undergo a purification treatment after relaying to meet the same health standards set for molluscs coming from class A areas, can be certified as organic because they are “equivalent” to those coming from class A areas.

I regret to inform you that the Commission does not share your position summarised above for the following reasons:

- The above-mentioned point 3.1.3.2(b) of new Regulation (EU) 2018/848 reads as follows: “ *with regard to bivalve molluscs and other species which are not fed by man but instead feed on natural plankton, the following rules shall apply: ... (b) “the growing areas shall be **suitable from a health point of view and shall either be of high ecological status** as defined by Directive 2000/60/EC or of **good environmental status** as defined by Directive 2008/56/EC³ or of **equivalent quality to the production zones classed as A in Regulation (EC) No 854/2004⁴.***”

¹ ARES(2021)2076070

² [Regulation \(EU\) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation \(EC\) No 834/2007 \(OJ L 150, 14.6.2018 p.1 \)](#)

³ Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

⁴ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).



until 13 December 2019 or the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation(EU) 2017/625⁵, from 14 December 2019."

I would like to bring to your attention the fact that these new provisions differ substantially from the current ones under Regulation (EC) No 834/2007⁶ and in a way, they can be seen as their development.

Indeed, Article 15(e) of Regulation (EC) No 834/2007 provides for the same organisms the following requirements: "*(ii) they shall be grown in waters **which meet the criteria for Class A or Class B areas** as defined in Annex II of Regulation (EC) No 854/2004; (iii) the growing areas shall be of **high ecological quality** as defined by Directive 2000/60/EC⁷ and, pending its implementation of a **quality equivalent to designated waters under Directive 2006/113/EC⁸**".*

This last Directive concerned specifically the requirements for water quality for shellfish and it has been repealed implicitly by the amendment of Directive 2000/60/EC (Water Framework Directive) in 2013⁹.

In the meantime, Regulation (EU) 2017/625 repealed Regulation (EC) 854/2004. In addition, Commission Implementing Regulation (EU) 2019/627¹⁰ adopted on the basis of Article 18(8) of Regulation (EU) 2017/625 confirmed the specific requirements (microbiological limits) for zones of production A, B and C (see Title V, Chapter I of that Regulation) as previously set in Regulation (EC) 854/2004¹¹.

⁵ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

⁶ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02007R0834-20081010&qid=1396976187958&from=EN>

⁷ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁸ Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters (OJ L 376, 27.12.2006, p. 14).

⁹ It covered coastal and brackish waters designated by Member States to the support of shellfish growth and parameters to comply with were set in its annex I (in particular comprehensive concerning possible contamination from microbial, chemicals, toxins).

¹⁰ Commission Implementing Regulation (EU) No 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

¹¹ Other specific horizontal rules are in force for presence/maximum levels of toxins and chemicals contaminations and health standards as those set in particular under Regulation (EC) 853/2004, Decision 2002/226 on ASP, Reg 2073/2005 and 2074/2005 on microbials, Reg 1881/2006 contaminants, Reg 786/2013 yessotoxins.

Commission Implementing Regulation (EU) 2019/627 lays down specific criteria for the classification of bivalve mollusc production areas and allows for the classification of class A zones where the shellfish can be collected for direct human consumption without further treatment. Live bivalve molluscs placed on the market from these areas must also meet the health standards laid down in Annex III, Section VII, Chapter V of Regulation (EC) No 853/2004¹².

Comparing the current and future legal provisions, it is evident that the co-legislators intended to introduce this change in organic production, which on the other hand has not been fully introduced in the case of algae.

In fact, for algae, which were referred to as “seaweeds” under Regulation (EC) 834/2007, Article 13(1)(a) provided for the growing areas to be of high ecological quality as defined by Directive 2000/60/EC and, pending its implementation, of a quality equivalent to designated waters under Directive 2006/113/EC and to be not unsuitable from a health point of view. In addition: *“Pending more detailed rules to be introduced in implementing legislation, wild edible seaweeds shall not be collected in areas which would not meet the criteria for Class A or Class B as defined in Annex II of Regulation (EC) No 854/2004 ...”*.

In the new Regulation (EU) 2018/848 Annex II part III, point 2.2.1. provides for algae the following:

*“2.2.1. **The collection of wild algae and parts thereof is considered as organic production provided that:***

*(a) **the growing areas are suitable from a health point of view and are of high ecological status as defined by Directive 2000/60/EC, or are of equivalent quality to:***

*— **the production zones classed as A and B in Regulation (EC) No 854/2004 of the European Parliament and of the Council, until 13 December 2019, or***

*— **the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, from 14 December 2019;”***

Point 2.2.2. reads as follows for algae cultivation: *“The cultivation of algae shall take place in areas with environmental and health characteristics at least equivalent to those outlined in point 2.2.1.(a) in order to be considered organic...”*.

Bearing in mind the above, the rules for the growing areas for the collection of wild algae include clear options for production zones A and B. However, for bivalves the co-legislators did not grant both options and limited them to zone A as laid down in point 3.1.3.2(b).

I am aware that this could have a negative impact for certain organic operators. However, it also has to be kept in mind that the conventional production systems of bivalve molluscs do not differ much in practice from organic production systems as such systems are mainly facilitating the deposition and growing of bivalves without external inputs. Therefore, the main differences between conventional and organic production are the prohibition to use artificially induced polyploid animals and the quality of water in the zone in which the molluscs are harvested.

¹² Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

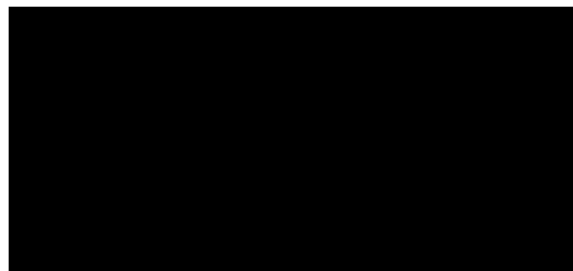
In conclusion, regarding the implementation of point 3.1.3.2(b) of part III of Annex II to Regulation (EU) 2018/848, **first, Member States shall determine whether a "growing area" is suitable from a health point of view for the production of shellfish** (determination which is occurring also for conventional production) and then **verify whether those growing areas identified as safe comply with at least one of the three categories** below:

- be of high ecological status under the Directive 2000/60/EC (Water Framework Directive),
- **or** be of good environmental status under the Directive 2008/56/EC (Marine Strategy Framework Directive),
- **or** be of equivalent quality to zone A of Regulation (EU) 2019/627.

The text "of equivalent quality to" zone A is currently to be interpreted as equivalent in terms of health status to zone A in case of third countries and for Member States the compliance is set in EU legislation and Guidance documents¹³.

The present opinion is provided on the basis of the facts as set out in your email and expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours sincerely,



■ Guidance EURL *Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004*".
https://eur1cefasc.org/media/14116/20181231-cg_issue-4-final.pdf