Bivalve molluscs: hygiene requirements

Published by AGRINFO on 09 Nov 2026

EU clarifies hygiene rules for bivalve molluscs, updates its registration document, and sets a mandatory date of 19 November 2028 for issuing registration documents via TRACES

Commission Delegated Regulation (EU) 2026/1829 of 24 July 2026 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene rules for live bivalve molluscs

Update

The European Union (EU) has introduced the following changes to the hygiene requirements for live bivalve molluscs (Regulation 853/2004).

- Only molluscs that are ready to be sold to consumers must have an identification mark; unpurified molluscs sent for purification should not have this identification mark.
- The registration document required when exporting live molluscs to the EU has been updated, including the information needed and its official format.
- From 19 November 2028, businesses must use the EU's online Trade Control and Expert System (TRACES) to issue registration documents. Exporters of molluscs and competent authorities in non-EU countries must take steps to ensure that issuing the registration document through TRACES is possible by that date, after which paper documents will no longer be accepted.
- The EU has introduced a clear definition of "re-immersion", which means keeping live molluscs in clean seawater tanks to maintain their condition.

Impacted products

Live bivalve molluscs

What is changing?

The EU has introduced the following changes relating to hygiene requirements for live bivalve molluscs, amending Regulation (EC) No 853/2004.

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*

Identification marks

Molluscs from Class B or C production areas are not fit for human consumption and must undergo purification (see Background). Prior to this new Regulation, all molluscs (purified or unpurified) put on the EU market required an identification mark. To ensure that unpurified molluscs are not sold to consumers, the EU has now changed the rules so that unpurified molluscs sent by an intermediary operator from the production area to purification centres or processing establishments should *not* carry an identification mark (amending Annex II, Section I, Part A).

Revised registration document

To align the Regulation with the standardised model available in TRACES, the EU has amended the registration document that must be provided when exporting live bivalve molluscs to the EU. The model for this registration document can be found in Annex III, Section VII, Chapter X. The information required in the registration document has been updated (see Annex III, Section VII, Chapter 1).

Mandatory use of TRACES

From **19 November 2028**, operators must issue the registration document in TRACES. Paper documentation will no longer be accepted from that date.

Re-immersion

Operators can store live molluscs in clean seawater tanks to maintain their condition. The new Regulation defines this process, known as “re-immersion” (Annex III, Section VII, point 1b).

Why?

The EU has amended the rules on identification marks to ensure that only molluscs fit for human consumption are put on the market. To improve the efficiency of official controls, the EU is gradually increasing the use of the electronic TRACES system for issuing documentation. As preparing to submit registration documents via TRACES may be complex, its use will only be mandatory from 19 November 2028.

Timeline

The amended hygiene requirements and registration document apply from **19 November 2026**.

The requirement to issue registration documents through TRACES applies from **19 November 2028**.

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*

Recommended Actions

Exporters of live bivalve molluscs should:

- ensure that unpurified live bivalve molluscs exported to the EU do not bear identification marks
- use the updated registration document for each consignment from 19 November 2026
- engage with national competent authorities to prepare for the issuing of registration documents in TRACES by November 2028.

Background

The natural purification of live bivalve molluscs (such as mussels, oysters, and clams) is carried out in “relaying areas”, which are clearly marked sea, estuarine, or lagoon areas only used for the natural purification of molluscs. The production and relaying areas for live bivalve molluscs are classified by the EU competent authorities responsible for official controls (Regulation 2019/627, Art. 52). The areas are classified as Class A, B, or C according to the level of faecal contamination:

- Class A: live bivalve molluscs may be collected for direct human consumption
- Class B: live bivalve molluscs must be purified to meet the EU requirements
- Class C: live bivalve molluscs can only meet EU requirements after relaying for a long period.

All live bivalve molluscs put on the EU market must meet the requirements in Regulation 853/2004 (Annex III, Section VII, Chapter V).

Resources

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

Commission Implementing Regulation (EU) 2019/627 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*

Sources

Commission Delegated Regulation (EU) 2026/1829 of 24 July 2026 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene rules for live bivalve molluscs

Visit the AGRINFO website to view the latest AGRINFO Update newsletters and search the database.

Disclaimer: *Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial support of the European Union. Its contents do not, however, reflect the views of the European Union.*

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*