

Deactivation of registrations (Article 22 – Duties of registrants)

A Question raised recently by auditors from the Belgian competent authorities during REACH audits performed at Only Representatives was: Why was a certain substance registration not deactivated, as there has been no import for some years?

Answer: Whether an existing registration submitted by an Only Representative on behalf of its Principal is to be deactivated (by declaring cessation of manufacture/import) is a business decision to be taken by the Principal; the Only Representative would implement such a decision, if taken.

There is no legal requirement to deactivate a registration merely because there were no imports in one or more calendar years. There is also no clear ruling on what “no import” means (less than 1 tonne/a, or absolutely nothing), and there may be very good reasons for no imports in one or more consecutive calendar years, such as:

A substance was intended to be sold in the EU, but market demand disappeared, the product is not competitive, a purchasing decision is still pending, etc.

A delivery of a substance may be sufficient to cover demand for more than one year, resulting in no imports in the following year.

Customers sometimes change suppliers frequently to secure supply chains (“not putting all eggs in one basket”), which may result in irregular imports.

There may be many different business reasons for maintaining an active registration, even if there are no imports in one or more years. The Only Representative may flag to its Principal that a tonnage band reduction, or even a declaration of cessation of manufacture/import, could be made, but the final decision always rests with the Principal and the Only Representative must respect this.

The following response was provided to one Belgian audit team in 2026, when the question of no imports into the EU of a REACH registered substance with an existing registration and the requirement to declare “cease manufacture/import” was discussed.

Given fluctuations in year-over-year imports of certain substances, ORO is sharing its views on this topic as follows: As explained below, while ORO agrees that registrations must be updated should the current tonnage band be exceeded, there is no corollary requirement to update registrations should imports fall into a lower tonnage band.

Article 22 of REACH (Further duties of registrants) defines potential reasons for updates to REACH registration dossiers, amongst others, in paragraph 1 point (c): “changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import.”

However, further clarification on this requirement can be found in COMMISSION IMPLEMENTING REGULATION (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331/24, 12.10.2020) where Article 3 (Changes in tonnage bands) states:

“1. In the case of a change falling within point (c) of Article 22(1) of Regulation (EC) No 1907/2006 that results in a **higher tonnage band**, the registration shall be updated and submitted to the Agency by no later than 3 months from the following date:

(a) in a case where new data is generated for an update derived from the application of Annex VII or Annex VIII to Regulation (EC) No 1907/2006, the date when all the final test reports needed for the update have been received;

(b) in a case not falling within point (a), the date when the higher tonnage band is reached.

For cases referred to in point (a) of the first subparagraph, a contract negotiation with a testing laboratory shall be initiated for all the relevant tests by no later than 3 months from the date when the higher tonnage band is reached.

The deadlines specified in paragraph 1 of this Article apply without prejudice to the obligation of a registrant to inform immediately the Agency of the additional information he would require, as soon as the higher tonnage band is reached, in accordance with Article 12(2) of Regulation (EC) No 1907/2006.

2. In the case of a change falling within point (c) of Article 22(1) of Regulation (EC) No 1907/2006 that involves cessation of manufacture or import, the registration shall be updated and submitted to the Agency by no later than 3 months from the date when manufacture or import ceased.

3. Paragraph 1 of this Article does not apply if the change occurs as a result of the registrant restarting manufacture or import in accordance with Article 50(2) of Regulation (EC) No 1907/2006. Instead, in that situation, the registration shall be updated and submitted to the Agency before manufacture or import is restarted.” (emphasis added)

In the recitals to Regulation (EU) 2020/1435, recital 6 also states: “However, for the purposes of point (c) of Article 22(1) of Regulation (EC) No 1907/2006, no deadline should be specified for the update triggered by a change to a lower tonnage band, given that such a change in tonnage may be of a temporary nature and the update would not have any negative consequence for the protection of human health and the environment.”

The absence of a deadline or requirement associated with a change to a lower tonnage band is appropriate, as Article 22(1)(c) should not be interpreted as meaning that a declaration of cessation of manufacture/import must follow because imports were below 1 tonne/annum. This would result in an administrative nightmare. Moreover, it is recognised that import of substances can naturally fluctuate, resulting in no imports at certain times, while it remains unforeseeable how much may be imported in the future.

As long as no tonnage band is exceeded, no deadline is deliberately defined in order to provide flexibility. Declaring cessation of manufacture/import following one year of imports below 1 tonne/annum and reactivating such a dossier the next time imports exceed 1 tonne/a would add no value for human health or the environment and is therefore considered temporary in nature, without triggering a deadline or an interpretation of “undue delay”. We agree that cessation of manufacture/import would be appropriate in cases where the non-EU manufacturer no longer offers the substance to any EU customers. However, in other cases — e.g., where the substance is offered to the market but no one is ordering it — ORO is of the opinion that it is not necessary to declare cessation of manufacture/import.