

## **REGULATION (EC) No 1907/2006 (REACH Regulation)**

*RELATED PROVISION: REGULATION (EC) No 1907/2006; COUNCIL REGULATION 833/2014; COUNCIL REGULATION 269/2014*

### **FREQUENTLY ASKED QUESTIONS – AS OF 9 DECEMBER 2022**

#### **1. How do EU sanctions, in particular Council Regulation (EU) No 269/2014 and Council Regulation (EU) No 833/2014, interplay with Regulation (EC) No 1907/2006 and other EU legislation on chemicals in general?**

*Last update: 1 July 2022*

European Union sanctions, including Council Regulation (EU) No 269/2014 and Council Regulation (EU) No 833/2014 apply as *lex specialis* with respect to Regulation (EC) No 1907/2006 and other Union legislation on chemicals in general. This means that, while both instruments must continue to be interpreted purposively, that is to say to give full effect to their objectives, the provisions of the latter should apply as long as they are not in conflict with EU sanctions or they cannot be derogated from (see Question 5).

#### **2. What does Council Regulation (EU) No 269/2014 entail for communication platforms<sup>1</sup> for data sharing and chemical companies?**

*Last update: 1 July 2022*

Under Council Regulation (EU) No 269/2014, the EU has designated a number of individuals and legal persons as subject to sanctions. Being a “designated person” means that all funds and economic resources, directly or indirectly belonging to, held or controlled by a designated person must be frozen. In practice, any EU legal and private person and EU Member State’s public institution doing business in the EU must prevent any transfer of, alteration of, access to, use of or other dealings with those funds or economic resources. The freezing of economic resources of a designated person means that any asset of a designated person, whether tangible or intangible, cannot be used by anyone to obtain other funds or assets. Property rights over data and vertebrate or non-vertebrate studies qualify as economic resources since they can be used by the data owner or the recipient of a letter of access to obtain economic benefits (e.g. via the submission of a registration dossier to the European Chemicals Agency [ECHA] or updates of an existing registration). Hence, they are subject to such restriction.

Council Regulation (EU) No 269/2014 also prohibits making funds or economic resources available to designated persons or persons owned/controlled by them. By way of example, this means that no further trade with those persons is possible as of the moment of their designation.

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<sup>1</sup> Communication platforms should be understood as any of the several possible ways in which companies can organise their cooperation under REACH. These forms of cooperation can vary from loose ways of cooperating (e.g. IT tools to communicate between all members of a joint submission) to more structured and binding models (e.g. consortia created by means of contracts). Participation in a SIEF (substance information exchange forum) was mandatory for phase-in substances until the last REACH registration deadline of 31 May 2018. After the end of the phase-in period, however, co-registrants remain encouraged to use similar informal communication platforms to enable them to meet their continuing registration and data sharing obligations under REACH.

This includes sharing data and studies or making available financial profits to a designated communication platform member, including if they are originating from costs sharing.

See also on this Commission FAQs on Sanctions adopted following Russia's military aggression against Ukraine ([‘Russia sanctions FAQs’](#)), Section A. Horizontal as well as Circumvention and Due diligence, and B. Individual financial measures.

**3. What does Council Regulation (EU) No 833/2014 entail for communication platforms for data sharing and chemical companies?**

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Council Regulation (EU) No 833/2014 provides for a number of trade restrictions. In particular, Article 5aa prohibits engaging in transactions with certain legal persons, entities or bodies. It is an obligation on the existing or potential registrants in REACH to take necessary actions to comply with Council Regulation (EU) No 833/2014. Business operators can seek guidance from their [National Competent Authorities \(NCAs\)](#).

See also on this Commission FAQs on Sanctions adopted following Russia's military aggression against Ukraine ([‘Russia sanctions FAQs’](#)), Section A. Horizontal as well as Circumvention and Due diligence, B. Individual financial measures.

**4. Should the EU members of a communication platform constituted for generating studies or for data sharing purposes, or an Only Representative (OR) comply with EU sanctions?**

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Yes. EU citizens as well as EU business operators incorporated or constituted under the law of a Member State or doing business in full or in part in the EU are required to comply with EU Sanctions (e.g. Article 13 of Council Regulation (EU) No 833/2014). This includes the different types of communication platforms governed by Union or national Law, as well as their members meeting the conditions indicated above and ORs pursuant to Article 8 of the REACH Regulation.

**5. Should I comply with the mandatory data sharing obligations under Articles 25–27 and 30 of the REACH Regulation and related obligations if the potential registrant is a company designated under Council Regulation (EU) No 269/2014, or owned/controlled by a designated person under Council Regulation (EU) No 269/2014?**

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No. As long as the potential registrant is designated under Council Regulation (EU) No 269/2014 or other EU sanctions (or owned/controlled by a designated person), it cannot receive economic resources from those who are required to comply with Article 11 of Council Regulation (EU) No 269/2014. Previous registrants owning the relevant data must refrain from entering data sharing negotiations and granting letters of access to those that are designated or owned/controlled by a designated person. Ongoing negotiations should be suspended as long as the person is designated or owned or controlled by a designated person. Note that derogations and exemptions under Council Regulation (EU) No 269/2014 may apply. It is an obligation of the data owner to

comply with EU sanctions; hence, data owners should investigate if the potential registrant is a company designated under Council Regulation (EU) No 269/2014, or owned/controlled by a designated person under Council Regulation (EU) No 269/2014 (see also Question 3).

A data owner that is a designated person or a company owned or controlled by a designated person is still obliged to enter mandatory data sharing negotiations. However, it cannot receive financial benefits from it (e.g. a designated member of the communication platform cannot receive funds stemming for instance from data sharing agreements and cost sharing as long as it is designated). Costs due to the designated data owner could be kept in an escrow account until the data owner is no longer designated. If a designated company is non-cooperative or requires payment of the share of the costs for access to studies, the potential registrant should indicate to ECHA that an agreement is not reachable due to the asset freeze derived from EU sanctions. ECHA should then decide whether to grant access to the data<sup>2</sup>.

**6. Should I comply with the mandatory data sharing obligations under Articles 25–27 and 30 of the REACH Regulation or related obligations if the potential registrant is a company that meets the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014?**

*Last update: 9 December 2022*

No. Article 5aa(1) of Council Regulation (EU) No 833/2014 prohibits to directly or indirectly engage in any transaction with:

- (a) a legal person, entity or body established in Russia, which is publically controlled or with over 50 % public ownership or in which Russia, its Government or Central Bank has the right to participate in profits or with which Russia, its Government or Central Bank has other substantial economic relationship, as listed in Annex XIX;
- (b) a legal person, entity or body established outside the Union whose proprietary rights are directly or indirectly owned for more than 50 % by an entity listed in Annex XIX; or
- (c) a legal person, entity or body acting on behalf or at the direction of an entity referred to in point (a) or (b) of this paragraph.

Granting a letter of access in exchange of cost sharing qualifies as a transaction and therefore it is not permitted in the cases mentioned under Article 5aa. Exemptions may apply, in particular Article 5(2). In this case, ECHA should grant access to the data (see Question 5). Exceptions might however apply (see Question 15).

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<sup>2</sup> While studies for registrations owned by designated persons or by persons owned or controlled by designated persons in principle must be frozen, the Court of Justice has held that ‘[...] the objective of ensuring animal protection is also pursued by the REACH Regulation, in particular by Article 13(1) and Article 25(1) thereof. According to that latter provision, testing on vertebrate animals for the purposes of that regulation is to be undertaken only as a last resort’ (Order of the President of the Court Case T-207/21 R, *Polynt v ECHA* Case T-207/21 R, ECLI:EU:T:2021:382. This is mandatory. As such, ECHA has the possibility to grant access to the vertebrate studies of a designated person, provided that the due costs are not made available to that person as long as he/she/it is designated.

**7. What should communication platforms do if they have entered a data sharing agreement with a company before it was designated or before the company that owns or controls it was designated under Council Regulation (EU) 269/2014?**

*Last update: 1 July 2022*

Having made funds or economic resources available to a person before it was designated does not qualify as a violation of EU sanctions. However, in general EU sanctions do not allow to continue providing goods and services to a designated person, even under a prior contract. It is for the communication platform to decide which actions are necessary, taking into account its business operations and existing agreements, to ensure compliance with the asset freeze obligation and the prohibition to make funds available to or for the benefit of designated persons. Only the necessary actions to comply with those obligations should be taken (see Question 14). For instance, a communication platform must make sure, also taking the appropriate contractual measures, that no further funds are made available to the designated members (e.g. from further implementation of existing cost-sharing agreement).

See however questions 9 and 11.

**8. What should communication platforms do if they have entered a data sharing agreement with a company before it met the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014?**

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Having engaged in transactions with a company before it met the criteria under letters (a)–(c) of Article 5aa does not violate Council Regulation (EU) No 833/2014. However, communication platforms should not engage in further transactions with those companies. It is for the communication platform to decide which actions are necessary, taking into account its business operations and existing agreements, to ensure compliance with Council Regulation (EU) No 833/2014. This may include to ensure that funds or economic resources including data stemming from existing agreements on cost-sharing or granted letters of access are not made available to that designated member of the platform.

See however questions 9 and 11.

**9. Do data sharing obligations after the submission of a registration dossier under Article 3 of Council Regulation 2019/1692 apply in case the communication platform has granted a letter of access to a company that has become designated or owned/controlled by a designated person, or a company that now meets the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014?**

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No. Further data sharing is not possible in this case. Should the lead registrant be a designated entity or owned/controlled by a designated person, or a company that now meets the criteria under letters (a)–(c) of Article 5aa, Council Regulation (EU) No 833/2014, the communication platform should take action to change its lead registrant. Exceptions might however apply (see Question 15).

**10. Can I submit a joint registration dossier as a lead registrant if a co-registrant is designated or is owned or controlled by a designated person?**

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No. Such a sub-submission would entail making economic resources available to a designated person. A lead registrant submitting such a registration dossier would be in violation of Council Regulation (EU) No 269/2014. Moreover, ECHA must freeze REACH registration dossiers as that would be for the benefit of a designated person or a person owned or controlled by a designated person.

**11. As an OR, can I represent a designated company or a company owned or controlled by a designated person, or a company that meets the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014, for instance to submit the update to the registration dossier pursuant to Article 22 of the REACH Regulation?**

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No, as this would be tantamount to making resources available to a designated person or entering a transaction prohibited under Article 5aa. Exceptions might however apply (see Question 15).

**12. Can I submit information under the fourth paragraph of Article 11 of the REACH Regulation together with a co-registrant that is designated or is owned or controlled by a designated person?**

*Last update: 1 July 2022*

No. See Question 10.

**13. Can I submit information under the fourth paragraph of Article 11 of the REACH Regulation together with a co-registrant that meets the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014?**

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Submitting such information with a co-registrant falling under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014 will likely entail engaging in a transaction, which is prohibited. Exceptions might however apply (see Question 15).

**14. How can I protect myself from claims from a potential registrant that is designated or owned or controlled by a designated person regarding the fact that I refused to enter negotiations under Article 25–27 and 30 of the REACH Regulation with it or from other actions I have taken to comply with EU sanctions?**

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All Council Regulations establishing EU sanctions envisage a standard provision which shields those required to comply with EU sanctions from claims from third parties for those very actions. By way of example, Article 11(1) of Council Regulation (EU) 269/2014 reads: ‘*No claims in connection with any contract or transaction the performance of which has been affected, directly or indirectly, in whole or in part, by the measures imposed under this Regulation, including claims for indemnity or any other claim of this type, such as a claim for compensation or a claim*

*under a guarantee, particularly a claim for extension or payment of a bond, guarantee or indemnity, particularly a financial guarantee or financial indemnity, of whatever form, shall be satisfied, if they are made by: (a) designated natural or legal persons, entities or bodies listed in Annex I; (b) any natural or legal person, entity or body acting through or on behalf of one of the persons, entities or bodies referred to in point (a).’*

Article 11(1)(a)–(b) of Council Regulation (EU) No 833/2014 mirrors the above provision of Council Regulation (EU).

**15. Can I import substances from a legal person, entity or body that meets the criteria under letters (a)–(c) of Article 5aa(1) of Council Regulation (EU) No 833/2014, if that is necessary for the purchase, import or transport of pharmaceutical, medical, agricultural and food products, including wheat and fertilisers?**

*Last update: 9 December 2022*

Yes. Council Regulation (EU) 2022/1269 of 21 July 2022 amended Council Regulation (EU) No 833/2014 to include an exemption under Article 5aa(3)(f) allowing transactions with legal persons, entities and bodies that meet the criteria under letters (a)–(c) of Article 5aa(1) provided that such transactions are necessary for the purchase, import or transport of pharmaceutical, medical, agricultural and food products, including wheat and fertilisers. This is under the condition that the underlying trade in goods is not otherwise restricted under Council Regulation (EU) No 833/2014<sup>3</sup>.

Since the provision in Article 5aa(3)(f) qualifies as an exemption, the importer or the OR is not required to obtain the authorisation of the NCA before importing the substance. However, if the substance is imported or used, even by distributors or downstream users, for other purposes than those contemplated under Article 5aa(3)(f), the importer or the OR can be considered liable for the infringement of Article 5aa by the NCA. It is for the importer or the OR to take the necessary actions in order to ensure that the uses by the distributors or downstream users are in line with the purposes indicated in Article 5aa(3)(f); this may include, among others, providing a notice/information to the latter notably on the scope of the uses permitted under Article 5aa(3)(f), including contractual arrangements in the relevant distribution agreements and having a monitoring/tracking system in place. Since Article 5aa(1) prohibits directly or indirectly engaging in any transaction with legal persons, entities and/or bodies that meet the criteria under letters (a)–(c), the relevant NCA can consider distributors or downstream users as in breach of such provision as well.

The importer or the OR should also take the necessary actions to ensure that its REACH registration is in line with the permitted uses (e.g. update the uses or discontinue the import of the substances for non-permitted uses and update the substance volume).

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<sup>3</sup> By way of example, see the restrictions under Article 3i of Council Regulation (EU) No 833/2014 concerning certain chemical substances included in Annex XXI.

**16. Can I purchase substances from a company designated or owned/controlled under Council Regulation (EU) No 269/2014, or from a legal person, entity or a legal person, entity or body that meets the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014, if that company holds a REACH registration?**

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No. It is prohibited to provide funds or economic resources to designated persons, even indirectly, or engage in transactions with companies that meet the criteria under letters (a)–(c) of Article 5aa of Council Regulation (EU) No 833/2014. Exceptions might however apply (see Question 15).