COMMISSION IMPLEMENTING REGULATION (EU) 2019/1692

of 9 October 2019

on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [1], and in particular Article 132 thereof,

Whereas:

(1) In order to avoid overloading authorities and natural or legal persons with the work arising from the registration of substances that were already on the internal market when Regulation (EC) No 1907/2006 entered into force, Article 23 of that Regulation established a transitional regime for phase-in substances. Consequently, a number of different transitional deadlines for the registration of such substances were laid down. It follows from Article 23(3) of that Regulation that the final registration deadline in that transitional regime expired on 1 June 2018.

(2) In order to ensure equality between market operators manufacturing or placing on the market phase-in and non-phase-in substances, it is necessary to specify the applicability, after the expiry of the transitional regime, of provisions that laid down favourable conditions for the registration of phase-in substances. Therefore, for those provisions, an appropriate, reasonable and clear cut-off date should be set, after which those provisions should either no longer apply or only apply in specific circumstances.

(3) Article 3(30) of Regulation (EC) No 1907/2006 sets conditions for the calculation of the quantities per year of phase-in substances based on the average production or import volumes for the three preceding calendar years. In order to ensure that market operators have sufficient time to make the necessary adjustments to their calculation methods, those conditions should, as a first measure, continue to apply until the specified cut-off date. To take into account the definition of 'per year' in Article 3(30) of Regulation (EC) No 1907/2006, it is appropriate to set the cut-off date at the end of this calendar year (31 December 2019).

(4) In line with the legislator's intent to reduce the possible impact of registration obligations on low volume substances, Article 12(1)(b) of Regulation (EC) No 1907/2006 lays down less stringent information requirements for the registration of certain low volume phase-in substances, provided that they do not meet the criteria in Annex III to Regulation (EC) No 1907/2006. Pursuant to Article 23(3) of that Regulation, those low volume phase-in substances needed to be registered by the deadline for registration on 1 June 2018. However after this deadline, to ensure equal treatment for registrants that join a registration or update their dossiers in accordance with Article 12(1)(b), that provision should, as a second measure, continue to apply after 1 June 2018.

[1] OJ L 396 30.12.2006, p. 1.

(5) On 1 June 2018, the formal operation of substance information exchange fora (SIEFs) ceased. However, as a third measure, the continuing data-sharing obligations of registrants should be reinforced and registrants should be encouraged to use similar informal communication platforms to enable them to meet their continuing registration and data-sharing obligations under both Regulation (EC) No 1907/2006 and Commission Implementing Regulation (EU) 2016/9 ([2]).

(6) It is appropriate to set out, as a fourth measure, that a potential registrant who pre-registered a phase-in substance in accordance with Article 28 of Regulation (EC) No 1907/2006 should, until the specified cut-off date, not be required to follow the inquiry process set out in Article 26 of that Regulation because the objective of the inquiry process has already been fulfilled through the pre-registration.

(7) It is necessary to ensure that data-sharing dispute processes are clearly identifiable. The data-sharing rules set out in Article 30 of Regulation (EC) No 1907/2006 should therefore continue to apply until the specified cut-off date. After that cut-off date, only the data-sharing rules in Articles 26 and 27 of that Regulation should apply.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Calculation of quantities of phase-in substances

The specific method for calculating quantities per year of phase-in substances, as set out in Article 3(30) of Regulation (EC) No 1907/2006, shall continue to apply only until 31 December 2019. Once a registrant has completed the registration of a substance, that registrant shall subsequently calculate his quantity of that substance per calendar year in accordance with Article 3(30) of Regulation (EC) No 1907/2006.

Article 2

Registration requirements for certain low volume phase-in substances

The expiry of the transitional regime for phase-in substances in Regulation (EC) No 1907/2006 shall not affect the applicability of Article 12(1)(b) of that Regulation.

Article 3

Data-sharing obligations after registration

After registering a substance, registrants, including those who jointly submit data with other registrants, shall continue to fulfil their data-sharing obligations in a fair, transparent and non-discriminatory way as specified in Title III of Regulation (EC) No 1907/2006 and in Implementing Regulation (EU) 2016/9. In that context, registrants may use informal communication platforms similar to the substance information exchange fora referred to in Article 29 of Regulation (EC) No 1907/2006.

Article 4

Duty to inquire and sharing of data for phase-in substances

1. Where data-sharing negotiations conducted in accordance with Article 30 of Regulation (EC) No 1907/2006 result in failure to reach an agreement, the provisions of that Article shall apply only until 31 December 2019.

([2]) Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 3, 6.1.2016, p. 41).

2. After 31 December 2019, pre-registrations made in accordance with Article 28 of Regulation (EC) No 1907/2006 shall no longer be valid and Articles 26 and 27 shall apply to all phase-in substances.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 October 2019.

For the Commission
The President
Jean-Claude JUNCKER