EUROPEAN
COMMISSION

Brussels, 5.6.2023
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COMMISSION IMPLEMENTING DECISION

of 5.6.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Beckman Coulter Ireland Inc and others for certain uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) and 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)

(Only the English text is authentic)

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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 64(8) thereof,

Whereas:

(1) 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ('4-tert-OPnEO') and 4-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO') are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 13 June 2019, Beckman Coulter Ireland Inc, Immunotech S.R.O., Immunotech S.A.S, Beckman Coulter GmbH, Beckman Coulter France S.A.S, Beckman Coulter Ceská republika S.R.O, Beckman Coulter, S.L.U., Beckman Coulter SPA Italy, BC Distribution B.V. ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-tert-OPnEO and 4-NPnEO[2]. The uses for which authorisation was sought are use of 4-tert-OPnEO and 4-NPnEO in formulation of NPnEO and OPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for the preparation of finished laboratory products (finished goods) or in-process use ('use 1'); use of 4-tert-OPnEO in in-process production use of OPnEO as a washing buffer used in the creation of in vitro diagnostic immunoassay particles ('use 2'); downstream use of OPnEO- or NPnEO-containing clinical laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, hematology and flow cytometry laboratory instruments and assays ('use 3'); downstream use of OPnEO- or NPnEO- containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory

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

[2] Different names and abbreviations are used to refer to the substances, including 'OPnEO' and 'NPnEO', in the chemical safety report.

instruments and assays for quality control and research and development ('use 4'); for phasing out of OPnEO-containing laboratory products from the market due to obsolescence or next generation formulations ('use 5').

(3) On 4 January 2021, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[3] and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinions that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties for the environment of 4-tert-OPnEO and 4-NPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-tert-OPnEO and 4-NPnEO are substances for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to those substances and authorisations may therefore only be granted with respect to those substances under Article 60(4) of that Regulation.

(5) RAC noted that risk to the environment cannot be excluded for non-threshold substances, even at low exposure levels. Consequently, RAC takes the emissions of the substances as a proxy for the risk.

(6) In its opinions on uses 1 and 2, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk to the environment posed by those uses. RAC noted that all solid waste and wastewater that could be contaminated with 4-tert-OPnEO and 4-NPnEO are collected for incineration, resulting in zero emission to environmental compartments. Having evaluated RAC's assessment, the Commission agrees with its conclusion.

(7) In its opinions on uses 3, 4 and 5, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective to limit the risk to the environment posed by those uses. In particular, RAC noted that the applicants did not ensure that solid waste and wastewater contaminated with 4-tert-OPnEO and 4-NPnEO are collected in all downstream users' level. As regards wastewater, RAC acknowledged that the applicants presented a new strategy for reformulation allowing for a significant reduction of 4-tert-OPnEO and 4-NPnEO emission to the environment during the first years of the review period, which would result in at least halving the emissions compared to 2020. Therefore, RAC recommended to collect all solid waste containing 4-tert-OPnEO and 4-NPnEO for adequate treatment, as well as to continue the collection of wastewater at the sites where such collection is already done. In this regard, RAC noted that if collection of wastewater for adequate treatment was recommended on sites where collection is not already done, its implementation would likely take a significant amount of time and would likely not be finalised before substitution. Therefore, RAC considered that a condition for the authorisation requiring downstream users to collect wastewater for adequate treatment, where not already done so, should not be imposed, and instead recommended the applicants to follow their reformulation strategy. As regards use 5,

[3] https://echa.europa.eu/documents/10162/865ea2c0-aa52-1901-5a22-e021652cb4d7
https://echa.europa.eu/documents/10162/11599ad1-ce9f-91a2-4f4f-69b29e57063c
https://echa.europa.eu/documents/10162/0387a602-6ff1-fe48-5254-238f7dc32818
https://echa.europa.eu/documents/10162/4edc0e20-2b3c-6b62-d745-fad0b6baf26f
https://echa.europa.eu/documents/10162/4a610cd0-b508-938f-fe1d-18d663a1d44e

RAC made the same considerations concerning collection of solid waste, thus it did not recommend collection of that waste for adequate treatment. Having evaluated RAC's assessment, the Commission agrees with its conclusion and its recommendations.

(8) Nevertheless, as regards uses 3 and 4, while agreeing with RAC's conclusion, the Commission considers that, in order to ensure that the reformulation strategy is properly followed and to facilitate the enforcement of that measure, it is appropriate to set out as a condition that the quantities of 4-tert-OPnEO and 4-NPnEO used in the relevant uses are reduced in line with the strategy's figures.

(9) Moreover, as regards uses 3, 4 and 5, taking into account the high volume of wastewater discharged into the sewage system, although with very low concentration of 4-tert-OPnEO and 4-NPnEO, the Commission considers it appropriate to require the downstream users where wastewater is not collected, to notify the relevant wastewater treatment plants of the discharge of wastewater contaminated with 4-tert-OPnEO and 4-NPnEO to the sewage system, as well as the competent authorities responsible under Directive 2000/60/EC of the European Parliament and of the Council[4] and Council Directive 91/271/EEC[5]. The Commission also considers it appropriate that wastewater continues to be collected for adequate treatment at the sites where it is already collected.

(10) Furthermore, the authorisation holders should conduct a study assessing the feasibility for their downstream users discharging wastewater into the sewage system to collect that wastewater contaminated with 4-tert-OPnEO and 4-NPnEO for adequate treatment. The adequate treatment should minimise releases to environmental compartments as far as technically and practically possible. The study should be based on representative information gathered from downstream users. On the basis of this study and if feasible, downstream users should implement the wastewater collection and the appropriate treatment.

(11) In its opinion on all uses, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the socio-economic benefits and the risk to the environment associated with the continued uses of 4-tert-OPnEO and 4-NPnEO. Taking into account SEAC's assessment, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the uses of 4-tert-OPnEO and 4-NPnEO, the estimated combined emissions from thousands of sites across the Union of up to hundreds of kilograms of 4-tert-OPnEO per year and up to thousands of kilograms of 4-NPnEO per year, the estimated combined benefits due to avoided profit losses, relocation costs, and job losses at minimum in the order between tens of millions of euro and hundreds of millions of euro over the review period, the estimated combined costs of avoiding releases of both 4-tert-OPnEO and 4-NPnEO in the order between tens of thousands of euro and hundreds of thousands of euro per kilogram, the qualitatively assessed additional socio-economic benefits of the continued uses of the substances due to the availability of in-vitro diagnostics kits used in various applications, as well as any relevant distributional impact, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of the continued uses of 4-tert-OPnEO

[4] 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).

[5] Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135 30.5.1991, p. 40).

and 4-NPnEO outweigh the risk to human health or the environment arising from those uses.

(12) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicants or its downstream users, an authorisation may be granted if the applicants for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible.

(13) In its opinions on all uses, SEAC concluded that there were no suitable alternative substances or technologies available for the applicants by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that further research is required to establish whether the identified alternatives achieve the necessary dispersing, wetting, lysing, solubilisation and stabilisation performance to meet the specifications of in-vitro diagnostics devices. The Commission therefore considers that it cannot be deemed that the identified alternatives allow the functionality needed for the uses for which authorisation is sought. Thus, the Commission agrees with SEAC's conclusion and considers that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicants.

(14) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of 4-tert-OPnEO and 4-NPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report as well as the conditions set out in this Decision are fully applied.

(15) The Commission has based its assessment on the relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on the existence of a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional emissions information.

(16) In its opinions on uses 1, 2 and 3, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and, in particular, the socio-economic benefits, the estimated emissions, the lack of suitable alternatives within a shorter timeline, as well as the high performance requirements, testing, and regulatory approvals necessary for medicinal devices.

(17) In its opinion on use 4, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 7 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular, the socio-economic benefits, the estimated emissions, the lack of suitable alternatives within a shorter timeline, as well as the high performance and testing requirements for the products within that use.

(18) In its opinion on use 5, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 5 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular, the socio-economic benefits, the estimated emissions, and the time to phase out the products within that use.

(19) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(20) This Decision does not affect the obligation of the authorisation holders to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holders under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible [or the obligation of the employer to eliminate or reduce to a minimum risks to the health and safety of workers at work involving hazardous chemical agents in accordance with Article 5(2) of Council Directive 98/24/EC[6]. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[7], 92/85/EEC[8], 94/33/EC[9], and 98/24/EC, as well as any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(21) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[10] or Directive 2010/75/EU of the European Parliament and of the Council[11], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the

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6 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

7 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

8 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

9 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

10 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

11 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

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

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 to the following persons for the following uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) and 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO):

Authorisation number	Authorisation holder	Authorised use
REACH/23/15/0 REACH/23/15/1 REACH/23/15/2	Beckman Coulter Ireland Inc. Immunotech S.R.O. Immunotech S.A.S	Formulation of 4-tert-OPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for preparation of finished laboratory products (finished goods) or in-process use
REACH/23/15/3 REACH/23/15/4	Beckman Coulter Ireland Inc. Beckman Coulter GmbH	Formulation of 4-NPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for preparation of finished laboratory products (finished goods) or in-process use
REACH/23/15/5	Beckman Coulter Ireland Inc.	In-process production use of 4-tert-OPnEO as a washing buffer used in the creation of in vitro diagnostic immunoassay particles
REACH/23/15/6 REACH/23/15/7	Beckman Coulter Ireland Inc. Immunotech S.R.O.	Downstream use of 4-tert-OPnEO containing clinical

[12] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

REACH/23/15/8	Beckman Coulter France S.A.S.	laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, hematology and flow cytometry laboratory instruments and assays
REACH/23/15/9	Beckman Coulter Ceská republika s.r.o.	
REACH/23/15/10	Beckman Coulter, S.L.U.	
REACH/23/15/11	Beckman Coulter SPA Italy	
REACH/23/15/12	BC Distribution B.V.	
REACH/23/15/13	Beckman Coulter Ireland Inc.	Downstream use of 4-NPnEO containing clinical laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, hematology and flow cytometry laboratory instruments and assays
REACH/23/15/14	Beckman Coulter GmbH	
REACH/23/15/15	Beckman Coulter France S.A.S	
REACH/23/15/16	Beckman Coulter Ceská republika s.r.o.	
REACH/23/15/17	Beckman Coulter, S.L.U.	
REACH/23/15/18	Beckman Coulter SPA Italy	
REACH/23/15/19	BC Distribution B.V.	
REACH/23/15/20	Beckman Coulter Ireland Inc.	Downstream use of 4-tert-OPnEO containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development
REACH/23/15/21	Immunotech S.R.O.	
REACH/23/15/22	Immunotech S.A.S	
REACH/23/15/23	Beckman Coulter France S.A.S	
REACH/23/15/24	Beckman Coulter Ceská republika s.r.o.	
REACH/23/15/25	Beckman Coulter, S.L.U.	
REACH/23/15/26	Beckman Coulter SPA Italy	
REACH/23/15/27	BC Distribution B.V.	
REACH/23/15/28	Beckman Coulter Ireland Inc.	Downstream use of 4-NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development
REACH/23/15/29	Beckman Coulter GmbH	
REACH/23/15/30	Beckman Coulter France S.A.S	
REACH/23/15/31	Beckman Coulter Ceská republika s.r.o.	
REACH/23/15/32	Beckman Coulter, S.L.U.	
REACH/23/15/33	Beckman Coulter SPA Italy	
REACH/23/15/34	BC Distribution B.V.	
REACH/23/15/35	Beckman Coulter Ireland Inc	Phase out of 4-tert-OPnEO-containing laboratory products from the market due to obsolescence or next generation formulations
REACH/23/15/36	Immunotech S.R.O.	
REACH/23/15/37	Immunotech S.A.S	
REACH/23/15/38	Beckman Coulter France S.A.S	
REACH/23/15/39	Beckman Coulter Ceská republika s.r.o.	
REACH/23/15/40	Beckman Coulter, S.L.U.	

REACH/23/15/41 Beckman Coulter SPA Italy
REACH/23/15/42 BC Distribution B.V.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports[13], and, as regards the authorisations bearing numbers REACH/23/15/6 to REACH/23/15/42, to the conditions set out in Articles 2 and 3.

Article 2

1. The authorisations bearing numbers REACH/23/15/6 to REACH/23/15/42, shall be subject to the conditions set out in paragraphs 2 to 6.

2. The authorisation holders shall reduce, at the latest by the end of 2025, the total annual quantity of 4-tert-OPnEO and 4-NPnEO used for the authorised uses bearing numbers REACH/23/15/6 to REACH/23/15/34, combined, by at least 93% compared to the total annual quantities used at the end of 2020. The authorisation holders shall provide the relevant documentation, including the reduction progress, upon request, to the competent authority of the Member State where the authorised uses take place.

3. The downstream users shall continue to collect wastewater contaminated with 4-tert-OPnEO and 4-NPnEO for adequate treatment, where the collection is already done. The adequate treatment shall minimise releases of 4-tert-OPnEO and 4-NPnEO to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters does not constitute adequate treatment.

4. Without prejudice to paragraph 3 and to the requirements set in accordance with Directive 91/271/EEC regarding the discharge of industrial wastewater into collecting systems and urban wastewater treatment plants, the downstream users shall, in cases where wastewater contaminated with 4-tert-OPnEO and 4-NPnEO is not already being collected for adequate treatment in accordance with paragraph 3, submit a notification to the following bodies, in accordance with the legislation transposing Directives 91/271/EEC and 2000/60/EC, as well as with national provisions of the Member States where the uses take place:

   (a) the competent authorities responsible under Directive 2000/60/EC;

   (b) the competent authorities responsible under Directive 91/271/EEC;

   (c) the wastewater treatment plant connected to the sewage system into which they are discharging that wastewater.

   That notification shall indicate the fact that the downstream users are discharging wastewater contaminated with 4-tert-OPnEO and 4-NPnEO, indicating the annual volume of wastewater discharged and the amount of 4-tert-OPnEO and 4-NPnEO released, calculated from the mass balance at the downstream users' site. Downstream users shall, upon request, make a copy of this notification available to the competent authority of the Member State where the authorised uses take place.

   The authorisation holder shall provide the downstream users with the information on the amount of 4-tert-OPnEO and 4-NPnEO present in its products, for the purpose of the mass balance analysis referred to in the second subparagraph.

[13] https://ec.europa.eu/docsroom/documents/44415

5. The authorisation holders shall finalise by 5 June 2024 a study on the feasibility of collecting wastewater contaminated with 4-tert-OPnEO and 4-NPnEO as liquid waste for adequate treatment by their downstream users, or of any other adequate treatment methods, which minimise releases to environmental compartments as far as technically and practically possible. The authorisation holders shall base that study on specific information ensuring the representativeness of the downstream users referred to in paragraph 4 and shall make it available without delay to those downstream users.

   The downstream users shall act upon the results of the study and, if feasible, implement without delay the collection and adequate treatment of wastewater contaminated with 4-tert-OPnEO and 4-NPnEO as liquid waste for adequate treatment. In the event that downstream users assess that such collection and adequate treatment of wastewater is not feasible, they shall provide the relevant justification upon request by the competent authority of the Member States where the authorised uses take place.

6. The authorisation holders and downstream users shall document and maintain the results of the feasibility study and the measures implemented in accordance with paragraph 5, and make them available upon request, to the competent authority of the Member States where an authorised use takes place.

Article 3

As regards the authorisations bearing numbers REACH/23/15/6 to REACH/23/15/34, the following condition shall apply: the downstream users shall collect all solid waste contaminated with 4-tert-OPnEO and 4-NPnEO, for adequate treatment. The adequate treatment shall minimise releases of 4-tert-OPnEO and 4-NPnEO to environmental compartments as far as technically and practically possible.

Article 4

1. As regards the authorisation bearing numbers REACH/23/15/0 to REACH/23/15/19, the review period shall expire on 4 January 2033.

   The authorisation shall cease to be valid on 4 January 2033 with regard to any authorisation holder who has not submitted the review report for those uses in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

2. As regards the authorisation bearing numbers REACH/23/15/20 to REACH/23/15/34, the review period shall expire on 4 January 2028.

   The authorisation shall cease to be valid on 4 January 2028 with regard to any authorisation holder who has not submitted the review report for those uses in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2026.

3. As regards the authorisation bearing numbers REACH/23/15/35 to REACH/23/15/42, the review period shall expire on 4 January 2026.

   The authorisation shall cease to be valid on 4 January 2026 with regard to any authorisation holder who has not submitted the review report for those uses in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2024.

Article 5

Where an authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall provide the information gathered in accordance with Article 2(6), including, if relevant, an update of the feasibility study.

Article 6

Upon request, the authorisation holders shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised uses take place in an official language of that Member State.

Article 7

This Decision is addressed to:

1. Beckman Coulter Ireland Inc, Lismeehan, O'Callaghan's Mills, VP94 PP63 Clare, Ireland;
2. Immunotech S.R.O., Radiova 1, 10227 Prague 10, Czech Republic;
3. Immunotech S.A.S, 130 Avenue de Lattre de Tassigny, 13009 Marseille, France;
4. Beckman Coulter GmbH, Europark Fichtenhain B13 47807 Krefeld, Germany;
5. Beckman Coulter France S.A.S, 130 Avenue de Lattre de Tassigny, 13009 Marseille, France;
6. Beckman Coulter Ceská republika s.r.o., Radiová 1, 102 27 Prague, Czech Republic;
7. Beckman Coulter, S.L.U., Plaza Europa 41-43 L'Hospitalet de Llobregat 08902 Barcelona, Spain;
8. Beckman Coulter SPA Italy, Via Roma 108 20060 Cassina de' Pecchi, Italy;
9. BC Distribution B.V., Bijsterhuizen 3140 6604 LV Wuchen, The Netherlands.

Done at Brussels, 5.6.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION