EUROPEAN
COMMISSION

Brussels, 1.8.2023
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COMMISSION IMPLEMENTING DECISION

of 1.8.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Siemens Healthcare Diagnostics Products GmbH for five uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

(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') is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 20 May 2019, Siemens Healthcare Diagnostics Products GmbH ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for five uses of 4-tert-OPnEO[2]. The five uses for which authorisation was sought are use of 4-tert-OPnEO in isolation of protein from recombinant cell cultures for the production of IVD kits (protein cell extraction) ('use 1'); in formulation of IVD kit reagents ('use 2'); in formulation of IVD wash solutions ('use 3'); in IVD kit reagents on diagnostic analyser systems ('use 4'); and in IVD wash solutions on diagnostic analyser systems ('use 5').

(3) On 2 October 2020, 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.

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1 OJ L 396, 30.12.2006, p. 1.

2 Different names and abbreviations are currently used to refer to the substance, including 'OPE' in the chemical safety report.

3 https://echa.europa.eu/documents/10162/c809588e-f2f4-d9cb-7a3b-be54e1e226ef
https://echa.europa.eu/documents/10162/b23e6e8c-620f-e8af-1a5f-9d5f25b3b32f
https://echa.europa.eu/documents/10162/94e58149-776b-6864-be1f-55eb4b676601
https://echa.europa.eu/documents/10162/840b5d92-b48b-91ab-9e9d-2224e19f16dc
https://echa.europa.eu/documents/10162/796d77db-9f1f-ce43-12f0-a6e8e3099faa%20

(4) RAC concluded in its opinions that it is not possible to determine a predicted no-effect concentration (PNEC) for the endocrine disrupting properties for the environment of 4-tert-OPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-tert-OPnEO is a substance 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 that substance and authorisations may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(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 substance 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. In particular, RAC noted that already as of 2020, most of the liquid waste is foreseen to be collected and sent for incineration. However, due to residual releases of 4-tert-OPnEO originating from wastewater from washing of emptied laboratory scale vessels drained to on-site sewage treatment plant, RAC recommended monitoring programmes as well as a study on the feasibility to collect that remaining wastewater. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(7) In its opinion on use 3, 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. In particular, RAC noted that only solid waste is incinerated and that wastewater containing 4-tert-OPnEO is released to the municipal sewage system without adequate treatment and concluded that the applicant has not demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. Therefore, RAC recommended as condition for authorisation that all emissions of 4-tert-OPnEO to the environment, due to 4-tert-OPnEO in the wastewater from the cleaning of equipment after formulation and filling processes, should be subject to adequate treatment with a view to minimise releases to environmental compartments, specifying that release into the municipal sewer system or to surface waters is not considered adequate treatment. Moreover, RAC recommended to carry out a monitoring programme in order to evaluate the effectiveness of risk management measures and operational conditions in place and to confirm that emissions are reduced to as low a level as is technically and practically possible. Having evaluated RAC's assessment, the Commission agrees with that conclusion and recommendations.

(8) In its opinions on uses 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. In particular, RAC noted that at downstream users' sites wastewater containing 4-tert-OPnEO is released to the municipal sewage system without adequate treatment and concluded that the applicant has not demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. RAC considered that collecting solid and liquid waste for adequate treatment is feasible as some downstream users are already collecting it. RAC therefore recommended as a condition for authorisation to collect all wastewater for adequate treatment, specifying that release into the municipal sewage system or to surface waters is not considered

adequate treatment. Having evaluated RAC's assessment, the Commission agrees with that conclusion.

(9) Nevertheless, the Commission notes that the collection of all wastewater resulting from uses 4 and 5 as recommended by RAC would lead to incineration of large volumes of liquid waste containing only minimal amounts of 4-tert-OPnEO as availability of other treatments or pre-treatments for such wastewater is currently limited. Moreover, it is expected that the ongoing substitution activities of the applicant will significantly reduce the amount of the substance used for uses 4 and 5 and thereby decrease the emissions to the environment from those uses. Furthermore, the Commission notes the societal need to ensure that, in the meantime, the diagnosis of human diseases served through uses 4 and 5 of 4-tert-OPnEO continues to be adequately supported.

(10) Based on those considerations and in order to allow a better enforcement of the measure, the Commission considers it appropriate to impose as conditions that the quantities of 4-tert-OPnEO used in uses 4 and 5 are reduced in line with the substitution activities' figures, that wastewater continues to be collected for adequate treatment at the sites where it is already collected while at the sites where wastewater is not currently collected, the downstream users notify the wastewater treatment plants of the discharge of wastewater contaminated with 4-tert-OPnEO 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].

(11) Furthermore, the authorisation holder should conduct a study assessing the feasibility for its downstream users discharging wastewater into the sewage system to collect that wastewater contaminated with 4-tert-OPnEO 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.

(12) SEAC concluded in its opinions on uses 1, 2 and 3, that it has no substantial reservations on the quantitative and the qualitative elements of the applicant's assessment of the socio-economic benefits and the risk to the environment associated with the continued uses of the substance. 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 use of the substance, the estimated emissions at one site covered by the three uses of less than three kilograms of the substance per year, the estimated combined benefits due to avoided profit losses, avoided job losses, and avoided costs for shifting to new analyser systems for hospitals and laboratories at a minimum in the order of between hundreds of millions of euros and billions of euros over the entire review period, the estimated combined cost of avoiding the remaining releases of the substance in the order of between hundreds of millions of euros and billions of euros per kilogram, and the qualitatively assessed additional socio-economic benefits of the continued uses due to the availability of in vitro diagnostic ('IVD') kits to correctly detect certain cancers, kidney and liver diseases and blood

[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).

disorders, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of the substance outweigh the risk to human health and the environment arising from those uses.

(13) SEAC concluded in its opinions on use 4 and use 5, that it has no substantial reservations on the quantitative and the qualitative elements of the applicant's assessment of the socio-economic benefits and the risk to the environment associated with the continued uses of the substance. 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 use of the substance, the estimated emissions at thousands of sites across the whole Union covered by the two uses of up to 2000 kilograms of the substance per year, the estimated combined benefits due to avoided profit losses, avoided job losses, and avoided costs for shifting to new analyser systems for hospitals and laboratories at a minimum in the order of between hundreds of millions of euros and billions of euros over the entire review period, the estimated combined cost of avoiding the remaining releases of the substance in the order of between thousands of euros and tens of thousands of euros per kilogram, and the qualitatively assessed additional socio-economic benefits of the continued use due to the availability of IVD kits that help in the correct diagnosis of cancers, kidney and liver diseases, blood disorders, heart diseases, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of the substance outweigh the risk to human health and the environment arising from those uses.

(14) 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 applicant or its downstream users, an authorisation may be granted if the applicant 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.

(15) In its opinions on all uses, SEAC concluded that there were no available alternative substances or technologies for the applicant by the sunset date. The Commission, having evaluated SEAC's assessments and relevant information available, acknowledges that the assessed alternatives are still under development and more time will be needed for research and testing in order to demonstrate sufficient specificity of the test in detecting a certain protein with high accuracy, sufficient sensitivity of the test to detect the target protein, or sufficient stability to ensure a long shelf-life. Taking into account the high requirements needed for 4-tert-OPnEO when used in IVD kits, reagents and wash solutions, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the uses applied for. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives for all five uses both in the Union and for the applicant.

(16) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise all uses of 4-tert-OPnEO 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.

(17) 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 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.

(18) In its opinion on use 1, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 9 years and, in its opinions on uses 2, 3, 4 and 5, 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 level of emissions of the substance and the socio-economic benefits, the lack of suitable alternatives within a shorter timeline, the high performance requirements in combination with the strict regulatory approval process for IVD kits and, for uses 2 to 5, the time needed to phase out some of the product lines.

(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 holder 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 holder 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, or any national binding occupational limit values which may be stricter than the applicable Union limit values.

(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

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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).

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 of the European Parliament and of the Council[12] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[13]. 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 for the following uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

Authorisation number	Authorised use
REACH/23/12/0	In isolation of protein from recombinant cell cultures for the production of IVD kits (protein cell extraction)
REACH/23/12/1	In formulation of IVD kit reagents
REACH/23/12/2	In formulation of IVD-wash solutions
REACH/23/12/3	In IVD-kit reagents on diagnostic analyser systems
REACH/23/12/4	In IVD-wash solutions on diagnostic analyser systems

[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).

[12] 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).

[13] 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).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports[14], and, as regards the authorisations bearing numbers REACH/23/12/2 to REACH/23/12/4, to the conditions set out in Articles 2 and 3 of this Decision.

Article 2

1. As regards the authorisation bearing number REACH/23/12/2, the conditions set out in paragraphs 2 to 6 shall apply.

2. The authorisation holder shall collect wastewater contaminated with 4-tert-OPnEO originating from the cleaning of equipment after formulation and filling processes, for adequate treatment. The treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Release into the sewage system or to surface waters does not constitute adequate treatment.

3. The authorisation holder shall carry out a mass balance analysis. This analysis shall:

   (a) be carried out for the first time by 1 November 2023 and afterwards annually;

   (b) include details of the calculations carried out;

   (c) include the assumptions made, if any;

   (d) include the corresponding release values.

4. The authorisation holder shall carry out a monitoring programme of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site wastewater treatment plant. The monitoring programme shall:

   (a) be carried out at least 4 times per year and during the time of operation. The frequency of the measurements shall be such as to capture the variability in concentrations of the substance and its principal degradation products in the wastewater due to changes or operational fluctuations in the process;

   (b) be based on an analytical method capable of adequately characterising the substance and its principal degradation products in wastewater with appropriately low limits of quantification;

   (c) be recorded with details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

5. The authorisation holder shall use the information gathered in the measurements or calculations referred to in paragraphs 3 and 4 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

6. The authorisation holder shall document and keep the information obtained in accordance with paragraphs 3 and 4, as well as the outcome and conclusions of the review and of any action taken in accordance with paragraph 5. The authorisation

[14] Uses 1, 2, 3: https://ec.europa.eu/docsroom/documents/43350
Uses 4, 5: https://ec.europa.eu/docsroom/documents/43351

holder shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. As regards the authorisations bearing numbers REACH/23/12/3 and REACH/23/12/4, the conditions set out in paragraphs 2 to 6 shall apply.

2. The authorisation holder shall reduce, at the latest by the end of 2025, the total annual quantity of 4-tert-OPnEO used for the authorised uses referred to in paragraph 1, combined, by at least 72 % compared to the total annual quantities used at the end of 2020. The authorisation holder 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 for adequate treatment, where the collection is already done. The adequate treatment shall minimise releases of 4-tert-OPnEO 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 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 downstream users are discharging wastewater contaminated with 4-tert-OPnEO, indicating the annual volume of wastewater discharged and the amount of 4-tert-OPnEO released, calculated from the mass balance at the downstream users' sites. The downstream users shall, upon request, make a copy of this notification available to the competent authority of the Member States where the authorised uses take place.

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

5. The authorisation holder shall finalise by 1 August 2024 and thereafter when new information becomes available, a study on the feasibility of collecting wastewater contaminated with 4-tert-OPnEO as liquid waste for adequate treatment by its downstream users, or of any other adequate treatment methods, which minimises releases to environmental compartments as far as technically and practically possible. The authorisation holder 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 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 holder 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 authorities of the Member States where an authorised use takes place.

Article 4

1. As regards the authorisation bearing number REACH/23/12/0, the review period shall expire on 4 January 2030.

   The authorisation shall cease to be valid on 4 January 2030 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2028.

2. As regards the authorisations bearing numbers REACH/23/12/1, REACH/23/12/2, REACH/23/12/3, REACH/23/12/4, the review period shall expire on 4 January 2033.

   The authorisations shall cease to be valid on 4 January 2033 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

Article 5

1. As regards the authorisation bearing numbers REACH/23/12/0 and REACH/23/12/1, the monitoring arrangements set out in paragraphs 2 to 6 shall apply.

2. The authorisation holder shall carry out a mass balance analysis. This analysis shall:

   (a) be carried out for the first time by 1 November 2023 and afterwards annually;

   (b) include details of the calculations carried out;

   (c) include the assumptions made, if any;

   (d) include the corresponding release values.

3. The authorisation holder shall carry out a monitoring programme of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site wastewater treatment plant. The monitoring programme shall:

   (a) provide an initial sampling frequency which is sufficient to demonstrate daily fluctuations;

   (b) once established, be carried out at least four times per year throughout the whole time while the plant is in operation;

   (c) be based on an analytical method capable of adequately characterising the substance and its principal degradation products in wastewater with appropriately low limits of quantification;

(d) be recorded with details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

4. The authorisation holder shall use the information gathered in the measurements or calculations referred to in paragraphs 2 and 3 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

5. The authorisation holder shall finalise by 1 August 2024 and afterwards when new information becomes available, a study to collect the remaining wastewater for adequate treatment which minimises releases to environmental compartments as far as technically and practically possible. The authorisation holder shall act in accordance with the outcome of that study and, if feasible, implement without delay the collection of such wastewater.

6. The authorisation holder shall document and keep the information referred to in paragraphs 2 and 3, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 4, together with the results of the feasibility study and the measures implemented in accordance with paragraph 5. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where an authorised use takes place.

Article 6

Where the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, that report shall contain the following information:

(a) as regards the authorisations bearing numbers REACH/23/12/0 and REACH/23/12/1, the authorisation holder shall include the information gathered in accordance with Article 5(6);

(b) as regards the authorisations bearing number REACH/23/12/2, the authorisation holder shall include the information obtained in accordance with Article 2(6);

(c) as regards the authorisations bearing numbers REACH/23/12/3 and REACH/23/12/4, the authorisation holder shall provide the information obtained in accordance with Article 3(6) including, if relevant, an update of the feasibility study.

Article 7

Upon request, the authorisation holder 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 an authorised use takes place in an official language of that Member State.

Article 8

This Decision is addressed to Siemens Healthcare Diagnostics Products GmbH, Emil-von-Behring-Str.76., 35041 Marburg, Germany.

Done at Brussels, 1.8.2023

For the Commission
Thierry BRETON
Member of the Commission