



Brussels, 27.6.2023
C(2023) 3851 final

ANNEX 3

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU) .../...

supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to the sustainable use and protection of water and marine resources, to the transition to a circular economy, to pollution prevention and control or to the protection and restoration of biodiversity and ecosystems and for determining whether that economic activity causes no significant harm to any of the other environmental objectives and amending Delegated Regulation (EU) 2021/2178 as regards specific public disclosures for those economic activities

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ANNEX III

Technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to pollution prevention and control and for determining whether that economic activity causes no significant harm to any of the other environmental objectives

1. MANUFACTURING

1.1. Manufacture of active pharmaceutical ingredients (API) or active substances

Description of the activity

Manufacture of active pharmaceutical ingredients (API) or active substances.

The economic activities in this category could be associated with NACE code C21.1 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. The activity complies with all of the requirements specified below relating to product substitution.

1.1. The API complies with one of the following requirements:

- (a) the API is a naturally occurring substance, such as vitamins, electrolytes, amino acids, peptides, proteins, nucleotides, carbohydrates and lipids and, in line with the European Medicines Agency Guideline on the environmental risk assessment of medicinal products for human use (EMA ERA guideline)¹, is generally considered to be degradable in the environment²;
 - (b) where the API does not comply with the requirements specified in point (a), the API, its key human metabolites and its key transformation products in the environment comply with one of the following:
 - (i) are classified as readily biodegradable based on at least one of the test methods
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¹ European Medicines Agency Guidelines on the environmental risk assessment of medicinal products for human use, version of [adoption date] available at <https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use-scientific-guideline>.

² Key metabolites are human metabolites likely to be excreted into the environment. Those metabolites are identified in (non-)clinical studies on the metabolism of medicinal products available in the marketing authorization applications. Such metabolites are to be identified according to EMA/CPMP/ICH/286/1995, page 8. Key transformation products (TP) of these key human metabolites of the parent compound (API) are those that exceed 10% of Dissolved Organic Carbon (DOC) or Total Organic Carbon (TOC) of the parent compound.

from the OECD Guidelines for the Testing of Chemicals, Test 301 (A-F), Ready Biodegradability³, in accordance with the pass value for ready biodegradability as defined in that guideline;

- (ii) can be concluded to be mineralised based on a specific Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)⁴ of the OECD Guidelines for the Testing of Chemicals⁵ compared to persistence criteria as defined in the EMA ERA guideline.

1.2. The API qualifies as an appropriate substitute to another API, within the same therapeutic area or the substance class, that is available in the market or was available during last 5 years and that does not comply with the requirements described in point 1.1.

Compliance with this requirement is demonstrated through a publicly available analysis verified by an independent third party.

1.3. The manufacturing process of the API does not involve the use of substances, whether on their own or in mixtures, that meet the criteria set out in Article 57 of Regulation (EC) 1907/2006 except where it is assessed and documented by the operator that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions⁶.

2. The activity complies with the following requirements regarding the emission of pollutants:

2.1. Where the activity falls within its scope, the emission limit values are lower than the mid-point of the BAT-AEL ranges⁷ set out in:

- (a) the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector for emissions to air of new installations
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³ OECD Guidelines for the Testing of Chemicals, Test 301 (A-F), Ready Biodegradability, version of [adoption date] available at <https://www.oecd.org/chemicalsafety/risk-assessment/1948209.pdf>. OECD 301 (A-F) test is used to identify substances which are assumed to rapidly and ultimately biodegrade, i.e., mineralised under aerobic environmental conditions).

⁴ Higher-tier studies (OECD 308) result with so-called half-lives indicating the time after which 50 % biodegradation of the API is achieved. Half-lives acceptable to demonstrate sufficiently quick biodegradation, i.e., non-persistence, according to the Regulation (EC) No 1907/2006, Annex XIII, which is also referenced in the EMA ERA guideline, apply.

⁵ OECD Guidelines for the Testing of Chemicals, Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, version of [adoption date] available at: https://www.oecd-ilibrary.org/environment/test-no-308-aerobic-and-anaerobic-transformation-in-aquatic-sediment-systems_9789264070523-en.

⁶ The Commission will review the exceptions from the prohibition from manufacturing, placing on the market or use of the substances referred to in points (f) and (g) once it will have published horizontal principles on essential use of chemicals.

⁷ The requirements under this point tackle the pollutants identified under the key environmental issues of each BREF document or the BAT-AEL of the relevant BAT conclusions Commission Implementing Decisions. Where BAT-AEL differentiate between “existing” and “new plants”, operators demonstrate compliance with BAT-AEL for new plants. When there is not a BAT-AEL range but a single value, emission levels are below such value. When the BAT-AEL range is expressed as follows: “<x-y unit” (i.e the lower-end BAT-AEL of the range is expressed as ‘lower than’), the mid-point is calculated using x and y. Averaging periods are the same as in the BAT-AEL of the BREF documents outlined above.

(or for existing installations within 4 years of the BATC publication) where relevant conditions apply⁸;

- (b) the Best Available Techniques Reference Document (BREF) for Manufacture of Organic Fine Chemicals (OFC)⁹ for the manufacturing activity under conditions not covered by the BATC mentioned above;
- (c) the best available techniques (BAT) conclusions for common waste water and waste gas treatment/management systems in the chemical sector¹⁰;
- (d) the Best Available Techniques Reference Document (BREF) for the Large Volume Inorganic Chemicals – Solids and Others industry¹¹;
- (e) the Best Available Techniques Reference Document (BREF) for the manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers¹²;
- (f) the Best Available Techniques Reference Document (BREF) for the production of speciality inorganic chemicals (SIC)¹³; for the manufacturing activity under conditions not covered by the BATC mentioned above.

Plants within the BAT-AEL range(s) moving to the mid-point ambition do not trigger any significant cross-media impact. Installations that have been granted a derogation in accordance with the procedure set out in Article 15(4) of Directive 2010/75/EU are not considered as fulfilling the technical screening criteria for the period of the derogation.

2.2. Where a continuous measurement methodology for a certain pollutant is available, the operator applies Continuous Emission Monitoring Systems (CEMS), Continuous Effluent Quality Monitoring Systems (CEQMS) and other measures ensuring the regular verification of non-deterioration of environment.

2.3. The operator applies solvent waste segregation for solvent recovery from concentrated waste streams, where technically applicable.

Solvents included in Table 1 of the European Medicines Agency ICH guideline Q3C (R8) on impurities: guideline for residual solvents¹⁴ are avoided.

⁸ Commission Implementing Decision (EU) 2022/2427 of 6 December 2022 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for common waste gas management and treatment systems in the chemical sector (OJ L 318, 12.12.2022, p. 157).

⁹ The Best Available Techniques Reference Document (BREF) for Manufacture of Organic Fine Chemicals, available at https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/ofc_bref_0806.pdf.

¹⁰ Commission Implementing Decision (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/management systems in the chemical sector (OJ L 152, 9.6.2016, p. 23).

¹¹ Best Available Techniques (BAT) Reference Document for the Large Volumes Inorganic Chemicals-Solids and Others industry, (version of [adoption date]: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/lvic-s_bref_0907.pdf).

¹² Best Available Techniques (BAT) Reference Document for the manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers (version of [adoption date]: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/lvic_aaf.pdf).

¹³ The Best Available Techniques Reference Document (BREF) for the production of speciality inorganic chemicals (SIC), (version of [adoption date]: <https://eippcb.jrc.ec.europa.eu/reference/production-speciality-inorganic-chemicals>).

The maximum solvents loss from total inputs does not exceed a 3% loss. Total volatile organic compound (VOC) recovery efficiency is at least 99%.

The operator verifies that no fugitive VOC emission occurs beyond the criteria specified below as to the parts per million volumetric (ppmv) thresholds by carrying out Leak detection and repair (LDAR) campaigns, at least every 3 years. Investments for the use of high integrity equipment are recommended, provided that these are installed in existing plants for cases mentioned under BAT 23 point b of the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector (WGC), whereas the pressure threshold is brought to 200 bar. The minimal verification schedule may be reduced in cases where quantification of total VOC emissions from the plant is periodically qualified with tracer correlation (TC) or with optical absorption-based techniques, such as differential absorption light detection and ranging (DIAL) or solar occultation flux (SOX) or other measures of equivalent performance.

Diffuse emissions of substances or mixtures classified as CMR1A or 1B from leaky equipment do not exceed a concentration of 100 ppmv¹⁵.

The LDAR campaigns have the features described in BAT19 of the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector, which include detecting, repairing and maintaining leaks within 30 days of detection and a leak threshold that is lower than or equal to 5000 ppmv for substances or mixtures other than those classified as CMR 1A or 1B, which are reviewed and updated for the continuous improvement of the installation. Solvent losses and recovery efficiency of VOC are monitored based on a solvent management plan using a mass balance for verification of compliance, in accordance with Chapter V of Directive 2010/75/EU.

2.4. Sewage, refuse, and other waste (including solids, liquids, or gaseous by-products from manufacturing) are disposed of in a safe, timely, and sanitary manner. Containers or pipes for waste material are clearly identified. Analytical data demonstrating the conversion of these substances and their residues to non-hazardous waste materials are available at the facility and kept up to date.

Do no significant harm ('DNSH')

(1) Climate change mitigation	Where the activity involves on-site generation of heat/cool or co-generation including power, the direct GHG emissions of the activity are lower than 270 gCO ₂ e/kWh. For the refrigerant threshold, the Global Warming Potential does not
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¹⁴ European Medicines Agency ICH guideline Q3C (R8) on impurities: guideline for residual solvents. Step 5, 2022, version of [adoption date] available at https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-33.pdf.

¹⁵ Where the exemption under criterion 1.3 applies.

	<p>exceed 150 in cooling of the substance.</p> <p>Where active pharmaceutical ingredients (API) or active substances are made from substances listed in Sections 3.10 to 3.16 of Annex II to Commission Delegated Regulation (EU) 2021/2139, the GHG emissions do not exceed the limits set out in their respective criteria for DNSH to climate change mitigation.</p> <p>The substitution does not lead to an increment of lifecycle GHG emissions. Lifecycle GHG emissions are calculated using Recommendation 2013/179/EU or, alternatively, using ISO 14067:2018¹⁶ or ISO 14064-1:2018¹⁷. Quantified life-cycle GHG emissions are verified by an independent third party.</p>
(2) Climate change adaptation	<p>The activity complies with the criteria set out in Appendix A to this Annex.</p>
(3) Sustainable use and protection of water and marine resources	<p>1. Waste water treatment:</p> <p>The performance of wastewater treatment processes conducted by or on behalf of the manufacturing plant does not lead to any deterioration of water bodies and marine resources.</p> <p>When activities fall within their scope, they meet the requirements of Directives 91/271/EEC, 2008/105/EC, 2006/118/EC, 2010/75/EU, 2000/60/EC, (EU) 2020/2184, 76/160/EEC, 2008/56/EC and 2011/92/EU.</p> <p>The activity implements best practices specified in the Joint Research Centre Best Environmental Management Practice for the Public Administration Sector¹⁸.</p> <p>Where waste water treatment is conducted by an urban wastewater treatment plant on behalf of the manufacturing plant, it is ensured that:</p> <p>(a) the load of pollutants released by the manufacturing plant has no negative effect in the treatment process of the urban waste water treatment plant;</p>

¹⁶ ISO standard 14067:2018, Greenhouse gases — Carbon footprint of products — Requirements and guidelines for quantification, version of [adoption date] available at: <https://www.iso.org/standard/71206.html>.

¹⁷ ISO standard 14064-1:2018, Greenhouse gases — Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals, version of [adoption date] available at: <https://www.iso.org/standard/66453.html>.

¹⁸ Joint Research Centre, Best Environmental Management Practice for the Public Administration Sector, 2019, version of [adoption date] available at <https://op.europa.eu/en/publication-detail/-/publication/6063f857-7789-11e9-9f05-01aa75ed71a1/language-en>.

	<p>(b) the load and characteristics of pollutants do not pose any risk or harm to the health of the staff working in waste water treatment plants;</p> <p>(c) the urban waste water treatment plant is designed and equipped appropriately to abate the released polluting substances;</p> <p>(d) the overall load of the concerned pollutants discharged to the water body is not increased compared to the situation where the emissions from the installation concerned remained compliant with emission limit values set for direct releases;</p> <p>(e) the usability of the sewage sludge for nutrient (re)cycling is not affected.</p> <p>For installations where additional pollutant limits or stricter conditions have been included in their environmental permit compared to the requirements of the legislation mentioned above, these stricter conditions apply.</p> <p>2. Soil and groundwater protection: Appropriate measures are in place to prevent emissions to soil and regular surveillance is conducted to avoid leaks, spills, incidents or accidents occurring during the use of equipment and during storage.</p> <p>3. Water Consumption: Operators assess the water footprint of the chemical production processes in line with ISO 14046:2014¹⁹ and ensure that they do not contribute to water scarcity. Based on this assessment, operators provide a declaration that they do not contribute to water scarcity which is verified by an independent third party.</p> <p>4. The activity complies with the criteria set out in Appendix B to this Annex.</p>
(4) Transition to a circular economy	<p>The activity assesses the availability of and, where feasible, adopts techniques that support:</p> <p>(a) reuse and use of secondary raw materials and reused components in products manufactured;</p> <p>(b) design for high durability, recyclability, easy disassembly and adaptability of products manufactured;</p> <p>(c) waste management that prioritises recycling over disposal, in the manufacturing process;</p>

¹⁹ ISO 14046:2014 Environmental management — Water footprint — Principles, requirements and guidelines, version of [adoption date] available at: <https://www.iso.org/standard/43263.html>.

	(d) information on product ingredients along the supply chain.
(6) Protection and restoration of biodiversity and ecosystems	The activity complies with the criteria set out in Appendix D to this Annex.

1.2. Manufacture of medicinal products

Description of the activity

Manufacture of medicinal products.

The economic activities in this category could be associated with NACE code C21.2 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. The activity complies with one of the following sets of requirements set out in point 1.1. or 1.2. relating to product substitution. In any case, the activity complies with the requirements set out in point 1.3.

1.1. The medicinal product complies with the following requirements set out in points 1.1.1. and 1.1.2.:

1.1.1. The medicinal product complies with one of the following requirements:

- (a) the ingredients that constitute the formulation of the medicinal product are naturally occurring substances such as vitamins, electrolytes, amino acids, peptides, proteins, nucleotides, carbohydrates and lipids and, in line with European Medicines Agency Guideline on the environmental risk assessment of medicinal products for human use (EMA ERA guideline)²⁰, are generally considered to be degradable in the environment²¹;

²⁰ European Medicines Agency Guidelines on the environmental risk assessment of medicinal products for human use, version of [adoption date] available at <https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use-scientific-guideline>.

²¹ Key metabolites are human metabolites likely to be excreted into the environment. Those metabolites are identified in (non-)clinical studies on the metabolism of medicinal products available in the marketing authorization applications. Such metabolites are to be identified according to EMA/CPMP/ICH/286/1995, page 8. Key transformation products (TP) of these key human metabolites of the parent compound (API) are those that exceed 10% of Dissolved Organic Carbon (DOC) or Total Organic Carbon (TOC) of the parent compound.

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- (b) where the ingredients that constitute the formulation of the medicinal product do not comply with the requirements specified in point (a), those ingredients, their key human metabolites and their key transformation products in the environment comply with one of the following:
- (i) are classified as readily biodegradable based on at least one of the test methods from the OECD Guidelines for the Testing of Chemicals, Test 301 (A-F), Ready Biodegradability²², in accordance with the pass value for ready biodegradability as defined in that guideline;
 - (ii) can be concluded to be mineralised based on a specific Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)²³ of OECD Guidelines for the Testing of Chemicals²⁴ compared to persistence criteria as defined in the EMA ERA guideline.

1.1.2. The medicinal product qualifies as an appropriate substitute to another medicinal product, within the same therapeutic area or the substance class, that is available in the market or was available during last 5 years and that does not comply with the requirements described in point 1.1.1.

Compliance with this requirement is demonstrated through a publicly available analysis verified by an independent third party.

1.2. The manufacturer proves that there are no ingredients to produce an alternative medicinal product that qualifies as an appropriate substitute, within the same therapeutic area or the substance class, that comply with the requirements described in point 1.1.1. The activity complies with all the requirements specified in points 1.2.1 to 1.2.6.

1.2.1. The manufacturer performs an analysis that there is no appropriate substitute to the produced medicinal product, publishes the core results of that analysis and demonstrates that they started initiatives to develop that alternative.

1.2.2. In line with the EMA ERA guidelines, the PEC/PNEC ratio for the medicinal product obtained in the Environmental Risk Assessment is below 1.

1.2.3. Packaging and distribution systems allow adjusting the sold amount to the required amount by the treatment/s, taking into account the applicable national legislation.

1.2.4. Public information, such as leaflets or websites, updated according to the state of the art, is provided about dose and dosing method to minimize the excess of dosed API.

1.2.5. Packaging and distribution systems allow using the most efficient dosing system

²² OECD Guidelines for the Testing of Chemicals, Test 301 (A-F), Ready Biodegradability, version of [adoption date] available at <https://www.oecd.org/chemicalsafety/risk-assessment/1948209.pdf>. OECD 301 (A-F) test is used to identify substances which are assumed to rapidly and ultimately biodegrade, i.e., mineralised under aerobic environmental conditions).

²³ Higher-tier studies (OECD 308) result with so-called half-lives indicating the time after which 50 % biodegradation of the API is achieved. Half-lives acceptable to demonstrate sufficiently quick biodegradation, i.e., non-persistence, according to the Regulation (EC) No 1907/2006, Annex XIII, which is also referenced in the EMA ERA guideline, apply.

²⁴ OECD Guidelines for the Testing of Chemicals, Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, version of [adoption date] available at: https://www.oecd-ilibrary.org/environment/test-no-308-aerobic-and-anaerobic-transformation-in-aquatic-sediment-systems_9789264070523-en.

available according to the state of the art and considering the kind of administration, such as by health care professionals or domestic. The manufacturer publishes the main results of that analysis.

1.2.6. The manufacturer contributes to mitigating the environmental impact of incorrect waste disposal of unused medicinal product, including by providing relevant information to the downstream users on appropriate disposal of unused medicinal product.

1.3. The manufacturing process does not involve the use of substances, whether on their own or in mixtures, that meet the criteria set out in Article 57 of Regulation (EC) 1907/2006 except where it is assessed and documented by the operator that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions²⁵.

2. The activity complies with the following requirements regarding the emission of pollutants:

2.1. Where the activity falls within its scope, the emission limit values shall be lower than the mid-point of the BAT-AEL ranges²⁶ set out in:

- (a) the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector²⁷ for emissions to air of new installations (or for existing installations within 4 years of the BATC publication) where relevant conditions apply;
- (b) the Best Available Techniques Reference Document (BREF) for Manufacture of Organic Fine Chemicals (OFC)²⁸; for the manufacturing activity under conditions not covered by the BATC mentioned above;
- (c) the best available techniques (BAT) conclusions for common waste water and waste gas treatment/management systems in the chemical sector²⁹;
- (d) the Best Available Techniques Reference Document (BREF) for the Large Volume Inorganic Chemicals – Solids and Others industry³⁰;

²⁵ The Commission will review the exceptions from the prohibition from manufacturing, placing on the market or use of the substances referred to in points (f) and (g) once it will have published horizontal principles on essential use of chemicals.

²⁶ The requirements under this point tackle the pollutants identified under the key environmental issues of each BREF document or the BAT-AEL of the relevant BAT conclusions Commission Implementing Decisions. Where BAT-AEL differentiate between “existing” and “new plants”, operators demonstrate compliance with BAT-AEL for new plants. When there is not a BAT-AEL range but a single value, emission levels are below such value. When the BAT-AEL range is expressed as follows: “<x-y unit” (I.e the lower-end BAT-AEL of the range is expressed as ‘lower than’), the mid-point is calculated using x and y. Averaging periods are the same as in the BAT-AEL of the BREF documents outlined above.

²⁷ Implementing Decision (EU) 2022/2427.

²⁸ The Best Available Techniques Reference Document (BREF) for Manufacture of Organic Fine Chemicals, (version of [adoption date]: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/ofc_bref_0806.pdf).

²⁹ Implementing Decision (EU) 2016/902.

³⁰ Best Available Techniques (BAT) Reference Document for the Large Volumes Inorganic Chemicals-Solids and Others industry, (version of [adoption date]: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/lvic-s_bref_0907.pdf).

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- (e) the Best Available Techniques Reference Document (BREF) for the manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers³¹;
 - (f) the Best Available Techniques Reference Document (BREF) for the production of speciality inorganic chemicals (SIC) for the manufacturing activity under conditions not covered by the BATC mentioned above ³².

Plants within the BAT-AEL range(s) moving to the mid-point ambition do not trigger any significant cross-media impact.

Installations that have been granted a derogation in accordance with the procedure set out in Article 15(4) of Directive 2010/75/EU are not considered as fulfilling the technical screening criteria for the period of the derogation.

2.2. Where a continuous measurement methodology for a certain pollutant is available, the operator applies Continuous Emission Monitoring Systems (CEMS), Continuous Effluent Quality Monitoring Systems (CEQMS) and other measures ensuring the regular verification of non-deterioration of environment.

2.3. The operator applies solvent waste segregation for solvent recovery from concentrated waste streams, where technically applicable.

Solvents included in Table 1 of the European Medicines Agency ICH guideline Q3C (R8) on impurities as specified in the guideline for residual solvents³³ are avoided in medicinal products.

The maximum solvents loss from total inputs does not exceed a 3% loss. Total volatile organic compound (VOC) recovery efficiency is at least 99%.

The operator verifies that no fugitive VOC emission occurs beyond the criteria specified below as to the parts per million volumetric (ppmv) thresholds by carrying out Leak detection and repair (LDAR) campaigns, at least every 3 years. Investments for the use of high integrity equipment are recommended, provided that these are installed in existing plants for cases mentioned under BAT 23b of the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector, whereas the pressure threshold is brought to 200 bar. The minimal verification schedule may be reduced in cases where quantification of total VOC emissions from the plant is periodically qualified with tracer correlation (TC) or with optical absorption-based techniques, such as differential absorption light detection and ranging (DIAL) or solar occultation flux (SOX) or other measures of equivalent performance.

³¹ Best Available Techniques (BAT) Reference Document for the manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers (version of [adoption date]: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/lvic_aaf.pdf).

³² The Best Available Techniques Reference Document (BREF) for the production of speciality inorganic chemicals (SIC) (version of [adoption date]: <https://eippcb.jrc.ec.europa.eu/reference/production-speciality-inorganic-chemicals>).

³³ European Medicines Agency ICH guideline Q3C (R8) on impurities: guideline for residual solvents. Step 5, 2022, version of [adoption date] available at https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-33.pdf.

Diffuse emissions of substances or mixtures classified as CMR1A or 1B from leaky equipment do not exceed a concentration of 100 ppmv³⁴.

The LDAR campaigns have the features described in BAT19 of the best available techniques (BAT) conclusions for common waste gas management and treatment systems in the chemical sector, which include detecting, repairing and maintaining leaks within 30 days of detection and a leak threshold is lower than or equal to 5000 ppmv for substances or mixtures other than those classified as CMR 1A or 1B, which are reviewed and updated for the continuous improvement of the installation. Solvent losses and recovery efficiency of VOC are monitored based on a solvent management plan using a mass balance for verification of compliance, in accordance with Chapter V of Directive 2010/75/EU.

2.4. Sewage, refuse, and other waste (including solids, liquids, or gaseous by-products from manufacturing) are disposed of in a safe, timely, and sanitary manner. Containers or pipes for waste material are clearly identified. Analytical data demonstrating the conversion of these substances and their residues to non-hazardous waste materials are available at the facility and kept up to date.

Do no significant harm ('DNSH')

<p>(1) Climate change mitigation</p>	<p>Where the activity involves on-site generation of heat/cool or co-generation including power, the direct GHG emissions of the activity are lower than 270 gCO₂e/kWh.</p> <p>For the refrigerant threshold, the Global Warming Potential does not exceed 150 in cooling of the substance.</p> <p>Where medicinal products are made from substances listed in Sections 3.10 to 3.16 of Annex II to Commission Delegated Regulation (EU) 2021/2139, the GHG emissions do not exceed the limits set out in their respective technical screening criteria for DNSH to climate change mitigation.</p> <p>The substitution does not lead to an increment of lifecycle GHG emissions. Lifecycle GHG emissions are calculated using Recommendation 2013/179/EU or, alternatively, using ISO 14067:2018³⁵ or ISO 14064-1:2018³⁶. Quantified life-cycle GHG emissions are verified by an independent third party.</p>
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³⁴ Where the exemption under criterion 1.3 applies.

³⁵ ISO standard 14067:2018, Greenhouse gases — Carbon footprint of products — Requirements and guidelines for quantification, version of [adoption date] available at: <https://www.iso.org/standard/71206.html>.

(2) Climate change adaptation	The activity complies with the criteria set out in Appendix A to this Annex.
(3) Sustainable use and protection of water and marine resources	<p>1. Waste water treatment:</p> <p>The performance of wastewater treatment processes conducted by or on behalf of the manufacturing plant does not lead to any deterioration of water bodies and marine resources.</p> <p>When activities fall within their scope, they meet the requirements of Directives 91/271/EEC, 2008/105/EC, 2006/118/EC, 2010/75/EU, 2000/60/EC, (EU) 2020/2184, 76/160/EEC, 2008/56/EC and 2011/92/EU.</p> <p>The activity implements best practices specified in the Joint Research Centre Best Environmental Management Practice for the Public Administration Sector³⁷.</p> <p>Where wastewater treatment is conducted by an urban wastewater treatment plant on behalf of the manufacturing plant, it is ensured that:</p> <ul style="list-style-type: none"> (a) the load of pollutants released by the manufacturing plant has no negative effect in the treatment process of the urban waste water treatment plant; (b) the load and characteristics of pollutants do not pose any risk or harm to the health of the staff working in waste water treatment plants; (c) the urban waste water treatment plant is designed and equipped appropriately to abate the released polluting substances; (d) the overall load of the concerned pollutants discharged to the water body is not increased compared to the situation where the emissions from the installation concerned remained compliant with emission limit values set for direct releases; (e) the usability of the sewage sludge for nutrient (re)cycling is not affected. <p>For installations where additional pollutant limits or stricter conditions have been included in their environmental permit compared to the requirements of the legislation mentioned above, these stricter conditions apply.</p>

³⁶ ISO standard 14064-1:2018, Greenhouse gases — Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals, version of [adoption date] available at: <https://www.iso.org/standard/66453.html>.

³⁷ Joint Research Centre, Best Environmental Management Practice for the Public Administration Sector, 2019, version of [adoption date] available at <https://op.europa.eu/en/publication-detail/-/publication/6063f857-7789-11e9-9f05-01aa75ed71a1/language-en>.

	<p>2. Soil and groundwater protection: Appropriate measures are in place to prevent emissions to soil and regular surveillance is conducted to avoid leaks, spills, incidents or accidents occurring during the use of equipment and during storage.</p> <p>3. Water Consumption: Operators assess the water footprint of the chemical production processes in line with ISO 14046:2014³⁸ and ensure that they do not contribute to water scarcity. Based on this assessment, operators provide a declaration that they do not contribute to water scarcity which is verified by an independent third party.</p> <p>4. The activity complies with the criteria set out in Appendix B to this Annex.</p>
(4) Transition to a circular economy	<p>The activity assesses the availability of and, where feasible, adopts techniques that support:</p> <ul style="list-style-type: none"> (a) reuse and use of secondary raw materials and reused components in products manufactured; (b) design for high durability, recyclability, easy disassembly and adaptability of products manufactured; (c) waste management that prioritises recycling over disposal, in the manufacturing process; (d) information on product ingredients along the supply chain.
(6) Protection and restoration of biodiversity and ecosystems	<p>The activity complies with the criteria set out in Appendix D to this Annex.</p>

2. WATER SUPPLY, SEWERAGE, WASTE MANAGEMENT AND REMEDIATION ACTIVITIES

2.1. Collection and transport of hazardous waste

Description of the activity

Separate collection and transport of hazardous waste³⁹ prior to treatment, material recovery or disposal, including the construction, operation and upgrade of facilities involved in the

³⁸ ISO 14046:2014 Environmental management — Water footprint — Principles, requirements and guidelines, version of [adoption date] available at: <https://www.iso.org/standard/43263.html>.

³⁹ Hazardous waste is waste which displays one or more of the hazardous properties listed in Annex III of Directive 2008/98/EC. It includes streams such as hazardous waste fractions produced by households, waste oils, batteries, non-depolluted waste from electrical and electronic equipment (WEEE), non-

collection and transport of such waste, such as hazardous waste transfer stations, as a means for appropriate treatment.

The economic activities in this category could be associated with several NACE codes, in particular E38.12 and F42.9 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. Hazardous waste is source segregated and collected separately from non-hazardous waste to prevent cross-contamination. Appropriate measures are taken to ensure that during separate collection and transport, hazardous waste is not mixed nor diluted either with other categories of hazardous waste or with other waste, substances or materials.

2. Proper collection and handling prevent leakage of hazardous waste during collection, transport, storage and delivery to the treatment facility, which is permitted to treat hazardous waste, according to national legislation.

3. Where a given waste classified as hazardous has also a transport status of dangerous goods under the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)⁴⁰, the transport complies with the relevant requirements set by the ADR.

4. The activity uses waste collection vehicles which conform to at least EURO V standards⁴¹.

5. During collection and transport, hazardous waste is packaged and labelled in accordance with the international and Union standards in force.

6. The operator collecting hazardous waste complies with record-keeping obligations including as regards quantity, nature, origin, destination, frequency of collection, mode of transport and treatment method set out by applicable Union and national legislation.

7. For waste from electrical and electronic equipment (WEEE):

- (a) the main categories of WEEE set out in Annex III to Directive 2012/19/EU are collected separately;
- (b) collection and transport preserve the integrity of WEEE and prevent the leakage of hazardous substances such as ozone-depleting substances, fluorinated greenhouse gases or mercury contained in fluorescent lamps;
- (c) a management system is set up by the collection and logistics operator to manage environmental, health and safety risks.

Compliance with normative requirements for collection and logistics set in CLC/EN 50625-1:2014⁴² and CLC/TS 50625-4:2017⁴³ or with regulatory requirements that are equivalent to

depolluted end-of-life vehicle, certain healthcare waste, such as infectious and cytotoxic waste, etc. A comprehensive classification of hazardous waste can be found in the European List of Waste (established by Commission Decision 2000/532/EC).

⁴⁰ Version of [adoption date], available at <https://unece.org/transport/standards/transport/dangerous-goods/adr-2023-agreement-concerning-international-carriage>.

⁴¹ In accordance with Regulation (EU) 2018/858.

those set in CLC/EN 50625-1 and CLC/TS 50625-4 is a proof of compliance with the requirement that the collection and transport preserve the integrity of WEEE and batteries and prevents the leakage of hazardous substances.

8. When the waste is stored, the activity complies with the requirements set out in BAT 4 of the best available techniques (BAT) conclusions for waste treatment⁴⁴.

Do no significant harm ('DNSH')

(1) Climate change mitigation	N/A
(2) Climate change adaptation	The activity complies with the criteria set out in Appendix A to this Annex.
(3) Sustainable use and protection of water and marine resources	The activity complies with the criteria set out in Appendix B to this Annex.
(4) Transition to a circular economy	Separately collected waste is not mixed in waste storage and transfer facilities with other waste or materials with different properties. Recyclable ⁴⁵ waste is not disposed of, incinerated or co-incinerated.
(6) Protection and restoration of biodiversity and ecosystems	The activity complies with the criteria set out in Appendix D to this Annex.

2.2. Treatment of hazardous waste

Description of the activity

Construction, repurposing, upgrade, and operation of dedicated facilities for the treatment of hazardous waste, including the incineration of non-recyclable hazardous waste⁴⁶ (operations

⁴² CLC/EN 50625-1: 2014 Collection, logistics & Treatment requirements for WEEE - Part 1: General treatment requirements.

⁴³ Collection, logistics & treatment requirements for WEEE -- Part 4: Specification for the collection and logistics associated with WEEE.

⁴⁴ Implementing Decision (EU) 2018/1147.

⁴⁵ 'Recyclable waste' is waste that can be recycled in accordance with Article 3(17) of Directive 2008/98/EC.

⁴⁶ 'Non-recyclable waste' is waste that cannot be recycled in accordance with Article 3(17) of Directive 2008/98/EC.

D10), biological treatment of hazardous waste (operations D8) and physico-chemical treatment (operations D9)⁴⁷.

The activity does not include:

- (a) disposal operations (as set out in Annex I to the Directive 2008/98/EC) of hazardous waste such as landfilling or permanent storage.
- (b) incineration of recyclable hazardous waste and incineration of non-hazardous waste;
- (c) treatment and disposal of toxic live or dead animals and other contaminated waste;
- (d) treatment and disposal of radioactive nuclear waste.

The economic activities in this category could be associated with several NACE codes, in particular E38.22 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. For all waste treatment processes, the activity complies with the following criteria:

1.1. According to the type of activity, the activity complies with the requirements set out either in the best available techniques (BAT) conclusions for waste treatment⁴⁸ or the best available techniques (BAT) conclusions for waste incineration⁴⁹.

Facilities that have been granted a derogation in accordance with the procedure set out in Article 15(4) of Directive 2010/75/EU are not considered as compliant with the Technical Screening Criteria.

1.2. During the pre-acceptance procedures, at least the following information is gathered:

- (a) expected date of arrival at the waste treatment plant;
- (b) contact details of the waste producer, the sector which the waste originates from and the nature of process producing the waste, including the variability of the process;
- (c) the estimated quantity expected to be delivered to the operator per delivery and per year;
- (d) description of the waste, including composition, hazardous properties of the waste, waste code and the suitable treatment route.

1.3. During the acceptance procedures, the following elements are in place:

- (a) a reception facility equipped with a laboratory to analyse samples on site and documented analytical standard operating procedures, with the option to sub-contract analyses to accredited external contract laboratories;
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⁴⁷ As set out in Annex I to Directive 2008/98/EC.

⁴⁸ Implementing Decision (EU) 2018/1147.

⁴⁹ Commission Implementing Decision (EU) 2019/2010 of 12 November 2019 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for waste incineration (OJ L 312, 3.12.2019, p. 55).

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- (b) documented sampling procedure consistent with relevant standards, such as EN 14899:2005⁵⁰;
 - (c) documented analysis of the relevant physico-chemical parameters for the treatment;
 - (d) a dedicated quarantine waste storage area, as well as written procedures to manage non-accepted waste.

The personnel dealing with the pre-acceptance and acceptance procedures is able, due to their profession or experience, to deal with all necessary questions relevant for the treatment of the wastes in the waste treatment facility. The procedures are intended to pre-accepting and accepting wastes at the waste treatment plant only if a suitable treatment route is available and the disposal or recovery route for the output of the treatment is determined.

For ‘blending or mixing activities’ (as set out in Annex I, section 5.1(c) of Directive 2010/75/EU), the operator is not using dilution to lower the concentration of one or more hazardous substances present in the waste, with the aim for the resulting waste mix to be declassified and become ‘non-hazardous waste’ and thus be subsequently treated in facilities non-dedicated to the treatment of hazardous waste. Dilution is not used as a ‘substitute’ to the adequate treatment of the waste.

2. For the physico-chemical treatment of solid or pasty waste, any treatment for the purpose of treating waste prior to final disposal, such as in hazardous waste landfills, is designed to fulfil the following requirements:

- (a) limit at 6% the Total Organic Carbon (TOC) maximum concentration in each single input waste to the landfill;
- (b) limit at 1 000 mg/kg dry matter Dissolved Organic Carbon (DOC) content of the output waste after a leaching test with L/S = 10 l/kg based on EU Standard EN 12457-2:2002⁵¹.

3. For the physico-chemical treatment of waste with calorific value, measures are taken in order to avoid dilution and dispersion of hazardous substances, and to avoid any high loads released into the air due to inappropriate final treatment of waste with calorific value. Any treatment installation prior to final thermal treatments (incineration or co-incineration) is to be designed with the purpose of limiting the content of hazardous substances (and meet other related criteria) for each single input waste treated at the physico-chemical treatment installation, so that the acceptance levels at the entrance of the final thermal treatment installations are respected.

4. For the treatment of aqueous liquid waste, the biological treatability of the waste water resulting from the treatment of the water-based liquid waste in a biological waste water treatment plant is judged based on the following criterion:

Dissolved Organic Carbon DOC elimination of >70% in 7 days (>80% when adapted inoculum is used) in accordance with EN ISO 9888⁵² (Zahn Wellens), or other commonly

⁵⁰ EN 14899:2005 Characterization of waste - Sampling of waste materials - Framework for the preparation and application of a Sampling Plan.

⁵¹ EN 12457-2:2002 Characterisation of waste - Leaching - Compliance test for leaching of granular waste materials and sludges - Part 2: One stage batch test at a liquid to solid ratio of 10 l/kg for materials with particle size below 4 mm (without or with size reduction).

⁵² EN ISO 9888:1999 Water quality — Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium — Static test (Zahn-Wellens method), version of [adoption date] available at: <https://www.iso.org/standard/28121.html>.

accepted, equivalent industry standards and methodologies used to assess bio-elimination and related performances.

5. For the treatment of waste containing Persistent Organic Pollutants (POP), all waste containing POP substances listed in Annex IV to Regulation (EU) 2019/1021 are controlled and traced as hazardous waste in accordance with Article 17 of Directive 2008/98/EC. Specific requirements of Articles 7(4), 17, 18 and 19 of Directive 2008/98/EC apply. In case of transboundary movement, requirements of Chapter I of the Regulation (EC) No 1013/2006 of the European Parliament and of the Council⁵³ apply.

The tracking system in place in the installations based on the best practices referred to above allows the monitoring of:

- (a) the effective separation of each part of a product or waste such as waste equipment, containing or contaminated with POP above the levels defined in Annex IV to Regulation (EU) 2019/1021;
- (b) the effective destruction or irreversible transformation of the POP waste in compliance with Articles 7(2) – 7(4) and Annex V to Regulation (EU) 2019/1021.

6. For the treatment of mercury-containing waste⁵⁴, all installations likely to treat waste consisting of, containing or contaminated with mercury or mercury compounds (as defined in Article 11 of the Minamata Convention), implement the traceability system set out in Article 14 of Regulation (EU) 2017/852 or a similar traceability system. Based on this tracking system, the installations treating mercury-containing waste monitor the effective safe fate of mercury and mercury compounds in appropriate final destination.

7. For the (non-combustion) treatment of healthcare waste, the installation implements the best practices set out in the WHO handbook on safe management of wastes from health-care activities⁵⁵.

A non-combustion healthcare waste installation has specific acceptance procedure, monitors and can prove that the following types of healthcare waste are not accepted for treatment:

- (a) cytotoxic waste;
- (b) pharmaceutical waste;
- (c) chemical waste;
- (d) radioactive waste.

The technologies used are certified by an independent certification body.

Do no significant harm ('DNSH')

⁵³ Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

⁵⁴ Mercury-containing waste means waste consisting of, containing or contaminated with mercury or mercury compounds.

⁵⁵ WHO, Safe management of wastes from health-care activities, 2nd edition, 2014, version of [adoption date] available at https://www.euro.who.int/__data/assets/pdf_file/0012/268779/Safe-management-of-wastes-from-health-care-activities-Eng.pdf.

(1) Climate change mitigation	N/A
(2) Climate change adaptation	The activity complies with the criteria set out in Appendix A to this Annex.
(3) Sustainable use and protection of water and marine resources	The activity complies with the criteria set out in Appendix B to this Annex. Relevant techniques are deployed for the protection of water and marine resources, as set out in the best available techniques (BAT) conclusions for waste treatment ⁵⁶ .
(4) Transition to a circular economy	N/A
(6) Protection and restoration of biodiversity and ecosystems	The activity complies with the criteria set out in Appendix D to this Annex.

2.3. Remediation of legally non-conforming landfills and abandoned or illegal waste dumps

Description of the activity

Remediation of legally non-conforming landfills⁵⁷ and of abandoned or illegal waste dumps⁵⁸ that have been closed and are not taking in further waste other than possibly inert or biostabilised waste to be used as landfill cover material (as far as allowed in the environmental permit for the remediation project).

The activity may include any of the following remediation strategies and sub-activities typically implemented as part of projects aimed at removing, controlling, containing or diminishing polluting emissions⁵⁹ from non-conforming landfills and abandoned or illegal dumpsites:

⁵⁶ Implementing Decision (EU) 2018/1147.

⁵⁷ The term ‘landfill’ is defined in Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1) as a “waste disposal site for the deposit of the waste onto or into land (i.e., underground)” including both non-hazardous and hazardous waste.

A ‘legally non-conforming’ landfill is a landfill that does not comply with the operational and technical requirements defined in relevant EU or national legislation.

⁵⁸ A ‘waste dump’ is a site used for the disposal of waste that is not equipped with pollution abatement systems.

⁵⁹ ‘Emission’ means the release in the environment, as a result of human activities, of substances, preparations, organisms or micro-organisms (as set out in Article 2 of Directive 2004/35/CE of the

- (a) remediation through environmental isolation of non-conforming or illegal landfills or dumpsites at the present site, including:
 - (i) physical isolation, concentration, structural stabilisation and protection of the non-conforming or illegal landfill or dumpsite, including application of hydraulic barriers, sealing, drainage and cover layers;
 - (ii) installation, operation and maintenance of drainage and separate collection and treatment systems for leachates and run-off water prior to discharge;
 - (iii) installation, operation and maintenance of landfill gas collection, abatement and control systems, including wells, piping and flaring systems;
 - (iv) application of top soil and vegetation cover for renaturation purposes;
- (b) remediation through excavation and removal of non-conforming or illegal landfills or dumpsites with subsequent treatment, recovery or disposal of excavated waste, including:
 - (i) selective excavation of the waste deposited on the site, loading and transport to existing permitted treatment, recovery or disposal facilities with separate management of non-hazardous and hazardous waste;
 - (ii) sorting and recovery of materials and fuels from excavated non-hazardous waste, including the installation, operation and maintenance of dedicated facilities and equipment for the duration of the remediation project;
- (c) remediation through decontamination of soils, surface and groundwater at the place of pollution, including the following:
 - (i) selective excavation, loading, transport, temporary storage, backfilling of soil, with separate management of non-contaminated and contaminated soils;
 - (ii) treatment of contaminated soil or water, either in situ or ex situ, using in particular physical, chemical or biological methods, including the installation, operation and maintenance of dedicated facilities for the duration of the remediation project;
 - (iii) application of hydraulic barriers, active and passive barriers intended to limit/prevent migration of pollutants.

The activity also includes all of the following sub-activities that are required to prepare, plan, monitor and follow-up on the above remediation measures:

- (a) preparatory investigations, including data collection and surveying activities (in particular geological or hydrological), technical feasibility and environmental impact studies required to define the remediation project;
- (b) site preparation, including earth moving and levelling works, construction or reinforcement of perimeter walls or fences, primary access and internal roads, demolition of buildings or other structures on the landfill site;
- (c) monitoring and control of the remediation measures, including:
 - (i) sampling of soil, water, sediment, biota or other materials;

European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p. 56).

- (ii) laboratory analysis of samples to identify the nature and concentration of pollutants;
- (iii) installation, operation and maintenance of monitoring facilities and equipment such as observation wells in and outside the perimeter of the landfill site;
- (d) implementation of other environmental protection and pollution prevention and control measures to comply with the conditions imposed in the environmental permit for the remediation project, including measures for safeguarding safety of operations on-site and health of workers, such as for fire control, flood protection, hazardous waste management.

The activity does not include:

- (a) the permanent closure, rehabilitation and after care of existing or new landfills that comply with the Council Directive 1999/31/EC⁶⁰, or for activities located in third countries having equivalent national legislation or otherwise aligned with recognized international industry standards⁶¹;
- (b) landfill gas transformation for utilization as energy carrier or industry feedstock;
- (c) redevelopment of the remediated site for other economic use such as recreational, residential or commercial areas, installation of photovoltaic (PV) panels;
- (d) compensatory measures for pollution caused by the landfill or dumpsite such as the development and operation of alternative water supply systems for affected population living in the surrounding area.

The economic activities in this category could be associated with several NACE codes, in particular E39, E38.2, E38.32 and F42.9 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. The activity complies with all of the following criteria:

- (a) the remediation activity is not undertaken by the operator⁶² that caused the pollution or a producer of waste or a person acting on behalf of that operator or producer in order to comply with the Directive 2004/35/CE of the European Parliament and of the Council⁶³ or, for activities located in third countries, with an equivalent national legislation or international standards that apply the polluter-pays-principle to the remediation of environmental pollution caused by economic activities;
 - (b) relevant contaminants are removed, controlled, contained or diminished using physical, chemical, biological or other methods to ensure that the landfill and the
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⁶⁰ Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, OJ L 182, 16.7.1999, p. 1.

⁶¹ Such as, at the international level, landfill operational guidelines published by the International Solid Waste Association (ISWA).

⁶² As defined in Article 2, point 6, of Directive 2004/35/CE.

⁶³ Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.04.2004, p. 56).

contaminated area (land, water body or other), taking into account its use at the time of the damage or approved future use of the area, no longer pose any significant risk of adversely affecting human health and the environment, as specified in national regulatory standards or, where such standards are not available, in an internal risk-assessment taking into account the characteristic and the extent of the impacted area (land, water body or other), the type, properties (persistence, mobility and toxicity) and concentration of the substances, preparations, organisms or micro-organisms, possible migration pathways and the probability of dispersion⁶⁴.

2. The activity is prepared and conducted in line with best industry practice and includes all of the following elements:

- (a) the non-conforming or illegal landfill or dumpsite to be remediated has been closed and is not taking in further waste other than possibly inert or biostabilized waste to be used as landfill cover material (as far as allowed in the environmental permit for the remediation project);
- (b) preparatory investigations including site-specific surveys and physical, chemical or microbiological data collection are carried out in line with best industry practice and best available techniques to establish:
 - (i) the location, characteristics and extent of the landfill and the polluted area;
 - (ii) the underlying geological and hydrological conditions;
 - (iii) the likely quantity, composition and sources of the landfilled waste;
 - (iv) soil and water pollution originating from it as well as the risks to human health and the environment.
- (c) the results of such remedial investigations are inputs for a feasibility study that defines the objectives, targets and scope for the remediation and evaluates alternative remedial options;
- (d) the remedial options are analysed in accordance with the requirements set out in Annex II to Directive 2004/35/CE and in Annexes I and III to Directive 1999/31/EC, or for activities located in third countries in equivalent national law or commonly accepted international standards⁶⁵, and described in a feasibility study produced for the landfill remediation project that convincingly demonstrates how the selected remedial option is the overall best solution to meet the defined remediation objectives and targets;
- (e) the landfill remediation project, including accompanying monitoring and control plan, is approved by the competent authority and consulted on with local stakeholders in accordance with national legal requirements;
- (f) all materials and fuels recovered from landfilled waste meet relevant quality

⁶⁴ See Directive 2004/35/CE, Annex II, point 2. For remediation activities outside the EU, unless equal or more stringent standards are mandatory under national legislation, reference is made to the UNEP Guidance on the management of contaminated sites.

⁶⁵ See Directive 2004/35/CE, Annex II, point 1.3.1. For remediation activities outside the EU, reference is made to the UNEP Guidance on the management of contaminated sites and the standards and guidance documents for landfill management published by the International Solid Waste Association, including International Guidelines for Landfill Evaluation (2011), Roadmap for Closing Waste Dumpsites (2016) and Landfill Operational Guidelines (2014, 2019).

standards or user specifications for the intended recovery operations and do not represent a risk for the environment or human health;

- (g) any hazardous waste extracted or otherwise produced by the remediation activity is subject to appropriate collection, transport, treatment, recovery or disposal by an authorized operator, in accordance with national legal requirements;
- (h) soil and groundwater remediation methods based exclusively on reducing pollutant concentrations through dilution or watering down are not used;
- (i) a control and monitoring plan is implemented, including measures to control the impacts of the remediation activities and to verify the achievement of the remediation objectives and targets, for at least 10 years in case of excavation and removal of the landfill or dumpsite and for at least 30 years in case of environmental isolation of the landfill or dumpsite, unless a different duration sufficient to guarantee long-term risk control is defined in national legislation or by the competent regulatory authority for the specific remediation project.

Do no significant harm ('DNSH')

(1) Climate change mitigation	Where the landfill body contains significant amounts of biodegradable waste, a system for landfill gas capture and abatement and a monitoring plan for landfill gas leakage is in place in accordance with operational and technical requirements of Directive 1999/31/EC, or for activities located in third countries in accordance with equivalent national law or commonly accepted international industry standards ⁶⁶ .
(2) Climate change adaptation	The activity complies with the criteria set out in Appendix A to this Annex.
(3) Sustainable use and protection of water and marine resources	The activity complies with the criteria set out in Appendix B to this Annex. Remedial measures are protective of water and marine resources and apply best industry practices and technology ⁶⁷ with the aim of:

⁶⁶ For remediation activities outside the EU, reference is made to the UNEP Guidance on the management of contaminated sites and the standards and guidance documents for landfill management published by the International Solid Waste Association, including International Guidelines for Landfill Evaluation (2011), Roadmap for Closing Waste Dumpsites (2016) and Landfill Operational Guidelines (2014, 2019).

⁶⁷ For remediation activities outside the EU, reference is made to the UNEP Guidance on the management of contaminated sites and the standards and guidance documents for landfill management published by the International Solid Waste Association, including International Guidelines for Landfill Evaluation

	<ul style="list-style-type: none"> (a) reducing the generation of leachates from the landfill and avoiding outflow or infiltration of leachates into the surrounding soil and any potential hazard to groundwater and surface water; (b) separately collecting and appropriately treating run-off water and leachates before discharge; (c) tracking and analysing leachate generation rates and leachate concentration and composition in the after-care period through appropriate control and monitoring systems and processes; (d) separately collecting and appropriately treating polluted soil in and around the landfill in order to block the pathway from the landfill to waterbodies through heavily soaked soil.
(4) Transition to a circular economy	Where the remediation project foresees the excavation and removal of the existing landfill or dumpsite, the excavated waste is managed in accordance with the waste hierarchy principle, prioritizing recycling over other types of material recovery, over incineration and disposal, to the extent that this is technically feasible and does not increase risks for the environmental or human health.
(6) Protection and restoration of biodiversity and ecosystems	<p>The activity complies with the criteria set out in Appendix D to this Annex.</p> <p>Where applicable, the introduction of invasive alien species is prevented or their spread is managed in accordance with Regulation (EU) No 1143/2014.</p>

2.4. Remediation of contaminated sites and areas

Description of the activity

The activity includes:

- (a) decontamination or remediation of soils and groundwater in the polluted area, either in situ or ex situ, in particular using physical, chemical or biological methods;
- (b) decontamination or remediation of contaminated industrial plants or sites;
- (c) decontamination or remediation of surface water and its shores following accidental pollution, such as through collection of pollutants or through physical, chemical or biological methods;
- (d) cleaning up oil spills and other types of pollutants on or in:
 - (i) surface water including rivers, lakes, coastal waters or transitional waters;
 - (ii) groundwater as defined in Directive 2000/60/EC;

(2011), Roadmap for Closing Waste Dumpsites (2016) and Landfill Operational Guidelines (2014, 2019).

- (iii) marine water as defined in Directive 2008/56/EC;
- (iv) sediments (for all surface water types);
- (v) aquatic ecosystems;
- (vi) buildings;
- (vii) soil;
- (viii) terrestrial ecosystems ;
- (e) material abatement of hazardous substances, mixtures or products, such as asbestos or lead-based paint;
- (f) other specialised pollution-control activities;
- (g) clean-up after disasters from natural hazards, such as flooding, or earthquake;
- (h) remediation of disused mining sites or legacies not associated with extraction revenues;
- (i) containment operations, hydraulic barriers, active and passive barriers intended to limit or prevent migration of pollutants.

The activity also includes all activities that are required to prepare, plan, monitor and follow-up the decontamination or remediation activity itself, such as:

- (a) preparatory investigations, including data collection and surveying activities (in particular geological or hydrological), technical feasibility and environmental impact studies required to define the remediation project;
- (b) monitoring and control of the remediation measures, including:
 - (i) sampling of soil, water, sediment, biota or other materials;
 - (ii) laboratory analysis of samples to identify the nature and concentration of pollutants;
 - (iii) installation, operation and maintenance of monitoring facilities and equipment such as observation wells in and outside the perimeter of the remediation site;
- (c) demolition of contaminated buildings or other structures, dismantling large-scale machinery and equipment (i.e., decommissioning) and removal of surface sealing and concreting;
- (d) earth moving or dredging, including excavation, landfilling, levelling, construction or reinforcement of perimeter walls or fences, primary access and internal roads and any other activities necessary to operate the decontamination;
- (e) implementation of other environmental protection and pollution prevention and control measures to comply with the conditions imposed in the environmental permit for the remediation project, including measures for safeguarding safety of operations on-site and health of workers (such as for fire control, flood protection, hazardous waste management), protection of workers, site access control, management of invasive species before or during decontamination or remediation, reinforcement operations carried out prior to or during decontamination.

This economic activity does not include:

- (a) pest control in agriculture;
- (b) purification of water for water supply purposes;

- (c) decontamination or remediation of nuclear plants and sites;
- (d) treatment and disposal of hazardous or non-hazardous waste unrelated to the site contamination problem;
- (e) morphological remediation;
- (f) remediation of legally non-conforming landfills and abandoned or illegal waste dumps unrelated to the site under remediation (See Section 2.3. of this Annex);
- (g) emergency services (see Section 14.1. of Annex II to Delegated Regulation (EU) 2021/2139);
- (h) outdoor sweeping and watering of streets.

The economic activities in this category could be associated with several NACE codes, in particular 39, 33.20, 43.11, 43.12, 71.12, 71.20, 74.90, 81.30 in accordance with the statistical classification of economic activities established by Regulation (EC) No 1893/2006.

Technical screening criteria

Substantial contribution to pollution prevention and control

1. Remediation activities are not carried out by the operator⁶⁸ that caused the pollution or a person acting on behalf of that operator in order to comply with the requirements of Directive 2004/35/CE or, for activities located in third countries, with environmental liability provisions based on the ‘polluter-pays’ principle according to national law.

2. The relevant contaminants are removed, controlled, contained or diminished using mechanical, chemical, biological or other methods so that the contaminated area (land, water body or other), taking into account its use at the time of the damage or approved future use of the area, no longer poses any significant risk of adversely affecting human health and the environment⁶⁹, as set out in one of the following:

- (a) national regulatory standards;
- (b) where these standards are not available, an internal site-specific risk-assessment taking into account the characteristic and the extent of the impacted area (land, water body or other), the type, properties (persistence, mobility and toxicity) and concentration of the substances, preparations, organisms or micro-organisms, possible migration pathways and the probability of dispersion⁷⁰.

3. The remediation activity is conducted in line with best industry practice and includes all of the following elements:

- (a) the original operational activity or defective plant and ancillary equipment that led to
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⁶⁸ As defined in Article 2, point 6, of, Directive 2004/35/CE.

⁶⁹ See Directive 2004/35/CE , Annex II, point 2.

⁷⁰ See Directive 2004/35/CE , Annex II, point 2. For activities in third countries, unless more stringent standards are mandatory under national legislation, UNEP Guidance on the management of contaminated sites (UNEP/MC/COP.3/8/Rev.1) - Guidance_Contaminated_Sites_EN.pdf (mercuryconvention.org) are applied.

the contamination has been stopped or addressed so as not to be a potential source of further contamination before any assessment or remediation activity is undertaken (except long-range transboundary air pollution or other unidentifiable diffuse sources);

- (b) preparatory investigations including site-specific surveys and physical, chemical or microbiological data collection are carried out in line with best industry practice and best available techniques to establish the following elements used to define the environmental targets for the remediation and evaluate the remedial options:
 - (i) the location, characteristics and extent of the contaminated site;
 - (ii) the underlying geological and hydrological conditions;
 - (iii) the likely quantity, composition and sources of contamination;
 - (iv) soil and water pollution originating from it as well as the risks to human health and the environment.
- (c) the remedial options are analysed in line with Annex II to Directive 2004/35/CE⁷¹ and the most suitable remedial measures are defined in a dedicated remediation plan, including monitoring requirements and plan;
- (d) any hazardous or non-hazardous waste or contaminated soils extracted or otherwise produced by the remediation activity is subject to appropriate collection, transport, treatment, recovery or disposal by an authorized operator, in accordance with legal requirements and care is taken to prevent any mixing of excavated contaminated soils and non-contaminated soils;
- (e) remediation methods do not include reducing pollutant concentrations through dilution or watering down, unless a full justification, for reason other than cost considerations, is provided in the remediation plan;
- (f) control, monitoring or maintenance activities are carried out in the after-care phase of at least 10 years, unless a different duration sufficient to guarantee long-term risk control is defined in the national law or in the remediation and monitoring plan (see point 4).

4. The specific remediation and monitoring plan is approved by the competent authority in accordance with national legal requirements, following consultation with local stakeholders.

Do no significant harm ('DNSH')

(1) Climate change mitigation	The activity does not involve the degradation of land with high carbon stock ⁷² .
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⁷¹ See Directive 2004/35/CE, Annex II, point 1.3.1.
For activities in third countries, in accordance with equivalent applicable national law or international standards (such as UNEP Guidance on the management of contaminated sites (UNEP/MC/COP.3/8/Rev.1) -Guidance_Contaminated_Sites_EN.pdf (mercuryconvention.org)) requiring remediation based on an alternative, transparently described process and valuation approach to define a suitable strategy, which comprises primary remedial measures (including monitoring requirements), complementary and compensatory remedial measures in a dedicated remediation plan.

	Measures to reduce scope 1 and scope 2 GHG emissions ⁷³ of the full removal or treatment process are included in the remediation plan.
(2) Climate change adaptation	The activity complies with the criteria set out in Appendix A to this Annex.
(3) Sustainable use and protection of water and marine resources	The activity complies with the criteria set out in Appendix B to this Annex.
(4) Transition to a circular economy	At least 70% (by weight) of the non-hazardous construction, demolition or other waste materials (excluding naturally occurring material defined in category 17 05 04 in the European List of Waste established by Decision 2000/532/EC) generated on the site under remediation is prepared for reuse, recycling and other material recovery, including backfilling operations using waste to substitute other materials, in accordance with the waste hierarchy and the EU Construction and Demolition Waste Management Protocol ⁷⁴ , unless a clear justification is given in the approved Remediation Plan based on technical or environmental reasons, other than cost considerations.
(6) Protection and restoration of biodiversity and ecosystems	The activity complies with the criteria set out in Appendix D to this Annex. The following is to be ensured: (a) in the Union, in relation with Natura 2000 sites: the activity does not have significant effects on Natura 2000 sites in view of their conservation objectives on the basis of an appropriate assessment carried out in accordance with Article 6(3) of Directive 92/43/EEC; (b) in the Union, in any area: the activity is not detrimental to the recovery or maintenance of the populations of species protected under Directives 92/43/EEC and 2009/147/EC at a favourable conservation status. The activity is also not detrimental to the recovery or maintenance of the habitat types concerned and protected under

⁷² Land with high-carbon stock means wetlands, including peatland, and continuously forested areas grasslands, mangroves and seagrass meadows within the meaning of Article 29(4)(a), (b) and (c) of Directive (EU) 2018/2001.

⁷³ 'Scope 1 GHG emissions' means the direct greenhouse gas emissions occurring from sources that are owned or controlled by the operator. 'Scope 2 GHG emissions' means the indirect greenhouse gas emissions from the generation of the electricity consumed by the operator.

⁷⁴ EU Construction & Demolition Waste Management Protocol, September 2016: <https://ec.europa.eu/docsroom/documents/20509/>.

Directive 92/43/EEC at a favourable conservation status;

(c) the introduction of invasive alien species is prevented, or their spread is managed in accordance with Regulation (EU) No 1143/2014.

APPENDIX A: GENERIC CRITERIA FOR DNSH TO CLIMATE CHANGE ADAPTATION

I. Criteria

The physical climate risks that are material to the activity have been identified from those listed in the table in Section II of this Appendix by performing a robust climate risk and vulnerability assessment with the following steps:

- (a) screening of the activity to identify which physical climate risks from the list in Section II of this Appendix may affect the performance of the economic activity during its expected lifetime;
- (b) where the activity is assessed to be at risk from one or more of the physical climate risks listed in Section II of this Appendix, a climate risk and vulnerability assessment to assess the materiality of the physical climate risks on the economic activity;
- (c) an assessment of adaptation solutions that can reduce the identified physical climate risk.

The climate risk and vulnerability assessment is proportionate to the scale of the activity and its expected lifespan, such that:

- (a) for activities with an expected lifespan of less than 10 years, the assessment is performed, at least by using climate projections at the smallest appropriate scale;
- (b) for all other activities, the assessment is performed using the highest available resolution, state-of-the-art climate projections across the existing range of future scenarios⁷⁵ consistent with the expected lifetime of the activity, including, at least, 10 to 30 year climate projections scenarios for major investments.

The climate projections and assessment of impacts are based on best practice and available guidance and take into account the state-of-the-art science for vulnerability and risk analysis and related methodologies in line with the most recent Intergovernmental Panel on Climate Change reports⁷⁶, scientific peer-reviewed publications, and open source⁷⁷ or paying models.

For existing activities and new activities using existing physical assets, the economic operator implements physical and non-physical solutions ('adaptation solutions'), over a period of time of up to five years, that reduce the most important identified physical climate risks that are material to that activity. An adaptation plan for the implementation of those solutions is drawn up accordingly.

⁷⁵ Future scenarios include Intergovernmental Panel on Climate Change representative concentration pathways RCP2.6, RCP4.5, RCP6.0 and RCP8.5.

⁷⁶ Assessments Reports on Climate Change: Impacts, Adaptation and Vulnerability, published periodically by the Intergovernmental Panel on Climate Change (IPCC), the United Nations body for assessing the science related to climate change produces, <https://www.ipcc.ch/reports/>.

⁷⁷ Such as Copernicus services managed by the European Commission.

For new activities and existing activities using newly-built physical assets, the economic operator integrates the adaptation solutions that reduce the most important identified physical climate risks that are material to that activity at the time of design and construction and has implemented them before the start of operations.

The adaptation solutions implemented do not adversely affect the adaptation efforts or the level of resilience to physical climate risks of other people, of nature, of cultural heritage, of assets and of other economic activities; are consistent with local, sectoral, regional or national adaptation strategies and plans; and consider the use of nature-based solutions⁷⁸ or rely on blue or green infrastructure⁷⁹ to the extent possible.

II. Classification of climate-related hazards⁸⁰

	Temperature-related	Wind-related	Water-related	Solid mass-related
Chronic	Changing temperature (air, freshwater, marine water)	Changing wind patterns	Changing precipitation patterns and types (rain, hail, snow/ice)	Coastal erosion
	Heat stress		Precipitation or hydrological variability	Soil degradation
	Temperature variability		Ocean acidification	Soil erosion
	Permafrost thawing		Saline intrusion	Solifluction
			Sea level rise	
Acute	Heat wave	Cyclone, hurricane, typhoon	Drought	Avalanche
	Cold wave/frost	Storm (including blizzards, dust and sandstorms)	Heavy precipitation (rain, hail, snow/ice)	Landslide
	Wildfire	Tornado	Flood (coastal,	Subsidence

⁷⁸ Nature-based solutions are defined as ‘solutions that are inspired and supported by nature, which are cost-effective, simultaneously provide environmental, social and economic benefits and help build resilience. Such solutions bring more, and more diverse, nature and natural features and processes into cities, landscapes and seascapes, through locally adapted, resource-efficient and systemic interventions’. Therefore, nature-based solutions benefit biodiversity and support the delivery of a range of ecosystem services.(version of [adoption date]: <https://ec.europa.eu/research/environment/index.cfm?pg=nbs>).

⁷⁹ See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Green Infrastructure (GI) — Enhancing Europe’s Natural Capital (COM/2013/0249 final).

⁸⁰ The list of climate-related hazards in this table is non-exhaustive, and constitutes only an indicative list of most widespread hazards that are to be taken into account as a minimum in the climate risk and vulnerability assessment.

			fluvial, pluvial, ground water)	
			Glacial lake outburst	

APPENDIX B: GENERIC CRITERIA FOR DNSH TO SUSTAINABLE USE AND PROTECTION OF WATER AND MARINE RESOURCES

Environmental degradation risks related to preserving water quality and avoiding water stress are identified and addressed with the aim of achieving good water status and good ecological potential as defined in Article 2, points (22) and (23), of Regulation (EU) 2020/852, in accordance with Directive 2000/60/EC⁸¹ and a water use and protection management plan, developed thereunder for the potentially affected water body or bodies, in consultation with relevant stakeholders.

Where an Environmental Impact Assessment is carried out in accordance with Directive 2011/92/EU and includes an assessment of the impact on water in accordance with Directive 2000/60/EC, no additional assessment of impact on water is required, provided the risks identified have been addressed.

The activity does not hamper the achievement of good environmental status of marine waters or does not deteriorate marine waters that are already in good environmental status as defined in point 5 of Article 3 of Directive 2008/56/EC⁸², taking into account the Commission Decision (EU) 2017/848 in relation to the relevant criteria and methodological standards for those descriptors.

⁸¹ For activities in third countries, in accordance with applicable national law or international standards which pursue equivalent objectives of good water status and good ecological potential, through equivalent procedural and substantive rules, i.e. a water use and protection management plan developed in consultation with relevant stakeholders which ensures that 1) the impact of the activities on the identified status or ecological potential of potentially affected water body or bodies is assessed and 2) deterioration or prevention of good status/ecological potential is avoided or, where this is not possible, 3) justified by the lack of better environmental alternatives which are not disproportionately costly/technically unfeasible, and all practicable steps are taken to mitigate the adverse impact on the status of the body of water.

⁸² The definition laid down in point 5 of Article 3 of Directive 2008/56/EC provides in particular that good environmental status is to be determined on the basis of the qualitative descriptors laid down in Annex I to that Directive.

APPENDIX D: GENERIC CRITERIA FOR DNSH TO PROTECTION AND RESTORATION OF BIODIVERSITY AND ECOSYSTEMS

An Environmental Impact Assessment (EIA) or screening⁸³ has been completed in accordance with Directive 2011/92/EU⁸⁴.

Where an EIA has been carried out, the required mitigation and compensation measures for protecting the environment are implemented.

For sites/operations located in or near biodiversity-sensitive areas (including the Natura 2000 network of protected areas, UNESCO World Heritage sites and Key Biodiversity Areas, as well as other protected areas), an appropriate assessment⁸⁵, where applicable, has been conducted and based on its conclusions the necessary mitigation measures⁸⁶ are implemented.

⁸³ The procedure through which the competent authority determines whether projects listed in Annex II to Directive 2011/92/EU is to be made subject to an environmental impact assessment (as referred to in Article 4(2) of that Directive).

⁸⁴ For activities in third countries, in accordance with equivalent applicable national law or international standards requiring the completion of an EIA or screening, for example, IFC Performance Standard 1: Assessment and Management of Environmental and Social Risks.

⁸⁵ In accordance with Directives 2009/147/EC and 92/43/EEC. For activities located in third countries, in accordance with equivalent applicable national law or international standards, that aim at the conservation of natural habitats, wild fauna and wild flora, and that require to carry out (1) a screening procedure to determine whether, for a given activity, an appropriate assessment of the possible impacts on protected habitats and species is needed; (2) such an appropriate assessment where the screening determines that it is needed, for example IFC Performance Standard 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources.

⁸⁶ Those measures have been identified to ensure that the project, plan or activity will not have any significant effects on the conservation objectives of the protected area.