

COMPARISON TABLE
to the Draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to the Resolutions of the Cabinet of Ministers of Ukraine of May 10, 2024, No. 539 and of July 23, 2024, No. 847"

Content of the provision of the act of legislation	Content of the relevant provision of the draft act
Resolution of the Cabinet of Ministers of Ukraine dated May 10, 2024 No. 539 "On Approval of the Technical Regulations on Hazard Classification, Labeling and Packaging of Chemical Products"	
... 2. To establish that: chemical products that were made available on the market before the entry into force of this Resolution and do not meet the requirements of the Technical Regulation shall be made available on the market within <i>one year</i> from the date of entry into force of this Resolution; There is no norm for chemicals, no hazard classification shall be carried out in accordance with the criteria specified in paragraphs 3.11.2.1-3.11.2.3, 4.2.2.1-4.2.2.3, 4.3.2.1-4.3.2.4, 4.4.2.1-4.4.2.4 of Annex I to the Technical Regulation, and hazard information shall not be provided in accordance with paragraphs 3.11.4.1, 4.2.4.1, 4.3.4.1 and 4.4.4.1 of Annex I to the Technical Regulation. Chemicals shall be made available on the market until <i>November 1, 2026</i>; for mixtures, no hazard classification shall be carried out in accordance with the criteria specified in paragraphs 3.11.2.1-3.11.2.3, 4.2.2.1-4.2.2.3, 4.3.2.1-4.3.2.4, 4.4.2.1-4.4.2.4 of Annex I to the Technical Regulation, and hazard information shall not be provided in accordance with paragraphs 3.11.4.1, 4.2.4.1, 4.3.4.1 and 4.4.4.1 of Annex I to the Technical Regulation. Mixtures shall be made available on the market until <i>1 May 2026, in the event that mixtures are made available on the</i>	... 2. To establish that: chemical products that were made available on the market before the entry into force of this Resolution and do not meet the requirements of the Technical Regulation, shall be made available on the market within 18 months from the date of entry into force of this Resolution; making available on the market of chemical products, the labeling and/or packaging of which does not meet the requirements of Sections 3 and/or 4 of the Technical Regulation and which was put into circulation before January 1, 2027, cannot be prohibited or restricted until July 1, 2028 for reasons of non-compliance with these requirements; for chemicals, no hazard classification is carried out in accordance with the criteria specified in paragraphs 3.11.2.1-3.11.2.3, 4.2.2.1-4.2.2.3, 4.3.2.1-4.3.2.4, 4.4.2.1-4.4.2.4 of Annex I to the Technical Regulation, and no hazard information is provided in accordance with paragraphs 3.11.4.1, 4.2.4.1, 4.3.4.1 and 4.4.4.1 of Annex I to the Technical Regulation. Chemicals are made available on the market until November 15, 2027; for mixtures, hazard classification is not carried out in accordance with the criteria specified in paragraphs 3.11.2.1-3.11.2.3, 4.2.2.1-4.2.2.3, 4.3.2.1-4.3.2.4, 4.4.2.1-4.4.2.4 of Annex I to the Technical Regulation, and hazard information is not entered in accordance with paragraphs 3.11.4.1, 4.2.4.1, 4.3.4.1 and 4.4.4.1 of Annex I to the Technical Regulation. Mixtures are provided on the market until May 1, 2028.

market for the first time after that date, - until May 1, 2028. ...	...
4. The Ministry of Environmental <i>Protection and Natural Resources</i> shall ensure the implementation of the Technical Regulations.	4. The Ministry of Economy , Environment and Agriculture shall ensure the implementation of the Technical Regulations.
Technical Regulations on Hazard Classification, Labeling and Packaging of Chemical Products, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 539 dated May 10, 2024	
... 6. In some cases, by the decision of the <i>Ministry of Environment</i> , the requirements of this Technical Regulation may not be applied to chemical products, if it is necessary in the interests of ensuring the defense of the state. ... 55. Manufacturers and importers of chemicals may decide on their hazard classification in accordance with paragraph 49 of this Technical Regulation, which differs from the hazard classification for identical chemicals specified in the Register of Hazard Classification and Hazard Information Elements of Chemical Products, and, together with proper justification, provide an appropriate notification on the hazard classification and hazard information elements of chemical products. products to <i>the Ministry of Environment</i> in accordance with paragraph 126 of this Technical Regulation. ... 62. If the name in accordance with the IUPAC nomenclature, which is indicated in accordance with subparagraph 1) of paragraph 60 of this Technical Regulation, exceeds 100 characters, one of the other names of the chemical substance, for example, a trivial name, trade name or abbreviation, may be indicated instead, if such an alternative name was	... 6. In some cases, by the decision of the Ministry of Economy , the requirements of this Technical Regulation may not be applied to chemical products, if it is necessary in the interests of ensuring the defense of the state. ... 55. Manufacturers and importers of chemicals may decide on their hazard classification in accordance with paragraph 49 of this Technical Regulation, which differs from the hazard classification for identical chemicals specified in the Register of Hazard Classification and Hazard Information Elements of Chemical Products, and, together with proper justification, provide an appropriate notification on the hazard classification and hazard information elements of chemical products. products to the Ministry of Economy in accordance with paragraph 126 of this Technical Regulation. ... 62. If the name in accordance with the IUPAC nomenclature, which is indicated in accordance with subparagraph 1) of paragraph 60 of this Technical Regulation, exceeds 100 characters, one of the other names of the chemical substance, for example, a trivial name, trade name or abbreviation, may be indicated instead, if such an alternative name was indicated in the notification on the classification of hazards and elements

indicated in the notification on the classification of hazards and elements of information on the hazard of chemical products to the *Ministry of Environment*.

...

75. Manufacturers, importers and subsequent users of chemical products that are a mixture of chemical substances may use an alternative name for a particular chemical substance in the hazard information of chemical products or in the safety data sheet of chemical products instead of the identifier of the chemical substance in accordance with paragraphs 60 - 63 of this Technical Regulation, if the chemical meets the relevant criteria set out in Part A of Annex I to this Technical Regulation, and the manufacturer of chemical products, in accordance with the established Procedure for registration of notifications on the use of an alternative name of a chemical substance, approved by the Cabinet of Ministers of Ukraine, submitted a notification on the use of an alternative name of a chemical substance to the *Ministry of Environment*.

...

121. Authorized bodies in the field of chemical safety and management of chemical products may submit to the *Ministry of Environment* their proposals for the approval of national hazard classifications and information on the hazard of chemicals, specific concentration limits and multipliers for certain chemicals, or proposals for revision of the current approved national hazard classification and information on the hazard of a chemical substance.

122. Manufacturers, importers and subsequent users of chemicals may submit to the *Ministry of Environment* their proposals for the approval of national hazard classifications and hazard information for chemicals, specific concentration limits and multipliers for certain chemicals, provided that there is no corresponding entry for a particular chemical substance in Part B of Annex VI to this Technical Regulation with an approved hazard classification and hazard information for the relevant hazard classes and differentiations within the class, which are indicated in

of information on the hazard of chemical products to the **Ministry of Economy**.

...

75. Manufacturers, importers and subsequent users of chemical products that are a mixture of chemical substances may use an alternative name for a particular chemical substance in the hazard information of chemical products or in the safety data sheet of chemical products instead of the identifier of the chemical substance in accordance with paragraphs 60 - 63 of this Technical Regulation, if the chemical meets the relevant criteria set out in Part A of Annex I to this Technical Regulation, and the manufacturer of chemical products in accordance with the established Procedure for registration of notifications on the use of an alternative name of a chemical substance, approved by the Cabinet of Ministers of Ukraine, submitted a notification on the use of an alternative name of a chemical substance to the **Ministry of Economy**.

...

121. Authorized bodies in the field of chemical safety and management of chemical products may submit to **the Ministry of Economy** their proposals for the approval of national hazard classifications and information on the hazard of chemicals, specific concentration limits and multipliers for certain chemicals, or proposals for the revision of the current approved national hazard classification and information on the hazard of a chemical substance.

122. Manufacturers, importers and subsequent users of chemicals may submit to **the Ministry of Economy** their proposals for the approval of national hazard classifications and information on the hazard of chemicals, specific concentration limits and multipliers for certain chemicals, provided that there is no corresponding entry for a certain chemical substance in Part B of Annex VI to this Technical Regulation with an approved hazard classification and hazard information for the relevant hazard classes and differentiations within the class, which are indicated in the relevant proposal.

the relevant proposal.

...

124. In the event of a decision on the need to amend the List of approved national hazard classifications and elements of information on the hazard of chemicals in accordance with the submitted proposals, the *Ministry of Environment* shall develop a draft regulatory legal act on amendments to Part B of Annex VI to this Technical Regulation.

...

126. Manufacturers, importers, or their groups that provide chemicals on the market, including as part of chemical products, which meet the classification criteria for a particular hazard class or differentiation within the class, which are specified in Parts B – E of Annex I to this Technical Regulation, must submit to the *Ministry of Environment* notification in paper or electronic form by means of information and communication systems about the hazard classification and hazard information for the relevant chemical, which must contain the following information for its inclusion in the Hazard Classification Register and elements of information on the hazard of chemical products:

...

138. *The Ministry of Environment* or the State Market Surveillance Authority may make requests to suppliers of chemical products to provide any information specified in paragraph 136 of this Technical Regulation.

139. If the information specified in paragraph 136 of this Technical Regulation has already been received by the *Ministry of Environment* in the process of state registration of chemicals or in notifications in accordance with paragraph 126 of this Technical Regulation, it shall use this information without requests to suppliers, and the State Market Surveillance Authority shall make relevant requests directly to *the Ministry of Environment*.

...

Annex I to the Technical Regulation

...

124. In the event of a decision on the need to amend the List of approved national hazard classifications and elements of information on the hazard of chemicals in accordance with the submitted proposals, the **Ministry of Economy** shall develop a draft regulatory legal act on amendments to Part B of Annex VI to this Technical Regulation.

...

126. Manufacturers, importers, or their groups that provide chemicals on the market, including as part of chemical products, that meet the classification criteria for a particular hazard class or differentiation within the class, which are specified in Parts B – D of Annex I to this Technical Regulation, must submit to **the Ministry of Economy** notification in paper or electronic form by means of information and communication systems about the hazard classification and hazard information for the relevant chemical, which must contain the following information for its inclusion in the Hazard Classification Register and elements of information on the hazard of chemical products:

...

138. **The Ministry of Economy** or the state market surveillance body may make requests to suppliers of chemical products to provide any information specified in paragraph 136 of this Technical Regulation.

139. If the information specified in paragraph 136 of this Technical Regulation has already been received by the **Ministry of Economy** in the process of state registration of chemicals or in notifications in accordance with paragraph 126 of this Technical Regulation, it shall use this information without requests to suppliers, and the state market surveillance body shall make relevant requests directly to **the Ministry of Economy**.

...

Annex I to the Technical Regulation

APPENDIX I

APPENDIX I HAZARD CLASSIFICATION REQUIREMENTS AND HAZARD INFORMATION FOR HAZARDOUS CHEMICAL PRODUCTS ... 4.1.1.3.2. While these hazard classification criteria apply to all chemicals and their mixtures, it should be noted that in order to carry out a proper hazard classification of certain chemicals, for example, metals, it may become necessary to use special guidelines developed and published by the <i>Ministry of Environment</i>. ... Annex VI to the Technical Regulation APPENDIX VI APPROVED NATIONAL HAZARD CLASSIFICATIONS AND CHEMICAL HAZARD INFORMATION ... 2. PART B. FORMAT FOR SUBMITTING PROPOSALS FOR APPROVAL OF NATIONAL HAZARD CLASSIFICATIONS AND HAZARD INFORMATION This part defines the general principles for the preparation of proposals for the approval of national hazard classifications and hazard information and relevant justifications. When preparing any proposal for the approval of national hazard classifications and hazard information, any information contained in the documents provided by business entities together with the application for state registration of a chemical substance, which is available in the Chemical Safety Information System, as well as other available reliable information, must be taken into account. If previously available information on the hazardous properties of	HAZARD CLASSIFICATION REQUIREMENTS AND HAZARD INFORMATION FOR HAZARDOUS CHEMICAL PRODUCTS ... 4.1.1.3.2. While the specified hazard classification criteria apply to all chemicals and their mixtures, it should be noted that in order to carry out a proper hazard classification of certain chemicals, for example, metals, it may become necessary to use special guidelines developed and published by the Ministry of Economy. ... Annex VI to the Technical Regulation APPENDIX VI APPROVED NATIONAL HAZARD CLASSIFICATIONS AND CHEMICAL HAZARD INFORMATION ... 2. PART B. FORMAT FOR SUBMITTING PROPOSALS FOR APPROVAL OF NATIONAL HAZARD CLASSIFICATIONS AND HAZARD INFORMATION This part defines the general principles for the preparation of proposals for the approval of national hazard classifications and hazard information and relevant justifications. When preparing any proposal for the approval of national hazard classifications and hazard information, any information contained in the documents provided by business entities together with the application for state registration of a chemical substance, which is available in the Chemical Safety Information System, as well as other available reliable information, must be taken into account. If previously available information on the hazardous properties of chemicals, which is necessary for the hazard classification, was not provided to the Ministry of Economy, the proposal must indicate reliable
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chemicals, which is necessary for the hazard classification, has not been provided to the *Ministry of Environment*, the proposal must indicate reliable and properly documented results of the relevant tests.

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Annex VII to the Technical Regulation
ANNEX VII

INFORMATION PROVIDED FOR THE DEVELOPMENT OF
EMERGENCY MEDICAL CARE MEASURES IN CASE OF DAMAGE
BY CHEMICAL PRODUCTS AND PREVENTIVE MEASURES

...

3.1. Manufacturers, importers and subsequent users of chemical products who provide mixtures of chemical substances classified as hazardous by physical hazards or hazards to human health on the market must provide information to the Ministry of Health for the development of preventive and therapeutic measures, in particular measures for the provision of emergency or emergency medical care in case of damage by appropriate mixtures.

Part B of this Annex sets out the requirements for the information to be provided. This information must be provided by electronic means in XML format, which is developed and published on its website of the *Ministry of Environment*.

...

3.4. The intended use of the mixture must be indicated in accordance with the product categorization system developed by the *Ministry of Environment*.

...

5.1. The applicant must create a unique identifier of the formula, hereinafter referred to as the UIF, by electronic means developed by the *Ministry of Environment*. The UIF is a unique alphanumeric code that uniquely connects the information provided about the composition of a

and properly documented results of the relevant tests.

...

Annex VII to the Technical Regulation
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INFORMATION PROVIDED FOR THE DEVELOPMENT OF
EMERGENCY MEDICAL CARE MEASURES IN CASE OF DAMAGE
BY CHEMICAL PRODUCTS AND PREVENTIVE MEASURES

...

3.1. Manufacturers, importers and subsequent users of chemical products who provide mixtures of chemical substances classified as hazardous by physical hazards or hazards to human health on the market must provide information to the Ministry of Health for the development of preventive and therapeutic measures, in particular measures for the provision of emergency or emergency medical care in case of damage by appropriate mixtures.

Part B of this Annex sets out the requirements for the information to be provided. This information must be provided by electronic means in XML format, which is developed and published on the website of **the Ministry of Economy**.

...

3.4. The intended use of the mixture must be indicated in accordance with the product categorization system developed by **the Ministry of Economy**.

...

5.1. The applicant must create a unique identifier of the formula, hereinafter referred to as the UIF, using electronic means developed by the **Ministry of Economy**. The UIF is a unique alphabetic-numeric code that uniquely connects the information provided about the composition of a mixture or group of mixtures with a specific mixture or group of mixtures.

mixture or group of mixtures with a specific mixture or group of mixtures. ... 6.1. <i>The Ministry of Environment</i> develops, maintains and updates the UIF generator, the XML format for providing information and the product categorization system, and must also publish them free of charge on its website. 6.2. <i>The Ministry of Environment</i> provides technical and scientific guidance, technical support and tools that facilitate the provision of information by applicants to the Ministry of Health. ... PART B FORMAT FOR PROVIDING INFORMATION 1.1. Format for providing information Relevant information should be provided to the Ministry of Health in a format determined by the <i>Ministry of Environment</i>. The format for providing information should include the following elements:	... 6.1. The Ministry of Economy develops, maintains and updates the UIF generator, the XML format for providing information and the product categorization system, and must also publish them free of charge on its website. 6.2. The Ministry of Economy provides technical and scientific guidance, technical support and tools that facilitate the provision of information by applicants to the Ministry of Health. ... PART B FORMAT FOR PROVIDING INFORMATION 1.1. Format of information provision Relevant information should be provided to the Ministry of Health in a format determined by the Ministry of Economy. The format of information provision should include the following elements:
Resolution of the Cabinet of Ministers of Ukraine dated July 23, 2024 No. 847 "On Approval of the Technical Regulation on the Safety of Chemical Products"	
... 2. To establish that: 1) chemical products that were made available on the market before the entry into force of this Resolution and do not meet the requirements of the Technical Regulations shall be made available on the market within <i>a year</i> from the date of entry into force of this Resolution; 2) paragraphs 17, 18, 20, 21, 67 and 72 of the Technical Regulation do not apply if the existing chemical is produced or made available on the market: in a weight quantity of 1000 tons per year or more - until October 1 , 2026; in weight quantities from 100 to 1000 tons per year - until June 1,	... 2. To establish that: 1) chemical products that were made available on the market before the entry into force of this Resolution and do not meet the requirements of the Technical Regulation, shall be made available on the market within 18 months from the date of entry into force of this Resolution; 2) paragraphs 17, 18, 20, 21, 67 and 72 of the Technical Regulation do not apply if the existing chemical is produced or made available on the market: in a weight quantity of 1000 tons per year or more - until October 1 , 2029; in weight quantities from 100 to 1000 tons per year - until June 1,

2028; in weight quantities from 1 to 100 tons per year - until March 1, 2030;	2031; in weight from 1 to 100 tons per year - until March 1, 2033;
3) <i>subparagraph 2 of this paragraph does not apply to an existing chemical substance that meets the criteria for hazard classification in accordance with the Technical Regulation on Hazard Classification, Labeling and Packaging of Chemical Products, approved by the Resolution of the Cabinet of Ministers of Ukraine dated May 10, 2024, No. 539 (Official Gazette of Ukraine, 2024, No. 46, Article 2864):</i> ...	3) paragraphs 17, 18, 20, 21, 67 and 72 of the Technical Regulation shall not apply until October 1, 2028, if the existing chemical meets the hazard classification criteria in accordance with the Technical Regulation on the Hazard Classification, Labeling and Packaging of Chemical Products, approved by the Resolution of the Cabinet of Ministers of Ukraine dated May 10, 2024 No. 539 (Official Gazette of Ukraine, 2024, No. 46, Century. 2864): ...
3. The Ministry of Environmental <i>Protection and Natural Resources shall</i> ensure the implementation of the Technical Regulations.	3. The Ministry of Economy , Environment and Agriculture shall ensure the implementation of the Technical Regulations.
Technical Regulation on the Safety of Chemical Products, approved by the Resolution of the Cabinet of Ministers of Ukraine dated July 23, 2024 No. 847	
... 7. In some cases, by the decision of the <i>Ministry of Environment</i> , the requirements of this Technical Regulation may not be applied to chemical products, if it is necessary in the interests of ensuring the defense of the state. ... 13. For the purposes of this Technical Regulation, the following terms are given are used in the following sense:... assessment of chemical substances – an in-depth study of the hazardous properties of chemicals by the <i>Ministry of Environment</i> and authorized bodies in the field of chemical safety and management of chemical products, if there are doubts about the adequacy and effectiveness of risk control measures to ensure the safety of chemical products, identified by registrants in the Technical Dossiers and Reports on the safety of a chemical substance; ... 16. In the cases provided for in paragraph 15 of this Technical Regulation,	... 7. In some cases, by the decision of the Ministry of Economy , the requirements of this Technical Regulation may not be applied to chemical products, if it is necessary in the interests of ensuring the defense of the state. ... 13. For the purposes of this Technical Regulation, the following terms are given are used in the following sense:... assessment of chemicals – an in-depth study of the hazardous properties of chemicals by the Ministry of Economy and authorized bodies in the field of chemical safety and management of chemical products, if there are doubts about the adequacy and effectiveness of risk control measures to ensure the safety of chemical products, identified by registrants in the Technical Dossiers and Reports on the safety of a chemical substance; ... 16. In the cases provided for in paragraph 15 of this Technical Regulation, the Ministry of Economy shall not disclose data identifying the

the *Ministry of Environment* shall not disclose data identifying the manufacturer or importer to other manufacturers, importers or their authorized representatives, except for cases when these data must be provided in full to the bodies authorized to carry out state supervision (control) in the field of chemical safety and management of chemical products, the National Police of Ukraine, the Security Service of Ukraine at their request.

...

18. A manufacturer or importer who produces, imports or makes available on the market a chemical substance in the amount of one ton per year or more, or in total as part of any types of chemical products, must submit to *the Ministry of Environment* an application for state registration of a chemical substance in paper or electronic form by means of the Unified State Web Portal of Electronic Services (hereinafter referred to as the Diia Portal) (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety....

20. The manufacturer or importer of the polymer must submit an application in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety for the state registration of monomers and other chemicals in the composition of the polymer to the *Ministry of Environment*, if the monomers and other chemicals in the polymer have not previously been registered by the previous bidder, and if both of the following conditions are met:

...

21. The manufacturer or importer of the product must submit to *the Ministry of Environment* an application in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety for state registration of chemicals that are part of the product, if both of the following conditions are met:

manufacturer or importer to other manufacturers, importers or their authorized representatives, except for cases when these data must be provided in full to the bodies authorized to carry out state supervision (control) in the field of chemical safety and management of chemical products, the National Police of Ukraine, the Security Service of Ukraine at their request.

...

18. A manufacturer or importer who produces, imports or makes available on the market a chemical substance in the amount of one ton per year or more, or in total as part of any types of chemical products, must submit to **the Ministry of Economy** an application for state registration of a chemical substance in paper or electronic form by means of the Unified State Web Portal of Electronic Services (hereinafter referred to as the Diia Portal) (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety.

...

20. The manufacturer or importer of the polymer must submit an application in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety for the state registration of monomers and other chemicals as part of the polymer to the **Ministry of Economy**, if the monomers and other chemicals in the polymer have not previously been registered by the previous bidder, and if both of the following conditions are met:

...

21. The manufacturer or importer of the product must submit **an application to the Ministry of Economy** in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Chemical Safety Information System for the state registration of chemicals that are part of the product, if both of the following conditions are met:

...

... 22. The manufacturer or importer of the product must provide the <i>Ministry of Environment</i> with a notification on the chemical substance in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Chemical Safety Information System in accordance with paragraph 24 of this Technical Regulation, if such a chemical meets the criteria, which are set out in paragraph 258 of this Technical Regulation and are prioritized in accordance with subparagraph 1 of paragraph 260 of this Technical Regulation, and both of the following conditions are met: ... 27. An application for state registration of a chemical substance under the simplified procedure of state registration shall be submitted to <i>the Ministry of Environment</i> in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Information System for Ensuring Chemical Safety and the documents attached to it: ... 32. In order to apply the exemption in accordance with paragraph 31 of this Technical Regulation, the manufacturer or importer of chemical products, or the manufacturer of the product, must submit to the <i>Ministry of Environment</i> a notification on the use of a chemical substance for scientific (scientific, technical) work in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local authorities integrated with it. Self-Government, the Information System for Ensuring Chemical Safety, noting the following information: ... 33. <i>The Ministry of Environment</i> checks the completeness of the information provided in the notification, assigns the number and date to the notification, and within three days provides them to the applicant, and upon request to the authorized bodies in the field of chemical safety and management of chemical products and bodies authorized to carry out state	22. The manufacturer or importer of the product must submit to the Ministry of Economy a notification on a chemical substance in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Chemical Safety Information System in accordance with paragraph 24 of this Technical Regulation, if such a chemical meets the criteria, which are set out in paragraph 258 of this Technical Regulation and are prioritized in accordance with subparagraph 1 of paragraph 260 of this Technical Regulation, and both of the following conditions are met: ... 27. An application for state registration of a chemical substance under the simplified procedure of state registration shall be submitted to the Ministry of Economy in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, the Chemical Safety Information System and the documents attached to it: ... 32. In order to apply the exemption in accordance with paragraph 31 of this Technical Regulation, the manufacturer or importer of chemical products, or the manufacturer of the product, must submit to the Ministry of Economy a notification on the use of a chemical substance for scientific (scientific) work in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local authorities integrated with it. Self-Government, the Information System for Ensuring Chemical Safety, noting the following information: ... 33. The Ministry of Economy checks the completeness of the information provided in the notification, assigns the number and date to the notification, and provides them to the applicant and, upon request, to the authorized bodies in the field of chemical safety and management of chemical products and bodies authorized to carry out state supervision (control) in the field of chemical safety and management of chemical products.
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supervision (control) in the field of chemical safety and management of chemical products.

34. *The Ministry of Environment* shall make a decision on the imposition of special conditions in order to ensure the use of the chemical substance in conditions of proper exposure control in accordance with the requirements of the national legislation on labor protection and the environment only by the company's personnel, or by the specified consumers, with whom it is envisaged to cooperate in carrying out scientific (scientific and technical) work, as well as in order to prevent any supply of the chemical substance to the general public, and to ensure that, that the residual quantities of the chemical will be collected for treatment as waste after the expiry of the period of exemption from state registration in accordance with paragraph 31 of this Technical Regulation, as well as provide this decision in paper or electronic form.

35. A manufacturer or importer of chemical products may start production or import of a chemical substance not earlier than fourteen calendar days from the date of notification on the use of a chemical substance for scientific (scientific and technical) work, and must comply with all special conditions that were determined by the decision of the *Ministry of Environment* in accordance with paragraph 34 of this Technical Regulation.

36. *The Ministry of Environment* shall decide to extend the five-year period of exemption from state registration for a maximum of five years, or in the case of the use of chemicals exclusively for the development of medicines or veterinary drugs, or for chemicals that are not provided on the Ukrainian market – to extend the exemption period for a maximum of ten years at the request of the manufacturer or importer or manufacturer of products, if such extension is justified by the program of scientific (scientific and technical) work.

37. *The Ministry of Environment* sends draft decisions adopted in accordance with paragraphs 34 and 36 of this Technical Regulation to the authorized body in the field of chemical safety and management of chemical products and makes decisions taking into account the comments and proposals submitted to them.

38. *The Ministry of Environment* ensures the confidentiality of

34. **The Ministry of Economy** shall make a decision on the imposition of special conditions in order to ensure the use of the chemical substance in conditions of proper exposure control in accordance with the requirements of the national legislation on labor protection and environment only by the company's personnel, or by the specified consumers, with whom it is envisaged to cooperate in carrying out scientific (scientific and technical) work, as well as in order to prevent any supply of the chemical substance to the general public, and to ensure that, that the residual quantities of the chemical will be collected for treatment as waste after the expiry of the period of exemption from state registration in accordance with paragraph 31 of this Technical Regulation, as well as provide this decision in paper or electronic form.

35. A manufacturer or importer of chemical products may start production or import of a chemical substance not earlier than fourteen calendar days from the date of notification on the use of a chemical substance for scientific (scientific and technical) work, and must comply with all special conditions that were determined by the decision of the **Ministry of Economy** in accordance with paragraph 34 of this Technical Regulation.

36. **The Ministry of Economy** shall decide to extend the five-year period of exemption from state registration for a maximum of another five years, or in the case of the use of chemicals exclusively for the development of medicines or veterinary drugs, or for chemicals that are not provided on the Ukrainian market – to extend the exemption period for a maximum of ten years at the request of the manufacturer or importer or manufacturer of products, if such extension is justified by the program of scientific (scientific and technical) work.

37. **The Ministry of Economy** sends draft decisions adopted in accordance with paragraphs 34 and 36 of this Technical Regulation to the authorized body in the field of chemical safety and management of chemical products and makes decisions taking into account the comments and proposals provided to them.

38. **The Ministry of Economy** shall ensure the confidentiality of information received from the applicant.

39. The applicants have the right to appeal against the decisions taken by **the Ministry of Economy** in court in accordance with the requirements of

information received from the applicant. 39. Applicants have the right to appeal against decisions made by the <i>Ministry of Environment</i> in court in accordance with the requirements of the current legislation. 48. In the event that the production or import of a registered chemical for one manufacturer or importer reaches the following tonnage range, the manufacturer or importer shall inform the <i>Ministry of Environment</i> as soon as possible of the additional information that it must provide in accordance with paragraph 47 of this Technical Regulation. ... 54. Ecotoxicological and toxicological tests should be carried out according to the relevant methods of the Organization for Economic Co-operation and Development (OECD) according to the principles of Good Laboratory Practice (GLP) in accredited testing laboratories, or other international standards defined by the <i>Ministry of Environment</i> as equivalent. ... 66. Other chemical substances that are produced or imported in the amount of one ton per year or more, or in total as part of any types of chemical products, exclusively <i>for production as part of</i> plant protection products (pesticides) or disinfectants (biocides) are subject to state registration of the chemical substance in accordance with the provisions of Section 2 of this Technical Regulation. ... 67. Any producer of an on-site intermediate chemical in the amount of one ton per year or more must submit an application to the <i>Ministry of Environment</i> for state registration of a chemical substance in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, Information system for ensuring chemical safety. ... 72. Any manufacturer or importer of an isolated intermediate chemical	the current legislation. ... 48. In case of production or import of a registered chemical for one manufacturer or importer reaches the following tonnage range, the manufacturer or importer shall inform the Ministry of Economy as soon as possible of the additional information that he must provide in accordance with paragraph 47 of this Technical Regulation. ... 54. Ecotoxicological and toxicological tests should be carried out according to the relevant methods of the Organization for Economic Co-operation and Development (OECD) according to the principles of Good Laboratory Practice (GLP) in accredited testing laboratories, or other international standards determined by the Ministry of Economy as equivalent. ... 66. Other chemical substances that are produced or imported as separate substances in the amount of one ton per year or more, or in total as part of any types of chemical products, solely for the purpose of production of plant protection products (pesticides) or disinfectants (biocides) are subject to state registration of the chemical substance in accordance with the provisions of Section 2 of this Technical Regulation. ... 67. Any producer of an on-site isolated chemical in the amount of one ton per year or more must submit an application to the Ministry of Economy for state registration of a chemical substance in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, Information system for ensuring chemical safety. ... 72. Any manufacturer or importer of an isolated intermediate chemical that is transported in the amount of one ton per year or more must submit an application for state registration of a chemical to the Ministry of Economy in paper or electronic form by means of the Diia Portal (if technically possible), including through information systems of state authorities and local self-government bodies integrated with it,
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that is transported in the amount of one ton per year or more must submit an application for state registration of a chemical to the *Ministry of Environment* in paper or electronic form by means of the Diia Portal (if technically possible), including through the information systems of state authorities and local self-government bodies integrated with it, Information system for ensuring chemical safety.

...

83. *The Ministry of Environment* registers an application for state registration of a chemical substance for its use in any correspondence before the completion of the procedure for state registration of a chemical substance, the date of state registration of a chemical substance, subject to the successful completion of this procedure, is considered to be the date of registration of the application.

84. *The Ministry of Environment shall* check the completeness of the information provided in each application for state registration of a chemical substance and the documents attached thereto in accordance with paragraphs 40, 47, 68, 73 of this Technical Regulation, as well as check the payment for the state registration of a chemical substance within three weeks from the date of submission of the application for state registration of a chemical substance. Verification of the completeness of the information provided shall not provide for an assessment of the quality or adequacy of the information or consideration of any justifications, but must provide for consideration of the results of analytical studies carried out for the purpose of identifying the chemical, which must correspond to the information about the chemical.

85. If the results of the inspection indicate that the documents attached to the application for state registration of a chemical substance have not been provided in full or do not include the necessary information, the *Ministry of Environment*, before the expiration of the three-week period in accordance with paragraph 84 of this Technical Regulation, shall inform the applicant for state registration of a chemical substance in paper or electronic form that, what additional information must be provided to complete the procedure for state registration of a chemical substance, as well as to set a deadline for its submission.

86. An applicant for state registration of a chemical substance shall

Information system for ensuring chemical safety.

...

83 of the **Ministry of Economy** registers an application for state registration of a chemical substance for its use in any correspondence before the completion of the procedure for state registration of a chemical substance, the date of state registration of a chemical substance, subject to the successful completion of this procedure, is considered to be the date of registration of the application.

84. **The Ministry of Economy shall** check the completeness of the information provided in each application for state registration of a chemical substance and the documents attached thereto in accordance with paragraphs 40, 47, 68, 73 of this Technical Regulation, as well as check the payment for the state registration of a chemical substance within three weeks from the date of submission of the application for state registration of a chemical substance. Verification of the completeness of the information provided shall not be provide for an assessment of the quality or adequacy of the information or consideration of any justifications, but must provide for consideration of the results of analytical studies carried out for the purpose of identifying the chemical, which must correspond to the information about the chemical.

85. If the results of the inspection indicate that the documents attached to the application for state registration of a chemical substance have not been provided in full or do not include the necessary information, the **Ministry of Economy**, before the expiration of the three-week period in accordance with paragraph 84 of this Technical Regulation, shall inform the applicant for state registration of a chemical substance in paper or electronic form that, what additional information must be provided to complete the procedure for state registration of a chemical substance, as well as to set a deadline for its submission.

86. An applicant for state registration of a chemical substance shall accordingly supplement the application for state registration of a chemical substance and submit it together with the documents attached to the application to the **Ministry of Economy** within the established deadline.

87. Upon receipt of the amended application for state registration of a chemical substance in accordance with paragraphs 85 and 86 of this

accordingly supplement the application for state registration of a chemical substance and submit it together with the documents attached to the application to the *Ministry of Environment* within the established deadline.

87. Upon receipt of an amended application for state registration of a chemical substance in accordance with paragraphs 85 and 86 of this Technical Regulation, the *Ministry of Environment* shall re-verify the information provided in accordance with paragraph 84 of this Technical Regulation.

88. *The Ministry of Environment* shall make a decision on refusal of state registration of a chemical substance and notify the applicant thereof in paper or electronic form, if the applicant for state registration of a chemical substance has not provided all the necessary information as part of an amended application for state registration of a chemical substance within the established deadline, or if the results of analytical studies conducted for the purpose of identification of a chemical substance, do not correspond to the information about the chemical.

89. If the *Ministry of Environment* confirms the completeness of the information provided in the application for state registration of a chemical substance, the number and date of state registration of a chemical substance shall be assigned and provided to the registrant, who shall subsequently use them in any correspondence regarding state registration.

90. Upon completion of the procedure for state registration of a chemical substance, *the Ministry of Environment* shall enter the relevant data into the State Register of Chemicals.

91. If a new applicant for state registration of a chemical substance has provided additional new information in its application for state registration of a chemical substance, the *Ministry of Environment* shall notify other registrants of an identical chemical substance within three weeks that new information is available in the State Register of Chemicals.

92. The registrant shall update his/her technical dossier and/or report on the safety of the chemical substance with the introduction of relevant new information and provide relevant information to *the Ministry of Environment* in the following cases:

Technical Regulation, **the Ministry of Economy** shall re-verify the information provided in accordance with paragraph 84 of this Technical Regulation.

88. **The Ministry of Economy** shall make a decision on refusal of state registration of a chemical substance and notify the applicant thereof in paper or electronic form, if the applicant for state registration of a chemical substance has not provided all the necessary information as part of the supplemented application for state registration of a chemical substance within the established deadline, or if the results of analytical studies conducted for the purpose of identifying a chemical substance, do not correspond to the information about the chemical.

89. If the **Ministry of Economy** confirms the completeness of the information provided in the application for state registration of a chemical substance, the number and date of state registration of a chemical substance shall be assigned and provided to the registrant, who shall subsequently use them in any correspondence regarding state registration.

90. Upon completion of the procedure for state registration of a chemical substance, **the Ministry of Economy** shall enter the relevant data into the State Register of Chemicals.

91. If a new applicant for state registration of a chemical substance has provided additional new information in its application for state registration of a chemical substance, the **Ministry of Economy** shall notify other registrants of the identical chemical substance within three weeks that new information is available in the State Register of Chemicals.

92. The registrant shall update his/her technical dossier and/or report on the safety of the chemical substance with the introduction of relevant new information and provide relevant information to **the Ministry of Economy** in the following cases:

...

93. In the event of a change in accordance with subparagraph 1 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier to **the Ministry of Economy** no later than three months after the change has occurred.

94. In case of changes in accordance with subparagraph 2 of paragraph 92

... 93. In the event of a change in accordance with subparagraph 1 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier to <i>the Ministry of Environment</i> no later than three months after the change has occurred. 94. In case of changes in accordance with subparagraph 2 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier to <i>the Ministry of Environment</i> no later than three months after the changes have occurred. 95. In case of changes in accordance with subparagraph 3 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the <i>Ministry of Environment</i> no later than three months after the following date: ... 96. Paragraph 95 of this Technical Regulation does not apply to the case of resumption of production or import after cessation. Instead, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the <i>Ministry of Environment</i> before starting the resumption of production or import. 97. In case of changes in accordance with subparagraph 4 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to <i>the Ministry of Environment</i> no later than three months after the following date: ... 98. In case of changes in accordance with subparagraph 5 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the <i>Ministry of Environment</i> no later than six months after receiving new information on the risks of negative effects of the chemical on human health or the environment. 99. In case of change in accordance with subparagraph 6 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to	of this Technical Regulation, the registrant must submit an updated technical dossier to the Ministry of Economy no later than three months after the changes have occurred. 95. In case of changes in accordance with subparagraph 3 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the Ministry of Economy no later than three months after the following date: ... 96. Paragraph 95 of this Technical Regulation does not apply to the case of resumption of production or imports after cessation. Instead, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the Ministry of Economy before starting the resumption of production or imports. 97. In case of change in accordance with subparagraph 4 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the Ministry of Economy no later than three months after the following date: ... 98. In the event of a change in accordance with subparagraph 5 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to the Ministry of Economy no later than six months after receiving new information on the risks of negative effects of the chemical on human health or the environment. 99. In case of changes in accordance with subparagraph 6 of paragraph 92 of this Technical Regulation, the registrant must provide an updated technical dossier and an updated report on the safety of the chemical to the Ministry of Economy no later than: ... 100. In case of changes in accordance with subparagraph 7 of paragraph 92 of this Technical Regulation, the registrant must submit an updated Technical Dossier and an updated report on the safety of a chemical to the Ministry of Economy no later than twelve months after the
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the *Ministry of Environment* no later than:

...

100. In the event of a change in accordance with subparagraph 7 of paragraph 92 of this Technical Regulation, the registrant must submit an updated Technical Dossier and an updated report on the safety of a chemical to the *Ministry of Environment* no later than twelve months after the amendment of the report on the safety of a chemical substance or instructions for safe use.

101. In the event of a change in accordance with subparagraph 8 of paragraph 92 of this Technical Regulation, the registrant shall submit an updated technical dossier and an updated report on the safety of the chemical to the *Ministry of Environment* no later than six months after the date on which the registrant determined the need to conduct new tests on vertebrate animals, in accordance with Annex IX or Annex X to this Technical Regulation. In the case of registration of a group of chemicals, the deadline for granting The update is twelve months.

102. In the event of a change in accordance with subparagraph 9 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier to the *Ministry of Environment* no later than three months after the changes have taken place.

103. In case of changes simultaneously in accordance with several subparagraphs of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and/or an updated report on the safety of a chemical to the *Ministry of Environment* at the latest deadline specified in paragraphs 93-103 of this Technical Regulation.

In the event of changes simultaneously in accordance with more than one subparagraph of paragraph 92, including amendments to the chemical safety report or instructions for safe use, the registrant must submit an updated chemical safety report to the *Ministry of Environment* no later than 12 months from the date of receipt of the test results required for the update.

104. By way of derogation from the requirements of paragraphs 93-102 of this Technical Regulation, if the update by the registrant in accordance with paragraph 92 of this Technical Regulation depends on the previous update of the technical dossier and/or the report on the safety of the

amendment of the report on the safety of a chemical substance or instructions for safe use.

101. In the event of a change in accordance with subparagraph 8 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and an updated report on the safety of the chemical to **the Ministry of Economy** no later than six months after the date on which the registrant determined the need to conduct new tests on vertebrate animals, in accordance with Annex IX or Annex X to this Technical Regulation. In the case of registration of a group of chemicals, the deadline for providing an update is twelve months.

102. In the event of a change in accordance with subparagraph 9 of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier to **the Ministry of Economy** no later than three months after the changes have occurred.

103. In case of changes simultaneously in accordance with several subparagraphs of paragraph 92 of this Technical Regulation, the registrant must submit an updated technical dossier and/or an updated report on the safety of a chemical substance to the **Ministry of Economy** at the latest deadline specified in paragraphs 93-103 of this Technical Regulation.

In the event of changes simultaneously in accordance with more than one subparagraph of paragraph 92, including amendments to the chemical safety report or instructions for safe use, the registrant must submit an updated chemical safety report to the **Ministry of Economy** no later than 12 months from the date of receipt of the test results required for the update.

104. By way of derogation from the requirements of paragraphs 93-102 of this Technical Regulation, if the update by the registrant in accordance with paragraph 92 of this Technical Regulation depends on the previous update of the technical dossier and/or the report on the safety of the chemical by the lead registrant, then other registrants of the identical chemical must update their technical dossiers and submit them to the **Ministry of Economy**:

...

105. The registrant shall submit to **the Ministry of Economy** an updated technical dossier after entering information in accordance with the

chemical by the lead registrant, then other registrants of the identical chemical must update their technical dossiers and submit them to the *Ministry of Environment*:

...

105. The registrant shall submit to the *Ministry of Environment* an updated technical dossier after entering information in accordance with the decisions of the *Ministry of Environment*, which are adopted in accordance with paragraphs 211, 216, 232 of this Technical Regulation, no later than the deadline for providing the update, which is specified in the relevant decision.

106. The *Ministry of Environment* shall check the completeness of the information provided in each updated technical dossier in accordance with paragraph 84 of this Technical Regulation.

107. The *Ministry of Environment*, after verifying the completeness of the information provided specified in paragraph 106 of this Technical Regulation, shall notify other registrants of an identical chemical substance that new information on a particular registrant is available in the State Register of Chemicals.

...

109. If the technical dossier is updated in accordance with subparagraph 3 of paragraph 92 of this Technical Regulation, the submission of such an update to the *Ministry of Environment* is considered to be the submission of a new application for state registration of a chemical substance.

...

113. Any summaries of studies or other research results submitted by registrants to the *Ministry of Environment* to comply with the requirements of this Technical Regulation may be freely used by other manufacturers or importers for the purposes of state registration of chemicals in accordance with this Technical Regulation twelve years after their submission to the *Ministry of Environment*.

114. Applicants for state registration of new chemicals or existing chemicals that have not passed the procedure of preliminary state registration of a chemical substance in accordance with paragraph 140 of this Technical Regulation must make a request to the *Ministry of Environment* for information on state registration of an identical chemical

decisions of the **Ministry of Economy**, which are adopted in accordance with paragraphs 211, 216, 232 of this Technical Regulation, no later than the deadline for providing the update, which is specified in the relevant decision.

106. The **Ministry of Economy** checks the completeness of the information provided in each updated technical dossier in accordance with paragraph 84 of this Technical Regulation.

107. The **Ministry of Economy**, after verifying the completeness of the information provided specified in paragraph 106 of this Technical Regulation, shall notify other registrants of an identical chemical substance that new information on a particular registrant is available in the State Register of Chemicals.

...

109. If the technical dossier is updated in accordance with subparagraph 3 of paragraph 92 of this Technical Regulation, the submission of such an update to the **Ministry of Economy** is considered to be the submission of a new application for state registration of a chemical substance.

...

113. Any summaries of studies or other research results submitted by registrants to the **Ministry of Economy** to comply with the requirements of this Technical Regulation may be freely used by other manufacturers or importers for the purposes of state registration of chemicals in accordance with this Technical Regulation twelve years after their submission to the **Ministry of Economy**.

114. Applicants for state registration of new chemicals or existing chemicals that have not passed the procedure of preliminary state registration of a chemical substance in accordance with paragraph 140 of this Technical Regulation must make a request to the **Ministry of Economy** for information on state registration of an identical chemical substance in accordance with the provisions of this Technical Regulation by other business entities.

...

116. If an identical chemical substance has not previously been registered in accordance with the provisions of this Technical Regulation, the **Ministry of Economy** shall notify the business entity that made the

substance in accordance with the provisions of this Technical Regulation by other business entities.

...

116. If an identical chemical has not previously been registered in accordance with the provisions of this Technical Regulation, the *Ministry of Environment* shall notify the business entity that made the request in accordance with paragraph 114 of this Technical Regulation.

117. In the event that an identical chemical has already been registered earlier, but less than 12 years ago, in accordance with the provisions of this

of the Technical Regulation, the *Ministry of Environment* shall provide the business entity that has made a request in accordance with paragraph 114 of this Technical Regulation with the names and contact details of all registrants of this chemical substance and a list of summaries of studies provided by them, as well as at the same time provide these registrants with the name and contact details of such a business entity.

Studies on vertebrate animals cannot be repeated. With regard to the available research results, data exchange with the applicant for state registration of a chemical substance should be carried out in accordance with paragraphs 119-139 of this Technical Regulation.

118. In the event that several business entities have made requests in accordance with paragraph 114 of this Technical Regulation for an identical chemical substance, the *Ministry of Environment* shall provide each of these business entities with the names and contact details of all business entities that have made such a request.

...

127. The model of proportional allocation and reimbursement of costs in accordance with subparagraph 3 of paragraph 121 of this Technical Regulation shall contain provisions on the allocation of costs for activities that may need to be carried out as a result of the adoption of decisions of the *Ministry of Environment* during the assessment of chemicals in accordance with paragraph 229 of this Technical Regulation.

128. When developing a model for proportional allocation and reimbursement of costs in accordance with subparagraph 3 of paragraph 121 of this Technical Regulation, the number of potential registrants and

request in accordance with paragraph 114 of this Technical Regulation.

117. In the event that an identical chemical has already been registered earlier, but less than 12 years ago, in accordance with the provisions of this

of the Technical Regulation, the **Ministry of Economy** shall provide the business entity that has made a request in accordance with paragraph 114 of this Technical Regulation with the names and contact details of all registrants of this chemical substance and a list of summaries of studies provided by them, as well as at the same time provide these registrants with the name and contact details of such a business entity.

Studies on vertebrate animals cannot be repeated. With regard to the available research results, data exchange with the applicant for state registration of a chemical substance should be carried out in accordance with paragraphs 119-139 of this Technical Regulation.

118. In the event that several business entities have made requests in accordance with paragraph 114 of this Technical Regulation for an identical chemical, the **Ministry of Economy** shall provide each of these business entities with the names and contact details of all business entities that have made such a request.

...

127. The model of proportional allocation and reimbursement of costs in accordance with subparagraph 3 of paragraph 121 of this Technical Regulation shall contain provisions on the allocation of costs for activities that may need to be carried out as a result of the adoption of decisions of the **Ministry of Economy** when assessing chemicals in accordance with paragraph 229 of this Technical Regulation.

128. When developing a model for proportional allocation and reimbursement of costs in accordance with subparagraph 3 of paragraph 121 of this Technical Regulation, the number of potential registrants and the probable need to provide additional information to the **Ministry of Economy**, with the exception of costs resulting from its decisions when assessing chemicals in accordance with paragraph 229 of this Technical Regulation, should be taken into account.

...

132. If a certain registrant has ceased its activities, it may still be a

the probable need to provide additional information to the *Ministry of Environment* should be taken into account, with the exception of costs resulting from its decisions when assessing chemicals in accordance with paragraph 229 of this Technical Regulation.

...

132. If a certain registrant has ceased its activities, it may still be a participant in the distribution of costs related to the decision-making of the *Ministry of Environment* when conducting the assessment of chemicals in accordance with paragraph 229 of this Technical Regulation.

...

135. If no agreement has been reached in accordance with paragraph 120 of this Technical Regulation, the applicant for state registration of a chemical substance must inform the *Ministry of Environment* and registrants thereof not earlier than one month after receiving information from the *Ministry of Environment* in accordance with paragraph 117 of this Technical Regulation.

136. Not later than one month from the date of receipt of the notification from the applicant for state registration of a chemical substance in accordance with paragraph 135 of this Technical Regulation, *the Ministry of Environment* shall grant the applicant the right to refer to the information that must be provided in the technical dossier in accordance with subparagraphs e and f of subparagraph 1 and subparagraph 2 of paragraph 40 of this Technical Regulation, which was provided by the lead registrant in its technical dossier, provided that, at the request of *the Ministry of Environment*, the applicant can provide confirmation of payment of the share of costs to the registrants in accordance with paragraph 131 of this Technical Regulation.

Registrants can file a lawsuit against the applicant for state registration of a chemical substance for pro rata reimbursement of costs in court in accordance with current legislation. *The Ministry of Environment* may develop and publish guidance on the calculation of the proportional share of costs to facilitate calculations. Subject to the provision of a full study report to the applicant for state registration of a chemical, registrants can file a claim for equal reimbursement of costs in court in accordance with current legislation.

participant in the distribution of costs related to the decision-making of the **Ministry of Economy** when conducting the assessment of chemicals in accordance with paragraph 229 of this Technical Regulation.

...

135. If no agreement has been reached in accordance with paragraph 120 of this Technical Regulation, the applicant for state registration of a chemical substance must inform the **Ministry of Economy** and registrants thereof not earlier than one month after receiving information from the **Ministry of Economy** in accordance with paragraph 117 of this Technical Regulation.

136. Not later than one month from the date of receipt of the notification from the applicant for state registration of a chemical substance in accordance with paragraph 135 of this Technical Regulation, **the Ministry of Economy** shall grant the applicant the right to refer to the information that must be provided in the technical dossier in accordance with subparagraphs e and f of subparagraph 1 and subparagraph 2 of paragraph 40 of this Technical Regulation, which was provided by the lead registrant in its technical dossier, provided that, at the request of **the Ministry of Economy**, the applicant can provide confirmation of payment of the share of costs to the registrants in accordance with paragraph 131 of this Technical Regulation.

Registrants can file a lawsuit against the applicant for state registration of a chemical substance for pro rata reimbursement of costs in court in accordance with current legislation. **The Ministry of Economy** may develop and publish guidance on the calculation of the proportional share of costs to facilitate calculations. Subject to the provision of a full study report to the applicant for state registration of a chemical, registrants can file a claim for equal reimbursement of costs in court in accordance with current legislation.

137. In the event that the applicant for state registration of a chemical substance is unable to pay an equal or proportional share of costs in accordance with paragraphs 121 and 131 of this Technical Regulation due to the failure of the lead or other registrants to provide appropriate reasonable invoices for payment of the share of costs, or due to ignoring its requests in accordance with paragraph 119 of this Technical

137. In the event that the applicant for state registration of a chemical substance is unable to pay an equal or proportional share of costs in accordance with paragraphs 121 and 131 of this Technical Regulation due to the failure of the lead or other registrants to provide appropriate reasonable invoices for payment of the share of costs, or due to ignoring its requests in accordance with paragraph 119 of this Technical Regulation, and if the applicant has provided relevant reasonable evidence, *The Ministry of Environment* shall decide to grant such an applicant the right to refer to the information that must be provided in the technical dossier in accordance with subparagraphs e and f of subparagraph 1 and subparagraph 2 of paragraph 40 of this Technical Regulation, which was submitted by the lead registrant in its technical dossier, without providing evidence of payment of an equal share of costs to the registrants in accordance with paragraph 131 of this Technical Regulation.

138. The host and other registrants have the right to appeal against *the decision of the Ministry of Environment* in accordance with paragraph 137 of this Technical Regulation in court in accordance with the current legislation.

139. The established deadlines for state registration of existing chemicals or the deadlines for the provision of additional information in accordance with this Technical Regulation may be extended to a maximum of four months as a result of receipt of an appropriate substantiated request from the lead registrant (or the lead applicant for state registration) by the decision of the *Ministry of Environment*.

...

141. An application for preliminary state registration of a chemical substance must be submitted by a business entity to the *Ministry of Environment* and include the following information:

142. Applications for preliminary state registration of a chemical substance must be submitted by business entities to the *Ministry of Environment* within *one year* from the date of entry into force of this Technical Regulation.

143. *Within* a month from the date of expiry of the period provided for in

Regulation, and if the applicant has provided relevant reasonable evidence, **The Ministry of Economy** shall decide to grant such an applicant the right to refer to the information that must be provided in the technical dossier in accordance with subparagraphs e and f of subparagraph 1 and subparagraph 2 of paragraph 40 of this Technical Regulation, which was submitted by the lead registrant in its technical dossier, without providing evidence of payment of an equal share of costs to the registrants in accordance with paragraph 131 of this Technical Regulation.

138. The host and other registrants have the right to appeal to **the Ministry of Economy** in accordance with paragraph 137 of this Technical Regulation in court in accordance with the current legislation.

139. The established deadlines for state registration of existing chemicals or deadlines for the provision of additional information in accordance with this Technical Regulation may be extended to a maximum of four months as a result of receipt of a relevant substantiated request from the lead registrant (or the lead applicant for state registration) by the decision of the Ministry of **Economy**

...

141. An application for preliminary state registration of a chemical substance must be submitted by a business entity to the **Ministry of Economy** and include the following information:

142. Applications for preliminary state registration of a chemical substance must be submitted by business entities to the **Ministry of Economy** within **two years** from the date of entry into force of this Technical Regulation.

143. **The Ministry of Economy**, within a month from the date of expiration of the period provided for in paragraph 142 of this Technical Regulation, publishes on its website and updates the list of existing chemicals for which business entities have passed the procedure of preliminary state registration of a chemical substance in accordance with paragraphs 140, 141 and 142 of this Technical Regulation, which must contain for each chemical substance the name of the chemical substance and its identifier in the form of a CAS number, if such was assigned, or another identifier, all assigned numbers of the previous state registration,

paragraph 142 of this Technical Regulation, the Ministry of Environment publishes on its website and updates the list of existing chemicals for which business entities have passed the procedure of preliminary state registration of a chemical substance in accordance with paragraphs 140, 141 and 142 of this Technical Regulation, which must contain for each chemical substance the name of the chemical substance and its identifier in the form of a CAS number, if such was assigned, or another identifier, all assigned numbers of the previous state registration, as well as the nearest stipulated deadlines for submitting an application for state registration of an existing chemical substance.

144. After the publication of the list in accordance with paragraph 143 of this Technical Regulation, the user of the relevant chemical has the right to inform *the Ministry of Environment* by means of e-mail about the use of a certain chemical substance supplied by the supplier and which has not transferred to the next user the corresponding number of the previous state registration of the existing chemical.

...

146. *The Ministry of Environment* shall assign the appropriate number and date of the preliminary state registration of the chemical substance and notify it within three days of the applicant for the preliminary state registration of the chemical substance for transfer to subsequent users and use in any correspondence with him until the completion of the procedure for state registration of the chemical substance.

147. Applicants for state registration of an identical chemical substance must establish information exchange consortia or join a consortium, select a lead applicant for state registration of a chemical substance and send an official notification of the creation of an information exchange consortium to the *Ministry of Environment* indicating the contact details of all applicants and the selected lead applicant for state registration of a chemical substance.

...

155. Within one month from the date of the request in accordance with paragraphs 153 and 154 of this Technical Regulation, the owner of the results of the relevant study, who is a member of the consortium, shall provide proof of its value to the consortium member that made the request

as well as the nearest stipulated deadlines for submitting an application for state registration of an existing chemical substance.

144. After the publication of the list in accordance with paragraph 143 of this Technical Regulation, the user of the relevant chemical substance has the right, by means of e-mail, to inform **the Ministry of Economy** about the use of a certain chemical substance supplied by the supplier and which has not transferred to the next user the corresponding number of the previous state registration of the existing chemical.

...

146. **The Ministry of Economy** shall assign the appropriate number and date of the preliminary state registration of the chemical substance and notify it within three days of the applicant for the preliminary state registration of the chemical substance for transfer to subsequent users and use in any correspondence with him until the completion of the procedure for state registration of the chemical substance.

147. Applicants for state registration of an identical chemical substance must establish information exchange consortia or join a consortium, select a lead applicant for state registration of a chemical substance and send an official notification of the creation of an information exchange consortium to the **Ministry of Economy**, indicating the contact details of all applicants and the selected lead applicant for state registration of a chemical substance.

...

155. Within one month from the date of the request in accordance with paragraphs 153 and 154 of this Technical Regulation, the owner of the results of the relevant study, who is a member of the consortium, shall provide proof of its value to the consortium member that made the request and issue an appropriate invoice for payment of a proportionate share of the costs of the relevant study. The participants and the owner shall make every effort to ensure that the that the costs of obtaining and processing the data for which the exchange takes place are distributed in a fair, proportionate, transparent and non-discriminatory manner. This can be facilitated by compliance with the cost allocation guidelines developed and published **by the Ministry of Economy** and based on these principles. If the participants and the owner cannot reach such an

and issue an appropriate invoice for payment of a proportionate share of the costs of the relevant study. The participants and the owner shall make every effort to ensure that the that the costs of obtaining and processing the data for which the exchange takes place are distributed in a fair, proportionate, transparent and non-discriminatory manner. This can be facilitated by compliance with the guidelines on the allocation of costs, which are developed and published by *the Ministry of Environment* and based on these principles. If the participants and the owner cannot reach such an agreement, the costs must be distributed equally.

...

158. In the case of application of paragraph 157 of this Technical Regulation, the consortium members shall make every effort to reach an agreement on which of the consortium members should conduct the study on behalf of the other participants, as well as provide the *Ministry of Environment* with a reliable summary of the study or a full report on the study.

159. An agreement in accordance with paragraph 158 of this Technical Regulation must be reached within the time limit set by the *Ministry of Environment*.

160. If an agreement in accordance with paragraph 158 of this Technical Regulation has not been reached, the *Ministry of Environment* shall decide which consortium member should conduct the relevant study.

...

163. If the owner of the results of tests on vertebrate animals refuses to provide confirmation of its cost to other consortium members, does not issue appropriate invoices for payment of a proportional share of costs, or does not submit full research reports on time, his application for state registration of a chemical substance will not be accepted by the *Ministry of Environment* until it provides relevant information to other consortium members.

164. In the case of application of paragraph 163 of this Technical Regulation, other interested members of the consortium have the right to submit an application for state registration of a chemical substance without fulfilling the relevant information requirement, providing appropriate explanations in the technical dossier. The study is not allowed

agreement, the costs must be distributed equally.

...

158. In the case of application of paragraph 157 of this Technical Regulation, the consortium members must make every effort to reach an agreement on which of the consortium participants should conduct the study on behalf of the other participants, as well as provide the **Ministry of Economy** with a reliable summary of the study or a full report on the study.

159. An agreement in accordance with paragraph 158 of this Technical Regulation must be reached within the time limit set by the **Ministry of Economy**.

160. If an agreement in accordance with paragraph 158 of this Technical Regulation has not been reached, the **Ministry of Economy** shall decide which consortium member should conduct the relevant study.

...

163. If the owner of the results of tests on vertebrate animals refuses to provide confirmation of its cost to other consortium members, does not issue appropriate invoices for payment of a proportional share of costs, or does not submit full research reports on time, his application for state registration of a chemical substance will not be accepted by the **Ministry of Economy** until he provides relevant information to other consortium members.

164. In the case of application of paragraph 163 of this Technical Regulation, other interested members of the consortium have the right to submit an application for state registration of a chemical substance without fulfilling the relevant information requirement, providing appropriate explanations in the technical dossier. The study is not allowed to be repeated, except for cases when within twelve months from the date of state registration by other participants the owner has not provided them with test results, and the **Ministry of Economy** decided to re-conduct the test. However, if such information has already been submitted by another registrant, the **Ministry of Economy** decides to grant other participants the right to refer to this information in their technical files.

...

166. The owners of the study have the right to appeal against the decisions

to be repeated, except for cases when within twelve months from the date of state registration by other participants the owner has not provided them with test results, and *the Ministry of Environment* has decided to re-conduct the test. However, if such information has already been submitted by another registrant, *the Ministry of Environment* decides to grant other participants the right to refer to this information in their technical files.

...

166. The owners of the study have the right to appeal against the decisions made by the *Ministry of Environment* in accordance with paragraphs 160 and 163 of this Technical Regulation in court in accordance with the current legislation.

...

197. If applicants for state registration of a chemical substance or registrants cannot enter certain types of use in the Technical Dossiers in accordance with paragraph 195 of this Technical Regulation due to the impossibility of controlling the risks of negative impact on human health or the environment, applicants must notify the *Ministry of Environment* in paper or electronic form and relevant subsequent users, and not to supply the chemical to subsequent users without these reasons in the chemical product safety data sheet or information in accordance with paragraph 180 of this Technical Regulation. Manufacturers or importers shall include this type of use in the update of the technical dossier in Section 3.7 in accordance with Annex VI to this Technical Regulation.

...

203. In the following cases, before starting or continuing a certain use of a chemical registered under a previous participant in the supply chain, the following users must provide a notification in paper or electronic form in accordance with paragraph 204 of this Technical Regulation to the *Ministry of Environment*:

...

204. In accordance with paragraph 203 of this Technical Regulation, notifications from the following users to the *Ministry of Environment* must include:

...

206. *The Ministry of Environment* shall consider any proposals for

made by **the Ministry of Economy** in accordance with paragraphs 160 and 163 of this Technical Regulation, in court in accordance with the current legislation.

...

197. If applicants for state registration of a chemical substance or registrants cannot enter certain types of use in the Technical Dossiers in accordance with paragraph 195 of this Technical Regulation due to the impossibility of controlling the risks of negative impact on human health or the environment, applicants must notify the **Ministry of Economy** in paper or electronic form and relevant subsequent users, and not to supply the chemical to subsequent users without these reasons in the chemical product safety data sheet or information in accordance with paragraph 180 of this Technical Regulation. Manufacturers or importers shall include this type of use in the update of the technical dossier in Section 3.7 in accordance with Annex VI to this Technical Regulation.

...

203. In the following cases, before starting or continuing a certain use of a chemical registered under the previous participant in the supply chain, the following users must provide a notification in paper or electronic form in accordance with paragraph 204 of this Technical Regulation to the **Ministry of Economy**:

...

204. In accordance with paragraph 203 of this Technical Regulation, notifications from the following users to the **Ministry of Economy** must include:

...

206. **The Ministry of Economy** shall consider any proposals for conducting new tests, in accordance with subparagraph 1 of paragraph 40, subparagraphs 4 and 5 of paragraph 47, and subparagraph 6 of paragraph 204 of this Technical Regulation.

...

208. **The Ministry of Economy** publishes information on the submitted proposals for conducting new tests on vertebrate animals on its website, namely: the name of the chemical, the indicator to be obtained as a result of the relevant test, and the deadline for submission of comments by

conducting new tests, in accordance with subparagraph 1 of paragraph 40, subparagraphs 4 and 5 of paragraph 47, and subparagraph 6 of paragraph 204 of this Technical Regulation.

...

208. *The Ministry of Environment* publishes information on the submitted proposals for conducting new tests on vertebrate animals on its website, namely: the name of the chemical, the indicator to be obtained as a result of the relevant test, and the deadline for submission of comments by interested parties on the proposal.

209. *The Ministry of Environment* shall provide an opportunity for interested parties to provide comments, comments, as well as similar results of similar or similar tests already carried out, within forty-five calendar days from the date of submission of a proposal for conducting new tests on vertebrate animals.

210. Proposals, comments or results of such tests in accordance with paragraph 209 of this Technical Regulation shall be taken into account when preparing decisions of *the Ministry of Environment* in accordance with paragraph 211 of this Technical Regulation.

211. As a result of consideration of the proposal to conduct new tests on vertebrate animals, *the Ministry of Environment* makes one of the following decisions:

...

212. Decisions of the *Ministry of Environment*, which are specified in paragraphs 211, 216, 219 and 232 of this Technical Regulation, should be made according to the procedure set out in paragraphs 245-248 of this Technical Regulation.

The Ministry of Environment shall make a decision in accordance with paragraph 211 of this Technical Regulation:

...

213. Applicants for state registration of a chemical, registrants or subsequent users must submit the results of new tests in the form of reliable summaries of studies to *the Ministry of Environment* no later than the deadline specified in the relevant decision of the *Ministry of Environment* on conducting new tests on vertebrate animals.

214. *The Ministry of Environment* has the right at any time to check any

interested parties on the proposal.

209. **The Ministry of Economy** shall provide an opportunity for interested parties to provide comments, comments, as well as similar results of similar or similar tests already carried out, within forty-five calendar days from the date of submission of a proposal for conducting new tests on vertebrate animals.

210. Proposals, comments or results of such tests in accordance with paragraph 209 of this Technical Regulation shall be taken into account when preparing decisions of **the Ministry of Economy** in accordance with paragraph 211 of this Technical Regulation.

211. As a result of consideration of the proposal to conduct new tests on vertebrate animals, **the Ministry of Economy** shall make one of the following decisions:

...

212. Decisions of the **Ministry of Economy**, which are specified in paragraphs 211, 216, 219 and 232 of this Technical Regulation, should be made according to the procedure set out in paragraphs 245-248 of this Technical Regulation.

The Ministry of Economy shall make a decision in accordance with paragraph 211 of this Technical Regulation:

...

213. Applicants for state registration of a chemical, registrants or subsequent users must submit the results of new tests in the form of reliable summaries of studies to **the Ministry of Economy** no later than the deadline specified in the relevant decision of the **Ministry of Economy** to conduct new tests on vertebrate animals.

214. **The Ministry of Economy** has the right at any time to check any technical dossier obtained in the process of state registration of chemicals for compliance with the requirements of this Technical Regulation, namely:

...

215. **The Ministry of Economy** shall provide access to the current list of technical dossiers that have already been checked by it in accordance with paragraph 214 of this Technical Regulation to other authorized executive bodies in the field of chemical safety and management of chemical

technical dossier obtained in the process of state registration of chemicals for compliance with the requirements of this Technical Regulation, namely:

...

215. *The Ministry of Environment* shall provide access to the current list of technical dossiers that have already been checked by it in accordance with paragraph 214 of this Technical Regulation to other authorized executive bodies in the field of chemical safety and management of chemical products.

216. When checking the quality of data of the technical dossier in accordance with paragraph 214 of this Technical Regulation, *the Ministry of Environment* has the right to decide on the provision of the necessary information by updating the technical dossier in accordance with paragraph 92 of this Technical Regulation, indicating the deadline for such updating within twelve months from the date of the start of the inspection.

217. *In* accordance with paragraph 214 of this Technical Regulation, the Ministry of Environment conducts an inspection of the provided technical dossiers for each category of tonnage ranges:

...

218. *The Ministry of Environment* has the right to change the annual share of technical files subject to inspection in accordance with paragraph 214 of this Technical Regulation, as well as to change the criteria for the priority of inspections specified in paragraph 217 of this Technical Regulation.

219. *The Ministry of Environment* checks the information provided during the update of the technical dossier in accordance with paragraph 92 of this Technical Regulation, and if the information in the updated technical dossier does not meet all the requirements of this Technical Regulation, makes a decision to provide the necessary information by updating the technical dossier in accordance with paragraph 216 of this Technical Regulation.

220. As a result of the inspection of the technical dossier, including the verification of new information obtained under the decisions in accordance with paragraphs 216 and 219 of this Technical Regulation,

products.

216. When checking the quality of data of the technical dossier in accordance with paragraph 214 of this Technical Regulation, **the Ministry of Economy** has the right to make a decision to provide the necessary information by updating the technical dossier in accordance with paragraph 92 of this Technical Regulation, indicating the deadline for such updating within twelve months from the date of the start of the inspection.

217. **The Ministry of Economy** shall inspect in accordance with paragraph 214 of this Technical Regulation the provided technical dossiers for each category of tonnage ranges:

...

218. **The Ministry of Economy** has the right to change the annual share of technical dossiers subject to inspection in accordance with paragraph 214 of this Technical Regulation, as well as to change the criteria for the priority of inspections specified in paragraph 217 of this Technical Regulation.

219. **The Ministry of Economy** checks the information that was provided during the update of the technical dossier in accordance with paragraph 92 of this Technical Regulation, and if the information in the updated technical dossier does not meet all the requirements of this Technical Regulation, makes a decision to provide the necessary information by updating the technical dossier in accordance with paragraph 216 of this Technical Regulation.

220. As a result of the inspection of the technical dossier, including the verification of new information obtained under the decisions in accordance with paragraphs 216 and 219 of this Technical Regulation, **the Ministry of Economy** shall draw a conclusion on the results of the data quality check in the technical dossiers and shall provide access to it through the Chemical Safety Information System or by other means of electronic communication to other authorized executive bodies in the field of chemical safety, and management of chemical products.

...

221. **The Ministry of Economy** shall develop criteria for prioritizing chemicals for further assessment of chemicals in accordance with

the Ministry of Environment shall draw a conclusion on the results of the data quality check in the technical dossiers and provide access to it through the Chemical Safety Information System or by other means of electronic communication to other authorized executive bodies in the field of chemical safety and management of chemical products.

...

221. *The Ministry of Environment* shall develop criteria for prioritizing chemicals for further assessment of chemicals in accordance with paragraph 229 of this Technical Regulation.

...

223. *The Ministry of the Environment*, on the basis of the prioritization carried out in accordance with paragraph 221 of this Technical Regulation, must develop a draft Plan for conducting chemical assessments for three years indicating the chemicals to be assessed in each year.

224. Certain chemicals should be included in the draft three-year Chemical Assessment Plan if the *Ministry of Environment* has reasonable grounds to believe that they pose a risk to human health and the environment.

225. *The Ministry of Environment* shall submit the first draft of the Chemical Assessment Plan to other commissioners of the *Ministry of Environment* 3 years after the entry into force of this Technical Regulation for approval.

226. *The Ministry of Environment* annually submits a draft Plan for Chemical Assessments for approval to the authorized bodies in the field of chemical safety and management of chemical products by February 28 of each year.

227. *The Ministry of Environment* approves the Plan for Chemical Assessments, taking into account the comments and proposals submitted to it in accordance with paragraphs 225 and 226 of this Technical Regulation.

228. *The Ministry of Environment* publishes the approved Plan for Chemical Assessments on the official website.

229. *The Ministry of Environment* conducts assessments of chemicals in

paragraph 229 of this Technical Regulation.

...

223. **The Ministry of Economy**, on the basis of the prioritization carried out in accordance with paragraph 221 of this Technical Regulation, must develop a draft Plan for Chemical Assessments for three years, indicating the chemicals to be assessed in each year.

224. Certain chemicals must be included in the draft three-year Chemical Assessment Plan if the **Ministry of Economy** has reasonable grounds to believe that they pose a risk to human health and the environment.

225. **The Ministry of Economy** shall submit the first draft of the Plan for Chemical Assessments to other commissioners of the **Ministry of Economy** 3 years after the entry into force of this Technical Regulation for approval.

226. **The Ministry of Economy** annually submits a draft Plan for Chemical Assessments for approval to the authorized bodies in the field of chemical safety and management of chemical products by February 28 of each year.

227. **The Ministry of Economy** approves the Plan for Chemical Assessments, taking into account the comments and proposals submitted to it in accordance with paragraphs 225 and 226 of this Technical Regulation.

228. **The Ministry of Economy** publishes the approved Plan for Chemical Assessments on the official website.

229. **The Ministry of Economy** conducts assessments of chemical substances in accordance with the approved Plan for Chemical Assessments in accordance with paragraph 227 of this Technical Regulation.

230. In order to assess chemicals, the **Ministry of Economy** has the right to additionally involve any scientific institutions and other necessary individual specialists, and must also take into account the comments and suggestions of other authorized bodies in the field of chemical safety and management of chemical products.

231. Other authorized bodies in the field of chemical safety and management of chemical products have the right to submit proposals for the inclusion of a certain chemical substance in the Chemical Assessment

<i>accordance with the</i> approved Plan for Chemical Assessments in accordance with paragraph 227 of this Technical Regulation. 230. For the purpose of assessing chemicals, the <i>Ministry of Environment</i> has the right to additionally involve any scientific institutions and other necessary individual specialists, and must also take into account the comments and suggestions of other authorized bodies in the field of chemical safety and management of chemical products. 231. Other authorized bodies in the field of chemical safety and management of chemical products have the right to submit proposals for the inclusion of a certain chemical substance in the Chemical Assessment Plan to the <i>Ministry of Environment</i>, which considers these proposals and, if there are good reasons, to include the relevant chemicals in the next annual draft update of the Chemical Assessment Plan in accordance with paragraph 226 of this Technical Regulation. 232. If the <i>Ministry of Environment</i> considers that additional information is necessary for the assessment of chemicals, including cases where the provision of such information was not required from registrants for the purposes of state registration of chemicals in accordance with Annexes VII-X to this Technical Regulation, <i>the Ministry of Environment</i> shall decide to provide certain additional information with the establishment of deadlines for the provision of information within 12 months after approval Plan for conducting chemical assessments in accordance with paragraph 227 of this Technical Regulation. 233. Registrants who have received a decision in accordance with paragraph 232 of this Technical Regulation must provide the relevant additional information to <i>the Ministry of Environment</i> no later than the established deadline. 234. <i>The Ministry of Environment</i> shall consider the additional information provided and may make a second decision in accordance with paragraph 232 of this Technical Regulation within twelve months after receiving additional information, if the latter does not meet the requirements of the previous decision. 235. <i>The Ministry of Environment</i> shall complete the chemical assessment procedure no later than twelve months from the date of commencement of	Plan of the Ministry of Economy, which considers these proposals and, if there are good reasons, to include the relevant chemicals in the next annual draft update of the Chemical Assessment Plan in accordance with paragraph 226 of this Technical Regulation. 232. If the Ministry of Economy considers that additional information is required for the assessment of chemicals, including cases where the provision of such information was not required from registrants for the purposes of state registration of chemicals in accordance with Annexes VII-X to this Technical Regulation, the Ministry of Economy makes a decision on the provision of certain additional information with the establishment of deadlines for providing information within 12 months after the approval of the Chemical Assessment Plan in accordance with paragraph 227 of this Technical Regulation. 233. Registrants who have received a decision in accordance with paragraph 232 of this Technical Regulation must provide the relevant additional information to the Ministry of Economy no later than the established deadline. 234. The Ministry of Economy shall consider the additional information provided and may make a second decision in accordance with paragraph 232 of this Technical Regulation within twelve months after receiving additional information, if the latter does not meet the requirements of the previous decision. 235. The Ministry of Economy shall complete the procedure for assessing a chemical substance no later than twelve months from the date of commencement of the assessment, or from the date of provision of additional information in accordance with paragraph 232 of this Technical Regulation. ... 238. Upon completion of the assessment of chemicals, the Ministry of Economy decides how to use this information in the procedures for forming and maintaining a list of particularly hazardous chemicals and a list of toxic chemicals, imposing restrictions on the production, use or marketing of chemical products, or adding chemicals to Annex XIV to this Technical Regulation. 239. The Ministry of Economy shall notify other authorized bodies in the
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the assessment, or from the date of provision of additional information in accordance with paragraph 232 of this Technical Regulation.

...

238. Upon completion of the assessment of chemicals, the *Ministry of Environment* decides how to use this information in the procedures for forming and maintaining a list of particularly hazardous chemicals and a list of toxic chemicals, imposing restrictions on the production, use or making available on the market of chemical products, or adding chemicals to Annex XIV to this Technical Regulation.

239. *The Ministry of Environment* shall notify other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or by other means of electronic communication about its decisions in accordance with paragraph 238 of this Technical Regulation and provide them with appropriate recommendations.

240. As a general rule, the assessment in accordance with paragraph 229 of this Technical Regulation should not be carried out for on-site isolated intermediate chemicals that are produced and used only under strictly controlled conditions, but if the *Ministry of the Environment*, in particular in accordance with the information provided by the competent authorities in the field of chemical safety and management of chemical products, has reason to believe that the risks to human health or the environment during the the use of such on-site isolated intermediate chemicals is equivalent to the risks in the use of chemicals that meet the criteria in accordance with paragraph 258 of this Technical Regulation and these risks are not adequately controlled, and requests for:

...

241. *The Ministry of Environment* sends the draft decisions specified in paragraphs 211, 216, 219 and 232 of this Technical Regulation to the relevant registrants or subsequent users for the opportunity to provide comments within thirty calendar days from the date of receipt of the draft decisions.

242. *The Ministry of Environment* shall make appropriate decisions according to the procedure specified in paragraphs 245-248 of this

field of chemical safety and management of chemical products through the Chemical Safety Information System or by other means of electronic communication about its decisions in accordance with paragraph 238 of this Technical Regulation and provide them with appropriate recommendations.

240. As a general rule, the assessment in accordance with paragraph 229 of this Technical Regulation should not be carried out for on-site isolated intermediate chemicals that are produced and used only under strictly controlled conditions, but in the event **that the Ministry of Economy**, in particular, in accordance with the information provided by the competent bodies in the field of chemical safety and management of chemical products, has reason to believe that the risks to human health or the environment during the the use of such on-site isolated intermediate chemicals is equivalent to the risks in the use of chemicals that meet the criteria in accordance with paragraph 258 of this Technical Regulation and these risks are not adequately controlled, and requests for:

...

241. **The Ministry of Economy** sends the draft decisions specified in paragraphs 211, 216, 219 and 232 of this Technical Regulation to the relevant registrants or subsequent users for the opportunity to provide comments within thirty calendar days from the date of receipt of the draft decisions.

242. **The Ministry of Economy** shall make appropriate decisions according to the procedure specified in paragraphs 245-248 of this Technical Regulation.

243. In the event that the registrant has ceased production or import, or the subsequent user has ceased the use of the relevant chemical after receiving the decisions referred to in paragraphs 211, 216, 219 and 232 of this Technical Regulation, the registrant or subsequent user must provide a notification to **the Ministry of Economy** that in the future the relevant state registration of the chemical substance is no longer valid, therefore he is not obliged to provide additional information on the relevant chemical, or if the registrant resumed activities after termination, he must provide a notice of resumption of activities in paper or electronic form to the **Ministry of Economy**.

Technical Regulation.

243. In the event that the registrant has ceased production or import, or the subsequent user has ceased the use of the relevant chemical after receiving the decisions referred to in paragraphs 211, 216, 219 and 232 of this Technical Regulation, the registrant or subsequent user must provide a notification to the *Ministry of Environment* that in the future the relevant state registration of the chemical is no longer valid, therefore he is not obliged to provide additional information on the relevant chemical, or if the registrant resumed activities after termination, he must provide a notice of resumption of activities in paper or electronic form to the *Ministry of Environment*.

244. *The Ministry of Environment* shall submit to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or by other means of electronic communication, a notification on the termination of production, import and use of a certain chemical substance by the relevant business entity, or a notification on the resumption of activities after termination.

245. *The Ministry of Environment* shall submit draft decisions specified in paragraphs 211, 216, 219 of this Technical Regulation, together with the comments received from registrants and subsequent users to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

Decision-making of *the Ministry of Environment* when assessing the quality of data in technical dossiers

245. *The Ministry of Environment* shall submit draft decisions specified in paragraphs 211, 216, 219 of this Technical Regulation, together with the comments received from registrants and subsequent users to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

...

247. *The Ministry of Environment shall* , within ninety calendar days from the date of submission of draft decisions to the relevant registrants or subsequent users, adopt an appropriate decision, taking into account the

244. **The Ministry of Economy** shall submit to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or by other means of electronic communication, a notification on the termination of production, import and use of a certain chemical substance by the relevant business entity, or a notification on the resumption of activities after termination.

245. **The Ministry of Economy** shall submit draft decisions specified in paragraphs 211, 216, 219 of this Technical Regulation, together with the comments received from registrants and subsequent users to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

Decision-making of the **Ministry of Economy** when assessing the quality of data in technical dossiers

245. **The Ministry of Economy** shall submit draft decisions specified in paragraphs 211, 216, 219 of this Technical Regulation, together with the comments received from registrants and subsequent users to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

...

247. **The Ministry of Economy** , within ninety calendar days from the date of submission of draft decisions to the relevant registrants or subsequent users, in order to be able to provide comments in accordance with paragraph 241 of this Technical Regulation, shall adopt an appropriate decision, taking into account the additions and comments received.

248. Business entities have the right to appeal against decisions made by **the Ministry of Economy** in accordance with paragraph 247 of these Technical Regulations in court in accordance with the current legislation.

Decision-making of the **Ministry of Economy** during the assessment of chemicals

249. **The Ministry of Economy** shall submit the draft decisions specified in paragraph 232 of this Technical Regulation, together with the comments received from registrants and subsequent users to other

additions and comments received, in order to provide comments in accordance with paragraph 241 of this Technical Regulation.

248. Business entities have the right to appeal against decisions made by the *Ministry of Environment* in accordance with paragraph 247 of this Technical Regulation in court in accordance with the current legislation.

Decision-making of the *Ministry of Environment* during the assessment of chemicals

249. The *Ministry of Environment* shall submit the draft decisions specified in paragraph 232 of this Technical Regulation, together with the comments received from registrants and subsequent users to other authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

...

251. The *Ministry of Environment* shall, within ninety calendar days from the date of submission of draft decisions to the relevant registrants or subsequent users for the opportunity to provide comments in accordance with paragraph 241 of this Technical Regulation, make an appropriate decision, taking into account the additions and comments received.

252. Business entities have the right to appeal against decisions made by the *Ministry of Environment* in accordance with paragraph 251 of these Technical Regulations in court in accordance with the current legislation.

Sharing costs and sharing information to provide additional information on the decisions of the *Ministry of Environment*

253. In the event that registrants or subsequent users are required to conduct a test according to the decisions of the *Ministry of Environment* in accordance with paragraphs 211, 216, 219 and 232 of this Technical Regulation, they must make every effort to reach an agreement on which of them conducts the test on behalf of other registrants or subsequent users and notify the *Ministry of Environment* thereof.

254. The notification referred to in paragraph 253 of this Technical Regulation must be provided within ninety calendar days from the date of receipt of decisions of the *Ministry of Environment* in accordance with paragraphs 211, 216, 219 and 232 of this Technical Regulation.

255. In the event that the *Ministry of Environment* has not received a

authorized bodies in the field of chemical safety and management of chemical products through the Chemical Safety Information System or other means of electronic communication.

...

251. The **Ministry of Economy**, within ninety calendar days from the date of submission of draft decisions to the relevant registrants or subsequent users for the opportunity to provide comments in accordance with paragraph 241 of this Technical Regulation, shall make an appropriate decision, taking into account the additions and comments received.

252. Business entities have the right to appeal against decisions made by the **Ministry of Economy** in accordance with paragraph 251 of this Technical Regulation in court in accordance with the current legislation.

Sharing costs and sharing information to provide additional information on the decisions of the **Ministry of Economy**

253. In the event that registrants or subsequent users are required to conduct a test according to the decisions of the **Ministry of Economy** in accordance with paragraphs 211, 216, 219 and 232 of this Technical Regulation, they must make every effort to reach an agreement on which of them conducts the tests on behalf of other registrants or subsequent users and notify the **Ministry of Economy** thereof.

254. The notification referred to in paragraph 253 of this Technical Regulation must be provided within ninety calendar days from the date of receipt of the decisions of the **Ministry of Economy** in accordance with paragraphs 211, 216, 219 and 232 of this Technical Regulation.

255. In the event that the **Ministry of Economy** has not received notification of an agreement in accordance with paragraph 253 of this Technical Regulation within the specified period, it shall appoint one of the registrants or from subsequent users to conduct new trials or studies in order to provide additional information on behalf of the other registrants and subsequent users, and the costs of conducting new trials or studies shall be distributed equally among all registrants. by the respective registrants and subsequent users.

...

257. By 1 March, the **Ministry of Economy** shall annually publish on its

notification of reaching an agreement in accordance with paragraph 253 of this Technical Regulation within the specified period, it shall appoint one of the registrants or from subsequent users to conduct new trials or studies in order to provide additional information on behalf of other registrants and subsequent users, and the costs of conducting new trials or studies shall be distributed equally among all by the respective registrants and subsequent users.

...

257. *The Ministry of Environment* annually publishes on its official website by March 1 consolidated reports on the quality assessments of data in technical dossiers and assessments of chemicals carried out in the previous year, together with recommendations for potential applicants for state registration of a chemical substance to improve technical dossiers and the information to be provided.

...

260. According to the defined and reasoned hazard classification of chemicals that meet the criteria specified in paragraphs 258-259 of this Technical Regulation, the *Ministry of Environment* shall establish the following lists of chemicals according to the procedure in accordance with paragraphs 261-266 of this Technical Regulation:

...

261. Authorized executive bodies in the field of chemical safety and management of chemical products may prepare a dossier in accordance with Annex XV to this Technical Regulation for the inclusion of a chemical substance in one of the lists specified in paragraph 260 of this Technical Regulation and submit it to the *Ministry of Environment*.

262. If necessary, the *Ministry of Environment* shall prepare a dossier in accordance with Annex XV to this Technical Regulation for the inclusion of a chemical substance in one of the lists specified in paragraph 260 of this Technical Regulation.

263. *The Ministry of Environment* publishes on the official website the dossier prepared or received in accordance with Annex XV to this Technical Regulation for the possibility of comments by interested parties within 60 calendar days.

264. After the deadline for submission of comments, *the Ministry of*

official website consolidated reports on the quality assessments of data in technical dossiers and assessments of chemical substances carried out in the previous year, together with recommendations for potential applicants for state registration of a chemical substance to improve technical dossiers and the information to be provided.

...

260. According to the defined and reasoned classification of the hazard of chemicals that meet the criteria specified in paragraphs 258-259 of this Technical Regulation, the **Ministry of Economy** creates the following lists of chemicals according to the procedure in accordance with paragraphs 261-266 of this Technical Regulation:

...

261. Authorized executive bodies in the field of chemical safety and management of chemical products may prepare a dossier in accordance with Annex XV to this Technical Regulation for the inclusion of a chemical substance in one of the lists specified in paragraph 260 of this Technical Regulation and submit it to the **Ministry of Economy**.

262. If necessary, the **Ministry of Economy** shall prepare a dossier in accordance with Annex XV to this Technical Regulation for the inclusion of a chemical substance in one of the lists specified in paragraph 260 of this Technical Regulation.

263. **The Ministry of Economy** publishes on the official website the dossier prepared or received in accordance with Annex XV to this Technical Regulation for the possibility of comments by interested parties within 60 calendar days.

264. After the deadline for comments, the **Ministry of Economy** shall decide to include a certain chemical substance in the relevant list specified in paragraph 260 of this Technical Regulation and publish it on the official website.

...

266. **The Ministry of Economy** shall publish and update the lists specified in paragraph 260 of this Technical Regulation within five working days after the adoption of decisions in accordance with paragraph 264 of this Technical Regulation.

...

Environment shall decide to include a certain chemical substance in the relevant list specified in paragraph 260 of this Technical Regulation and publish it on the official website.

...

266. *The Ministry of Environment* publishes and updates the lists specified in paragraph 260 of this Technical Regulation within five working days after the adoption of decisions in accordance with paragraph 264 of this Technical Regulation.

...

268. Authorized executive bodies in the field of chemical safety and management of chemical products may submit a reasonable proposal for the inclusion of chemicals in Annex XIV to this Technical Regulation to the *Ministry of Environment*.

269. *The Ministry of Environment* has the right to put forward a proposal to add chemicals to Annex XIV to this Technical Regulation.

270. If a proposal is received in accordance with paragraphs 268 or 269 of this Technical Regulation, the *Ministry of Environment* shall consider such a proposal, and if reasonably necessary, make a conclusion on the expediency of withdrawing a particularly hazardous substance from the market and amend Annex XIV to this Technical Regulation in accordance with the established procedure.

...

272. *The Ministry of Environment* shall take into account the technical feasibility of processing applications for obtaining a permit for the use of a particularly hazardous chemical substance that is withdrawn from the market, and shall include the following chemicals in Annex XIV to this Technical Regulation as a matter of priority:

...

273. *The Ministry of Environment* publishes an opinion in accordance with paragraph 270 of this Technical Regulation on the official website for the possibility of receiving comments from interested parties within three months, in particular on certain uses that should not be subject to the requirement to obtain a permit for the use of a particularly hazardous chemical that is withdrawn from the market, and take into account the information provided.

268. Authorized executive bodies in the field of chemical safety and management of chemical products may submit a reasonable proposal for the inclusion of chemicals in Annex XIV to this Technical Regulation to the **Ministry of Economy**.

269. **The Ministry of Economy** has the right to put forward a proposal to add chemicals to Annex XIV to this Technical Regulation.

270. In case of receipt of a proposal in accordance with paragraphs 268 or 269 of this Technical Regulation, **the Ministry of Economy** shall consider such a proposal, and, if reasonably necessary, make a conclusion on the expediency of withdrawing a particularly hazardous substance from the market and amend Annex XIV to this Technical Regulation in accordance with the established procedure.

...

272. **The Ministry of Economy** shall take into account the technical capacity of processing applications for obtaining a permit for the use of a particularly hazardous chemical substance that is withdrawn from the market, and shall include the following chemicals in Annex XIV to this Technical Regulation:

...

273. **The Ministry of Economy** publishes an opinion in accordance with paragraph 270 of this Technical Regulation on the official website for the possibility of receiving comments from interested parties within three months, in particular on certain uses that should not be subject to the requirement to obtain a permit for the use of a particularly hazardous chemical that is withdrawn from the market, and take into account the information provided.

...

278. If the authorized executive body in the field of chemical safety and management of chemical products considers that the production, use or introduction into circulation of a chemical substance, including as part of other chemical products, poses an uncontrolled risk to human health and/or the environment, it may make a request to the **Ministry of Economy** on the preparation of a proposal for the establishment of restrictions on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this

... 278. If the authorized executive body in the field of chemical safety and management of chemical products considers that the production, use or introduction into circulation of a chemical substance, including as part of other chemical products, poses an uncontrolled risk to human health and/or the environment, it may make a request to the <i>Ministry of Environment</i> on the preparation of a proposal for the establishment of restrictions on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this Technical Regulation. 279. <i>The Ministry of Environment</i>, if necessary, prepares proposals for establishing restrictions on the production, use or placing on the market of a chemical substance in the format of a dossier in accordance with Annex XV to this Technical Regulation. After the date in accordance with subparagraph 4 of paragraph 271 of this Technical Regulation for chemicals listed in Annex XIV of this Technical Regulation, the <i>Ministry of Environment</i> determines whether the use of this chemical in the composition of products poses an uncontrolled risk to human health or the environment. If the <i>Ministry of Environment</i> determines that the risk to human health or the environment is uncontrollable, the <i>Ministry of Environment</i> prepares a proposal to establish a restriction on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this Technical Regulation. 280. <i>Within</i> twelve months from the date of receipt of the request in accordance with paragraph 278 of this Technical Regulation, the Ministry of the Environment shall prepare an appropriate proposal to establish restrictions on the production, use or putting into circulation of a chemical substance. 281. <i>When</i> preparing proposals in accordance with paragraphs 279-280 of this Technical Regulation, the Ministry of Environment has the right to use any technical dossiers, reports on the safety of a chemical substance or other results of risk assessment available in the Chemical Safety Information System, as well as any available reliable scientific information on the hazards and risks posed by the chemical.	Technical Regulation. 279. The Ministry of Economy, if necessary, prepares proposals for establishing restrictions on the production, use or putting into circulation of a chemical substance in the format of a dossier in accordance with Annex XV to this Technical Regulation. After the date, in accordance with subparagraph 4 of paragraph 271 of this Technical Regulation, for chemicals listed in Annex XIV of this Technical Regulation, the Ministry of Economy determines whether the use of this chemical in the composition of products poses an uncontrolled risk to human health or the environment. If the Ministry of Economy determines that the risk to human health or the environment is uncontrollable, the Ministry of Economy prepares a proposal to establish a restriction on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this Technical Regulation. 280. Within twelve months from the date of receipt of the request in accordance with paragraph 278 of this Technical Regulation, the Ministry of Economy shall prepare an appropriate proposal to establish restrictions on the production, use or putting into circulation of a chemical substance. 281. When preparing proposals in accordance with paragraphs 279-280 of this Technical Regulation, the Ministry of Economy has the right to use any technical dossiers, reports on the safety of a chemical substance or other results of risk assessment that are available in the Chemical Safety Information System, as well as any available reliable scientific information on the hazards and risks posed by the chemical. 282. Authorized executive bodies in the field of chemical safety and management of chemical products must provide the necessary information to the Ministry of Economy at its request. 283. If the Ministry of Economy or other authorized executive body in the field of chemical safety and management of chemical products considers that certain established restrictions on production, use or putting into circulation, which are specified in Annex XVII to this Technical Regulation, should be revised, it may make a request in accordance with paragraph 278 of this Technical Regulation, or the Ministry of Economy
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282. Authorized executive bodies in the field of chemical safety and management of chemical products must provide the necessary information to the *Ministry of Environment* at its request.

283. If the *Ministry of Environment* or other authorized executive body in the field of chemical safety and management of chemical products considers that certain established restrictions on production, use or putting into circulation, which are specified in Annex XVII to this Technical Regulation, should be reviewed, it may make a request in accordance with paragraph 278 of this Technical Regulation, or the *Ministry of Environment* may prepare a proposal for establishing a restriction on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this Technical Regulation.

284. The *Ministry of Environment* publishes on the official website all prepared proposals for establishing restrictions on the production, use or placing on the market of a chemical in the format of a dossier in accordance with Annex XV to this Technical Regulation, indicating the date of publication in order to be able to provide within six months from the date of publication by interested parties their comments, or the results of socio-economic analysis in accordance with Annex XVI to this Technical Regulation. regulations, or other information on the advantages and disadvantages of the proposed restrictions.

285. Within nine months from the date of publication in accordance with paragraph 284 of this Technical Regulation, the *Ministry of Environment* shall conclude on the effectiveness of the proposed restriction on the production, use or placing on the market of a chemical substance to control risks to human health and/or the environment, taking into account the comments received from stakeholders.

286. Within one year from the date of publication, in accordance with paragraph 284 of this Technical Regulation, the *Ministry of Environment* shall develop a draft opinion on the socio-economic consequences of imposing a proposed restriction on the production, use or placing on the market of a chemical, taking into account the results of a socio-economic analysis in accordance with Annex XVI to this Technical Regulation, if

may prepare a proposal for establishing a restriction on the production, use or placing on the market of a chemical substance in dossier format in accordance with Annex XV to this Technical Regulation.

284. The **Ministry of Economy** publishes on the official website all prepared proposals for establishing restrictions on the production, use or placing on the market of a chemical substance in the format of a dossier in accordance with Annex XV to this Technical Regulation, indicating the date of publication in order to be able to provide within six months from the date of publication by interested parties their comments, or the results of socio-economic analysis in accordance with Annex XVI to this Technical Regulation. regulations, or other information on the advantages and disadvantages of the proposed restrictions.

285. Within nine months from the date of publication, in accordance with paragraph 284 of this Technical Regulation, the **Ministry of Economy** shall conclude on the effectiveness of the proposed restriction on the production, use or circulation of a chemical substance to control risks to human health and/or the environment, taking into account the comments received from interested parties.

286. Within one year from the date of publication, in accordance with paragraph 284 of this Technical Regulation, the **Ministry of Economy** shall develop a draft opinion on the socio-economic consequences of imposing a proposed restriction on the production, use or placing on the market of a chemical, taking into account the results of a socio-economic analysis in accordance with Annex XVI to this Technical Regulation, if any.

287. The **Ministry of Economy** publishes a draft opinion on the socio-economic consequences of imposing a proposed restriction on the production, use or circulation of a chemical substance for the possibility of comments by interested parties within 60 calendar days from the date of publication.

288. After the expiry of the period specified in paragraph 287 of this Technical Regulation, the **Ministry of Economy** shall, within fourteen calendar days, conclude on the socio-economic consequences of imposing a proposed restriction on the production, use or making available on the market of a chemical substance, taking into account the proposals

any. 287. <i>The Ministry of Environment</i> publishes a draft opinion on the socio-economic consequences of imposing a proposed restriction on the production, use or putting into circulation of a chemical substance for the possibility of comments by interested parties within 60 calendar days from the date of publication. 288. After the expiry of the period specified in paragraph 287 of this Technical Regulation, the <i>Ministry of Environment shall</i>, within fourteen calendar days, draw a conclusion on the socio-economic consequences of imposing a proposed restriction on the production, use or making available on the market of a chemical substance, taking into account the proposals received and comments of interested parties. 289. If the <i>Ministry of Environment</i> considers that the conclusion on the socio-economic consequences of imposing a proposed restriction on the production, use or making available on the market of a chemical significantly contradicts the conclusion on the effectiveness of the proposed restriction in reducing risks to human health and the environment, the period specified in paragraph 287 of this Technical Regulation may be extended to ninety days. 290. <i>The Ministry of Environment</i>, after developing conclusions in accordance with paragraphs 285 and 288 of this Technical Regulation, on their basis, taking into account all available information, and if necessary, in accordance with the established procedure, shall amend Annex XVII to this Technical Regulation. 291. After developing conclusions in accordance with paragraphs 285 and 288 of this Technical Regulation, the <i>Ministry of Environment</i> publishes them on the official website.	received and comments of interested parties. 289. If the Ministry of Economy considers that the conclusion on the socio-economic consequences of imposing a proposed restriction on the production, use or making available on the market of a chemical significantly contradicts the conclusion on the effectiveness of the proposed restriction in reducing risks to human health and the environment, the period specified in paragraph 287 of this Technical Regulation may be extended to ninety days. 290. The Ministry of Economy, after developing conclusions in accordance with paragraphs 285 and 288 of this Technical Regulation, shall amend Annex XVII to this Technical Regulation on their basis, taking into account all available information, and if necessary, in accordance with the established procedure. 291. After developing conclusions in accordance with paragraphs 285 and 288 of this Technical Regulation, the Ministry of Economy publishes them on the official website.
APPENDIX II REQUIREMENTS FOR THE DEVELOPMENT OF A CHEMICAL SAFETY DATA SHEET ... 2.1. Hazard classification of chemical products The hazard classification of chemical products must be indicated in accordance with the criteria	APPENDIX II REQUIREMENTS FOR THE DEVELOPMENT OF A CHEMICAL SAFETY DATA SHEET ... 2.1. Hazard classification of chemical products The hazard classification of chemical products must be indicated in accordance with the criteria

specified in Annex I to the Technical Classification Regulation. In case the supplier has provided a hazard classification notice and information on the hazard of a chemical substance to the <i>Ministry of Environment</i> according to paragraph 129 of the Technical Regulation on Classification, or the data on the hazard classification and hazard information were provided in the technical dossier under the procedure of state registration of chemicals, the hazard classification indicated in the chemical safety data sheet must be identical to the hazard classification that was specified in such a notification or technical dossier.	specified in Annex I to the Technical Classification Regulation. In case the supplier has provided a hazard classification notice and information on the hazard of a chemical substance to the Ministry of Economy according to paragraph 129 of the Technical Regulation on Classification, or the data on the hazard classification and hazard information were provided in the technical dossier under the procedure of state registration of chemicals, the hazard classification indicated in the chemical safety data sheet must be identical to the hazard classification that was specified in such a notification or technical dossier.
ANNEX VIII INFORMATION REQUIREMENTS APPLICABLE TO CHEMICALS PRODUCED OR IMPORTED IN QUANTITIES EQUAL TO OR GREATER THAN 10 TONNES PER YEAR(*) ...	ANNEX VIII INFORMATION REQUIREMENTS APPLICABLE TO CHEMICALS PRODUCED OR IMPORTED IN QUANTITIES EQUAL TO OR GREATER THAN 10 TONNES PER YEAR(*) ...
8.6.1. The study shall not be carried out if: — there are results of a reliable study of chronic or subchronic toxicity (90 days) for which the appropriate biological species, appropriate dose, appropriate solvent and appropriate route of exposure have been used; or — the chemical decomposes immediately and there is sufficient data on the degradation products; or — the relevant human exposure can be excluded in accordance with Section 3 of Annex XI to this Technical Specification Regulations. The appropriate route of exposure should be determined according to the following provisions: A study of exposure through the skin should be carried out if: 1) inhalation of the chemical is unlikely; and 2) skin contact is possible during the production and/or use of the chemical; and 3) the physicochemical and toxicological properties of the chemical indicate the possibility of a significant level of absorption through the skin. The study of the chemical substance by inhalation should be carried out provided that the probable route of exposure to the human body is inhalation, taking into account the pressure of the vapors of the chemical substance and/or the possibility of exposure to aerosols,	8.6.1. The study shall not be carried out if: — there are results of a reliable study of chronic or subchronic toxicity (90 days) for which the appropriate biological species, appropriate dose, appropriate solvent and appropriate route of exposure have been used; or — the chemical decomposes immediately and there is sufficient data on the degradation products; or — the relevant human exposure can be excluded in accordance with Section 3 of Annex XI to this Technical Specification Regulations. The appropriate route of exposure should be determined according to the following provisions: A study of exposure through the skin should be carried out if: 1) inhalation of the chemical is unlikely; and 2) skin contact is possible during the production and/or use of the chemical; and 3) the physicochemical and toxicological properties of the chemical indicate the possibility of a significant level of absorption through the skin. The study of the chemical substance by inhalation should be carried out provided that the probable route of exposure to the human body is inhalation, taking into account the pressure of the vapors of the chemical substance and/or the possibility of exposure to aerosols,

particles and droplets of such a size that can be inhaled. For nanoforms that do not have a high rate of dissolution in biological media, the study should include toxicokinetic studies, studies of the recovery period, and lung cleansing. Toxicokinetic studies do not need to be performed if equivalent toxicokinetic information on the nanoform is already available. The applicant for state registration of a chemical substance must submit proposals for conducting a new subchronic toxicity test (90 days) (paragraph 8.6.2 of Annex IX to this Technical Regulation) if: the frequency and duration of human exposure indicates the need for a longer study; and one of the following conditions is met: — other available data indicate that the chemical has hazardous properties that cannot be determined during a short-term study; or — the results of properly conducted toxicological studies indicate that the chemical or its metabolites accumulate in certain tissues or organs, the adverse effects of which may not be detected during short-term studies, but which may lead to adverse effects due to long-term exposure. The applicant for state registration of a chemical substance must submit proposals for conducting new tests or the Ministry of Environment may request their conduct in accordance with paragraph 211 of this Technical Regulation, if:

...

9.2. Further tests must be proposed by the applicant or requested by the *Ministry of the Environment*, if the results of the chemical safety assessment in accordance with Annex I to this Technical Regulation indicate the need to conduct a study on the decomposition of the chemical substance and its decomposition products. The choice of appropriate test methods and environment will depend on the results of the chemical safety assessment.

ANNEX XI

GENERAL RULES FOR ADAPTATION OF STANDARD INFORMATION REQUIREMENTS, WHICH ARE GIVEN IN ANNEXES VII-X TO THIS TECHNICAL REGULATION

particles and droplets of such a size that can be inhaled. For nanoforms that do not have a high rate of dissolution in biological media, the study should include toxicokinetic studies, studies of the recovery period, and lung cleansing. Toxicokinetic studies do not need to be performed if equivalent toxicokinetic information on the nanoform is already available. The applicant for state registration of a chemical substance must submit proposals for conducting a new subchronic toxicity test (90 days) (paragraph 8.6.2 of Annex IX to this Technical Regulation) if: the frequency and duration of human exposure indicates the need for a longer study; and one of the following conditions is met: — other available data indicate that the chemical has hazardous properties that cannot be determined during a short-term study; or — the results of properly conducted toxicological studies indicate that the chemical or its metabolites accumulate in certain tissues or organs, the adverse effects of which may not be detected during short-term studies, but which may lead to adverse effects due to long-term exposure. An applicant for state registration of a chemical substance must provide proposals for conducting new tests or may be required by the **Ministry of Economy** in accordance with paragraph 211 of this Technical Regulation, if:

...

9.2. Further tests must be proposed by the applicant or requested by the **Ministry of Economy** if the results of the chemical safety assessment in accordance with Annex I to this Technical Regulation indicate the need to conduct a study on the decomposition of the chemical substance and its decomposition products. The choice of appropriate test methods and environment will depend on the results of the chemical safety assessment.

ANNEX XI

GENERAL RULES FOR ADAPTATION OF STANDARD INFORMATION REQUIREMENTS, WHICH ARE GIVEN IN ANNEXES VII-X TO THIS TECHNICAL REGULATION

Annexes VII-X to this Technical Regulation establish standard requirements for the information to be provided in technical dossiers for chemicals produced or imported in the following quantities: 1 ton per year or more, information requirements in accordance with subparagraphs 1 and 2 of paragraph 47 of this Technical Regulation 10 tons per year or more, information requirements in accordance with subparagraph 3 of paragraph 47 of this Technical Regulation 100 tons per year or more, information requirements in accordance with subparagraph 4 of paragraph 47 of this Technical Regulation 1000 tons per year or more, information requirements in accordance with subparagraph 5 of paragraph 47 of this Technical Regulation. In addition to the special requirements set out in Column 2 of Annexes VII-X to this Technical Regulation, the applicant for state registration of a chemical may adapt the standard information requirements in accordance with the general rules set out in paragraph 1 of this Annex. *The Ministry of the Environment*, when conducting the assessment of chemicals, can verify these adaptations of typical information requirements.

...

1.2. Weight of evidence Evidence from various independent information sources, considered in the aggregate, may be sufficient to justify the conclusion that a chemical substance has or does not have a certain hazardous property, while if information from each information source is considered separately, this will not be sufficient to justify such a conclusion. The justification of 3 weight of evidence must be consistent with the information which would have been obtained to meet the information requirements based on the results of the study. Evidence obtained in accordance with newly developed test methods not already referred to in paragraphs 53 and 54 of this Technical Regulation, or obtained in accordance with methods recognized *by the Ministry of Environment* as equivalent, may be sufficient to justify the conclusion that the chemical has or does not have a certain hazardous property.

...

1.3. Quantitative or qualitative modeling of the structure-activity

Annexes VII-X to this Technical Regulation establish standard requirements for the information to be provided in technical dossiers for chemicals produced or imported in the following quantities: 1 ton per year or more, information requirements in accordance with subparagraphs 1 and 2 of paragraph 47 of this Technical Regulation 10 tons per year or more, information requirements in accordance with subparagraph 3 of paragraph 47 of this Technical Regulation 100 tons per year or more, information requirements in accordance with subparagraph 4 of paragraph 47 of this Technical Regulation 1000 tons per year or more, information requirements in accordance with subparagraph 5 of paragraph 47 of this Technical Regulation. In addition to the special requirements set out in Column 2 of Annexes VII-X to this Technical Regulation, the applicant for state registration of a chemical may adapt the standard information requirements in accordance with the general rules set out in paragraph 1 of this Annex. **The Ministry of Economy**, during the assessment of chemicals, can check these adaptations of typical information requirements.

...

1.2. Weight of evidence Evidence from various independent information sources, considered in the aggregate, may be sufficient to justify the conclusion that a chemical substance has or does not have a certain hazardous property, while if information from each information source is considered separately, this will not be sufficient to justify such a conclusion. The justification of 3 weight of evidence must be consistent with the information which would have been obtained to meet the information requirements based on the results of the study. Evidence obtained in accordance with newly developed test methods not already specified in paragraphs 53 and 54 of this Technical Regulation, or obtained in accordance with methods recognized **by the Ministry of Economy** as equivalent, may be sufficient to justify the conclusion that the chemical has or does not have a certain hazardous property.

...

1.3. Quantitative or qualitative modeling of the structure-activity

(Q)SAR relationship The results obtained from quantitative or qualitative modeling of the structure-activity (Q)SAR relationship may confirm the presence or absence of certain hazardous properties. The results of the (Q)SAR simulation may be used in lieu of test results if the following conditions are met: the results are based on a scientifically valid (Q)SAR model; the chemical is relevant to the scope (Q)SAR models; the results are sufficiently reliable and acceptable for hazard classification and risk assessment; and provided relevant and reliable documentation on the method used. <i>The Ministry of Environment</i>, with the involvement of stakeholders, develops and publishes guidelines for assessing the validity of (Q)SAR models and compliance with these conditions.	(Q)SAR relationship The results obtained from quantitative or qualitative modeling of the structure-activity (Q)SAR relationship may confirm the presence or absence of certain hazardous properties. The results of the (Q)SAR simulation may be used in lieu of test results if the following conditions are met: the results are based on a scientifically valid (Q)SAR model; the chemical is relevant to the scope (Q)SAR models; the results are sufficiently reliable and acceptable for hazard classification and risk assessment; and provided relevant and reliable documentation on the method used. The Ministry of Economy, with the involvement of stakeholders, develops and publishes guidelines for assessing the validity of (Q)SAR models and compliance with these conditions.
ANNEX XII GENERAL PROVISIONS FOR THE FOLLOWING USERS TO CARRY OUT A CHEMICAL SAFETY ASSESSMENT FOR CHEMICALS AND PREPARE A CHEMICAL SAFETY REPORT ... Stage 2: Review of the hazard assessment carried out by the supplier, if necessary ... If the next user believes that additional information is needed to develop a report on the safety of a chemical substance in addition to that provided by the supplier, then he must obtain such information himself. If such information can only be obtained as a result of new tests on vertebrate animals, then he must submit a reasonable proposal for conducting new tests and research strategies to the <i>Ministry of Environment</i> in accordance with subparagraph 6 of paragraph 204 of this Technical Regulation. Prior to receiving the results of the studies, the following user must include in his report on the safety of the chemical the risk control measures that he has implemented for which studies are being conducted. Risk control measures must be consistent with all nanoforms, according to its own uses or defined uses down the supply chain. This information must be consistent with nanoforms.	ANNEX XII GENERAL PROVISIONS FOR THE FOLLOWING USERS TO CARRY OUT A CHEMICAL SAFETY ASSESSMENT FOR CHEMICALS AND PREPARE A CHEMICAL SAFETY REPORT ... Stage 2: Review of the hazard assessment carried out by the supplier, if necessary ... If the next user believes that additional information is needed to develop a report on the safety of a chemical substance in addition to that provided by the supplier, then he must obtain such information himself. If such information can only be obtained as a result of new tests on vertebrate animals, then he must submit a reasonable proposal for conducting new tests and research strategies to the Ministry of Economy in accordance with subparagraph 6 of paragraph 204 of this Technical Regulation. Prior to receiving the results of the studies, the following user must include in his report on the safety of the chemical the risk control measures that he has implemented for which studies are being conducted. Risk control measures must be consistent with all nanoforms, according to its own uses or defined uses down the supply chain. This information must be consistent with nanoforms.

APPENDIX XV DOSSIER ... 2) establishing a restriction on the production, use or making available on the market of a chemical substance in accordance with paragraphs 278-279 of this Technical Regulation. The methodology for the preparation and format of each of the dossiers in accordance with this Annex shall comply with the requirements specified in Annex I to this Technical Regulation. When preparing any dossier, it is necessary to take into account the relevant information from the technical dossiers, as well as other available information. If certain information on hazardous properties has not been previously submitted to the <i>Ministry of Environment</i>, the dossier in accordance with this Annex must contain relevant reliable summaries of the studies.	APPENDIX XV DOSSIER ... 2) establishing a restriction on the production, use or making available on the market of a chemical substance in accordance with paragraphs 278-279 of this Technical Regulation. The methodology for the preparation and format of each of the dossiers in accordance with this Annex shall comply with the requirements specified in Annex I to this Technical Regulation. When preparing any dossier, it is necessary to take into account the relevant information from the technical dossiers, as well as other available information. If certain information on hazardous properties has not been previously submitted to the Ministry of Economy, the dossier in accordance with this Annex must contain relevant reliable summaries of studies.
ANNEX XVI SOCIO-ECONOMIC ANALYSIS (SEA) ... <i>The Ministry of Environment</i> develops and publishes guidelines for conducting SEA. The results of the SEA or additional materials to it must be provided in a format determined by the <i>Ministry of Environment</i>.	ANNEX XVI SOCIO-ECONOMIC ANALYSIS (SEA) ... The Ministry of Economy develops and publishes guidelines for conducting SEA. The results of the SEA or additional materials to it must be provided in a format determined by the Ministry of Economy.
APPENDIX XVII RESTRICTION OF PRODUCTION, USE OR PROVISION ON THE UKRAINIAN MARKET OF CHEMICAL PRODUCTS THAT POSE AN UNCONTROLLED RISK TO HUMAN HEALTH AND/OR THE ENVIRONMENT THAT CANNOT BE CONTROLLED ... 6. Asbestos fibers. 1. The production, placing on the market and use of these fibers, as well as products and mixtures containing these fibers, is prohibited after the	APPENDIX XVII RESTRICTION OF PRODUCTION, USE OR PROVISION ON THE UKRAINIAN MARKET OF CHEMICAL PRODUCTS THAT POSE AN UNCONTROLLED RISK TO HUMAN HEALTH AND/OR THE ENVIRONMENT THAT CANNOT BE CONTROLLED ... 6. Asbestos fibers. 1. The production, placing on the market and use of these fibers, as well as products and mixtures containing these fibers, is prohibited after the

date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation. However, the use of membranes for electrolytic equipment containing chrysotile is allowed until 01.01.2025, if such membranes are used only for such equipment or if chrysotile is used exclusively for the care of such membranes, provided that such use is carried out in accordance with the current regulations of Ukraine on the prevention and control of industrial pollution. Any subsequent user who uses this exception before December 31 of the current calendar year must submit to the *Ministry of Environment* a report on the amount of chrysotile used in the membrane, based on the exemption. Subsequent users must monitor chrysotile in the air of the work area in the context of occupational health and safety, the results of such monitoring must be included in this report. 2. The use of products containing asbestos fibers mentioned in paragraph 1 of this entry, which were already in operation before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation, must remain allowed until they are removed or until the end of their service life. However, *the Ministry of Environment* has the right, for human health reasons, to limit, prohibit or determine specific conditions for the use of such products until they are removed or until the end of their service life. *The Ministry of Environment* has the right to consent to the provision on the market of products that generally contain asbestos fibers, which were already in operation before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation, with the definition of special conditions of use that ensure a high level of labor protection.

...

16. Lead carbonates:

However, the *Ministry of Environment*, in accordance with the provisions of Convention 13 of the International Labor Organization, has the right to allow the use of this chemical on its own or as part of a mixture for the restoration and maintenance of works of art, historical buildings and their interiors, as well as making available on the market for such use.

date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation. However, the use of membranes for electrolytic equipment containing chrysotile is allowed until 01.01.2025, if such membranes are used only for such equipment or if chrysotile is used exclusively for the care of such membranes, provided that such use is carried out in accordance with the current regulations of Ukraine on the prevention and control of industrial pollution. Any subsequent user who uses this exception before December 31 of the current calendar year must submit to **the Ministry of Economy**, a report on the amount of chrysotile used in the membrane, based on the exemption. Subsequent users must monitor chrysotile in the air of the work area in the context of occupational safety, the results of such monitoring must be included in this report. 2. The use of products containing asbestos fibers mentioned in paragraph 1 of this entry, which were already in operation before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation, must remain allowed until they are removed or until the end of their service life. However, **the Ministry of Economy** has the right, for reasons of human health, to limit, prohibit or determine specific conditions for the use of such products until they are removed or until the end of their service life. **The Ministry of Economy** has the right to consent to the provision on the market of products that generally contain asbestos fibers, which were already in operation before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation, with the definition of special conditions of use that ensure a high level of labor protection.

...

16. Lead carbonates:

However, the **Ministry of Economy**, in accordance with the provisions of Convention 13 of the International Labor Organization, has the right to authorize the use of this chemical on its own or as part of a mixture for the restoration and maintenance of works of art, historical buildings and their interiors, as well as making it available on the market for such use.

17. Lead sulfates

17. Lead sulfates However, the <i>Ministry of Environment</i>, in accordance with the provisions of Convention 13 of the International Labor Organization, authorize the use of this chemical on its own or as part of a mixture for the restoration and maintenance of works of art, historic buildings and their interiors, as well as making available on the market for such use. ... 18a. Mercury ... 2. The restrictions specified in paragraph 1 of this entry do not apply to measuring instruments that were provided on the market before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation. However, the <i>Ministry of Environment</i> may restrict or prohibit the provision of such measuring instruments on the market. ... 23. Cadmium and its compounds By 01.01.2025, in accordance with paragraph 279 of this Technical Regulation, the <i>Ministry of Environment</i> must prepare a proposal for imposing a restriction in the form of a dossier in accordance with Annex XV to this Technical Regulation, to assess the need to impose restrictions on the use of cadmium and its compounds in plastic materials that are not specified in the first paragraph. ... 50. Polycyclic aromatic hydrocarbons (PAHs) ... 8. Until 01.01.2025, the <i>Ministry of Environment</i> shall revise the limits specified in paragraphs 5 and 6 in case of receipt of new scientific information, including information on the migration of surfactants from relevant products, information on the availability of alternatives to raw materials and, if appropriate, may initiate amendments to this record. ... 58. Ammonium nitrate ... 3. However, for the restrictions provided for in paragraph 2 of this entry,	However, the Ministry of Economy, in accordance with the provisions of Convention 13 of the International Labor Organization, authorize the use of this chemical on its own or as part of a mixture for the restoration and maintenance of works of art, historic buildings and their interiors, as well as making it available on the market for such use. ... 18a. Mercury ... 2. The restrictions specified in paragraph 1 of this entry do not apply to measuring instruments that were provided on the market before the date of entry into force of the Resolution of the Cabinet of Ministers of Ukraine, which approves this Technical Regulation. However, the Ministry of Economy may restrict or prohibit the provision of such measuring instruments on the market. ... 23. Cadmium and its compounds By 01.01.2025, in accordance with paragraph 279 of this Technical Regulation, the Ministry of Economy must prepare a proposal for imposing a restriction in the form of a dossier in accordance with Annex XV to this Technical Regulation, to assess the need to impose restrictions on the use of cadmium and its compounds in plastic materials that are not specified in the first paragraph. ... 50. Polycyclic aromatic hydrocarbons (PAHs) ... 8. Until 01.01.2025, the Ministry of Economy shall revise the limits specified in paragraphs 5 and 6 in case of receipt of new scientific information, including information on the migration of surfactants from relevant products, information on the availability of alternatives to raw materials and, if appropriate, may initiate amendments to this record. ... 58. Ammonium nitrate ... 3. However, for the restrictions provided for in paragraph 2 of this entry, the Ministry of Economy may, for socio-economic reasons, increase the
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the <i>Ministry of Environment</i> may, for socio-economic reasons, increase the limit to 20% of total nitrate or ammonium nitrogen (in terms of nitrogen in dry matter) for such products. ... 59. Dichloromethane ... 2. As an exception to paragraph 1 of this entry, the <i>Ministry of Environment</i> may allow the provision on the market and use of paint removers containing dichloromethane on the territory of Ukraine for certain types of activities by specially trained specialists with the determination of appropriate conditions for labor protection of such specialists. ... 63. Lead and its compounds ... 6. By 01.01.2025, the <i>Ministry of Environment</i> shall review paragraphs 1-5 of this record in case of receipt of new scientific information, including information on lead migration from relevant products, information on the availability of alternatives and, if appropriate, may initiate amendments to this record. ... 9. By 01.01.2025, the <i>Ministry of Environment</i> shall review paragraph 7, and subparagraphs 5, 6, 9 and 10 of paragraph 8 of this record in case of receipt of new scientific information, including information on the migration of lead from the relevant products in accordance with paragraph 7 of this record, information on the availability of alternatives, including requirements for the integrity of the coating, and, if appropriate, may initiate amendments to this record.... 72. Chemicals specified in Column 1 of the table in Appendix 12 to this Annex. ... 7. In case of receiving new scientific information, the <i>Ministry of Environment</i> may review the exceptions specified in subparagraph 4 of paragraph 3 of this record, and, if appropriate, may initiate amendments to this record.	limit to 20% of total nitrate or ammonium nitrogen (in terms of nitrogen in dry matter) for such products. ... 59. Dichloromethane ... 2. As an exception to paragraph 1 of this entry, the Ministry of Economy may allow the provision on the market and use of paints removers containing dichloromethane on the territory of Ukraine for certain types of activities by specially trained specialists with the determination of appropriate conditions for labor protection of such specialists. ... 63. Lead and its compounds ... 6. By 01.01.2025, the Ministry of Economy shall review paragraphs 1-5 of this record in case of receipt of new scientific information, including information on the migration of lead from the relevant products, information on the availability of alternatives and, if appropriate, may initiate amendments to this record. ... 9. By 01.01.2025, the Ministry of Economy shall review paragraph 7, and subparagraphs 5, 6, 9 and 10 of paragraph 8 of this record in case of receipt of new scientific information, including information on the migration of lead from relevant products in accordance with paragraph 7 of this record, information on the availability of alternatives, including requirements for the integrity of the coating, and, if appropriate, may initiate amendments to this record.... 72. Chemicals specified in Column 1 of the table in Appendix 12 to this Annex. ... 7. In case of receiving new scientific information, the Ministry of Economy may revise the exceptions specified in subparagraph 4 of paragraph 3 of this record, and, if appropriate, may initiate amendments to this record. ...
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... 78. Synthetic polymer microparticles ... 11. Starting from 2026, manufacturers and industrial subsequent users of synthetic polymer microparticles in the form of granules, flakes and powders used as raw materials for plastic production at industrial sites, as well as starting from 2027, other manufacturers of synthetic polymer microparticles and other industrial subsequent users of synthetic polymer microparticles must submit the following information to the <i>Ministry of Environment</i> by May 31 annually: ... 12. From 2027, suppliers of products that include synthetic polymer microparticles specified in subparagraphs 2, 4 and 5 of paragraph 4, and in paragraph 5, which are put into circulation for use by professional users and the general public, must annually submit the following information to the <i>Ministry of Environment</i> by May 31: ... 13. <i>The Ministry of Environment</i> shall provide access to the information received in accordance with paragraphs 11-12 to other authorized bodies in the field of chemical safety and management of chemical products.	78. Synthetic polymer microparticles ... 11. Starting from 2026, manufacturers and industrial subsequent users of synthetic polymer microparticles in the form of granules, flakes and powders used as raw materials for the production of plastic at industrial sites, as well as starting from 2027, other manufacturers of synthetic polymer microparticles and other industrial subsequent users of synthetic polymer microparticles must submit the following information to the Ministry of Economy by May 31 annually: ... 12. From 2027, suppliers of products that include synthetic polymer microparticles specified in subparagraphs 2, 4 and 5 of paragraph 4, and in paragraph 5, which are put into circulation for use by professional users and the general public, must annually submit the following information to the Ministry of Economy by May 31: ... 13. The Ministry of Economy shall provide access to the information received in accordance with paragraphs 11-12 to other authorized bodies in the field of chemical safety and management of chemical products.
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