

ACT
of 2026

amending Act No 258/2000 on the protection of public health and on amendments to certain related acts, as amended, and Act No 323/2025 on the single monthly employer report

Parliament has adopted the following Act of the Czech Republic:

DIVISION ONE

Amendment to the Public Health Protection Act

Article I

Act No 258/2000 on the protection of public health and on amendments to certain related acts, as amended by Act No 254/2001, Act No 274/2001, Act No 13/2002, Act No 76/2002, Act No 86/2002, Act No 120/2002, Act No 320/2002, Act No 274/2003, Act No 356/2003, Act No 362/2003, Act No 167/2004, Act No 326/2004, Act No 562/2004, Act No 125/2005, Act No 253/2005, Act No 381/2005, Act No 392/2005, Act No 444/2005, Act No 59/2006, Act No 74/2006, Act No 186/2006, Act No 189/2006, Act No 222/2006, Act No 264/2006, Act No 342/2006, Act No 110/2007, Act No 296/2007, Act No 378/2007, Act No 124/2008, Act No 130/2008, Act No 274/2008, Act No 227/2009, Act No 281/2009, Act No 301/2009, Act No 151/2011, Act No 298/2011, Act No 375/2011, Act No 466/2011, Act No 115/2012, Act No 333/2012, Act No 223/2013, Act No 64/2014, Act No 247/2014, Act No 250/2014, Act No 252/2014, Act No 82/2015, Act No 267/2015, Act No 243/2016, Act No 250/2016, Act No 298/2016, Act No 183/2017, Act No 193/2017, Act No 202/2017, Act No 225/2017, Act No 277/2019, Act No 205/2020, Act No 238/2020, Act No 403/2020, Act No 544/2020, Act No 36/2021, Act No 94/2021, Act No 261/2021, Act No 284/2021, Act No 363/2021, Act No 314/2022, Act No 384/2022, Act No 152/2023, Act No 167/2023, Act No 281/2023, Act No 412/2023, Act No 242/2024, Act No 321/2024, Act No 77/2025, Act No 152/2025, Act No 218/2025, Act No 236/2025, Act No 251/2025, Act No 270/2025, Act No 290/2025, Act No 314/2025 and Act No .../2026, is amended as follows:

1. The following sentences are added on separate lines at the end of footnote 62:

‘Commission Delegated Regulation (EU) 2024/370 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down conformity assessment procedures for products that come into contact with water intended for human consumption and the rules for the designation of conformity assessment bodies involved in those procedures.
Commission Delegated Regulation (EU) 2024/371 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing harmonised specifications for the marking of products that come into contact with water intended for human consumption.’.
2. In Division One, Title II, the heading of Part 1 reads as follows: **‘Water, products or materials that come into direct contact with water, agents that come into direct contact with water, water treatment technologies and equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use, swimming pools and saunas’.**

3. § 5, including the heading, reads as follows:

‘§ 5

General requirements for products or materials that come into direct contact with water, agents that come into direct contact with water and equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use

- (1) The manufacturer and importer of a product or material intended to come into direct contact with drinking, service, hot or raw water^{6a)}, during the collection, abstraction, transport, treatment, distribution, storage, supply metering and other activities relating to the handling of such water (hereinafter referred to as ‘product or material that comes into direct contact with water’), as well as the manufacturer and importer of chemical substances, chemical mixtures, filter media, membranes, ion exchangers or other agents that come into direct contact with drinking, service, hot or raw water (hereinafter referred to as ‘agent that comes into direct contact with water’) and the manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must, when placing them on the market or using them for their own needs, ensure that such products or materials that come into direct contact with water, agents that come into direct contact with water and equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use
- a) do not directly or indirectly endanger human health;
- b) do not contaminate drinking, service, hot or raw water to an extent greater than is strictly necessary in view of the intended purpose of the product or material that comes into direct contact with water, the agent that comes into direct contact with water or the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use, and do not have an adverse effect on its colour, odour or taste in contravention of the limits laid down by the implementing legislation; and
- c) do not promote the growth of micro-organisms.
- (2) The manufacturer and importer of equipment for the treatment of drinking water in a domestic distribution system or at the point of use must, when placing such equipment on the market, ensure that it does not remove minerals beneficial to health from drinking water in an unjustified or excessive manner.
- (3) The manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must, when placing such equipment on the market, ensure that the equipment is effective for the purpose for which it is intended.’.

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4. The following new § 5a to § 5h, including headings and footnotes 113 to 117, are inserted after § 5:

‘§ 5a

Products or materials that come into direct contact with water

- (1) The manufacturer and importer of a product or material that comes into direct contact with water must ensure that

- (a) only starting substances, compositions and constituents that comply with Commission Implementing Decision (EU) 2024/367¹¹³⁾ have been used in its manufacture;
- (b) before being placed on the market, the product has been assessed in accordance with the relevant testing procedures and methods laid down in Commission Implementing Decision (EU) 2024/368¹¹⁴⁾; and
- (c) its marking complies with the requirements laid down in Commission Delegated Regulation (EU) 2024/371¹¹⁵⁾.
- (2) The manufacturer of a product or material that comes into direct contact with water must ensure that the EU declaration of conformity drawn up pursuant to the third subparagraph of Article 2(5) of Commission Delegated Regulation (EU) 2024/370¹¹⁶⁾ (hereinafter referred to as the ‘EU declaration of conformity’) for any product or material that comes into direct contact with water that it places on the market in the Czech Republic is translated into Czech.
- (3) The distributor of a product or material that comes into direct contact with water must
- (a) ensure that the products or materials it makes available on the market comply with the requirements pursuant to § 5(1);
- (b) ensure that, for as long as it handles those products or materials before making them available on the market, their compliance with the requirements pursuant to § 5(1) is not jeopardised by storage and transport conditions; and
- (c) prevent the distribution of any product or material that it distributes and that comes into direct contact with water if it considers that the product or material does not comply with the requirements pursuant to paragraphs (1) and (2) and § 5(1); where such a product or material that comes into direct contact with water poses a risk to human health, it must immediately inform the manufacturer or importer and the competent public health protection authorities of that fact.
- (4) The distributor may only make available on the market products or materials that come into direct contact with water
- (a) for which an EU declaration of conformity has been drawn up; and
- (b) whose marking complies with the requirements laid down in Commission Delegated Regulation (EU) 2024/371.
- (5) The manufacturer and importer must always provide any product or material that comes into direct contact with water with instructions for use if, when used incorrectly, it could pose a risk to or harm the health of individuals or impair the quality of drinking, service, hot or raw water and, where necessary, include instructions on remedying the consequences of incorrect use. The distributor^{4a)} must always distribute such a product or material that comes into direct contact with water to a consumer or other user with instructions for use and, where applicable, instructions on how to remedy the consequences of incorrect use. The instructions pursuant to the first and second sentences must be in Czech.
- (6) For the collection, abstraction, transport, treatment, distribution, storage and metering of the supply of raw or drinking water and other similar purposes, the persons set out in § 3(2), customers^{6a)} and persons producing hot water set out in § 3(3) may only use products or materials that come into direct contact with water
- a) for which an EU declaration of conformity has been drawn up;

- b) whose marking complies with the requirements laid down in Commission Delegated Regulation (EU) 2024/371; and
 - c) that have been provided with instructions in accordance with paragraph (5).
- (7) More detailed requirements for the use of products or materials that come into direct contact with water set out in § 5(1) and § 5a is laid down by implementing legislation.
- (8) If a product or material that comes into direct contact with water meets the requirements laid down in paragraphs (1) and (2), it is deemed to be a product or material that comes into direct contact with water that complies with the requirements laid down in § 5(1).

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§ 5b

Agents that come into direct contact with water

- (1) The manufacturer and importer of a chemical substance or chemical mixture must place on the market only chemical substances or chemical mixtures
- (a) specified by implementing legislation pursuant to the first sentence of paragraph (8); or
 - (b) authorised pursuant to paragraph (6);
- that meet the requirements laid down by implementing legislation pursuant to the second sentence of paragraph (8).
- (2) The manufacturer and importer of a filter medium, membrane, ion exchanger or other agent that comes into direct contact with water must, before placing it on the market, ensure that the agent complies with the requirements laid down by implementing legislation pursuant to paragraph (9).
- (3) The manufacturer and importer of an agent that comes into direct contact with water must, before placing it on the market, arrange for the holder of an accreditation certificate^{4a)} or the holder of authorisation pursuant to § 83c to verify that the agent complies with the requirements specified in implementing legislation and that its use will not adversely affect drinking, service or hot water; they must ensure that a record of the verification is drawn up. The method of this verification and the form and scope of the verification record is laid down by implementing legislation.
- (4) The distributor of an agent that comes into direct contact with water must
- (a) ensure that the agent that comes into direct contact with water that it makes available on the market complies with the requirements pursuant to paragraphs (1) and (2) and § 5(1);
 - (b) ensure that, for as long as it handles that agent before making it available on the market, its compliance with the requirements pursuant to paragraphs (1) and (2) and § 5(1) is not jeopardised by storage and transport conditions; and
 - (c) prevent the distribution of any agent that comes into direct contact with water distributed by it if it considers that the agent that comes into direct contact with water

does not comply with the requirements pursuant to paragraphs (1) to (3) and § 5(1); if the agent that comes into direct contact with water poses a risk to human health, it must inform the manufacturer or importer and the competent public health protection authorities of that fact without delay.

- (5) The manufacturer and importer must always provide instructions for use for an agent that comes into direct contact with water which, if used incorrectly, could pose a risk to or harm the health of individuals or impair the quality of drinking, service, hot or raw water and, where necessary, include instructions on how to remedy the consequences of incorrect use. The distributor^{4a)} must always distribute such an agent that comes into direct contact with water to a consumer or other user accompanied by instructions for use and, where applicable, instructions on how to remedy the consequences of incorrect use. The instructions pursuant to the first and second sentences must be in Czech.
- (6) At the request of a manufacturer or importer, the Ministry of Health shall decide on the authorisation of a chemical substance or chemical mixture not laid down by implementing legislation. In addition to the particulars required by the Administrative Code, the application contains
- a) the designation of the type of chemical substance or chemical mixture and its trade name and chemical composition;
 - b) proof of the purity of the chemical substance or chemical mixture pursuant to the relevant technical standard, if such a standard exists;
 - c) a brief description of the manufacturing process, listing all raw materials and additives, including information on the degradation products arising during manufacture, processing, storage and, where applicable, ageing;
 - d) data on the concentration of the chemical substance or chemical mixture;
 - e) data on the concentration of the active substance in the chemical mixture;
 - f) data on the purpose and intended method of use of the chemical substance or chemical mixture;
 - g) a method for determining the active substance, other substances and admixtures, and their impurities, including interaction and decomposition products;
 - h) any available foreign documentation indicating whether the proposed chemical substance or mixture has been authorised in other Member States of the European Union or the European Economic Area, in the United Kingdom, Switzerland or Turkey, and for which uses;
 - i) data on the toxicity of the proposed chemical substance or mixture;
 - j) instructions for use of the chemical substance or chemical mixture;
 - k) a detailed description of the operating principle of the water treatment technology in which the chemical substance or chemical mixture is used;
 - l) information on the maximum proposed application dose of the chemical substance or chemical mixture;
 - m) proof that the treated drinking, service or hot water is safe for long-term consumption;
 - n) a method for checking the functionality and effectiveness of the technology in normal operating practice.

The Ministry of Health shall issue the authorisation pursuant to the first sentence if it finds that the use of the chemical substance or chemical mixture will not adversely affect the quality of drinking, service or hot water.

- (7) The persons referred to in § 3(2) when treating raw water^{6a)}, customers^{6a)} who subsequently treat drinking water and supply it to the public, and persons producing hot water referred to in § 3(3), when treating that water, may use only agents that come into direct contact with water that have been verified pursuant to paragraph (3), or chemical substances or chemical mixtures that have been authorised pursuant to paragraph (6).
- (8) The list of authorised chemical substances and chemical mixtures is laid down by implementing legislation. The requirements relating to the composition, purity, hygienic suitability and effectiveness, including requirements for the verification of effectiveness, and the conditions of use of chemical substances and chemical mixtures specified by implementing legislation pursuant to the first sentence and chemical substances and chemical mixtures authorised pursuant to paragraph (6), is laid down by implementing legislation.
- (9) The requirements for the hygienic suitability and safety of filter media, membranes, ion exchangers or other agents that come into direct contact with water is laid down by implementing legislation.

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§ 5c

Water treatment and water treatment technologies

- (1) The list of authorised water treatment technologies is laid down by implementing legislation. The requirements relating to effectiveness and safety and the conditions of use of water treatment technologies specified by implementing legislation pursuant to the first sentence and water treatment technologies authorised pursuant to paragraph (2) is laid down by implementing legislation.
- (2) At the request of a person referred to in § 3(2), the Ministry of Health shall decide on the authorisation of a water treatment technology not laid down by implementing legislation. In addition to the particulars required by the Administrative Code, the application contains
- a) the designation of the type of technology and, where applicable, its trade name;
 - b) a description of the purpose of the technology and the justification for its use;
 - c) instructions for use;
 - d) a detailed description of the operating principle of the technology for the treatment of drinking, service, hot or raw water, including the equipment used and the exact composition of the chemical substances and chemical mixtures, where their addition to drinking, service, hot or raw water forms part of the technology;
 - e) proof that the equipment, chemical substances and chemical mixtures used comply with the requirements laid down by implementing legislation;
 - f) data on microbiological, chemical and physical changes in the quality of treated drinking, service, hot or raw water, including by-products or degradation products arising as a result of the application of the proposed technology;
 - g) proof that the hygienic requirements laid down for drinking water quality are met;
 - h) methods for checking the functionality and effectiveness of the technology in normal operating practice;

- i) proof that the quality of treated drinking, service, hot or raw water does not pose a health risk when the water is consumed over a long period, where the technology is intended to alter the physical properties of drinking, service, hot or raw water or introduce into drinking, service, hot or raw water chemical substances not laid down by implementing legislation;
- j) any available foreign documentation indicating whether and under what conditions the technology has been authorised for the treatment of drinking water in other Member States of the European Union or the European Economic Area, in the United Kingdom, Switzerland or Turkey.

The Ministry of Health shall issue authorisation for the use of the water treatment technology if it considers that the use of the water treatment technology will not adversely affect the quality of drinking, service, hot or raw water in a manner inconsistent with the purpose of the water treatment technology specified in the application.

- (3) The persons referred to in § 3(2) when treating raw water^{6a)}, customers^{6a)} who subsequently treat drinking water and supply it to the public, and persons producing hot water referred to in § 3(3) may use only water treatment technologies
 - a) laid down by implementing legislation pursuant to the first sentence of paragraph (1); or
 - b) authorised pursuant to paragraph (2);
 that comply with the requirements laid down by implementing legislation pursuant to the second sentence of paragraph (1).

§ 5d

Equipment for the treatment of drinking or hot water in domestic distribution systems or at the point of use

- (1) The manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must, before placing it on the market, ensure that such equipment complies with the requirements laid down by implementing legislation pursuant to paragraph (7).
- (2) The manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must, before placing it on the market, ensure that such equipment uses only water treatment technologies laid down by implementing legislation pursuant to § 5c(1) or authorised pursuant to § 5c(2).
- (3) The manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must, before placing it on the market, arrange for a holder of an accreditation certificate^{4a)} or a holder of an authorisation pursuant to § 83c to verify that its use will not adversely affect drinking or hot water; they must ensure that a record of the verification is drawn up. The method of this verification and the form and scope of the verification record is laid down by implementing legislation.
- (4) A distributor of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must
 - a) ensure that the equipment it makes available on the market complies with the requirements pursuant to paragraph (1) and § 5;

- b) ensure that, for as long as it handles that equipment prior to making it available on the market, its compliance with the requirements pursuant to paragraph (1) and § 5 is not jeopardised by storage and transport conditions; and
 - c) prevent the distribution of any equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use that it distributes, if it considers that the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use does not comply with the requirements pursuant to paragraphs (1) to (3) and § 5; if the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use poses a risk to human health, it must inform the manufacturer or importer and the competent public health protection authorities of this fact without delay.
- (5) The manufacturer and importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must always provide instructions for use for any equipment that, if used incorrectly, could pose a risk to or harm the health of individuals or impair the quality of drinking or hot water and, where necessary, include instructions on how to remedy the consequences of incorrect use; the particulars of the instructions for use is laid down by implementing legislation. The distributor^{4a)} of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use must always distribute such equipment to a consumer or other user accompanied by instructions for use and, where applicable, instructions on how to remedy the consequences of incorrect use. The instructions pursuant to the first and second sentences must be in Czech.
- (6) Customers^{6a)} who subsequently treat drinking or hot water and supply it to the public must, for the treatment of drinking or hot water in a domestic distribution system or at the point of use, use only equipment that has been verified pursuant to paragraph (3).
- (7) The requirements relating to the hygienic suitability, effectiveness and marking of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use, including requirements for verifying its effectiveness, is laid down by implementing legislation.

Notification and inspection of notified conformity assessment bodies

§ 5e

- (1) The notifying authority pursuant to Article 3 of Commission Delegated Regulation (EU) 2024/370 is the Ministry of Health.
- (2) The Ministry of Health receives and assesses applications for the notification of conformity assessment bodies, inspects notified conformity assessment bodies to determine whether they fulfil the obligations laid down in Commission Delegated Regulation (EU) 2024/370, and establishes and carries out other procedures necessary for the notification of conformity assessment bodies and the inspection of notified conformity assessment bodies.

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§ 5f

Proceedings concerning the notification of a conformity assessment body

- (1) Proceedings concerning notification of a conformity assessment body are initiated upon an application submitted to the Ministry of Health by a conformity assessment body that is a legal person with registered office in the Czech Republic and is accredited in accordance with the ČSN EN ISO/IEC 17065 standard: Conformity assessment – Requirements for bodies certifying products, processes and services. In addition to the particulars required by the Administrative Code, an application pursuant to the first sentence must contain the particulars pursuant to Article 7(2) of Commission Delegated Regulation (EU) 2024/370.
- (2) The Ministry of Health shall request an opinion from the National Institute of Public Health for the purpose of assessing the application pursuant to paragraph (1). The National Institute of Public Health shall issue its opinion within 60 days of receipt of the request for an opinion.
- (3) In the proceedings concerning the notification of a conformity assessment body, the Ministry of Health shall decide within 180 days of the date of commencement of the proceedings.
- (4) If an applicant seeking notification as a conformity assessment body meets the requirements laid down in Commission Delegated Regulation (EU) 2024/370, the Ministry of Health shall notify the conformity assessment body in the Commission's information system on notified conformity assessment bodies; otherwise, it shall reject the application.
- (5) The Ministry of Health shall inform the applicant that the conformity assessment body has been notified and advise it that information on the date on which the entitlement to carry out the activities of a notified conformity assessment body arises may be obtained from the Commission's information system on notified conformity assessment bodies, and shall suspend the proceedings by means of a resolution recorded in the case file.
- (6) If the Commission or a Member State of the European Union raises an objection pursuant to paragraph (7) to the notification of a conformity assessment body, the Ministry of Health shall invite the applicant to remedy the deficiencies and grant it a reasonable time limit for doing so. If the Ministry of Health concludes that the applicant has remedied the deficiencies, it shall notify the conformity assessment body again in the Commission's information system on notified conformity assessment bodies. If the applicant fails to remedy the deficiencies within the specified time limit, the Ministry of Health shall reject the application.
- (7) The applicant's entitlement to carry out the activities of a notified body shall arise if neither the Commission nor any of the Member States of the European Union raises an objection to the notification of the conformity assessment body within two weeks of the notification being made available in the Commission's information system on notified conformity assessment bodies. The Ministry of Health shall record that fact in the case file and inform the applicant accordingly. Upon the entitlement arising, the applicant is deemed to have had its application granted.
- (8) Without undue delay after the entitlement arises, the Ministry of Health shall publish in the Bulletin of the Ministry of Health a notice concerning the entitlement to carry out the activities of a notified conformity assessment body, including
 - a) the scope of that entitlement;

- b) the date from which the notified conformity assessment body is entitled to carry out the activities of a notified conformity assessment body; and
- c) the identification number of the notified conformity assessment body in the Commission's information system on notified conformity assessment bodies.

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§ 5g

Inspection of notified conformity assessment bodies

- (1) The Ministry of Health shall decide on the suspension, restriction or withdrawal of the notification of a conformity assessment body pursuant to Article 10(1) of Commission Delegated Regulation (EU) 2024/370 or at the request of the notified conformity assessment body.
- (2) A notified conformity assessment body whose notification has been restricted or withdrawn by a final decision of the Ministry of Health must
 - a) inform, without undue delay, all manufacturers, authorised representatives, importers, distributors and conformity assessment bodies affected by the consequences of the change to its notification as a conformity assessment body of the decision taken by the Ministry of Health;
 - b) at the request of the affected manufacturer, authorised representative, importer or distributor, transfer the rights and obligations relating to conformity assessment to another notified conformity assessment body with which the affected manufacturer, authorised representative, importer or distributor has concluded a contract pursuant to § 5h(1), hand over the relevant documentation to that body and inform the Ministry of Health of the transfer of the rights and obligations, including the handover of the documentation;
 - c) ensure that relevant documentation relating to the activities of the notified conformity assessment body is available upon request to public health protection authorities for the period specified by the Ministry of Health in the decision restricting or withdrawing the notification of the conformity assessment body, having regard to the reasons for which the notification of the conformity assessment body was restricted or withdrawn.
- (3) The notified body that has assumed the rights and obligations pursuant to paragraph (2)(b) is entitled to use the documentation provided by the transferring notified conformity assessment body to complete pending conformity assessment cases.
- (4) If a notified conformity assessment body ceases to exist without a legal successor, that notified conformity assessment body must hand over the relevant documentation relating to its activities as a notified conformity assessment body to the Ministry of Health no later than the time of its deletion from the public register.
- (5) Where a notified conformity assessment body has ceased its activities as a notified conformity assessment body or its notification as a conformity assessment body has been restricted or withdrawn and the procedure pursuant to paragraph (2)(b) has not been followed, it must, without undue delay, hand over to the Ministry of Health the documentation relating to conformity assessment that the notified conformity

assessment body produced during its activities as a notified conformity assessment body.

- (6) The Ministry of Health shall ensure that the documentation received pursuant to paragraphs (4) and (5) is available upon request to the public health protection authorities.

§ 5h

Obligations of notified conformity assessment bodies

- (1) Notified conformity assessment bodies carry out conformity assessment activities in accordance with the conformity assessment procedures laid down in the relevant European Union legislation¹¹⁶⁾. In doing so, they act in their own name and on their own responsibility on the basis of a contract for inspection activities, the subject matter of which is conformity assessment activities or the inspection of compliance with the conditions under which a certificate pursuant to Commission Delegated Regulation (EU) 2024/370 was issued.
- (2) When carrying out conformity assessment, notified conformity assessment bodies must verify whether the product or material that comes into direct contact with water complies with the requirements laid down in the relevant European Union legislation¹¹⁴⁾.
- (3) If a notified conformity assessment body finds that a product or material that comes into direct contact with water does not comply with the requirements laid down in the relevant European Union legislation¹¹⁴⁾, it shall require the manufacturer to take corrective measures and shall not issue a certificate pursuant to Commission Delegated Regulation (EU) 2024/370.
- (4) If, in the course of an inspection of compliance with the conditions under which the certificate pursuant to Commission Delegated Regulation (EU) 2024/370 was issued, the notified conformity assessment body finds that a product or material that comes into direct contact with water no longer complies with the specified requirements, it shall require the manufacturer to take corrective measures and, depending on the nature and severity of the failure to comply with those requirements, may restrict or suspend the validity of that certificate or withdraw it.
- (5) If the manufacturer fails to take corrective measures or if those measures do not have the required effect, the notified conformity assessment body shall restrict or suspend the validity of the certificate pursuant to Commission Delegated Regulation (EU) 2024/370 or rescind it.
- (6) At the request of the manufacturer, the notified conformity assessment body must state the amount of the limit of insurance coverage agreed under liability insurance for harm caused by the activities of the notified conformity assessment body.
- (7) A notified conformity assessment body shall inform the Ministry of Health without undue delay of
 - a) all cases in which the issue of a certificate pursuant to Commission Delegated Regulation (EU) 2024/370 was refused, and all certificates pursuant to that Regulation that it has issued, suspended or rescinded;
 - b) all facts and changes affecting the scope and conditions of its notification as a conformity assessment body;

- c) all requests it has received from public health protection authorities and market surveillance authorities pursuant to other legislation¹¹⁷⁾ for information concerning conformity assessment activities carried out;
- d) upon request, of conformity assessment activities carried out within the scope of its notification as a conformity assessment body.

¹¹³⁾ Commission Implementing Decision (EU) 2024/367 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing the European positive lists of starting substances, compositions and constituents authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption.

¹¹⁴⁾ Commission Implementing Decision (EU) 2024/368 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards the procedures and methods for testing and accepting final materials as used in products that come into contact with water intended for human consumption.

¹¹⁵⁾ Commission Delegated Regulation (EU) 2024/371 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing harmonised specifications for the marking of products that come into contact with water intended for human consumption.

¹¹⁶⁾ Commission Delegated Regulation (EU) 2024/370 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down conformity assessment procedures for products that come into contact with water intended for human consumption and the rules for the designation of conformity assessment bodies involved in those procedures.

¹¹⁷⁾ Act No 87/2023 on market surveillance of products and on amendments to certain related acts (the Act on Market Surveillance of Products), as amended.’.

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5. In § 11(1)(a), the word ‘pharmacist,’ is inserted after the word ‘dentist,’ the words ‘or healthcare assistant’ are replaced by the words ‘, practical nurse or paediatric nurse’, the word ‘kurs’ is replaced by the word ‘kurz’ and the word ‘kursu’ is replaced by the word ‘kurzu’.
6. In § 13(1), the word ‘group⁹²⁾’ is replaced by the words ‘group⁷⁵⁾’, in the case of a children’s group of more than 12 children’.
7. In § 15(1), the words ‘, residential respite care facility’ are inserted after the word ‘seniors’ and, in the first sentence, the words ‘with the exception of a provider of community-based social services¹¹⁸⁾’, are inserted after the word ‘regime,’.

Footnote 118 reads as follows:

‘¹¹⁸⁾ § 33a of Act No 108/2006, as amended.’.

8. In the introductory part of § 26(1), the words ‘The manufacturer or importer’ are replaced by the words ‘The manufacturer and importer’ and the words ‘is obliged’ are replaced by the words ‘are obliged’.
9. In § 26(1)(b), the words ‘the manufacturer or importer is obliged’ are replaced by the words ‘the manufacturer and importer are obliged’.

10. In the first sentence of § 26(3), the words ‘the manufacturer or importer’ are replaced by the words ‘the manufacturer and importer’.

11. After § 27, a new § 27a is inserted, which, including the heading, reads as follows:

‘§ 27a

Certificate of free sale

- (1) A certificate of free sale is a public document certifying that a cosmetic product complies with the requirements concerning safety for human health laid down in directly applicable European Union legislation on cosmetic products⁶³). A certificate of free sale is issued to the manufacturer of a cosmetic product having its primary establishment in the territory of a Member State of the European Union and its primary or secondary establishment in the territory of the Czech Republic, at its request, for the purpose of exporting the cosmetic product to countries that are not Member States of the European Union and require that document.
 - (2) The application is submitted electronically to the Ministry of Health and must, in addition to the particulars required by the of Administrative Code, contain
 - a) the reference number of the cosmetic product for the purposes of electronic notification pursuant to Article 13 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, together with the Czech and English names of the product;
 - b) an inspection report from the regional public health authority confirming compliance with good manufacturing practice pursuant to Article 8 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council;
 - c) the cosmetic product safety report pursuant to Article 10 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.
 - (3) The Ministry of Health shall issue a certificate of free sale to the applicant if the labelling of the cosmetic product contains the particulars pursuant to paragraph (2)(a) and the documentation submitted pursuant to paragraph (2)(b) and (c) contains no facts that would prevent the issue of the certificate of free sale. Otherwise, it shall reject the application.
 - (4) The certificate of free sale is valid until the end of the fourth calendar year following the date of the most recent inspection of compliance with good manufacturing practice carried out by a regional public health authority.’.
12. In § 30(2), the words ‘and from the normal use of sports equipment and aids used in outdoor areas, and sound associated with announcing church and religious ceremonies and the time’ are inserted after the word ‘area’ and the words ‘relating to’ are replaced by the words ‘relating to protection or’.
13. In § 38(2), ‘(i)’ is replaced by ‘(j)’.
14. In § 40, the existing text is designated as paragraph (1) and the following paragraph (2) is added:
- ‘(2) The employer must, by means of the single monthly report pursuant to the Act on the Single Monthly Employer Report, provide the data pursuant to paragraph (1)(a), points 1 and 2, for each employee who performs work classified in category three or four, to
- (a) the Ministry of Health for the purposes of the exercise of state administration pursuant to § 80(1)(a) and (l); and

(b) the regional public health authority for the purposes of the exercise of state administration pursuant to § 82(2)(b), (k) and (t).’.

15. In § 40a(1), the number ‘39’ is replaced by ‘40’.

16. In § 40a(2), ‘(1)’ is inserted after the text ‘§ 40’.

17. In § 41, paragraph (1) reads as follows:

- (1) ‘The employer must notify the competent public health protection authority that
- a) biological agents in groups 2 to 4 specified by the Government Regulation laying down conditions for the protection of health at work¹¹²⁾ are to be used for the first time (hereinafter referred to as ‘use of biological agents’) or changes are to be made to their use; or
- b) work is to be carried out in which employees will be or may be exposed to asbestos or material containing asbestos (hereinafter referred to as ‘work involving asbestos’) or changes are to be made in the performance of such work; the employer is not required to notify work involving asbestos where the work involves sporadic and short-term exposure to asbestos^{33d)}; work involving sporadic and short-term exposure to asbestos and the procedure for determining sporadic and short-term exposure to asbestos is laid down by implementing legislation.’.

CELEX: 32000L0054

CELEX: 32009L0148

18. In § 41, the following new paragraphs (2) to (5) are inserted after paragraph (1):

- (2) ‘The particulars of the notification pursuant to paragraph (1) are laid down by implementing legislation⁹⁷⁾. In the case of work involving asbestos, the employer must also attach to the notification a certificate confirming that employees have completed training in the proper prevention of health risks when handling asbestos, the particulars of which are laid down by implementing legislation¹¹²⁾.
- (3) The employer must submit the notification pursuant to paragraph (1)(a) no later than 30 days before the commencement of the use of biological agents and whenever there is a change in the notified information or a change in the use of biological agents. In the event of a change in the use of biological agents, the employer must amend the measures adopted in relation to that change without delay and notify the competent public health protection authority of the change.
- (4) The employer must submit the notification pursuant to paragraph (1)(b) before the commencement of work involving asbestos and whenever there is a change in the notified information or a change in working conditions that may result in increased exposure to asbestos. On the basis of the notification pursuant to the first sentence, the competent public health protection authority shall decide on the authorisation of work involving asbestos. Work involving asbestos may not commence until the authorisation pursuant to the second sentence has become final.
- (5) In the event of a change in the notified information concerning technological procedures, technical and organisational measures to ensure the protection of the health of persons carrying out work involving asbestos and other persons present at or in the vicinity of the workplace where exposure to asbestos occurs or may occur, or the provision of personal protective equipment to persons, where that change may result in increased exposure to asbestos, the employer must, without delay, suspend work involving asbestos, adjust the technical and organisational measures to ensure the protection of the health of persons carrying out work involving asbestos and other persons present at or in the vicinity of the workplace

where exposure to asbestos occurs or may occur and notify the competent public health protection authority of that change. The competent public health protection authority shall conduct new proceedings concerning the authorisation of the change pursuant to the first sentence, in which it shall issue a new decision authorising work involving asbestos. Work involving asbestos may not continue until the authorisation pursuant to the second sentence has become final.’.

Paragraphs (2) to (7) are renumbered as paragraphs (6) to (11).

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19. § 41(7) is deleted. Paragraphs (8) to (11) are renumbered as paragraphs (7) to (10).
20. In § 41(8), the word ‘Obligation’ is replaced by the words ‘In the case of work involving asbestos, the obligations’ and the words ‘paragraphs (1) to (3) applies’ are replaced by the words ‘paragraph (1)(b) and paragraphs (2) and (4) to (6) apply’.
21. In § 41(9), the word ‘Authorities’ is replaced by the words ‘In the case of work involving asbestos, the authorities’, the number ‘5’ is replaced by ‘8’, and the words ‘paragraph (3)’ are replaced by the words ‘paragraph (4) or (5)’.
22. § 47a(4), including footnote 119, reads as follows:
 - (6) ‘Yellow fever vaccination may be carried out by a health service provider through
 - a) a physician with specialist qualifications in the field of hygiene and epidemiology, epidemiology or infectious diseases; or
 - b) a physician with specialist qualifications in the field of occupational medicine, general practice, general practice for children and adolescents or paediatrics, after completing a course in yellow fever vaccination which meets the requirements set out in the Act on the Conditions for Acquiring and Recognising Professional Qualifications and Specialist Qualifications for the Practice of the Medical Professions of Physician, Dentist and Pharmacist¹¹⁹⁾.

¹¹⁹⁾ § 22(3) of Act No 95/2004, as amended.’.

23. In § 47a, the following new paragraph (5) is inserted after paragraph (4):
 - (7) ‘The Ministry of Health keeps records of health service providers carrying out yellow fever vaccination. A health service provider carrying out yellow fever vaccination must notify the Ministry of Health in writing of the commencement of such vaccination; the notification of the commencement of vaccinations shall contain the general particulars of a submission required by the Administrative Code. A health service provider must also notify the Ministry of Health of the cessation of yellow fever vaccination or of any changes to the particulars referred to in the second sentence. The notification shall be submitted within 7 calendar days of the date on which yellow fever vaccination commenced or ceased or the date on which the changes pursuant to the third sentence occurred.’.

Paragraphs (5) and (6) are renumbered as paragraphs (6) and (7).

24. In § 47a(7), the number ‘4’ is replaced by ‘5’.
25. In § 79(1)(e), the text ‘(1)’ is inserted after the text ‘§ 40’.
26. In § 80(1)(f), the text ‘§ 5(6)’ is replaced by the text ‘§ 5b(6), § 5c(2), § 5f, § 5g’.
27. In § 80(1)(p), the words ‘or materials’ are inserted after the word ‘products’.

28. In § 82(2)(d), the text ‘(1)’ is inserted after the text ‘§ 40’, and the words ‘and § 40(2); to issue authorisations pursuant to § 41(4) and (5)’ are added at the end of the subparagraph.

29. § 83a(1)(d) reads as follows:

‘d) the verification of agents that come into direct contact with water pursuant to § 5b(3),’.

30. In § 83a(1), the following new subparagraph (e) is inserted after subparagraph (d):

‘e) the verification of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use pursuant to § 5d(3),’.

Subparagraphs (e) to (j) become subparagraphs (f) to (k).

31. In § 84(1)(l), the words ‘§ 5(6) to (10)’ are replaced by the text ‘§ 5b(6), § 5c(2)’ and the words ‘, § 41(4) and (5)’ are inserted after the text ‘§ 31(1)’.

32. In the introductory part of § 92a(1), the words ‘or material that comes into direct contact with water or an agent’ are inserted after the word ‘product’, the comma after the word ‘water’ is replaced by the word ‘or’, and the words ‘or chemical substances or chemical mixtures intended for the treatment of water to produce drinking water, service water or hot water’ are deleted.

33. § 92a(2) reads as follows:

„(2) The manufacturer or importer of a product or material that comes into direct contact with water commits an infraction by

a) failing to ensure that, when placing them on the market or using them for their own needs, those products or materials comply with the requirements laid down in § 5(1);

b) failing to ensure that only starting substances, compositions and constituents that comply with Commission Implementing Decision (EU) 2024/367 are used in their manufacture pursuant to § 5a(1)(a);

c) failing to ensure that, before being placed on the market, those products are assessed in accordance with the relevant testing procedures and methods laid down in Commission Implementing Decision (EU) 2024/368, pursuant to § 5a(1)(b);

d) failing to ensure that their marking complies with the requirements laid down in Commission Delegated Regulation (EU) 2024/371 pursuant to § 5a(1)(c); or

e) failing to provide the product or material with instructions pursuant to § 5a(5).’.

CELEX: 32020L2184

34. In § 92a, the following new paragraphs (3) to (5) are inserted after paragraph (2):

„(3) The manufacturer of a product or material that comes into direct contact with water commits an infraction by

a) failing to draw up an EU declaration of conformity for that product or material or to update it, in breach of Article 2(5) of Commission Delegated Regulation (EU) 2024/370; or

b) failing to translate into Czech the EU declaration of conformity for a product or material that comes into direct contact with water and that it places on the market in the Czech Republic pursuant to § 5a(2).

(4) The manufacturer or importer of an agent that comes into direct contact with water commits an infraction by

- a) failing to ensure that, before placing it on the market or when using it for its own needs, the agent that comes into direct contact with water complies with the requirements laid down in § 5(1);
- b) placing on the market a chemical substance or chemical mixture contrary to § 5b(1);
- c) failing to ensure that, before placing them on the market, filter media, membranes, ion exchangers or other agents that come into direct contact with water comply with the requirements pursuant to § 5b(2);
- d) failing to arrange for its verification before placing it on the market or to ensure that a record of that verification is drawn up pursuant to § 5b(3); or
- e) failing to provide the agent that comes into direct contact with water with instructions pursuant to § 5b(5).

(5) The manufacturer or importer of equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use commits an infraction by

- a) failing to ensure that, before placing it on the market or when using it for its own needs, the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use complies with the requirements pursuant to § 5;
- b) failing to ensure that, before placing it on the market, the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use complies with the requirements pursuant to § 5d(1);
- c) failing to ensure that, before placing it on the market, the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use uses only water treatment technologies in accordance with § 5d(2);
- d) failing to arrange for its verification before placing it on the market or to ensure that a record of that verification is drawn up pursuant to § 5d(3); or
- e) failing to provide the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use with instructions pursuant to § 5d(5).’.

Paragraphs (3) to (16) are renumbered as paragraphs (6) to (19).

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35. § 92a(9) reads as follows:

‘(9) The distributor of a product or material that comes into direct contact with water or an agent that comes into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use commits an infraction by

- a) failing to ensure that the product or material that comes into direct contact with water or the agent that comes into direct contact with water or the equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use that it makes available on the market complies with the requirements pursuant to § 5a(3)(a), § 5b(4)(a) or § 5d(4)(a);
- b) failing to ensure that, for as long as it handles those products or materials that come into direct contact with water or agents that come into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use before making them available on the

market, their compliance with the specified requirements pursuant to § 5a(3)(b), § 5b(4)(b) or § 5d(4)(b) is not jeopardised by storage and transport conditions;

c) failing to prevent the distribution of a product or material that comes into direct contact with water or an agent that comes into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use that it distributes, contrary to § 5a(3)(c), the part of the sentence before the semicolon, § 5b(4)(c), the part of the sentence before the semicolon or § 5d(4)(c), the part of the sentence before the semicolon;

d) failing to inform the manufacturer or importer of a product or material that comes into direct contact with water or an agent that comes into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use, or the competent public health protection authority, where such products or materials that come into direct contact with water or agents that come into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use pose a risk to human health pursuant to § 5a(3)(c), the part of the sentence after the semicolon, § 5b(4)(c), the part of the sentence after the semicolon or § 5d(4)(c), the part of the sentence after the semicolon; or

e) distributing a product or material that comes into direct contact with water or an agent that comes into direct contact with water or equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use without instructions pursuant to § 5a(5), § 5b(5) or § 5d(5).’.

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36. In § 92a, the following new paragraph (10) is inserted after paragraph (9):

‘(10) The distributor of a product or material that comes into direct contact with water commits an infraction by distributing a product or material that comes into direct contact with water contrary to § 5a(4).’.

Paragraphs (10) to (19) are renumbered as paragraphs (11) to (20).

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37. § 92a(13) is deleted.

Paragraphs (14) to (20) are renumbered as paragraphs (13) to (19).

38. In § 92a, the following new paragraphs (19) and (20), including footnote 120, are inserted after paragraph (18) and read as follows:

‘(19) A notified conformity assessment body commits an infraction by

a) failing to fulfil any of the obligations pursuant to § 5h; or

b) failing to fulfil the obligation to take out liability insurance pursuant to Article 5(10) of Commission Delegated Regulation (EU) 2024/370.

(20) An applicant under Commission Delegated Regulation (EU) 2024/369¹²⁰⁾ commits an infraction if, contrary to Article 13(3) of Commission Delegated Regulation (EU) 2024/369,

a) it fails to keep available all the information it requires to carry out its duties under this Regulation for the period laid down in the first subparagraph of Article 13(3) of Commission Delegated Regulation (EU) 2024/369; or

b) it fails to submit the information pursuant to subparagraph (a) or it fails to make it available to the public health protection authority without delay upon request.

¹²⁰⁾ Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down the procedure regarding inclusion in or removal from the European positive lists of starting substances, compositions and constituents.’.

Paragraph (19) is renumbered as paragraph (21).

39. § 92a(21)(a) to (d) read as follows:

a) ‘(a) CZK 3 000 000, in the case of an infraction under paragraph (1)(c), paragraph (2) (a) to (c), paragraph (3), paragraph (4)(a) to (c), paragraph (5)(a) to (c), paragraph (6)(b), points 1 or 2, paragraph (7)(a), points 1, 2, 5, 7, 12 or 13, paragraph (8), paragraph (10), paragraph (11)(a), paragraph (13)(c), paragraph (16)(b), points 1 or 2, or paragraph (17) or (18);

b) CZK 2 000 000, in the case of an infraction under paragraph (1)(a) or (b), paragraph (4)(d), paragraph (5)(d), paragraph (6)(a) or (c), paragraph (7)(a), points 10 or 14, paragraph (7)(b) or (c), paragraph (11)(d), paragraph (14), paragraph (16)(a) or (c), or paragraph (20);

c) CZK 1 000 000, in the case of an infraction under paragraph (2)(d) or (e), paragraph (4)(e), paragraph (5)(e), paragraph (6)(b), point 6 or 8, paragraph (7)(a), point 8, paragraph (9)(e), paragraph (11)(b), paragraph (12), paragraph (13)(b) or paragraph (15) or (19);

d) CZK 500 000, in the case of an infraction under paragraph (6)(b), points 3, 4, 5 or 7, paragraph (7)(a), points 3, 4, 6 or 9, paragraph (9)(a) to (d), paragraph (11)(c) or paragraph (16)(b), point 3;’.

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40. In § 92a(21)(e), the number ‘4’ is replaced by ‘7’.

41. In § 92a(21)(f), the number ‘10’ is replaced by ‘13’.

42. § 92b(1)(d) reads as follows:

‘d) using an agent that comes into direct contact with water that does not comply with the requirements pursuant to § 5b(7);’.

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43. In § 92b(1), the following new subparagraph (e) is inserted after subparagraph (d):

‘e) using a water treatment technology that does not comply with the requirements pursuant to § 5c(3);’.

Subparagraphs (e) to (g) become subparagraphs (f) to (h).

44. In § 92b(2)(b), the words ‘chemical substance or chemical mixture’ are replaced by the words ‘agent that comes into direct contact with water’, the text ‘§ 5(11)’ is replaced by the text ‘§ 5b(7)’ and, at the end of the subparagraph, the word ‘or’ is deleted.

45. In § 92b(2), the following new subparagraph (c) is inserted after subparagraph (b):

‘c) using a water treatment technology contrary to § 5c(3); or’.

Subparagraph (c) becomes subparagraph (d).

46. In § 92b(4), the words ‘or material that comes into direct contact with water’ are inserted after the word ‘product’, and the text ‘§ 5(12)’ is replaced by the text ‘§ 5a(6)’.

47. In § 92b, the following new paragraph (6) is inserted after paragraph (5):

‘(6) A customer who subsequently treats drinking water and supplies it to the public commits an infraction by

a) using an agent that comes into direct contact with water that does not comply with the requirements pursuant to § 5b(7);

b) using a water treatment technology that does not comply with the requirements pursuant to § 5c(3); or

c) using equipment that does not comply with the requirements pursuant to § 5d(6) for the treatment of drinking or hot water in a domestic distribution system or at the point of use.’.

Paragraphs (6) to (8) are renumbered as paragraphs (7) to (9).

48. In § 92b(9)(b), the words ‘or (f)’ are replaced by the words ‘, (e) or (g)’, and the words ‘or (c)’ are added at the end of the subparagraph.

49. In § 92b(9), at the end of subparagraph (c), the words ‘or paragraph (6)’ are added.

50. In § 92b(9)(d), the words ‘(6) or (7)’ are replaced by the words ‘(7) or (8)’.

51. In § 92b(9)(e), the words ‘(e) or (g)’ are replaced by the words ‘(f) or (h)’ and the text ‘(c)’ is replaced by the text ‘(d)’.

52. In § 92h(1), the text ‘(1)’ is added at the end of the text of subparagraph (d).

53. In § 92h(1), the following new subparagraph (e) is inserted after subparagraph (d):

‘e) failing to fulfil the obligation to provide the data pursuant to § 40(2) to the Ministry of Health or the regional public health authority;’.

Subparagraphs (e) to (k) become subparagraphs (f) to (l).

54. In § 92h(1)(f), the word ‘asbestos’ is replaced by the words ‘work involving asbestos’.

55. In § 92h(7), the number ‘5’ is replaced by the number ‘8’.

56. In § 92h(8), the number ‘7’ is replaced by the number ‘10’.

57. In § 92h, the following new paragraph (11) is inserted after paragraph (10):

‘(11) A natural person, legal person or sole trader that is a user to whom an employee of an employment agency is temporarily assigned commits an infraction by failing to fulfil the obligations pursuant to § 40a.’.

Paragraph (11) is renumbered as paragraph (12).

58. § 92h(12)(a) reads as follows:

‘a) CZK 3 000 000, in the case of an infraction under paragraph (1)(a), (i), (j) or (k), paragraph (3)(d), (e), (f), (g), (h), (j), (k), (l), (n) or (p), paragraph (4)(a), (b), (n), (x) or (y), or paragraph (5) or (11);’.

59. In § 92h(12)(b), the words ‘or (e)’ are replaced by the words ‘or (f)’.

60. In § 92h(12)(d), the words ‘paragraph (1)(g)’ are replaced by the words ‘paragraph (1)(h)’.

61. In § 92h(12)(e), the words ‘(f) or (k)’ are replaced by the words ‘(e), (g) or (l)’.

62. In § 92k(2)(d), the number ‘4’ is replaced by the number ‘5’.

63. In § 94(2), the words ‘§ 5(6) and (10)’ are replaced by ‘§ 5b(6), § 5c(2), § 5f’, ‘§ 27a,’ is inserted after ‘§ 21a,’ and the following sentence is inserted after the second sentence: ‘Only a person pursuant to § 41(1)(b) and § 41(2), (4) to (6) and (8) may be a party to the proceedings pursuant to § 41(4) and (5).’.

64. § 94(4) reads as follows:

‘(4) The first act in the proceedings pursuant to § 82(2)(d), the part of the text after the semicolon, § 82(2)(l), (m), (p) and (q), § 84(1)(c), the part of the text before the semicolon, § 84(1)(e), the part of the text before the semicolon, and § 84(1)(g), (n), (r), (u), (v) and (x) is the issuance of a decision. In the case of the procedure pursuant to § 53(3), the territorial jurisdiction of the public health protection authority is determined by the place where the natural person is staying at the time the relevant facts are established.’.

65. In the second sentence of § 97(2), the word ‘has’ is replaced by the word ‘have’, and the words ‘the manufacturer or importer of the product referred to in § 25(1)(a)’ are replaced by the words ‘the manufacturer and importer of the product referred to in § 25(a)’.

66. In § 99, the words ‘§ 5(6) and (10)’ are replaced by the text ‘§ 5b(6), § 5c(2)’ and the words ‘§ 41(4) and (5), § 61(2),’ are inserted after the text ‘§ 31(1),’.

67. In § 108(1), the words ‘§ 5(2), (3), (6) and (9) to (11)’ are replaced by the words ‘§ 5a(7), § 5b(3), (8) and (9), § 5c(1), § 5d(3), (5) and (7)’, the words ‘§ 41(1) and (7)’ are replaced by the words ‘§ 41(1)(b), § 41(2), first sentence, § 41(10)’ and the text ‘§ 47a(5)’ is replaced by the text ‘§ 47a(6)’.

68. In § 108(4), the words ‘§ 41(1), third sentence’ are replaced by the words ‘§ 41(2), second sentence’.

Article II

Transitional provisions

1. The requirements for products or materials that come into direct contact with water laid down in Act No 258/2000 on the protection of public health and on amendments to certain related acts, as amended from the effective date of this Act, apply only to products or materials that come into direct contact with water that are intended for use in installations put into service after the effective date of this Act or, in the case of repair or reconstruction, in installations put into service before the effective date of this Act.

2. Substances used in the manufacture of a product or material that comes into direct contact with water, in respect of which the manufacturer or importer of that product or material arranged for verification pursuant to § 5(3) of Act No 258/2000, as amended prior to the effective date of this Act, and substances in respect of which the Ministry of Health determined the permissibility, content or, where applicable, migration limit pursuant to § 5(6) (a) of Act No 258/2000, as amended prior to the effective date of this Act, from 13 July 2021 to 31 December 2026, may be used in the manufacture of products or materials that come into direct contact with water until 31 December 2032, provided that they comply with the parametric value of 5 µg/l Pb (lead) at the tap.

3. Where an obligation to modify a product that comes into direct contact with water referred to in point 2 arises under directly applicable legislation of the European Union governing ecodesign requirements for products¹⁾, a declaration of conformity for that product issued by 31 December 2026 pursuant to Act No 22/1997 on technical requirements for products and on

¹⁾ Commission Delegated Regulation (EU) No 811/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to the energy labelling of space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device.

Commission Delegated Regulation (EU) No 812/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to the energy labelling of water heaters, hot water storage tanks and packages of water heater and solar device.

amendments to certain acts, as amended prior to the effective date of this Act, and Act No 90/2016 on conformity assessment of specified products when made available on the market, as amended prior to the effective date of this Act, is deemed valid until 31 December 2032, to the extent covered by the assessment pursuant to § 5 of Act No 258/2000, as amended prior to the effective date of this Act.

4. Agents that come into direct contact with water pursuant to § 5b, water treatment technologies pursuant to § 5c and equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use pursuant to § 5d of Act No 258/2000, as amended from the effective date of this Act, which were placed on the market prior to the effective date of this Act in accordance with Act No 258/2000, as amended prior to the effective date of this Act, may continue to be placed on the market or used, but only until 31 December 2032. Agents that come into direct contact with water, water treatment technologies and equipment for the treatment of drinking or hot water in a domestic distribution system or at the point of use pursuant to the first sentence are deemed, for the period specified in that sentence, to comply with the requirements pursuant to § 5b to § 5d of Act No 258/2000, as amended from the effective date of this Act.

Commission Regulation (EU) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters.

Commission Regulation (EU) No 814/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for water heaters and hot water storage tanks.

Commission Regulation (EU) 2019/2023 of 1 October 2019 laying down ecodesign requirements for household washing machines and household washer-dryers pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending

Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1015/2010.

Commission Regulation (EU) 2019/2022 of 1 October 2019 laying down ecodesign requirements for household dishwashers pursuant to Directive 2009/125/EC of the European Parliament and of the Council amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1016/2010.

Commission Regulation (EU) 2019/2019 of 1 October 2019 laying down ecodesign requirements for refrigerating appliances pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 643/2009.

Commission Regulation (EU) 2019/2021 of 1 October 2019 laying down ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) No 642/2009.

Commission Regulation (EU) 2019/1784 of 1 October 2019 laying down ecodesign requirements for welding equipment pursuant to Directive 2009/125/EC of the European Parliament and of the Council. Commission Regulation (EU) No 666/2013 of 8 July 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for vacuum cleaners.

Commission Regulation (EU) 2019/424 of 15 March 2019 laying down ecodesign requirements for servers and data storage products pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 617/2013.

Commission Regulation (EU) 2023/1670 of 16 June 2023 laying down ecodesign requirements for smartphones, mobile phones other than smartphones, cordless phones and slate tablets pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) 2023/826.

Commission Regulation (EU) 2023/2533 of 17 November 2023 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household tumble dryers, amending Commission Regulation (EU) 2023/826, and repealing Commission Regulation (EU) No 932/2012.

Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC.

Commission Regulation (EU) 2024/1103 of 18 April 2024 implementing Directive 2009/125/EC of the European Parliament and of the Council as regards ecodesign requirements for local space heaters and separate related controls and repealing Commission Regulation (EU) 2015/1188.

DIVISION TWO

Amendment to the Act on the Single Monthly Employer Report

Article III

Act No 323/2025 on the single monthly employer report is amended as follows:

1. At the end of § 5(2)(i), the word ‘and’ is replaced by a semicolon.
2. At the end of § 5(2), the full stop is replaced by a semicolon and the following subparagraphs (k) and (l) are added:
‘k) the Ministry of Health; and
l) regional public health authorities.’.
3. At the end of § 31(4)(h), the word ‘or’ is deleted.
4. At the end of § 31(4), the full stop is replaced by a semicolon and the following subparagraphs (j) and (k) are added:
‘j) the Ministry of Health; or
k) regional public health authorities.’.

DIVISION THREE

TECHNICAL REGULATION

Article IV

This Act was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

DIVISION FOUR

EFFECTIVE DATE

Article V

This Act comes into effect on .