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**Draft Cabinet Regulation regarding plants and parts of plants which may not be used in foods: ex ante impact assessment report (summary)**

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| **Summary of the draft legislation** | |
| Purpose, solution and time of entry into force (500 characters without spaces) | The draft Cabinet regulation regarding plants and parts of plants which may not be used in foods (hereinafter the ‘draft regulation’) was produced to ensure a high level of consumer protection by laying down which plants and parts of plants it is prohibited to use in foods.  The draft regulation will enter into force on 1 January 2021. |

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| **I. Why is the draft legislation necessary?** | | |
| 1. | Legal basis | Article 4(18) of the Law on the supervision of the handling of food. |
| 2. | Current situation and issues that the draft legislation is intended to address; purpose and nature of the regulatory framework | Currently, there is no regulatory framework in Latvia or the EU laying down prohibitions on using plants or parts of plants in foods. Therefore, Member States govern this area through their own instruments, developing laws, resolutions, lists, guidelines, good manufacturing recommendations or other instruments.  In view of point 2 of the minutes/decision of the Cabinet of Ministers meeting of 2 July 2013 (minutes No 37, § 42), ‘Report on the current situation in the handling of food supplements and measures to be taken to improve the protection of consumer rights,’ the Ministry of Health submitted to the Ministry of Agriculture a list of plants and parts of plants the use of which should be prohibited in food supplements, and a list of plants and parts of plants the use of which should be restricted in food supplements.  Pursuant to subparagraph 3.1 of the minutes/decision of the Cabinet of Ministers meeting of 1 December 2015 (minutes No 64, § 34) on the draft regulation on requirements for food supplements, the Ministry of Agriculture was to prepare and submit to the Cabinet of Ministers amendments to the Law on the supervision of the handling of food, authorising the Cabinet of Ministers to establish a list of plants, parts of plants and plant products the use of which is prohibited or restricted in foods. Pursuant to subparagraph 3.2 of the minutes/decision, the Ministry of Agriculture was to prepare this list in cooperation with the Ministry of Health.  On 7 February 2017 at the Ministry of Agriculture in an interdepartmental meeting, the need for the legislative act was assessed, and it was decided that the prohibition and restrictions should apply to all food because if the restrictions were applied only to one category of food, namely food supplements, it would still be possible to use the prohibited or restricted plants in food categories other than food supplements, posing risks to consumer health. The prohibition and restrictions on the use of plants would also reduce the possibility of food entering Latvia from third countries where it is marketed in the country of origin as medicinal. Health care professionals have reported health problems in patients using herbal teas that are not registered as food supplements and are available as food, and therefore consumers have no information about the conditions of use of such tea, doses or warnings for certain consumer categories.  The proposal to establish a list of prohibited and restricted uses for plants was supported by the Food and Veterinary Service (hereinafter, the ‘Service’) and the Ministry of Health. In implementing supervisory measures, the Service has come across cases which raise doubts about the safety and suitability of certain foods, especially herbal teas, for all categories of consumers or their suitability for their intended use.  Pursuant to the amendments to the Law on the supervision of the handling of food of 27 April 2017 (Article 4(18)), the Cabinet of Ministers was authorised to establish a list of plants, parts of plants and other substances the use of which is prohibited or restricted in foods.  Under paragraph 27 of the transitional provisions of the Law, the legislation mentioned should have been issued by 31 December 2018. The Ministry of Agriculture prepared the draft Cabinet regulation entitled ‘Regulation on of plants, parts of plants and other substances the use of which is prohibited or restricted in foods’ (published in VSS 28.06.2018, ref. No 25, § 19, VSS-650) (hereinafter, ‘draft regulation (VSS-650)’), agreed it with the business community and non-governmental organisations and sent it as a draft technical regulation for agreement to the European Commission (hereinafter, ‘Commission’).  Written comments from the Commission on the draft regulation (VSS-650) were received on 14 January 2019. They stated that account had not been taken of the mutual recognition principle, since, under Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, (hereinafter, ‘Regulation No 764/2008’), food products produced and/or legally placed on the market in another European Union (hereinafter, ‘EU’) Member State may be freely placed on the market in Latvia even where they have been produced in accordance with technical rules that differ from the rules which must be observed by domestic products. The Commission also objected to Section II of the draft, entitled ‘II. Notification, registration and withdrawal of the registration of food containing plants and parts of plants prohibited or restricted for use in foods’, stating that the provisions on notification and registration may not apply to those food products containing plants the use of which is restricted which are produced and/or lawfully placed on the market of another EU Member States, as stipulated by Regulation (EC) No 764/2008.  Similarly, the Commission observed that Regulation (EC) No 764/2008 lays down rights and obligations for the competent authorities of states and rights and obligations for their enterprises that wish to sell products in a certain Member State which are already legally marketed in another Member State, when the competent authorities intend to bring in restrictive measures in relation to the products in accordance with the State’s technical rules. After receiving the Commission’s written comments, the Ministry of Agriculture produced a new draft regulation which only establishes a list of plants and parts of plants which may not be used in foods.  Regulation No 764/2008 was repealed on 19 April 2020, and replaced by Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (hereinafter, Regulation (EU) 2019/515). The aim of Regulation (EU) 2019/515 is to strengthen the functioning of the internal market by improving the application of the principle of mutual recognition and by removing unjustified barriers to trade.  Regulation (EU) 2019/515 applies in all Member States and in the states of the European Free Trade Association (EFTA) that are signatories to the Agreement on the European Economic Area (EEA). The mutual recognition principle is also used in relations between the European Union and Turkey. The obligation to apply the principle of mutual recognition to products lawfully manufactured and/or marketed in Turkey derives from European Union case-law associated with Articles 34 and 36 of the Treaty on the Functioning of the European Union.  The draft regulation falls within the sphere in which legislation is not harmonised at a European Union level, and therefore the provisions of Regulation (EU) 2019/515 are applied directly and a clause concerning the mutual recognition principle is not included in the draft regulation, since it is lawful to distribute on the Latvian market food which does not meet the requirements of this regulation but which is lawfully marketed in another European Union Member State or in Turkey or which originates from and is legally marketed in one of the European Free Trade Association countries that is a signatory to the Agreement on the European Economic Area, complying with the directly applicable provisions in the above-mentioned European Union legislation concerning the mutual recognition of goods. The new draft regulation will again be notified to the Commission.  Currently, pursuant to the amendments to the Law on the supervision of the handling of food of 21 November 2019 (Article 4(18)), the Cabinet of Ministers is authorised to establish a list of plants and parts of plants the use of which is prohibited in foods. Paragraph 30 of the transitional provisions of the Law on the supervision of the handling of food provides that the Cabinet of Ministers should issue the regulation mentioned in Article 4(18) of the law by 31 December 2020.  When drafting the regulation, the Service’s reports on plants and parts of plants which are used in foods and the concerns raised about their safety were assessed. Monographs of the European Medicines Agency (hereinafter ‘EMA’), scientific conclusions of the European Food Safety Authority (hereinafter ‘EFSA’) and technical regulations and guidelines of other EU Member States were taken into account. Plants contain multiple chemical compounds and individual components that can produce a physiological, therapeutic or toxic effect and are referred to as chemically active substances. Therefore, the list of prohibited and restricted plants was discussed with pharmaceutical experts. A chemically active substance may be found only in certain parts of a plant such as flowers, seeds, fruit, leaves, stem, bark, top or root rather than the whole plant. Therefore, the annex to the draft regulation specifies prohibitions on the use of whole plants and certain parts of plants.  The following chemically active substances may be found in plants or parts of plants: terpenoid, tropane, isoquinoline, piperidine, pyrrolizidine and steroidal alkaloids, hydroxycinnamic acid derivatives, saponins, proteolytic enzymes, cardenolide or cardiac glycosides, diterpenoids, phenethylamine derivatives, etc. which, when ingested, may cause disorders such as poisoning, vomiting, severe headache, hoarseness, fatigue or agitation, increased heart rate, hypotension and trembling of the extremities. In severe cases, the substances mentioned may cause dysfunction of the internal organs or paralysis or pose risks to life. Plants or parts of plants which are dangerous or may be detrimental to the health of consumers (annex to the draft regulation) may not be used in food.  With an increased interest in healthy lifestyles, consumers are showing a greater interest in natural food as a prerequisite for good health. This is leading to an increase in the range of foods produced from natural ingredients, and as plants are one of these ingredients they are therefore playing an ever greater part in the daily diets of consumers. Raising consumer awareness of the use of plants in food is a factor that helps consumers to make informed choices and pick products which best suit their individual needs.  Foods carrying product names such as ‘herbal tea’ or ‘medicinal herbal tea’ or similar names often contain one plant or parts of a plant or a mixture of plants. This type of food sometimes raises concerns about its suitability for use in the daily diet of consumers because plant ingredients have different physiological effects and are not necessarily suitable for all categories of consumers, for example for children, pregnant women or women who are breastfeeding.  If plant properties are indicative of a poisonous effect, the plant is included in the draft regulation's list of plants which may not be used in food (annex to the draft regulation).  Quite often, a plant can be used in various ways – as food for particular physiological purposes or as a pharmaceutical product that is as a herbal medicine for medical purposes. To establish a borderline between purposes of use, food and pharmaceutical laws are used, which provide definitions for food (foodstuff) and medicines of plant origin.  Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, explains that food or foodstuff means any substance or product, whether processed, partially processed or unprocessed, intended to be or reasonably expected to be ingested by humans. As a rule, food is not characterised as having any medicinal properties or capacity to prevent, treat or cure any diseases.  The Pharmaceutical Law provides that a medicinal product is any substance or combination of substances which presents properties that are needed for the treatment or prophylaxis of human and animal diseases, as well as any substance or combination of substances which may be used in or administered to humans or animals with the aim of either restoring, correcting or changing physiological functions causing pharmacological, immunological or metabolic effects or with the aim of making a medical diagnosis.  Regulation No 376 of the Cabinet of Ministers of 9 May 2006 on the procedure for the marketing authorisation of medicinal products provides that traditionally used herbal medicinal products are intended and made so that they can be used without the direct supervision of a medical practitioner for the purpose of conducting, diagnosing or monitoring treatment. These medicinal products should be used in certain strengths and doses, there should be sufficient data available about their traditional use, and their pharmacological effect should be demonstrated by their long-term use and experience.  The definition of medicinal products applicable to foodstuffs, and in particular food supplements, is analysed in the report from the Commission of 5 December 2008 to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements.  The report mentions the view of the European Court of Justice that the definition of a medicinal product: (1) by function should be interpreted restrictively, since it is designed to cover only products whose pharmacological properties have been scientifically observed, and not substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions;  (2) by presentation is subject, according to settled case-law, to broad interpretation, so as to avoid consumers being misled by improper presentation.  Thus, it is more specifically as regards presentation that some food supplements are liable to fall within the definition of medicinal product. It will be possible to significantly reduce this risk of a conflict of classification by applying the rules on health claims concerning foodstuffs in accordance with Regulation No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (hereinafter, ‘Regulation (EC) No 1924/2006’).  The use of plants in food is not harmonised at the EU level, and therefore the approach of Member States to the evaluation of plants and parts of plants varies. Some Member States have lists of both prohibited and restricted plants while some have only a list of permitted plants or apply guidelines for the use of plants in food, or else their pharmaceutical law defines the area where a plant may be used. The same applies to the maximum permissible amount of a plant in a food: one Member State may set the reference intake for a plant close to the minimum therapeutic limit of the medicinal product derived from the plant, while another Member State may set a much lower amount for the reference intake of the same plant through food. A situation where in one state a product is considered as food but in another as a medicinal product creates obstacles to free trade among EU Member States. These products are referred to as borderline products.  Pursuant to Regulation (EC) No 1924/2006, EFSA has now evaluated most substances that are found in plants and are known as botanical and other substances. The claims may be found on the website of the European Commission under the title ‘*Some function claims, for which the assessment by EFSA or the consideration by the Commission is not finalised*’[[1]](#footnote-1).  The European Commission has not taken a final decision on the evaluated claims that are included in the aggregate list. Information about the claims that have been evaluated or are being evaluated which relate to plants or other substances may be found in the ‘Register of Questions’ section of the EFSA website[[2]](#footnote-2) using the identification number (ID) or the plant’s Latin name or English name. The section ‘Database of health claims submitted to EFSA for evaluation’ may also be used – there you can find consolidated information about plants and other substances that have been submitted for evaluation to EFSA. Claims that are included in this section currently can be used subject to Article 28(5) and (6) of Regulation (EC) No 1924/2006.  Plants listed in the annex to the draft regulation comply with the definition of Article 2(2) of Regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (hereinafter, ‘Regulation (EC) No 1925/2006’); ‘other substances’ are substances other than a vitamin or a mineral that have a nutritional or physiological effect, and therefore substances whose use in foods is prohibited, restricted or under Community scrutiny are to be included in Annex III to Regulation (EC) No 1925/2006. So far, only two substance whose use in foods is prohibited have been listed in the mentioned annex – Yohimbe tree bark and preparations obtained from *Yohimbe* (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille), and the *Ephedra* plant and preparations obtained from *Ephedra* species. Therefore, for the safety of public health and consumer awareness, some Member States have found it necessary to adopt new legislation on the restriction or prohibition of certain plants or other substances in the manufacture of particular foods.  Currently provisions are applied in the draft regulation that are mentioned in Article 11(2)(b) of Regulation (EC) No 1925/2006. If, in the absence of EU provisions, a Member State considers it necessary to adopt new legislation on the restriction or prohibition of certain plants in the manufacture of particular foods, it must notify the European Commission under the procedure laid down in Article 12 of the Regulation. Information about the laws of some Member States is given in paragraph 4 of this section.  In exercising its supervisory functions over food containing plants and parts of plants, the Service applies the general food laws and regulations and in addition examines the information provided in various sources or the scientific findings found in the technical regulations of EFSA, the EMA, the World Health Organization, the other Member States and websites of their authorities in order to determine if such food can be considered harmless to the consumer. Such an examination is very labour-intensive, and food business operators (distributors, importers, manufacturers), experts from competent authorities and food safety agencies of other Member States have different interpretations of the application of the rules and regulations.  The annex to the draft regulation lays down the list of plants and parts of plants which may not be used in foods. The plants were included in the list based on the presence of the chemically active substance (toxic compound) in the plant, potential uses in food or pharmacy, pharmacological and toxicological properties, potential efficacy or harm, dosages and dosage limits, side effects and toxicity using the technical regulations on the use of plants in food of other Member States as an additional source of information. Some of the plants included in the annex to the draft regulation are used as medicinal products, including homoeopathic medicines. The annex to the regulation specifies plants that are harmful for health due to the presence of toxic compounds, if used in food. These are:  adonisi – Adonis spp. (cardiac glycosides), Areca, tropical – Areca catechu L. (piperidine alkaloids), aristolohcia – Aristolochia spp. (aristolochic acid), Arnika montana – Arnica montana L, (helenalin ether oil), Arnica chamissonis – Arnica chamissonis Less. (helenalin essential oil), wormseed – Chenopodium ambrosioides L. var. anthelminticum (L.) A.Gray, (ascaridole essential oil), false indigo – Baptisia spp. (quinolizidine alkaloids), bittersweet – Solanum dulcamara L. (steroidal alkaloids), deadly nightshade – Atropa belladonna L., (tropane alkaloids), yellow fumitory – Corydalis spp. (isoquinoline alkaloids), herb-paris – Paris quadrifolia L. (glycosides), petty spurge – Euphorbia spp., (diterpenoids), dumb cane – Dieffenbachia spp. (proteolytic enzymes), henbane – Hyoscyamus spp. (tropane alkaloids), ephedra –Ephedra spp, (protoalkaloids (phenethylamine derivatives)), snowy angel’s trumpe – Brugmansia spp. (tropane alkaloids), eagle fern – Pteridium aquilinum (L.) Kuhn. (sesquiterpene lactones, cyanogenic glycosides), pokeweeds – Phytolacca spp. (triterpene saponins, lectins), fritillaries – Frittillaria spp. (steroidal alkaloids), yellow jessamine – Gelsemium spp. (indole alkaloids), heliotropes – Heliotropium spp., (pyrrolizidine alkaloids), ipecacuanha Nicaragua, ipecacuanha Panama – Cephaelis acuminata (Benth.) Karst., syn. Uragoga acuminata (Benth.) O. Kuntze, Psychotria acuminata Benth (isoquinoline alkaloids), Ipecacuanha, Rio; Ipecacuanha, Brazil – Cephaelis ipecacuanha (Brot.) A. Rich., syn. Uragoga ipecacuanha (Brot.) BAILL., Psychotria ipecacuanha (Brot.) Muell, Arg. (auch Stokes) (isoquinoline alkaloids), holly – Ilex aquifolium L. (isoquinoline alkaloids), Yohimbe – Pausinystalia yohimbe (K. Schum) Pierre ex Beille (indole alkaloids), periwinkle – Vinca spp. (indole alkaloids), croton – Croton spp. (tiglic acid ), Madagascar periwinkle – Catharanthus roseus (L.) G.Don (indole alkaloids), lilies of the valley – Convallaria majalis L. (cardiac glycosides), ragworts – Senecio spp. (pyrrolizidine alkaloids), wild gingers – Asarum spp. (essential oil asarone), monk’s hood – Aconitum spp. (terpenoid alkaloids), lobelias – Lobelia spp. (piperidine alkaloids), mandragora – Mandragora officinarum L. (tropane alkaloids), Canadian moonseed – Menispermum canadense L. (isoquinoline alkaloids), Solomon’s seals – Polygonatum spp. (steroidal saponins), ox-eye beans – Mucuna pruriens (L.)DC., syn. Stizolobium pruriens (L.) Medik. (indole alkaloids), nightshade – Solanum nigrum L. (steroidal alkaloids), oleander – Nerium spp. (cardiac glycosides), common columbine – Aquilegia vulgaris L. (isoquinoline alkaloids), male fern – Dryopteris filix-mas (L.) Schott, syn. Aspidium filix-mas (L.) Sw., Lastrea filix-mas (L.) Presl., Polypodium filix-mas L. (phloroglucinol derivatives), jaborandi – Pilocarpus spp. (imidazole alkaloids), Fish poison tree – Piscidia piscipula (L.) Sarg., syn. Piscidia erythrina L. (alkaloids, cyanogenic glycosides), rauvolfia– Rauvolfia spp. (indole alkaloids), sassafras – Sassafras spp., (safrole), white bryony – Bryonia spp. (tetracyclic triterpene saponins), sida – Sida spp. (protoalkaloids (phenethylamine derivatives), strychnine trees – Strychnos spp. (indole alkaloids), strophanthus – Strophanthus spp., (cardiac glycosides), blue cohosh – Caulophyllum thalictroides (L.) Michx. (quinolizidine alkaloids), poison hemlock – Conium maculatum L. (piperidine alkaloids), comfrey – Symphytum spp. (pyrrolizidine alkaloids), thuja – Thuja spp. (essential oil thujone), drimia maritima – Urginea spp. (cardiac glycosides), foxgloves – Digitalis spp. (cardiac glycosides), thorn-apple – Datura spp. (tropane alkaloids), veratres – Veratrum spp. (steroidal alkaloids), naked ladies – Colchicum spp. (protoalkaloids), anemone – Anemone spp. (protoanemonin), mezereon – Daphne mezereum L. (diterpenoids), golden chain – Laburnum anagyroides Medik. syn. Cytisus laburnum L. (quinolizidine alkaloids). |
| 3. | Authorities and capital companies of public persons involved in the drafting of the regulation | Ministry of Health, State Agency of Medicines, Food and Veterinary Service. |
| 4. | Other information | Information about the technical regulations of certain Member States[[3]](#footnote-3), which are agreed with the European Commission and the Member States of the European Union pursuant to 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 and other useful information.  France: notification No 2012/0728/F[[4]](#footnote-4). The resolution specifies plants (except mushrooms) which may be used in food supplements and conditions for their use.  Italy: notification No 2017/276/I[[5]](#footnote-5). The Decree regulating the use of vegetable substances and preparations in food supplements lays down a list of substances and preparations of plant origin that may be used in food supplements and sets the requirements that need to be met in order to ensure they are safe (Annex 1 to the decree on substances and preparations of plant origin that may be used in food supplements and Annex 2, Documents to be prepared and requirements to be satisfied with regard to the use of substances and preparations of plant origin in food supplements).  Belgium: Notification No 2015/162/ B[[6]](#footnote-6). Royal Decree amending the Royal Decree of 29 August 1997 on the manufacture and trade of foods composed of or containing plants or plant preparations.  Romania: Notification No 2015/0152/ RO[[7]](#footnote-7). Order of the Ministry of Agriculture and Rural Development and the Ministry of Health with regard to the preparation, processing and marketing of medicinal and aromatic plants used on an as is basis, which are partially processed or processed as pre-dosed food supplements.  Czech Republic: Notification No 2016/257/ CZ[[8]](#footnote-8). Implementing Decree on food supplements and the composition of foodstuffs.  Lithuania: Notification No 2014/175/ LT[[9]](#footnote-9). Order of the Minister for Health of the Republic of Lithuania, amending Order No V-432 of the Minister for Health of the Republic of Lithuania of 13 May 2010 approving the Lithuanian Hygiene Norm HN 17:2010 – Food Supplements.  The Scientific Committee of The European Food Safety Authority (EFSA) has compiled a list of plants of the Member States (Compendium of botanicals.EFSA Journal 2012;10 (5):2663)[[10]](#footnote-10). The list of plants is provided for informational purposes only.  Germany has drawn up guidelines for the category ‘Plants and plant parts’[[11]](#footnote-11). They are designed to serve as a reference guide for businesses, the controlling authority and other interested persons about the appropriate use of plants and parts of plants in food (tea, spices, flavourings), pharmacy (herbal medicines) or novel food.  Austria has set requirements for herbal teas and plants that can be used in the manufacture of tea or tea-like products[[12]](#footnote-12). Information for interested persons. |

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| **II. Social, economic and administrative impacts of the draft legislation** | | |
| 1. | Target social groups who are or may be affected by the regulatory framework | The draft regulation applies to the following:  (1) Food business operators that produce food from plants. According to the Service in Latvia there are currently:  (a) 40 undertakings manufacturing food supplements;  (b) 46 undertakings processing medicinal plants;  (2) the Service that is in charge of supervising and controlling the handling of food;  (3) consumers using food containing plants or parts of plants. |
| 2. | Impact of the regulatory framework on the economy and the administrative burden | The draft regulation will facilitate the operation of enterprises involved in the handling of food as it sets clear conditions regarding the use of plants and parts of plants in food (food supplements, tea, syrup, and other food products) and so will help entrepreneurs to ensure the safety of these products.  The draft regulation will also facilitate the Service’s supervision measures and mutual understanding of the application of legislation with enterprises involved in the handling of food which use plants in the production of food. |
| 3. | Assessment of administrative costs | The draft does not affect this area. |
| 4. | Assessment of compliance costs | The draft does not affect this area. |
| 5. | Other information | No. |

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| **III. Impact on the State and local government budgets** |
| The draft does not affect this area. |

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| **IV. Impact of the draft legislation on the existing legal framework** |
| The draft does not affect this area. |

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| **V. Compliance of the draft legislation with the Republic of Latvia's international obligations** | | |
| 1. | Obligations to the European Union | The draft does not affect this area. |
| 2. | Other international obligations | The draft does not affect this area. |
| 3. | Other information | No. |

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| **Table 1 Conformity of the draft legislative act with EU laws** | | | |
| Date, number and title of the respective EU legislative act | The draft does not affect this area. | | |
| A | B | C | D |
| Article number of the respective EU legislative act (referencing every part of the legislative act: article, section, paragraph, subparagraph) | Draft clause which transposes or implements each clause of the EU legislative act mentioned in column A of the table or legislative act where the respective clause of the EU legislative act has been transposed or implemented | Information on whether the provisions of the EU legislative act mentioned in column A of the table are transposed or implemented fully or partly.  If a clause of the EU legislative act is transposed or implemented in part, explain and specify when and how the respective provision will be transposed or implemented in full.  Please specify the authority responsible for full implementation | Information on whether the project items listed in column B of this table go beyond the requirements of the EU legislative act item listed in column A of this table.  If the draft imposes stricter requirements than EU legislation, please give reasons and explain the proportionality.  Please specify all alternatives (including non-regulatory alternatives) which could be used to avoid imposing more stringent requirements than those stipulated in EU legislation |
| Has the Member State used discretionary rights to transpose or implement certain provisions of EU law? Why? | The draft does not affect this area. | | |
| Obligation to report to EU institutions and EU Member States in accordance with regulations governing the provision of information on draft technical regulations, State support and financial regulations (regarding monetary policy) | The draft regulation will be notified to the European Commission and EU Member States for the submission of an opinion, in accordance with:  (1) the requirements of Articles 5 and 6 of Directive [2015/1535/EU](http://eur-lex.europa.eu/eli/dir/2015/1535/oj/?locale=EN) 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;  (2) The requirements of Article 12 of Regulation (EC) No 1925/2006 of 20 December 2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. | | |
| Other information | Information on the draft regulation following its entry into force will be notified to the Product Contact Point [www.latvija.lv](http://www.latvija.lv), as Member States must provide accessible information online at the Product Contact Points, including information on the technical rules for products and their requirements, in accordance with Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012. | | |
| **Table 2 Obligations assumed through the draft legislation and arising from international laws or documents of international bodies or organisations. Measures to meet the obligations.** | | | |
| The draft does not affect this area. | | | |

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| **VI. Public involvement and communication efforts** | | |
| 1. | Planned public involvement and communication efforts related to the draft | The draft was emailed for approval to the Lauksaimnieku organizāciju sadarbības padome, Zemnieku saeima and Stādu audzētāju biedrība societies, the Latvian Food Enterprise Federation, the Latvian Association of Nutrition and Dietetic Professionals, the Latvian Dietitian Association, the Latvian Association of Food Traders, the Latvian Association of Traders, SIA L.Ē.V. (extraction plant), SIA Aptiekas produkcija, AS BIOLAT, AS GRINDEKS, SIA Lotos Pharma, SIA DEIVA, ZS DOKTUS, SIA MedPro Nutraceuticals, SIA SILVANOLS, AS RĪGAS FARMACEITISKĀ FABRIKA, AS OLAINFARM, SIA Inovatīvo biomedicīnas tehnoloģiju institūts, the SIA Vedic Institute of Healthcare and Research, SIA PRIMEA, the Lauku ceļotājs Country Tourism Association (including ZS RŪĶĪŠU TĒJA, ZS UPMAĻI, ZS OZOLIŅI, ZS INDRĀNI, IU Salvija, SIA 3x9 zālītes, Mārīte Merga and others). |
| 2. | Public involvement in the drafting of the regulation | Information about the draft regulation was posted on the Cabinet of Ministers’ website in the ‘Public involvement’ section and on the Ministry of Agriculture’s website in the ‘Public involvement’ section from 13 February 2020 to 27 February 2020.  <https://zm.gov.lv/zemkopibas-ministrija/apspriesanas/ministru-kabineta-noteikumu-projekts-noteikumi-par-izmantosanai-partik?id=887>  https://www.mk.gov.lv/content/ministru-kabineta-diskusiju-dokumenti. |
| 3. | Results of public involvement | No objections or suggestions were received concerning the draft regulation posted on the Cabinet of Ministers’ website www.mk.gov.lv or on the Ministry of Agriculture's website [www.zm.gov.lv](http://www.zm.gov.lv).  No opinions were received from non-governmental organisations.  Agreement was reached on the proposals put forward by the State Agency of Medicines. |
| 4. | Other information | No. |

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| **VII. Implementation of the draft legislation and its impact on bodies** | | |
| 1. | Bodies involved in implementing the draft | Food and Veterinary Service. |
| 2. | Impact of the draft’s implementation on administrative functions and institutional structures.  Set-up of new bodies, dissolution or restructuring of existing ones, impact on the human resources thereof | It is not necessary to create new bodies in connection with the draft regulation, nor to dissolve or restructure existing ones. The implementation of the draft regulation will not have any impact on the human resources available to the bodies. |
| 3. | Other information | No. |

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1. <https://www.efsa.europa.eu/en/topics/topic/article13> [↑](#footnote-ref-1)
2. <http://registerofquestions.efsa.europa.eu/> [↑](#footnote-ref-2)
3. <http://ec.europa.eu/growth/tools-databases/tris/en/> [↑](#footnote-ref-3)
4. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2012&num=728> [↑](#footnote-ref-4)
5. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=276> [↑](#footnote-ref-5)
6. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2015&num=162> [↑](#footnote-ref-6)
7. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2015&num=152> [↑](#footnote-ref-7)
8. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=257> [↑](#footnote-ref-8)
9. <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2014&num=175> [↑](#footnote-ref-9)
10. <http://www.efsa.europa.eu/en/efsajournal/pub/2663> [↑](#footnote-ref-10)
11. <https://www.bvl.bund.de/EN/07_TheFederalOffice/06_Events/Eventarchive/Stoffliste2014/Stoffliste_2014_node.htm> [↑](#footnote-ref-11)
12. <http://www.lebensmittelbuch.at/tee-und-teeaehnliche-erzeugnisse/tee/> [↑](#footnote-ref-12)