Unofficial Translation; Excerpts

Act No. 100/1997

Act on foodstuffs and tobacco products and on amendments and additions to related acts

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Part 38/1997

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110

ACT

dated April 24, 1997

on foodstuffs and tobacco products and amending and supplementing some related Acts

Parliament has passed this Act of the Czech Republic:

PART ONE

FOOD AND TOBACCO PRODUCTS

Section 1

Subject of the legislation

(1) This Act promulgates the relevant regulations of the European Union [18)] and regulates, further to the directly applicable regulations of the European Union [19)], the obligations of operators of food businesses, manufacturers, importers, retailers and wholesalers of tobacco products and products associated with tobacco products and regulates state supervision over compliance with obligations under this Act and directly applicable legislation of the European Union.
(2) This Act does not apply to drinking water [20)].

Section 2

Basic terms

(1) For the purposes of this Act the following terms are used
   a) control sample - a composite of all the incremental samples containing the sample or samples intended for official inspection, or also a sample intended for complementary expert assessment to meet the needs of the inspected entity, if so requested by the inspected entity,
   b) net quantity - the amount of food without packing or the average amount of food prescribed according to the implementing legislation or directly applicable legislation of the European Union,
   c) name [21)] - the product name, type, group or subgroup of food prescribed by other legislation [22)] or implementing regulation,
   d) destination - the place of the first intake of foodstuffs, including the place of any initial treatment or handling of foodstuffs in the Czech Republic,

e) quality - a set of characteristics of individual types, groups and subgroups of food and tobacco products, the limits of which are set herein, the implementing legislation or directly applicable EU regulation,
f) food production - cleaning, sorting, modification, manufacturing and processing, including related packaging and other modification of foodstuffs for the purpose of marketing, with the exception of activities consisting only in a separate packaging process or cutting or other method of cutting foodstuffs including their subsequent packaging,
g) food supplement - a foodstuff, the purpose of which is to supplement the normal diet and which is a concentrated source of vitamins and minerals or other substances with a nutritional or physiological effect, contained in the food alone or in combination, intended for direct consumption in small measured quantities,
h) marketing of tobacco products or products associated with tobacco products - the offering for sale or provision of goods, irrespective of their place of production, to consumers who are in a Member State of the European Union or in a Contracting State to the Agreement on the European Economic Area (hereinafter "EU Member State"), in return for payment or free of charge, even through distance selling; in the case of cross-border distance sales, the product is deemed to be marketed in the EU Member State in which the customer is located,
i) primary use of foodstuffs - use as specified by the manufacturer,
j) foodstuffs usable for other than primary use - safe foodstuffs, but do not meet the requirements for their primary use,
k) batch quantities of generically identical units, which were manufactured under the same conditions,
l) tobacco product - a product that can be used and includes wholly unmodified or partly genetically modified tobacco,
m) classification of carcasses of animals for slaughter (hereinafter the "classification of slaughter animals") a method of classifying carcasses of slaughter animals in classes in a manner prescribed by the applicable regulations of the European Union and the implementing regulation;
n) foodstuff of unknown origin - a foodstuff for which it is not possible to identify the food business operator that manufactured a foodstuff or a component thereof or delivered to another food business operator,
o) foodstuffs of animal origin - foodstuffs with set definitions laid out in sections 1.1, 1.10, 1.11, 1.12, 1.13, 1.14, 1.15, 2.1, 3.1, 3.4, 3.5, 3.6, 4.1, 5.1, 5.2, 5.3, 6, 7 and 8.1 second and third indent of Regulation (EC) of the European Parliament and of the Council No 853/2004, colostrum, blood, bee products and crocodile meat,
p) sales section - the part of the sales area at convenience stores defined by the counter, if the counter has no partitions, or the parts of the sales counter separated by partitions and related spaces in convenience stores used for the treatment and storage of foods marketed at the sales counter, if the counter has no partitions, or the part of the sales counter separated by partitions,
q) tobacco - means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco,
r) pipe tobacco - means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;
s) roll-your-own tobacco - means tobacco which can be used for making cigarettes by consumers or retail outlets,

t) smokeless tobacco product - means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use,
u) chewing tobacco - a smokeless tobacco product designed exclusively for chewing,
v) snuff - means a smokeless tobacco product that can be consumed via the nose,
w) tobacco intended for oral use - all tobacco products made wholly or partly of tobacco for oral use, except those which are intended for inhalation or chewing, in powder or particulate form or in any combination of these forms, provided especially in sachet portions or porous sachets,
x) tobacco products for smoking - means tobacco products other than a smokeless tobacco product,
y) cigarette - means a roll of tobacco that can be consumed via a combustion process, i.e.
    1. roll of tobacco capable of being smoked as they are and which are not cigars or cigarillos,
    2. rolls of tobacco, which, by simple non-industrial handling, are inserted into cigarette-paper tubes, or
    3. rolls of tobacco, which, by simple non-industrial handling, are wrapped in cigarette paper, or
z) cigar - a roll of tobacco that can be consumed via a combustion process, they may be smoked as they are, and given their properties and normal consumer expectations, are intended exclusively for smoking as they are
    1. with an outer wrapper of natural tobacco, or
    2. with a threshed blend filler and with an outer wrapper of the normal colour of a cigar, of reconstituted tobacco, covering the product in full, including, where appropriate, the filter but not, in the case of tipped cigars, the tip, where the unit weight, not including filter or mouthpiece, is not less than 2.3 g and not more than 10 g, and the circumference over at least one third of the length is not less than 34 mm;

Products consisting in part of substances other than tobacco but otherwise conforming to the criteria set out in this point shall be treated as cigars and cigarillos.

(2) For the purposes of this Act
a) cigarillo shall be considered to be a cigar weighing not more than 3 g
b) waterpipe tobacco - means a tobacco product that can be consumed via a waterpipe. For the purpose of this Directive, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;
c) novel tobacco product - means a tobacco product which
    1. does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and
    2. was placed on the market after 19 May 2014,
d) herbal product for smoking - means a product designed for smoking based on plants, herbs or fruits which contains no tobacco and that can be consumed orally or nasally via a combustion process;
e) electronic cigarette - means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges,

f) refill container - means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette,
g) 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives,
h) additive - means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging,
i) characterising flavour - means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product,
j) outside packaging - means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging,
k) cross-border sales of tobacco, electronic cigarettes or refills for the distance sales of tobacco, electronic cigarettes or refills to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in an EU Member State other than the EU Member State or the third country where that retail outlet is established,
l) manufacturer of tobacco product or tobacco-related products - means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark,
m) importer of tobacco or related products - means the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of an EU Member State;
n) retailer of tobacco products - means any outlet where tobacco products are placed on the market including by a natural person,
o) tobacco-related products, electronic cigarette, refills and herbal products for smoking,
p) distributor of tobacco products or tobacco-related products - means any natural or legal person who handles tobacco products or tobacco related products, and is not the manufacturer, importer or retailer of tobacco products or products associated with tobacco products,
q) reconstituted tobacco - tobacco sheet made by combining finely comminuted tobacco, tobacco waste and tobacco dust,
r) unit packet - means the smallest individual packaging of a tobacco or related product that is placed on the market,
s) flavouring - means an additive that imparts smell and/or taste,

. . .

Section 12

(1) Manufacturer not the manufacture of tobacco use
a) other than raw or technologically modified tobacco,
b) prohibited substances specified in the implementing regulation.

(2) Tobacco products placed on the market must not contain prohibited substances specified in the implementing regulation, which especially create the impression of the health benefits of tobacco products, cause discolouration issues, facilitate the inhalation of nicotine intake or increase the toxic or addictive effect of a tobacco product.

(3) The placing on the market of tobacco intended for oral use is prohibited.

(4) The placing on the market of cigarettes with a characterising flavour and roll-your-own tobacco with a distinctive flavour is prohibited.

(5) Additives may be used for the production of cigarettes and tobacco for roll-your-own cigarettes which are essential for their production, provided that these additives do not result in a certain characterising flavour and

a) which means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both,

b) toxicity, which means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure, or

c) has carcinogenic, mutagenic or reproductive toxicity properties.

(6) The placing on the market of cigarettes or tobacco intended for the rolling of cigarettes containing aromas in any of its components, particularly filters, paper, packaging or capsules, and other technical elements to change the taste or smell of tobacco smoke, or their intensity, is prohibited. Filters, paper and capsules shall not contain tobacco or nicotine.

Section 12a

(1) The manufacturer, importer, retailer and distributor of tobacco products or products associated with tobacco products shall comply with the requirements specified for foodstuffs in

a) section 3 1(a), (b) and (g) and section (3),

b) section 10(1) (a) and (c)

c) section 3 (1)(q)(1), (3) and (5)(r).

(2) The provisions of section 12(4)-(6) do not apply to tobacco products with a characterising flavour whose Union-wide sales volumes represent 3 % or more in a particular product category.

Section 12b

(1) The marking of unit packets and the outer packaging of tobacco products and the tobacco product itself may not include a forbidden element or feature, especially in written, pictorial, graphic or shape for, which is laid down in implementing legislation.

(2) The placing on the market of unit packets of cigarettes and unit packets of roll-your-own tobacco that do not meet the requirements for appearance, characteristics and contents of the packaging specified by the implementing legal regulation is prohibited.

(3) Emission levels of cigarettes manufactured or placed on the market must not exceed the maximum level set by the implementing legislation. The maximum level means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams. The placing on the market of cigarettes that exceed the maximum level of emissions is prohibited.

Unofficial Translation; Excerpts

Section 12d

Labelling of tobacco products for smoking

(1) Manufacturers, importers, retailers and distributors of tobacco products for smoking are obliged to ensure that unit packets and outer packaging of tobacco products intended for smoking are labelled in the manner as laid down by legislation
   a) with the name and surname or the name or business name and registered address of the manufacturer, distributor or importer of tobacco products,
   b) name of the type, group or subgroup of tobacco products as laid down in the implementing regulation under which the tobacco product is placed on the market; a tobacco product that cannot be labelled with the type, group or subgroup due to the components or technology used, are labelled with the name derived from the basic ingredients used or technology,
   c) data on the net amount, which means the amount in grams or kilograms of tobacco product without packaging or on the number of units contained in the package,
   d) country of origin or formation where the omission of that information could mislead the consumer about the true origin or formation of a tobacco product,
   e) batch or equivalent data which allows the determination of the place and time of manufacture,
   f) general warning,
   g) information message and
   h) combined health warning.

(3) Combined health warning means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, and it is connected to information on smoking cessation, laid down by the implementing legislation.

(4) The combined health warnings are divided into three groups, as laid down by the implementing legislation. Ove the course of three calendar years, only one group may be used for one calendar year. Within three years, one group may not be used more than once.

(5) Individual combined health warnings which are available for use in a given calendar year, must be displayed on each individual brands of tobacco products in the same number, in so far as is possible.

Section 12e

Labelling of tobacco products intended for smoking, other than cigarettes, roll-your-own tobacco and waterpipe tobacco

Manufacturers, importers, retailers and distributors of tobacco products for smoking other than cigarettes, roll-your-own tobacco or waterpipe tobacco are obliged to ensure that the unit packaging of the product and the outer packaging has been labelled in the manner laid down by legislation with

   a) data pursuant to section 12d(1)(a) to (d),
   b) a general warning, including information on smoking cessation laid down by the implementing legislation,
   c) the batch or equivalent data which allows the determination of the place and time of manufacture, and
   d) a health warning.

Section 12f

Labelling of smokeless tobacco products

Manufacturers, importers, retailers and distributors of smokeless tobacco products are required to ensure that the unit packets of the product and the outer packaging has been labelled in the manner laid down by legislation with

a) data pursuant to section 12d(1)(a) to (d),
b) a health warning and
c) batch or equivalent data which allows the determination of the place and time of manufacture.

Section 12g

Introduction of novel tobacco products to the market

(1) Manufacturers and importers of tobacco products are bound by the manner, extent and within the time limits set by the implementing legislation to notify the Czech Agriculture and Food Inspection via electronic remote data transmission information on novel tobacco products to be placed on the market.
(2) Novel tobacco products must conform to the requirements laid down by this Act and the implementing legislation. The fact that the provisions of this Act and the implementing legislation will be used for new tobacco products depends on whether these products were covered by the definition of a smokeless tobacco product or the definition of a tobacco product intended for smoking.
(3) Manufacturers and importers of new tobacco products are required to report to the Czech Agriculture and Food Inspection Authority via electronically remote data transmission any new or updated information on studies, research and other information notified under subsection 1. The Czech Agriculture and Food Inspection Authority may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information.
(4) Any information pursuant to sections 1 and 3 by the Czech Agriculture and Food Inspection Authority shall be made available to the European Commission.

Electronic cigarettes and refills

Section 12h

(1) Manufacturers, importers, retailers and distributors of electronic cigarettes or refills are required to ensure that these products meet the requirements in terms of the composition, appearance, quality and characteristics laid down by the implementing legislation.
(2) Manufacturer, importer, retailer and distributor of electronic cigarettes or refills them are required in the manner laid down by the implementing legislation to ensure that the unit packets or outer packaging of electronic cigarettes or refills state
   a) data pursuant to section 12d(1)(a) to (d),
   b) the list of all ingredients contained in the product,
   c) the nicotine content in the product,
   d) the amount of nicotine per dose,
   e) the batch or equivalent data which allows the determination of the place and time of manufacture,
   f) data on keeping the product out of the reach of persons under 18 years of age and
   g) a health warning.

(3) Manufacturers, importers, retailers and distributors of electronic cigarettes or refills them are obliged to ensure that units packets contain a leaflet containing
   a) instructions for the use and storage of the product,
   b) information that the product is not recommended for young people and non-smokers
   c) information on contraindications,
   d) warnings for specific risk groups,
   e) information on potential adverse effects,
   f) information on addictiveness and toxicity,
   g) contact details of the producer or importer and
   h) contact details of the manufacturer or importer and a legal or natural contact person within the EU Member State

(4) Manufacturers and importers of electronic cigarette or refills shall submit a notification to the Ministry of Health by means of electronic remote data transmission within the timescales and to the extent determined by the implementing legislation
   a) information about electronic cigarettes and refills that they intend to place on the market or import, and
   b) information on the electronic cigarette and refill market.

(5) A new notification shall be submitted for each substantial modification of the product pursuant to section 3(a).

(6) Manufacturers, importers and distributors of electronic cigarettes or refills are required
   a) to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products,
   b) to immediately take the corrective action necessary to bring the product concerned into conformity with this Act or implementing regulation, or to withdraw it from the market if it can be reasonably assumed that electronic cigarettes or refills that have been or are due to be placed on the market are not safe or of adequate quality or are otherwise inconsistent with this Act or implementing regulation, and
   c) in cases referred to in point b) immediately inform the Ministry of Health via electronic remote data transmission, specifying in particular the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

(7) The provisions of section 3(c), (d) and (g) shall not apply to electronic cigarettes, which cannot be used for nicotine-containing vapour, and refills, that do not contain nicotine.

Section 12i

(1) The Ministry of Health will publish on its website the information laid down by implementing regulation provided under section 12h(3)(a) section 12h(4) 4 and shall make available at the request of the European Commission or an EU Member State the information laid down by implementing regulation provided under section 12h(3)(b) and section 3. It shall not disclose information constituting trade secrets [51)]. The manufacturer or importer of electronic cigarette refills or to give them their submissions to the information that is a trade secret.

(2) The requirements under this Act shall not apply to electronic cigarettes and refills that are subject to the requirement for marketing authorisation under the Act on Pharmaceuticals and the legal requirements for medical devices.

(3) The Ministry of Health may request from the manufacturer or importer of electronic cigarettes or refills additional information, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

(4) The marking of unit packets and the outer packaging of electronic cigarettes and refills, as well as the electronic cigarette itself, may not include a forbidden element or feature, especially in written, pictorial, graphic or shape for, which is laid down in implementing legislation.
(5) The provisions of section 1 shall not apply to electronic cigarettes, which cannot be used for nicotine-containing vapour, and refills, that do not contain nicotine.

Section 12j

Herbal products for smoking

(1) The marking of unit packets and the outer packaging of herbal products for smoking and the herbal product for smoking itself may not include a forbidden element or feature, especially in written, pictorial, graphic or shape for, which is laid down in implementing legislation.
(2) Manufacturers, importers, retailers and distributors of herbal products for smoking are obliged to ensure that unit packets and outer packaging are labelled in the manner as laid down by implementing legislation
    a) data pursuant to section 12d(1)(a) to (d),
    b) a health warning and
    c) batch number.
(3) Manufacturers and importers of herbal products for smoking are required to submit to the Ministry of Health via electronic remote data transmission information on herbal products for smoking according to brand and type in a manner, extent and within the time limits laid down by the implementing legislation.
(4) Manufacturers and importers of herbal products for smoking are required to inform the Ministry of Health electronically remote data transmission in the event of a change in The information required under this section shall be provided within the period prescribed by the implementing legislation.
(5) The Ministry of Health will ensure the publication of information provided pursuant to sections 3 and 4 on its website. It shall not disclose information constituting trade secrets. Manufacturers and importers of herbal products shall provide information that constitute trade secrets on submission.

Information obligation

Section 13

(1) Manufacturers and importers of tobacco products are required to submit to the Ministry of Health via electronic remote data transmission information on the tobacco product according to brand and type in a manner, extent and within the time limits laid down by the implementing legislation.
(2) If there is a modification to the composition of a tobacco product in a manner that affects the information that has been provided under section 1, manufacturers and importers of tobacco products shall provide these facts in electronic form via remote data transmission to the Czech Agriculture and Food Inspection Authority.
(3) The Czech Agriculture and Food Inspection Authority will publish the information provided under sections 1 and 2 on its website. It shall not disclose information constituting trade secrets. Manufacturers and importers of tobacco products shall provide information that constitute trade secrets on submission of such data.
(4) Manufacturers and importers of tobacco products are required to submit via electronic remote data transmission to the Czech Agriculture and Food Inspection Authority internal and external

studies available to them on market research and preferences of various consumer groups, including young people and smokers, about the ingredients and emissions, as well as summaries of all market research performed when placing novel products on the market.

(5) The Czech Agriculture and Food Inspection Authority shall make available the information received pursuant to sections 1, 2 and 4, with the exception of information constituting a trade secret, to the European Commission and other EU Member States.

Section 13a

(1) Manufacturers and importers of cigarettes or roll-your-own tobacco containing an additive listed in a priority list established by the implementing legislation are required to carry out a comprehensive study of each additive.

(2) Manufacturers and importers of cigarettes or roll-your-own tobacco containing an additive specified in the priority list are required to provide a report on the outcome of the study referred to in subsection 1 and forward it electronically via remote data transmission to the Czech Agriculture and Food Inspection Authority and the European Commission.

(3) The manufacturers or importers referred to in section 1 shall submit supplementary information regarding the additives included in the priority list to the applicant electronically via remote data transmission, which shall form part of the report at the request of the State Agricultural and Food Inspection Authority or the European Commission.

(4) SMEs, as defined in Commission Recommendation 2003/361/EC (18) shall be exempted from the obligations pursuant to sections 1-3, if a report on that additive included in the priority list is prepared by another manufacturer or importer of tobacco products or a tobacco-related product.

Section 13b

(1) The obligation to provide the requested information shall lie primarily with the manufacturer of a tobacco product or a tobacco-related product, if the manufacturer is established in an EU Member State.

(2) The obligation to provide the requested information shall lie primarily with the importer of tobacco products or tobacco-related products, if the manufacturer of tobacco products or tobacco-related products is established outside an EU Member State and the importer is established inside an EU Member State.

(3) The obligation to provide the requested information shall lie jointly with the manufacturer of tobacco products or tobacco-related products and the importer of tobacco products or tobacco-related products if both are established outside an EU Member State.

(4) Tobacco products or tobacco-related products should not be placed on the market unless they have complied with the notification obligation pursuant to section 12g(1), section 12h(3), section 12h(4), section 12h(5)(c), section 12j(3), section 12j(4), section 13(1), section 13(2), section 13(4), section 13a(2), and section 13a(3).

Cross-border distance sales of tobacco products, electronic cigarettes and refills

Section 13c

(1) The establishment of retailers operating cross-border sales of tobacco products, electronic cigarettes and refills for distance sales shall be deemed to be in an EU Member State

a) in the case of a natural person: if he or she has his or her place of business in that EU Member State,

b) in the case of a legal entity, if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that EU Member State.

(2) Before commencing the placement of tobacco products on the market in the form of cross-border distance sales to consumers located in another EU Member State a retailer established in the Czech Republic is obliged to register in the manner and to the extent determined by the implementing legislation with the State Agricultural and Food Inspection Authority and the competent authorities of the EU Member State, where the actual or potential consumers are located.

(3) Before commencing the placement of tobacco products on the market in the form of cross-border distance selling to actual or potential consumers in the Czech Republic a retailer established in another EU Member State or in a third country is obliged to register with the manner and to the extent determined by the implementing legislation with the State Agricultural and Food Inspection.

(4) Before commencing the placement of electronic cigarettes or refills on the market in the form of cross-border distance sales to consumers located in another EU Member State a retailer established in the Czech Republic is obliged to register in the manner and to the extent determined by the implementing legislation with the Ministry of Health and the competent authorities of the EU Member State, where the actual or potential consumers are located.

(5) Before commencing the placement of electronic cigarettes or refills on the market in the form of cross-border distance sales to actual or potential consumers located in the Czech Republic a retailer established in another EU Member State or in a third country is obliged to register in the manner and to the extent determined by the implementing legislation with the Ministry of Health.

(6) Retailers may start to place tobacco products, electronic cigarettes or refills on the market in the form of cross-border distance sales from the moment of receipt of a registration certificate from the competent authorities in accordance with section 2 to 5

(7) The provisions of section 4 shall not apply to electronic cigarettes, which cannot be used for nicotine-containing vapour, and refills, that do not contain nicotine.

Section 13d

(1) The Czech Agriculture and Food Inspection Authority shall publish a list of registered retailers on its website under section 13c(2) and (3).

(2) The Ministry of Health shall publish a list of registered retailers on its website under section 13c(4) and 5.

Section 13e

Placement of tobacco products and tobacco-related products on the market

(1) If a tobacco product or a tobacco-related product is placed on the market in the Czech Republic, the information pursuant to section 12d to 12f, section 12h(1) and (2), section 12g(1) and (3) and section 12j(2) shall be provided in the Czech language.

(2) In the case of tobacco products and tobacco-related products offered for sale by means of distance communication all information pursuant to section 12d(1) (a) to (d) and (f) to (h), section 12e(a) and (b), section 12f(a) and (b), section 12h (1)(a) to (d), (f) and (g), section 12h (2) and section 12j(2) (a) and (b) must be provided before the purchase to the final consumer

Section 13f

Traceability of tobacco products

(1) Manufacturers, importers and distributors of tobacco products shall record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.
(2) Manufacturers, importers and distributors of tobacco products shall maintain complete and accurate records of all relevant transactions under section 1.
(3) Manufacturers and importers of tobacco products are obliged
    a) to conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data; these contracts may be concluded after prior approval by the European Commission,
    b) to ensure that the data storage facility shall be physically located on the territory of an EU Member State,
    c) to provide information that constitutes trade secrets or commercially sensitive information.
(4) Manufacturers of tobacco products are obliged
    a) to provide importers and distributors of tobacco products with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to section 3(a) and (b), and
    b) ensure an independent external expert who shall monitor the activities of third parties and which is approved by the European Commission.
(5) The independent third party referred to in section 3(a) shall ensure that the Commission, the Czech Agriculture and Food Inspection Authority, the Customs Administration of the Czech Republic, and the external auditor have full access to the data storage facilities. The Czech Agriculture and Food Inspection Authority may, in duly justified cases, grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with section 3(c).
(6) The external auditor shall submit an annual report to the Ministry and to the European Commission, assessing in particular any irregularities in relation to access under section 5.
(7) Manufacturers, importers and distributors of tobacco products are required to store the data in an unmodified form.

Section 14

State surveillance

(1) State surveillance over compliance with obligations under this Act shall be exercised by:
    a) the public health authorities, being the regional health departments, Ministry of Defence and Ministry of Interior,
    b) the State Veterinary Administration,
    c) the Czech Agriculture and Food Inspection Authority.
(2) The surveillance authorities referred to in subsection 1 shall cooperate and coordinate their audits in accordance with the auditing rules [13)].

Section 15

(1) The Ministry and the Ministry of Health shall, to the extent of its competence, manage and audit the operations of the state administration and the monitoring the occurrence of substances of toxicological concern in the food chain, and this shall be performed by state surveillance bodies. The monitoring of radiologically significant substances in the food chain is regulated by specific legislation.

(2) The authorities referred to in section 1 shall jointly draw up a plan for state surveillance and monitoring of relevant toxicological and radiological substances and standardize the procedures for the exercise of such activities.

(3) The Ministry, after consultation with the Ministry of Health, shall provide a rapid alert system in the development of the risk[15)] of a health threat from foodstuffs and shall coordinate the activities of the participating administrative authorities, surveillance bodies and other interested organisations.

(4) The Ministry shall provide a system of administrative assistance and cooperation[52)] and shall coordinate the activities of the participating administrative authorities, surveillance bodies and other interested organisations.

(5) In the rapid alert system under subsection 3 and in the system of administrative assistance and cooperation in accordance with subsection 4 the national contact point is the Czech Agriculture and Food Inspection Authority, which also fulfills the obligations laid down in this field by the directly applicable regulations of the European Union[52)] and special legislation.

(6) In a crisis situation and as part of the adopted economic measures for crisis situations the Ministry is permitted
   a) to propose and submit measures leading to the regulation of the extent of food production to the Government for approval,
   b) to propose and submit measures leading to the regulation of the extent of food import and export to the Government for approval,
   c) after the prior consent of the government to take measures to regulate exports and imports of food within the adopted economic measures for crisis situations,
   d) with the prior consent of the government to take measures to regulate the scale of production,
   e) to oblige food business operators to adjust the focus and scope of the manufacture of food stored in a crisis situation to ensure the basic needs of the population.

(7) The Ministry is the contact point and coordinates the preparation and processing of a single integrated multi-annual national control plan and annual report on the inspections conducted under Article 41 to 44 of Regulation (EC) No 882/2004.

(8) The Ministry shall accept applications
   a) for permits under the directly applicable EU regulations on genetically modified food and feed[34)],
   b) on the update of the list of nutrition claims,
   c) on entry in the register of traditional specialities guaranteed of the European Union,
   d) on authorising the placing on the market of novel foods or food ingredients,
   e) on approval of generic descriptions (names) that are traditionally used to indicate a particularity of a class of foods or beverages which could imply an effect on human health,
   f) on the approval of a health claim.

(9) Protective measures to the extent and under the conditions set by the directly applicable European Community law on nutrition and health claims on foods can be imposed by the

Ministry ex officio. The Ministry shall notify the European Commission and other EU Member States on the imposition of safeguard measures.

(10) The directorate general of Customs shall provide upon request to the Ministry and the competent surveillance authority under section 16(1) to (5) information about consignments placed under the free circulation customs procedure or customs export procedure, which are necessary for the performance of auditing of administrative and surveillance bodies without constituting a breach of confidentiality under the Tax Procedure Code, to wit:
   a) identification data of the importer or consignee, being the name or names and surname, place of residence or place of business, trade name, or the name and address of the addressee,
   b) description, including the trade name and type of product as classified in the combined nomenclature
   c) country of consignment and country of origin of the product,
   d) amounts expressed in volume, weight or number of units.

(11) The customs office on import of foodstuffs from third countries shall
   a) not allow such foodstuffs to enter the free circulation customs procedure if the importer fails to submit a certificate, certificate or other entry document in accordance with section 3(4)(a) or certificate under section 3(4)(c),
   b) immediately inform the competent state surveillance authority, if the consignment and its labelling does not match the presented certificate, certificate, or other input document,
   c) request the competent state supervision authorities for their binding opinion according to the Regulation (EC) of the European Parliament and of the Council No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products in cases where the consignment has properties that present a serious risk to health,
   d) not allow these foods into the free circulation customs procedure, in the case of food audited by the directly applicable European Union on official controls [15c)] and the importer fails to submit satisfactory results of the audit findings,
   e) suspend the procedure for the release of food into the free circulation customs procedure and shall immediately request that the competent surveillance authorities provide a binding opinion if the food has been reported in the rapid alert system [15d)].

(12) The surveillance authorities referred to in section 16 shall collect information on the following in the information systems of the surveillance bodies in the field of food law
   a) audited entities,
   b) the results of state surveillance over the implementation of obligations of food business operators and manufacturers, importers and distributors of materials and articles intended for contact with foodstuffs and
   c) administrative proceedings based on the audit findings from this state surveillance.

(13) The surveillance authorities referred to in section 16 are entitled to use the data collected in their information systems to regulate, control and coordination of state surveillance and public awareness. These cases are not covered by the confidentiality obligation as imposed under special legislation.

Section 15a

(1) The Ministry
   a) reviews, publishes, assesses the admissibility of objections and shall submit the applications pursuant to section 15(7)(c) including documentation, to the European Commission, using the procedure laid down by the directly applicable EU regulation on quality schemes for agricultural products and foodstuffs [35)]; the deadline for submission of objections is 3 months from the date of publication of the application,
   b) communicates of the data collected by monitoring the presence of substances of toxicological concern in the food chain to public health authorities and the State Health Institute at their request,
   c) provides the European Commission with information about the use of additional forms of expression and presentation referred to in Article 35 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council
   d) submits to the European Commission a request to update the Union list of food additives, food enzymes, food flavourings, source materials of food flavourings and food ingredients with flavouring properties used or intended for use in food.

(2) The Ministry of Health maintains a register of foods that have been notified under this Act, containing details of food labeling and information on food business operators who manufacture or place such foods on the market. Information from these records are communicated to the foodstuffs surveillance authority and on its website it shall publish information about the trade name of the product, its composition, the food business operator that food produced or placed on the market, use and recommendations for use in a range according to the label intended for consumers.

(3) If the customs authorities of the Czech Republic find in its performance that the obligation provided for in section 13f(1) has been violated, they shall inform the State Agricultural and Food Inspection Authority without delay.

Section 15b

(1) Czech Agriculture and Food Inspection Authority shall provide the information received under section 12g(1) and (3), section 13(1), (2) and (4) and section 13a(2) and (3) to the Ministry and the Ministry of Health without delay.

(2) The Ministry shall notify the Commission of any maximum emission levels they set for emissions from cigarettes other than the emissions of tar, nicotine and carbon dioxide and for emissions from tobacco products other than cigarettes

(3) The Ministry shall notify the Commission of a list of approved laboratories to measure emissions of tar, nicotine and carbon monoxide from cigarettes. Laboratories must not be directly or indirectly owned or controlled by the tobacco industry.

(4) The Ministry shall notify the Commission of the methods of measurement they set for emissions from cigarettes other than the emissions of tar, nicotine and carbon dioxide and for emissions from tobacco products other than cigarettes.

(5) The Ministry of Health is taking measures which prohibit a certain category of tobacco product or tobacco products for reasons related to the specific situation in the Czech Republic; these measures, together with the reasons for their introduction shall be notified to the European Commission; the measures take effect after approval by the European Commission or the expiry of a period of 6 months after its receipt by the European Commission.

Section 16

(1) Regional hygiene stations perform monitoring of compliance with the obligations of food business operators and manufacturers, importers, distributors and retailers of products related to tobacco products as laid down herein and hereunder
   a) for the operation of restaurant businesses, unless this monitoring is performed pursuant to subsection 2(a) or subsection 3(a),
   b) when determining the cause of damage or danger to health and the prevention of the spread of infectious diseases or other damage to health from food and
   c) for the production, distribution and placement of electronic cigarette, refills, and herbal products for smoking on the market.

(2) The Ministry of Defence performs monitoring of compliance with the obligations of food business operators as laid down herein and hereunder
   a) for the operation of restaurant services in the armed forces, in the Ministry of Defence and within its scope established by organisational components of state and contributory organisations and in premises used by them [53)], the regional military headquarters [54)], in military zone authorities and in military training areas [55)]
   b) when determining the cause of damage or danger to health and the prevention of the spread of infectious disease or other damage to health from food in the armed forces, the Ministry of Defence and in the scope established by organisational components of the state and contributory organisations, and in the premises used by them, regional military headquarters, in the military zone authorities and military training areas, and
   c) for the production of food, for packing, cutting or other method of dividing foodstuffs and for the placing on the market in the armed forces, in the Ministry of Defence and within its scope established by organisational components of state and contributory organisations and in premises used by them, the regional military headquarters, in military zone authorities and in military training areas.

(3) The Ministry of Interior performs monitoring of compliance with the obligations of food business operators as laid down herein and hereunder
   a) for restaurant businesses in the security forces [56)], with the exception of the Czech Prison Service, the Ministry of Interior and the organisational units of the state and contributory organisations established in its scope, including the premises used by them and facilities established by the Ministry of Interior under other legislation [57)],
   b) when determining the cause of damage or danger to health and the prevention of the spread of infectious disease or other damage to health from in the security forces, with the exception of the Prison Service of the Czech Republic, the Ministry of Interior and organisational components of the state and organizations established in its scope, including the premises used by them and facilities established by the Ministry of Interior under other legislation, and
   c) for the production of food, for packing, cutting or other method of dividing foodstuffs and for the placing on the market for the security forces with the exception of the Prison Service of the Czech Republic, the Ministry of Interior and organisational components of the state and organisations established in its scope, including the premises used by them and facilities established by the Ministry of Interior under other legislation

(4) The State Veterinary Administration performs monitoring of compliance with the obligations of food business operators as laid down herein and hereunder
   a) for production, storage, transportation, import and export of food of animal origin and packaging, cutting or other means of cutting food of animal origin, which takes place in

facilities authorised for such activity pursuant to section 22 of the Veterinary Act, unless this monitoring is performed pursuant to subsection 2(c) or subsection 3(c),

b) for placing food of animal origin on the market in marketplaces and market stalls. for placing food of animal origin on the market in sales departments and outlets other than self-service, where meat, milk, fish, poultry or eggs are processed, placing game on the market and on the arrival of food of animal origin from EU Member State in grocery stores if they are destinations and unless this check is performed pursuant to subsection 2(c) or subsection 3(c),

c) for the implementation of the classification of carcasses under section 4a and under directly applicable European Union regulations governing the classification of animals for slaughter and

d) for placing unprocessed bodies or parts of animals, milk, colostrum, eggs and bee products on the market in the operation of restaurant businesses, unless this monitoring is performed pursuant to subsection 2(a) or subsection 3(a).

(5) The Czech Agriculture and Food Inspection Authority performs monitoring of compliance with the obligations of food business operators and manufacturers, importers, distributors and retailers of tobacco products as laid down herein and hereunder

a) for food production, packaging, cutting or other means of cutting food and for placing food on the market, unless this monitoring is performed pursuant to subsection 2(c), subsection 3(c) or subsection 4(a) or (b),

b) for the production, distribution and placing of tobacco products on the market,

c) for the entry and import of foodstuffs from third countries, unless such surveillance is conducted in accordance with subsection 4, and for the entry and import of tobacco products from third countries, and

d) for the restaurant business, unless this monitoring is performed pursuant to subsection 2(a) or subsection 3(a).

(6) The sampling, preparing and testing of samples in order to ascertain compliance of food and tobacco products with legislation and consistency of the conditions of their production and placing on the market with legislation is done by the surveillance authorities of the manner and to the extent determined by the directly applicable EU regulation or the implementing regulation.

(7) The surveillance authority shall prepare a control sample which is shall at the request of the monitored entity split into two or more samples of the same size, one of which shall be given to the monitored entity for a supplementary expert opinion, and shall retain the other sample. The sample for a supplementary expert opinion under the first sentence shall not be taken and shall not be given to the monitored entity if it is not possible due to the very low quantity of available substrate or, in the case of products, highly perishable. The samples are sealed, labelled and stored in the manner stipulated by the implementing legislation. The surveillance authority shall make a written record of this procedure.

(8) Until the confirmation of the results of the test carried out under the implementing legislation, the test result should not be published by the surveillance authority, except in cases where a risk to human health can be assumed.

(9) The surveillance authorities referred to in subsection 1 shall also perform within its competences under subsection 1 surveillance over the fulfillment of the obligations of food business operators stemming from directly applicable European Union legislation.

(10) The basis for decisions of the surveillance authority may be the result of the laboratory of another surveillance authority or surveillance authority of another EU Member State, which carry out laboratory testing of samples taken during official controls [15g)].

(11) Where the surveillance authority ascertains that the deficiencies identified during a routine control have not been corrected within the prescribed period, the food business operator must compensate for additional costs of the control [15h)]. The implementing legislation provides for the amount of lump sum costs for additional controls paid by the food business operator. The compensation for the additional controls shall be decided by the surveillance authority. This compensation constitutes state budget revenue and is collected by the surveillance authority that imposed it.

(12) The food business operator is obliged to reimburse the costs incurred for the verification of compliance with the specifications according to the directly applicable European Union regulations on quality schemes for agricultural products and foodstuffs [35)] before placing foodstuffs on the market. The implementing legislation provides for the amount of the lump sum for the verification of compliance with the specifications. Costs of compensation for the verification of compliance with the specifications are decided by the surveillance authority. This compensation constitutes state budget revenue and is collected by the surveillance authority that imposed it.

(13) The implementing legislation provides for the amount of the lump sum incurred in connection with the entry of food from third countries according to the directly applicable European Union legislation on official controls [15j)]. Compensation for such costs shall be decided by the surveillance authority. This compensation constitutes state budget revenue and is collected by the authority that imposed it.

(14) The food business operator is obliged to pay the costs incurred in connection with the import of food from third countries, where provided by the directly applicable European Union regulations governing certain foodstuffs imported from third countries [24)]. The implementing legislation provides for a lump sum of costs incurred in connection with the import of foodstuffs from third countries. The Decree on the tariff for cost reimbursements [58)] lays down the costs for laboratory analysis of the samples, if performed by the laboratory of the surveillance authority. Compensation for such costs shall be decided by the surveillance authority. This compensation constitutes state budget revenue and is collected by the authority that imposed it.

(15) The rights and obligations of the public health protection authority when performing state surveillance pursuant to subsection 1(a) are regulated by special legislation. [15m)]

(16) The surveillance authorities under section 14 in accordance with the Government Decree on the rapid alert system [15d)] are obliged to immediately

a) notify the occurrence of foodstuffs that pose a risk to health to the national contact point under section 15(4) where it shall highlight cases where the risk to health may extend beyond the territory of the Czech Republic,

b) send information to the national contact point regarding the action taken or measures adopted based on notifications received and additional knowledge.

(17) The surveillance authorities referred to in subsection 1(b) and (c) are authorised to issue a certificate at the request of the food business operator under section 3(4)(c) and a certificate in accordance with section 3(5)(b).

. . .

Section 17c

(1) A manufacturer of tobacco products shall commit an administrative offence by
   a) contrary to section 12(1) using other than raw or technologically modified tobacco or illegal substances or an unacceptable amount thereof in the manufacture of tobacco products,
   b) contrary to section 12(5) using additives necessary for the manufacture of tobacco products resulting in a characteristic flavour or an increase in addictiveness, toxicity or carcinogenic, mutagenic or reprotoxic properties
   c) failing to provide importers and distributors of tobacco products the necessary equipment under section 13f(4)(a), or
   d) failing to provide an external expert pursuant to section 13f(4)(b).

(2) Manufacturers, importers, distributors or retailers of tobacco products shall commit an administrative offence by
   a) contrary to section 12(2) placing on the market tobacco products that contain banned substances specified in the implementing regulation,
   b) contrary to section 12(3) placing on the market tobacco intended for oral use.
   c) contrary to section 12(4) placing on the market of cigarettes with a characterising flavour and roll-your-own tobacco with a distinctive flavour.
   d) contrary to section 12(6) placing on the market cigarettes or roll-your-own tobacco containing flavourings,
   e) contrary to section 12(6) manufacturing, distributing, importing or placing on the market a tobacco product containing tobacco or nicotine in the filters, papers or capsules,
   f) contrary to section 12b(1) manufacturing, distributing, importing or placing on the market a tobacco product that contains a banned element or feature
   g) contrary to section 12b(2) placing on the market cigarettes or roll-your-own tobacco that do not meet the requirements on appearance, quality or contents of the unit packets,
   h) contrary to section 12b(3) placing on the market of cigarettes that exceed the maximum level of emissions,
   i) failing to label the tobacco product with a unique identifier in accordance with section 12c(1),
   j) failing to label the tobacco product with a security feature in accordance with section 12c(2),
   k) failing to label tobacco products intended for smoking under section 12d(1),
   l) failing to label tobacco products other than cigarettes intended for smoking, roll-your-own tobacco or waterpipe tobacco under section 12e,
   m) failing to label smokeless tobacco products under section 12f, or
   n) failing to comply with the notification obligation pursuant to Section 12g(1) or (3).

(3) A manufacturer or importer of tobacco products shall commit an administrative offence by
   a) failing to comply with the notification obligation pursuant to Section 13(1) or (2),
   b) failing to submit to the State Agricultural and Food Inspection a study under section 13(4),
   c) failing to conclude an agreement on data retention with an independent third party under section 13f(3)(a),
   d) failing to ensure that the data storage facility shall be physically located on the territory of an EU Member State according to section 13f(3)(b), or
   e) fails to provide information that constitutes trade secrets or commercially sensitive information under section 13f(3)(c).

(4) Manufacturers, importers, distributors or retailers of electronic cigarettes or refills shall commit an administrative offence by
   a) failing to provide the required data on the unit packets or outer packaging of electronic cigarettes or refills under section 12h(2), or
   b) fails to ensure that unit packets of electronic cigarettes or refills contain a leaflet with the required information under section 12h(3).

(5) Manufacturers, importers or distributors of electronic cigarettes or refills shall commit an administrative offence by
   a) failing to comply with the notification obligation pursuant to Section 12h(4),
   b) failing to introduce or maintain a system for collecting information under section 12h(6)(a),
   c) failing to take corrective action under section 12h(6)(b)
   d) failing to comply with the notification obligation pursuant to Section 12h(6)(c), or
   e) failing to comply with the additional disclosure obligation under section 12i(3).

(6) Manufacturers, importers, distributors or retailers of herbal products for smoking shall commit an administrative offence by
   a) placing on the market herbal products for smoking in conflict with section 12j(1), or
   b) failing to place information on the unit packet and outer packaging in accordance with section 12j(2) for herbal products for smoking.

Section 17d

(1) Manufacturers or importers of herbal products for smoking shall commit an administrative offence by failing to comply with the notification obligation under section 12j(3) or (4).

(2) Manufacturers or importers of cigarettes or roll-your-own tobacco containing an ingredient specified in the priority list shall commit an administrative offence by
   a) failing to undertake a comprehensive study of each additive under section 13a(1),
   b) failing to pass on the outcome of the study in accordance with section 13a(2), or
   c) failing to pass on additional information in accordance with section 13a(3).

(3) Manufacturers, importers, distributors or retailers of tobacco products or products which are related to tobacco shall commit an administrative offence by
   a) failing to comply with the requirements specified in section 12a(1)(a), or (c),
   b) failing to comply with the requirements specified in section 12a(1)(b)
   c) placing on the market tobacco products, or products which are related to tobacco products contrary to section 13b(4),
   d) failing to provide the required information in the Czech language under section 13e(1), or
   e) failing to provide the final consumer with the mandatory data under section 13e(2).

(4) Retailers of tobacco products or products which are related to tobacco shall commit an administrative offence by
   a) failing to comply with the registration requirement under section 13c(2), (3), (4) or (5), or
   b) initiating the placing of tobacco products, electronic cigarettes or refills on the market in contravention of section 13c(6).

(5) Manufacturers, importers or distributors of tobacco products shall commit an administrative offence by
   a) failing to keep records in accordance with section 13f(1),
   b) failing to keep records of all handling of tobacco products in accordance with section 13f(2), or
   c) failing to retain data under section 13f(7).

(6) A third party shall commit an administrative offence if it does not allow full access to the data storage devices to the European Commission, the Czech Agriculture and Food Inspection Authority or external experts under section 13f(5).

Section 17e

An external expert shall commit an administrative offence if they fail to submit an annual report to the Ministry or to the European Commission pursuant to section 13f(6).

Section 17f

For an administrative offence the following fines shall be imposed

a) CZK 1,000,000, for an administrative offence under section 17(1)(g), (h), (x), section 17(2)(d), section 17(4) or (5), section 17a(1), section 17a(2)(a) or (b), section 17a(3), (4) or (5), section 17b(1)(d), section 17c(2)(n), section 17c(2)(n), section 17c(3)(a), (b) or (e), section 17c(5)(a), (d) or (e), section 17d(1) or (2) or section 17e,
b) CZK 3,000,000, for an administrative offence under section 17(1)(f) (k), (l), (q), (s), (u) or (z), section 17(3), section 17a(2)(c), section 17b(1)(a), (b) or (c), section 17c(1)(c) or (d), section 17c(3)(c) or (d), section 17c(5)(b) or (c), section 17d(3)(a), (c) or (d), section 17d(4)(b), section 17d(5) or (6),
c) CZK 10,000,000, for an administrative offence under section 17(1)(a), (b), (d), (e), (j), (m), (n), (o), (r), (v) or (w), section 17(2) (c), (g), (h), (i) or (j), section 17a(6), section 17b(2), (3), (4), (5) or (6)(a) or (b), section 17c(1)(a) or (b), section 17c(2)(a) (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l) or (m), section 17c(4) or (6), section 17d(3)(b) or (e),
d) CZK 50,000,000, for an administrative offence under section 17(1)(c), (i), (p), (t) or (y), section 17(2)(a) (b), (e) or (f), section 17b(6)(c).

Section 17i

(1) A legal entity shall not be liable for an administrative offence if it proves that it had made every effort that could have been required of it to prevent a breach of its legal obligations.
(2) In assessing the level of the fine on the legal entity, the severity of the administrative offence shall be reflected, particularly the manner of its commission and its consequences and the circumstances under which it was committed.
(3) The liability of the legal entity for an administrative delict shall lapse if the administrative body fails to commence proceedings within 1 years from the date on which it learned of such delict, but not later than 3 years from the date on which it was committed.
(4) The responsibility for conduct that occurred in the business of the natural person or in direct connection therewith, shall be subject to the provisions of this Act on liability and sanctions for legal entities.
(5) Administrative offences are heard in the first instance
    a) by inspectors of the Czech Agriculture and Food Inspection Authority, in the case of administrative offences pursuant to section 17, 17a, section 17b(2)-(6), section 17c(1)-(3), section 17d(2)-(6), and section 17e,
    b) by regional health authorities, in the case of administrative offences pursuant to section 17(1), section 17(2), section 17(3)(b), section 17(4) and (5), Section 17a(2) to (6), and section 17b(1) to (5),
    c) by regional health authorities, in the case of administrative offences pursuant to section 17(1)(a) to (d), (f) to (v), (x) and (y), section 17(2), section 17b(6), section 17c(4) to (6), and section 17d(1), (3) and (4),

d) by the Ministry of Defence, in the case of administrative offences pursuant to section 17, section 17a(1) to (4), section 17a(6), and section 17b(2) to (6)
e) by the Ministry of the Interior, in the case of administrative offences pursuant to section 17, section 17a(1) to (4), section 17a(6), and section 17b(2) to (6).

(6) The surveillance authority may waive the imposition of a fine if the illegal situation is corrected in accordance with the measures in place [17)], or immediately after any breath of obligations is discovered, and did not involve a foodstuff that is injurious to health [59)] or deception involving the violation of certain intellectual property rights.

Enabling provisions

Section 18

(1) The Ministry shall lay down by decree
a) the method for the provision of information on food and tobacco products in relation to their breakdown by type, group or subgroup, and the means of identification of the batch;
b) the types of food and tobacco products, divided into groups and subgroups;
c) the amount and types of additives, conditions for use in food production and food and food groups in which these substances may occur,
d) the requirements for foods of plant origin and the handling thereof, rules for the sale and supply of small quantities of primary products and the handling thereof, and small quantities of products of plant origin,
e) the types of perishable foods which must be labeled with the use-by date;
f) the types of food from another EU Member State or from a third country, the scope of information obligations of recipients of such foods at the destination and the date and manner of their handover,
g) for different types of food, including frozen, for tobacco products, for selected components from which the food and tobacco products are manufactured, quality requirements, technological requirements, quality requirements related to the name and the permissible negative mass and volume discrepancies of packaging;
h) for different types of food, including frozen, for different types of tobacco products and ingredients from which the food is produced, which are listed in the decree, also
    1. temperature and relative humidity regimes during the storage or freezing of food,
    2. the means of storage and handling of food and tobacco products during their placing on the market
    3. the special requirements for transportation,
    4. the minimum technological requirements;
i) the conditions for the large scale sea transport of fats and oils, and sugars;
j) One or more additional forms of expression or presentation of the nutrition information applicable for the provision of food information to consumers, in addition to the methods provided for in Article 30 to 34 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council
k) for tobacco products
    1. the requirements for appearance, properties, content, composition and method for placement on the market,
    2. the maximum emission levels for cigarettes,
    3. the requirements for laboratories approved for measuring the emissions of tobacco products,

4. location and characteristics of the unique identifier, scope of the statements contained therein and the method for the handling of data, including their transfer, processing and storage, and access thereto,
5. the location and properties of the security feature,
6. Prohibited elements and features under section 12b(1),
7. additional compulsory information for tobacco products for smoking under section 12d(1)(i)
8. information on smoking cessation in accordance with section 12d(2) and groups of combined health warnings under section 12d(3),
9. the scope, time periods, method of information provision and the method for the handling of confidential information pursuant to section 13(1) and (4).
10. the priority list of ingredients, scope, elements, deadlines, method of processing, focus and method of presentation of the study in accordance with section 13a(1), the scope, deadlines and method for producing a report on the outcome of the study in accordance with section 13a(2) 2 and the scope, deadlines and method for submission of the report pursuant to section 13e(6),
11. the scope of data required for registration under section 13c(2) to (5) and the method of its execution,
12. a list of authorised substances for the manufacture of tobacco products and the permissible amount thereof,
13. List of prohibited substances, which may not contain tobacco products placed on the market,
14. the scope, terms and manner of reporting on new tobacco products,
15. additional requests for information about studies, research and other information on new tobacco products that are manufacturers and importers of new tobacco product obligated to notify pursuant to section 12g(3),

l) the method for carrying out the classification and labeling of carcasses of animals for slaughter, specimen classification report, the manner and extent of communication of classification results, the method and scope of specialist training, sitting examinations and issuing of certificates of proficiency, its period of validity and the method for renewal of certificates;

m) for food and tobacco products and for the conditions of their production and marketing
   1. requirements for collection and preparation of the samples, the requirements for packaging, labelling, transportation and preservation, including requirements for recording of sampling,
   2. requirements for professional qualifications of persons carrying out sampling, preparation and testing of control samples,
   3. requirements for testing of control samples and requirements for the test report,

n) particulars of the application and a list of submitted documentation for the approval of the procedure and method of food irradiation;

o) method for providing information in accordance with section 12g(1), section 12h(3), section 12j(3), and section 13(1), (2) and (4),

p) the lump sum cost of additional inspections under section 16(7), the lump sum cost of verifying compliance with the specifications in accordance with section 16(8), the lump sum of costs incurred in connection with the entry of food from third countries in accordance with section 16(9) and the lump sum of costs incurred in connection with the import of foodstuffs from third countries pursuant to section 16(9) and (10).

q) list of designated points of entry and the designated points of import under section 3(4)(b),

r) method for the treatment of bottled water,
s) the range of skills to obtain a certificate proving knowledge of funghi, method of testing, as well as the particulars of the application and certification,
t) food supplements, the requirements for their composition, labeling and method of use,
u) the provision of information about the dishes, the technological requirements for their production or training requirements for the method of placing food on the market, conditions for the storage and handling of food, sensory, physical, chemical and microbiological safety requirements of food and labelling requirements for foods in their production phase, preparation or placing on the market before offering them to consumers.

(2) The government shall establish by decree a rapid alert system on the emergence risk of health hazards from food or raw materials, in accordance with the applicable regulations of the European Union and in relation to similar systems in EU Member States; it shall simultaneously establish the tasks of the central government authorities involved in the rapid alert system.

Section 19

(1) The Ministry of Health shall establish the following by decree for existing foodstuffs
a) the conditions for the occurrence of substances of toxicological concern in foodstuffs and also groups of foods in which these substances can occur,
b) the foods that can be irradiated with ultraviolet rays or ionising radiation, the irradiation conditions, types of radiation and the maximum permissible radiation dose and method of labelling on the packaging to the effect that the food was contaminated,
c) the types of foods intended for special nutrition, requirements for the composition thereof and method of use,
d) additional rules for the selection of epidemiologically hazardous foodstuffs.

(2) The Ministry of Health stipulates the microbiological requirements for different types of food, excipients and additives and the manner of selection and number of samples, the method of monitoring and evaluation in the case of foodstuffs or the types thereof, for which there are no directly applicable regulations of the European Union and if so required for food safety.

(3) The Ministry of Health in cooperation with the Ministry shall establish on the basis of Article 11 of Regulation (EC) No 1925/2006 implementing regulation on the mandatory addition of vitamins and minerals to specified foods or categories of foods; or on the prohibition or restriction on the use of certain other substances in the manufacture of specified foods.

(4) The Ministry of Health shall issue a decree for
a) electronic cigarettes and refills
1. requirements for their composition, appearance, quality and performance
2. labelling requirements, including the non-permitted elements and features,
3. manner, deadlines and scope of reporting obligations,
4. the extent of data required for registration and the manner of the execution thereof,
b) herbal products for smoking
1. labelling requirements, including the non-permitted elements and features,
2. manner, deadlines and scope of reporting obligations.

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Unofficial Translation; Excerpts

PART SEVEN

Section 25

Act No. 634/1992, on consumer protection, as amended by Act No. 217/1993, Act No. 40/1995 and Act No. 104/1995, are amended as follows:

c) In Section 10(1)(c) the full stop at the end is deleted and instead of the word “spoil” the following words are added which, including footnote no. 9a), read: “under a separate Act. [9a)]

9a) Act No. 110/1997, on foodstuffs and tobacco products and amending and supplementing some related Acts.”

d) In section 11, before the first sentence the following sentence is inserted: “Czech data for foodstuffs must conform to the special Act. [9a)].”
e) In Section 23(1) the words “(b) to (d)” are replaced by “and, in the case of foodstuffs and tobacco products in accordance with section 3(b), sections 7 to 9, section 10(1)(c) and section 17”.
f) In Section 23(4)(a) after the word “of origin” the following words are added: “when selling in marketplaces, and in the sale of conditionally edible foodstuffs of animal origin.”
g) In section 24 after subsection (1) the following subsection (2) is added, as follows:

"(2) If it is not a breach of the obligations set out in section 3(a) and (c), section 6, section 10(1)(a) and (b) and section 11, subsection (1) shall not apply to food and tobacco products”.

The existing subsections 2 to 8 shall be renumbered 3 to 9.

PART EIGHT

COMMON, TRANSITIONAL AND FINAL PROVISIONS

Section 26

(1) The provisions of special Acts [16b)] concerning the conditions for the production and marketing of food and tobacco products in circulation, as well as the obligations of entrepreneurs connected therewith are not affected by this Act.
(2) In proceedings under special Acts in matters listed in Part One of this Act commenced before the effective date of this Act shall be governed by the existing regulations.

Section 27

(1) An entrepreneur who has launched the production of food and tobacco products before the effective date of this Act, shall report this fact under section 3(3) within six months of its effectiveness.
(2) Designation of the food produced and put into circulation before the effective date of this Act shall be assessed in accordance with existing regulations.
(3) Requirements for the quality and wholesomeness of foods produced before the effective date of this Act shall be assessed according to existing regulations.
(4) Binding opinions of hygienic authorities issued under a special Act to begin production and import of food before the effective date of this Act shall come into effect one year after the effective date of this Act. In this period the measures issued by the Chief Health Officer of the Czech Republic shall come into effect under a special Act. [17b)]

Section 28

This Act come into effect on September 1, 1997, with the exception of section 6, which come into effect on January 1, 1998, and section 3(1)(f) and (g), which come into effect on July 1, 1998.

. . .

Transitional provisions introduced by Act No. 180/2016 Article II

1. Foods placed on the market or labelled before the effective date of this Act, which do not comply with the requirements laid down by Act No. 110/1997, as amended, as effective from the date of entry into force of this Act may be sold until stocks are exhausted.
2. The provisions of section 9b(1) of Act No. 110/1997, as amended, as effective from the date of entry into force of this Act, shall not apply for a period of 3 years from the effective date of this Act to the registered combined trade mark "Czech product Guaranteed by the Foodstuff Chamber of the Czech Republic" no. 480690.
3. The provisions of section 9b(1) of Act No. 110/1997, as amended, effective from the date of entry into force of this Act shall not apply to trademarks [60)] containing the words "Czech foodstuffs", which were registered before the effective date of this Act, or to trademarks containing the words "Czech guild standards" which were registered before the effective date of this Act.
4. Roll-your-own tobacco and cigarettes that do not comply with the requirements laid down by Act No. 110/1997, as amended, effective from the date of entry into force of this Act, and which were manufactured or placed on the market and labelled before the effective date of this Act, may be offered for sale or sold within 3 months from the effective date of this Act.
5. Tobacco products except for roll-your own cigarettes and tobacco, and herbal products for smoking, which do not comply with the requirements laid down by Act No. 110/1997, as amended, effective from the date of entry into force of this Act, and which were manufactured or placed on the market and labelled before the effective date of this Act, may be offered for sale or sold until May 20, 2017 at the latest.
6. Electronic cigarettes and refills that do not comply with the requirements laid down by Act No. 110/1997, as amended, effective from the date of entry into force of this Act, and which were manufactured or placed on the market and labelled by November 19, 2016 at the latest, may be offered for sale or sold until May 20, 2017 at the latest.
7. Retailers operating on the effective date of this Act the cross-border distance sale of tobacco products, electronic cigarettes or refills may not continue to engage in cross-border distance sales unless they receive authorisation pursuant to section 13c(6) within 3 months at the latest from the effective date of this Act.
8. Administrative proceedings initiated under Act No. 110/1997, as amended, as effective prior to the effective date of this Act, and not ended by the effective date of this Act, shall be completed under Act No. 110/1997, as amended, as effective prior to the effective date of this Act.
9. Administrative proceedings initiated under Act No. 110/1997, as effective prior to January 1, 2017, with a food business operator who runs a catering service, and unfinished by January 1, 2017, shall be completed under Act No. 110/1997, as effective prior to January 1, 2017.

10. Audits initiated under Act No. 110/1997, as amended, as effective prior to the effective date of this Act, shall be completed under Act No. 110/1997, as amended, as effective prior to the effective date of this Act.
11. Audits of food business operators who run catering services, initiated under Act No. 110/1997, as amended, as effective prior to January 1, 2017, shall be completed under Act No. 110/1997, as effective prior to January 1, 2017.