

FOODSTUFFS ACT

Prom. SG. 90/15 Oct 1999, amend. SG. 102/21 Nov 2003, amend. SG. 70/10 Aug 2004, amend. SG. 87/1 Nov 2005, amend. SG. 99/9 Dec 2005, amend. SG. 105/29 Dec 2005, amend. SG. 30/11 Apr 2006, amend. SG. 31/14 Apr 2006, amend. SG. 34/25 Apr 2006, amend. SG. 51/23 Jun 2006, amend. SG. 55/7 Jul 2006, amend. SG. 96/28 Nov 2006, amend. SG. 31/13 Apr 2007, amend. SG. 51/26 Jun 2007, amend. SG. 36/4 Apr 2008, amend. SG. 69/5 Aug 2008, amend. SG. 23/27 Mar 2009, amend. SG. 41/2 Jun 2009, amend. SG. 74/15 Sep 2009, amend. SG. 82/16 Oct 2009, amend. SG. 93/24 Nov 2009, amend. SG. 23/23 Mar 2010, amend. SG. 25/30 Mar 2010, amend. SG. 59/31 Jul 2010, amend. SG. 80/12 Oct 2010, amend. SG. 98/14 Dec 2010, amend. SG. 8/25 Jan 2011, amend. SG. 54/17 Jul 2012, amend. SG. 77/9 Oct 2012, amend. SG. 68/2 Aug 2013, suppl. SG. 26/21 Mar 2014, amend. SG. 14/20 Feb 2015, suppl. SG. 56/24 Jul 2015, amend. SG. 28/8 Apr 2016, suppl. SG. 44/10 Jun 2016, suppl. SG. 88/8 Nov 2016, amend. SG. 58/18 Jul 2017, amend. and suppl. SG. 63/4 Aug 2017, amend. SG. 92/17 Nov 2017, amend. and suppl. SG. 59/17 Jul 2018, amend. and suppl. SG. 77/18 Sep 2018, suppl. SG. 106/21 Dec 2018

Chapter one. GENERAL PROVISIONS

Art. 1. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) This Act shall regulate:

1. the requirements for the foodstuffs, the measures and the conditions for providing hygiene of foodstuffs and their safety, the packaging, labelling, presentation, including their advertising;
2. the requirements for all stages of production, processing and distribution of foodstuffs;
3. the conditions and the order of production and trading foodstuffs;
4. the rights and obligations of the individuals who produce or trade foodstuffs;
5. the rules for implementing official control, including verification of the compliance with the normative requirements;
6. the legal capacities of the bodies for official control of the production and trade of foodstuffs;
7. the functions and legal capacities of the professional organizations of the producers of foodstuffs and of the Bulgarian Association of Food and Drink Industry (BAFDI) assigned to them by this Act.

(2) (amend. - SG 51/06; suppl. – 26/14) The requirements and the rules referred to in para 1 regarding wine, vinegar and alcoholic beverages shall be arranged by the Wine and Alcoholic Beverages Act.

(3) This Act shall not apply to primary production for private use or to the domestic preparation, handling or storage of foodstuffs for private consumption.

Art. 1a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) The aim of the Act is:

1. to guarantee the observance of the normative requirements for production and trade of foodstuffs in order to protecting the health and the interests of the consumers.
2. (in force from 01.01.2007) to provide the implementation of the European Communities legislation in the field of the foodstuffs and their safety on national level.

Art. 2. (1) (amend. - SG 31/06, in force from 14.04.2006) In the context of this Act foodstuff is every substance or product, whether processed, partially processed or unprocessed, which is intended to be, or reasonably expected to be consumed by humans.

(2) (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) Foodstuffs are also the beverages, the chewing gum and every substance, including water after its outflow from the water supply installations at the end consumer, used in the production of the food, preparation or processing, as well as the bottled natural mineral, spring and table water.

(3) (prev. para 2 – amend., SG 102/03) Shall not be considered as food in the meaning of this Act the following:

1. (amend. - SG 31/06, in force from 14.04.2006) feed;
2. (suppl. - SG 31/06, in force from 14.04.2006) live animals unless they are prepared for human consumption;
3. plants before the crop gathering;
4. medicines, in the meaning of the Act of the medicines and pharmacies in the human medicine;
5. the narcotic and psychotropic substances in the meaning of the Act of the control over the narcotic substances and precursors;
6. (amend. - SG 28/16, in force from 08.04.2016) the tobacco and tobacco products in the meaning of the Tobacco, Tobacco Products and Related Products Act;
7. (revoked – SG 31/06, in force from 14.04.2006)
8. cosmetic products;
9. (amend. - SG 31/06, in force from 14.04.2006) contaminants and residues from pesticides and from veterinary medical products;
10. (revoked – SG 31/06, in force from 14.04.2006)

Art. 2a. (1) (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017, prev. text of Art. 2a - SG 59/18) The Minister of Agriculture, Foods and Forestry and the Minister of Health Care shall conduct the state policy in the area of food safety.

(2) (new - SG 59/18) In exercising its powers under para. 1 the Minister of Agriculture, Food and Forestry shall issue ordinances on specific requirements for food safety and quality.

Chapter two. REQUIREMENTS FOR THE FOODSTUFFS

Art. 3. (amend., SG 102/03; prev. Text of Art. 3 – SG 51/07, in force from 26.06.2007) Offered on the market shall only be foodstuffs meeting the requirements of this Act and having nutritious value not lower than the one generated by their approved composition, and which are safe for human health.

(1) (new – SG 51/07, in force from 26.06.2007; amend. – SG 8/11, in force from 25.01.2011) Upon proposal by the branch organizations the minimum contents and proportions of the basic components of the approved composition of the foodstuffs referred to in para 1 shall be endorsed by the ordinances as per Art. 4.

Art. 4. (amend., SG 102/03, amend., SG 99/05) The specific requirements for groups of

foodstuffs, for concrete foodstuffs shall be determined by ordinances of the Council of Ministers.

Art. 4a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) Novel foodstuffs or food components are those which have not been offered for human consumption in the trade network on the territory of the Republic of Bulgaria or other member state of the European Union, and which belong to one of the following categories:

1. foods and food components which have new or purposefully modified primary molecular structure;
2. foods and food ingredients which consist of or are isolated from micro-organisms, mushrooms or basic water plants;
3. foods and food components which consist of or are isolated from plants or food ingredients or from animals which are not traditionally cultivated or breed and have no history of safe using as food;
4. foods and food components produced by a production process not traditional for them, leading to substantial changes in their contents or structure, whereas changes of their nutrition value, metabolism or the quantity of unwanted substances in them occur.

(2) The novel foodstuffs and the novel food components shall not:

1. pose a danger for the health of the consumer;
2. mislead the consumer;
3. differ from the foodstuffs or food components, they are intended to replace, regarding their nutrition values, to an extent that their usual consumption may lead to negative consequences for the consumer.

(3) The genetically modified foods, genetically modified organisms (GMO) for use in or as foods and the foods, containing ingredients produced from GMO, shall not:

1. have negative consequences on the human health or the environment;
2. mislead the consumer;
3. differ from the foodstuffs or food components, they are intended to replace, regarding their nutrition values, to an extent that their usual consumption may lead to negative consequences for the consumer.

(4) (new – SG 59/10) Using products and compounds which consist of, contain or are produced from GMO in the production of baby foods shall be prohibited.

Art. 4b. (new, SG 102/03) (1) The Council of Ministers shall determine by an ordinance the requirements for the bottled natural mineral, spring and table waters for drinking, the conditions and the order of using the methods of processing the natural mineral and spring waters and for import of mineral water.

(2) The persons processing natural mineral and spring water for bottling shall inform the Minister of Health about the methods used in the processing and shall submit the necessary documents determined by the ordinance under para 1.

(3) (new - SG 31/06, in force from 14.04.2006) The minister of health shall approve by an order a list of recognized natural mineral waters which comply with the requirements of the ordinance referred to in para 1.

(4) (new - SG 31/06, in force from 14.04.2006) The order and the list referred to I para 3 shall be promulgated in the State Gazette.

(5) (new - SG 31/06, in force from 14.04.2006) The minister of health shall annually provide to the European Commission an updated list as referred to in para 3.

(6) (new - SG 31/06, in force from 01.01.2007) The minister of health shall provide to the European Commission information on the natural mineral waters certified by him as referred to in Art.

4c or Art. 24a. The information shall be published in the internet establishment of the Ministry of health.

(7) (new - SG 31/06, in force from 01.01.2007) The Ministry of health shall provide all the applicable information for the recognized mineral waters, including the results from the systematic checks, upon request by the European Commission or a European Union members state.

Art. 4c. (new - SG 31/06, in force from 14.04.2006; suppl. – SG 41/09, in force from 02.06.2009) (1) The Minister of Health or a deputy minister authorized by him/her shall issue certificate for national mineral waters according to the order determined by the ordinance referred to in Art. 4b, para 1, which certifies that the mineral water by origin, ingredients and properties is appropriate for bottling for drinking purposes.

(2) The certificate referred to in para 1 shall be issued on the basis of analysis and conclusions from research conducted for:

1. the hydrological conditions and the exploitation characteristics of the mineral water deposits;
2. the physical, physicochemical, chemical, radiological and microbiological characteristics of the mineral water;
3. the pharmacological, physiological and clinical effects of the mineral water.

(3) The information referred to in para 2, item 1 shall be stored by the Ministry of Environment and Water.

(4) For the issuing of the certificate referred to in para 1 the Ministry of Environment and Water shall prepare a summary for the specific hydrological conditions and exploitation characteristics of the water derivation facility and shall provide it to the Ministry of Health.

(5) The analysis of the characteristics referred to in para 2, item 2 shall be conducted three times at intervals of two months upon issuing of a new certificate and once upon renewal of existing certificate by accredited laboratories for examination of mineral waters, determined by an order of the minister of health and the minister of environment and waters.

(6) The conclusion for the effects referred to in para 2, item 3, which shall represent an expert balneological valuation, shall be prepared by a medical institution determined by the minister of health.

(7) The certificate shall be valid for a period of 5 years from the date of its issuing.

(8) Renewal of the certificate shall be allowed before the expiration of the period referred to in para 7.

(9) (in force from 01.01.2007) Issuing of a certificate as referred to in para 1 shall not be necessary for placing on the market of the recognized mineral water, included in the published in the Official Journal of the European Communities list.

Art. 5. (1) (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health, in coordination with the Minister of Agriculture, Foods and Forestry shall determine by ordinances maximum admissible quantities of contaminants and residues from pesticides in the foodstuffs.

(2) (amend. - SG 31/06, in force from 14.04.2006) Prohibited is the production and the trade of foodstuffs which contain contaminants and residues from pesticides above the maximum admissible quantities determined by the order of para 1.

(3) (new, SG 102/03) The use of seeds for sowing which have been treated by plant protection products shall not permitted in the production of foodstuffs.

Art. 6. (1) (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) The introduction

of additives and flavourings and the use of solvents and other auxiliary substances in the production of foodstuffs shall be admitted when:

1. (amend., SG 102/03) the necessity of using them for achieving definite technological effect is proven;

2. they do not present hazard for the health of the consumers in the quantities in which they are used;

3. (amend., SG 102/03) their using does not lead to misleading of the consumers regarding the type and the characteristics of the food.

(2) (amend., SG 102/03; suppl. - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 82/09, in force from 16.10.2009; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 14/15, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health, in coordination with the Minister of Economy and with the Minister of Agriculture, Foods and Forestry shall determine by ordinances:

1. (amend. and suppl., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) the types of additives, flavourings, solvents and other auxiliary substances which can be used in the production of foodstuffs and the admissible maximum levels for some of them in the readymade foodstuffs;

2. (amend. - SG 31/06, in force from 14.04.2006) the specific criteria and requirements for purity of the additives and flavourings designated for introduction in the foodstuffs;

3. (suppl., SG 102/03) the conditions and the order of permitting the using of solvents and other auxiliary substances, of new additives, as well as of the expansion of the range of application of already permitted additive;

4. (amend. – SG 102/03; amend. - SG 31/06, in force from 14.04.2006) the raw materials, the additives and the auxiliary substances for production, storing and using flavourings;

5. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) the information related to the additives and the flavourings which must be marked on their packing, in the accompanying documentation and on the foodstuffs in which they are introduced;

6. (amend. - SG 31/06, in force from 14.04.2006) the procedures of taking samples and the methods of analysis of the qualitative and quantitative proving of additives, flavourings or their substances in or on the foodstuffs.

(3) (new - SG 31/06, in force from 01.01.2007) Placing on the market and the use of primary smoke condensates and primary tar fractions in or on foods or upon the production of derived smoke flavourings intended for use in or on foods, shall be carried out upon valuation and receiving of authorization according to the order of Regulation 2065/2003 of the European Parliament and of the Council of the European Union.

(4) (new - SG 31/06, in force from 01.01.2007) The list of the approved primary smoke condensates and the primary tar fractions and the conditions for their use in or on foods shall be prepared according to the order of Regulation 2065/2003.

(5) (new - SG 31/06, in force from 01.01.2007) For issuing of approval for inclusion of primary smoke condensates and primary tar fractions in the list referred to in para 4, the person, who intends to place them on the market, shall submit an application in written at the Ministry of Health.

(6) (new - SG 31/06, in force from 01.01.2007) The application shall contain:

1. applicant data:

a) name, unified civil number, number of the identity document and permanent address - for the natural persons;

b) name, seat, management address and identity code BULSTAT - for the sole traders and the legal persons;

2. the type of wood material used for the production of primary smoke condensates and/or primary tar fractions;

3. detailed information for the methods for production of primary smoke condensates and/or

primary tar fractions and for the further processing in the production of derived smoke flavourings;

4. the qualitative and quantitative chemical composition of the primary smoke condensates and/or primary tar fractions and the characterisation of the portion which has not been identified; the chemical specifications of the primary smoke condensates and/or primary tar fractions, information on the stability and the degree of variability of the chemical composition shall be of major importance; the portions which have not been identified (the amount of substances whose chemical structure is not known) shall be as small as possible and shall be characterised by appropriate analytical methods (chromatographic or spectrometric);

5. a validated analytical method for sampling, identification and characterisation of the primary smoke condensates and/or primary tar fractions;

6. information on the intended use levels in or on specific foods or food categories;

7. toxicological data following the advice of the Scientific Committee on Food given in its report on smoke flavourings of 25 June 1993 or its latest update;

8. a reasoned declaration, affirming that the product complies with the requirements referred to in para 1, items 2 and 3;

9. summary on the product dossier.

(7) (new - SG 31/06, in force from 01.01.2007) The application shall be filled and submitted in accordance to the Guidance on submission of a dossier for evaluation by the European Food Safety Authority, of 07 October 2004 (amend. – 27 April 2005).

(8) (new - SG 31/06, in force from 01.01.2007) In a 14-day period the Ministry of Health shall inform the applicant in written that the application was received, explicitly indicating the date of its receipt.

(9) (new - SG 31/06, in force from 01.01.2007) The Ministry of Health shall immediately inform and send for opinion the application referred to in para 6 as well as any other additional information submitted by the applicant to the European Food Safety Authority in compliance with the requirements of Regulation 2065/2003.

(10) (new - SG 31/06, in force from 01.01.2007) The modification, suspension and revocation of the authorisation shall be carried out according to the order of Regulation 2065/2003.

(11) (new - SG 31/06, in force from 01.01.2007) Authorisations referred to in para 3 shall be renewable for 10-year periods on application to the European Commission by the authorisation holder, at the latest 18 months before the expiry date of the authorisation. The renewal of the validity of the authorization shall be carried out according to the order determined by Regulation 2065/2003.

(12) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Health Care shall notify in writing the Ministry of Agriculture, Foods and Forestry of the applications submitted under para 5.

Art. 6a. (new, SG 102/03) (1) (amend. - SG 31/06, in force from 14.04.2006) The food additives shall be delivered to the consumers only pre-packed.

(2) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care in coordination with the Minister of Agriculture, Foods and Forestry shall determine by an ordinance:

1. (amend. - SG 31/06, in force from 14.04.2006) the requirements for food additives;

2. (amend. - SG 31/06, in force from 14.04.2006) the food substances (vitamins and minerals) which may be used in the production of food additives;

3. (amend. - SG 31/06, in force from 14.04.2006) the criteria for purity of the food substances to be used in food additives;

4. (amend. - SG 31/06, in force from 14.04.2006) the information to be marked in labelling the food additives.

Chapter two "a".

FOODSTUFFS OF TRADITIONALLY SPECIFIC CHARACTER (NEW - SG 31/06, IN FORCE FROM 14.04.2006; REVOKED – SG 96/06, IN FORCE FROM 01.01.2007)

Art. 6b. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6c. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6d. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Chapter two "b".

ORGANIC PRODUCTION OF FOODSTUFFS OF PLANT OR ANIMAL ORIGIN (NEW - SG 31/06, IN FORCE FROM 14.04.2006; REVOKED – SG 96/06, IN FORCE FROM 01.01.2007)

Art. 6e. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6f. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6g. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6h. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6i. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6j. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6k. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6l. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6m. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6n. (new - SG 31/06, in force from 01.01.2007; revoked – SG 96/06, in force from 01.01.2007)

Art. 6o. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6p. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6q. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 6r. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Chapter three.

REQUIREMENTS FOR THE PACKING, LABELLING, PRESENTATION AND ADVERTISEMENT OF THE FOODSTUFFS (TITLE AMEND. - SG 31/06, IN FORCE FROM 14.04.2006)

Art. 7. (amend. - SG 31/06, in force from 14.04.2006) (1) For the packing of foodstuffs and for contact with foodstuffs shall be used only materials and articles, including active and intelligent materials and articles, produced in compliance with the good production practice in a way that at normal and foreseeable conditions of use they do not transfer to the food their own components in quantities posing danger to the human health or leading to unacceptable changes in the composition of the food or to deterioration of the organoleptic characteristics of the food.

(2) The labeling, presentation and advertisement of food contact materials and articles shall not mislead the consumers.

Art. 8. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) (suppl. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care and the Minister of Environment and Waters in coordination with the Minister of Agriculture, Foods and Forestry shall determine by ordinances:

1. the specific requirements to the active and intelligent food contact materials and articles;
2. the list of substances authorised for use in the manufacturing of food contact materials and

articles, the criteria for their purity and the special conditions of use for these substances and/or the materials and articles in which they are incorporated;

3. lists of authorised substances incorporated in active or intelligent food contact materials and articles, of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;

4. the permissible limits on the specific and general migration of constituents of the materials and articles into or on to foodstuffs they are in contact with;

5. the basic rules to ensure compliance, to carry out control of the food contact materials and articles and of the substances they are made from as well as the rules concerning the collection of samples and the methods of analysis;

6. the requirements for labelling and the way of indication that the materials and articles are intended to contact with foods.

(2) (in force from 01.01.2007) Placing on the market and the use of substances other than those in the lists referred to in para 1, items 2 and 3 shall be carried out after evaluation and authorization according to the order of Regulation 1935/2004 of the European Parliament and the Council of the European Union.

(3) (in force from 01.01.2007) For authorization for inclusion in the lists referred to in para 1, items 2 and 3 the person, requesting to place on the market new substance, shall submit an application in writing to the Ministry of Health.

(4) (in force from 01.01.2007) The application shall contain:

1. data for the applicant:

a) name, unified civil number, number of the identity document and permanent address for the natural persons;

b) name, seat, management address and identity code BULSTAT for the sole traders and the legal persons;

2. a technical dossier containing the information specified in the guidelines for the safety assessment of a substance of the European Food Safety Authority;

3. a summary of the technical dossier.

(5) (in force from 01.01.2007) The Ministry of Health shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt explicitly stating the date of receipt of the application.

(6) (in force from 01.01.2007) The Ministry of Health shall without delay inform and send for opinion the application referred to in para 4 and any other supplementary information supplied by the applicant to the European Food Safety Authority in compliance with the requirements of Regulation 1935/2004.

(7) (in force from 01.01.2007) Modification, suspension and revocation of the authorization shall be carried out according to the order determined by Regulation 1935/2004.

(8) (in force from 01.01.2007) The food contact materials and articles shall be accompanied by a declaration stating they comply with the rules applicable to them.

(9) (in force from 01.01.2007) The producers and traders of food contact materials and articles shall observe the requirements concerning their traceability determined by Regulation 1935/2004.

(10) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Health Care shall notify in writing the Ministry of Agriculture, Foods and Forestry of the applications submitted as per para 3.

Art. 9. (1) (suppl. - SG 31/06, in force from 14.04.2006) The producers and the sellers of foodstuffs shall be obliged to offer to the consumers in the country foodstuffs labelled in Bulgarian language. It shall be allowed the data on the labels to be presented in other languages except Bulgarian.

(2) (amend., SG 102/03) Not admitted in the labelling of the foodstuffs shall be marking which impute or suggest qualities to the food related to prevention of the occurrence or treatment or diagnostics of diseases of people.

(3) (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) The labelling, advertising and presentation of the foodstuffs, including their form, appearance, packing, packing material or object, way of commercial arrangement and the available information for them in the mass media shall not mislead the consumers.

Art. 9a. (new – SG 59/10) The advertising of genetically modified foodstuffs by way of advertisements or other forms of commercial communications, in which participate children as performers, or which present children consuming such foods, or intended for child audience.

Art. 10. (1) (amend. - SG 31/06, in force from 14.04.2006; suppl. – SG 25/10; amend. – SG 59/10) In labelling the food shall be included data for the name by which the food is sold, a list of the components and the quantity of some of them, the quantitative content of GMO and its unique code, the expiration term of the food and the conditions in which it must be stored, the net quantity of the pre-packaged in the absence of the consumer foodstuffs, the name/firm, the headquarters and address of the producer or the person placing the food on the market, the country of origin for the imported foods, marking of the batch to which the food belongs, instructions for use if necessary, as well as the real volumetric alcohol contents for drinks, containing more than 1,2 % vol. The font size of the GMO content mark according to Article 4, paragraph 6 of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, called hereinafter "Regulation (EC) No 1830/2003" shall be two times bigger than the rest of the indication notice and with different font size and colour of the main indication.

(2) (new – SG 59/10) In case the food contains or consists of genetically modified organisms in a proportion no higher than the thresholds established in Regulation (EC) No 1830/2003, the type, the quantity, the unique identifier for GMO and the words "Contains GMO" shall by all means be written on the package, provided that the size thereof is no less than 25 percent of the package, written in capital letters in a clearly visible colour.

(3) (prev. text of para 2 – SG 59/10, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health, in coordination with the Minister of Agriculture, Foods and Forestry shall determine by an ordinance the conditions and the requirements for the presentation of the nutrition information in labelling the foodstuffs.

(4) (amend. - SG 31/06, in force from 14.04.2006; prev. text of para 3 – SG 59/10) The Council of Ministers shall determine by an ordinance the requirements for the labelling and presentation of the foodstuffs.

(5) (new – SG 59/10) The terms and the procedure according to which foods are allowed to bear a label "Without GMO" shall be set out in the ordinance under para 4.

Art. 11. (revoked, SG 102/03)

Chapter four.

PRODUCTION AND TRADE OF FOODSTUFFS

Art. 12. (amend., SG 102/03) (1) (amend. - SG 31/06, in force from 14.04.2006) Production and trade of foodstuffs in the country shall be carried out only in establishments registered by the order of this Act which:

1. meet the hygiene and/or veterinary sanitary requirements determined by a normative act;
2. (suppl. – SG 8/11, in force from 25.01.2011) have developed technological documentation for the groups of foodstuffs to be produced on the establishment or apply national standards or standards developed by branch organizations and endorsed by a competent body;

3. have implemented:

a) good practices of production and trade of foodstuffs and a system of analysis of the risks and the critical control points or procedures in compliance with its principles in case overall implementation of the system is impossible;

b) food safety management system.

4. a list of the groups of foodstuffs or meals to be produced or sold on the establishment.

(2) (amend. SG 87/05; amend. – SG 98/10, in force from 01.01.2011; amend. – SG 8/11, in force from 25.01.2011) Registration of an establishment for production or trade of foodstuffs, except for production sites of bottled natural mineral, spring and table water, shall be carried out by the District Foodstuffs Safety Directorate (DFSD) at the location of the establishment.

(3) (new – SG 8/11, in force from 25.01.2011) The registration of an establishment for production, preparation or processing of bottled natural mineral, spring and table waters shall be carried out by the Regional Health Inspectorate (RHI) at the location of the establishment.

(4) (amend. - SG 105/05, in force from 01.01.2006; prev. text of para 3, amend. – SG 8/11, in force from 25.01.2011) In order to register the persons under para 1 shall file an application in a form, stating the name and address of the person, respectively seat, address of management, and BULSTAT/UIC regarding persons registered in the Republic of Bulgaria, while the persons, registered in another Member State of the European Union or a state – party to the Agreement on the European Economic Area – another identification code or number, as well as the address of the site. Attached to the application shall be a list of the group of foodstuffs or meals which are to be produced or sold at the respective site.

(5) (new – SG 59/10; prev. text of para 4 – SG 8/11, in force from 25.01.2011) To the application under para 4 producers of foodstuffs shall be attached declarations in a form, certifying the introduction or non-introduction of additives and flavourings in the food, as well as compounds of a certain additive and substances present in the end product, even in another form, which are derived from GMO during production of food in the site.

(6) (new – SG 59/10; prev. text of para 5, amend. – SG 8/11, in force from 25.01.2011) Para 5 shall not apply to tradesmen and mass caterers.

(7) (prev. text of para 4, suppl. – SG 59/10; prev. text of para 6, amend. – SG 8/11, in force from 25.01.2011) In case any incompleteness or irregularity is found in the presented documents under para 4 and 5 within 10 days from filing the application the respective body shall inform in writing the person about that and shall determine the deadline for its rectification.

(8) (suppl. SG 87/05; prev. text of para 4, suppl. – SG 59/10; prev. text of para 7, amend. – SG 8/11, in force from 25.01.2011) Within 30 days from filing the documents under para 4 or from rectification of the incompleteness or irregularity under para 7 the respective body shall carry out an inspection on the spot for compliance of the establishment with the requirements under para 1. In case of established non-compliance with the requirements the body shall issue instructions and determine an appropriate term for bringing in compliance.

(9) (prev. (6) – SG 87/05; amend. - SG 31/06, in force from 01.05.2006; prev. text of para 6, amend. – SG 59/10; amend. – SG 8/11, in force from 25.01.2011; suppl. – SG 54/12) Within 15 days

after the inspection, or after bringing the establishment in compliance with the prescription under para 8, the respective body shall make registration of the establishment and issue a certificate of registration. The establishment shall be registered for the applied activities for production and/or trade with foodstuffs only if the producer or the trader has proved that the establishment complies with the normative requirements.

(10) (prev. (7), amend. SG 87/05; amend. - SG 31/06, in force from 01.05.2006; prev. text of para 8, amend. - SG 59/10; amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011; revoked - SG 54/12)

(11) (new - SG 23/09, in force from 30.03.2009; prev. text of para 9 - SG 59/10; amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011) The Regional Health Inspectorates shall notify the DFSD of the registered pharmacies under Art. 229a, Para 1 of the Medicinal Products in Human Medicine Act. The District Foodstuffs Safety Directorates shall register the pharmacies in the register under Art. 14, Para 1.

Art. 12a. (new - SG 31/06, in force from 01.01.2007) (1) (amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011) The District Foodstuffs Safety Directorate, respectively the Regional Health Inspection, shall temporary register a establishment for production and/or trade with foodstuffs for a period of up to three months in case the establishment complies only with the requirements of Art. 12, para 1, items 1 and 2.

(2) (amend. - SG 59/10; amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011; amend. - SG 54/12) In the cases of para 1 DFSD, respectively RHI, shall implement a check on-site of the establishment in the period for which the temporary registration was issued and shall register the establishment according to the order of Art. 12, para 9 in case it complies with the requirements of Art. 12, para 1.

(3) (amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011) If the check referred to in para 2 establishes considerable progress but the establishment still does not comply with the requirements of Art. 12, para 1, DFSD, respectively RHI, may extend the period of temporary registration to a maximum period of 6 months.

Art. 13. (amend., SG 102/03) (1) (amend. - SG 59/10; amend. - SG 8/11, in force from 25.01.2011) In case of failure to rectify incompleteness of the filed documents under Art. 12, para 7 and/or for non-fulfilment of a prescription under art. 12, para 8, the respective body under Art. 12, para 2 or 3 shall make a motivated refusal of registration and shall inform the applicant for that.

(2) (amend. - SG 8/11, in force from 25.01.2011) If no decision is announced by the respective body under art. 12, para 2 or para 3, considered shall be a presence of a tacit assent and art. 28 and 29 of the Act on Limitation of the Administrative Regulation and the Administrative Control over the Business Activity shall apply respectively. The applicant shall have the right to carry out production or trading on the establishment upon preliminary written notification about that to the respective body, and where it does not announce an explicit refusal within 7 days from receipt of the notification.

(3) In the cases of tacit assent the respective body shall be obliged to make the entry in the register under art. 14, para 1 within 14 days from the written notification under para 2, unless he has announced a refusal under para 1 or 2.

Art. 14. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) (amend. - SG 98/10, in force from 01.01.2011; amend. - SG 8/11, in force from 25.01.2011) The District Foodstuffs Safety Directorate, respectively RHI, shall keep a regional register of the establishments for production

and trade with foodstuffs according to their competence under art. 12, para 2 and 3, containing:

1. the number and the date of issuance of the certificate of the registered establishment;
2. data for the establishment;
3. type of the establishment (for production or trade);
4. groups of foodstuffs produced or offered on the registered establishment;
5. (new – SG 59/10; amend. – SG 8/11, in force from 25.01.2011) the information set out in Art. 12, para 5;
6. (prev. text of item 5 – SG 59/10; amend. – SG 8/11, in force from 25.01.2011) veterinary registration number of the establishments where such is required;
7. (prev. text of item 6 – SG 59/10) the company name or the name of the person carrying out activity of production or trade on the establishment;
8. (prev. text of item 7 – SG 59/10) date of deletion of the registration and the grounds for that;
(2) (amend. and suppl. - SG 31/06, in force from 14.04.2006; amend. – SG 98/10, in force from 01.01.2011; revoked – SG 8/11, in force from 25.01.2011)
(3) (amend. - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 98/10, in force from 01.01.2011; amend. – SG 8/11, in force from 25.01.2011) On the grounds of the registers of all DFSD and RHI at the Bulgarian Food Safety Agency (BFSA), respectively of the Ministry of Health Care, shall maintain national registers of the establishments for production and trading of foodstuffs, which shall be computerized. The national registers of the establishments for production and trading of foodstuffs shall be public and shall be published in Internet.

Art. 14a. (New – SG 96/06, in force from 01.01.2007; amend. – SG 8/11, in force from 25.01.2011) In case the national registers under art. 14 are used for the purpose of allocation of tariff or production quotas, DFSD, respectively RHI, shall include data regarding the production capacity of the production sites in them.

Art. 15. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 59/10; amend. – SG 98/10, in force from 01.01.2011; amend. – SG 8/11, in force from 25.01.2011) The producers and traders shall notify DFSD, respectively RHI, in writing for changes of the circumstances subject to entry under Art. 14, para 1, items 2, 3, 5, 6 and 7 as well as for pausing and resuming the activity in the establishment in the day of occurrence of the change. The changes shall be entered in the register in a 14-day period of the notification.

(2) In the cases of amendment of the foodstuff groups which the site shall produce or trade, as well as in event of change of the activity of the site, a new registration shall be made under the procedure of Art. 12.

Art. 16. (amend., SG 102/03) (1) The validity of the registration and of the certificate shall be without a fixed term.

(2) (amend. - SG 31/06, in force from 14.04.2006; amend. – SG 98/10, in force from 01.01.2011; amend. – SG 8/11, in force from 25.01.2011) The registration shall be written off and the certificate shall be nullified by an order of the Director of DFSD, respectively RHI:

1. for termination of the activity at a request of the person carrying out the production or trade on the establishment;
2. for a change of the purpose of the establishment;
3. for established violation of the normative requirements for production and trade of foodstuffs

presenting direct danger for the health of people;

4. (amend. - SG 31/06, in force from 14.04.2006) for systematic violations of the hygiene of the foodstuffs and of Art. 12, para 1, item 3 established by the competent bodies;

5. (amend. - SG 31/06, in force from 14.04.2006) non-fulfilment of a compulsory administrative measure under art. 30, para 1, items 5, 6, 8, 10 and 11.

(3) (new – SG 87/05; amend. – SG 98/10, in force from 01.01.2011; revoked – SG 8/11, in force from 25.01.2011)

(4) (prev. (3) – SG 87/05; amend. - SG 31/06, in force from 01.05.2006) In the cases of written off registration under para 2, item 3, 4 or 5 the person for whom the violations have been established shall be deprived of the right to register again the same establishment.

(5) (prev. (4) – SG 87/05; amend. – SG 8/11, in force from 25.01.2011) By a decision of the managing board of BAFPBI the chairman of the managing board shall send a well-grounded alert to the respective bodies as per Art. 12, para 2 and 3 for suspected violation of the normative requirements for production or trade of foodstuffs. On receiving such a signal the control body shall carry out inspection, notifying the managing board of BAFPBI about the results.

Art. 16a. (new - SG 31/06, in force from 14.04.2006) (1) The producers and traders shall provide and control the compliance with the normative requirements to the foodstuffs, produced or offered under their control.

(2) The producers and traders shall be liable for the compliance with the normative requirements for hygiene of the foodstuffs at each stage of the production, processing and distribution of foods.

Art. 17. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) The producers and the traders of foodstuffs including the persons who carry out primary production and activities connected with it shall be obliged to observe the hygienic requirements and to implement the good practices at each stage of the production, processing and distribution of foods.

(2) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health and/or the Minister of Agriculture, Foods and Forestry shall determine by an ordinance:

1. the requirements to the producers and traders of foodstuffs including to the persons who carry out primary production and the activities connected with it.

2. the hygienic requirements to the primary production;

3. the hygienic requirements to the establishments for production and trade with foodstuffs;

4. the conditions for production and trade with foodstuffs.

(3) (amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) For fulfilment of the requirements under para 2 the branch organisations of the producers and traders of foodstuffs, jointly with the competent bodies, shall develop in sub-branches guides for application of good practices and for implementation of the system for hazard analysis and critical control points in the production and trade of foodstuffs. The said guides shall be endorsed by the Minister of Agriculture, Foods and Forestry, respectively the Minister of Health Care – regarding bottled natural mineral, spring and table waters.

(4) (amend. – SG 8/11, in force from 25.01.2011; amend. – SG 44/16, in force from 10.06.2016) Upon approval of the guides referred to in para 3 the competent minister shall consider the opinion of the Center of Risk Assessment on the Food Chain developed in compliance with the following requirements:

1. compliance of the guides with the requirements of Code Alimentarius (Codex Alimentarius);

2. applicability in the sectors they are developed for;
3. compliance with the normative requirements;
4. coordination with the guides of the European Commission for implementation of procedures based on the principles of the system of hazard analysis and critical control points.

Art. 18. (1) (amend., SG 102/03; amend., SG 70/04; amend. - SG 31/06, in force from 14.04.2006) The producers and traders of foods shall put in place, implement and maintain a food safety management system or a system of danger analysis and critical control points and if the full implementation of the system is impossible – procedures based on the principles of the system of hazard analysis and critical control points.

(2) The producers and traders shall carry out review the system referred to in para 1 and shall update it in cases of modifications in the product, the process as a whole or its stages.

Art. 19. (amend., SG 102/03; revoked - SG 31/06, in force from 14.04.2006; new - SG 56/15)
(1) The contract of purchase of foods for subsequent sale may not:

1. contain a prohibition or a limitation for a contracting party to offer or purchase goods or services to or from third parties;
2. contain a prohibition or a limitation for a contracting party to provide the same or better commercial terms to third parties;
3. prescribe sanctions for provision of the same or better commercial terms to third parties;
4. be amended unilaterally, unless explicitly provided in the contract;
5. provide for remuneration for services, which are not actually rendered;
6. provide for the transfer of unjustified or disproportionate commercial risk to one of the parties;
7. provide for a term of payment longer than 30 days from the date of receipt of the delivery invoice or another invitation for payment; where the invoice or invitation has been received before receipt of the goods, the term shall commence on the day following the day of receipt of the goods, despite that the invoice or payment invitation precede it;
8. contain a prohibition or a limitation to a contracting party to transfer receivables to third parties.

(2) Any agreement in breach of Para 1 shall be null and void.

Art. 19a. (new, SG 102/03; revoked - SG 31/06, in force from 14.04.2006)

Art. 19b. (new – SG 59/10) (1) Sale of genetically modified foodstuffs shall be carried out as provided for in Art. 10, para 4.

(2) Distribution and sale of genetically modified foodstuffs in nurseries, children's kitchens, kindergartens and schools shall be prohibited.

Art. 20. (amend., SG 102/03) (1) Shall not be permitted placing on the market of foodstuffs which:

1. is not safe for consumption by the consumers;
2. damages or may damage the health of people;
3. is unfit for consumption by people.

(2) When a foodstuff, which is not safe for the consumers, is a part of a consignment or a lot of foodstuffs of equal characteristics, it shall be considered that the whole lot or consignment does not meet the requirements for safety, except where, after an inspection and/or laboratory tests, it is established that the remaining part of the lot or consignment is safe.

(3) (revoked - SG 31/06, in force from 14.04.2006)

(4) (revoked - SG 31/06, in force from 14.04.2006)

Art. 20a. (new - SG 31/06, in force from 14.04.2006) (1) When a producer or a trader of foods supposes or establishes that the foods he imported, produced, processed, prepared or distributed do not comply with the safety requirements, he shall immediately undertake measures for their withdrawal from the market in case the foods are not under his direct control and shall notify the competent bodies about this.

(2) If it is likely that the food have reached the consumers, the producer or the trader referred to in para 1 shall notify clearly and effectively the consumers for the causes of the withdrawal from the market.

(3) When the application of the measures referred to in para 1 and 2 is not sufficient to provide high level of health protection, the producer or the trader shall notify the consumers to return the already delivered foodstuffs.

(4) In the cases referred to in para 1 – 3 the producers and the traders of foods shall be obliged:

1. to immediately inform the competent bodies for the undertaken measures;

2. not to obstruct the cooperation of other persons with the competent bodies meant to prevent, reduce or remove the possible (originating) from the foods risk for the health which the food delivered by them imposes;

3. to cooperate with the competent bodies for the undertaken activities to avoid or reduce the risk for the health which the food delivered by them imposes;

4. to return the price for the food paid by the consumer.

Art. 20b. (new - SG 31/06, in force from 14.04.2006) The persons who carry out retail trade and distribution of foods without affecting their integrity, safety, packaging and labelling shall be obliged within the limits of their activity to:

1. implement measures for withdrawal from the market of foodstuffs which do not comply with the safety requirements;

2. cooperate with the producers and the competent bodies at withdrawal of foods from the market and provide information necessary for their traceability.

Art. 21. The merchants shall be obliged to offer to the consumers the foodstuffs in the same good condition in which they have received them.

Art. 21a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) The producers and traders of foods shall ensure the traceability of foodstuffs and all other substances intended for implementation or which are assumed to be implemented in foods at all stages of production, processing and distribution as for the purpose:

1. they request and store information for each of their suppliers of foods, animals, bred for the purpose of food production, and of substances intended for implementation or which are assumed to be implemented in foodstuffs;

2. they store information of the producers and traders of foodstuffs to which they have delivered their products.

(2) For the implementation of the requirements referred to in para 1 the producers and traders of foodstuffs shall implement and apply systems and procedures for collection and storage of information which allow it to be provided to the competent bodies upon request.

(3) For the implementation of the requirements referred to in para 1 the producers and traders shall label and/or mark the foodstuffs in a way ensuring their traceability.

(4) (new – SG 59/10) Producers shall demand and keep the results from laboratory analyses, provided according to Art. 23h and the requirements set out in Regulation (EC) No 1830/2003, with regards to the provided genetically modified additives and flavourings, as well as components of a certain additive as well as substances intended for use in the foodstuffs.

(5) (new – SG 59/10; amend. – SG 8/11, in force from 25.01.2011) Producers shall take samples in order to ensure compliance with the announced information as per Art. 12, para 5 at regular intervals set out in the introduced food safety management system or danger analysis and critical control points system as per Art. 18, para 1.

Art. 21b. (new – SG 23/10) (1) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall issue an ordinance in order to regulate the specific requirements for direct deliveries of small quantities of raw materials and foodstuffs of animal origin.

(2) (amend. – SG 8/11, in force from 25.01.2011) The ordinance mentioned in para 1 shall also define the specific requirements for:

1. direct delivery of small quantities carried out by the producer to end users or to local retail trade sites carrying out direct deliveries of small quantities of:

a) primary products – raw milk, bee honey, eggs from hens and quails, as well as fresh and chilled marine and freshwater fish;

b) fresh meat from birds and rabbits, butchered at the farm;

c) shot big and small game or game big and small meat;

2. delivery of foodstuffs of animal origin processed and/or manufactured at a retail trade site to end users or to other retail trade sites as a side, local and limited activity.

Art. 22. (amend., SG 102/03) (1) Processing of foodstuffs by ionizing radiation shall be permitted in the presence of a grounded technological necessity for that, there is no danger for the health of the consumers and it is to the benefit of the end consumer.

(2) The radiation treatment of foodstuffs may be applied only for the following purposes:

1. reduction of the danger of food generated diseases by destruction of pathogenic organisms;

2. reduction of the decay of the foodstuffs by slowing down or stopping of the processes of decay and destruction of the decay micro-organisms;

3. reduction of the losses in storing the foodstuffs by slowing down the maturing, sprouting or germination;

4. removal of the organisms harmful for the plants and foodstuffs of vegetal origin.

Art. 22a. (new, SG 102/03) (1) (suppl. – SG 41/09, in force from 02.06.2009) The treatment of the foodstuffs by ionizing radiation shall be carried out only by persons having obtained registration for the activity of treating foodstuffs by ionizing radiation issued by the Minister of Health or by a deputy minister authorized by him/her.

(2) (suppl. – SG 41/09, in force from 02.06.2009) The radiation of each individual kind of

foodstuff shall be carried out after an issuance of individual permits for that by the Minister of Health or by a deputy minister authorized by him/her.

Art. 22b. (new, SG 102/03) (1) (amend. - SG 105/05, in force from 01.01.2006; suppl. - SG 34/06, in force from 01.10.2006; amend. – SG 8/11, in force from 25.01.2011) For obtaining registration for carrying out processing of foodstuffs by ionizing radiation may be applied by an able bodied individual and corporate body registered in the Republic of Bulgaria, which shall be filed with the Minister of Health in a form, containing the name and the address of the individual, respectively name, seat and address of management, and BULSTAT/UIC regarding persons registered in the Republic of Bulgaria, while the persons, registered in another Member State of the European Union or a state – party to the Agreement on the European Economic Area – another identification code or number, as well as the address of the site. Attached to the application shall be a list of the group of foodstuffs or meals which are to be produced or sold at the respective site:

1. (amend. – SG 54/12) data of the registry number of the licence for using sources of ionizing radiation under art. 15, para 3, item 2 of the Safe Use of Nuclear Power Act;

2. type of the source of ionizing radiation;

3. standardized methods of determining the total average consumed dose of the field and in the irradiated foodstuff.

(2) On establishing incompleteness of the filed documents under para 1 and/or in case of necessity of presenting further information the applicant shall be informed in writing within 14 days from filing the application for the period within which he shall remove the established incompleteness and/or present the information. For failure to do so within the set period the application shall not be considered.

(3) The Minister of Health or a person authorized by him shall carry out the registration or shall make a motivated refusal of registration within one month from filing the application, respectively from the expiration of the period under para 2.

(4) (amend. - SG 30/06, in force from 12.07.2006) The explicit or tacit refusal of registration shall be subject to appeal by the order of the Administrative procedure code.

(5) The registration for processing foodstuffs by ionizing radiation shall have a term of validity equal to the term of validity of the licence under art. 15, para 3, item 2 of the Safe Use of Nuclear Power Act. A certificate shall be issued to the person within the period under para 3.

(6) The registration shall be terminated:

1. upon the death of the individual, respectively upon declaring bankruptcy or liquidation of the corporate body;

2. withdrawal, termination or expiration of the term of the licence under para 1, item 1;

3. systematic violation of the requirements of the law by the registered person;

4. upon establishing that the registered person has presented untrue information having served as grounds for the registration;

5. upon request of the registered person.

(7) On establishing violation in the cases of para 6, item 3 and 4 administrative penalties or proprietary sanctions stipulated by this Act shall be imposed on the persons.

(8) A public register shall be kept for the registration and issued certificates containing:

1. data for the person;

2. the term of the registration;

3. the data under para 1, item 3;

4. date and grounds for termination of the registration.

(9) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care shall notify in writing the Minister of Agriculture, Foods and Forestry of

the registrations that have been made or annulled.

(10) (prev. text of para 9, suppl. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care in coordination with the Minister of Agriculture, Foods and Forestry shall issue an ordinance for determining the kinds of foodstuffs which may be processed by ionizing radiation, as well as the conditions and the order thereof.

Art. 22c. (new, SG 102/03) (1) (amend. - SG 31/06, in force from 14.04.2006; suppl. – SG 41/09, in force from 02.06.2009) A food irradiation permit shall be issued by the Minister of Health or by a deputy minister authorized by him/her for each individual kind of foodstuff.

(2) For the issuance of a food irradiation permit its producer shall file an application to the Ministry of Health containing the kind of the foodstuff to be radiated, the establishment where the radiation shall be carried out and the substantiation of the necessity and the purpose of the radiation.

(3) Attached to the application under para 2 shall be a declaration by the person having submitted the foodstuff for irradiation, declaring whether the foodstuff or a part of it have been subjected to radiation in advance.

(4) The food irradiation permit or a refusal of that shall be issued within a month from filing the application.

(5) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care shall notify in writing the Minister of Agriculture, Foods and Forestry of the issued food irradiation permits.

(6) (amend. - SG 30/06, in force from 12.07.2006; prev. text of para 5 – SG 8/11, in force from 25.01.2011) The explicit or tacit refusal shall be subject to appeal by the order of the Administrative Procedure Code.

Art. 23. (1) (prev. text of art. 23 – SG 102/03) Every person occupied in the production and trade of foodstuffs shall be subject to preliminary and periodical medical examinations by the order established for that.

(2) (new, SG 102/03 – in force from January 1, 2005; amend. – SG 59/10) Employed under a contract in every establishment for production of foodstuffs shall be a person with higher or high vocational education in the sphere of the food industry or having a qualification in the same sphere according to the Crafts Act. Employment of a specialist shall not be required if the person under art. 14, para 1, item 7 meets these requirements.

(3) (new - SG 31/06, in force from 14.04.2006) The producers and traders of foods shall provide to the persons referred to in para 1 in accordance with the activities they implement education for observance of the hygienic requirements, the rules for good practices and the implementation of the system of safety management of the foods or the system of hazard analysis and critical control points and in case it is inapplicable – the procedures in compliance with its principles.

Chapter four "a".

CONDITIONS AND ORDER FOR PLACING ON THE MARKET OF NOVEL FOODSTUFFS, NOVEL FOOD INGREDIENTS AND GENETICALLY MODIFIED FOODSTUFFS (NEW - SG 31/06, IN FORCE FROM 14.04.2006)

Art. 23a. (new - SG 31/06, in force from 14.04.2006) (1) Commission of Novel and Genetically Modified Foodstuffs further called "the commission" shall be established at the Minister of Health which shall:

1. implement initial assessment of the applications for authorization for placing on the market of novel foodstuffs and novel food ingredients;

2. (in force from 01.01.2007) provide opinion concerning received from the European Commission, European Food Safety Authority or from the competent body of another European Union member state:

a) reports for implemented initial assessment of novel foodstuffs and novel food ingredients;

b) notifications on placing on the market of novel foodstuffs or novel food ingredients referred to in Art. 4a, para 1, items 2 and 3, which on the basis of available and scientifically recognized information or on the basis of opinion of a competent body of a European Union member state, notified according to the order of Regulation 258/97 of the European Parliament and the Council of the European Union have been recognized to be significantly equivalent to traditionally used foodstuffs or food ingredients;

c) applications for authorizations for placing on the market of genetically modified foodstuffs, GMO for use in or as foodstuffs and foodstuffs containing ingredients, produced from GMO;

3. (in force from 01.01.2007) implement upon request from the European Commission safety evaluation of the foodstuffs in accordance to Regulation 1829/2003 of the European Parliament and the Council of the European Union;

4. provide opinions on other questions of the competence of the Minister of Health, raising from the implementation of this Act concerning the safety of novel foodstuffs and novel food ingredients, genetically modified foodstuffs, GMO for use in or as foodstuffs and foodstuffs containing ingredients, produced from GMO;

5. take part in the development of draft statutory instruments in relation to safety of new foodstuffs and new nutrients, genetically modified foods, GMOs for use in or as food as well as the food containing ingredients derived from GMOs;

6. (new – SG 59/10) maintain an electronic register for its activity in the web site of the Ministry of Health.

(2) The Commission shall consist of 15 habilitated scientists in the field of medicine, biotechnology, toxicology, molecular biology, molecular genetics, feeding, food technologies, agronomy, stockbreeding and environment protection.

(3) (amend. – SG 36/08; amend. – SG 74/09, in force from 15.09.2009; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 68/13, in force from 02.08.2013, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health, Minister of Agriculture, Foods and Forestry and Minister of Education and Science shall propose for members of the Commission four habilitated scientists each and the Minister of Environment and Waters shall propose three habilitated scientists.

(4) The members of the Commission shall be appointed by an order of the Minister of Health for a period of 4 years.

(5) (amend. – SG 36/08; amend. – SG 82/09, in force from 16.10.2009; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 14/15, amend. – SG 58/17, in force from 18.07.2017) In the work of the Commission shall participate without the right to vote one representative of each of the Ministry of Health, Ministry of Agriculture, Foods and Forestry, Ministry of Environment and Waters, Ministry of Economy and two representatives from BAFDI.

(6) The representatives referred to in para 5 shall be determined by an order of the Minister of Health upon the proposal of the heads of the respective institutions and organizations.

(7) The Commission shall adopt rules for its activity which shall be approved by the Minister of Health.

(8) The members of the Commission and the persons referred to in para 5 shall sign declarations for not spreading of confidential information. For a period of three years after termination or expiration of their mandate the members of the Commission shall be obliged not to spread confidential information they have learned upon or on occasion of implementation of their official

duties.

(9) For implementation of activities referred to in para 1, items 1, 2 and 3 the members of the Commission shall be paid according to an order, determined by the rules referred to in para 7.

Art. 23b. (new - SG 31/06, in force from 14.04.2006) (1) A person who intends to place on the market novel foodstuff or novel food ingredient shall be obliged to carry out assessment of the risk for the human health before placing on the market.

(2) a person intends to place on the market genetically modified foodstuff, GMO to be used in or as food or food, containing ingredients, produced from GMO, shall be obliged to carry out before placement on the market:

1. assessment of the risk for the human health;
2. assessment of the risk for the environment.

(3) The assessment of the risk shall be carried out for every single case on the basis of existing scientific and technical data and shall include:

1. Analysis of all potential negative consequences for the human health and/or the environment, which may occur directly or indirectly up and played month on the market of novel food or novel food ingredients, genetically modified foodstuff, GMO to be used in or as food or food, containing ingredients, produced from GMO, including analysis for potential cumulative long term constituencies from the placing of these foods on the market;

2. conclusion for the potential effect to the human health and/or the environment upon consumption.

(4) In the presence of new scientific information for novel foodstuffs or novel food ingredients, genetically modified foods, GMO for use in or as foods or foods, containing ingredients, produced from GMO, and for the consequences from their placing on the market for the human health new assessment shall be implemented.

(5) The assessment of the risk for the environment shall be carried out according to the order of the Genetically Modified Organisms Act.

Art. 23c. (new - SG 31/06, in force from 14.04.2006) (1) (in force from 01.01.2007) Placement on the market of novel foodstuff or novel food ingredient shall be carried out only after authorization according to the order of Regulation 258/97.

(2) For novel foodstuffs or novel food ingredients referred to in Art. 4a, para 1, items 2 and 3 which on the basis of existing and acknowledged scientific information or on the basis of opinion of a competent body of but a European Union Member State notified according to the order of Regulation 258/97, are recognized as significantly equivalent to traditionally used foodstuffs or food ingredients regarding the contents, nutrition values, metabolism, expected use and unwanted substances content, the procedure referred to in Art. 23e shall be applied.

(3) For authorization referred to in para 1 every person, who intends to place novel foodstuff and novel food ingredient on the territory of Bulgaria for the first time, shall submit application in written to the Ministry of Health.

(4) Simultaneously with the submission of the application referred to in para 3 the applicant shall send a copy of the application to the European Commission.

(5) The applications shall contain:

1. data of the applicant:

a) name and permanent address for the natural persons;

b) name, seat, management address and/or identity code BULSTAT – for the sole traders and the legal persons;

2. technical dossier for the novel food or the novel food ingredients which shall include information necessary for assessment of the risk for the human health from placing on the market of the novel food or food ingredient:

- a) the category of the novel food or novel food ingredient referred to in Art. 4a, para 1;
- b) data of the source used for the production of the novel food or novel food ingredient;
- c) specification of novel food or novel food ingredient;
- d) data of toxic, allergic and other harmful for the health effects;
- e) data of the presence of the novel food or novel food ingredient in the food consumption of the population;

3. reports of the assessment of the risk of the novel foodstuff or novel food ingredient as well as other data which proves the compliance with the requirements of Art. 4a, para 2, accompanied by description of the used methods and bibliographic reference;

4. (amend. – SG 59/10) proposal of the way of labelling and presentation of the novel foodstuff or novel food ingredient in compliance with the requirements of the ordinance referred to in Art. 10, para 4;

5. the conditions for placement on the market of novel food or novel food ingredient, if present, including the way of use and preparation if necessary;

6. proposal for a plan for observational of the negative effects on the human health after the placement on the market of the novel food or the novel food ingredient;

7. summary of the technical dossier and the assessment of the risk for the human health;

8. additional information.

(6) The applicant may refer to information or results of previous applications of other applicants or to present additional information which he considers appropriate, only if the information and the results are not confidential or the other applicants have given consent in written.

(7) The application shall explicitly indicate which documents and/or information the applicant wants to be considered confidential and for the purpose they shall be attached separately.

(8) The application and the documents attached to it shall be submitted in Bulgarian or English language on paper or in electronic form.

(9) The application shall be accompanied by a document for paid taxes of amount determined by a tariff of the Council of Ministers.

Art. 23d. (new - SG 31/06, in force from 14.04.2006) (1) (in force from 01.01.2007) The initial assessment of the application and the attached documents shall be carried out by the commission referred to in Art. 23a, para 1 or by another competent assessment body of a European Union member state according to the procedure determined in Regulation 258/97.

(2) In a period of three months from receipt of an application meeting with the requirements referred to in Art. 23, para 5, a report for initial assessment shall be prepared.

(3) (in force from 01.01.2007) The report referred to in para 2 shall contain conclusions concerning the necessity of implementation of additional assessment according to the order, determined by Regulation 258/97.

(4) (in force from 01.01.2007) The Ministry of Health shall send the report for primary assessment to the European Commission.

(5) (in force from 01.01.2007) In compliance with the procedure determined by Regulation 258/97 each European Union member state may express opinion or propose motivated objection to the report for primary assessment.

(6) (in force from 01.01.2007) The applicant shall provide to the European Union member states upon request information and copies of documents relevant to the submitted to application.

(7) (suppl. – SG 41/09, in force from 02.06.2009) The Minister of Health or a deputy minister

authorized by him/her shall issue authorization for placing on the market of novel food or novel food ingredient on the condition that:

1. additional assessment is not required and
2. motivated objection referred to in para 5 was not received.

(8) (in force from 01.01.2007) The Ministry of Health in compliance with the procedure of Regulation 258/97 shall immediately notify the applicant that he is allowed to place on the market novel foodstuff or novel food ingredient or a decision according to the order para 9 shall be taken.

(9) (in force from 01.01.2007) In case additional assessment as referred to in para 3 is required or upon submitted motivated objection as referred to in para 5, the procedure and the order for decision taking, determined by Regulation 258/97, shall be implemented.

(10) (in force from 01.01.2007) The decision referred to in para 9 shall define the scope of the authorization and shall establish, where appropriate:

1. the conditions of use of the novel food or novel food ingredient;
2. the designation of the novel food or novel food ingredient, and its specification;
3. specific labelling requirements.

(11) (in force from 01.01.2007) The European Commission shall inform the applicant of the decision referred to in para 9 taken.

(12) The list of the authorized for placing on the market novel foods and novel food ingredients shall be published in the official journal and the Internet side of the Ministry of Health.

(13) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Health Care shall notify the Minister of Agriculture, Foods and Forestry in writing of the issued authorizations as per para 7.

Art. 23e. (new - SG 31/06, in force from 01.01.2007) (1) A person placing on the market novel foodstuffs or novel food ingredients referred to in Art. 23c, para 2 shall immediately notify the European Commission.

(2) The notification referred to in para 1 shall be accompanied by the relevant documents referred to in Art. 23c, para 2.

(3) Information of the received notifications shall be published annually according to the order of Regulation 258/97.

Art. 23f. (new - SG 31/06, in force from 01.01.2007) (1) Placing on the market of genetically modified foodstuffs, GMOs for use in or as foods or feeds, containing ingredients, produced from GMOs, shall be carried out only after authorization of the European Commission according to the order of Regulation 1829/2003 of the European Parliament and the Council of The European Union and upon compliance with the respective conditions determined in the authorization.

(2) The person who intends to place on the market genetically modified foodstuffs, GMOs for use in or as foods or feeds, containing ingredients, produced from GMOs, shall submit an application in written to the Ministry of Health in order to receive authorization.

(3) When a product referred to in para 1 is placed on the market only as food for human consumption, the application shall contain explicit statement for that, based on data which can be verified.

(4) When a product referred to in para 1 may be used as food for human consumption or as fodder, one application shall be submitted to the Minister of Health.

(5) The application referred to in para 2 shall contain:

1. applicant data:
 - a) name, unified civil number, number of the identity document and permanent address - for the

natural persons;

b) name, seat, management address and identity code BULSTAT - for the sole traders and the legal persons;

2. technical dossier of the genetically modified foodstuff, GMO for use in or as foods or food, containing ingredients, produced from GMOs which shall contain information necessary for implementation of assessment of the risk for the human health from placing on the market of such foodstuffs:

a) name and designation of the food, its specification, including the type of genetic modification;

b) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;

c) where applicable, a detailed description of the method of production and processing;

d) copies of the study reports, including, where available, independent, peer-reviewed studies, which have been carried out and any other additional information which is available to demonstrate compliance with the requirements referred to in Art. 4a, para 3;

e) (amend.- SG 59/10) analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of the foodstuffs they are intended to replace, having regard to the limits of natural variations for such characteristics as composition, nutritional value or nutritional effect, intended use of the food and implications for the health of certain sections of the population or a proposal for labelling the food in accordance with the requirements of the ordinance referred to in Art. 10, para 4;

3. (amend.- SG 59/10) a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with the requirements of the ordinance referred to in Art. 10, para 4;

4. where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

5. description of the methods for detection, sampling and identification of the genetic modification and, where applicable, for the detection and identification of the genetic modification in the food and/or in foods produced from it;

6. samples of the food and their control samples, and information as to the existence and the place where the reference material can be accessed;

7. a summary of the dossier in a standardised form and summary of the human health risk assessment;

8. where appropriate, a proposal for post-market monitoring regarding use of the food.

(6) In the case of an application referred to in para 2 relating to a GMO for use in or as food, references to "food" in para 5 shall be interpreted as referring to "genetically modified food".

(7) In the case of GMOs for use in or as food or food, containing ingredients, produced from GMOs, the application referred to in para 5 shall also be accompanied by:

1. the complete technical dossier of the GMO and the conclusions of the risk assessment carried out under the Genetically Modified Organisms Act or, where the placing on the market of the GMO has been authorised under the Genetically Modified Organisms Act, a copy of the authorisation decision;

2. a monitoring plan for negative environmental effects after placing of the GMO on the market, developed in compliance with the requirements of the Genetically Modified Organisms Act, as well as a proposal for the duration of the monitoring.

(8) Where the application concerns a substance referred to in Art. 2, para 1, the use and placing on the market of which is subject, under other provisions of other European Community law, to its inclusion on a list of substances authorised, this must be explicitly stated in the application and information on the status of the substance under the relevant legislation must be provided.

(9) The application referred to in para 5 shall be filled and presented in compliance with the

requirements of Regulation 641/2004 of the European Commission and with recommendations of the European Commission and guides of the European Food Safety Authority, adopted under Regulation 1829/2003.

(10) The application shall be submitted in Bulgarian and English languages on paper or in electronic form.

(11) The application shall explicitly indicate which documents and/or information the applicant wants to be considered confidential and for the purpose they shall be attached separately.

(12) The application shall be accompanied by a current status certificate of the applicant's registration, in case he is a sole trader or legal person.

(13) Where appropriate, the application shall be accompanied by information on the genetically modified foodstuff, GMO for use in or as food or food, containing ingredients, produced from GMOs placed on the market outside the territory of the country.

(14) The applicant may refer to information or results of previous applications of other applicants or to present additional information which he considers appropriate, only if the information and the results are not confidential or the other applicants have given consent in written.

(15) (new – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Health Care shall notify the Ministry of Agriculture, Foods and Forestry in writing of the applications submitted as per para 2.

Art. 23g. (new - SG 31/06, in force from 01.01.2007) In a 14-day period the Ministry of Health shall inform the applicant in written that the application was received, explicitly indicating the date of its receipt.

(2) The Ministry of Health shall immediately notify and send the application referred to in Art. 23c as well as the attached documents to the European Food Safety Authority in compliance with the requirements of Regulation 1829/2003.

(3) The European Food Safety Authority shall give its opinion according to the condition and the order determined by Regulation 1829/2003.

(4) Authorization for placing on the market of genetically modified foodstuffs, GMOs for use in or as food or foods, containing ingredients, produced from GMOs, shall be provided in compliance with the procedure determined by Regulation 1829/2003; the European Commission shall notify the applicant of the decision.

(5) The list of the authorized for placing on the market genetically modified foodstuffs, GMOs for use in or as food or foods, containing ingredients, produced from GMOs, shall be published in the official journal and the Internet site of the Ministry of Health.

(6) The modification, suspension and revocation of the authorisation for placing on the market of genetically modified foodstuffs, GMOs for use in or as food or foods, containing ingredients, produced from GMOs, shall be carried out according to the order of Regulation 1829/2003.

(7) Authorisations referred to in para 4 shall be renewable for 10-year periods on application to the European Commission by the authorisation holder, at the latest one year before the expiry date of the authorisation. The extension of the validity of the authorization shall be carried out according to the order determined by Regulation 1829/2003.

(8) The authorization-holders referred to in para 4 and the persons responsible for placing on the market shall be obliged to comply with the conditions and restrictions for placing on the market of genetically modified foodstuffs, GMOs for use in or as foods or food, containing ingredients, produced from GMOs, described in the authorization.

(9) The authorization-holders referred to in para 4 who are required to implement post-market monitoring and/or monitoring plan for negative environmental effects after placing on the market of GMOs shall carry out the monitoring and provide information according to the order of Regulation

1829/2003.

(10) The authorisation-holders referred to in para 4, who wish to modify the terms of the authorisation, shall submit an application referred to in Art. 23f, para 2 in accordance with the procedure determined by Regulation 1829/2003.

Art. 23h. (new - SG 31/06, in force from 14.04.2006) (1) The persons, placing on the market genetically modified foods, containing or consisting of GMOs, including in bulk, shall be obliged to provide information to the customers in written that the food contains or consists of GMOs as well as the unique code of GMO.

(2) (suppl.- SG 59/10) The producers and traders of the foods referred to in para 1 shall be obliged to provide information to the customers in writing that the food contains or consists of GMOs as well as the unique code of GMO in the documents accompanying the consignment and on the label of the product and also in the following stages of its placing on the market.

(3) The producers and traders referred to in para 1 and 2 shall be obliged to implement a system and procedures for:

1. storage of the information referred to in para 1 and 2;
2. identification of the persons from who they bought or sold the foodstuffs referred to in para 1.

(4) The information referred to in para 1 shall be stored for a period of 5 years from the conclusion of each deal.

(5) (in force from 01.01.2007; amend. and suppl. – SG 59/10) At labelling of genetically modified foodstuffs, containing or consisting of GMOs, and foods, containing ingredients, produced from GMOs, in addition to the requirements, determined by the ordinance referred to in Art. 10, para 4, the requirements of Regulation 1829/2003 shall be observed and Regulation (EC) No 1830/2003.

Chapter five. IMPORT AND EXPORT OF FOODSTUFFS

Art. 24. (1) (amend., SG 102/03; suppl. - SG 31/06, in force from 14.04.2006) Imported in the country shall be foodstuffs which meet the requirements of the Foodstuffs Act, the Veterinary Practice Act, Plants Protection Act and the statutory instruments on implementation thereof.

(2) (amend., SG 102/03; amend. - SG 31/06, in force from 01.01.2007) Imported in the country may be also foodstuffs, which comply with the requirements, acknowledged as equivalent by the European Community, or with the requirements determined by agreement between the European Community and an exporting country.

(3) (new, SG 102/03; revoked - SG 31/06, in force from 14.04.2006)

(4) (new- SG 59/10) In case of import of foodstuffs containing or consisting of GMO, the importer shall provide the required information in the documents accompanying the consignment relating to the type and the quantity of GMO.

Art. 24a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) (suppl. – SG 41/09, in force from 02.06.2009) Import of bottled mineral water in the country and its distribution in the trade network shall be carried out upon obtaining a certificate for import from the Minister of Health or a deputy minister authorized by him/her.

(2) For issuing of the certificate referred to in para 1 the importer of bottled natural mineral water shall submit an application to the Minister of Health which shall contain:

1. name, seat and management address of the company-importer;
2. name and management address of the foreign company-producer;
3. the country from which the natural mineral water is imported;
4. the trade mark (trade name) of the natural mineral water.

(3) The application referred to in para 2 shall be accompanied by:

1. a copy of the court decision for registration of the Bulgarian company-importer, according to the Commerce Act and certificate for current legal state;
2. a copy of the official document of recognition of the water as natural mineral issued by the competent body of the respective country;
3. a document, issued by the competent body of the respective country, certifying that the natural mineral water complies with the requirements, determined by the ordinance referred to in Art. 4b. para 1;
4. protocols for implemented examinations of the water by accredited laboratories.

(4) (suppl. - SG 77/18, in force from 01.01.2019) The Minister of Health or an official appointed from the staff of the ministry shall issue the certificate or a motivated refusal in a 10-days period from the submission of the documents referred to in para 2 and 3.

(5) The explicit or tacit refusal shall be subject to appeal according to the order of the Act on the Supreme Administrative Court.

(6) The imported natural mineral waters for which a certificate (permit) has been issued for import shall be included in an individual section of the list of the natural mineral waters referred to in Art. 4b, para 3.

(7) The term of validity of the certificate shall be 5 years.

(8) Renewal of the certificate shall be allowed before the expiration of the term under para 7, as for the purpose a current document as referred to in para 3, item 3 shall be submitted to the Ministry of Health.

(9) If the current document under para 3, item 3 is not presented within the term, of para 7 the respective natural mineral water shall be written off the list under para 6.

Art. 24b. (new, SG 102/03) The conditions and the order of importing raw materials and foodstuffs of animal origin in the country shall be settled by the order of the Veterinary Practice Act.

Art. 25. (1) (prev. text of Art. 25 – SG 31/06, in force from 14.04.2006) Applied for the foodstuffs of local production shall also be the requirements of the country importer if it does not contradict an international agreement.

(2) (new - SG 31/06, in force from 14.04.2006) With the explicit consent of the importing country exported may be foodstuffs which do not comply with the requirements of this Act, the Veterinary Practice Act, Plants Protection Act and the statutory instruments their implementation, upon the condition that the foodstuffs are safe for the human health and the importing country was notified for the reasons and circumstances the foodstuffs may not be placed on the market.

Art. 25a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) The requirements of the importing country shall be applicable as well for the foodstuffs intended for export or re-export for placing on the market of a third-country.

(2) With the explicit consent of the competent body of the importing country exported or re-exported may be also foodstuffs, which comply with the normative requirements of the European Community, but are safe for the human health and the importing country was fully informed for the

reasons and circumstances the foodstuffs may not be placed on the Single European market.

(3) In case the provisions of a bilateral trade agreement between the European Community or one of the European Union member states and a third country are applicable, the export shall be carried out according to the provisions of the agreement.

Chapter six.

OFFICIAL CONTROL OVER THE FOODSTUFFS (TITLE AMEND. - SG 31/06, IN FORCE FROM 14.04.2006)

Art. 26. (1) (amend - SG 31/06, in force from 14.04.2006) Subject to official control according to this Act shall be:

1. (amend - SG 31/06, in force from 14.04.2006) all stages of the production, processing and distribution of foodstuffs;

2. the condition and the way of using the grounds, the buildings, the installations and their adherent areas, the technical and the material equipment, the transport vehicles related to the production and trade of foodstuffs;

3. the raw materials, the components, the additives and the other products used in the production of foodstuffs;

4. the technological processes for production of foodstuffs;

5. the washing, cleaning, disinfecting, disinsecting and deratisating preparations and processes;

6. the materials and the objects designated for contact with the foodstuffs;

7. the prefabricated and ready made foodstuffs;

8. (suppl. - SG 80/10) the labelling, presentation and advertising of the foodstuffs, including their compliance with Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, called hereinafter "Regulation (EC) No 510/2006", and Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed, called hereinafter "Regulation (EC) No 509/2006";

9. the methods and means of storing and preserving the foodstuffs;

10. the hygiene of the persons who enter in contact, directly or indirectly with the materials and the products under item 3, 5, 6 and 7.

11. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) the good practices of production and trade of foodstuffs, the system of the food safety management, the system of hazard analysis and critical control points or the respective procedures based on its principles, as well as the technological documentation.

(2) The control under para 1 shall regard both the foodstuffs which are produced and sold on the territory of the country and the foodstuffs for export.

Art. 27. (amend - SG 31/06, in force from 14.04.2006) (1) The official control shall be exercised systematically on the basis of the risk and at appropriate frequency as to provide food safety by taking into consideration:

1. the established risks connected with the foodstuffs, with the production and trade of foodstuffs, with the use of foodstuffs or with the processes, materials, substances, activities or action that may affect the food safety;

2. the documentation of the producers and traders of foodstuffs concerning the compliance with the normative requirements;

3. data for established upon previous checks non-compliance of the activity of the producer and

the trader with the normative requirements documented by the competent bodies;

4. the reliability of the implemented by the producer or the trader checks in the establishment;
5. any other information which may prove incompatibility.

(2) The official control shall be carried out without preliminary notification, including without planning, except for audits, for the implementation of which the producers and traders shall be notified.

(3) The official control shall be carried out at all stages of production, processing and distribution of foodstuffs and shall include control of the establishments for production and trade of foodstuffs, the use and storage of foodstuffs, the processes, the materials, the substances, the activities or actions, including the transportation of foodstuffs.

(4) The state control shall consist of one or several of the following activities:

1. inspections of:

a) buildings, adjacent areas, premises, facilities and technological equipment, including transportation vehicles, used in the production and trade with foodstuffs, facilities used in the primary production as well as of foodstuffs;

b) raw materials, ingredients, supplementary substances and other products, used in the production and handling of foodstuffs;

c) semi-cooked foodstuffs;

d) food contact materials and articles;

e) cleaning and maintenance preparations and processes as well as pesticides;

f) (suppl. - SG 80/10) labelling, presenting and advertisement of foodstuffs including their compliance with Regulation (EC) No 510/2006 and Regulation (EC) No 509/2006;

2. checks of the hygiene conditions in the establishments for production and trade with foodstuffs;

3. evaluation of the procedures of application of the good practices, the system of the food safety management, the system of hazard analysis and critical control points or its principles in case of its inapplicability;

4. taking samples and specimens and performing analyses and tests;

5. control of the hygiene of the personnel;

6. inspection of the documentation and records which may have connection with the assessment of the compliance with the requirements of the food legislation;

7. hearing of the managers and the personnel in the food production and trade enterprises;

8. accounting the values registered by the measuring instruments used in the establishment for production and trade with foodstuffs;

9. inspections of the registered values by the measuring instruments in the establishment by using own measuring instruments by the competent bodies;

10. (new – SG 8/11, in force from 25.01.2011) conformity assessment of the quality features of the foodstuffs with the requirements of national or other standards, worked out by branch organizations and endorsed by a competent body;

11. (prev. text of item 11 – SG 8/11, in force from 25.01.2011) other activities ensuring the enforcement of the objectives of the law.

(5) (new – SG 59/10) The official control shall also be exercised by way of alerts and complains by citizens. In case any offences are established, regarding which have been issued instructions or imposed fines, producers and traders shall pay a fee for the check in amount specified in a tariff as per Art. 36c.

Art. 27a. (new - SG 31/06, in force from 14.04.2006) (1) The official control of foodstuffs upon import, export and placing on the market of foodstuffs shall be carried out identically.

(2) The competent bodies shall carry out inspection of the foodstuffs upon import for

compatibility with the normative requirements regardless of the place of origin of the shipment.

(3) In case the competent bodies establish non-compliance upon inspection carried out at the place of receiving or at the time of storage or transportation of an imported shipment, they shall undertake respective measures, including return of the shipment in the country of origin.

(4) (in force from 01.01.2007) Upon trade with European Union member states the persons who receive shipments of foodstuffs shall notify in written the competent bodies before the import in order to organize the control.

Art. 27b. (new - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 28. (amend., SG 102/03; amend., SG 70/04; amend. - SG 31/06, in force from 14.04.2006) (1) (amend. – SG 8/11, in force from 25.01.2011) The Bulgarian Food Safety Agency (BFSA) shall exercise official control over all foodstuffs, except for the bottled natural mineral, spring and table waters.

(2) (new – SG 8/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall also carry out conformity assessment of the quality features of foodstuffs with the requirements from national and other standards, developed by branch organizations and endorsed by a competent body, as well as technical documentation.

(3) (new – SG 8/11, in force from 25.01.2011) The official control over bottled natural mineral, spring and table waters shall be exercised by the RHI bodies at the Ministry of Health Care.

(4) (prev. text of para 2 – SG 8/11, in force from 25.01.2011) The competent bodies shall:

1. carry out effective and expedient official control at all stages of production, processing and distribution of foodstuffs;

2. carry out official control without conflicts of interests;

3. dispose with their own laboratory or have contracts with a laboratory of enough capacity and qualified staff for effective and efficient implementation of official control;

4. dispose with appropriate and correctly maintained facilities and equipment to ensure effective and efficient implementation of official control by the staff;

5. develop plans for action in emergency situations (contingency plans).

(5) (prev. text of para 3, amend. – SG 8/11, in force from 25.01.2011) The plans referred to in para 4, item 5 shall determine the necessary measures which shall be immediately implemented in case a certain foodstuff is found to impose serious risk for the health of the people or the animals directly or through the environment.

Art. 28a. (new - SG 31/06, in force from 14.04.2006) (1) The competent bodies shall carry out internal audits and may organize the implementation of external audits. The audits shall be carried out upon compliance with the requirements for transparency.

(2) (in force from 01.01.2007) On the base of the results of the audits the competent bodies shall undertake measures to attain the objectives of Regulation 882/2004 of the European Parliament and the Council of the European Union.

Art. 28b. (new - SG 31/06, in force from 14.04.2006) (1) The competent bodies shall carry out activities for education of the officials who will implement the official control of the foods, by organizing;

1. education in the field of their competences, which shall allow them to competently implement their obligations and carry out coordinated official inspections;
 2. additional education concerning current questions in the field of their competence.
- (2) The competent bodies shall provide conditions for cooperation in all fields of the food control.

Art. 29. (amend., SG 102/03; revoked – SG 8/11, in force from 25.01.2011)

Art. 29a. (new, SG 102/03; revoked – SG 8/11, in force from 25.01.2011)

Art. 29b. (new - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 29c. (new - SG 31/06, in force from 14.04.2006) (1) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 8/11, in force from 25.01.2011) The official control of foodstuffs shall be carried out using appropriate methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

(2) (amend. - SG 8/11, in force from 25.01.2011) The official control of foods shall be carried out according to procedures in conformity with the requirements of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

(3) (revoked – SG 8/11, in force from 25.01.2011)

(4) (revoked – SG 8/11, in force from 25.01.2011)

Art. 29d. (new - SG 31/06, in force from 14.04.2006) The competent body within a 14-day period from the date of finishing the inspection shall provide to the respective producer or trader of foodstuffs a copy of the report of the implemented inspection.

Art. 29e. (new - SG 31/06, in force from 14.04.2006) The competent body shall provide objectivity, quality and coordination of the official inspections.

Art. 29f. (new - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 29g. (new - SG 31/06, in force from 14.04.2006) (1) For the effective implementation of the official control of foodstuffs, a Single multi-annual national control plan shall be prepared.

(2) (in force from 01.01.2007) One year after the implementation of the multi-annual national control plan, and subsequently every year, a report for its implementation shall be submitted to the European Commission.

(3) (amend. - SG 8/11, in force from 25.01.2011) The plan under para 1 and the report mentioned in para 2 shall be drawn up according to COMMISSION DECISION No 2007/363/EEA of

21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council and Commission Decision of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council.

(4) (in force from 01.01.2007) The plan referred to in para 1 may be adjusted during its implementation on the basis of:

1. new legislation;
2. the emergence of new diseases or health risks;
3. changes to the structure, management or operation of the competent bodies;
4. results of official checks;
5. scientific findings;
6. amendments of the guidelines of the European Commission for the preparation of the plans.

(5) (in force from 01.01.2007) The preparation and the adoption of the report and its submission the European Commission shall be carried out within six months after the expiration of the year it refers to.

Art. 30. (amend. - SG 31/06, in force from 14.04.2006) (1) The competent bodies shall have the right:

1. to free access to all establishments for production and trade of foodstuffs as well as to the transporting vehicles;
2. to require information and documents related to the production and trade of foodstuffs and to receive copies of them;
3. to take samples and specimens for laboratory analyses and tests;
4. to indicate in written the particular nonconformities with the normative requirements established by them without giving instructions for the way of their elimination;
5. to propose to the State approval commission for entering in exploitation of the constructions in the Republic in Bulgaria a decision for refusal for approval of establishments for production and trade with foodstuffs in case of established fundamental violations of the norms and the requirements determined by a normative act;
6. to stop the operation of the establishments for production and trade with foodstuffs;
7. to carry monitoring;
8. to stop the realisation of foodstuffs which directly or indirectly threaten the health of people and to order their returning, deprivation, destruction, reprocessing or using for other purposes;
9. to issue acts for established administrative offences;
10. to restrict the access to the establishments under prohibition through certifying signs;
11. to restrict or prohibit placing on the market the foodstuffs;
12. to undertake the necessary actions ensuring the food safety and compliance with the normative requirements;
13. to undertake any other actions necessary for implementation of their competences.

(2) The competent bodies shall carry out the activities of control according to the principle of transparency as for that purpose they shall duly provide to the society the necessary information for their control activities.

(3) In fulfilment of their duties the competent bodies shall be obliged to keep secret the facts and circumstances they learn, which are of confidential nature or represent a secret as to protect the interests of the individuals and corporate bodies.

Art. 30a. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) In the cases the control bodies upon official control have established non-compliance with the normative requirements, some of the actions are referred to in Art. 30, para 1 shall be undertaken so as the producer or the trader of foodstuffs to implement correctional actions for elimination of that in compliance and the reasons for its existence.

(2) Upon implementation of the actions referred to in para 1 the competent bodies shall take into consideration the essence of the non-compliance and the documentation kept by the producer or the trader.

(3) The competent bodies shall undertake the necessary measures for prohibition of the sale of foodstuffs or shall order their withdrawal from the market when, despite of its compliance with the specific requirements for safety, there are grounded reasons to believe that the food is dangerous.

Art. 30b. (new, SG 102/03) (1) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall maintain a system of fast notification in cases of a danger for the human health ensuing from a foodstuff let on the market.

(2) (new - SG 8/11, in force from 25.01.2011) The Ministry of Health Care and the BFSa shall be competent contact points of the system of fast notification under para 1.

(3) (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; prev. text of para 2 – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Ministry of Agriculture, Foods and Forestry shall be responsible for the coordination of the activity of the system for fast notification referred to in para 1.

(5) (prev. text of para 03 - SG 31/06, in force from 14.04.2006; amend. – SG 8/11, in force from 25.01.2011) On receiving information for the existence of a serious danger for the human health ensuing from a foodstuff let on the market the bodies under Art. 28 shall be obliged to take immediate actions of notification through the system of fast notification.

(5) (prev. text of para 04 - SG 31/06, in force from 14.04.2006; amend. – SG 8/11, in force from 25.01.2011) The bodies under Art. 28 shall submit to the consumers information regarding the existence and the nature of the danger, the data for identification of the food and the taken measures.

(6) (new - SG 31/06, in force from 14.04.2006) the officials who have access to the system for fast notification shall be obliged not to divulge the information, constituting secret protected by the law, learned by them upon or on occasion of implementation of their activity. This requirement shall not be applied regarding the information which shall be provided to the society for protection of the human health.

(7) (new - SG 31/06, in force from 14.04.2006) the protection of the information referred to in para 6 shall not impede the competent bodies to spread the necessary information connected with the implementation of the official control of foodstuffs.

(8) (new - SG 31/06, in force from 14.04.2006) For observance of the requirements for confidentiality referred to in para 6 the officials shall sign a declaration for not spreading information, constituting secret protected by the law.

(9) (new – SG 77/12, in force from 09.10.2012) The Council of Ministers shall determine in an ordinance the conditions and order for development of the fast notification system referred to in Para 1.

Art. 31. (amend., SG 102/03) (1) The persons who manufacture and trade foodstuffs shall be obliged:

1. (amend. - SG 31/06, in force from 14.04.2006) to fulfill the prescriptions of the competent bodies;

2. (amend. - SG 31/06, in force from 14.04.2006) not to obstruct the competent bodies in exercising their legal capacities under this Act;

3. to keep documentation according to the requirements of this Act.

(2) The persons who manufacture and trade foodstuffs shall have the right:

1. to appeal acts of the bodies under this Act;

2. within three working days from receipt of the notification for the result from the analysis of the taken samples of foodstuffs and the conclusions of the control bodies to request a control expertise.

Art. 32. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) (1) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, respectively the Minister of Health Care – regarding bottled natural mineral, spring and table waters, by an order shall designate laboratories that may carry out the analysis of samples of foodstuffs taken during official controls.

(2) The laboratories referred to in para 1 shall be accredited and operate in compliance with BDS EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories".

(3) The accreditation of testing laboratories may relate to individual tests or groups of tests.

(4) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, respectively the Minister of Health Care – regarding bottled natural mineral, spring and table waters, shall determine national reference laboratories for testing of foodstuffs.

(5) (in force from 01.01.2007) The laboratories referred to in para 4 shall:

1. collaborate with the European Community reference laboratory in their area of competence;

2. coordinate the activity of the laboratories referred to in para 1;

3. organise comparative tests between the laboratories referred to in para 1 and ensure appropriate follow-up on the basis of the analysis and assessment of the results of the implemented comparative tests;

4. ensure the dissemination to the competent bodies and laboratories referred to in para 1 of information that the European Community reference laboratory supplies;

5. provide scientific and technical assistance to the competent bodies.

(6) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, suppl. – SG 58/17, in force from 18.07.2017, suppl. - SG 77/18, in force from 01.01.2019) The Minister of Health or an official appointed from the staff of the ministry, respectively the Minister of Agriculture, Foods and Forestry or an official appointed from the staff of the ministry, shall close by an order the designated according to the order of para 1 laboratories which do not comply with the requirements of para 2.

(7) (suppl. - SG 77/18, in force from 01.01.2019) The order referred to in para 6 shall be appealed before the relevant administrative court according to the order of the Act on the Supreme Administrative Court.

Art. 32a. (new - SG 31/06, in force from 01.01.2007) (1) The competent bodies may delegate the implementation of certain activities, connected with the official control, to control bodies according to the conditions and the order laid down by Regulation 882/2004.

(2) (revoked – SG 8/11, in force from 25.01.2011)

(3) The competent bodies shall deprive a control body referred to in para 1 of its competences, connected with the delegated activities of official control in compliance with the conditions and the order of Regulation 882/2004.

(4) In case of delegation of certain activities connected with the official control, the competent bodies shall notify in written the European Commission; the notification shall indicate the delegating competent body, the activities it delegates, as well as the control body delegated to implement the specific activities.

Art. 33. (amend. - SG 31/06, in force from 14.04.2006) (1) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, amend. – SG 58/17, in force from 18.07.2017) The conditions and the order of sampling of foodstuffs and the requirements to the analysis methods, used for the purpose of the official control, shall be determined by an ordinance of the Minister of Health in coordination with the Minister of Agriculture, Foods and Forestry.

(2) Upon lack of normative requirements for sampling and analysis methods, the internationally recognised and national rules and methods, laid by standards, shall applied. In such cases other methods, corresponding to the objectives and developed in accordance with scientific protocols, shall be also used.

(3) Where para 2 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

(4) The analysis methods shall be characterized by the following criteria:

1. accuracy;
2. applicability (matrix and concentration range);
3. limit of detection;
4. limit of determination;
5. precision;
6. repeatability;
7. reproducibility;
8. recovery;
9. selectivity;
10. sensitivity;
11. linearity;
12. measurement uncertainty;
13. other criteria that may be selected as required.

(5) The compliance of a certain method with the requirements referred to in para 2 shall be determined by collaborative laboratory tests.

(6) In case of difference in the interpretation of the results of laboratory tests of foodstuff samples, where different analysis methods were applied, valid shall be the results, obtained using the methods compliant with the criteria referred to in para 4.

Art. 34. (amend. - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 35. (amend. - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 36. (revoked – SG 8/11, in force from 25.01.2011)

Art. 36a. (new - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 36b. (new - SG 31/06, in force from 14.04.2006) (1) The competent bodies shall cooperate with the respective control bodies of other European Union member states according to the order of Regulation 882/2004.

(2) The competent bodies of other member states may carry out official control of establishments for production and trade with foodstuffs on the territory of the Republic of Bulgaria.

Art. 36c. (new - SG 31/06, in force from 14.04.2006) (1) (amend. – SG 8/11, in force from 25.01.2011) Fees shall be collected for issuing of certificates under this Act and implementation of official control of foodstuffs in accordance with the Tariff of the Fees under the Bulgarian Food Safety Agency Act and with the Health Act – regarding bottled natural mineral, spring and table waters.

(2) (in force from 01.01.2007) The amounts of the fees referred to in para 1 shall be determined by tariffs, approved by the Council of Ministers in accordance to the factors, indicated in Regulation 882/2004.

Art. 37. (amend., SG 102/03) (1) (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) In case of immediate and great danger for the public health by consumption of definite foodstuffs the Minister of Agriculture, Foods and Forestry and/or the Minister of Health Care shall determine by an order the necessary measures for removal of the danger.

(2) The measures under para 1 shall be:

1. prohibition of letting on the market or order for termination of the letting on the market of the foodstuff;

2. prohibition of using the foodstuff;

3. determining special conditions for letting the foodstuff on the market;

4. other appropriate measures depending on the situation.

(3) The orders under para 1 shall be promulgated in the State Gazette.

Chapter six "a".

PROFESSIONAL ORGANISATIONS OF THE PRODUCERS OF FOODSTUFFS (new, SG 102/03)

Art. 37a. (new, SG 102/03) (1) Professional organizations of the producers of foodstuffs are the branch organizations of the producers of foodstuffs registered under the conditions and by the order of the Non-Profit Legal Entities Act.

(2) The branch organizations of the producers of foodstuffs shall have the right to:

1. (amend. - SG 31/06, in force from 14.04.2006) work out in their branches guides for the good production practices, guides for implementation of the system of hazard analysis and critical control points in the production of foodstuffs, as well as other professional requirements for the purpose of providing the quality and safety of the foodstuffs;

2. participate in the working out of strategies, analyses, programmes and statements for the development of the respective branch and contribute to their fulfillment;

3. create and maintain database for experts in the respective branch for rendering assistance to

the producers of foodstuffs, as well as to the state bodies;

4. work out ethic codes stipulating the professional ethics in the sub-branches of the food industry and non-admission of disloyal competition between the producers of foodstuffs;

5. inform the competent bodies about violations in the production and/or trade of foodstuffs;

6. participate in the working out of normative acts for the respective branch or give opinion on drafts of such acts;

7. organize the holding of competitions for improvement of the qualification of the persons occupied in the production of foodstuffs;

8. (amend. - SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) work out branch standards for the groups of foodstuffs and present them to the Ministry of Agriculture, Foods and Forestry and the Ministry of Health Care for information;

9. (new - SG 31/06, in force from 14.04.2006) provide information concerning development of positions for participation in the meetings of the operating units of the European Commission and the operating units and committees of the Council of the European Union.

Art. 37b. (new, SG 102/03) The Bulgarian Association of food processing and beverage industry (BAFPBI) is a national inter-professional organization of the producers of foodstuffs having the right to:

1. participate in the working out of strategies and programmes for development of the production and trade of foodstuffs;

2. (amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, amend. – SG 58/17, in force from 18.07.2017) assist the Ministry of Agriculture, Foods and Forestry and the Ministry of Health in working out reports for the state of the production and processing of foodstuffs;

3. (amend. - SG 31/06, in force from 14.04.2006) participate in the working out and give opinion on draft normative acts concerning food safety;

4. carry out coordination of the activity of the branch organizations and producers of foodstuffs, including those which are not its members, with regard of their rights under this Act.

Art. 37c. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) The branch organizations of the producers of foodstuffs shall assist the work of the state bodies and of the bodies of the local independent government and local administration in implementing the policy and strategy for development of the foodstuff industry.

Art. 37d. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006) The regional governors and the municipal councils shall submit to the BAFPBI and to the branch organizations of the producers of foodstuffs premises – state or municipal property, necessary for carrying out their activity by the order of the State Property Act, respectively of the Municipal Property Act.

Art. 37e. (new, SG 102/03) (1) (amend. - SG 31/06, in force from 14.04.2006) The state bodies and administrative bodies, as well as the bodies of the local independent government and local administration shall render assistance and shall submit information to the BAFPBI for exercising its functions stipulated by this Act.

(2) (amend. - SG 31/06, in force from 14.04.2006) In working out draft normative acts related to the administrative regulation and the administrative control of the foodstuff industry the competent state bodies shall require statements from the respective branch organizations. In the event that, within 7

working days from receipt of the request, a statement is not presented, it shall be considered that the organization has no remarks on the draft.

Chapter six "b".

NATIONAL CONSULTATIVE COUNCIL FOR A BETTER FUNCTIONING OF THE FOOD CHAIN SUPPLY. DISPUTE RESOLUTION COMMISSION (new - SG 56/15)

Art. 37f. (new - SG 56/15) (1) (amend. – SG 58/17, in force from 18.07.2017) At the Minister of Agriculture, Foods and Forestry shall be created a National Consultative Council for a Better Functioning of the Food Chain Supply (National Council).

(2) (amend. – SG 58/17, in force from 18.07.2017) The composition of the National Council shall include representatives of the Ministry of Agriculture, Foods and Forestry, the Ministry of Economy, the Executive Agency of Promotion of Small and Medium-Sized Enterprises, the professional organisations of food producers and the branch organisation of the food traders.

(3) (amend. – SG 58/17, in force from 18.07.2017) The chairman of the National Council shall be the Minister of Agriculture, Foods and Forestry.

(4) The National Council shall promote the negotiation of agreements between associations of food producers and traders, issue opinions, advice and recommendations in relation to problems in the chain of food supply and in relation to normative acts, including their implementation, etc.

(5) The National Council shall be summoned by its chairman or at the request of one third of the Council members, who shall propose an agenda.

(6) The National Council may be supported by commissions and working groups.

(7) The members of the National Council shall not receive remuneration for its work therein.

(8) (amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall issue regulations on the organisation and operation of the National Council.

Art. 37g. (new - SG 56/15) (1) (amend. – SG 58/17, in force from 18.07.2017) At the Minister of Agriculture, Foods and Forestry shall be established a mediation commission, which shall assist in the out-of-court dispute resolution between food producers and traders, including in the compliance with the good practices and non-implementation of unfair commercial practices.

(2) (amend. – SG 58/17, in force from 18.07.2017) The mediation commission shall carry out its activities in accordance with regulations, issued by the Minister of Agriculture, Foods and Forestry.

(3) The proceedings before the mediation commission shall be free.

Art. 37h. (new - SG 56/15) (1) (amend. – SG 58/17, in force from 18.07.2017) The mediation commission shall be composed of a chairman appointed in an order of the Minister of Agriculture, Foods and Forestry, and members - persons proposed by the professional organisations of food producers and the branch organisations of the food traders represented in the National Council. The list of the proposed members shall be approved by the Minister of Agriculture, Foods and Forestry.

(2) As a chairman of the mediation commission shall be elected a person with a higher degree in law and legal practice of at least 10 years.

(3) The members of the mediation commission shall be specialists in a branch related to the chain of food supply and shall possess higher degree in law or economics.

(4) The mediation commission shall carry out mediation proceedings in a panel of three, including the chairman and two members, which shall be chosen from the list referred to in Para 1 by each one of the parties.

(5) The mediation proceedings may be conducted by the chairman only or by one of the members of the mediation commission, where the parties have agreed thereto in writing.

(6) In the mediation proceedings shall not participate a commission member:

1. who is a spouse or in concubinage, or a relative of direct, indirect lineage up to fourth degree

or in law up to third degree with any of the parties in the dispute;

2. who has been a representative or attorney of the opposed parties;

3. who has been in employment or civil relationship with any of the opposed parties during the last three years;

4. of whom exist other circumstances giving rise to reasonable doubt about his impartiality.

(7) The chairman or a member of the commission shall recuse themselves in case of any of the circumstances referred to in Para 6.

(8) The chairman and the commission members shall sign a declaration on the lack of the circumstances referred to in Para 6 in each procedure they are involved in and shall present it to the opposed parties.

(9) Each of the parties in the dispute shall have the right to request recuse of the chairman or a member of the commission in the cases referred to in Para 6.

(10) The chairman and the commission members shall not be allowed to disclose information they have learned in relation to performance of their duties.

Art. 37i. (new - SG 56/15) (1) The mediation proceedings shall be initiated pursuant to a written appeal by a food producer or trader in the sense of this Law.

(2) The appeal shall describe the facts and circumstances relevant for the dispute, the claims and the chosen member of the mediation commission from the list under Art. 37h, Para 1. Enclosed with the appeal shall be all documents required to clarify the subject of the dispute.

(3) Examination shall be refused for anonymous appeals, appeals related to a dispute, which has been examined in finalised mediation proceedings before a mediation commission or where the dispute has been referred for resolution to a judicial body.

(4) Finalised mediation proceedings may be resumed in case of new facts and circumstances and the dispute was not referred for resolution to a judicial body or the case is about the performance of an agreement achieved between the parties in the dispute.

(5) If the appeal is incomplete or unclear or lacks sufficient document support, the mediation commission shall leave it without motion, inform the applicant and provide a 14-day period to remedy the deficiencies.

(6) The appeal shall be sent to the affected persons, which shall provide an opinion and evidence within 14 days.

(7) Within one month from opening the mediation proceedings the chairman of the commission shall specify a date, time and place to conduct the hearing and send an invitation for participation to the parties in the dispute.

Art. 37j. (new - SG 56/15) (1) The mediation commission shall examine the dispute in an open hearing and may request from the parties additional documents, information or evidence, where necessary.

(2) The mediation commission may appoint an expert witness to clarify the dispute.

Art. 37k. (new - SG 56/15) (1) The mediation proceedings shall end by executing a written agreement between the parties. The agreement shall be drawn up by the commission within three months from opening the mediation proceedings and shall be made available to the parties in the dispute.

(2) The parties in the dispute shall sign the agreement within 10 days from making it available to them.

(3) In case that within the term under Para 1 the mediation commission has not made available a written agreement or the agreement was not accepted by the parties in the dispute, the proceedings shall be terminated.

Chapter six "c".

FOOD BANKING. PERMIT FOR A FOOD BANK OPERATOR (NEW - SG 88/16, IN FORCE

FROM 01.01.2017)

Art. 37l. (New - SG 88/16 , in force from 01.01.2017) (1) Food banking under this Act may be performed only by entities authorized to become food bank operators.

(2) Permits for food bank operators shall be issued by the Executive Director of the Bulgarian Food Safety Agency.

(3) Food banking activities shall include:

1. donations of food from manufacturers and food traders;
2. storage, safe-keeping and/or cutting and packaging of donated food;
3. giving the donated food to needy persons in compliance with the requirements of control and food safety under this Act.

(4) (amend. – SG 58/17, in force from 18.07.2017) The list of foods subject to food banking shall be approved with an order by the Minister of Agriculture, Foods and Forestry, after consultation with the Minister of Finance, upon a reasoned proposal from the Executive Director of the Bulgarian Food Safety Agency. The order and the list shall be published on the websites of the Ministry of Agriculture, Foods and Forestry and the Bulgarian Food Safety Agency.

(5) The list under par. 4 shall contain information about the dates, from which and by which food may be donated, before the expiry date or shelf life date of the respective food item.

(6) Food bank operators, authorized under this Act, shall provide and supervise compliance with the statutory requirements towards the food donated to them.

(7) The Bulgarian Food Safety Agency shall perform control over food bank operators with respect to the safety of the foods received and donated.

(8) The Minister of Labour and Social Policy shall approve with an order a list of the groups of needy persons and of persons providing social services, to whom the food bank operators can provide donated food. The order and the list shall be published on the website of the Ministry of Labour and Social Policy.

(9) Foods which are donated to the food bank operator must be marked by manufacturers or traders of foods with "donation, not for sale". The marking shall be placed on the consumer packaging of the food in a way that prevents its removal without damaging the integrity of the packaging and without concealing any part of the information contained on the label. For donated foods which are not packaged in consumer packaging, the marking shall be placed on the transport packaging.

Art. 37m. (New - SG 88/16 , in force from 01.01.2017) The permit for a food bank operator may be issued to an entity who meets all the following conditions:

1. is a legal non-profit entity established for the public benefit and registered in the Central Register at the Ministry of Justice under Art. 45, para. 1 of The Non-Profit Legal Entities Act;
2. has no enforceable public debts;
3. has own or rented locations and/or spaces in facilities for carrying out the activities related to food banking, which meet the hygiene and/or veterinary and health requirements, laid down by a normative act and registered pursuant to Art. 12;
4. the sites under item 3 are located on the territory of not less than 20 per cent of the districts in the country;
5. has own and/or leased vehicles when necessary to carry out activities in food banking, which meet the requirements for transportation of food in Annex II, Chapter IV of Regulation (EC) № 852/2004, or which are registered according to Art. 245 of the Veterinary Practices Act;
6. has own network or a network of partner organizations for donating food;
7. uses a reporting system which allows the authorities of the Bulgarian Food Safety Agency and the revenue authorities of the National Revenue Agency to inspect the donated, stored and provided foods, including by donors identified by a unique identification code under BULSTAT.

Art. 37n. (New - SG 88/16 , in force from 01.01.2017) (1) For the issuance of a permit for a

food bank operator, a written application shall be submitted to the Executive Director of the Bulgarian Food Safety Agency.

(2) The application under par. 1 shall contain the data of Art. 12, para. 4, as well as information about the type of foods to be received, stored and delivered.

(3) To the application under par. 1 shall be added the following documents:

1. (revoked - SG 63/17, in force from 01.01.2018)
2. proof of ownership or lease contract of the premises and/or spaces under Art. 37m, item 3, and a copy of the certificate of registration of an object according to Art. 12;
3. user manual for the accounting system used;
4. plan for the performance of the activity, containing information on:
 - a) activities in food banking, which will be carried out;
 - b) the annual projected volume of received and donated foods;
 - c) the maximum storage capacity for storing the donated foods - by type of food;
 - d) the manner of destruction of the non-donated foods within the expiry date or shelf life;
5. financial statement for the sources of funding and providing the necessary resources to perform the activities of food banking, including the destruction of donated foods, which have not been provided free of charge by the food bank to needy persons;
6. a declaration that the entity is not in termination proceedings under the Non-profit legal entities Act.

(4) (new - SG 63/17, in force from 01.01.2018, amend. - SG 92/17, in force from 01.01.2018)

The Executive Director of the Bulgarian Food Safety Agency shall request ex officio information about presence or absence of obligations under the Art. 87, Para. 11 of the Tax-insurance Procedure Code for respective candidate.

Art. 37o. (New - SG 88/16, in force from 01.01.2017) (1) The application of Art. 37n, para. 1 shall be viewed by officials authorized by the Executive Director of the Bulgarian Food Safety Agency.

(2) Should irregularity be found in the application of Art. 37n, para. 1, the person shall be informed with a message indicating to remedy the deficiencies within 14 days from receipt of the message.

(3) When irregularities are not rectified within the deadline under par. 2, the application shall be returned to the person and the proceedings shall be terminated by a decision of the Executive Director of the Bulgarian Food Safety Agency.

(4) Within 30 days of receipt of the application, respectively of removal of irregularities in it, the Executive Director of the Bulgarian Food Safety Agency shall issue the permit or a reasoned refusal to issue it.

(5) Failing to rule within the deadline shall be considered as a silent refusal.

(6) Decisions under par. 3 and 4 may be appealed under the Administrative Procedure Code.

(7) In case of refusal, the applicant may submit a new application for permit issuance no earlier than 90 days from the decision of refusal, respectively from the entry into force of the court decision, with which the appeal is dismissed as unfounded.

Art. 37p. (New - SG 88/16, in force from 01.01.2017) The Executive Director of the Bulgarian Food Safety Agency shall refuse to issue a permit when:

1. the applicant has provided false information or false documents that are relevant for the authorization;
2. the applicant is not eligible for authorization.

Art. 37q. (New - SG 88/16, in force from 01.01.2017) (1) The permit for a food bank operator shall be issued for a period of 5 years.

(2) The permit under par. 1 shall include:

1. name of the authority issuing it;
2. name and registration number of the act;

3. legal and factual grounds for issuing the act;
4. name, headquarters, management address and unified identification code of the entity;
5. term of validity of the permit;
6. facilities where the activity shall be carried out;
7. date of entry into force of the permit.

Art. 37r. (New - SG 88/16, in force from 01.01.2017) The entity authorized to operate a food bank shall be obliged to notify the Executive Director of the Bulgarian Food Safety Agency of any changes in circumstances, under which the permit has been issued, within 14 days of their occurrence, by presenting the necessary documents.

Art. 37s. (New - SG 88/16, in force from 01.01.2017) (1) In the Bulgarian Food Safety Agency shall be kept a register of issued permits for operators of food banks. The Executive Director of the Bulgarian Food Safety Agency shall determine by order the persons to manage and update the register of permits issued for food banks operators.

(2) The register under par. 1 shall be public.

(3) The register under par. 1 shall be kept by creating a computer database and records for the entities and including the circumstances subject to entry.

(4) The circumstances subject to entry shall only be the ones provided for in Art. 37t, para. 1 and the subsequent changes thereto.

(5) Entries in the registry shall be made on the basis of decisions by the Executive Director of the Bulgarian Food Safety Agency.

(6) The entry of the circumstances of the person concerned shall be done based on the data contained in the documents submitted to the Executive Director of the Bulgarian Food Safety Agency, or collected by him ex officio.

(7) For each person subject to entry in the register, an electronic file shall be created in the computerized database, with a unique code, in which the prescribed entries are made.

(8) For each person subject to entry in the register, a file shall be opened for each separate permit, in which all the relevant documents are ordered, as well as the acts of the Executive Director of the Bulgarian Food Safety Agency.

(9) The information subject to entry in the register shall be updated within 14 days after receipt of the notification under Art. 37r.

Art. 37t. (New - SG 88/16, in force from 01.01.2017) (1) In the register under Art. 37s, para. 1 shall be entered:

1. the name of the non-profit legal entity established for the public benefit;
2. unified identification code under BULSTAT;
3. the date of receipt of the application for permit;
4. the date and number of the decision, based on which the permit is issued;
5. the date and number of the decision, with which the Executive Director of the Bulgarian Food Safety Agency amends or supplements the permit issued;
6. the address and the kind of facilities the activity will be carried out;
7. the imposed proprietary sanctions and enforcement measures.

(2) The Executive Director of the Bulgarian Food Safety Agency shall provide free and unlimited electronic access to the register through the website of the Bulgarian Agency Food Safety.

Art. 37u. (New - SG 88/16, in force from 01.01.2017) (1) The validity of the permit for a food bank operator shall be extended for a further period of 5 years, if the person has made a written request for this at least 6 months before the expiry of the permit and meets the requirements of Art. 37m.

(2) In the proceedings for an extension of the permit shall be applicable respectively the procedure and the deadlines for submitting and processing of applications for issuing a permit.

Art. 37v. (New - SG 88/16, in force from 01.01.2017) (1) The validity of an issued permit for a food bank operator shall be terminated by a decision of the Executive Director of the Bulgarian Food

Safety Agency in the following cases:

1. upon expiry of the permit's validity;
2. at the request of the food bank operator, including upon transfer of the property, with which the activity of food banking is executed;
3. in systematic obstruction of the activities of the control authorities;
4. if the food bank operator fails to start to operate within 12 months of the entry into force of the permit;
5. where the food bank operator no longer meets the conditions, under which the permit was issued;
6. when the operator of the Food Bank is imposed a proprietary sanction with as effective penal decree for repeated violations of the provisions of this Act and/or of the Value Added Tax Act;
7. upon termination of the legal non-profit entity.

(2) The proceedings of termination of validity of a permit shall begin upon a reasoned decision of the competent authority or by a written request of the food bank operator.

(3) The food bank operator shall submit a request for termination of validity of the permit which shall contain:

1. the name, head office, management address and identification code under BULSTAT of the applicant;
2. the registration number of the permit;
3. motivation for the requested termination.

(4) The request shall be accompanied by documents proving the grounds for termination.

(5) Where the Executive Director of the Bulgarian Food Safety Agency begins proceedings of termination of validity of an issued permit, the food bank operator shall be sent a written notice which shall explicitly state the grounds for termination. The food bank operator may submit a written statement on the grounds for termination of validity of the permit within 14 days.

(6) The decision to terminate the validity of the permit may be appealed under the Administrative Procedure Code.

(7) Whoever has their permit for a food bank operator terminated upon decision of the competent authority, shall not be able to apply for a new permit for the same activity for a period of two years.

Chapter seven. ADMINISTRATIVE PENAL PROVISIONS

Art. 38. (1) (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 59/10) Who produces and sells a novel foodstuff or novel food ingredient, genetically modified foodstuff, GMO for use in or as food or food, containing ingredients, produced from GMO in violation of this Act, unless subject to a more severe penalty shall be fined with 25 000 levs to 35 000 levs and for repeated commitment of the same offence - with 35 000 levs to 70 000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006; amend. – SG 59/10) For violation under para 1 committed by a corporate body or sole entrepreneur proprietary sanction amounting to 50 000 levs to 70 000 levs shall be imposed and for repeated offence - from 70 000 levs to 110 000 levs.

Art. 38a. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 38b. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 38c. (new - SG 31/06, in force from 14.04.2006; revoked – SG 8/11, in force from 25.01.2011)

Art. 38d. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 38e. (new - SG 31/06, in force from 14.04.2006; revoked – SG 96/06, in force from 01.01.2007)

Art. 39. (1) (amend. - SG 31/06, in force from 14.04.2006) Who uses additives, flavorings and solvents which are not permitted in the production of foodstuffs or which are in quantities larger than the determined, unless subject to a more severe penalty, shall be fined with 250 levs to 500 levs and for repeated commitment of the same offence - with 500 levs to 1000 levs.

(2) For violation under para 1 committed by a corporate body or sole entrepreneur proprietary sanction shall be imposed in amount from 500 levs to 1000 levs and for repeated offence - from 1000 levs to 3000 levs.

Art. 39a. (new - SG 31/06, in force from 14.04.2006) (1) Who places on the market or uses unauthorized primary smoke condensates and primary tar fractions in or on foodstuffs or in the production of derived smoke flavorings, unless subject to a more severe penalty, shall be fined with 15 000 to 35 000 levs and for repeated commitment of the same violation – with 35 000 to 70 000 levs.

(2) Where the violation referred to in para 1 was committed by a legal person or a sole entrepreneur, propriety sanction amounting from 2 000 to 5 000 levs shall be imposed and for repeated violation – from 70 000 to 110 000 levs.

Art. 40. (1) Who uses materials and objects for contact with foodstuffs which are not permitted for this purpose, unless subject to a more severe penalty shall be fined with 250 levs to 500 levs and for repeated commitment of the same offence - from 500 levs to 1000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) Who packs foodstuffs in packings which transfer to the food their own components in quantities posing danger to the human health, leading to unacceptable changes in the composition of the food or to deterioration of its organoleptic characteristics, unless subject to a more severe penalty, shall be fined with 250 levs to 500 levs and for repeated commitment of the same offence - 500 levs to 1000 levs.

(3) For violation under para 1 and 2 committed by an individual or sole entrepreneur proprietary sanction from 500 levs to 1000 levs shall be imposed and for repeated offence - from 1000 levs to 3000 levs.

Art. 40a. (new - SG 31/06, in force from 14.04.2006) (1) Who places on the market or uses unauthorized substances for use in production of food contact materials or articles, unless subject to a

more severe penalty, shall be fined with 1 000 to 3 000 levs, and for repeated violation – from 3 000 to 5 000 levs.

(2) Who places on the market food contact materials and articles unaccompanied by statement for compliance with the applicable requirements shall be fined with 3 000 to 5 000 levs and for repeated violation – with 5 000 to 10 000 levs.

(3) For violation referred to in para 1 and 2 committed by a legal person or a sole entrepreneur, proprietary sanction amounting from 5 000 to 10 000 levs shall be imposed and for repeated violation – proprietary sanction from 10 000 to 20 000 levs.

Art. 41. (1) (suppl., SG 102/03) Who violates the provisions and the requirements related to the presentation, the labelling and the advertising of the foodstuffs, unless subject to a more severe penalty, shall be fined with 250 levs to 500 levs and for repeated commitment of the same offence - with 500 levs to 1000 levs.

(2) For violation under para 1 committed by a corporate body or sole entrepreneur shall be imposed proprietary sanction amounting from 500 levs to 1000 levs and for repeated offence - from 1000 levs to 3000 levs.

Art. 42. (1) (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006) Who produces or trades foodstuffs in establishments not registered according to this Act, unless subject to a more severe penalty, shall be fined with 1 500 levs to 2 000 levs and for repeated commitment of the same offence - with 2 000 levs to 4 500 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) For violation under para 1 committed by a corporate body or sole entrepreneur shall be imposed proprietary sanction from 2 000 levs to 4 500 levs and for repeated offence - from 4 500 levs to 6 000 levs.

Art. 43. (1) (amend. - SG 31/06, in force from 14.04.2006) Who produces and sells foodstuffs in violation of Art. 17, para 1 and Art. 18, para 1 of this Act, unless subject to a more severe penalty shall be fined with 2 000 levs to 3 000 levs and for repeated offence - with 3 000 levs to 7 000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) For violation under para 1 committed by a corporate body or sole entrepreneur shall be imposed proprietary sanction of 3 000 levs to 5 000 levs and for repeated offence - from 5 000 levs to 7 000 levs.

Art. 44. (1) (amend. - SG 31/06, in force from 14.04.2006; amend. – SG 51/07, in force from 26.06.2007) Who produces, trades or imports in the country foodstuffs which do not meet the requirements of this Act or of the by-laws for its implementation, unless subject to a more severe penalty, shall be fined with 1 000 levs to 2 000 levs and for repeated offence - with 2 000 levs to 4 000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) For violation under para 1 committed by corporate body or sole entrepreneur shall be imposed proprietary sanction of 2 000 levs to 4 000 levs and for repeated offence - from 4 000 levs to 6 000 levs.

Art. 44a. (new – SG 23/10) (1) Whoever produces and supplies small amounts of raw materials and foodstuffs of animal origin in violation of the requirements of the ordinance under Art. 21b, shall be punished by a fine amounting from BGN 200 to 2000, and in case of repeated offence 0 by a fine

amounting from BGN 500 to 5000.

(2) If a violation under para 1 has been committed by a legal person or a sole trader, shall be punished by a proprietary sanction amounting from BGN 500 to 5000, and in case of repeated offence – from BGN 700 to 7000.

Art. 45. (amend. - SG 31/06, in force from 14.04.2006) Who works or admits to work a person occupied in the production and trade of foodstuffs in violation of Art. 23, para 1 shall be fined with 500 levs to 1 000 levs and for repeated commitment - with 1 000 levs to 2 500 levs.

Art. 45a. (new, SG 102/03) (1) Who carries out treatment of foodstuffs by ionizing radiation in violation of art. 22b or art. 22c shall be punished by a fine of 1000 to 3000 levs.

(2) Where the violation under para 1 is committed by a corporate body or sole entrepreneur a proprietary sanction of 2000 to 5000 levs shall be imposed.

(3) For repeated violation under para 1 a fine of 2000 to 5000 levs shall be imposed, and to corporate bodies and sole entrepreneur – a proprietary sanction of 3000 to 10 000 levs.

Art. 45b. (new, SG 102/03 – in force from January 1, 2005) (1) Who produces foodstuffs in violation of art. 23, para 2 shall be punished by a fine of 500 to 1500 levs.

(2) Where the violation under para 1 is committed by a corporate body or sole entrepreneur a proprietary sanction of 1000 to 3000 levs shall be imposed.

(3) For repeated violation under para 1 a fine of 1000 to 3000 levs shall be imposed, and to corporate bodies and sole entrepreneur – a proprietary sanction of 2000 to 10 000 levs.

Art. 46. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 8/11, in force from 25.01.2011) Who refuses or prevents the exercising of official control in the establishments for production and trade of foodstuffs or the taking of samples by the competent bodies, unless subject to a more severe penalty, shall be fined with 500 levs to 1000 levs and for repeated offence - with 1000 levs to 1500 levs.

Art. 47. (1) (amend. - SG 31/06, in force from 14.04.2006) Who does not fulfil a prescription of the competent bodies under this Act, unless subject to a more severe penalty shall be fined with 250 levs to 500 levs and for repeated offence - with 500 levs to 1500 levs.

(2) For violation under para 1 committed by a corporate body or sole entrepreneur shall be imposed proprietary sanction from 500 levs to 1500 levs and for repeated violation - from 1500 levs to 3000 levs.

Art. 48. (1) (amend. - SG 31/06, in force from 14.04.2006) Who violates the provisions of this Act or the ordinances for its implementation, other than the cases under Art. 38 - 47, shall be fined with 500 levs to 1 000 levs and for repeated commitment of the same offence - with 1 000 levs to 2 000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) For violation under para 1 committed by a corporate body or sole entrepreneur shall be imposed proprietary sanction from 1 000 levs to 2 000 levs and for repeated offence - from 2 000 levs to 4 000 levs.

Art. 48a. (new, SG 102/03) (1) (amend. - SG 31/06, in force from 14.04.2006) An official who does not make an entry in the register under art. 14 of an establishment under the conditions of art. 13, para 3 shall be fined by 1 500 to 3 000 levs.

(2) (amend. - SG 31/06, in force from 14.04.2006) For repeated violation under para 1 the offender shall be fined by 3 000 to 5 000 levs.

Art. 49. (1) (amend. – SG 8/11, in force from 25.01.2011) The offences under Art. 38 - 48 shall be established by acts issued by the inspectors of the official control according to Art. 28.

(2) (amend. - SG 31/06, in force from 14.04.2006) The penalty decrees shall be issued by the head of the respective competent body depending on the subordination of the official who has established the offence.

Art. 49a. (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; revoked – SG 8/11, in force from 25.01.2011)

Art. 50. The issuance of the acts, the issuance, the appeal and the fulfilment of the penalty decrees for the offences shall be carried out according to the provisions of the Administrative Violations and Penalties Act.

Art. 51. (1) (amend. - SG 31/06, in force from 14.04.2006; amend. – SG 8/11, in force from 25.01.2011) The administrative measures under Art. 30, item 5 and 6 shall be imposed by an order of the director of DFSD or RHI.

(2) (amend. - SG 31/06, in force from 14.04.2006) The measures under Art. 30, para 1, item 8 shall be imposed by an order of:

1. the heads of the bodies under para 1 when the value of the foodstuffs is up to 10 000 levs;

2. (amend., SG 70/04; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 8/11, in force from 25.01.2011) the executive director of BFSa or the chief state health inspector when the value of the foodstuffs is from 10 000 levs to 100 000 levs;

3. (amend., SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; amend. – SG 8/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017, suppl. - SG 77/18, in force from 01.01.2019) the Minister of Agriculture, Foods and Forestry or the Minister of Health Care or an officials appointed from the staff of the ministry when the value of the foodstuffs is over 100 000 levs.

(3) (amend. - SG 30/06, in force from 12.07.2006, suppl. - SG 77/18, in force from 01.01.2019) The orders under para 1 and 2 shall be subject to appeal before the relevant administrative court by the order of the Administrative procedure code.

(4) The appeal of the orders under para 1 shall not stop their fulfilment.

Art. 52. (new, SG 102/03; amend. - SG 31/06, in force from 14.04.2006; amend. – SG 98/10, in force from 01.01.2011; amend. – SG 8/11, in force from 25.01.2011) For every quarter DFSD, respectively RHI shall send to BAFPBI information for the issued and enacted penal provisions for systematic violation and for violations threatening the environment or the health of the consumers.

Art. 53. (New - SG 88/16, in force from 01.01.2017) (1) Whoever carries out activities in food banking without permission under this Act, unless subject to a more severe punishment shall be fined from BGN 1 500 to BGN 3 000, and for a repeated offense - a fine from BGN 2 000 to BGN 6 000.

(2) For violation under par. 1, committed by a legal entity or sole trader, a pecuniary sanction shall be imposed in the amount from BGN 2 500 to BGN 4 500, and for a repeated offense - from BGN 5 000 to BGN 7 000.

Art. 54. (New - SG 88/16, in force from 01.01.2017) Food bank operator who refuses or impedes the performance of official control in the food banking facilities, or the sample taking by the competent authorities, unless subject to a more severe punishment, shall be punished with a proprietary sanction from BGN 500 to BGN 1 000, and for a repeated offense of such kind - with a proprietary sanction from BGN 1 000 to BGN 1 500.

Art. 55. (New - SG 88/16, in force from 01.01.2017) Food bank operator who sells donated food or gives donated food to persons who are not included in the list under Art. 37l, para. 8, unless subject to a more severe punishment, shall be punished with a proprietary sanction in the amount of 20 per cent of the market value of the food provided against payment, but not less than BGN 1 000. For a repeated violation, the amount of the proprietary sanction shall be 40 percent of the market value of the food provided against payment, but not less than BGN 2 000.

Art. 56. (New - SG 88/16, in force from 01.01.2017) (1) In cases of violations of Art. 53 and 55, the acts establishing the violations shall be drafted by the officials authorized by the Executive Director of the Bulgarian Food Safety Agency, and the penalty decrees shall be issued by the Executive Director of the Bulgarian Food Safety Agency or officials authorized by him/her.

(2) In cases of violations of Art. 54, the acts establishing the violations shall be drafted by officials of the respective competent authority, and the penalty decrees shall be issued by the Head of the respective competent authority depending on the subordination of the official who established the violation.

Additional provisions

§ 1. (amend. - SG 31/06, in force from 14.04.2006) In the context of this Act:

1. "Active food contact materials and articles" means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

2. "Hazard analysis and critical control points (HACCP)" is a system of provision of food safety at all units of the food chain from obtaining the raw materials to the end user, based on the following principles: identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; identifying the critical control points at the technological process which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; establishing critical limits at each critical control point which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; establishing and implementing effective monitoring procedures at critical control points; establishing corrective actions when monitoring indicates that a critical control point is not under control; establishing procedures, which shall be carried out regularly, to verify that the measures for implementation of the indicated principles are working effectively; establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the indicated principles.

3. "Risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication.

4. "Food safety" means that the food is not injurious to the health of the consumer when prepared and/or consumed in compliance with the conditions of handling.

5. "Validation" means collection of evidence that the proposed safety measures are appropriate and effective.

6. "Verification" means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled.

7. "Sampling for analysis" means taking food or any other substance (including from the environment) relevant to the production, processing and distribution of food or to the health of animals, in order to verify through analysis compliance with the normative requirements.

8. "Genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered by techniques allowed by a special law.

9. "Genetically modified food" means food containing, consisting of or produced from GMOs.

10. "Genetically modified organism for use in or as food" means a GMO that may be used as food or as a source material for the production of food.

11. "Group of producers of foods" means company of food producers, established according to the Obligations and Contracts Act or the Commerce Act or association under the Non-Profit Legal Entities Act or a cooperation under the Cooperatives Act. Other interested persons may be members of the company, the association or the cooperation.

12. "Groups of foodstuffs" are foodstuffs united on the basis of their origin and composition as follows:

- a) milk and dairy products;
- b) meat and meat products;
- c) fish, fish products and other sea food and fish products;
- d) eggs and egg products;
- e) butters and fats;
- f) cereals and foodstuffs on cereal basis;
- g) potatoes and root crops;
- h) legumen;
- i) vegetables - raw, cooked, tinned, frozen, dried, fermented, vegetable juice;
- j) fruits - fresh, frozen, dried, tinned, in the form of nectars and fruit juices, jams, marmalade, jellies and stewed fruits;
- k) kernels and oleaginous seeds;
- l) sugar, sugar and chocolate products, honey;
- m) spices - fresh and dried;
- n) soft drinks and bottled natural mineral, spring and table water;
- o) beer, wine and high-alcohol drinks;
- p) coffee, tea, cocoa;
- q) other foodstuffs - mayonnaise and dressings; baby food; fruit and herbal tea; table salt;
- r) meat and meat-and-vegetable cans;
- s) ready to use foodstuffs – canned, frozen, concentrated or dried;
- t) special foodstuffs which, due to their specific composition or way of production are clearly discerned from the foodstuffs for normal consumption.
- u) (new - SG 106/18) organically grown foods and prepacked or non-packaged products.

13. "Food additives" mean any substances which are usually not used as food or as typical food ingredients, irrespectively of whether they have nutrition characteristics, which the intentional addition to the food at its production, processing, treatment, packing, transportation or storage turns them or it is expected to turn them, directly or indirectly, into ingredient of the food or its secondary products.

14. "Good practice" means a system of basic hygienic and technological rules for work, which shall be applied in the production and trade of foodstuffs, in order to minimize the risk of food

contamination by human or production activity. The rules concern the design, condition and maintenance of the buildings, premises, machines, facilities and technical equipment, of used raw materials, basic, auxiliary and packing materials, their receiving and storing, the hygiene and training of the personnel, the systems of tracking and control of the quality and the technological process, the keeping of documentation.

15. "Document" means information and its carrier.

16. "Equivalent" means different systems or measures capable of meeting the same objectives.

17. "Equivalence" means the capability of different systems or measures to meet the same objectives.

18. "Stage of production, processing and distribution" means any stage, including import, from the production of a food, up to its supply to the final consumer including the primary production, storage, transport and sale.

19. "Labelling" means any texts, designations, trade marks, brand names, pictorial matter or symbols accompanying or referring to a certain food or placed on its packaging in the form of label, ring or cover placed on it, or described in documents, guides or announcements accompanying them.

20. "Foodstuff misleading the consumer" means food which has a composition, qualities and characteristics which do not meet the normative requirements but in appearance, labelling, presentation and advertising claims it.

21. "Contaminant" means any substance which is not added intentionally to the foodstuffs but appears there as result of production, including activities carried out at plant production, stock-breeding and veterinary medicine, processing, treatment, packing, transportation and storage or as a result of environment pollution. Foreign bodies such as parts of insects, animal hairs, etc. are not contaminants.

22. "Record" means a document indicating achieved results or providing evidence of implemented action.

23. "Inspection" means evaluation of the compliance by means of observation and assessment, accompanied where needed by measuring, testing and comparison.

24. "Intelligent food contact materials and articles" means materials and articles which monitor the condition of packaged food or the environment surrounding the food.

25. "Cosmetic product" means every substance or preparation intended for contact with different external parts of the human body – skin (the epidermis), hair, nails, oral and external sex organs or the teeth and the mucous membrane of the mouth cavity, exclusively or most of all for their cleaning, scenting, change of the appearance and/or correction of the smells and/or protection and maintenance of good condition.

26. (amend. – SG 8/11, in force from 25.01.2011) "Competent bodies" under this Act are the Bulgarian Food Safety Agency and the Regional Health Inspectorates.

27. "Quality control" means the physical and legal activities, carried out by authorized persons, intended for verification whether the stated quality complies with the quality requirements for fruits and vegetables.

28. "Control body" means an independent third party to which the competent body has delegated certain official control tasks.

29. "Final consumer" means the person who consumes the food and will not use it as part of any food business operation or activity.

30. "Migration" means a process of passing and penetration of low-molecular substances of the materials and articles to the foodstuffs they are contacting.

31. (amend. – SG 8/11, in force from 25.01.2011) "Multi-annual control plan" means a document containing description established by the competent bodies containing general information on the structure and organisation of the official control regarding the food chain in the country.

32. "Monitoring" means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the level of compliance with normative requirements.

33. "Surveillance" means a careful observation of the activities of one or more food production and/or trade establishments.

34. "Food unfit for human consumption" means a food unfit for consumption according to its designation as a result of pollution, micro-biological changes, expired term of fitness or broken entity of the package.

35. "Unfair competition" means any activity or inactivity in the production and/or trade of foodstuffs which contradicts the good practice and hurts or may hurt the interests of the competitors in their inter-relations or in their relations with the consumers.

36. "Non-compliance" means non-compliance with the normative requirements for food safety.

37. "Food production establishment" means any premises or building where obtaining, partial or full processing, preparation, packing, pre-packing, bottling, labeling and storage of foodstuff intended for human consumption is carried out.

38. "Risk communication" means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, food industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

39. "Audit" means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

40. "Hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

41. "Residuals" means traces of one or more substances or their residual metabolites and decomposition products, used as plant protection agents, established in or on samples of foodstuff of plant or animal origin, intended for human consumption.

42. "Official control of foodstuffs" means control that the competent bodies perform for the verification of compliance with the normative requirements of production and trade of foodstuffs for human health protection and consumer information.

43. "Official certification" means the procedure by which the competent body or bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance.

44. "Risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

45. "Repeated offence" is an offence committed within one year from the enactment of the penalty decree by which the offender has been punished for an offence of the same kind.

46. "Misleading name" means name referring to an apparent food characteristic but non-compliant with the food specification or with the consumer expectations of the food characteristic.

47. "Program" means a system of procedures and their typical documents.

48. "Food producer" means any natural or legal person who produces and/or processes foodstuffs or presents himself as producer by placing on the food, its packing or the accompanying trade documentation his name, his production or any other identification sign.

49. "Production" means a complete or partial process of production, processing, preparation, packing, labelling and storing foodstuffs.

50. "Traceability" means the ability to trace and follow a food, fodders, food-producing animal or substance intended to be, or expected to be incorporated into a food, through all stages of production, processing and distribution.

51. "Procedure" means established way of implementation of activity or a process.

52. "Process" means a set of interdependent and interacting activities which transform the resources in results.

53. "Placing on the market" means the holding of food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

54. "Risk" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

55. "System" means a set of interconnected and interacting elements.

56. "System of management of the food safety" means either a system of programs and procedures based on the good production practice and the principles of the system of Hazard analysis and critical control points (HACCP), the implementation of which establishes conditions for independent control and ensures the food safety, or a system compliant with the requirements of Codex Alimentarius or BDS ISO 22 000.

57. "Systematic offences" means three or more similar offences of the normative requirements for the production and trade of foodstuffs, committed within one year period, for which the persons have been punished by administrative penalties by enacted penal provisions.

58. "Raw materials of animal origin" means raw materials, obtained from animals, bred by humans for commercial or non-commercial purposes or inhabiting the wild nature.

59. "Third country" means a country which is not member of the European Community.

60. "Trade" means a process of import, export, storage, transportation, sale and presentation for sale of foodstuffs, offering of foodstuffs by mass caterers, as well as offering the consumers free foodstuff samples.

61. "Trader of foodstuffs" means any natural or legal person which carries out trade of foodstuffs in the sense of item 60.

62. "Unique code" means any combination of digits and Latin letters intended to identify GMOs.

63. "Risk management" means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

64. "Food hygiene" means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.

65. "Food for personal consumption" means food not intended to be placed on the market.

66. "Food for personal needs" means food intended for use in the households.

67. "Food which is not safe for consumption by the consumers" means a food which damages or may damage the health of people or which is unfit for consumption, whereas in its determining as such the following shall be taken into consideration:

a) the conditions of its normal consumption by and at every stage of the production, processing and offering of the foodstuff;

b) the information presented to the consumers including by labeling or other accessible to the consumer information for protection against specific harmful for the health effects of a certain foodstuff or group of foodstuffs.

68. "Foodstuff damaging or which can damage the health of people" means a foodstuff determined as such on the grounds of:

a) the used additives or components, the obtaining of main components of the foodstuff, as well as the applied methods of technological processing;

b) the immediate, short-term and long-term effects of the foodstuff on the health of the consumers and the future generations;

c) the possible cumulative toxic effects of the consumption of the foodstuff;

d) the specific receptivity of definite groups of the population when certain foodstuff is designated for consumption by these groups.

69. "Foodstuffs of animal origin" means foodstuffs obtained from animals with or without food

additives, which did or did not undergo the respective technological treatment or processing.

70. "Food chain" means the sequence of stages and activities/operations carried out in the production, processing, distribution, storage and manipulation of foodstuffs and their components from obtaining to their consumption.

71. "Food information" means the data for energy and nutrition substances composition as well as the nutrition claims laid upon labeling of foodstuffs.

72. "Food additives" means foodstuffs for supplementing the normal diet, representing concentrated sources of vitamins and minerals or other substances having nutritious or physiological effect, used separately or in combination, offered on the market in dosed forms as capsules, tablets, and the like, as powder, phials containing liquid and other similar liquid or powder forms to be taken in pre-dosed small quantities.

73. "Food, produced from GMOs" means food derived, in whole or in part, from GMOs, but not containing or consisting of GMOs.

74. "Food industry" means any undertaking, whether for profit or not and whether public or private, carrying out the activities related to the stages of production, processing and distribution of food.

75. (new - SG 88/16, in force from 01.01.2017) "Systematic obstruction" is creating difficulties for the control authorities in carrying out their activities twice or more times within a calendar year.

§ 1a. (new, SG 102/03; revoked – SG 8/11, in force from 25.01.2011)

§ 1b. (new - SG 31/06, in force from 14.04.2006) (1) Upon the preparation, evaluation, amendment and supplementing of normative acts regulating the food safety, the applicable international standards and scientific information shall be taken into consideration.

(2) Upon preparation of normative acts regulating the food safety, the results of the implemented risk analysis shall be taken into consideration, except for the cases of inapplicability of the risk analysis.

(3) Risk analysis shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(4) Risk management shall take into account the results of risk assessment and the opinions of the scientific organizations and, where necessary, provisional protection measures shall be applied.

(5) Provisional protection measures may be adopted when following an assessment of available information the possibility of harmful effects on health is identified but no scientific evidence for its occurrence exists. The measures shall be applied pending further scientific information for a more comprehensive risk assessment.

(6) The adopted provisional measures shall be:

1. proportionate to the measures required to achieve life and health protection of the people;
2. no more restrictive to trade than is required to achieve life and health protection of the people;

3. in regard to the technical and economic feasibility and other legitimate factors;

4. periodically reviewed, depending on the nature of the risk to life or health of people and the scientific information needed to conduct a more comprehensive risk assessment.

(7) Upon preparation, evaluation and amendment and supplementing of the normative acts regulating the food safety, the state bodies shall carry out open and transparent public consultations except for the cases referred to in Art. 37.

§ 1c. (new - SG 31/06, in force from 14.04.2006) The provisions of the law concerning the producers and traders of foodstuffs from European Union member states shall be applicable also to the producers and traders of foodstuffs from the European Economic Area.

§ 1d. (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009; revoked – SG 8/11, in force from 25.01.2011)

§ 1e. (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 82/09, in force from 16.10.2009; amend. – SG 93/09, in force from 25.12.2009; amend. - SG 14/15, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, respectively the Minister of Economy and the Minister of Health, shall provide to the interested persons the opportunity to use the provisions of the documents and acts referred to in Art. 6, para 6, item 7 and para 7, Art. 8, para 4, item 2, Art. 17, para 4, item 1 and Art. 23f, para 5, item 2, letter "b" and para 9 in the website of the Ministry.

Transitional and concluding provisions

§ 2. The producers of foodstuffs found until the enactment of this Act shall bring their production activity and shall register in compliance with the requirements of the law within two years from its enactment and under Art. 18 --with the introduction of the system.

§ 3. The merchants of foodstuffs found by the enactment of this Act shall bring their activity in compliance with the requirements of the law and under Art. 18 - with the introduction of the system.

§ 4. The ordinances for the implementation of this Act shall be issued within six months from its enactment.

The Act was adopted by the 38th National Assembly on September 30, 1999 and was affixed with the official seal of the National Assembly.

§ 5. (new - SG 31/06, in force from 14.04.2006; amend. – SG 36/08; amend. – SG 93/09, in force from 25.12.2009, amend. – SG 58/17, in force from 18.07.2017) The implementation of the Act shall be assigned to the Minister of Health and the Minister of Agriculture, Foods and Forestry who shall issue instructions on its implementation.

Transitional and concluding provisions (SG 102/03; amend. - SG 31/06, in force from 14.04.2006)

§ 56. Within one month from the enactment of this Act the Ministry of Economy shall submit the register of the enterprises for production of foodstuffs and the accompanying documentation to the bodies under art. 12, para 2.

§ 57. (1) Enterprises manufacturing foodstuffs and having registration in the Ministry of economy (Ministry of Industry) by the order of art. 12, shall receive on its grounds officially issued certificates by the order of this Act by the respective body under art. 12, para 2.

(2) The procedures of registration of enterprises manufacturing foodstuffs for which documents have been file din the Ministry of Economy (ministry of Industry) according to art. 12, shall be concluded by the order of this Act by the bodies under art. 12, para 2 without filing a new application and documents.

(3) By December 31, 2004 the producers of foodstuffs under para 1 shall complete the data of their registration according to the requirements of this Act.

§ 58. Within 6 months fro the enactment of this Act the person carrying out production and/or trade of foodstuffs in establishments which are not registered for production or trading foodstuffs shall file a request for registration under the conditions and by the order of art. 12.

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§ 60. For the purposes of the state control, by December 31, 2004, the Minister of health and the Minister of Agriculture and Forests may order fulfilment of analyses and tests in other not accredited laboratories for testing foodstuffs in the system of the Ministry of Health, respectively of the Ministry of Agriculture and Forests, different from those under art. 32.

§ 61. (amend. SG 87/05; revoked - SG 31/06, in force from 14.04.2006)

**Transitional and concluding provisions
TO THE TAX-INSURANCE PROCEDURE CODE**

(PROM. – SG 105/05, IN FORCE FROM 01.01.2006)

§ 88. The code shall enter in force from the 1st of January 2006, except Art. 179, Para 3, Art. 183, Para 9, § 10, item 1, letter "e" and item 4, letter "c", § 11, item 1, letter "b" and § 14, item 12 of the transitional and concluding provisions which shall enter in force from the day of promulgation of the code in the State Gazette.

**Transitional and concluding provisions
TO THE ADMINISTRATIVE PROCEDURE CODE**

(PROM. – SG 30/06, IN FORCE FROM 12.07.2006)

§ 137. In the Foodstuffs Act (prom. - SG 90/99; amend. - SG 102/03; 70/04; 87, 99 and 105/05) the words "Administrative Proceedings Act" shall be replaced by "Administrative Procedure Code".

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§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:

1. division three, § 2, item 1 and § 2, item 2 – with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 – 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4§ 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 – with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;

2. paragraph 120, which shall enter into force from the 1st of January 2007;

3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE FOODSTUFFS ACT (PROM. – SG 31/06, IN FORCE FROM 14.04.2006; AMEND. – SG 96/06, IN FORCE FROM 01.01.2007)

§ 86. Until approving of control bodies of foodstuffs of traditionally specific character by the Minister of Agriculture and Health the control shall be carried out by the Minister of Agriculture and Forests or persons authorized by him.

§ 87. (revoked – SG 96/06, in force from 01.01.2007)

§ 88. (1) Establishments for retail trade offering only foodstuffs of animal origin, which are not registered by RIPCPH according to the order referred to in Art. 12, shall receive certificates issued by RVO ex officio.

(2) Initiated in RIPCPH procedures for registration of retail trade establishments offering only foodstuffs of animal origin shall be transferred to RVO ex officio without submission of new application and documents for registration.

(3) The Minister of Health shall provide the Minister of Agriculture and Forests with the information from the register concerning the establishments referred to in para 1 within a period of three months from the enforcement of this Act.

§ 89. § 61 of the transitional and concluding provisions of the Act Amending and Supplementing the Foodstuffs Act (prom. – SG 102/03; amend. – SG 87/05) shall be revoked.

§ 90. All establishments for production and trade of foodstuffs shall put in place the system or the procedures referred to in Art. 18, para 1 and implement them from 01 January 2007.

§ 91. Guides and rules for good production practice in the production and trade of foodstuffs in sub-branches developed and coordinated before the enforcement of this Act shall be set in compliance with Art. 17, para 3 and 4 within a three month period from the enforcement of this Act.

§ 92. (amend. and suppl. – SG 51/07, in force from 26.06.2007) Until 31 July 2007 the Council of Ministers shall present to the National Assembly a strategy and a draft of an Act concerning the establishment of the National Foodstuffs Safety Agency.

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§ 96. (amend. – SG 96/06, in force from 01.01.2007) The Act shall enter into force from the day of its promulgation in the "State Gazette" except for:

1. § 21, items 3 and 4, § 25, item 2 and § 93, item 1 concerning Art. 257, para 1, item 5 from the Veterinary Practice Act which shall enter into force from May 1st 2006;

2. § 2 concerning Art. 1a, item 2, § 6 concerning Art. 4b, para 6 and 7, § 7 concerning Art. 4c, para 9, § 9, item 3, § 18 concerning Art. 8, para 2 – 9, § 22, § 35 concerning Art. 23a, para 1, items 2 and 3, Art. 23c, para 1, Art. 23d, para 1, 3 – 6 and 8 – 11, Art. 23e, Art. 23g and Art. 23h, para 5, § 26, item 2, § 39, § 43 concerning Art. 27a, para 4, § 45 concerning Art. 28a, para 2, § 48 concerning Art. 29g, para 2, 4 and 5, § 53 concerning Art. 32, para 5, § 54 and § 59 concerning Art. 36a, para 4, Art. 36b, para 2, which shall enter into force from January 1st 2007.

**Transitional and concluding provisions
TO THE COMMERCIAL REGISTER ACT**

(PROM. – SG 34/06, IN FORCE FROM 01.10.2006)

§ 56. This Act shall enter into force on October 1, 2006 except § 2 and § 3 which shall enter into force from the day of promulgation of the Act in State Gazette.

**Transitional and concluding provisions
TO THE ACT ON APPLYING THE GENERAL ORGANIZATIONS OF THE MARKETS OF
AGRICULTURAL PRODUCTS OF THE EUROPEAN UNION**

(PROM. – SG 96/06, IN FORCE FROM 01.01.2007)

§ 12. The Act shall enter into force from the 1st of January 2007, except for § 7, which shall enter into force from the day of promulgation of the Act in State Gazette.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE LIVESTOCK ACT**

(PROM. - SG 51/07, IN FORCE FROM 26.06.2007)

§ 69. This Act shall enter into force from the day of its promulgation in the State Gazette.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE FISHERIES AND AQUACULTURE
ACT**

(PROM. - SG 36/08)

§ 60. In the Foodstuffs Act (prom. – SG 90/99; amend. – SG 102/03, SG 70/04, SG 87, 99 and 105/05, SG 30, 31, 34, 51, 55 and 96/06 and SG 31 and 51/07) everywhere the words "the Minister of Agriculture and Forests", "Minister of Agriculture and Forests" and "the Ministry of Agriculture and Forests" shall be replaced respectively with "the Minister of Agriculture and Food Supply", "Minister of Agriculture and Food Supply" and "the Ministry of Agriculture and Food Supply".

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. – SG 41/09, IN FORCE FROM 02.06.2009)

§ 96. The Act shall enter into force from the day of its promulgation in State Gazette, except for the following:

1. paragraphs 3, 5, 6 and 9, which shall enter into force from 1 January 2009;
2. paragraphs 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall enter into force from 1 July 2009;
3. paragraph 21, which shall enter into force from 1 June 2010.

**Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VOCATIONAL EDUCATION AND
TRAINING ACT**

(PROM. – SG 74/09, IN FORCE FROM 01.10.2009)

§ 48. The Act shall enter into force from the date of its promulgation in the State Gazette, except for § 1, which shall enter into force from the 15th of September 2009 and § 47, which shall enter into force from the 1st of October 2009.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE TOURISM ACT**

(PROM. – SG 82/09, IN FORCE FROM 16.10.2009)

§ 59. This Act shall enter into force from the date of its promulgation in the State Gazette.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MINISTRY OF INTERIOR ACT**

(PROM. – SG 93/09, IN FORCE FROM 25.12.2009)

§ 98. In the Foodstuffs Act (prom. SG 90/99; amend. – SG 102/03, SG 70/04, SG 87, 99 and 105/05; SG 30, 31, 34, 51, 55, 80 and 96/06; SG 31, 51 and 53/07; SG 36 and 69/08, and SG 23, 41, 74 and 82/09) the following amendments are made:

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2. In the remaining provisions of the Act the words "food supply" shall be replaced with "foods".
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§ 100. The Act shall enter into force one month after its promulgation in the State Gazette, except for § 1, 2, 21, 36, 39, 41, 44, 45, 49, 50, 51, 53, 55, 56, 57, 59, 62, 63, 64, 65, 70 and 91, which shall enter into force from the day of its promulgation.

Transitional and concluding provisions
TO THE LAW ACT AMENDING AND SUPPLEMENTING THE FOODSTUFFS ACT

(PROM. – SG 59/10)

§ 19. (1) Within 6 months from the entry into force of this Act the food producers shall submit declarations as per Art. 12, para 4 regarding registered food production sites.

(2) Within 6 months from the entry into force of this Act the food producers shall bring the introduced food safety management systems or system for danger analysis and critical control points in compliance with the requirements of this Act.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(AMEND. – SG 98/10, IN FORCE FROM 01.01.2011)

§ 120. In the Foodstuffs Act (prom. - SG 90/99; amend. - SG 80 /10) the words “the Regional Inspectorate for Preservation and Control of Public Health”, “the Regional Inspectorates for Preservation and Control of Public Health” and “RIPCPh” shall be replaced everywhere by “the Regional Health Inspectorate”, “the Regional Health Inspectorates” and “RHI”.

§ 121. The Act shall enter into force from January 1, 2011, except for the following:

1. paragraphs 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44, § 56, item 1 and 2, § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102, item 3, 4, 5, 7 and 8, § 105, т. 1, 3 and 5, § 107, item 1, 2, 3, 4, 6, letter "a", item 7, 10, 11, 13 and 15, letter "a", § 109, 110, 112, 113, § 115, item 5, § 116, item 4 and 6, § 117, item 5 and 7 and § 118, item 1, which shall enter into force from the date of promulgation of the Act in the State Gazette;

2. paragraph 102, item 1, 2 and 6, which shall enter into force from March 1. 2011;

3. paragraphs 22, item 1 (regarding Art. 36, para 1, sentence two), § 37, § 48, item 2, § 51 and 59, which shall enter into force from July 1, 2011;

4. paragraph 102/107, item 15, letter "b", which shall enter into force from September 30, 2011.

Transitional and concluding provisions
TO THE LAW ON BULGARIAN FOOD SAFETY AGENCY

(PROM. - SG 8/11, IN FORCE FROM 25.01.2011)

§ 30. The Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE COMMODITY EXCHANGES AND
THE WHOLESALE MARKETS ACT

(PROM. - SG 77/12, IN FORCE FROM 09.10.2012)

§ 17. Those persons who by the entry into force of this Act carry out wholesale trade in available foodstuffs and flowers at an independent site, shall submit a notification to the Commodity Exchanges and Wholesale Markets State Commission within three months from entry into force of this Act.

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§ 19. The Act shall enter into force from the date of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE YOUTH ACT
(PROM. - SG 68/13, IN FORCE FROM 02.08.2013)

§ 55. The Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON PROTECTION OF THE
COMPETITION

(PROM. - SG 56/15)

§ 11. Within 6 months from entry into force of the present Act the contracts on sale of foods, executed before its entry into force, shall be modified in compliance with the Foodstuffs Act.

§ 12. The National Consultative Council for a Better Functioning of the Food Chain Supply and the mediation commission at the Minister of Agriculture and Foods shall be created within three months from entry into force of the present Act.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE TOBACCO AND TOBACCO
PRODUCTS ACT

(PROM. – SG 28/16, IN FORCE FROM 08.04.2016)

§ 40. This Act shall enter into force on the day of its promulgation in the State Gazette, except for:

1. paragraph 5, § 7 with reference to Art. 30, par. 2, item 12 and item 15 – 18, § 8 with reference to Art. 31a, § 9 with reference to Art.32, par. 2, § 10 – 16 and § 17 with reference to Art.35f – 35n, § 18, § 19, § 21 – 26 and § 28 – 36 which shall enter into force on 20 May 2016;

2. paragraph 17 with reference to Art. 35o – 35s, which shall enter into force on:

a) 20 May 2019 – for the manufacturing and sale of cigarettes and tobacco for manual rolling of cigarettes;

b) 20 May 2024 – for the manufacturing and sale of tobacco products, other than cigarettes and tobacco for manual rolling of cigarettes.

Transitional and concluding provisions
TO THE ACT ON THE CENTER OF RISK ASSESSMENT ON THE FOOD CHAIN

(PROM. - SG 44/16, IN FORCE FROM 10.06.2016)

§ 12. The Act shall enter into force from the date of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VALUE ADDED TAX ACT
(PROM. - SG 88/16, IN FORCE FROM 01.01.2017)

§ 9. This Act shall enter into force on January 1, 2017.

Concluding provisions
TO THE ACT AMENDING THE ACT ON BULGARIAN FOOD SAFETY AGENCY
(PROM - SG 58 FROM 2017, IN FORCE FROM 18.07.2017)

§ 73. In the Foodstuffs Act (prom., SG 90/1999, amend., SG 102 of 2003, 70 of 2004, 87, 99 and 105 of 2005, SG 30, 31, 34, 51, 55, 80 and 96 of 2006, SG 31, 51 and 53 of 2007, SG 36 and 69 of 2008, SG 23, 41, 74, 82 and 93 of 2009, SG 23, 25, 59, 80 and 98 of 2010, SG 8 of 2011, SG 54 and 77 of 2012, SG 68 of 2013, SG 26 of 2014, SG 14 and 56 of 2015, and SG 28, 44 and 88 of 2016) everywhere the words "Ministry of Agriculture and Food", "the Minister of Agriculture and Food" and "the Minister of Agriculture and Food" shall be replaced by "the Ministry of Agriculture, Foods and Forestry", "the Minister of Agriculture, Foods and Forestry" and "the Minister of Agriculture, Foods and Forestry" respectively.

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§ 76. The act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE TAX-INSURANCE PROCEDURE
CODE

(PROM. - SG 63/17, IN FORCE FROM 04.08.2017)

§ 83. (1) The Act shall enter into force on the day of its promulgation in the State Gazette with the exception of:

1. § 64, which shall enter into force on 1 January 2022;
2. § 68, item 1, which shall enter into force on 1 January 2018;
3. § 68, item 2, which shall enter into force on 30 June 2017;
4. § 69, which shall enter into force on 1 January 2018;
5. § 71, Para. 1, which shall enter into force on 26 April 2017;
6. § 6 and § 72 - § 82, which shall enter into force on 1 January 2018.

(2) Within 6 months from the entering into force of this Act, the secondary legislation acts containing the obligation to present a certificate of the presence or absence of obligations of the persons, shall be brought into compliance with it.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE TAX-INSURANCE PROCEDURE
CODE

(PROM. - SG 92/17, IN FORCE FROM 01.01.2018)

§ 31. The Act shall enter into force on 1 January 2018 with the exception of:

1. Paragraphs 1, 4 to 9, § 10, items 2 and 3, § 26 and 29, which shall enter into force three days after the promulgation of the Act in the State Gazette;
2. Paragraph 14, Para. 5 and 6, which shall enter into force on 1 January 2019.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON REGISTRATION AND CONTROL OF AGRICULTURAL AND FORESTRY MACHINERY

(PROM. - SG 59 OF 2018)

§ 27. The Minister of Agriculture, Foods and Forestry shall bring the ordinances issued by him in compliance with this Act within 6 months of its entry into force.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE ADMINISTRATIVE PROCEDURE CODE

(PROM. - SG 77/18, IN FORCE FROM 01.01.2019)

§ 156. The Act shall enter into force on 1 January 2019, with the exception of:

1. paragraphs 4, 11, 14, 16, 20, 30, 31, 74 and § 105 item 1 on the first sentence, and item 2 which shall enter into force on 10 October 2019;
2. paragraphs 38 and 77, which shall enter into force two months after the promulgation of this Act in the State Gazette;
3. paragraph 79, items 1, 2, 3, 5, 6 and 7, § 150 and 153, which shall enter into force on the day of the promulgation of this Act in the State Gazette.