UNOFFICIAL TRANSLATION DISCLAIMER THIS IS AN UNOFFICIAL ENGLISH TRANSLATION OF DECREE NO. 61/2016 OF THE MINISTER OF AGRICULTURE. THE OFFICIAL TEXT IS THE HUNGARIAN VERSION.

Decree No. 61/2016 (15 September) of the Minister of Agriculture on indicating the absence of genetically modified organisms (GMOs)

Pursuant to the authorisation granted under \S 76(2)49. of Act XLVI of 2008 on the food chain and its official supervision, and acting within the scope of my duties as defined in \S 65(2) of Government Decree No. 152/2014 (6 June) on the duties and powers of the members of the Government, I hereby decree the following:

1. General provisions

Section 1

This Decree shall apply to

- a) the following prepacked and non-prepacked products from GMO-free production, intended for the final consumer:
 - aa) fresh, chilled, frozen meat (hereinafter collectively referred to as 'meat'),
 - ab) fresh, chilled, frozen fish (hereinafter collectively referred to as 'fish'),
 - ac) drinking milk (hereinafter referred to as 'milk'),
 - ad) eggs,
- *ae)* honey and other apiculture products intended as food (hereinafter collectively referred to as 'apiculture products'),
- af) plants and plant products (hereinafter collectively referred to as 'products of plant origin'), and
- ag) foods containing ingredients under points (aa)–(af) (points (aa)–(ag) hereinafter collectively referred to as 'food from GMO-free production'¹),
 - $b)^2$

c) the use of the indication referring to the absence of GMOs or to origin from GMO-free production (hereinafter collectively referred to as 'GMO-free label') on packaging or labels, in accompanying documents or in documents made available to the final consumer.

- (1) For the purposes of this Decree:
- a) transition period: a period of transition from non-GMO-free production to GMO-free production, during which the requirements concerning GMO-free production are applied;
- b) GMO: a genetically modified organism pursuant to Section 2(b) of Act XXVII of 1998 on gene technology activities;

¹ Amended by Section 8 (a) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

² Repealed by Section 8 (b) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

- c) produced from GMOs: a term under Article 2(10) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (hereinafter referred to as 'Regulation (EC) No 1829/2003');
- d)³ feed that can be used in GMO-free production: any feed that must not be labelled under Regulation (EC) No 1829/2003 and 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 (hereinafter referred to as 'Regulation (EC) No 1830/2003) as a product containing GMO, consisting of GMO, produced from GMO or containing ingredients produced from GMO;
- *e) GMO-free production:* the application of provisions laid down in this Decree in the process of plant cultivation, animal rearing, feed and food manufacturing, production, processing, marketing and transport;
- *f) produced by means of GMOs:* a term as defined by Article 2(v) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (hereinafter referred to as 'Council Regulation (EC) No. 834/2007/EC).
- (2) In addition to the provisions of paragraph (1), for the purpose of this Decree, the definitions under the following legislation shall also be taken into account:
 - a) Act XLVI of 2008 on the food chain and its official supervision, and
- *b)* Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

2. General conditions for using the GMO-free label

- (1) The GMO-free label shall only be used for food from GMO free production or for food containing such ingredient. The GMO free label may be used for products of plant origin containing a single ingredient, if the genetically modified variety of the given plant species was or is the subject of a production or marketing licence in the European Union.
- (2) The GMO-free label may be used on the packaging or label, in accompanying documents or in the document made available to the final consumer if the requirements laid down in this Decree are met and the absence of GMOs in the products can be verified in accordance with Section 9.
 - (3) The GMO-free label shall not be used

³ Established by Section 1 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

- a) in the case of meat or eggs of animals living in the wild whose diet cannot be traced, fish living in the wild whose diet cannot be traced, and processed food made therefrom,
- $b)^4$ in the case of food, which pursuant to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 must be marked as products containing GMOs, consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs.
- (4) In the case of food from GMO-free production, the use of veterinary medicinal products produced from or by means of GMOs shall not exclude the use of GMO-free label.
 - (5) If bearing the GMO-free label,
- a)⁵ food shall not contain any food additives, processing aids or enzymes produced from GMOs,
- b) food shall not contain any food additives, processing aids or enzymes produced by means of GMOs.

except if they can be used in organic food production pursuant to Council Regulation (EC) No 834/2007 and Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.⁶

3. Provisions regarding food of plant origin⁷

Section 4

- $(1)^8$ The proportion of GMO in food of plant origin bearing the GMO-free label shall not exceed 0.1 %, provided that the GMO have been authorised for marketing in the European Union and their presence in the food is accidental or technically unavoidable.
- $(2)^9$ In the case of food consisting of multiple ingredients, the limit value determined in paragraph (1) shall apply to the individual ingredients.

4. Provisions regarding food of animal origin

- (1) In the case of meat, fish, milk, eggs and food containing these ingredients, the GMO-free label may be used if the conditions set out in this section are complied with during animal rearing.
 - (2)¹⁰ Only feed that can be used in GMO-free production may be given to animals

⁴ Amended by Section 7(a) and Section 8(c) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

⁵ Amended by Section 8(d)(e) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

⁶ Amended by Section 8(d) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

⁷ Amended by Section 8(f) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

⁸ Amended by Section 7(b) and Section 8(c) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

⁹ Amended by Section 8(c) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

Decree No. 61/2016 (15 September) of the Minister of Agriculture on indicating the absence of genetically modified organisms (GMOs)

- a) in the case of mammals, at least after weaning,
- b) in the case of poultry, from the age of three days,
- c) in all other cases, from the birth or hatching of the animal.
- (3)¹¹ If feeding the animal under paragraph (2) was not started at the time defined therein, the GMO-free label may be used for products originating or made therefrom after the following transition period:
 - a) for bovine animals, sheep and goats
 - aa) at least three months before the milk to be labelled is drawn,
 - ab) for the meat to be labelled, at least twelve months prior to slaughter;
 - b) for pigs, at least four months prior to slaughter;
 - c) for poultry
 - ca) at least six weeks prior to the production of eggs to be labelled,
 - cb) for the meat to be labelled, at least three months prior to slaughter;
 - d) for turkeys, at least three months prior to slaughter.

5. Provisions regarding apiculture products

Section 6

The GMO-free label may be used on apiculture products if the apiculture product comes from a hive which, for at least a year prior to extracting the apiculture product, complied with the following conditions:

- a) nectar and pollen sources within a 5.5-km radius of the hive consist of non-genetically modified plants,
 - b)¹² bees were fed with feed that can be used in GMO-free production.

6. Requirements concerning the text referring to the absence of GMOs and the indication thereof

- (1)¹³ Only the following text referring to the absence of GMOs shall be indicated on the packaging, label, in the accompanying documents and in the document made available to the final consumer of a food produced in accordance with the provisions of this Decree: 'from GMO-free production'.
- (2)¹⁴ In the case of meat, fish, milk and eggs and of food containing these ingredients, the text "the meat/the milk/the eggs are derived from animals fed with feed that can be used in GMO-free

¹⁰ Established by Section 3 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹¹ Amended by Section 7(c) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹² Established by Section 4 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹³ Amended by Section 8(c) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹⁴ Amended by Section 7(d) of Decree No. 27/2017 (30 May) of the Minister of Agriculture

production" or "the fish was fed with feed that can be used in GMO-free production" in one field of vision with the text "from GMO-free production".

- (3)¹⁵ In the case of food consisting of multiple ingredients, the text referring to the absence of GMOs with the exception under paragraphs (4) and (5) may only be indicated in the naming of the food or on the packaging or label, in accompanying documents or in documents made available to the final consumer, if the food
 - a) contains ingredients only from GMO-free production, or
- b) contains such ingredients of animal origin under subparagraphs aa)-ae) of Section 1(a) that are from GMO-free production and at least one of such ingredients amounts to at least 10% of the weight of the food, furthermore the ingredients of plant origin contained in the food have no such genetically modified species that have been or are the subject of a production or marketing licence in the European Union.
- (4)¹⁶ If, in the case of food consisting of multiple ingredients, the GMO-free label under paragraph (3) is used, and the food contains ingredients of plant origin that have no such genetically modified variety that have been or are the subject of a production or marketing licence in the European Union, the labelling under paragraph (1) shall be included in the list of ingredients directly after the ingredient from GMO-free production in question or in notes after the list of ingredients.
- (4a)¹⁷ If the conditions specified in paragraph (3) are not satisfied in the case of a food consisting of multiple ingredients, the GMO-free label may only be included in the list of ingredients directly after the ingredient in question or in notes after the list of ingredients, provided that the given ingredient from GMO-free production amounts to at least 10 % of the weight of the food calculated without the ingredients listed in paragraph (5).
- (5)¹⁸ The fact that, in addition to ingredients listed under paragraph (3), the food also contains added water, salt, spices, as well as food additives, processing aids, or enzymes that can be used in GMO-free production pursuant to Section 3(5) shall not exclude the use of the text referring to the absence of GMOs under paragraph (3).
- (6) Information related to products bearing the GMO-free label shall not suggest that, owing to the absence of GMOs, the product has special properties, organoleptic or nutritional characteristics, or that its impact on health or the environment is more favourable than that of similar products not bearing the GMO-free label.

7. Provisions regarding the facilities of food enterprises 19

_

¹⁵ Established by Section 5 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹⁶ Established by Section 5 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹⁷ Introduced by Section 5 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹⁸ Amended by Section 7(e) and Section 8 (e)(g) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

¹⁹ Amended by Section 7(f) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

- (1)²⁰ The provisions of this Decree shall be observed in the entire food enterprise facility producing food from GMO-free production.
- (2)²¹ If it is not possible to operate the entire food enterprise facility in accordance with paragraph (1), to prevent mixtures, GMO-free production shall be separated in space or time from non-GMO-free production in the food enterprise facility. Mixtures shall be prevented also during storage and transport.

8. Verifying the absence of GMOs

Section 9

- (1)²² During the production and marketing of feed that can be used in GMO-free production and food from GMO-free production, the producer and the distributor shall ensure the traceability of the products produced and the materials used for the production. The producer and the distributor must be able to prove with documents to the inspection authority for the entire GMO-free production process that the conditions defined in this Decree for using the GMO-free label are met.
- (2)²³ If food of plant origin originates in a country where the cultivation of a genetically modified variety of the given plant is permitted, compliance with the conditions of GMO-free label shall be certified with the findings of a laboratory accredited per consignment or an official laboratory.
- (3) Documents verifying the absence of GMOs shall be kept for five years, starting from the date of placing the product bearing the GMO-free label on the market.

Section 10

- (1) The food chain inspection body shall monitor compliance with the provisions of this Decree during the course of GMO-free production in accordance with Act XLVI of 2008 on the food chain and its official supervision as well as decrees issued pursuant to the authorisation granted therein. The tracing of GMO-free production is based on self-monitoring and official monitoring.
- (2) Producers and distributors shall continually monitor compliance with the provisions regarding GMO-free production within the framework of self-monitoring.

9. Final provisions

²⁰ Amended by Section 8 (e)(h) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

²¹ Amended by Section 8 (i) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

²² Amended by Section 7 (g) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

²³ Amended by Section 8 (d) of Decree No. 27/2017 (30 May) of the Minister of Agriculture.

This Decree shall enter into force on the fifth day following its promulgation.

Section 12

Packaging materials and labels that do not comply with the provisions of this Decree may be used until the first day of the fourth month following this Decree's entry into force; products bearing such indication may be placed on the market until their best before or use-by date.

Section 12/A²⁴

Pursuant to the effective requirements of this Decree prior to the effective date of Minister of Agriculture Decree No. 27/2017 (30 May) on the amendment of Minister of Agriculture Decree No. 61/2006 (15 September) on indicating the absence of genetically modified organisms (hereinafter referred to as 'Amendment Decree'), feed bearing an GMO-free label may be produced for two months of the effective date of the amendment Decree and marketed until the expiration of their 'use by' date.

Section 13

Products bearing the indication referring to the absence of GMOs, which were produced or placed on the market in any Member State of the European Union or in Turkey, or produced in an EFTA State party to the Agreement on the European Economic Area, in accordance with applicable national legislation, need not comply with the technical provisions defined in this Decree provided that the provisions governing consumer protection offer the same level of protection as those laid down in this Decree.

Section 14

The preliminary notification of this draft Decree has been submitted as stipulated in Articles 5–7 of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

²⁴ Introduced by Section 6 of Decree No. 27/2017 (30 May) of the Minister of Agriculture.