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**STANDARD ON THE DEFINITION OF THE
GMO-FREE PRODUCTION PROCESSES OF
FOOD AND ITS LABELLING**

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1 BACKGROUND AND INTRODUCTION

On the initiative of the Ministry of Agriculture and the Environment of the Republic of Slovenia and the Danube Soya Initiative, the Ministers responsible for Agriculture of the broader Danube region met on 23 August 2013 in Moravske Toplice to discuss the implications of the regional cooperation for protein security in the Danube region. In their joint declaration, Ministers agreed amongst others to „single out the consumer freedom of choice by creating a transparent international standard for the traceability of production, control and certification system of labelling of products as GMO-free for plant-based, processed and animal agricultural products”.

The “Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ GmbH)” is committed to support this process in the context of the regional project “Promotion of GMO-free quality soya from the Danube Region”. The team of Umweltbundesamt (Environment Agency Austria) in close coordination with GIZ and Danube Soya Initiative, was responsible for coordinating and chairing a participatory expert process to establish a GMO-free labelling standard for food products and an associated control system for the Danube Region.

The objective of the overall GIZ project is strengthening of economically, ecologically and socially viable GMO-free soya production in selected areas of the Danube Region.

The titles of the two standards are as follows:

- Standard on the definition of the GMO-free production processes of food and its labelling
- Standard on the risk-based control of the GMO-free production processes

The final texts of the standards will be provided to the participating countries for their consideration and implementation. They intend to support and give guidance especially to the countries which do not yet have their own national approaches for GMO-free labelling and control in place. All other European countries, interested in establishing GMO-free labelling and control, are kindly invited to make use of these final texts of the standards as well.

2 OBJECTIVE

This Standard creates the basis for a „GMO-free production” of food in order to ensure traceability, transparency and control of the production processes and to protect the consumers' interests. Rules are set out for a “GMO-free production” throughout all stages of the food chain as well as for the use of terms regarding “GMO-free production” for labelling, presentation and advertising purposes. This standard should be implemented and used as part of a package which also includes the standard on the risk-based control of GMO-free production. If appropriate, links are made between the two documents.

3 SCOPE OF APPLICATION

This Standard governs the requirements for food of which the labelling, presentation, advertising or business documents evoke the impression that it is produced without the use of GMOs (genetically modified organisms) or products produced from or by GMOs. This in any case includes formulations such as “produced or processed without gene technology”, “GE-free”, “non-genetically modified”, “GMO-free”, “without gene technology” or “without the use of gene technology” as well as terms such as “fed without genetically modified animal feed” and the like. A list of the concrete wording used in different countries can be found in Annex 1 to this standard.

Provided that the necessary requirements are fulfilled, it should be possible to also allow certified organic-products to be labelled as GMO-free according to this Standard.

4 DEFINITIONS OF TERMS¹

- a) “GMO-free production”: application of the production process as set out in the rules of this standard at all stages of production, processing, marketing and transport of food and feed.
- b) “GMO-free”: originating from a GMO-free production or referring to such a production.
- c) “Operator”: the individual or entity responsible for ensuring the compliance with the rules of this standard within the business under its control.
- d) “Plant production”: production of agricultural crop products.
- e) “Livestock production”: animals (including fish, reptiles and amphibians) reared or kept for the production of food, or for other farming purposes. This does not include: wild animals; animals intended for use in sporting or cultural events (shows); experimental or laboratory animals; non-domesticated invertebrate animals.
- f) “Aquaculture”: the rearing or cultivation of aquatic organisms using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment.
- g) “Transition period”: transition to GMO-free production within a given period of time, during which the provisions concerning GMO-free production have been applied.
- h) “Labelling”: any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food;
- i) “Advertising”: any representation to the public by any means other than a label that is intended or likely to influence and shape attitude, belief or behaviour in order to promote directly or indirectly the sale of GMO-free products.
- j) “Presentation”: in particular the form or appearance of the food or its packaging, the packaging material used, the manner of its arrangement as well as the environment in which it is sold.
- k) “Certification body”: an independent third party carrying out inspection and certification in the field of GMO-free production in accordance with the provisions of this standard.
- l) “Plant protection products”: Products used to protect plants or plant products against all harmful organisms or preventing the action of such organisms. For this standard, only the active agents of the plant protection product are taken into account.
- m) “Genetically modified organism (GMO)”: an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
- n) “Produced from GMOs”: derived in whole or in part from GMOs, but not containing or consisting of GMOs.
- o) “Produced by GMOs”: derived by using a GMO as the last living organism in the production process, but not consisting of, containing or produced from GMOs.
- p) “Organisation”: a group of companies from the same or different sectors of GMO-free production.
- q) Critical components: crops for which genetically modified varieties exist which are agriculturally cultivated as well as raw materials or products which are made from such crops; food ingredients from animal origin and food ingredients such as enzymes, additives etc. that are not labelled according to Council Regulation (EC) 1829/2003 but may be produced by GMOs.

¹ The definitions are taken from the EU-legislation, where applicable.

5 PRODUCTION REGULATIONS

5.1 Principles

5.1.1 GMOs and products produced from or by GMOs

Food:

GMOs and products produced from or by GMOs² shall not be used as food, additive or processing aid for food.

Feed and other products:

GMOs and products produced from GMOs shall not be used as animal feed, additive or processing aid for animal feed, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and livestock in GMO-free production.

Both for food and feed production the prohibition on use of GMOs and products produced by and from GMOs shall not apply to veterinary medicinal products.

5.1.2 Certificate or confirmation of compliance for critical components

In order to ensure that no GMOs or products produced from GMOs have been used, an operator needs to make sure that the products or ingredients are not labelled according to EU regulations 1829/2003 or 1830/2003, a certificate for critical components is included or a confirmation of compliance of GMO-free production for products not falling under the scope of EU regulations 1829/2003 and 1830/2003 is provided.

5.1.3 Proof of non-use of GMOs or products produced from GMOs

For the purpose of the proof of non-use of GMOs or products produced from GMOs with regard to products other than food and animal feed or products produced by GMOs, operators shall require the vendor to provide a confirmation that the products supplied have not been produced from or by GMOs, if they purchase or use such non-GMO-free products from third parties. Such confirmation shall not be required for products, for which according to the latest state of knowledge no methods used in practice are known indicating that the products are GMOs, contain GMOs or are produced from or by GMOs. This currently (2015) applies for example to pure minerals, mineral fertilisers, chemically synthesised agents of plant protection products or specific plant or animal species as well as specific micro-organisms.

5.2 General requirements

5.2.1

The entire farm shall be managed in compliance with this standard on GMO-free production.

- a) However, a farm may be split up into clearly separated units or for aquaculture in production sites, which are not all managed according to the provisions for GMO-free production. As regards livestock production, these must be distinguishable as different production sectors. As regards aquaculture, the same species may be involved, provided that there is adequate separation between the production sites. As regards plants, different, easily distinguishable varieties shall be used.
- b) Where in accordance with section a) not all units of the farm are managed in compliance with the rules for GMO-free production, the operator shall keep the area, livestock and products used for, or produced by, the GMO-free units separate from the

² Examples for products produced by GMOs: Vitamin C or rennet produced by a genetically modified micro-organism.

area, livestock and products not used for, or produced by GMO-free units and keep adequate records for at least 5 years to show the separation.

5.2.2

Processing plants shall meet the following requirements:

The production of processed, GMO-free food or animal feed suitable for the production of GMO-free food shall be kept separate in space or time from the production of processed, non-GMO-free food or animal feed not suitable for the production of GMO-free food.

5.3 Special requirements for food

5.3.1 Seeds or vegetative propagating material

For the production of food, only plant ingredients of agricultural origin shall be used, of which the seeds or vegetative propagating material are no GMOs and for which there is no risk of a presence of GMOs for the harvested material.

5.3.2 Livestock

For the production of food, only livestock ingredients of agricultural origin, including aquaculture, shall be used, which originate from livestock that are no GMOs and were bred using input products in line with this standard since birth or, in case of mammals, at least following weaning.

GMO-free aquaculture must be based on the rearing of young stock originating from GMO-free broodstock.

5.3.3 Beekeeping

Beekeeping products such as honey, royal jelly and pollen can only be regarded as GMO-free if there is no agricultural land with genetically modified plants (including experimental field trials) within at least 3 km from the location of beehives. The restriction applies to the entire grazing season. Substances that are used in beekeeping like feed must be in conformity with the criteria of this standard on feed. There is no specific conversion period for bees.

5.3.4 Transition periods

Livestock that has not been bred in compliance with this standard since birth or, in case of mammals, at least following weaning, must pass through the following transition periods, i.e. must be fed with animal feed suitable for the production of GMO-free food, until a product produced from or with such livestock can be placed on the market according to this standard:

- the entire fattening period for pigs (starting with a maximum weight of 35 kilograms);
- 3 months for livestock for milk production, 2 weeks in case of acquisition of new animals already in milk for the renewal of the herd;
- 6 weeks for poultry for egg production;
- Chicks may not be older than 3 days, when converted to GMO-free production for poultry;
- the entire fattening period for aquaculture animals.
- For other farm animals, during the year prior to slaughter, for those whose life span is less than 1 year, for the three quarters of their life span.

5.3.5 Exceptions

If food with more than one ingredient does not fully fulfill the GMO-free requirements, it is possible to declare one or more of the ingredients as GMO-free in the list of ingredients. A GMO-free label may only be used if all ingredients fulfill the requirements of this standard.

A food may also be labelled as GMO-free if it contains less than 1% ingredients of animal origin which do not completely meet the criteria of this standard. Nevertheless, such ingredients must not be labelled according to Regulation (EC) No 1829/2003 or 1830/2003. Each ingredient of a food product can only be rated as fully complying or not complying with this standard.

In the case of food additives, processing aids, flavours, enzymes, amino acids and other micronutrients, as well as vitamins, where there are no such substances available on the market other than those produced by genetically modified organisms, these substances may be used if they are part of the list of substances drawn up by the European Commission, pursuant to Article 22(2)(g) in conjunction with Article 37 (2) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products.

6 PROOF OF NON-USE OF GMOS

There is a strong link between this chapter of the Standard and the Standard on risk-based control of GMO-free production.

6.1 Proof by operators and/or organisations

Operators and/or organisations that place food with descriptions as defined by this standard on the market shall provide adequate traceable proof that the requirements of the standard are met. They shall provide documentation regarding the preparation, treatment, processing or mixing of the food or the feeding of animals that the requirements prescribed for the use of the claim have been adhered to. Suitable and traceable documentation shall be the following, in particular

- binding statements³ on the part of the upstream supplier that the prerequisites for labelling have been complied with,
- analysis reports or documentation showing with sufficient certainty that the prerequisite for labelling has been complied with.
- Certificate for any critical component (see standard on risk-based control of GMO-free production).

Operators and/or organisations shall have their activity controlled by an accredited certification body.

6.2 Control

The compliance with this standard shall be controlled at all stages of production, transport, processing and marketing. The control of proper production, processing and labelling shall be based on self-controls and external controls according to ISO 17065 (see standard on risk-based control of GMO-free production).

6.3 Self controls and external controls

Self-controls (consistent with the provisions of the standard on the risk-based control of GMO-free production) shall be continuously carried out under the responsibility of the operator and/or the organisation. Tools for the documentation and performance of self-controls shall be used. External controls and the certification shall be carried out on a continuous basis by a company accredited for the control of GM-free production and pursuant to ISO 17065, respectively. The controls shall be done on a risk basis, taking into account the concept of critical components (see standard on the risk based control of GMO-free production). The risk ratings and controls shall be done systematically and so that they can be traced.

6.4 Threshold

The adventitious and technically unavoidable presence of GMOs authorized in the EU as well as products from and by GMOs authorized in the EU shall not be taken into consideration, if the compliance with EU Regulations 1829/2003 and 1830/2003 or with legislation of the country aligned with those Regulations can be demonstrated through the control and the

³ An example for a suitable template for binding statements can be found in the InfoXgen system (<http://www.infoxgen.com/en/zusicherungserklaerung-bio.html>)

percentage is not higher than 0,9 % per ingredient. The goal is to keep the presence of GMOs in GMO-free products as low as possible.

The GMO-content of any raw material used for the production of GM-free food or of animal feed suitable for GM-free production must therefore not exceed 0.9% per ingredient provided that it is adventitious and technically unavoidable.

Contamination with approved GMOs, at levels below the limit of quantification (0.1% as a rule) per ingredient, is generally regarded as technically unavoidable or accidental.

6.5 Analytical testing

An analytical evidence of approved GMOs or products produced from or by approved GMOs above 0.1 % and below 0.9% must be regarded as indication to control the effectiveness of the measures in the context of production. This shall also apply to evidence from process controls for GMOs or products produced from or by GMOs. The laboratory undertaking the analysis has to be accredited pursuant to ISO 17025, respectively (see standard on the risk-based control of GMO-free production).

6.6 Terms for labelling

Terms for labelling and advertising as laid down by this standard shall not be used, if these evidences are not kept or if justified doubts as to the compliance with the requirements of this standard cannot be dispelled.

7 LABELLING, PRESENTATION AND ADVERTISING

7.1 Impression for a GMO-free Label

Food is considered labelled as defined by this standard, if the labelling, presentation, advertising or business documents evoke the impression that the product has been produced according to the rules of this standard.

7.2 Proof of compliance

Descriptions indicating that food originates from GMO-free production may only be used in the labelling and advertising of food, if all ingredients of such products have been produced in accordance with the rules set out in this standard.

7.3 Avoid misleading consumers

Terms, including terms used in trademarks, as well as labelling, presentation and advertising practices liable to mislead consumers or users by suggesting that the concerned food or the ingredients used for its production comply with the rules set out in this standard, shall not be used.

7.4 Clear labelling

Labelling and advertising for food produced according to the provisions of this standard shall contain a clear reference to GMO-free production in accordance with this standard: e.g. **Produced without GMO**, or **from GMO free production** or similar wordings. Annex 1 to this standard contains a list of the wording currently used in the different countries.

7.5 Certification body

The labelling must specify the name of the certification body of the operator or organisation, which has carried out the last preparation step or processing.

The indications referred to in section 6.3 and 6.4 must be easy to understand and shall be marked in a conspicuous place in the same visual field in such a way as to be easily visible, clearly legible and indelible.

7.6 Label for Animal Feed

The following labelling may be used for animal feed: “suitable for the production of GMO-free food” according to this standard. Annex 1 to this standard contains a list of the wording currently used in the different countries.

8 REGIONAL AND NATIONAL CONSULTATION AND ADVISORY COMMITTEES FOR GMO-FREE PRODUCTION

8.1 Regional Consultation and Advisory Committee

It is recommended to set up a regional consultation and advisory committee consisting of one representative of the responsible authorities of the Danube region member countries and if appropriate additional experts in the field of GMO-free production, labelling and control of food.

The tasks of this committee are, inter alia to ensure information exchange and concrete advice on topics related to the implementation of this standard.

8.2 National consultation and advisory committees

In addition to the regional committee national committees may be established by the responsible authority in the respective country to provide advice on any topics related to this standard on the national level.

ANNEX 1: LIST OF THE CONCRETE WORDING CURRENTLY USED IN THE DIFFERENT COUNTRIES FOR THE LABELLING OF GMO-FREE PRODUCTS

Food:

Austria: "ohne Gentechnik hergestellt", "Gentechnik-frei erzeugt"

France: „sans OGM“

Slovenia: „Pridelano/proizvedeno brez GSO – brez gensko spremenjenih organizmov“

Hungary: "GMO-mentes termelésből"

Germany: "ohne Gentechnik"

The following wordings are translations of the German wording "ohne Gentechnik" authorized by the German Verband Lebensmittel ohne Gentechnik – Association Food produced without Genetic Engineering – for the use of the common "Ohne GenTechnik"-seal in non-German speaking countries:

Italian: No OGM

Spanish: Sin transgénicos

English: Non GMO

Feed:

Austria: „geeignet zur Herstellung gentechnikfreier Lebensmittel“

Slovenia: „Primerno za proizvodnjo živil po zasebnem standardu Pridelano/proizvedeno brez GSO – brez gensko spremenjenih organizmov“