2021

GMO-free label Trademark Regulation

fresh, chilled, *frozen* **meat**

eggs

fresh, *chilled*, frozen **fish**

drinking **milk,** *dairy products*

honey and ***apiculture*** products

certain **plants** and *plant products*

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1. Related legislations

The current version of the following legislations shall be taken into consideration for the certification of GMO-free food trademark:

- Decree No. 61/2016 (IX. 15.) of the Minister of Agriculture on indicating the absence of GMOs;
- Act XXVII of 1998 on Gene Technology Activities;
- Act XI of 1997 on the Protection of Trademarks and Geographical Indications;
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (hereinafter Regulation (EC) No 1829/2003);
- 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 Regulation (EC) No 1830/2003);

- 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 Regulation (EC) No 834/2007);
- 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 (hereinafter Regulation (EC) No 889/2008);
- Regulation (EC) No 767/2009 of the European Parliament and of the council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC;
- Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired (hereinafter Regulation (EU) No 619/2011).

2. Basic information relating to the GMO-free food trademark

2.1. The following label is the subject of this Regulation:

2.1.1. Full name of the label: From GMO free production food trademark.
2.1.2. Abbreviated name of the label: GMO free food trademark.
2.1.3. The design of the label: coloured, graphic.
2.1.4. The shape and colours of the label design: White circle surrounded by tricolour, inscription “From GMO free production” and green plant motif.

2.2. The Protection provided under the Nice Classification System for the GMO-free food trademark:

Those goods under Classes 29, 30, 31 and 32 in the Nice Classification System may bear the Trademark that is covered by Decree No. 61/2016 (IX.15.) of the Minister of Agriculture on indicating the absence of genetically modified organisms.

CLASS 29: Meat, fish, poultry and game; meat extracts; preserved, frozen, dried and cooked fruits and vegetables; jellies, jams, compotes; eggs; milk, cheese, butter, yoghurt and other milk products; oils and fats for food.

CLASS 30: Coffee, tea, cocoa and artificial coffee; rice; pasta and noodles; tapioca and sago; flour and preparations made from cereals; bread, pastries and confectionery; chocolate, ice cream, sorbets and other edible ices; sugar, honey, treacle; yeast, baking-powder; salt; seasonings, spices, vinegar, sauces and other condiments, ice (frozen water).

CLASS 31: Raw and unprocessed agricultural, aquacultural, horticultural and forestry products; raw and unprocessed grains and seeds; fresh fruits and vegetables, fresh herbs; natural plants and flowers; bulbs, seedlings and seeds for planting; live animals; foodstuffs and beverages for animals; malt.

CLASS 32: Beers, non-alcoholic beverages, mineral and aerated waters, fruit beverages and fruit juices, syrups and other non-alcoholic preparations for making beverages.

3. Presentation of the Trademark Holder

Name: Ministry of Agriculture (hereinafter: Trademark Holder)

Registered office: 1055 Budapest, Kossuth Lajos tér 11.

Mailing address: 1860 Budapest Pf.1.

Phone: 0617952000

E-mail: info@am.gov.hu

Website: gmo.kormany.hu/gmo-mentes-jeloles;

Representative: Dr István Nagy, Minister of Agriculture

4. Presentation of the Certification Body

The Trademark Holder has assigned the Food Chain Safety Centrum Non-Profit Limited Liability Company to carry out certification procedures.

Name: Food Chain Safety Centrum Non-Profit Limited Liability Company (hereinafter Certification Body)

Registered office: 1024 Budapest, Keleti Károly utca 24.

Mailing address: 1751 Budapest Pf.12

Phone: +36701980782

E-mail: info@elbc.hu

Website: www.elbc.hu

Representative: Szilárd Demetrovics, Managing Director

The company is a fully state-owned economic operator founded by the National Food Chain Safety Office in order to support the performance of food chain safety supervisory tasks pursuant to paragraph 1 of Article 38/D of Act XLVI of 2008 on the food chain and its official supervision.

5. The Trademark Holder’s goal

The Trademark Holder’s main goal is to clearly distinguish goods produced from genetically modified (hereinafter: GM) organism-free (hereinafter: GMO-free) production within the product assortment, establish a GMO-free product chain and, by this, to develop GMO-free agriculture in Hungary and strengthen its reputation.

By labelling and promoting GMO-free products, the Trademark Holder’s further objectives include the followings:

- Increase consumer awareness in order to ensure that consumers look for and give preference to foodstuffs labelled as GMO-free;
- Ensure cooperation is formed between food producers and wholesale as well as retail dealers to guarantee quality compliance of the GMO-free products chain.

The Trademark Holder welcomes any cooperation with committed producers and dealers that are producing or selling GMO-free foods and whose products meet the Hungarian and EU marketing requirements. By using different means, campaigns and facilitating cooperation, the Trademark Holder wishes to urge food producers to use GMO-free raw materials and feeds and retail stores to promote GMO-free goods.

6. General quality requirements applicable to goods marked with the GMO-free food trademark

6.1. The product complies with Decree No. 61/2016 (IX. 15.) of the Minister of Agriculture on indicating the absence of GMOs (hereinafter: Decree). Accordingly, the following products can be labelled with the GMO-free food trademark (hereinafter: Trademark): **Prepacked and non-prepacked products from GMO-free production, intended for the final consumer**

- fresh, chilled, frozen meat,
- fresh, chilled, frozen fish,
- drinking milk,
- eggs,
- honey and other apiculture products intended as food,
- plants and plant products,
- as well as foods containing the above listed ingredients, except for those foods among them where the GMO-free indication may only be included in the list of ingredients or in notes following the list of ingredients.

6.2. The product has been received the appropriate qualification in the qualification and certification procedure of the Certification Body (see Chapter 4).

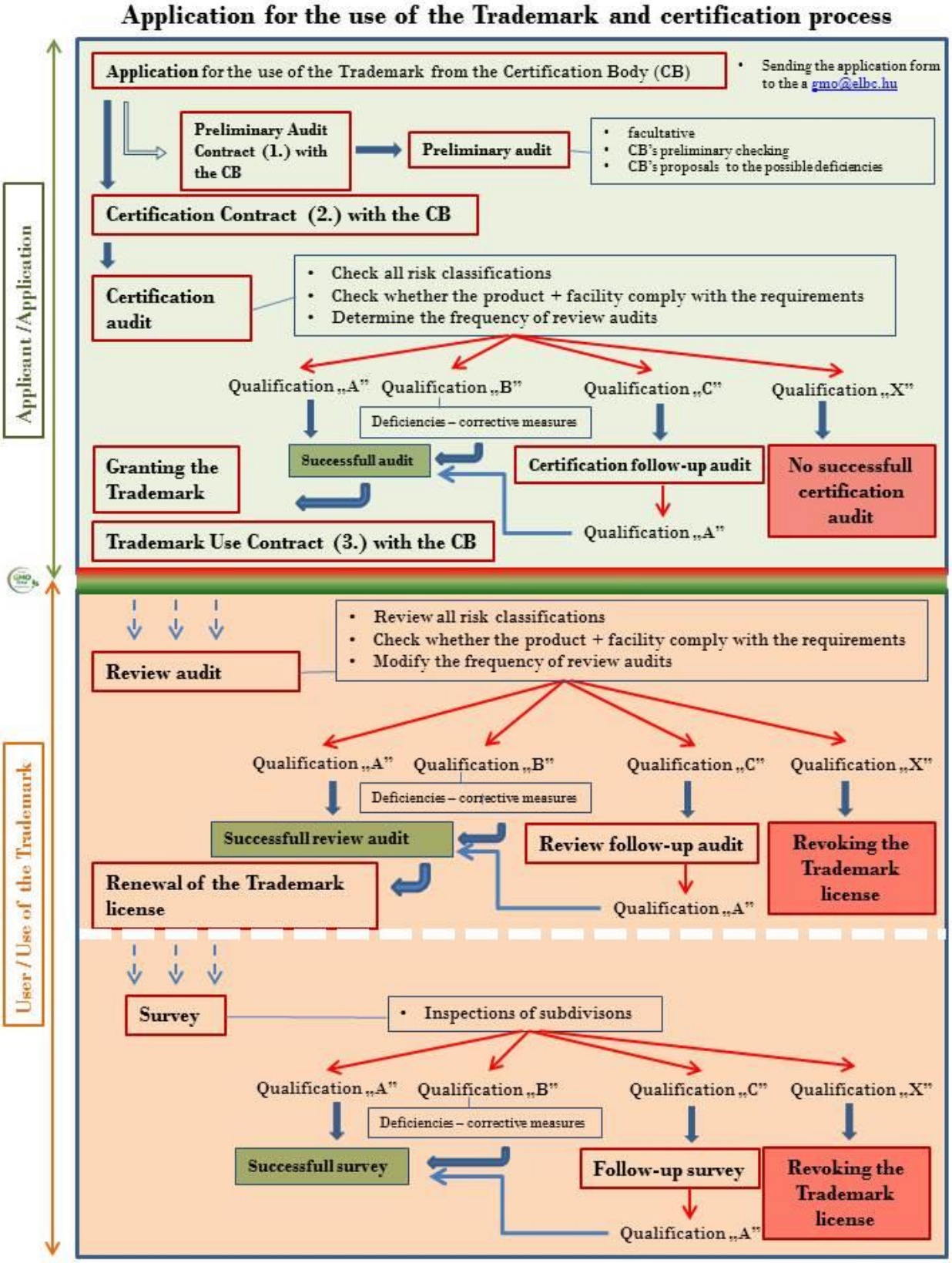
6.3. **Feeds or feed materials** cannot be labelled with a Trademark. However, in case of the certification of feeds or feed materials, the text “*Certified by (name of Certification Body), this product may be used in GMO-free production”* can be indicated in order to establish a GMO-free product chain for the purpose of assisting producers and users.

6.4. **Facilities (including livestock farms)** cannot be provided with a Trademark. However, in case of certifying facilities (including livestock farms), if production (including keeping animals) there complies with the requirements of GMO-free production, the facility (including a livestock farm) can be granted a certificate with the text *“GMO-free production certified by (name of the Certification Body) is carried out in the facility”* in order to establish a GMO-free product chain for the purpose of assisting producers and users.

7. The rules of certification

In certifying the Trademark, the requirements shall apply to prepacked and non-prepacked foods intended for the final consumers, to feed or feed materials and to the facility (including a livestock farm) alike. The certification itself always applies to the product intended to be labelled as “GMO-free” in a given facility (including livestock farms). If the production of a product is transferred to another facility, site, plant or production line, the certification will become invalid.

The main steps of the process of application for the use of the Trademark, the certification and the follow-up audit are shown in Flowchart 1. The entire process and the types of audits are presented below. For the details of audit procedures, see Point 7.3.


Application for the use of the Trademark and certification process
Applicant /Application
Application for the use of the Trademark from the Certification Body (CB)
Sending the application form to the a gmo@elbc.hu
Preliminary Audit Contract (1.) with the CB
Preliminary audit
facultative
CB's preliminary checking
CB's proposals to the possible deficiencies
Certification Contract (2.) with the CB
Certification audit
Check all risk classifications
Check whether the product + facility comply with the requirements
Determine the frequency of review audits
Qualification „A"
Qualification „B"
Qualification „C"
Qualification „X"
Deficiencies – corrective measures
Granting the Trademark
Successfull audit
Certification follow-up audit
No successfull certification audit
Qualification „A"
Trademark Use Contract (3.) with the CB
User / Use of the Trademark
Review audit
Review all risk classifications
Check whether the product + facility comply with the requirements
Modify the frequency of review audits
Qualification „A"
Qualification „B"
Qualification „C"
Qualification „X"
Deficiencies – corrective measures
Successfull review audit
Review follow-up audit
Revoking the Trademark license
Renewal of the Trademark license
Qualification „A"
Survey
Inspections of subdivisons
Qualification „A"
Qualification „B"
Qualification „C"
Qualification „X"
Deficiencies – corrective measures
Successfull survey
Follow-up survey
Revoking the Trademark license
Qualification „A"

1. Flowchart

7.1. The certification process

Certification is based on risk-based inspections (see Chapter 9). In a certification audit, the products and the producers and/or facilities are classified in risk categories based on their type. The type, scope and frequency of inspections are determined based on such classification by taking into account the principle that low-risk facilities require less frequent inspections than sites with higher risk.

7.1.1. Preliminary audit

The Applicant may request the Certification Body to conduct a preliminary audit. The preliminary audit shall take place following conclusion of a Preliminary Audit Contract with the Certification Body. During the audit, the Certification Body shall assess the facilities of the business to ascertain compliance thereof with the provisions of the Decree and the Trademark Regulation. A report shall be made of the audit, based on which the business shall find out about what deficiencies it needs to address in order to successfully pass a certification audit.

7.1.2. Certification audit

The certification audit shall take place after application for Trademark use (see Points 8.1.1 and 8.1.2) and conclusion of a Certification Contract with the Certification Body (see Point 8.1.4). During the certification audit, the inspectors of the Certification Body shall:

- perform all necessary risk classifications (see Chapter 9),
- check whether the product and the facility comply with all the requirements of the Decree and the Trademark Regulation, and
- determine the frequency of review audits.

The certification audit shall be successful if all requirements are fully met, i.e. are met with qualification "A".

In the case of qualification "B", the deficiencies found by the Certification Body may be remedied by means of subsequently submitting the relevant supporting documents by the deadline set by the Certification Body. If the Certification Body decides that the Applicant has adequately addressed the deficiencies, the certification audit shall be deemed successful.

In the case of qualification "C", the Certification Body shall identify the deficiencies that the Applicant must address for a successful audit and shall set a deadline for doing so. In the case of qualification "C", an on-site or office-based certification follow-up audit is possible in order to verify that the deficiencies have been rectified.

In case of qualification "X", the Applicant shall not be granted the right to use the Trademark.

7.1.3. Certification follow-up audit

In the case of qualification "C" obtained during the certification audit, a certification follow-up audit may be carried out, during which the Certification Body re-examines the corrective measures taken by the Applicant to eliminate the deficiencies uncovered during the certification audit. Depending on the nature of the corrective measures, the Certification Body decides whether an on-site or office-based follow-up audit shall take place. If the Applicant successfully passes the certification follow-up audit, i.e. with qualification "A", it shall be deemed a successful certification audit.

7.1.4. Granting the Trademark

If the Applicant successfully passes the certification audit (see Point 8.1.5), the Applicant shall enter into a Trademark Use Contract with the Certification Body (see clause 8.1.5). Use of the Trademark may only begin upon conclusion of the contract. Having been granted the Trademark, the Applicant shall become a User. After conclusion of the contract, it may affix the Trademark to the certified product produced in the certified facility and use it in its communication as specified in Point 8.1.7.

In case of certification of feed or feed materials or a facility (including livestock farms), if the Applicant successfully passes the certification audit it shall be issued a certificate specified in Points 6.3 and 6.4.

7.1.5. Review audit

The use of the trademark shall be reviewed from time to time, which is served by the review audit. The frequency of the review audits *(Table 1)* depends on the risk category classifications. The certification audit and the review audit have the same procedure and content but their evaluation is different. During the review audit, the inspectors of the Certification Body shall repeatedly:

- perform the revision of all necessary risk classifications (see Chapter 9);
- check whether the product and the facility comply with all the requirements of the Decree and the Trademark Regulation; and
- modify the frequency of review audits accordingly.

The certification audit is successful if all requirements are fully met, i.e. are met with the qualification "A".

In the case of qualification "B", the deficiencies found by the Certification Body may be remedied by means of subsequently submitting the relevant supporting documents by the deadline set by the Certification Body. If the Certification Body decides that the Applicant has adequately addressed the deficiencies, the review audit shall be deemed successful.

In the case of qualification "C", the Certification Body shall identify the deficiencies that the Applicant must address for a successful review audit and shall set a deadline for doing so. In the

case of qualification “C”, an on-site or office-based review follow-up audit is possible in order to verify that the deficiencies have been rectified.

If the User receives an “X” qualification in the review audit, the use of the trademark shall be revoked (see Point 7.1.11.1).

Risk category of the facility	Frequency of review audits
Minimum-risk facility (0)	every three years
Low-risk facility (1)	every two years
Medium-risk facility (2)	yearly
High-risk facility (3)	every six months

Table 1: Frequency of review audits

If various activities classified into different risk categories are performed within the same facility, the highest category shall be taken into consideration for determining the frequency of the review audit.

7.1.6. Review follow-up audit

In the case of qualification “C” obtained during the review audit, a review follow-up audit may be carried out, during which the Certification Body re-examines the corrective measures taken by the Applicant to eliminate the deficiencies uncovered during the review audit. Depending on the nature of the corrective measures, the Certification Body decides whether an on-site or office-based follow-up audit shall take place. If the Applicant successfully passes the review follow-up audit, i.e. with qualification “A”, it shall be deemed a successful review audit.

7.1.7. Renewal of the trademark license

If the User has passed the review audit successfully, it can continue using the Trademark.

7.1.8. Survey

A survey is a random inspection. The Certification Body may conduct a survey at the facility without prior notice at any time to check whether the requirements included in the Decree and Trademark Regulation are complied with. The frequency of the survey shall depend on the risk

category of the facility. In the case of a high-risk facility surveys shall be held at least six monthly and in the case of facilities in other risk categories at least annually. A survey typically covers one or more subdivisions. A report is made of the survey. During a survey the same requirements shall be inspected as during the audits.

A survey will be successful if all requirements are met with the qualification “A”.

In the case of qualification “B”, the deficiencies found by the Certification Body may be remedied by means of subsequently submitting the relevant supporting documents by the deadline set by the Certification Body. If the Certification Body decides that the Applicant has adequately addressed the deficiencies, the survey shall be deemed successful.

In the case of qualification “C”, the Certification Body shall identify the deficiencies that the Applicant must address and shall set a deadline for doing so. In the case of qualification “C”, an on-site or office-based follow-up survey is possible in order to verify that the deficiencies have been rectified.

7.1.9. Follow-up survey

In the case of qualification “C” obtained during the survey, a certification follow-up survey may be carried out, during which the Certification Body re-examines the corrective measures taken by the Applicant to eliminate the deficiencies uncovered during the survey. Depending on the nature of the corrective measures, the Certification Body decides whether an on-site or office-based follow-up survey shall take place. If the Applicant successfully passes the survey, i.e. with qualification “A”, it shall be deemed a successful survey.

7.1.10. Scope extension audit

If during the validity period of the certification the User wishes to have new product groups, processes or production lines certified in addition to the already certified processes, it can request a scope extension certification audit whereby the Certification Body shall examine the product group, process or production line for compliance with the provisions of the Decree and the Trademark Regulation.

The scope extension audit shall take place following conclusion of a Scope Extension Certification Contract with the Certification Body.

The process and outcome of the scope extension audit shall be similar to that of a certification audit.

The Certification Body shall determine whether a full inspection should be performed or only the fulfilment of specified requirements should be inspected.

If the scope extension audit is successful, the original Trademark Use Agreement shall be amended.

7.1.11. Revoking the trademark license

The trademark license may be revoked in two ways.

7.1.11.1. At the initiative of the Certification Body

If the User has been given the qualification "X" at a review audit or the User has repeatedly breached the provisions of the Trademark Regulation or the trademark use agreement, the Certification Body may suspend or revoke the trademark license and terminate the trademark use agreement.

7.1.11.2. At the initiative of the User

If the User decides not to continue to use the Trademark on its product, it shall officially inform the Certification Body thereof. The obligations related to using the Trademark shall remain binding as long as there is a contractual relationship between the User and the Certification Body.

7.2. Procedures of different types of inspections

The audits, follow-up audits, the survey and the follow-up survey shall be carried out by at least two auditors. A survey and the follow-up survey typically mean the inspection of sub-divisions and therefore their scope can be reduced compared to the following description.

7.2.1. Introductory meeting

At the introductory meeting, the areas covered by and the scope of the audit shall be determined, the audit procedure presented, declarations made about the independence of the audit and about privacy, the basic questions related to the audit procedure clarified by each party, the duration of the audit determined, and actions to be taken in relation to non-compliances, if any, explained.

7.2.2. Visiting the facility

As part of visiting the facility, the production areas and premises are viewed, the employees are interviewed, compliance with the requirements applicable to the system is checked (with special focus on the separate handling of the source materials, identification of contamination risks, etc.) and samples are taken.

7.2.3. Checking the documents

When checking the documents, the relevant documents (organisational chart, quality management system, delivery notes) of the facility/undertaking are inspected, compliance with the requirements related to the system is checked (statements related to the source materials, self-monitoring system, etc.) and material flows (traceability) are also checked.

7.2.4. Preparing minutes

On-site audit minutes shall contain only the fact that an audit is made and the subject matter thereof. The detailed findings are summarised by the Certification Body in a written report.

7.2.5. Closing meeting

The final discussion will include a summary of the findings, clarification of non-conformities, determination of corrective measures and deadlines and closure of the audit minutes.

7.2.6. Evaluation - written report

The auditors evaluate the fulfilment of production requirements under the laws and this Trademark Regulation related to GMO-free production and the observance thereof. In doing so, the fulfilment of each requirement is classified in accordance with different qualification levels *(Table 2)*. A list of GMO-free production laws and requirements under this Trademark Regulation is contained in *Annex 1*.

If the requirements are not fulfilled in full (qualifications "B" or "C"), during inspections, an explanation shall be added to the minutes for the Applicant/User as to what corrective actions need to be taken by it.

Qualification	Description
A	Fully satisfies the requirements.
B	Slight deviation from the requirements.
C	Moderate deviation from the requirements.
N.A.	Not applicable (to be justified)
X*	Significant deviation from the requirements or the level of risk is not manageable or the legal requirements are not met.

Table 2: Levels of qualification

* The following deviations shall have qualification "X":

- The self-monitoring system is inadequate.
- The follow-up system is incomplete.

- The employees do not know their responsibilities.
- The processing processes are not adequately isolated (in space and/or time).
- Storage is not strictly isolated.
- Genetically modified organisms demonstrably occurred on the production area, though technically this could have been avoided.

7.3. Verification obligation

The verification obligation related to the GMO-free nature of foods or food ingredients bearing the Trademark applies to the entity placing the product on the market. If the Trademark is to be put on a pre-packaged product and the entity placing it on the market is only involved in trading the product, then the requirements shall pass on to the producer of the product.

If the food bearing the Trademark or any ingredient thereof is of animal origin, then the verification requirements shall apply to forage, keeping live animals and to all interim phases up to food production.

8. Conditions for using the GMO-free food trademark

8.1. General conditions

8.1.1. The use of the Trademark can be applied for with the Certification Body by any natural or legal person (see Point 4) that owns the food and has the necessary official licences for its activities.

8.1.2. The Applicant may apply for the use of the Trademark by completing the application form that can be downloaded from the website of the Certification Body and then sending it to the gmo@elbc.hu website in electronic format.

8.1.3. Following the application, if the Applicant so requests, it concludes a Preliminary Certification Agreement with the Certification Body, which contains the detailed rules of the preliminary audit. During the preliminary audit, the inspectors of the Certification Body shall carry out a preliminary assessment. The Certification Body shall notify the Applicant of the findings.

8.1.4. After submission of the application, the Certification Body shall enter into a Certification Agreement with the Applicant containing the detailed rules of the certification process and trademark use.

8.1.5. The precondition for indicating, i.e. using the Trademark on the product is to be compliant during the certification process conducted by the Certification Body.

8.1.6. If the Applicant has passed the certification procedure, the Certification Body shall enter into a Trademark Use Agreement with the Applicant containing the detailed rules of trademark use. Having been granted the Trademark, the applicant shall become a User. The User shall only be entitled to use the Trademark under the conditions specified in the agreement. As from the conclusion of the contract, the User may affix the Trademark to the certified product manufactured in the certified facility.

8.1.7. The User may use the Trademark only on products certified by the Certification Body. The User may use the Trademark in order distinguish its goods as specified in the Corporate Identity Manual. The Trademark may be used as a label on the packaging of the product, as a visual element of the corporate identity in the User’s business premises, in advertisements and marketing documents about the User’s activities, including teleshopping, online and offline advertising and marketing materials about the User’s products. When using it as an element of corporate identity in business premises, it has to be made clear which product or product group inside the business premise the Trademark applies to. Communication may not suggest that all the products in the entire business premise are GMO-free, if products not having a Trademark are also sold in such business premise. The User is not entitled to suggest that the Trademark is its own property, to assign the utilisation of the Trademark to third parties and to use it on its products that are unverified or are classified into a product class that differs from the one included in the agreement. The Certification Body shall regularly check the utilisation of the Trademark by the User.

8.1.8. The User shall pay a user charge as determined in the pricing conditions of the Certification Body. For more information on tariffs see the website of the Certification Body. The Certification Body shall keep separate records of the user charge and use the user charge primarily for the improvement of the Trademark and activities aimed at the wider popularization of the Trademark.

8.1.9. The User and the Certification Body shall promptly inform each other of any fact or circumstance that they become aware of and which may undermine the interests of either of the parties. Such are for example the unauthorised use of the Trademark and the tarnishing of the good reputation of the Trademark. In such cases the Certification Body shall act *ex officio*.

8.1.10. The User and the Certification Body may make a proposal to the Trademark Holder for improving the trademark and the Trademark Regulation. The accepted modifications shall be made available to the User by the Certification Body without requiring any additional payment.

8.2. Special requirements applicable to facilities

8.2.1. Description of the facility

The facility shall have a facility description containing the following information:

- Product sheets of all raw materials, source materials and feeds, as well as additives, enzymes, flavours and processing aids produced, stored, transported and treated in the facility.
- List of suppliers.
- List, name and description of production lines.
- List of sub-contractors/toll manufacturers involved in the GMO-free production process, together with their roles and the description of their activities. These undertakings shall engage in the certification process by means of a contract.
- The manufacturing formulas/formulas of the products labelled or intended to be labelled with the Trademark bearing also the names of the responsible persons approving the formulas or formula modifications.
- The presentation of all premises, manufacturing sites and production lines, including also the outsourced manufacturing processes where appropriate.

The description of the facility shall take into consideration in particular the (potential) points of entry of GM feeds, feed materials and food materials.

If both, foods intended to be labelled with the Trademark and traditional food are produced or stored in the facility, a schematic drawing of the facility shall also be drawn up where the separation of the production processes of the two types of foods, or, if separation is only in time, the points where cross-contamination may occur, are indicated.

If in addition to non-genetically modified feed, genetically modified feed are also produced, stored, processed or used in the same facility, a schematic drawing of the plant shall also be drawn up indicating clearly the location of all stables and pens, including all animal species and

stable locations, feed storage locations and equipment used for producing and processing feed (mixers, equipment stores, feeding equipment, etc.), including also all equipments not directly located on the premise.

8.2.2. Regulating responsibilities in the facility; organisational structure

The facility shall have a description of the structure of the plant, an organisational chart containing the responsibilities and the deputation rules. Records shall be kept of all persons (including, for example, auxiliary workers, trainees, contract workers) working in the establishment. The register of employees shall allow identifying persons who are responsible for the production of the product that intends to be labelled or is labelled with the Trademark. The employees shall carry out their activities in accordance with their jobs and shall be familiar with their related responsibilities and obligations.

8.2.3. Self-monitoring system

The most important goal of the self-monitoring system of the facility is to ensure separate handling, processing and monitoring of GM and non-GM source materials and also to prevent any contamination by genetically modified organisms. A risk analysis shall be carried out and preventive measures put in place to ensure no legitimate labelling obligation exists under Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 and that GMO contamination of food intended for the final consumer does not exceed the levels laid down in the Decree.

The relevant manufacturing formula and specifications of all end products labelled or intended to be labelled with the Trademark shall be available in the facility.

The registers signed and dated shall be clearly legible. The registers shall be kept in a way to exclude the probability of subsequent modifications. Product documentation shall be safeguarded as required by law.

On the basis of the risk assessment made in the framework of self-monitoring, the facility shall draw up a laboratory testing plan containing the sampling plan and establishing the procedure in case of a positive test result.

Through the regular checking of the implemented system, the facility shall continue to reduce the frequency of contaminations by GM materials. To this end, the facility shall implement actions to eliminate the sources of adventitious and technically unavoidable contaminations with genetically modified materials and to reduce the introduction of such materials to the minimum. The effectiveness of the actions implemented shall be regularly checked by the plant.

8.2.4. The training of employees

All employees involved in the operation of the facility shall undergo training about the requirements of the GMO-free system and the related business processes prior to switching to GMO-free production and, after that, at least once a year and new recruits shall receive the same training before taking up work. Training documentation shall cover the contents, the name of the participants, the place of training and the name of instructors.

8.3. Traceability

8.3.1. Monitoring system

A monitoring system is in use in the facility that ensures the immediate and unambiguous identification of all products that are intended to be labelled or are labelled with the Trademark, feeds or feed materials to be used in GMO-free production, and live animals given feeds to be used in GMO-free production. Products that have already left the plant shall be traceable within one business day. The system shall be suitable for making such quantitative reports and evaluations that allow for drawing conclusions related to the flows of goods and their pertinence.

8.3.2. Checking the acceptance of goods

Upon acceptance of goods, the documents of the product shall be checked. This documentation may include:

- a separate declaration of GMO-free status for the consignment in question,
- a certificate issued by the certification body,
- laboratory test results,
- additional remarks on the delivery note, or
- contractual arrangements for the supply of GMO-free products,

which can prove GMO-free status.

8.3.3. Separation of the flows of goods, exclusion of technically avoidable mixing

GMO-free production and traditional production shall be separated. Such separation can be done in space or in time. Concurrent production may only be done if there is separation in space.

If separation is in time, relevant actions shall be in place to ensure that cross-contamination with genetically modified materials is reduced to the technically unavoidable minimum. Such actions can be in particular: storing the materials used for the production of trademarked products in a separate and marked place, providing the tools used for their preparation with a permanent mark as to their use, making the trademarked products in separate shifts or at the beginning of the same shift, cleaning, disinfection of the shared equipment and production lines, training the employees. These actions need to be documented and their performance shall be recorded.

For foods of animal origin, food producers shall ensure that traditional and GMO-free products are demonstrably separated.

In the case of feed and feed materials used in GMO-free production, in order to assess whether the presence of GM organisms is to be deemed technically unavoidable or accidental, it is necessary to examine the criteria set out in Point 8.5.

8.3.4. Livestock records and compliance with transition periods and animal feeding requirements

Each individual of each animal species kept in the facility for the purposes of food production shall be recorded. In addition, it shall be determined whether these animals are fed in compliance with the rules of GMO-free production. Live animals no longer to be found at the plant shall be traceable within one business day.

If further animals are purchased, the transition periods stipulated in the Decree shall be taken into special account and complied with. Based thereon,

a) for bovine animals, sheep and goats
   - at least three months before the milk to be labelled is drawn,
   - 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
   - at least six weeks prior to the production of the eggs to be labelled,
   - for the meat to be labelled, at least three months prior to slaughter;
d) for turkeys, at least three months prior to slaughter.

The procedure ensuring transition periods shall be properly documented. Upon the purchase of animals, whether the transition period was kept can be proven if the former owner is also engaged in certified GMO-free production.

The feed ratios shall be listed for each animal species included in the livestock records. For this, a separate record shall be drawn up for each animal species. If different ratios are applied for the different animal species, for example based on their life stage or the season, such ratios shall be recorded separately.

The feed ingredients shall be precisely named and if compound feeds are used, the exact type and manufacturer shall be provided. The original or a copy of the documents proving usability in GMO-free production shall be kept together with the description of the feed ratios.

Agricultural holdings shall maintain a feed register containing the place of origin, quantity and consumption of the feed used, as well as the time when it was used and the purpose it was used for. The feed register shall be kept updated.

8.3.5. Special requirements applicable to apiaries

Apiaries, as well as keeping and feeding bees shall be governed by the general requirements applicable to livestock, livestock farming and feeding livestock.

The apiculture product intended to be labelled with the Trademark shall come from a hive that had satisfied the following conditions for at least one year prior to the extraction of the apiculture product:

- within a 5.5 km radius of the hive, the nectar and pollen sources are from non-GM plants,

- the feed of bees does not contain genetically modified organisms or ingredients produced from genetically modified organisms.

The special documentation related to apiculture (a copy of the notification given to the municipal clerk) shall be available.

8.4. Complaint and recall management

Complaints related to the absence of GMOs from clients or other entities (authorities), as well as the deviations within the self-monitoring system shall be documented and properly evaluated. In the course of this, relevant corrective actions shall be implemented.

In case deviations are found concerning products already on the market, a product recall system shall be put in place which shall also make the information of clients possible. During the inspection, the inspector shall have the opportunity to inspect the recall system through a sample.

8.5. Managing contaminations

Under the Decree, food of plant origin may be labelled with the Trademark only if the occurrence of contamination is adventitious or technically unavoidable, the GMO causing the contamination is authorized to be marketed in the European Union and the level of contamination does not exceed 0.1%. In the case of food consisting of multiple ingredients, the limit value shall apply to the individual ingredients.

Under the Decree, feed may only be used in GMO-free production if the contamination is adventitious or technically unavoidable, the GMO causing the contamination is authorized to be marketed in the European Union and the level of contamination does not exceed 0.9%.

It shall be proven whether the Applicant took the necessary steps to prevent any contamination with feeds containing genetically modified organisms.

To decide whether the presence of GM materials is technically unavoidable or adventitious, the following aspects need to be checked:

- Does the facility have a contractual agreement with the supplier related to the prevention of the occurrence of genetically modified organisms?
- Are appropriate actions taken in the plant in order to isolate, in space and/or time, the processes containing GM organisms from those not containing GM organisms?
- In the case of products imported from third countries where the labelling obligations under EU law do not apply, were the relevant actions taken by the facility to avoid GM organisms (contract, certificate, laboratory test results, sampling plans, etc.)?
- How often do GM organisms occur below 0.9%?

Special attention shall be paid during the standard quantitative laboratory testing of raw plant materials and feed ingredients that the GMO content shall be determined for each plant species. Consequently, even the slightest contamination of a non-genetically modified plant with

genetically modified organisms (e.g. pollen from pollination) may influence the test results and lead to unfounded non-conformity or refusal.

9. Monitoring the conditions of trademark use

Inspection is based on the risk classification of food and food materials and ingredients, feed and feed materials, the facility and the production process, for which this chapter provides criteria.

9.1. Risk classification of the ingredients

With regard to food materials ingredients, difference is made between risk-free and risky materials in trademark certification.

9.1.1. Risk-free ingredients

Risk-free ingredients are ingredients that are not suitable for genetic modification by nature, such as minerals; substances from non-genetically modified plants or plants that currently do not have known genetically modified varieties in the world.

9.1.2. Risky ingredients

- Ingredients of plant origin whose genetically modified varieties are approved in the European Union (e.g. maize, soybean, cotton, rapeseed, sugar beet).
- Ingredients of plant origin whose genetically modified varieties are not approved in the European Union but are included in the Rapid Alert System for Food and Feed (RASFF) of the European Union (e.g. rice, papaya, wheat, flax).
  Website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
- Ingredients of animal origin.
- Enzymes, additives.

9.2. Risk classification of facilities and activities

The following risk categories and the monitoring established based on such categories apply to the Users, the facilities and the activities.

With plant growing facilities in Hungary, the risk of contamination with GM substances is minimal (Risk category 0), in view of the fact no cultivation of any kind of genetically modified plant variety/hybrid is authorised in Hungary according to the legislation in force.

The risk classification of facilities and activities is shown in *Table 2* below.

		Agricultural production Livestock farming[1]	Processing		Trading, storage, transportation (collectively: process) [4]
			Feed production[2]	Food production[3]	
Risk category	0 (minimum-risk facility)	If the feed(s) or feed material(s) used for animal feed and stored in the facility is (are) **exclusively** of a kind(s) - of which no GM variety exists, OR - of which a GM variety exists but is not approved for cultivation or marketing in Hungary and in the country of origin of the given feed or feed ingredient, OR - which can be used in GMO-free production as certified by an independent accredited certification body. * The issue of separation is not relevant because GM feed or GM feed materials cannot be used to feed animals.	If the feed(s) or feed material(s) stored in the facility is (are) **exclusively** of a kind(s) - of which no GM variety exists, OR - of which a GM variety exists but is not approved for cultivation or marketing in Hungary and in the country of origin of the given feed or feed ingredient, OR - in whose case the plant materials used can be used in GMO-free production as certified by an independent accredited certification body. * The issue of separation is not relevant because GM feed or GM feed materials cannot be manufactured in the facility.	If **exclusively*** raw a material(s) is/are used, processed: - which is (are) (a) non-risky material(s) (Chapter 9.1.1), OR - which is (are) (a) risky material and has GM variety which, however, is not given marketing authorisation in their country of origin or in Hungary, OR - whose GMO-free status has been certified by an independent accredited certification body * The issue of separation is not relevant because GM food or GM food materials cannot be manufactured in the facility.	If the process **exclusively*** involves the following materials: - risk-free materials, OR - risky materials of plant origin, whose GM variety cannot be marketed in Hungary, OR - feed(s) that can be used in GMO-free production, OR - materials that be used in GMO-free production as certified by an independent accredited certification body. * The issue of separation is not relevant because GM food/feed is not affected by the process.
	1 (low-risk facility)	If the feed(s) or feed material(s) used for animal feed and stored in the facility is (are) **exclusively*** of a kind(s) - that come(s) from a country where the GM variety of the given plant is grown but comes from GMO-free production AND - this fact is clearly shown in the purchase documentation. * The issue of separation is not relevant because GM feed or GM feed materials cannot be used in the facility.	If the manufacturing of GM feed and feed that can be used in GMO-free production: - takes place in premises separated from each other AND - appropriate measures are in place in order to minimize the mixing of GM feed with feed that can be used in GMO-free production.	1. If the plant ingredients falling in the category of risky materials, processed and used in the facility are required to be labelled under Regulation (EC) 1829/2003. OR 2. If in the facility: - there is processing of plant raw materials belonging to the category of risky materials that are required to be labelled under Regulation (EC) 1829/2003, AND - the place of processing is adequately separated from the place of GMO-free production, AND - contamination can be prevented.	If in the facility: - there is also storage or transportation of GM organisms AND - this takes place in premises separated from each other AND - appropriate measures are in place to avoid contamination.

Table 2

[1] Upon the risk classification of facilities engaged in livestock farming or apiculture, only **the entire facility, the plant or a totally separated unit can be certified**. The classification aspects shall be checked for each product of animal origin used as ingredient of the product labelled by the Trademark and the classification shall be carried out.

[2] The classification applies to fixed and mobile feed-mills. If there are no separate delivery points in the facility for receiving ingredients that can be used in GMO-free production and GM ingredients or the rate or volume of GMO-free production is smaller than that of traditional production, the frequency of surveys and sampling shall be increased.

[3] Sample shall be taken from risky materials of plant origin based on the approved sampling plan. The Certification Body may require further sampling.

[4] **This column applies to products that are stored and transported in bulk, non-packaged, in open packaging or easily damaged packaging.** The storage and transportation processes of the feeds used and GMO-free foods shall be checked based on the approved sampling plan. Sample shall be taken from risky materials of plant origin at the place of storage and in the transportation vehicle based on the approved sampling plan. The Certification Body may require further sampling.

		Agricultural production Livestock farming[5]	Processing		Trading, storage, transportation [8]
			Feed production[6]	Food production[7]	
Risk category	2 (medium-risk facility)	If the feeding of animals, mixing, storage and transportation take place close to each other within the facility AND - the chances of mixing different feeds are high AND - appropriate measures are in place in order to minimize the mixing of GM feed with feed that can be used in GMO-free production.	If the manufacturing of GM feed and feed that can be used in GMO-free production: - takes place in premises not separated from each other AND - appropriate measures are in place in order to minimize the mixing of GM feed with feed that can be used in GMO-free production.-.	If in the facility: - there is processing of plant raw materials belonging to the category of risky materials that are required to be labelled under Regulation (EC) 1829/2003, AND/OR - raw materials of animal origin coming from non-GMO-free production AND - appropriate measures are in place in order to minimize the chances of mixing.	If in the facility: - there is also storage or transportation of GM organisms AND - storage and transportation take place not separated from each other AND - appropriate measures are in place to avoid contamination.
	3 (high-risk facility)	If GM feed and feed that can be used in GMO-free production: - have a high probability of mixing AND - no appropriate measures are in place to prevent mixing. **High risk facilities cannot be certified.**	If GM feed manufactured in the facility and feed that can be used in GMO-free production: - has a high probability of mixing AND - no appropriate measures are in place to prevent mixing. **High risk facilities cannot be certified.**	If in the facility: - there is processing of plant raw materials belonging to the category of risky materials that are required to be labelled under Regulation (EC) 1829/2003, AND/OR - raw materials of animal origin coming from non-GMO-free production AND - no measures are taken to prevent mixing. **High risk facilities cannot be certified.**	If in the facility: - there is also storage or transportation of GM organisms AND - there is a high probability of mixing AND - appropriate measures are not in place to avoid contamination. **High risk facilities cannot be certified.**

Table 2

[5] Upon the risk classification of facilities engaged in livestock farming or apiculture, only **the entire facility, the plant or a totally separated unit can be certified**. The classification aspects shall be checked for each product of animal origin used as ingredient of the product labelled by the Trademark and the classification shall be carried out.

[6] The classification applies to fixed and mobile feed-mills. If there are no separate delivery points in the facility for receiving ingredients that can be used in GMO-free production and GM ingredients or the rate or volume of GMO-free production is smaller than that of traditional production, the frequency of surveys and sampling shall be increased.

[7] Sample shall be taken from risky materials of plant origin based on the approved sampling plan. The Certification Body may require further sampling.

[8] **This column applies to products that are stored and transported in bulk, non-packaged, in open packaging or easily damaged packaging.** The storage and transportation processes of the feeds used and GMO-free foods shall be checked based on the approved sampling plan. Sample shall be taken from risky materials of plant origin at the place of storage and in the transportation vehicle based on the approved sampling plan. The Certification Body may require further sampling.

Apiculture is considered to be of medium risk if the hives are nearer than 5.5 km to the national border and GMO cultivation is allowed in that neighbouring country.

9.3. Sampling frequency

Within the framework of the self-monitoring system the User shall take samples, based on the risk classification, from ingredients, additives, enzymes, flavours and processing aids intended to be used where the laboratory testing of GMO content is technically detectable (products of plant origin that have genetically modified varieties). The test results obtained within the framework of the self-monitoring system shall be made available to the auditor upon request.

Samples shall be taken in compliance with the sampling guide of the National Food Chain Safety Office applicable to genetically modified organisms. Samples shall be taken by the supplier and the receiving party together and a record shall be taken of the sampling.

Samples shall primarily be taken from compound feeds, risky feed ingredients and risky food ingredients of plant origin. The sampling frequency shall be as follows (Tables 3 and 4).

Feed			
Area / Risk category	Risky plant ingredients	Feed manufacturer (Feed mix)	Storage, transportation
0	Random sampling	1 / 10.000 t	Random sampling
1	1 / 10.000 t	1 / 2.000 t at least 6 times a year	1 / 10.000 t
2.3	1 / 10.000 t	1 / 2.000 t at least 6 times a year	1 / 10.000 t

Table 4: Sampling frequency of feed

Food			
Area / Risk category	Risk-free plant ingredients	Risky plant ingredients	Processed product
0	Once a year	Each purchase	Once a year
1	Once a year	Each purchase	3 times a year
2.3	Once a year	Each purchase	6 times a year

Table 4: Sampling frequency of food

Auditors may take samples during the certification audit, the review audit and the survey while taking into account the risk classification and may send such samples for laboratory testing.

10. Procedure in case of unauthorised trademark use

The Trademark Holder and the Certification Body are entitled to act in cases of unauthorised trademark use. The Trademark Holder and the Certification Body shall do their best to terminate unauthorised trademark use and to enforce any and all legal and property-related consequences arising therefrom. The User shall inform the Trademark Holder and the Certification Body, orally or in writing, upon becoming aware of any unauthorised trademark use.

In the case of unauthorised trademark use, the Trademark Holder shall act as provided in Act XI of 1997 on the Protection of Trademarks and Geographical Indications.

11. Improving the trademark and its good reputation

The Working Group set up by the Trademark Holder and involving also the members of the Certification Body shall draw up a plan for the promotion of the certification trademark and the improvement of its good reputation. Such plan shall focus on campaigns that allow for the introduction of the certification trademark to consumers and producers, as well as for increasing its publicity and improving its good reputation. Trademark users eligible under the Trademark Use Agreement may participate in the campaign.

Annex 1 List of requirements

The following list of requirements shall serve as an aid containing the requirements of the Decree and the Trademark Regulation. Its purpose is to provide help for the evaluation detailed in Section 7.3.6. The User shall comply with the provisions of the Decree and the Trademark Regulation. The individual requirements in the list below shall be interpreted in conjunction with other requirements of the Decree and the Trademark Regulation.

Part A of the Annex contains the requirements laid down in the Decree whose evaluation can be yes/no/not applicable.

Part B of the Annex contains the more detailed requirements set out in the Trademark Regulation whose qualification can be A/B/C/N.R./X, based on *Table 2* of the Trademark Regulation.

	Requirements	Qualification (yes, no, not applicable)
Part A: Based on the Decree		
1.	The GM variety of a *single-ingredient* ***product*** *of plant origin that can be used in GMO-free production* was or is subject to an authorisation for cultivation or palcing on the market in the European Union [Article 3 (1) of the Decree].	
2.	The *meat, eggs and fish or processed foodstuffs produced from these,* labelled or is intended to be labelled with the Trademark, originate from an animal that can be traceable in its nutrition [Article 3 (3) a) of the Decree]	
3.	The ***foodstuff*** that is intended to be or is labelled with the Trademark is not subject to the labelling requirements pursuant to Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 [Article 3 (3) b) of the Decree].	
4.	The food additive, processing aid or enzyme used for the production of the ***foodstuff*** that is intended to be or is labelled with a Trademark may be used for producing organic feed or food pursuant to Regulation (EC) 834/2007 and Regulation (EC) 889/2008 [Article 3 (5) a)-b)].	
5.	The ***food*** of *plant origin* labelled or intended to be labelled with a Trademark contains no more than 0.1% genetically modified organism having authorisation for placing on the market in the European Union and its presence is adventitious or technically unavoidable[Article 4 (1)].	
6.	The ***feed*** *can be used in GMO-free production, i.e*. it contains no more than 0.9% genetically modified organism having authorisation for placing on the market in the European Union and its presence is adventitious or technically unavoidable [Article 2 (1) d) of the Decree].	
7.	The requirements and transition periods related to feeding animals are complied with during manufacturing [Article 4 (1) of the Decree].	

8.	The ***apiculture product*** that is intended to be or is labelled with a Trademark originates from a hive in whose surrounding of a diameter of 5.5 km radius, the vegetation serving as the source of nectar and pollen has, at least in the preceding one year, consisted of non-GMO plants [Article 6 a) of the Decree]-	
9.	The ***apiculture product*** that is intended to be or is labelled with a Trademark originates from a hive where bees were given feed that can be used in GMO-free production [Article 6 b) of the Decree].	

	Requirements	Qualification (A/B/C/N.A./X)
Part A: Pursuant to the Trademark Regulation ***In accordance with Point 8.2. (by completing the relevant part)***		
1.	The description of the facility is available in the facility.	
2.	The description of the facility contains	
	• the names and the product sheets of all raw materials, source materials and feeds, as well as additives, enzymes, flavours and processing aids produced, stored, transported and treated in the facility.	
	• the list of suppliers.	
	• the list, name and description of production lines.	
	• the list of sub-contractors/toll manufacturers involved in the GMO-free production process, together with their roles and the description of their activities.	
	• the manufacturing sheets/formulas of the products are labelled or intended to be labelled with the Trademark/or can be used in the GMO-free production, bearing also the names of the responsible persons approving the formulas or formula modifications.	
	• the presentation of all premises, manufacturing sites and production lines, including also the outsourced manufacturing processes, where appropriate.	
	• the (potential) entry points of GM feeds, feed materials and food ingredients.	
3.	In the event of manufacturing and storing foodstuffs intended to be labelled with the Trademark and traditional foodstuffs in the same facility, the schematic drawing of the facility is available.	
4.	In the event of manufacturing, storing, processing or using non-GM and GM feed in the same facility, the schematic drawing of the facility is available.	
5.	The description of the plant structure is available in the facility.	

6.	The organisational chart contains the responsibilities and the deputation rules.	
7.	The register of employees is comprehensive.	
8.	The register of employees allows establishing who are responsible for the production of the product labelled or to be labelled with the Trademark/to be used in GMO-free production.	
9.	The employees know their responsibilities.	
10.	A self-monitoring system is in place in the facility.	
11.	The registers are legible and authentic.	
12.	Subsequent modifications of the registers can be excluded.	
13.	Storing the product documentation in compliance with the statutory requirements is taken care of.	
14.	The facility has a laboratory testing plan developed based on the risk assessment.	
15.	The facility has a procedure in place in case of a positive laboratory test result.	
16.	The facility has a sampling plan relating to GM organisms.	
17.	The facility has an action plan for preventing the origins of adventitious or technically unavoidable contaminations with GM organisms.	
18.	The facility regularly monitors the effectiveness of actions implemented to ensure the absence of GMOs.	
19.	Those working in the facility regularly receive training about the requirements of the GMO-free system and the related operating processes.	
20.	Training is documented.	
21.	The training documentation indicates the contents, the names of the participants, the date and place of training and the names of instructors.	
In accordance with Point 8.3. (by completing the relevant part)		
22.	A monitoring system is in use in the facility that ensures the immediate and unambiguous identification of all products that are intended to be labelled or are labelled with the Trademark/feeds or feed materials to be used in GMO-free production/live animals given feeds to be used in GMO-free production.	
23.	The products that have already left the plant are traceable within one business day.	

24.	Live animals no longer to be found at the livestock farm are traceable within one business day.	
25.	The traceability system is suitable for making such quantitative reports and evaluations that allow for drawing conclusions related to the flows of goods and their pertinence.	
26.	The documents of the product proving GMO-free status are checked in the course of acceptance of goods.	
27.	GMO-free production and conventional production take place in separated spaces (e.g. in a livestock farm, the mode of production differs by stable or pen).	
28.	GMO-free production and conventional production take place at different times (e.g. appropriate measures are taken to minimise cross-contamination with GM materials).	
29.	GMO-free products/products that can be used on GMO-free production and non-GMO-free products are stored separately.	
30.	If separation is in time, the actions to prevent cross-contamination are documented and a register is kept of their observance.	
31.	For foods of animal origin, traditional and GMO-free products are separated.	
32.	Records are available of each individual of each animal species kept in the facility.	
33.	Animals are fed in accordance with the rules of GMO-free production.	
34.	The feed ratios are indicated for each animal species included in the livestock records.	
35.	If different ratios are applied to the different animal species (for example based on their life stage or the season) such ratios are recorded separately.	
36.	The names of feed components are accurate (the type and manufacturer are indicated).	
37.	The original or a copy of the documents proving usability in GMO-free production are kept on records together with the description of the feed ratios.	
38.	The feed register contains the data of the supplier, the place of origin, quantity and consumption of the feed used, as well as the time when it was used and the purpose it was used for.	
39.	The feed register is kept updated.	
40.	Specific documentation related to apiculture is available.	

In accordance with Point 8.4		
41.	The documentation and evaluation of complaints related to the absence of GMOs is adequate.	
42.	Corrective actions are taken for answering complaints.	
43.	A product recall/feed recall system is available.	
44.	The product recall system is suitable for informing customers.	