Authorisation for placing on the market and use of yield enhancing substances
Hungary

Yield enhancing substance is a collective noun including multiple products such as fertilisers, mineral fertilisers, organic fertilisers subject to authorisation, composts, earth worm humus, soil and plant conditioner products, growing media and microbiological products. They can be yield enhancing substances subject to authorisation and EC fertilisers. The placing on the market of the EC fertilisers is not subject to authorisation.

From this list it is clear that the yield enhancing substances reach the food chain and in the environment if applied either to the soil or directly on plants. A precondition for their application is their benefit for soil or crops which should be supported by studies and tests. Furthermore their proper use should not cause harmful side effects on plants, soils, on human or animal health, and pose no unacceptable risk to the environment and nature.

The legal regulation of their placing on the market and use should fulfil these objectives.

In accordance with *paragraph (6) of Article 5 of the* ***Act XLVI of 2008 on food chain and its official control (hereinafter: Act XLVI/2008),*** any **product subject to authorisation** shall only be placed on the market and used in Hungary under the **authorisation** granted by the food chain control body, according to the implementing ***Decree 36/2006. (V. 18.) FVM on the authorisation, storage, marketing and use of yield enhancing substances (hereinafter: Decree 36/2006)***:

- **products subject to authorisation***:* plant protection products, active substances, adjuvants, additives of plant protection product, products with a plant protection effect, plant protection equipment and material (other than instruments), **yield enhancing substance (other than EC-fertilizer within the meaning of Regulation 2003/2003/EC)** and any other products subject to authorization used for similar purposes, the placing on the market and use of which are subject to authorization
- **yield enhancing substance***:* any material of natural origin or manufactured by physical, chemical, biological or other artificial procedures, or any mixture of them intended for marketing, suitable for plant nutrition or influencing the nutrient supply or fertility of soils (except for water, carbon-dioxide and untreated farmyard manure without additives).

Types of yield enhancing substances

Chemical fertiliser subject to authorisation: means yield enhancing substances manufactured in the industry using chemical processes and applied as nutrient supply to crops.

Organic fertiliser subject to authorisation: means yield enhancing substances manufactured in the industry using organic matter of plant or animal origin and applied to improve nutrient supply to crops or serving as a soil conditioner for the improvement of soil structure.

Mineral fertiliser: means yield enhancing substances manufactured in the industry using substances of mineral origin and applied to improve nutrient supply to crops or serving as a soil conditioner for the improvement of soil structure.

Compost: means yield enhancing substances produced by the composting process using materials of organic, inorganic or mineral origin and applied to improve nutrient supply to crops or to improve nutrient supply capacity of the soil, specified in provisions of other legislation.

Worm compost: means sieved earthworm excrement applied to improve nutrient supply to crops or to influence productivity of the soil.

Soil improver: means yield enhancing substances manufactured in the industry used to change unfavourable properties and to maintain beneficial properties of the soil.

Soil conditioner product: means yield enhancing substances manufactured in the industry and having a beneficial effect on the physical, chemical and biological properties of the soil.

Microbiological product: means yield enhancing substances containing micro organisms (bacteria, fungi, algae) which improve soil fertility, impact plant development and, in case of the agricultural use of compost, promote the composting processes and which are exempt from agents infectious for man or influencing the natural micro flora of the soil adversely.

Growing medium: means any soil, soil mixtures and other substrates, whether solid or liquid, providing a suitable medium for plants for rooting and growing.

Plant conditioner product: means a preparation manufactured from organic or inorganic materials with favourable influence on the growth, yield and general conditions of plants and which has an effect on plant life cycles primarily by influencing the nutrient supply.

The yield enhancing substance containing plant protection product has to be authorised in compliance with the legislation governing the authorisation of plant protection products in such a way that both the studies and evaluation necessary for the authorisation of yield enhancing substances must be made.

The yield enhancing substance can also be authorised as **product family** that is yield enhancing substances produced by the same manufacturer, in the same state for the same use containing the same basic materials in different composition shall be grouped in one family group.

STEPS OF THE AUTHORISATION PROCESS

- **studies necessary for the authorisation**
- **authorisation procedure**

1. STUDIES NECESSARY FOR THE AUTHORISATION

A **precondition for the issuance of the authorisation** is that the yield enhancing substances should have favourable impact on soil or the crops supported by studies and tests. Furthermore their proper use should not cause harmful side effects on plants, soils, on human or animal health, and pose no unacceptable risk to the environment and nature.

In order to prove the above conditions, the studies under *Annex 2 to Decree 36/2006* should be performed before the start of the authorisation procedures. These studies and tests are required to state the quality requirements and harmlessness of the products and to prove their efficacy. This period still does not make part of the real authorisation procedures. During the test period and the authorisation procedures, it is not permitted to place on the market and use the products, even if the test results comply with the authorisation requirements.

Though the *Act XLVI/2008* and the *Decree 36/2006* relatively unambiguously state the definitions of yield enhancing substances and each product types, furthermore *Annex 2 to Decree 36/2006* contains all details of tests/product types necessary for the authorisation, **the applicant has the possibility for preliminary negotiation with the competent authority.** They can discuss the following questions:

- can the particular product be classified as yield enhancing substance,
- if the product is a yield enhancing substance, is it subject to authorisation or an EC fertiliser,
- if it is a yield enhancing substance subject to authorisation, to which product type is it classified under *Annex 1 to Decree 36/2006,* as regards its raw materials and intended uses,
- determination of the studies and tests specified for raw materials and intended uses, because certain studies must be performed, but there are tests which are necessary depending on the raw materials used for the production of the substance,
- in case of a combination of several product types, analyses and trials featuring all product types must be conducted,
- in case of authorisation of a product family, the studies specified in *Annex 2 to Decree 36/2006* shall be carried out with the products previously agreed upon with the competent authority – based on raw materials posing public health and environmental risks,
- the members of a product family should be different in the percentage composition of the raw materials,
- what previous studies are already available for the applicant and how far they can be accepted for the authorisation in Hungary according to the requirements of the *Decree 36/2006*,
- if the product was produced or placed on the market in a Member State of the European Union or in Turkey, or produced in an EFTA-country taking part in the EEA agreement in compliance with their current regulations, mutual recognition can be used in the authorisation procedure (see details of mutual recognition later).

This negotiation is particularly important for preparations at the border line of plant protection products and yield enhancing substances. In principle it is stated that the basis for classification is the purpose of use. If the formulation is intended for pest management, it is authorised as plant protection product, and if it is intended for use aiming at plant nutrition, it shall be authorised as yield enhancing substance.

Let’s see an example: if a formulation with active substance iron sulphate is used for moss control, then it is authorised as plant protection product, and if it is used for iron deficiency treatment, then it shall be authorised as yield enhancing substance. If the iron content is at the minimum iron content set out in Annex 1 to Regulation 2003/2003 EC concerning the fertilisers, it can be placed on the market without any special authorisation procedures.

1.1 Summary of the types of studies necessary for the authorisation

- Physical, chemical examinations using 3 x 1 kg or litre of sample
- Testing toxic elements using 3 x 1 kg or litre of sample
- Microbiological classification using 3 x 1 kg or litre sample.
- Testing organic contaminants from 3 x 1 kg or litre sample
- Testing germination inhibition, weed propagation using 4 x 3 kg sample.
- Biological efficacy trial
- Hygienic microbiological tests from 3 x 0,5 kg samples
- Radiobiological tests from 3 x 0,5 kg sample
- Depending on the quality of the raw materials used for the production of the substance, additional studies may be required.

1.1.1 Physical and chemical analyses

In these analyses, the parameters characteristic for the quality of particular product type are studied; if *Annex 3 to Decree 36/2006* specified certain limits, the analyses are compulsory, furthermore any parameters which the manufacturer wants to declare.

For compost, the following parameters must be studied:

- appearance: colour, odour, physical state,
- pH (10% aqueous suspension),
- volume per mass,
- dry matter content,
- organic matter content,
- total water soluble salt content,
- particle size distribution,
- N, P_2O_5, K_2O, Ca, Mg.

If the manufacturer uses raw materials for the production of compost which contain other nutrients, e.g. micro elements in addition to the above elements, and the manufacturer wants to declare it, then he shall proceed for the determination of these.

1.1.2 Study of toxic elements

It is **compulsory** for all product types as regards the human, animal and plant health as well as environmental aspects. However the range of studied elements may change by product type. Analysis of the following toxic elements is compulsory: As, Cd, Co, Cr, Cu, Hg, Ni, Pb, Se.

1.1.3 Microbiological qualification

The quality parameters should be defined primarily for microbiological preparations. In microbiological preparations the number of bacteria shall be minimum 10^6 CFU/g or CFU/cm^3, and the number of algae minimum 10^5 cells/g or cells/cm^3. If the number of bacteria, micro fungi or algae is lower, they shall not be classified as microbiological preparations, but if the manufacturer wants to declare the number of microorganisms, he should perform the analysis (CFU = Colony Forming Unit).

1.1.4 Analysis of organic contaminants

Organic contaminants shall be analysed if wastes containing organic contaminants are used for the production of the substances. They are of concern for human health aspects because of carcinogenic effect.
The range of tests depends on the type and quality of wastes and the following tests are generally needed, however study of other parameters may be required depending on the quality of raw materials.

- formulation containing municipal wastes, municipal sewage sludge:
    - total PAH content (19 compounds),
    - mineral oil content (TPH C5-C40),

- formulation containing industrial wastes, industrial sewage sludge:
    - total PAH content (19 compounds),
    - mineral oil content (TPH C5-C40),
    - total marker PCB content (PCB-28, 52, 101, 118, 138, 153, 180),

- formulation containing wastes originating in burning and paper manufacturing:
    - total PCDD/F content expressed in WHO TEQs.

1.1.5 Analysis of germination inhibition and weed propagation

Analysis is made with mustard seed test to detect the eventual phytotoxicity. It is compulsory for the following product types:

- organic fertilisers,
- composts,
- worm humus,
- soil improvers containing organic matters,
- microbiological preparations,

1.1.6 Efficacy trials

Efficacy trial is carried out to prove the efficiency of the formulation. The range of studies required for the authorisation of each product type is very diversified.

The principle is that **no efficacy trial shall be carried out** with product types of yield enhancing substances subject to authorisation if according to the quality requirements (minimum organic matter content, minimum nutrient content, etc.) specified in the ***Decree 36/2006*** the biological efficiency of the formulation can be deduced. These product types are as follows:

- fertilisers subject to authorisation
- organic fertilisers subject to authorisation
- composts
- worm humus
- soil improvers
- growing media.

If the raw materials used for the production of the formulation or the preparations with specific use justify it, efficacy trials can be required also for the above yield enhancing substances.

Mineral fertilisers: at least one field trial and one pot test, altogether 4 efficacy trials shall be carried out with each plant using 2 field crops and 2 horticultural crops.

Soil improvers *(not classified under point 6.1 of Annex 3 to Decree 36/2006,* i.e. not "traditional" soil improvers) and **soil conditioner products:** 2 field or pot trials/different soil type, altogether 4 efficacy trials are required.

Microbiological products: the following efficacy trials are needed based on the mode of use:

- Symbiotic micro organisms: 1 greenhouse test in case of seed-dressing (Roux-tube test).
- Cellulose degrading micro organisms
    - for composting: 1 greenhouse test on two types of soil (Cellulose digesting test).
    - for stubble treatment:
        - 1 greenhouse test on two types of soil (measurement of stubble breaking activity):
        - carbon transformation test
        - cellulose degrading activity
- Yield enhancing microorganisms effective through the soil
    - pot test with monocot-dicot on 2 different soil types,
    - 2 field or pot trials/2 different soil types, altogether 4 efficacy trials are required
- In case of microorganisms effective on the plants at least 3 field or glasshouse tests/cultivation sector*, and in case of plant-specific formulations at least 2 field or glasshouse tests/plant are required.

In case of **plant conditioner products** at least 3 field or glasshouse tests/cultivation sector*, and in case of plant-specific formulations at least 2 field or glasshouse tests/plant are required.

*As regards the efficacy trials, the cultivation sectors shall mean the following:

- under field conditions,
- vegetables,
- fruit and grapevine,
- ornamental plants,
- forest, public area,
- others.

1.1.7 Microbiological studies concerning soil hygiene

The hygienic microbiological tests shall include the following parameters considered as risk factors of concern with regards of human and animal health and soil hygiene:

- Faecal coliform bacterial count,
- Faecal Streptococcus bacterial count,
- *Pseudomonas aeruginosa* count,
- *Salmonella sp.*,
- Egg number of human parasitic intestinal worms.

1.1.8 Radiation biology test

It shall be made only with products containing **peat originating from import**.

1.1.9 Additional tests required depending on the quality of the raw materials used

Additional ecotoxicological (*Daphnia*-test, fish test, algae test) and **other tests,** e.g. as regards the elements outside the required toxic elements, may also be required, depending on the quality of the raw materials, mainly in case of products containing industrial wastes, used for the production of product.

1.2 Who can perform the tests?

Tests (except the efficacy trials) specified in *Annex 2 to the Decree 36/2006* may be **carried out by laboratories accredited for these tests in Hungary or in member states making part of the Agreement of the European Economic Area (hereinafter: EEA member states)**. The limit of detection in the tests applied for micro-elements and toxic elements may be maximum the reported value or 10 % of the limit value of the element concerned.

The efficacy trials specified in *Annex 2 to the Decree 36/2006***, carried out for authorisation purposes** (aiming at evaluating the efficiency and eventual harmful effects) **can only be performed by any testing facility having qualification for Good Experimental Practice (GEP qualification), in addition to the competent authority**. Those accredited tests made in the EEA Member States may be accepted that were carried out in the **South-East zone** comparable to the Hungarian agro-ecological conditions and specified in the EPPO standard PP 1/241(1) of the European and Mediterranean Plant Protection Organisation (EPPO).

1.3 Necessity of experimental use permit

- Trials, except for laboratory and micro plot tests, with unauthorised product or in area other than specified in the authorisation may only be carried out at request and with experimental permit granted by the Pest County Government Office responsible for plant protection and soil conservation (hereinafter: Pest County Government Office).
- Yield enhancing substances may be used for experimental purposes if, based on the data provided in the application for experimental use, they do not cause any harmful effects on crops, soils, human or animal health or any unacceptable adverse effect on the environment and nature.
- Application for experimental use of yield enhancing substances shall be submitted to the Pest County Government Office (Plant Protection and Soil Conservation Department, H-1135 Budapest, Lehel út 43-47., Hungary) under Annex 5. http://portal.nebih.gov.hu/ugyintezes/noveny/nyomtatvanyok
- Trials with unauthorised yield enhancing substances or in area other than specified in the authorisation may be carried out only by university graduated experts.
- The size of the experimental area shall be determined by the Pest County Government Office during the evaluation of the application, but the total size of the experimental areas cannot be larger than 20 ha/year.
- The trials shall be supervised by the district office.
- The field trials carried out with products not authorised yet shall be publicly demonstrated and the trial results made available only with the previously obtained

permit of the Pest County Government Office. This activity is considered as use for experimental purpose.

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- **In the authorization procedure only trials carried out according to the experimental use permit can be accepted, therefore the permit should be attached to the application document for authorisation.**
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2 AUTHORISATION PROCEDURE

2.1 The procedure shall start with an application:

- The applicant can be
  - the manufacturer
  - any natural person, legal entity or business operator having no legal entity approved by the manufacturer.
- The application shall be submitted in one copy with the data and annexes specified in *Annex 1 to Decree 36/2006*: http://portal.nebih.gov.hu/ugyintezes/noveny/nyomtatvanyok
- Signed and stamped report of the studies shall be attached to the application.

2.2 Competent authority for authorisation: National Food Chain Safety Office
Directorate for Plant Protection, Soil Conservation and Agri-environment

2.3 Duration of the authorisation procedure: maximum 5 months if all the documents are available

2.4 Fee of authorisation procedure:

- all yield enhancing substances (except composts) HUF 100.000,
- composts HUF 150.000
- product family:
  - up to 3 family members HUF 200.000 (in case of composts HUF 300.000),
  - for all additional family members, increased by HUF 30.000

2.5 Validity of authorisation 10 years

2.6 Conditions for issuing the authorisation, the evaluation aspects

The authorisation shall be issued if during the evaluation of the documentation, the yield enhancing substance complies with:

- the objective of use indicated in the application supported by the following studies
  - efficacy trials,
  - trials with active substance
- they have favourable effects on the soil and cultivated crops, in case of technically reliable use they do not have any harmful effect on plants, soils, human or animal health or any unacceptable risk to the environment and nature, supported by tests and studies

- phytotoxicity tests,
- test of organic contaminants,
- hygienic microbiological tests,
- toxic element studies.

The maximum limits of the parameters studied/product type are shown in *Annex 3 to Decree 36/2006*.

2.6.1 Limits laid down for toxic elements:

- As 10 mg/kg d.m. (other than peat and peat containing growing media 30 mg/kg d.m.)
- Cd 2 mg/kg d.m. (other than P-fertilisers: 20 mg/kg P_2O_5 d.m.)
- Co 50 mg/kg d.m. (no need for testing in case of NPK-fertilisers)
- Cr 100 mg/kg d.m.
- Cu 100 mg/kg d.m. (no need for testing in case of fertilisers, organic fertilisers subject to authorisation, in case of composts 300 mg/kg d.m.)
- Hg 1 mg/kg d.m.
- Ni 50 mg/kg d.m.
- Pb 100 mg/kg d.m.
- Se 5 mg/kg d.m.
    - below the use volume of 0.5 l/ha may be three times that of the value laid down in Annex 3,
    - between 0.5 l/ha and 1 l/ha it may be two times that of the value laid down in Annex 3.

2.6.2 Limits concerning organic contaminants

- total PAH content (19 compounds) < 1,0 mg/kg d.m.
- benz(a)pyrene content < 0,1 mg/kg d.m.
- mineral oil content (TPH C5-C40) < 100,0 mg/kg d.m.
- total marker PCB content (sum of PCB-28, 52, 101, 118, 138, 153, 180) < 0,1 mg/kg d.m.
- total PCDD/F content expressed in WHO TEQs < 5,0 mg/kg d.m. T.E.Q

2.6.3 Microbiological provisions concerning soil hygiene

- Faecal coliform bacterial count < 10 pcs/g or 10 pcs/ml
- Faecal Streptococcus bacterial count < 10 pcs/g or 10 pcs/ml
- *Pseudomonas aeruginosa* count < 10 pcs/g or 10 pcs/ml
- *Salmonella* sp. 2x10 g or ml negative
- Egg number of human parasitic intestinal worms 100 g or 100 ml negative

2.7 Repeated issuance of authorisation

As the authorisation is valid for 10 years, repeated issuance of the authorisation may be asked and all studies must be conducted with the exception of efficacy trials.

If the legal provisions changed meanwhile compared to the testing requirements set out for the first authorisation, the competent authority may provide for the performance of additional efficacy trials.

2.8 Amendment to the authorisation

The authorisation may be modified at request or officially.

- The authorisation holder may apply for the amendment of authorisation. Data and test results providing sound basis for the amendment of authorisation shall be attached to the application for modification.

- The competent authority may officially modify the authorisation, if based on new knowledge of technical and scientific aspects, it can be proved that the yield enhancing substance even if used according to provisions shall pose a risk to human and animal health, soil and the environment, as well as the plants specified in the authorisation.

Amendment to the authorisation shall not prolong the validity of the authorisation.

2.9 Interruption and suspension of the authorisation

The authorisation may be interrupted at the authorisation holder's request.

The competent authority may officially provide for the suspension of the authorisation

- in case of court trial concerning the authorisation holder's right for placing the yield enhancing substance on the market, until the trial is legally terminated,
- in case of failure and quality objections found at studying the product stability and control of sales.

Suspension of the authorisation may be terminated at the authorisation holder's request, if the holder describes the causes for the product's quality problems, the measures taken for their termination and the test results obtained with official samples taken from the product manufactured after the mistakes were eliminated.

During the interruption and suspension period of the authorisation, the yield enhancing substance may not be placed on the market and kept on the market.

Termination or suspension of the authorisation shall not prolong the validity of the authorisation.

2.10 Withdrawal of the authorisation

The authorisation may be withdrawn at request or officially.

- The authorisation must be withdrawn if the authorisation holder applies for it.
- The competent authority shall officially withdraw the authorisation if

  - any of the requirements for authorisation subsequently change and the authorisation holder does not meet the obligation for providing information therefore certain authorised product does not comply with the changed requirements for authorisation based on the result of trial carried out at a later date,

- based on new knowledge of technical and scientific aspects, it can be proved that the yield enhancing substance even if used according to provisions shall pose a risk to human and animal health, soil and the environment, as well as the plants specified in the authorisation,
- it is justified as regards the Community approval of the active substance in the yield enhancing substance as active substance of plant protection product,
- false or misleading data were provided as regards the facts used as bases for the issuance of the authorisation.

2.11 Mutual recognition of goods in the authorisation of yield enhancing substance

2.11.1 Legal background of mutual recognition of goods

The Act 7 of 2009 on the application of mutual recognition in relation to rules ensuring the free movement of goods of the Treaty establishing the European Community placed the Decree 36/2006 under the effect of *Regulation (EC) 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.*

At the same time paragraph (1) of Article 7 of *Act 7 of 2009* states that the technical rules shall only be applied for goods produced or placed on the market in a Member State of the European Union or in Turkey under their current regulations, furthermore produced in a country (other than the above states) taking part in the agreement with the EEA in compliance with the current regulations, if the current provisions of the particular state do not provide equal protection with the technical rules as regards the validity of the forcing requirements to be met by the technical rules, and under paragraph (2) if the equivalence of protection can only be stated in case of a part of the technical rules, the good should comply with the remaining part of the technical rules.

***Article 5 of Decree 36/2006* specifies the specific rules concerning the mutual recognition of goods.**

In order to be able to declare the equivalence of protection (protection of life and health of humans, animals and plants, protection of consumers and of the environment), an application shall be submitted to the competent authority. The documents necessary for the declaration of equivalence in accordance with the legislation on the application of mutual recognition in relation to provisions on the free movement of goods specified in the Treaty establishing the European Community shall be attached to the application.

If the equivalence of protection cannot be declared on the basis of the submitted documents, the competent authority shall provide for the performance of trials missing under *Annex 2* to *Decree 36/2006* and may ask for the missing data.

2.11.2 Procedural practice in testing the equivalence of protection

The food chain control body, acting as competent authority asks the clients to submit the documentation available for the particular yield enhancing substance.

- If the formulation has already been authorised in a member state, the competent authority requests the authorisation and the legislation under which the authorisation

was granted. The competent authority compares the legislation with the Hungarian regulation in order to state the equivalence of protection. If the equivalence of protection cannot be declared on the basis of the submitted documents, the competent authority shall provide for the performance of missing trials.

- If there is no "prior authorisation obligation" for yield enhancing substances in a member state, but there is a legislation the provisions of which are subsequently considered, the applicant must submit the certificate of the responsible authority to the competent authority certifying that the formulation complies with the legal provisions. The competent authority shall examine in this case the equivalence of protection as specified above.

- If in a member state the yield enhancing substances are not subject to authorisation and there is no legislation governing their quality, the competent authority requests that the studies and tests specified in the Hungarian legislation should be attached to the application.