

LEGAL ASPECTS OF THE USE OF PLANT STRENGTHENERS (BIOSTIMULANTS) IN EUROPE

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Abstract

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Some EU member states allow the use in agriculture of a class of substances, known as plant strengtheners, under national laws. Plant strengtheners (biostimulants) enhance the resistance of plants to harmful organisms and protect plants against non-parasitic impairments. They are “borderline” products because the boundaries between plant protection products and fertilizers are not clear and univocal. There is no European regulatory framework for these substances. This fragmented and contradictory situation can prejudice the fair productive competitiveness of agriculture systems in Europe.

Key words: grey zone, borderline products, plant strengtheners, biostimulants

Abbreviations: BVL: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety); CTGB: College voor de toelating van gewasbeschermingsmiddelen en biociden (Board for the Authorisation of Plant Protection Products and Biocides); D.P.R.: Decree of President of Republic; D.M.: Ministerial Decree; EBIC: European Biostimulants Industry Council; EC: European Community; EEC: European Economic Community; EOCC: European Organic Certifiers Council; EU: European Union; NF: Norme Française; OMDF: Otros medios de defensa fitosanitaria; PflSchG: Pflanzenschutzgesetz (Plant Protection Act); RUB: Regeling Uitzondering Bestrijdingsmiddelen (Regulation exemptions Pesticide); WGB: Wet Gewasbeschermingsmiddelen en Biociden

Introduction

Plant strengtheners (Corroborantii, Pflanzenstärkungsmittel, Pflanzenhilfsmittel, Regeling Uitzondering Bestrijdingsmiddelen-RUB, Otros medios de defensa fitosanitaria, Aditif agronomiques) are a class of agricultural products used in agriculture in some member states. Plant strengtheners enhance the resistance of plants to harmful organisms and protect plants against non-parasitic impairments. They are “borderline” because the boundaries between plant protection products and fertilizers are not clear and univocal. They are different both from plant protection products, because they act only on plant strength without direct effects against pests, and from fertilizers, because they have no main nutritional activity.

There are no clear European laws that regulate these products. National laws concerning the placing of plant strength-

eners on the market have been promulgated by some member states but others do not recognize the category of plant strengtheners. The authorization of plant strengtheners is an easier process than that of plant protection products. This fragmented and contradictory situation could be jeopardizing the fair productive competitiveness of European agriculture systems.

There is also great confusion concerning the use of these substances, for example, algae extracts are considered as fertilizers in Italy, plant protection products in Germany and plant strengtheners in Spain. Moreover, amino acids are unregulated in some countries, categorised as fertilizers in others and some amino acids are assimilated as pesticides in other markets. Some member states allow the marketing of the active substance both as a plant strengthener and as a fertilizer, as well as a plant protection product. However in other countries, such as Germany, the active substance that is

authorized as a plant strengthener cannot be authorized as a fertilizer or as a plant protect product.

Plant strengtheners are a grey area, which needs debating by member states.

The European Commission Services drafted a working document "Data requirements for plant strengtheners with low risk profile" (SANCO/1003/2001 rev. 3) in co-operation with member states in 2001. It was not intended to produce legally binding effects and by its nature does not prejudice any measure taken by a member state, however it is a very useful tool for defining the authorization procedure of plant strengtheners. The Commission Services consider plant strengtheners as a plant protection product (regulated by Directive 91/414/EEC) for which until now in many member states no applications for approval have been submitted. There are several reasons why no applications for approval have been submitted:

- doubts on the legal aspects of plant strengtheners, regarding whether these are covered by Directive 91/414/EEC or not;
- the high costs of an application for a plant strengthener in relation to its limited use;
- the nature of the products and the expected low risk profile of most plant strengtheners.

The Commission and the member states regard it as a matter of priority that plant strengtheners should be authorised within the European Union as soon as possible as plant protection products. The dossier requirements for chemical plant protection products are based on substances with high-risk profiles. Therefore, for plant strengtheners with a "low risk profile", a minimum dossier requirement is laid down for an initial examination of the product. If the first examination deems it necessary, additional information will need to be provided case by case. If plant strengtheners have a high-risk profile or are based on microbial, the dossier requirements for chemical plant protection products are fully applicable.

Regulation EC No. 1107/2009 replaced Directive 91/414/EEC in June 2011. This regulation considers four categories of substances: standard, low-risk active substances, basic substances and candidates for substitution. Plant strengtheners could belong to basic substances or low-risk active substances.

In 2010 the European Organic Certifiers Council (EOCC) produced a document entitled "EOCC Compendium: Grey areas in Annex I and II of Regulation 889/2008 (Regulation laying down detailed rules for the implementation of Council Regulation EC No. 834/2007 on the organic production and labelling of organic products with regard to organic production, labelling and control). The intent was to analyze and disclose current critical points concerning the evaluation of inputs from a certifier's point of view. It was meant to provide

a basis for defining possible solutions. The EOCC highlights that all Organic Certifiers have a problem with the evaluation of inputs. It is not clear which criteria should be used for the evaluation of inputs, therefore the EOCC strongly recommend that the Commission provide guidelines on the matters discussed in the document. With regard to plant strengtheners, the EOCC highlights that there is a huge variety in interpretation, leading to inequality. For a more harmonized European Union policy on the use of plant strengtheners in organic agriculture, three solutions are possible:

1) a third Annex with plant strengtheners should be added for these products, not included in Annex I or II of Regulation EC No. 889/2008;

2) plant strengtheners should be considered as fertilizers and should be regulated by Regulation EC No. 2003/2003 relating to fertilizers;

3) plant strengtheners should be considered as plant protection products and should be regulated by Regulation EC No 1107/2009 relating to plant protection products.

It is worth noting that the European Biostimulants Industry Council (EBIC) was formed in June 2011 to foster the role of the biostimulants sector in helping agriculture to produce more with less. Biostimulants include diverse formulations of compounds, substances and other products that are applied to plants or soils to regulate and enhance the crop's physiological processes, thus making them more efficient. Biostimulants act on plant physiology through different pathways than nutrients, to improve crop vigour, yields, quality and post-harvest shelf life/conservation.

Biostimulants foster plant growth and development throughout the crop life cycle from seed germination to plant maturity in a number of ways, including but not limited to:

- improving the efficiency of the plant's metabolism to induce yield increases and enhanced crop quality;
- increasing plant tolerance to and recovery from abiotic stresses;
- facilitating nutrient assimilation, translocation and use;
- enhancing quality attributes of produce, including sugar content, colour, fruit seeding, etc.;
- regulating and improving plant water balance;
- enhancing certain physicochemical properties of the soil and fostering the development of complementary soil microorganisms.

Securing appropriate European regulation for the specific characteristics of biostimulants is a top priority for the Council because it is the foundation of a truly European market for this innovative class of products. The current fragmented and uncertain regulatory framework prevents biostimulants from making their full contribution to sustainable agriculture and to society in general (EBIC, 2011).

An appropriate regulatory instrument is necessary to ensure the safety of consumers, environmental sanitation and the proper placing on the market of these products.

Regulations on **Corroborantii** (Plant Strengtheners) in Italy

In 2001, a regulation concerning the use of particular natural products in organic farming was promulgated. It was similar to other laws promulgated by some member states and was made with the intent of helping Italian organic farmers and not put these farmers at a disadvantage compared to those of other member states. Article 38, "Provisions for the use of natural and particular products in organic farming" of D.P.R. No. 290/2001 "Regulation concerning the simplification of authorization procedures for the production, marketing and sale of plant protection products and related adjuvant" stipulated that copper sulphate, raw or refined sulphur, ferrous sulphate, the products listed in Annex II B of Regulation EEC No. 2092/91 (on the organic agricultural production) and the products listed in Annex 2 of D.P.R. No. 290/2001 (propolis, Kieseluhr - diatomaceous earth, rock and stone powder, sodium silicate, sodium bicarbonate, gelatine, products based on medicinal and aromatic plants, biodynamic products) did not need any authorization if they were placed on the market under names strictly related to the components. This deregulation displeased Agrochemical Companies because it caused unfair competition given that other plant protection products were subject to a long expensive authorization procedure, and it undermined the image of organic farming, whose strong points are production safety and quality. The European Commission launched infringement proceedings against Italy because by allowing the placing of some products on the market without authorization Italy failed to comply with Directive 91/414/EEC. The European Commission also contested the discrimination between organic and conventional farming, because these products were not subject to authorization for use in organic agriculture whereas they were subject to authorization for use in conventional agriculture. Italy repealed paragraphs 1 and 2 of article 38 to avoid incurring the penalty imposed by the European Commission. The Italian Ministry of Agriculture, Food and Forestry began a long and meticulous task of reformulating Article 38 in concert with the other appointed ministries and stakeholders. The ministries tried to mediate between divergent opinions, to get a shared agreement and to comply with European legislation on plant protection products. D.P.R. No. 290/2001 was amended on 28 February 2012. The amended D.P.R. No. 290/2001 states the following:

✓ definition of **corroborantii**: the natural products listed in Annex 1 of Ministerial Decree No. 18354/2009. **Corroborantii** enhance the resistance of plants to harmful organisms and protect plants against non-parasitic impairments. Products that have physical and mechanical activities are also considered **corroborantii**. These products can be considered as neither fertilizers nor plant protection products (Article 2 "Definitions");

✓ eligibility criteria: **corroboranti** may be marketed without authorisation only if: they are placed on the market using names strictly related to the component and they are not in a mixture; proper use has no harmful effects on human and animal health, and on the environment; they have been included in Annex I of D.M. No. 18354/2009; the label reports information on its qualitative and quantitative composition, field and precautions for use, name and address of applicant and the factory of production, and the packaging and intended use (Article 38 "Provisions for certain products used in organic, biodynamic and conventional agriculture");

✓ the procedure that must be followed for including new **corroboranti** in Annex I of D.M. No. 18354/09: the application must include an assessment of the possible effects on human and animal health and on the environment; name and address of applicant and the factory of production and packaging; information on composition; field and precautions for use; label. The application must be sent to the Ministry of Agriculture, Food and Forestry and will be evaluated by the technical commission appointed by the Ministry of Agriculture, Food and Forestry (Article 38 "Provisions for certain products used in organic, biodynamic and conventional agriculture");

✓ a database should be set up on the authorized **corroboranti** to help certifiers, operators, inspectors and consumers (Article 40 "Databases").

We hope that this new regulation will clarify and help to overcome the confusion because products marked in Italy as **corroboranti** do not often fulfil the eligibility criteria of **corroboranti**.

It should be finally noted that Legislative Decree No. 75/2010 concerning the placing on the market of fertilizers regulates biostimulant products, without defining the term. Biostimulant products are listed in Annex 6 point 4.1 of Legislative Decree No. 75/2010. These products are based on rhizospheric bacteria, mycorrhizal fungi, algae extracts, amino acids and peptides.

A European common framework regulation is necessary to allow the use of plant strengtheners and to help organic farmers. The norms outlined in this subsection with regard to the Italian scenarios should be seen as tempo-

rary regulations until the time comes when there will be a common European regulatory framework concerning plant strengtheners.

Regulation on Pflanzenstärkungsmittel in Germany

German law concerning plant protection “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)” was promulgated in 1998. This law regulated the placing of plant protection products and plant resistance improvers on the market. Article 2 “Definitions” defined plant resistance improver in addition to plant protection product (Schüler, 2003). Plant resistance improvers (Pflanzenstärkungsmittel) meant substances:

- a) solely intended to enhance the resistance of plants to harmful organisms;
- b) intended to protect plants against non-parasitic impairments;
- c) intended for use on cut ornamental plants except for planting material.

Plant resistance improvers could be marketed only if:

1. with the intended and proper use or as a result of such use they did not have any harmful effects on human and animal health, groundwater or the natural balance;
2. they were included in a list of plant resistance improvers issued by the Federal Office of Consumer Protection and Food Safety;
3. the wording “plant resistance improvers” and the list number were stated on the containers and outer packaging or package.

On 14 February 2012, the product group of strengtheners was re-defined when the plant protection legislation was re-structured. The new “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)” in Article 2 provides the new definition of plant strengthener, which is the new term used to indicate plant resistance improver. Plant strengtheners are substances and mixtures including microorganisms which are exclusively intended to maintain plant health in general, as long as they are not plant protection products according to Article 2 (1) of Regulation EC No 1107/2009 or they are intended to protect plants against non-parasitic impairments. Products whose priority lies in providing plants with nutrients and trace elements and promoting growth should rather be classified as plant growth improvers or soil improvers, and as such are subject to the Fertilisers Act.

The placing on the market of plant strengtheners is provided for in Article 45 of the new “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)”. The following requirements must be met:

- when used correctly and for their intended purpose, plant strengtheners must not have any harmful effects on human and animal health or groundwater or any other unacceptable effects, in particular on the environment;
- the Federal Office of Consumer Protection and Food Safety (BVL) must be notified before a product is placed on the market;
- plant strengtheners must be labelled according to the provisions of the new “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)”. Legislation on hazardous substances may require additional labelling.

The BVL checks to see whether the product complies with the definition of a plant strengthener and whether the other requirements for plant strengtheners have been fulfilled. The BVL keeps a list of plant strengtheners that could be placed on the market. The list of plant strengtheners according to Article 45 of the new “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)” is updated on a monthly basis. The BVL can prohibit products from being placed on the market if there are indications that they do not fulfil the definition of a plant strengthener or could cause harmful effects on human and animal health, groundwater or the environment. If a product’s label is confusing, e.g. if it suggests properties of a plant protection product, the BVL can summon the party intending to place it on the market to change the text within three months. If this does not happen, the BVL can prohibit the product from being placed on the market. Now the list of plant strengtheners includes one hundred thirty-three products.

Plant strengtheners that were listed before 14 February 2012 according to Article 31 of the old “Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)” remained on the market for a transition period until 14 February 2013 (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, 2012).

Our examination on German law focuses on the fact that German farmers may have use substances such as garlic extract, hydrolyzed proteins and microorganisms such as *Aureobasidium pullulans* and *Bacillus subtilis* as plant resistance improvers, which are authorized as plant protection products in other European Countries and listed in Annex I of Regulation EU No. 540/2011 (list of approved active substances in Europe for use in plant protection products). German farmers may have also use substances such as potassium phosphite and ethylenediaminetetraacetic acid as plant resistance improvers, which are authorized as fertilizers in other European member states.

It should be highlighted that plant strengtheners are used both in organic and in conventional farming in Germany, but they are very important in organic farming.

Regulation on Pflanzenhilfsmittel in Austria

The Austrian Fertiliser Regulation, in force since 2004, stipulates that all Pflanzestärkungsmittel authorised in Germany are treated as plant conditioners (Pflanzenhilfsmittel) and are allowed for use in Austria without further evaluations. These products are allowed both in organic and in conventional agriculture (Hozzank and Hartl, 2004; Bundesamt für Ernährungssicherheit, 2004).

Regulation on Regeling Uitzondering Bestrijdingsmiddelen in the Netherlands

In the Netherlands until 2007 plant protection products with low risk for man and the environment were placed on the market without being subject to the usual approval procedures stipulated in the “Bestrijdingsmiddelenwet 1962” (Pesticide Act, 1962). Plant protection products with low risk for man and the environment were regulated by Regeling Uitzondering Bestrijdingsmiddelen-RUB (Regulation exemptions Pesticide) and listed in Annex I of the above-mentioned regulation (Boeringa and Trapman, 2003).

After 17 October 2007 with the new regulation “Wet Gewasbeschermingsmiddelen en Biociden - WGB” concerning the authorization, the placing on the market and the use of plant protection products and biocides, the “Bestrijdingsmiddelenwet 1962” was repealed and consequently the Regeling Uitzondering Bestrijdingsmiddelen was repealed. Since then it has no longer been possible therefore to make a request for the inclusion of new active substances in the RUB list. However, commercial products containing active substances that had been in the RUB list are still allowed today and can therefore be used for a transitional period. The “College voor de toelating van gewasbeschermingsmiddelen en biociden” (CTGB) is the organization that authorizes plant protection products. On 1 February 2012, the CTGB published in the Official Journal of the Netherlands, a notice (“Voornemen tot intrekking RUB – toelatingen”) concerning their intention of withdrawing RUB authorization from 1 July 2012. This decision arose from the need to comply with Regulation EC No. 1107/2009 concerning the placing of plant protection products on the market that replaced Directive 91/414/EEC on 14 June 2011. In order to prevent the disappearance from the market of substances that are useful to farmers, on 16 March 2012 the CTGB decided to postpone the withdrawal of authorization for RUB products to 1 January 2014, thus enabling these products to be used for a further 18 months. In this way a reasonable period of time was granted to companies to comply with the authorization under Regulation EC No. 1107/2009 (College voor de toelating van gewasbeschermingsmiddelen en biociden, 2012).

The use of RUB products in organic farming is however subject to their inclusion in Annex II of Regulation EC No. 889/08.

Regulation on Otros medios de defensa fitosanitaria in Spain

Otros medios de defensa fitosanitaria (OMDF, i.e. plant strengtheners) are allowed under ORDEN APA/1470/2007 in Spain. This regulation lays down the law concerning the placing on the market of particular means of protection. ORDEN APA/1470/2007 was enacted in order to fill the legal vacuum that had been created following the entry into force of Royal Decree No. 824/2005 on fertilisers, which had expressly excluded OMDFs from the legislation, though they had previously been included in the fertilizers. ORDEN APA/1470/2007 regulates biological control agents (not exotic), traps, other means or devices to control pests and other different products from plant protection products. Otros medios de defensa fitosanitaria enhance the resistance of plants to harmful organisms and protect plants against non-parasitic impairments. ORDEN APA/1470/2007 does not concern plant protection products, fertilizers, exotic biological control agents and machinery for the application of plant protection products. An appropriate commercialization notification is requested for the inclusion of OMDF in an appropriate register (Registro Oficial de Productos y Material Fitosanitario). OMDF’s notification must report information on its identity and features, label, field of use, further information, technical documentation and receipt of payment of the fee under Law No. 43/2002. Notification of the biological control agent must be sent to the Agriculture Directorate-General of Ministry of Agriculture, in other cases the notification must be sent to the competent body of the Autonomous Community. The Autonomous Community must send a note on the OMDF’s benefit to the above-mentioned Agriculture Directorate-General within one month. The same procedure is adopted for requesting modifications to the registered OMDF.

Agriculture Directorate-General may review the authorized OMDF if:

- 1) in the light of scientific and technological development the product no longer satisfies the stipulated criteria;
- 2) there are risks for humans, animals and the environment;
- 3) false and misleading information is reported;
- 4) the quality of marketed products does not correspond to the characteristics reported in the notification for inclusion in the register.

The review of the authorized OMDF must be communicated to applicants and may lead to the maintenance, modifi-

cation, suspension or removal of products from the Registro Oficial de Productos y Material Fitosanitario.

In addition to official controls, pursuant to Law No. 43/2002, the Directorate-General may implement a monitoring program of authorized OMDF, in coordination with the competent authorities of the Ministries of Health, Consumption and the Environment.

The OMDF list used in Spain is available on website of Ministerio de Agricultura, Alimentación y Medio Ambiente (2007).

Regulation on Additifs agronomiques in France

The French norm NF U 44-204, promulgated on September 2011, defines additifs agronomiques as substances able to give additional properties to fertilizers, soil conditioners or mixtures of these. They are a new kind of substances able to improve the agronomic effectiveness of fertilizers and soil conditioners, and reduce the environmental impact due to agriculture. Additifs agronomiques include microbial preparations, humic substances and plant growth and/or development stimulators. Plant growth and development stimulators are fertilizers able to promote nutrition and/or plant growth and/or plant development and/or enhance plant resistance against non-parasitic impairments (indirect nutritional effect). Additifs agronomiques must be authorized for marketing under Article L 255-2 of the rural and maritime fishing Code (Code rural et de pêche maritime). The French norm NF U 44-204 concerns only authorized additifs agronomiques mixed with fertilizers, soil conditioners or both. This norm does not concern plant protection products.

Conclusions

The aim of this paper was to analyse current legislative instruments concerning plant strengtheners promulgated by some member states at a national level in Europe. An analysis of the national regulatory framework highlights large differences between member states. The use of plant strengtheners is a critical point. Although plant strengtheners are defined in a similar way in some countries, it is not very clear which products can be marketed as plant strengtheners. The regulatory framework is very varied and fragmented, thus it is necessary to change the current scenario and to harmonize legislations concerning plant strengtheners. It is essential to guarantee homogeneity and to overcome differences in the regulations of member states that help some farmers and penalize others. This fragmented and contradictory situation can prejudice the fair competitiveness of the European ag-

riculture system. The same security levels for humans and the environment should be ensured throughout the European Union, however this seems difficult without a harmonized system of laws covering all agricultural products.

The European Union thus needs to find a way to overcome this critical issue. European common guidelines on plant strengthener's authorization should be drawn up and national laws concerning plant strengtheners should be repealed as in the Netherlands.

Regulation EC No. 2003/2003 concerning fertilizers could provide an opportunity to solve this issue. In fact, the European Commission is revising Regulation EC No. 2003/2003, whereas Regulation EC No. 1107/2009 is not able to solve this grey area in the near future, as it has recently replaced Directive 91/414/EEC, therefore its amendment appears unlikely. An amended Regulation EC No. 2003/2003 could extend its scope to other fertilisers and fertilising materials including organic fertilisers, growing media, soil improvers and possibly "biostimulants", which is the new term used to identify plant strengtheners. The European Commission commissioned an *ad hoc* study on plant biostimulants to evaluate substances and materials covered by this term and the possible future regulatory status for these products (European Commission, 2012). The Working Group on Fertilisers of the European Commission proposed a definition for biostimulants: "Plant biostimulants means a material which contains substance(s) and/or microorganisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to benefit nutrient uptake, nutrient use efficiency, tolerance to abiotic stress, and/or crop quality, independently of its nutrient content". The amended Regulation EC No. 2003/2003 should avoid any overlap with other regulatory frameworks such as Regulation EC No. 1107/2009 or Reach Regulation. It should enter in force in 2015.

In November 2012, the first International Scientific Congress specifically on the use of biostimulants was held in Strasbourg. This congress was a very important opportunity to discuss scientific, technical and regulatory aspects of biostimulants, which could contribute to increasing the yield and quality of productions and promote sustainable agricultural models.

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