



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Placing on the market of micro-organisms

– an overview for Germany

- German Plant Protection Act plus Regulation (EC) No 1107/2009
 - plant protection products
 - plant strengtheners
- German Fertilisers Act (*Düngegesetz*) plus national regulation for fertilisers (*Düngemittelverordnung*)
 - soil improvers
 - plant growth improver (*Pflanzenhilfsmittel*)

products (plant strengtheners 1)

§ 2 No 10 German Plant Protection Act (6th Feb 2012)

Plant strengtheners are substances and mixtures including micro-organisms which

- a) 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*
- b) are intended to protect plants against non-parasitic impairments*

products (plant strengtheners 2)

maintainance of plant health

- no biocidal action, e. g. against harmful organisms
- certain products for cut flowers

protection against non-parasitic impairments

- waxes
 - wound dressings or sealants (pruning and grafting of shrubs and trees)
 - products for reducing water evaporation, e. g. grafts during transport ...
- white coatings of tree trunks (against frost cracks)
- and others

§ 45 German Plant Protection Act

... further provisions for the placing on the market of plant strengtheners:

- notification (procedure) including a small dossier
- cooperation duties of the company / distributor
- *The BVL can prohibit the placing on the market of the product*
 - *when harmful effects on human and animal health, groundwater or the environment can be expected*
 - *the product cannot be defined as a plant strengthener*
- *If the label suggests properties of a PPP, the BVL can summon the company to change the label.*

Definition of plant protection products (PPP), Article 2 of the Regulation (EC) No 1107/2009

PPP are products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

- *protecting plants or plant products against all harmful organisms or preventing the action of such organisms, ...;*
- *influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient; ...*

PPP ./ plant strengtheners (1)

→ **Plant resistance improvers are PPP!
and are subject to Regulation (EC) No
1107/2009**

PPP ./ plant strengtheners (2)

definition of PPP

- active substances (approved or pending)
- mode of action (direct or biocidal, preventive, inducing the plants own resistance *i. e.* elicitors ...)

μ-organisms as active substances

- 36 μ-organisms are approved
 - bacteria, fungi, yeasts, viruses
 - *Bacillus subtilis* str. QST 713
 - *Pythium oligandrum* M1
 - *Trichoderma harzianum* strains T-22 and ITEM 908
 - ...
- 11 are pending

http://ec.europa.eu/sanco_pesticides/public/index.cfm

PPP ./.. plant strengtheners (3)

examples of former plant strengtheners (μ -organisms only)

- „Boni Protect forte“ (*Aureobasidium pullulans*, appr. 02/2014)
- „Proradix“ (*Pseudomonas* sp., appr. 02/2014)
- preparations with *Trichoderma* spp. (first appr. 05/2009)

provisions for μ -organisms in PPP

special guidelines for μ -organisms

SANCO/10754/2005 rev. 5

identity and biological properties

- taxonomic level → strain level
- identity and biological properties
- metabolites, toxins
- mode of action
- human health
 - toxicity
 - pathogenicity
 - infectiveness
- environment
 - fate and behaviour
 - effects on non-target organisms

provisions for μ -organisms in plant strengtheners

similar as for μ -organisms in PPP!

- identity and biological properties
 - taxonomic level → strain level
 - identity and biological properties
 - metabolites, toxins
 - mode of action
- human health
 - toxicity
 - pathenogenicity
 - infectiveness

Regulation (EC) No 2003/2003

- only for mineral fertilisers
 - organic material cannot be placed on the market as an EC-fertiliser
- *national and harmonised regulations co-exist!*
- plus regulation for free trading of products, *i. e.* Regulation (EC) No 764/2008

§ 2 DüngG (German Fertilisers Act)

Soil improvers: Substances without significant concentrations of nutrients and also microorganisms, which are intended

- a) to influence the biological, chemical or physical properties of the soil in order to improve the conditions for plant growth or
- b) to promote the nitrogen fixation by symbiotic organisms

Plant growth improvers (Pflanzenhilfsmittel): Substances without significant concentrations of nutrients, which are intended

- to act on plants in a biological or chemical way in order to achieve a beneficial effect on plant cultivation, production or application,

→ as far as they are not plant strengtheners in the sense of § 2 No 10 German Plant Protection Act

[unofficial translation]

DüMV (German regulation for fertilisers).

national regulation for products which are placed on the market

- nutrient concentrations
- list of substances which are allowed in fertiliser products (including soil improvers and plant aids)
- declaration
- contaminants
- co-formulants
- and other provisions

(German regulation for fertilisers)..

Tables, especially Annex II Table 7:

7.4.5 living microorganisms: bacteria, fungi

- *uses:*
 - *to inoculate the soil*
 - *to stimulate plant growth and to improve the vitality of plants*
- *micro-organisms must be specified*

fertilisers in Germany

- tables with ingredients and other provisions
- no further assessment of products

→ *no approvals of individual products!*

- list of products?
- procedure for new ingredients or products:

(German regulation for fertilisers)...

Placing onto the market of new fertilisers, soil improvers, growing media or plant growth improver (Pflanzenhilfsmittel):

- German fertiliser legislation does not provide for a formal 'request procedure'
- new fertiliser products should be applied for at the Federal Ministry of Food and Agriculture (BMEL)
- applications will be evaluated by the Scientific Advisory Board on Fertiliser Issues
- possible result: amendment the existing rules

Instructions regarding the documentation required for requests to amend/alter fertiliser regulations:

http://www.bmel.de/DE/Ministerium/Organisation/Beiraete/_Texte/DuengInverkehrbringenEN.html

www.bvl.bund.de > Plant Protection Products >
general information, definitions, lists, forms, advice, news...

→ however, the BVL is not the designated authority for
fertilisers and fertiliser products but for PPP and plant
strengtheners

fertilisers

- advice and surveys: authorities of the German ‘Länder’
- new products: BMEL

the remaining question

which legislation is relevant for a certain product?

→ check

- purpose
 - protection against diseases, plant health

or

 - nutrition
- composition, substances
- mode of action
- intended uses

***Thank you
for your kind attention!***

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