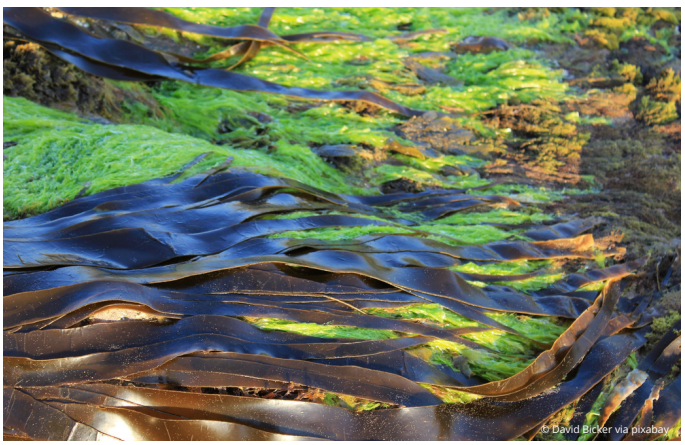
How to bring plant biostimulant products to the EU market

New Legislative framework for Plant Biostimulant products

Plant biostimulants can be brought to the market in the EU by complying to either:
• the **national regulation of the EU countries**, or
• the new **EU Regulation EU 2019/1009 on Fertilising Products (**FPR) in force since 16th July 2022.

The FPR gives producers of plant biostimulants the option to bring their products on the internal EU market with a CE-marking. Plant Biostimulant products with CE-marking can be marketed in all countries of the EU without any additional requirements or prerequisites imposed at the national level.

The FPR is optional: producers may also opt to continue to bring their plant biostimulants to the national market following national regulations on biostimulants. These biostimulants may be brought to the market of other EU countries by applying to the Mutual recognition principle. In that case, EU countries can restrict the market entry by placing additional requirements or prerequisites.



Plant Biostimulant products definition

Within the EU, **plant biostimulants** are defined (EC1107/2009 art.3.34 and FPR art 47.2) as:
A product for the purpose of stimulating plant nutrition processes with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

a. Nutrient use efficiency,
b. Tolerance to abiotic stress,
c. Quality traits,
d. Availability of confined nutrients in soil or rhizosphere.

The stimulation is independent of the product's nutrient content.

Difference between biostimulants and related products

Plant biostimulants are distinguished from **fertiliser products**, which are defined as products the function of which is to provide nutrients to plants or mushrooms.

Biostimulants also have to be distinguished from products like elicitors, growth regulators or other products that aim to improve characteristics of plants like tolerance to biotic stress, plant resistance etc. Products with such claims are defined as **plant protection products** (PPP) which have the function to influence the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant. PPP are regulated under the regulation EC 1107/2009 on plant protection products (PPPR). Plant biostimulants are excluded from the scope of the PPPR.

Products can have **dual functions**, where they function as both a biostimulant and a plant protection product. In that case the product will be regulated under the scope of the PPPR and excluded from the FPR.

Plant biostimulants as EU-fertilising products with CE marking

Plant biostimulants that are placed on the EU market with an CE marking must comply with the prerequisites of the Regulation (EU) 2019/1009 on fertilising products (FPR). Specific requirements on plant biostimulants are laid down:

- product requirements in Annex 1 PFC 6;
- component requirements in Annex II;
- labelling requirements (Annex III);
- conformity assessment procedure (Annex IV). For biostimulants the conformity assessment will require the certification by a notified body (NoBo).

PFC 6 Plant biostimulants, product requirements

The definition of plant biostimulant used in the regulation is claim-based. All claims made about the biostimulant must be indicated on the label and the claimed effects must be demonstrated during the conformity assessment procedure. Demonstrating that a product is indeed a *bona fide* plant biostimulant depends on the demonstration of its effect.

The CEN has developed Technical Specifications (TS) that can be used to the demonstrate the claimed effect of the product. The type of information that can be used to demonstrate the efficacy of the claim:

- field and/or protected crop experimental data;
- controlled condition data (e.g.: laboratory data, greenhouse, growth chamber);
- literature review (only peer reviewed, analytical methods used as given in the CEN-TS).

The CEN/TS 17700-1 norm specifies the general principles for justifying the product claims for plant biostimulants by experimental trials. The norm specifies:

1) Quality criteria for trials, including:
- trial design (control, plot size, application rates, number of replications);
- the statistical analysis;
- for trials with plants: crop groupings, minimum number of successful trials for effects claimed for a specific crop, entire crop group, two of more entire crop groups or without being limited to specific crop grouping;
- for trials without plants, effects claimed for specific soil type and all pH's, or specific pH ranges or all types of soil texture categories, or for all soil types and all pH categories.

2) Quality criteria on the type or organization in charge of trial. The organization should ensure that the trails are conducted following the relevant technical specifications, with verification of the quality criteria, planning and conduction of the trials.

3) Specification of the information to be collected in individual trials, such as:

- Experimental conditions (objective and basic information on trial site)
- Trial conditions
- Application of the product
- Recording measurements
- And on the presentation of the results, including raw data, analysis data and conclusions from the trial observation.

In addition:

- For claims on the nutrient use efficiency, norm CEN/TS 17700-2, gives the assessment indices to validate the claim of enhanced nutrient efficiency, and specifications for the performance of the trials.
- For claims on tolerance to abiotic stress, norm CEN/TS 17700-3, specifies the types of abiotic stresses (thermal, light, mechanical stress, water stress and chemical stress), gives specification for trial design, and the agronomic markers that can be used to validate the claim.
- For the claims on quality traits the CEN/TS 17700-4 norm gives definitions for the quality traits (agronomical, marketable, and nutritional traits) and distinguishes organoleptic and techno-functional properties. It contains examples of specific quality claims, references to sources for methods that can be used to measure markers, and examples of markers that can be used to validate the claim. It also contains some specifications on the performance of the trials.
- For claims on the availability of confined nutrients in soil or rhizosphere, the CEN/TS 17700-5 norm gives the assessment markers to demonstrate the availability of nutrients by measuring either soil and rhizosphere or plant samples. Methods to analyse that content of the specific contents in soil or plant samples are also given as reference. The nom also contains specifications on the performance or the trials.

The NoBos and market surveyance authorities involved in the conformity assessment will accept the experimental data or literature reviews performed according to the CEN technical specifications. However, use of these CEN-TS are not compulsory. Producers may use other methods or assessment criteria and markers for which they can prove that these will be just as good.

Apart from the agronomical performance, plant biostimulants should also be safe for the environment. Therefore, the content of heavy metals in plant biostimulants is limited according to the following table:

metal	limit	
cadmium (Cd)	1.5	mg/ kg dry matter
hexavalent chromium (Cr VI)	2	mg/ kg dry matter
lead (Pb)	120	mg/ kg dry matter
mercury (Hg)	1	mg/ kg dry matter
nickel (Ni)	50	mg/ kg dry matter
inorganic arsenic (As)	40	mg/ kg dry matter
copper (Cu)	600	mg/ kg dry matter
zinc (Zn)	1500	mg/ kg dry matter

Plant biostimulants are categorised in microbial and non-microbial plant biostimulants. These contain different CMC materials and differ in the pathogen risks and specification.

PFC 6A MICROBIAL PLANT BIOSTIMULANTS

A microbial plant biostimulant shall consist of a micro-organism or a consortium of the following micro-organisms (defined in CMC 7):

- Azotobacter spp.
- Mycorrhizal fungi
- Rhizobium spp.
- Azospirillum spp

These may include the dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which have undergone no other processing than drying or freeze-drying.
When the microbial plant biostimulant is in liquid form, the plant biostimulant shall have a pH optimal for contained micro-organisms and for plants.

Pathogens in a microbial plant biostimulant must not exceed the limits set out in the following table:

Micro-organisms/their toxins, metabolites	Sampling plans		
	n	c	
Salmonella spp.	5	0	Absence in 25 g or 25 ml
Escherichia coli	5	0	Absence in 1 g or 1 ml
Listeria monocytogenes	5	0	Absence in 25 g or 25 ml
Vibrio spp.	5	0	
Shigella spp.	5	0	
Staphylococcus aureus	5	0	
Enterococcaceae	5	2	10 CFU/g
Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium	5	2	105 CFU/g or ml
Yeast and mould count unless the microbial plant biostimulant is a fungus	5	2	1 000 CFU/g or ml

Where:
n = number of units comprising the sample,
c = number of sample units giving values over the defined limit.

PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT

Plants biostimulants that do not belong to PFC 6A are considered non-microbial plant biostimulants. They may solely consist of component materials that belong to **one or more of the CMCs** o**f annex II, except CMC 7** which is limited to the PFC 6A. microbial biostimulants.

The component materials must meet the definition and prerequisites of the CMC that they belong to. The CMC are defined in Annex II of the FPR. CMCs that are most relevant for the biostimulants component materials are:

CMC 1: Virgin material substances and mixtures
CMC 2: Plants, plant parts or plant extracts
CMC 3: Compost
CMC 4: Fresh crop digestate
CMC 5: Digestate other than fresh crop digestate
CMC 6: Food industry by-products
CMC 11: By-products within the meaning of the Waste Framework Directive 2008/98/EC

The CMC prerequisites can include requirements on REACH registration, certain treatment processes, specification of processing conditions (including time-temperature trajectory and feedstock materials), and are further specified in Annex II of the FPR.

Currently (February 2023) no ingredients that are derived of animal by-products are allowed as component material. These ingredients will have to obtain an 'end point in the manufacturing chain' under the regulation (EC) 1069/2009 on Animal By-Products (ABP) before they can be included in the relevant CMCs of the FPR (including as feedstocks for the compost and digestates CMCs, or as a component material for CMC 10 Derived products within the meaning of ABP Regulation).

Pathogens in a non-microbial plant biostimulant must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
***Salmonella* spp.**	5	0	0	Absence in 25 g or 25 ml
Escherichia coli* or *Enterococcaceae	5	5	0	1 000 in 1 g or 1 ml

Where:
n = number of samples to be tested,
c = number of samples where the number of bacteria expressed in CFU is between m and M,
m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,
M = maximum value of the number of bacteria expressed in CFU.

This information has been compiled by NMI within the NWE interreg project ReNu2Farm.
For feedback and information please contact Laura.vanScholl@nmi-agro.nl or Brent.Riechelman@nmi-agro.nl
Version 1.1: March 2023

Based on the Regulation EU/2019/1009 (consolidated version May 2022), Communication from the Commission concerning the visual appearance of the label on EU fertilising products referred to in Annex III to Regulation (EU) 2019/1009 of the European Parliament and of the Council 2021/C 119/01

How to label your Plant biostimulants with CE marking

Labelling of plant biostimulants with CE marking

EU fertilising products have to be labelled according to the specifications in Annex II of the FPR.

Plant biostimulants that are brought to the market as an EU fertilising product can be recognised by the CE marking. The CE mark has to be affixed to the label. The location of the CE marking on the label is free to choose.

For **Plant Biostimulants**, the following information has to be provided on the label:

- The PFC designation, either as microbial plant biostimulant or non-microbial plant biostimulant,
- A list of all ingredients above 5 % by product weight or volume (in the case of products in liquid form by dry weight), in descending order of magnitude, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation.
- Instructions for use, including application method(s), growth stage and number of applications for the claimed function for each target crop of crop group (with reference to the terminology in the CEN technical specifications).
- Any other relevant instructions related to the efficacy of the product, including soil management practices, chemical fertilisation, incompatibility with plant protection products, recommended spraying nozzles size, sprayer pressure and other anti-drift measures.
- Recommended storage conditions;
- Relevant information to control risks to human, animal or plant health, safety or the environment should be included. Pictograms (except CLP hazard pictograms if the product is not classified) may be used as long as they are clear and not misleading.
- in case applicable: any labelling information as required from other EU regulations such as the CLP regulation.
- Where the EU fertilising product contains a component material which, as a food or feed would be subject to maximum residue limits(*) MRL, and whereby that component material contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.

(*) pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council, MRL set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council), or maximum levels established pursuant to Council Regulation (EEC) No 315/93 (3) or Directive 2002/32/EC of the European Parliament and of the Council (4)

- Physical form of the product
- Quantity by mass or volume
- Production and expiry dates;
- A type number, batch number or other means of identification
- Contact details of the producer or distributor.
- The certification number as issued by the NoBo after conformity assessment module D1.

For **microbial plant biostimulants**, the following additional information should be given on the label.

- All intentionally added micro-organisms shall be indicated.
- Where the micro- organism has several strains, the intentionally added strains shall be indicated. Their concentration shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g., colony forming units per gram (cfu/g).
- The label shall contain the following phrase: 'Micro-organisms may have the potential to provoke sensitising reactions.

Additional optional information

Additional information may be given. These should be clearly separated from the required information above, for instance by a horizontal line.

Additional information:

(a) shall not mislead the user, for example by attributing properties to the product that it does not possess, or by suggesting that the product possesses unique characteristics which similar products also have;

(b) shall relate to verifiable factors;

(c) shall not make claims such as 'sustainable' or 'environmentally friendly' unless such claims refer to legislation, or clearly identified guidelines, standards, or schemes, with which the EU fertilising product complies; and

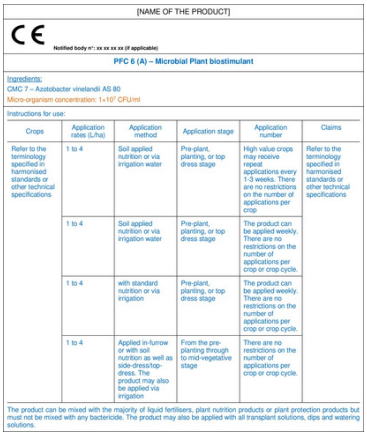
(d) shall not make claims by means of statements or visual representations that the EU fertilising product prevents or treats plant diseases or protects plants against harmful organisms.

If the product is authorised for use in organic farming according to EU legislation (Implementing Regulation EU 2021/1165), this may be stated on the label.

Ingredients that account for less than 5% by weight may be listed as additional information.

Indication of national labels and certifications, if applicable.

Detailed examples of labels can be found in the Guidance document on EU fertilising product labelling:



[NAME OF THE PRODUCT]

CE

Notified body n°: xx xx xx xx (if applicable)

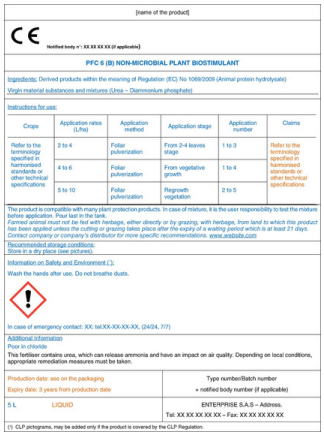
PFC 6 (A) – Microbial Plant biostimulant

Ingredients:
CMC 7 – Azotobacter vinelandii AS 80
Micro-organism concentration: 1×10⁷ CFU/ml

Instructions for use:

Crops	Application rates (L/ha)	Application method	Application stage	Application number	Claims
Refer to the terminology specified in harmonised standards or other technical specifications	1 to 4	Soil applied nutrition or via irrigation water	Pre-plant, planting, or top dress stage	High value crops may receive repeat applications every 1-3 weeks. There are no restrictions on the number of applications per crop	Refer to the terminology specified in harmonised standards or other technical specifications
	1 to 4	Soil applied nutrition or via irrigation water	Pre-plant, planting, or top dress stage	The product can be applied weekly. There are no restrictions on the number of applications per crop or crop cycle.	
	1 to 4	with standard nutrition or via irrigation	Pre-plant, planting, or top dress stage	The product can be applied weekly. There are no restrictions on the number of applications per crop or crop cycle.	
	1 to 4	Applied in-furrow or with soil nutrition as well as side-dress/top-dress. The product may also be applied via irrigation	From the pre-planting through to mid-vegetative stage	There are no restrictions on the number of applications per crop or crop cycle.	

The product can be mixed with the majority of liquid fertilisers, plant nutrition products or plant protection products but must not be mixed with any bactericide. The product may also be applied with all transplant solutions, dips and watering solutions.



[name of the product]

CE

Notified body n°: XX XX XX XX (if applicable)

PFC 6 (B) NON-MICROBIAL PLANT BIOSTIMULANT

Ingredients: Derived products within the meaning of Regulation (EC) No 1069/2009 (Animal protein hydrolysate)
Virgin material substances and mixtures (Urea – Diammonium phosphate)

Instructions for use:

Crops	Application rates (L/ha)	Application method	Application stage	Application number	Claims
Refer to the terminology specified in harmonised standards or other technical specifications	2 to 4	Foliar pulverization	From 2-4 leaves stage	1 to 3	Refer to the terminology specified in harmonised standards or other technical specifications
	4 to 6	Foliar pulverization	From vegetative growth	1 to 4	
	5 to 10	Foliar pulverization	Regrowth vegetation	2 to 5	

The product is compatible with many plant protection products. In case of mixture, it is the user responsibility to test the mixture before application. Pour last in the tank.
Farmed animal must not be fed with herbage, either directly or by grazing, with herbage, from land to which this product has been applied unless the cutting or grazing takes place after the expiry of a waiting period which is at least 21 days.
Contact company or company's distributor for more specific recommendations. www.website.com

Recommended storage conditions:
Store in a dry place (see pictures).

Information on Safety and Environment (1):

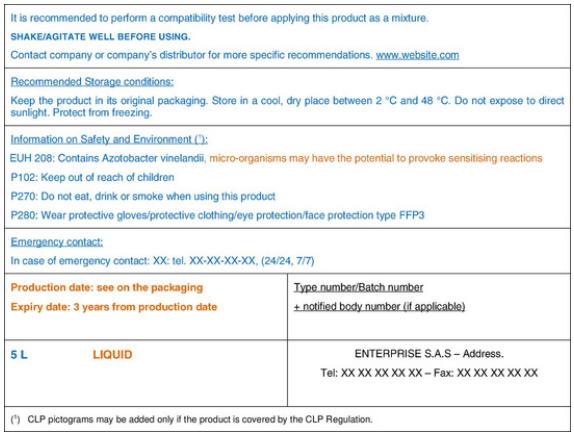
Wash the hands after use. Do not breathe dusts.

In case of emergency contact: XX: tel.XX-XX-XX-XX, (24/24, 7/7)

Additional information
Poor in chloride
This fertiliser contains urea, which can release ammonia and have an impact on air quality. Depending on local conditions, appropriate remediation measures must be taken.

Production date: see on the packaging Expiry date: 3 years from production date	Type number/Batch number + notified body number (if applicable)
5 L LIQUID	ENTERPRISE S.A.S – Address. Tel: XX XX XX XX XX – Fax: XX XX XX XX XX

(1) CLP pictograms, may be added only if the product is covered by the CLP Regulation.



It is recommended to perform a compatibility test before applying this product as a mixture.

SHAKE/AGITATE WELL BEFORE USING.

Contact company or company's distributor for more specific recommendations. www.website.com

Recommended Storage conditions:

Keep the product in its original packaging. Store in a cool, dry place between 2 °C and 48 °C. Do not expose to direct sunlight. Protect from freezing.

Information on Safety and Environment (1):

EUH 208: Contains Azotobacter vinelandii, micro-organisms may have the potential to provoke sensitising reactions
P102: Keep out of reach of children
P270: Do not eat, drink or smoke when using this product
P280: Wear protective gloves/protective clothing/eye protection/face protection type FFP3

Emergency contact:

In case of emergency contact: XX: tel. XX-XX-XX-XX, (24/24, 7/7)

Production date: see on the packaging **Expiry date: 3 years from production date**	Type number/Batch number + notified body number (if applicable)
5 L **LIQUID**	ENTERPRISE S.A.S – Address. Tel: XX XX XX XX XX – Fax: XX XX XX XX XX

(1) CLP pictograms may be added only if the product is covered by the CLP Regulation.

Official Journal of the European Union 2021/119/01 vol 64.

These instructions have been carefully compiled, but ultimately the legal text of the European Commission remains leading. The project partners of the ReNu2Farm accept no liability for any errors or damage of any kind that are the direct or indirect result of the use of these instructions.

This information has been compiled by NMI within the NWE interreg project ReNu2Farm.
For feedback and information please contact Laura.vanScholl@nmi-agro.nl or Brent.Riechelman@nmi-agro.nl
Version 1.1: March 2023

Based on the Regulation EU/2019/1009 (consolidated version May 2022), Communication from the Commission concerning the visual appearance of the label on EU fertilising products referred to in Annex III to Regulation (EU) 2019/1009 of the European Parliament and of the Council 2021/C 119/01

Conformity assessment for Plant biostimulants with CE marking

Conformity assessment of Plant biostimulants with CE marking

Producers of EU fertilising products have to carry out the relevant conformity assessment procedure or have it carried out. For plant biostimulant products, this will involve the certification by a notified body.

Producers' obligations:

For the conformity assessment, producers of EU fertilising products will have to:

- draw up the technical documentation (TD) in which the compliance with the requirements of Annex I and Annex II are demonstrated;
- carry out the relevant conformity assessment procedure in collaboration with a 'notified body' (NoBo);
- draw up an EU declaration of conformity (EU DOC) and affix the CE marking;
- keep TD and EU DOC for 5 years.

Technical documentation

The TD shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). In general it includes the following information:

- general description of the product, claimed function and intended use;
- description of each component material their component material category (CMC), origin and/or manufacturing process;
- if the product contains by-products (CMC 6 and CMC 11) - evidence for compliance with requirements of Directive 2008/98/EC;
- if total Cr> 200 mg/kg - maximum quantity and exact source;
- drawings, schemes, descriptions and explanations of the manufacturing process;
- a list of CEN technical specification norms and/or other relevant technical specifications applied;
- results of calculations, examinations, etc.;
- test reports;
- a specimen of the label and/or the leaflet

The notified body shall issue an EU-type examination certificate to the manufacturer after completion of the conformity assessment procedure.

A **guidance document and IT-tool** for the elaboration of the technical documentation will be published by the EC towards the end of 2023 (in prep. 2023).

Conformity assessment modules

Annex IV of the FPR describes several conformity assessment procedure modules for EU fertilising products. For the plant biostimulant products, the available conformity assessment procedures are Module B+C or the Module D1.

The **Module B+C EU-type examination** is the conformity assessment procedure in which the producer provides a NoBo the technical documentation and product samples. The NoBo examines the information and verifies and attests that the technical design of the EU fertilising product meets the requirements of the FPR. No auditing on the production location is required.

Module D1 Quality assurance of the production process is the conformity assessment procedure where the producer fulfils the obligations on the technical documentation, the manufacturing and quality system. The producer ensures and declares on his or her sole responsibility that the products concerned, satisfy the requirements of the FPR. The notified body shall assess the quality system to determine whether it satisfies the requirements. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

Module D1 is more comprehensive and is required when the plant biostimulant product contains material from either one of the CMCs 3,5,12,13,14,or 15.

Where compliance of the plant biostimulant with the FPR is certified by a NoBo, the producer shall draw up an EU declaration of conformity (template in Annex V of the FPR).

Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market.

This information has been compiled by NMI within the NWE interreg project ReNu2Farm.
For feedback and information please contact Laura.vanScholl@nmi-agro.nl or Brent.Riechelman@nmi-agro.nl
Version 1.1: March 2023

Based on the Regulation EU/2019/1009 (consolidated version May 2022), Communication from the Commission concerning the visual appearance of the label on EU fertilising products referred to in Annex III to Regulation (EU) 2019/1009 of the European Parliament and of the Council 2021/C 119/01

Interreg North-West Europe ReNu2Farm
European Regional Development Fund
AGENTSCHAP INNOVEREN & ONDERNEMEN
Vlaanderen is ondernemen