

## D4.11. Report on the Impact of the Legal Framework novIGRain

Co-Creation Workshops – 1 <sup>st</sup> Session	
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## **Introduction:**

Throughout this document we will assess the detailed impact of the legal framework on our novIGRain Novel Protectant (hereunder called Product) and Versatile Application Technology (hereunder called Machine) as well as the overall legal framework in which the Grain Storage management has to operate.

## **Legal Framework of the Product:**

### **A. Plant Protection Products Regulation (EC 1107/2009):**

The Product that will be developed, to be sprayed on the grain with the Spraying Machine, before, or during storage, is what is commonly called a Plant Protection Product. Although it is very specifically used, and has as sole purpose, to Protect the Grain from Insect infestations, it falls under the same legislative umbrella as all the other Plant Protection Products, regulated in Europe by the Plant Protection Products Regulation (EC 1107/2009); see: [https://ec.europa.eu/food/plants/pesticides/legislation-plant-protection-products-ppps\\_en](https://ec.europa.eu/food/plants/pesticides/legislation-plant-protection-products-ppps_en)

This Regulation covers both the assessment of the active ingredient in a product, as well as the final product which is made available on the market, together with the enviro-social impact, the conditions of uses and warehousing and also the afterlife of grain following treatment.

And hence the Product that will be put on the market after the novIGRain project will need to fulfill the following requirements:

- a) it shall be sufficiently effective;
- b) it shall have no immediate or delayed harmful effect on human, or animal health;
- c) it shall not have any unacceptable effects on plants or plant products;
- d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;
- e) it shall have no unacceptable effects on the environment:
  - i. its fate and distribution in the environment;
  - ii. its impact on non-target species, including on the ongoing behaviour of those species;
  - iii. its impact on biodiversity and the ecosystem.

The process for compliance to this Regulation is lengthy and costly and covers assessments of all following aspects, of both the active ingredient in the Product as well as the Product itself:

- a) Evaluation of the Product's efficacy on the targeted organisms at the required concentration(s) for use;
- b) Physical and Chemical Properties of the active ingredient as well as the Product;
- c) Toxicological evaluation of the active ingredient as well as the Product used at required concentration(s) for use, including Maximum Residue Levels on the intended crops (Grain). See also further in this document;
- d) Eco-Toxicological evaluation of the active ingredient as well as the Product used at required concentration(s) for use.

It involves a long series of very detailed studies, trials and testing according to determined guidelines.

Within the novIGRain project all these aspects have been taken into account from the start and will be implemented during the project to enable a fully compliant development of the Product, as well as after the project for dossier submission to the Plant Protection Product's authorities.

Once both the active substance and the product formulation has been approved, the goal is to spread the novel product and technology Worldwide. The targeted areas beside the EU are the great cereal producing areas, like USA, Canada, Australia, Argentine, Ukraine, Russia. In some of the listed countries larvicides have been used for grain treatment for many years, hence the approval of the formulation itself seems to be executed more smoothly.

#### B. REACH (EC 1907/2006):

This regulation aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. See: [https://ec.europa.eu/environment/chemicals/reach/reach\\_en.htm](https://ec.europa.eu/environment/chemicals/reach/reach_en.htm)

Although this regulation is mainly meant for companies producing and distributing chemicals, this also has an impact on the development of the product within the novIGRain project.

The reason is that the product is formulated not only with an active ingredient, but also with a series of co-formulants which have to meet the REACH requirements.

Again within the novIGRain project all these aspects have been taken into account from the start and will be implemented during the project to enable a product development which is safe for humans and environment, as well as after the project for dossier submission to the Plant Protection Product's authorities.

#### C. CLP (EC 1272/2008) & SDS:

This is the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) which is based on the United Nations' Globally Harmonised System (GHS) and its purpose is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.

CLP defines the content of the label and the organisation of the various label elements. The label should be firmly attached to one or more of the packaging's surfaces and has to include the following:

- a) The name, address and telephone number of the supplier
- b) The nominal quantity of a substance or mixture in packages made available to the general public (unless this quantity is specified elsewhere on the package)
- c) Product identifiers
- d) Where applicable, hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation.

Besides this information, a recent extra information has been added to the above obligations, which is the UFI number (unique formula identifier) which helps all European Poison Centers to find harmonized information of every product through a centralized database.

When products are supplied to customers, the manufacturer and/or distributors have the obligation to supply to its customers the Safety Data Sheet (SDS) of the product supplied, and according to above CLP and REACH requirements.

Furthermore, for the overall safety, Poison Centres have been recently established throughout the EU, where every formulation and product has the relevant SDS and immediate assistance can be given.

The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures where:

- a) a substance or a mixture meets the criteria for classification as hazardous according to CLP; or
- b) a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), according to the criteria given in Annex XIII of REACH, or;
- c) a substance is included in the candidate list for eventual authorisation according to Article 59 (1) of REACH for any other reasons.

See also Guidance on the compilation of SDS:

[https://echa.europa.eu/documents/10162/23036412/sds\\_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20](https://echa.europa.eu/documents/10162/23036412/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20)

These aspects also make part of the product development in the novIGRain project and will be implemented once the product has been fully developed and made available on the market.

#### D. Processing and Storage (Directive 2012/18/EU)

Processing and storage of the Product at Manufacturing site, storage at Distribution site as well as at storage at the Users' site will need to comply to the Seveso-III Directive on the prevention of major accidents involving dangerous substances.

However, as accidents may nevertheless occur, it also aims at limiting the consequences of such accidents not only for human health but also for the environment.

The Directive covers establishments where dangerous substances may be present (e.g. during processing or storage) in quantities exceeding certain thresholds.

Depending on the amount of dangerous substances present, establishments are categorised in lower and upper tier, the latter are subject to more stringent requirements.

The legal framework established by the Directive creates a continuous improvement cycle of prevention, preparedness and response to major accidents. The cycle is closed by provisions on lesson learning.

Operators are obliged to take all necessary measures to prevent major accidents and to limit their consequences for human health and the environment. The requirements include:

- a) Notification of all concerned establishments;
- b) Deploying a major accident prevention policy;
- c) Producing a safety report for upper-tier establishments;

- d) Producing internal emergency plans for upper tier establishments;
- e) Providing information in case of accidents.

These aspects also make part of the product development in the novIGRain project and will be implemented when the Product has been developed and will have to be stored for trial purposes during the project, as well as once the product has been fully developed and made available on the market.

For comparison with other legislations in the world, hereby two examples:

Australia's system for regulating agricultural chemicals is a shared responsibility between the Australian and state and territory governments. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent Australian Government agency that regulates agricultural chemicals up to and including the point of supply. State and territory governments have regulatory responsibility after products are supplied for use. This includes the storage, use and possession of agricultural chemicals.

In the United States of America the EPA (Environmental Protection Agency) and the FDA (US Food and Drug administration) have several guidances and decrees for regulating and governing the condition of chemical uses. The US policy is specifically strict.

E. Transport (Directive 2008/68/EC):

Every transport of the Product from Manufacturing site towards Distributor and/or Users will need to comply to the European Directive on the inland transport of dangerous goods.

This Directive describes the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and, in so far as is relevant, the International Carriage of Dangerous Goods by Inland Waterways (ADN).

The ADR, RID and ADN lay down uniform rules for the safe international transport of dangerous goods. Such rules are also extended to national transport in order to harmonise across the Community the conditions under which dangerous goods are transported and to ensure the proper functioning of the common transport market.

For the Product the main rule that will apply is the ADR rule, which is described briefly hereunder:

- a) The ADR serves the safety in road traffic and requires the trained handling of dangerous goods;
- b) Drivers of dangerous goods transports must have a dangerous goods driving license, an ADR certificate;
- c) Vehicles that are to transport dangerous goods also require ADR approval. The approval is granted according to the dangerous goods that the vehicles are allowed to transport;
- d) The Driver will have to affix on the back of the truck specific sign(s) according to the classification of the products contained in the vehicle. He will also have to follow specific routes if products are classified as highly dangerous, toxic or explosive.

These aspects also make part of the product development in the novIGRain project and will be implemented when the Product has been developed and will have to be transported for trial purposes during the project, as well as once the product has been fully developed and made available on the market.

#### F. Treatment of Packaging and Remnants:

Within the PPP Regulation there is also a provision on the handling and storage of plant protection products and treatment of their packaging and remnants, which states:

A professional user or distributor who carries out any of the operations with a PPP must take all reasonable precautions to ensure that such operations do not endanger human health or the environment which are:

- a) The storing, handling, diluting or mixing of plant protection products before application;
- b) The handling of the packaging and remnants of plant protection products;
- c) The disposal of tank mixtures remaining after the application of plant protection products;
- d) The cleaning of plant protection product application equipment after the application of that product;
- e) The recovering or disposing of plant protection product remnants and their packaging.

All the practical requirements are also set-out on the label, SDS and Technical information that should be supplied by the Producer and/or Distributor to the final user of the Product.

These aspects also make part of the product development in the novIGRain project and will be implemented when Product has been developed and will be used for trial purposes during the project, as well as once the product has been fully developed and made available on the market.

#### G. Dosage and Maximum Residue Level (EC 396/2005):

Within the PPP Regulation and in combination with Regulation EC 396/2005, the Maximum Residue Levels (MRL's) are determined in or on food and feed of plant or animal origin. The treatment with the Product and with the Machine, with as purpose to store the Grain in the Silo, will need to comply to these Regulations.

Before, during and after application, an applicator will have to ensure the MRL's set forward by the EFSA and according to Regulation EC 396/2005 are not exceeded within the stored grain.

#### **Legal Framework of the Machine:**

The ULV machinery which will allow spraying of the "Product" on the grain at a certain concentration follows strict rules of compliance to two specific Norms, which are described hereunder:

##### A. Electrical Materials for Explosive Atmospheres:

The EN 60079-0 (2018) Norm specifies the general requirements for construction, testing and marking of Ex Equipment and Ex Components intended for use in explosive atmospheres.

### B. Electrical Materials for Explosive Atmospheres:

The EN 60079-31 (2014) Norm is applicable to electrical equipment protected by enclosure and surface temperature limitation for use in explosive dust atmospheres. It specifies requirements for design, construction and testing of electrical equipment and Ex Components. This standard supplements and modifies the general requirements of the above EN 60079-0 (2018) Norm.

Both Normalisations described above, of the machinery, implies that a series of steps are taken to ensure the ULV machinery will not cause any explosion in a silo where, due to high dust concentrations in the air can lead to the so called “Dust Explosion”.

Once the ULV equipment has been built taking into account these norms, the equipment can be labelled with the following CE marks: CE EX II 3 D TC III C T6 IP65

When the EU approval is at hand, the specific local technical regulations will be counted and calculated with.

### **Legal Framework regarding Grain Storage in general:**

For this part we rely on the European Guide to Good Hygiene Practices, for the collection, storage, trading and transport of cereals, oilseeds, protein crops, other plant products and products derived thereof.

See: <http://www.coceral.com/data/1490094920SANTE-2016-11958-02-00-EN-ORI-00.pdf>

On the other hand, in case of transport, export, or import of cereals one has to be very well equipped with knowledge and the rules of conditions of acceptance, otherwise the treated cereals will not be accepted by the destination country. Guidance to end users will be prepared.