

Declaration of compliance with the "prohibition of genetically modified organisms" pursuant to the provisions of Regulation (EU) 2018/848	
Name, address of vendor:	
Name of the product/crop:	Article number:
Component(s)/variety	Last organism(s) able to reproduce (only for fabricated inputs like fertilisers/ insecticides etc.)

I declare that this product was manufactured neither 'from' nor 'by' GMOs as those terms are used in Article 3 of the Regulation (EU) 2018/848\*. I do not have any information which could suggest that this statement is inaccurate.

Thus, I declare that the above named product complies with Article 3 of the Regulation (EU) 2018/848\* regarding the prohibition of the use of GMOs.

We undertake to inform our customer and its control body/authority immediately if this declaration is withdrawn or modified, or if any information comes to light which would undermine its accuracy.

I authorise bio.inspecta, which supervises our customer to examine the accuracy of this declaration and if necessary to take samples for analytic proof. I also accept that this task may be carried out by an independent institution which has been appointed in writing by bio.inspecta.

The undersigned takes responsibility for the accuracy of this declaration.

Country, place, date, signature of vendor:	Company stamp of vendor ( <i>if appropriate</i> ):

\* Please see on the next page.



# \*Excerpt from Regulation (EU) 2018/848 and related Directive 2001/18/EC

## 2018/848, Article 3, Definitions:

- (58) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;
- (59) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs
- (60) 'produced by GMOs' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;

## Directive 2001/18/EC

## Article 2

#### Definitions

For the purposes of this Directive:

'organism'means any biological entity capable of replication or of transferring genetic material; 'genetically modified organism (GMO)'means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

## Annex I A

Techniques referred to in Artcile 2(2)

## Part 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

- 1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
- 2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
- 3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

## Part 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

- 1) in vitro fertilisation,
- 2) natural processes such as: conjugation, transduction, transformation,
- 3) polyploidy induction.

## Annex I B

Techniques referred to in Artcile 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

1) mutagenesis,

2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.