

## **Government Response: The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019**

### **Technical Scrutiny Point 1 - Response**

The UK Government is responsible for collating information regarding the transposition of EU legislation in this area, and placed a notification on the National Execution Measures database on our behalf. Defra contacted the Department for Natural Resources in the Welsh Government on 25 September 2019 to request an update on the progress of the transposition of Directive (EU) 2018/350. The Welsh Government advised there would be a late transposition but the delay would be minimal. On 9 October 2019 the Welsh Government contacted Defra to advise that the 2018 Directive had been implemented by way of the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019, laid on 8 October 2019.

### **Technical Scrutiny Point 2 - Response**

The Welsh Government agrees that the cross-reference should be to paragraph 14(g) and will take steps to make the correction identified by the Committee.

### **Technical Scrutiny Point 3 - Response**

#### **Point i:**

The Welsh Government is of the view that the requirements set out in Section B.4(f) of Annex III B of the 2001 Directive (which is inserted by the Annex to the 2018 Directive) are captured by the wording of paragraph 40 of Schedule 1 to the 2002 Regulations, which provides a requirement to supply information relating to the methods and procedures to protect the site.

In the context of making an application, the Welsh Government considers that the requirement to provide information on site protection would by its nature capture the provision of information concerning the methods and procedures set out in section B.4(f). Having considered the scope and nature of information that relates to site protection, the Welsh Government considers that the wording of Schedule 1 captures the methods and procedures referred to by the Committee, without expressly needing to include the text quoted. For example, the wording of the 2002 Regulations would require details to be provided about the Standard Operating Procedures that authorised personnel have to follow, and other details which together would both capture and extend beyond the points set out in section B.4(f).

#### **Point ii:**

The Welsh Government is of the view that the text quoted by the Committee is captured by and reflected in the Regulations without the need to expressly mirror the

wording. Specifically, the Committee is asked to refer to regulation 7, and paragraph 18 of Schedule 1A that is to be inserted in the 2002 Regulations. This requires:

*The following information on the comparative analysis of agronomic and phenotypic characteristics and of composition—*

- (a) choice of a conventional counterpart and any additional comparators used in comparative analyses,*
- (b) choice of field site location for producing plant material for comparative analyses,*
- (c) experimental design including statistical analysis,*
- (d) selection of plant material for analysis, where relevant,*
- (e) comparative analysis of agronomic and phenotypic characteristics,*
- (f) comparative analysis of composition, if relevant...*

This provision, read together with the amendment to regulation 17 of the 2002 Regulations, which is provided for at regulation 5 of the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019, captures the requirements of the Directive (EU) 2018/350 without expressly quoting the words referred to by the Committee.

#### **Technical Scrutiny Point 4 - Response**

##### **Points i, ii and iv:**

The Welsh Government agrees with the points raised and will take steps to make the corrections identified by the Committee.

##### **Point iv:**

The Welsh Government appreciates that within the Regulations, the word 'nodweddion' has been used to convey both 'traits' and 'characteristics' in Welsh. This choice of wording follows the wording used in the Welsh text of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and has been used for reasons of consistency. It is accepted that the words have specific meanings in the field of genetics. Given the usage of the term in the 2002 Regulations it is considered that differentiating between the terms within the 2019 Regulations could introduce uncertainty as regards the interpretation of the 2002 Regulations. The Welsh Government will consider the usage of the terms within the 2002 Regulations, with a view to differentiating between 'traits' and 'characteristics', at an appropriate point in the future.