

SL(5)362 - The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019

Background and Purpose

The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 amend the existing implementation of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs (“the Deliberate Release Directive”). The Directive specifies a framework of controls on the release of GMOs, both for trial purposes and for placing on the market.

Under the Directive, proposed releases require prior authorisation, based on the GMO in question passing a scientific assessment of its potential impact on human health and the environment. In the case of releases for trial, the decision whether to approve lies with Member States, and, in the UK, these decisions are devolved, including to Wales. By contrast, decisions on GMO releases for commercial marketing are currently taken collectively at EU level. The Directive also deals specifically with GMO seeds for cultivation: in this regard, the Directive allows Member States to block cultivation in their territory, despite the seeds having EU approval. Decisions on this matter are also devolved to Wales.

The Directive is implemented in Wales by The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (“the 2002 Deliberate Release Wales Regulations”).

The Regulations under scrutiny also amend the Genetically Modified Organisms (Transboundary Movements) (Wales) Regulations 2005 (“the 2002 Transboundary Movements Wales Regulations”), which govern the export of GMOs from Wales, as part of the EU, to third (non-EU) countries. The key requirement is for the planned first export of a GMO intended for environmental release to be notified to the receiving country for approval before shipment.

The 2002 Transboundary Movements Wales Regulations currently implement, in Wales, Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003. This EU Regulation, in turn, implements an international treaty (to which the EU and UK are each a Party), the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity Regulation.

Most of the amendments to these two Wales statutory instruments are made under powers in paragraph 1(1) of Schedule 2, and paragraph 21 of Schedule 7, to the EUWA. Paragraph 1(1) of Schedule 2 gives the Welsh Ministers the power to address, within devolved competence, failures of retained EU law to operate effectively, and other deficiencies in retained EU law, arising from the UK’s withdrawal from the European Union. Paragraph 21 of Schedule 7 gives Welsh Ministers the power to make provision that is supplementary, consequential, incidental, transitional, transitory or saving, when addressing those failures or deficiencies, including the power to restate any retained EU law in a clearer or more accessible way.

The Wales statutory instruments amended by these Regulations constitute retained EU law for the purposes of section 2 of the European Union (Withdrawal) Act 2018 (“EUWA”). The EU Regulations and Decisions referred to in these Regulations also constitute retained EU law, under section 3 of the EUWA.



Some amendments made do not, however, arise out of the UK's withdrawal from the EU, but, rather, correct out of date references. These amendments are made using powers given under section 2(2) of the European Communities Act 1972 ("the ECA"). Although that Act will be repealed on exit day by section 1 of the EUWA, the amendments made to domestic legislation will continue to have effect, by virtue of section 2 of that Act.

The amendments made by the Regulations under scrutiny can be broadly categorised as:

- Removing references to provisions being 'in accordance with [particular EU legislation]', and other references to EU law or obligations, and instead referring to that EU law or those obligations as they are transformed into retained EU law by virtue of the EUWA;
- Copying out definitions within EU instruments, so that they become part of domestic legislation, instead of defining terms by reference to those EU instruments; alternatively, specifying that references should be to specific 'versions' of pieces of EU legislation, so that post-Brexit changes to that legislation will not read across;
- Updating references to other sets of legislation that will be changed following EU exit or where references were simply to an out of date piece of legislation;
- Changing references from EU law concepts to UK ones, e.g. changing 'Member State level' to 'any law of any part of the UK'; and
- Removing provisions which requires Welsh Ministers to take action on an EU level, such as to notify the Commission or other EU Member States.

Procedure

Negative.

Technical Scrutiny

11 points are identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(i) – that there appears to be doubt as to whether it is intra vires, or Standing Order 21.2(ii) – that it appears to make unusual or unexpected use of the powers conferred by the enactment under which it is made

1.1 Regulation 3(10(a))

1.1.1 Regulation 3(10(a)) substitutes (inter alia) a new paragraph (4) in regulation 25 of the 2002 Deliberate Release Wales Regulations. Regulation 25 of the 2002 Deliberate Release Wales Regulations deals with consent to market GMOs, and the original paragraph (4) provided that the maximum period for which the National Assembly (now, the Welsh Ministers) could grant consent was 10 years. The amendments made by these regulations appear to remove that cap on consent periods.

1.1.2 We cannot immediately see how the cap would cause a failure of retained EU law to operate effectively, or other deficiency in retained EU law, arising from the UK's withdrawal from the European Union; and therefore we cannot see how removing the cap falls within the powers given to the Welsh Ministers by paragraph 1(1) of Schedule 2 to the EUWA. Moreover, we



consider that removing a cap on GMO consent periods cannot be said to fall within the power in paragraph 21 of Schedule 7 to the EUWA; it does not appear to us to be supplementary, consequential, incidental, transitional or transitory provision.

1.2 Regulation 3(16)(b)

- 1.2.1 This provision inserts a new paragraph (3A) into regulation 35 of the 2002 Deliberate Release Wales Regulations, which deals with data to be included on a public register of information about GMOs, maintained by the Welsh Ministers under section 122 of the Environmental Protection Act 1990 (and under obligations in and under the Deliberate Release Directive).
- 1.2.2 New paragraph (3A) will mean that additional information will be placed on a public register when someone applies for permission to market a GMO. Confidential information is, however, exempt.
- 1.2.3 We note that applications for permission to market will, post-Brexit, be decided by the Welsh Ministers, not the European Commission. For that reason, we understand why new sub-paragraph (3A)(e) is appropriate; it makes administrative sense for the Welsh Ministers to assign an application reference code to each application and to link this to any information about that application on the register. Therefore, we see sub-paragraph (3A)(e) as covered by the incidental powers provided by paragraph 21 of Schedule 7 to the EUWA.
- 1.2.4 In relation to the other sub-paragraphs, however, we are less clear as to vires. The provisions do not appear to be required by pre-Brexit EU law, and therefore the powers given by the ECA do not seem relevant. In terms of the powers provided by the EUWA, we would expect these to be used to replace, as closely as possible, any obligations on the Commission to put information about applications to market GMOs in the public domain.
- 1.2.5 However, it appears to us that the Commission's obligations in this regard are to publish the summary information provided by the applicant, together with the Member State's assessment of the application, if favourable. Clearly, the second part of this obligation will fall away once the Welsh Ministers become the final decision-taker and so it is appropriate not to replicate this in the regulations. But the first part of the obligation appears to be transferred to the Welsh Ministers by new sub-paragraph (i), inserted into regulation 35(3). At first sight, this would appear to us appropriate to prevent any failure in retained EU law to operate effectively, arising out of the UK's withdrawal from the EU (taken together with the new provision in sub-paragraph (3A)(e)).
- 1.2.6 We wish to emphasise that we are very supportive of the aim of transparency in Welsh Minister decisions, and particularly so on subjects that directly affect all citizens of Wales, such as the availability of GMOs on the market. However, what we are concerned with here is vires to ensure that transparency. If new paragraph (3A)(a)-(d) and (f)-(g) go further than giving the Welsh Ministers duties which mirror the present Commission obligations to publish, it is difficult to see how this is covered either by the powers in paragraph 1 of Schedule 2 to the EUWA, or the supplemental ones in paragraph 21 of Schedule 7. Therefore we would ask the Welsh Ministers to clarify these matters so as to remove any doubt about vires.



2. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation
- 2.1 Regulation 3(2)(a) and (f), amending definitions contained in regulation 2(1) of the 2002 Deliberate Release Wales regulations
 - 2.1.1 Regulation 3(2)(a) changes the definition of an “approved product”, for the purposes of permission to be marketed in Wales. Essentially, the present definition of an “approved product” becomes the definition of a “pre-exit approved product”, by virtue of a new definition inserted into regulation 2(1) of the 2002 Deliberate Release Wales regulations by regulation 3(2)(f) of the present Regulations.
 - 2.1.2 The new definition of an “approved product” is, in essence a product that has either been given consent by the Welsh Ministers under section 111(1) of the Environmental Protection Act 1990, or authorised under Regulation 1829/2003 EC, known (and referred to in the present regulations) as the Food and Feed Regulation.
 - 2.1.3 The Food and Feed Regulation will pass into domestic law on exit day, by virtue of section 3 of the EUWA. Regulation 3 of the present regulations will not come into force until exit day. Therefore, for the purposes of post-Brexit Welsh law, authorisation under the Food and Feed Regulation appears to mean an authorisation granted after exit day. This is also logical in view of the creation of a separate definition for “pre-exit approved product[s]”.
 - 2.1.4 However, this raises two issues. First, the Food and Feed Regulation is already in force. Further explanation is requested as to why the definition of a “pre-exit approved product” does not include products approved under that Regulation before exit day.
 - 2.1.5 The second issue is a Merits point and is reported below under Standing Order 21.3(ii).
- 2.2 Regulation 3(6)(b) and (c), amending regulation 17(2)(g) and (j) of the 2002 Deliberate Release Wales Regulations
 - 2.2.1 These provisions update the references to documents setting out the format for applications for consent to market GMOs, where those applications are made to the Welsh Ministers. They are, therefore, important provisions for applicants. Regulation 3(6)(b) provides that applicants must provide a monitoring plan prepared, inter alia, according to a format set out in the Annex to Commission Decision 2002/811/EC.
 - 2.2.2 The application forms set out in that Annex refer in a number of places to the European Community (now, of course, the European Union) and to the European Commission. In particular, they require an applicant to describe, as part of the monitoring plan that forms a mandatory part of the application, the conditions in which the applicant will report to the Commission. More explanation is required as to why and how the format set out in this Annex is appropriate for post-Brexit applications for consent to the Welsh Ministers.
 - 2.2.3 Regulation 3(6)(c) relates to the mandatory summary which has to form part of the application. We raise, below, the point that the document identified in regulation 3(6)(c) as setting out the format for this summary appears not to be the correct one. For the purposes of this reporting point, we will assume that the intention was to mandate applicants to follow the format set out in the Annex to Council Decision 2002/812 EC.



2.2.4 That Annex also includes a number of references to the EC (*sic*) which appear to require further explanation. For instance, applicants are required to state whether their product is being notified to another “Member State”, and whether another product with the same combination of GMOs has been placed on the “EC market” by another person. In the latter case, it is not clear to us how applicants will have this information after the UK leaves the EU. Applicants are also required to provide an estimate of the demand in export markets for “EC supplies” of the product (pre-Brexit, UK supplies would of course have counted as EC supplies but will not do so post-Brexit).

2.3 Regulation 3(8)(b), amending regulation 22(6) of the 2002 Deliberate Release Wales Regulations

Our concerns about this provision are similar to those set out in 1.2. Applicants are required, by the new provision, to provide information in a format set out in the Annex to a Commission Decision (2003/71/EC). That Annex makes various references that appear difficult to operate post-Brexit, including a requirement for applicants to quote a “European notification number”.

2.4 Regulation 3(9)(a)(ii), amending regulation 24(1)(e) of the 2002 Deliberate Release Wales Regulations

2.4.1 This provision replaces regulation 24(1)(e) of the 2002 Deliberate Release Wales regulations with a new provision. The fact of replacement does not require further explanation, as the original provision places a duty on the Welsh Ministers *vis a vis* the European Commission, which will clearly no longer be operable after exit day. However, we consider that the placement of the new provision in regulation 24(1) does require some explanation. Regulation 24(1)(d) deals with the Welsh Ministers’ duties to notify an applicant of their decision. The original 24(1)(e) dealt with action following that decision. However, the new 24(1)(e) requires the Welsh Ministers to take into account certain matters in taking their decision. Logically, therefore, it appears that the new regulation 24(1)(e) should precede regulation 24(1)(d), not follow it.

2.5 Regulation 3(16)(b) and (17), amending regulations 35 and 36 of the 2002 Deliberate Release (Wales) Regulations

2.5.1 As discussed above, regulation 3(16)(b) imposes duties on the Welsh Ministers to publish additional information in the public register concerning GMOs. However, regulation 3(17) does not amend regulation 36 of the 2002 Deliberate Release (Wales) Regulations so as to prescribe a deadline for the Welsh Ministers to do so. It may be that it was not the Welsh Ministers’ policy intention to impose such a deadline on themselves. However, regulation 36 of the 2002 Deliberate Release (Wales) Regulations does so for all the other categories of information listed in regulation 35 (although the amendments made by the regulations under scrutiny lift those deadlines in relation to pre-Brexit decisions of the European Commission or other Member States).

2.5.2 Further explanation of the absence of a deadline for publication of the relevant information is, therefore, requested.



2.6 Throughout regulation 3

- 2.6.1 A number of the amendments made by regulation 3 have the effect that the 2002 Deliberate Release Wales regulations will use two different names to refer to what is now the same legal person, i.e. “the [former] National Assembly for Wales” and “the Welsh Ministers”. All these references are to be interpreted as references to the Welsh Ministers, by virtue of paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006. However, that will not be immediately apparent to those seeking to understand the legislation. In certain places, both names will appear in the same provision – for instance, in regulation 24 of the 2002 Deliberate Release Wales regulations (see regulation 3(9)(a) of the regulations under scrutiny).
- 2.6.2 In our view, the Welsh Ministers would have had the vires to change all references to the National Assembly into references to themselves, where appropriate, under paragraph 21 of Schedule 7 to the EUWA, as they would be supplementary or incidental to provision made under paragraph 1(1) of Schedule 2 to that Act, and would restate retained EU law (the Wales statutory instruments amended) in a clearer and more accessible way.
- 2.6.3 However, we understand that the Welsh Government is working under severe pressure to make all the essential amendments to retained EU law, as it applies in Welsh devolved competence, before exit day and that it may not always have been practicable to make amendments that were, arguably, desirable without being necessary for post-exit operability.
- 2.6.4 We also request further explanation of the rationale behind amendments to the way in which some EU legislation is referred to in the regulations. This legislation will become retained EU law on exit day, by virtue of the EUWA.
- 2.6.5 Regulation 3(2)(e) provides that references in the 2002 Deliberate Release Wales regulations to the First Simplified Procedure (crop plants) Decision is a reference to that Decision as it applied immediately before exit day. However, the regulations do not amend other references to retained direct EU law in the 2002 Deliberate Release Wales regulations in that way (for instance, the references, in regulation 2 of those regulations, to the Food and Feed Regulation, Council Regulation 1829/2003/EC).
- 2.6.6 Nor are new references in the regulations to retained direct EU law (EU Regulations and Decisions) treated in this way (see for instance the reference to Council Decision 2002/813/EC, inserted by regulation 3(4)(b)).
- 2.6.7 It appears to us that all of these references to EU legislation – whether existing in or newly inserted into the 2002 Deliberate Release Wales regulations - will be treated as references to the EU legislation as it applied immediately before exit day, by virtue of the European Union (Withdrawal) Act 2018 (Consequential Modifications and Repeals and Revocations) (EU Exit) Regulations 2019, currently in draft. This is because none of the references are “ambulatory” (i.e. they are not stated to be references to the EU instruments as amended from time to time by the EU institutions; nor are they stated to be references to those instruments as they applied at a particular time prior to exit day). Indeed, it would be outside the EUWA powers to render new references in domestic law to EU instruments ambulatory in this sense; the EUWA does not give Ministers powers to track future EU-law developments in this way, in subordinate legislation.



- 2.6.8 Further explanation of the rationale for the Welsh Ministers choosing to make provision of the kind of regulation 3(2)(e) in some cases and not others is therefore requested in the interests of transparency, both for the Assembly and the users of the legislation.
- 2.7 Regulation 4 – amendments to the Schedule to the 2005 Transboundary Movements Wales regulations
- 2.7.1 Many provisions of the 2005 Transboundary Movements Wales regulations are dependent on “the specified Community provisions”, i.e. those provisions of Regulation (EC) No. 1946/2003 listed in the Schedule to the regulations. For example, regulation 3 provides that the National Assembly (now, the Welsh Ministers) must enforce and execute the specified Community provisions, while regulation 8 provides that it is an offence for anyone to contravene, or fail to comply with, the specified Community provisions. Therefore, the exact meaning of the specified Community provisions is extremely important.
- 2.7.2 Regulation 4 of the regulations under scrutiny amends the description of two of the “specified Community provisions” in the Schedule. Both of the amendments appear, in themselves, appropriate in terms of adapting the 2005 Transboundary Movements Wales regulations in consequence of the UK leaving the EU. One simply removes a reference to “the Commission”, while the other amends the rules on what authorisations are necessary to export GMOs for direct use as food or feed or for processing. Previously, authorisation for import into a particular country could have been agreed within the EU; the regulations under scrutiny replace this from exit day with a provision that permission to market in the UK is sufficient.
- 2.7.3 However, it is not clear to us how these amendments are effective unless the relevant provisions of Regulation No. 1946/2003 itself are amended in the same way, as retained EU law. The provisions in the Schedule to the 2005 Transboundary Movements Wales regulations are defined as provisions of that Regulation. In light of that definitional link it seems to us dubious that the effect of those provisions, for the purposes of the 2005 Regulations, can be altered simply by amending the Schedule, and not the underlying EU Regulation (as it will exist in domestic law after exit day). Once again, we emphasise that non-compliance with the provisions of the Schedule constitutes an offence; the second example given in the previous paragraph is an example of a situation where this could be directly relevant.
- 2.7.4 We recognise that the issue we have identified may be being avoided or rectified by other Brexit-related legislation. However, as we said in our recent report on The Common Agricultural Policy (Miscellaneous Amendments)(Wales)(EU Exit) Regulations 2019, we consider that it is incumbent on the Welsh Government to seek to explain, better and more fully, to the Assembly and to citizens how each piece of Welsh EU exit legislation fits into the whole picture of UK and EU legislation – current and intended - on the particular subject-matter. The appropriate place for this would appear to be the EM accompanying statutory instruments.
- 2.7.5 Moreover, as we have repeatedly said in previous Reports, clarity in the criminal law is of particular importance. For all these reasons, therefore, we call on the Welsh Government to provide a further explanation of these provisions.



3. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

3.1 Regulation 3(6)(c)

As set out above, this provision changes the document which sets out the format for applications for deliberate release authorisations. It is, therefore, an important provision for applicants. It provides that the correct format is that set out in “the Annex to Commission Decision 2002/812 EC”. However, there appears to be no Commission Decision with that number. There is, however, a Council Decision with that number, the Annex to which appears to be the relevant document.

3.2 Regulation 3(10)(b)(ii)

This provision amends regulation 25(5) of the 2002 Deliberate Release Wales regulations. It refers to “regulation (3) of the Seeds (National Lists of Varieties) Regulations 2001”. This is clearly an incorrect reference, as regulations are not identified by numbers in brackets. Having considered the 2001 Regulations referred to, it appears to us that the intention was to refer to “regulation 3”. We consider that this is simply a typographical error and that there is no real risk of confusion with another provision of the 2001 statutory instrument. However, it should be corrected so as to remove any doubt for users of the legislation.

Merits Scrutiny

One point is identified for reporting under Standing Order 21.3 in respect of this instrument.

4. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Assembly

4.1 Regulation 3(2)(a) and (f), amending regulation 2(1) of the 2002 Deliberate Release Wales Regulations

4.1.1 This point relates to the amendments made by regulation 3(2)(a) and (f) to the definition of an “approved product” in the 2002 Deliberate Release Wales regulations, for the purposes of permission to be marketed in Wales. Detail of these two provisions is set out above, under paragraph 2.1, relating to Standing Order 21.1(v).

4.1.2 These provisions also raise a merits point. The Food and Feed Regulation gives the function of authorising products for marketing to the European Commission, assisted by an EU Committee, and on the basis of a scientific opinion from the European Food Safety Authority (“EFSA”). If the Food and Feed Regulation, once imported into domestic law on exit day, is not amended in that regard, the Commission will be able to continue giving authorisations that are recognised in the UK, including in Wales. This would be consistent with the overall intention of the EUWA, to maintain continuity, as far as practicable and for the time being, between pre- and post-Brexit law derived from the EU.

4.1.3 However, it is of political importance that marketing certificates for food and feed products made of, or including, genetically-modified ingredients, issued by an EU body, will continue to be recognised in Wales after Brexit. This is particularly so given the controversy within the UK and in Wales over the safety or otherwise of genetically-modified food.



- 4.1.4 We recognise that the Food and Feed Regulation may have been, or may be about to be, amended in some relevant way, as retained EU law, by UK Government subordinate legislation under the EUWA. We also recognise the difficulties facing the Welsh Ministers in seeking to legislate under extreme time pressure and in a context in which a great deal of other related legislation is also being made, both by them and by the UK Government.
- 4.1.5 However, we consider that, where such independencies exist between different pieces of legislation, made or to be made, in such an important area of law, they should be explained, or at least pointed to, in the Explanatory Memorandum accompanying the subordinate legislation for scrutiny.

Implications arising from exiting the European Union

One point is identified for reporting under Standing Order 21.3 in respect of this instrument.

The last sentence of paragraph 4.5 of the Explanatory Memorandum states:

Wales intends to follow England, Northern Ireland and Scotland's approach on the release of GMO's.

This may be simply a question of infelicitous language, but we do not consider that the Welsh Government should simply "follow" the approach of other nations of the UK; particularly on such an important and controversial matter. "Following" is a very different matter from agreeing a common approach with the governments of those other nations. We note that the Intergovernmental Agreement between the Welsh and UK Governments of 24 April 2018 identified "Agriculture - GMO marketing and cultivation", as well as various matters concerning food, as areas where both governments would agree that common UK frameworks – legislative or otherwise - were likely to be required, and we assume that the sentence highlighted above is attempting to reflect this agreement.

Government Response

A government response is required.

Committee Consideration

The Committee considered the instrument at its meeting on 18 March 2019 and reports to the Assembly in line with the technical and merits points above.

