

LEGISLATIVE CONSENT MEMORANDUM

The Genetic Technology (Precision Breeding) Bill

1. This legislative consent memorandum is laid under Standing Order (“SO”) 29.2. SO29 prescribes that a legislative consent memorandum must be laid, and a legislative consent motion may be tabled, before Senedd Cymru if a UK Parliamentary Bill makes provision in relation to Wales for any purpose within, or which modifies, the legislative competence of the Senedd.
2. On 27 June 2022 the Minister for Climate Change wrote to the Llywydd outlining concerns with the Bill and stating that, because of the absence of meaningful engagement by the UK Government prior to introduction and the complexity of the issues raised in the Bill, it would not be possible to respond within the normal two-week period set out in SO 29. The letter also outlined the UK Government’s choice not to engage with the Welsh Government until the Bill had its first reading in the House of Commons, and expressed concern at the limited engagement officials have had with the UK Government since that point.
3. The fact that the UK Government chose not to work within the Common Frameworks that are in place in several policy areas affected by the Bill, or engage with the Welsh Government until the Bill’s introduction, meant the impacts of the Bill on Wales have not been properly considered.
4. The Genetic Technology (Precision Breeding) Bill (“the Bill”) was introduced in the House of Commons on 25 May 2022. The Bill can be found at: <https://bills.parliament.uk/publications/48320/documents/2404>. The Bill had its second reading in the House of Lords in November 2022 and Committee Stage is expected sometime in December.

Policy Objective(s)

5. The UK Government’s stated policy objectives are that the Bill will reduce the regulatory burden and financial barriers in place for researchers and commercial breeders using precision breeding technologies.
6. This Bill removes the plants and animals produced using modern biotechnologies, and the food and feed derived from them, from Genetically Modified Organisms (GMO) regulation if those organisms could have occurred naturally or been produced by traditional methods. It replaces existing GMO controls with a lighter touch regulatory framework.

Summary of the Bill

7. The Bill is sponsored by the Department for Environment, Food and Rural Affairs
8. The Bill makes provision for:

- Bringing in two mandatory notification systems for precision bred organisms (PBOs), one for non-marketing purposes (research and development) and one for marketing purposes.
- Allowing for new powers to introduce on-going obligations to report information relating to the health and welfare of precision bred vertebrate animals, and to prescribe the processes and powers the Secretary of State can use to take the necessary action in response to this post-marketing animal welfare information.
- Creating a duty on the Secretary of State to create and maintain a new public register of notified information.
- Granting powers to create a new regulatory framework for food and feed derived from PBOs. This framework will include a procedure for making precision bred food and feed marketing authorisations including a new proportionate risk assessment. The framework will also set out the requirements to be satisfied before a food and feed marketing authorisation can be issued.
- Granting powers for the Food Standards Agency (FSA) to establish, publish and update a public register for PBOs authorised for food and feed use. An entry on this register would indicate that a PBO and products derived from it, have been authorised to enter the market for food and feed uses based on the recommendation of the FSA.
- Granting powers to create an inspection and enforcement regime, including civil sanctions, in order to secure compliance with the obligations under the Bill.

There are no mandatory labelling or traceability requirements for the marketing of precision bred organisms.

Provisions in the Bill for which consent is required

9. It is Welsh Government's view that the Bill is a relevant bill as it makes relevant provision in relation to Wales because of the UK Internal Market Act 2020 ("UKIMA"). The effect of the requirements in UKIMA mean that the provisions in this Bill will in essence allow the sale and marketing of PBOs in Wales, which currently Welsh legislation does not allow. It is therefore, WG view that the Bill, by virtue of UKIMA, makes provision in relation to Wales for a purpose which is within the legislative competence of the Senedd.
10. The Bill puts in place a new regulatory framework in England for precision bred organisms. It will have direct application only in England but as a result of UKIMA it will have significant implications in relation to Wales. As such, the effect of the Bill as a whole is to introduce a regulatory framework that will impact Wales. The Annex outlines clauses of particular relevance that Welsh Government considers provide the key features of the framework. GMOs, plants, animal health and welfare, food and feed, and agriculture are all within the scope of the Bill provisions and are provisions within the legislative competence of the Senedd.

11. Clause 41 of the Bill amends the Environmental Protection Act 1990. This clause, combined with the general provisions in clauses 42 to 48 removes Precision Bred Organisms from the current regulatory regime that exists for Genetically Modified Organisms in England.
12. Clause 1 defines a precision bred organism. For a precision bred organism to be marketable in England it will need to satisfy a number of requirements. A person will need to notify the Secretary of State if they intend to release a precision bred organism, i.e. a plant or animal, into the environment in England (clauses 3 and 4 of the Bill). If they wish to market it they will need first need to apply for confirmation that the organism is a precision bred organism under the Bill (clauses 5-8). Further requirements are in place for the marketing of precision bred animals (clause 11), including relating to animal welfare assessment. Part 3 of the Bill sets out a framework for regulation of food and feed produced from precision bred organisms (clause 26). The Bill also sets out monitoring obligations, enforcement and costs. (Clauses 20, 28, 31, 32 and 38).
13. Whilst the application of the Bill is limited to England only, the mutual recognition principle in the United Kingdom Internal Market Act 2020 (UKIMA) will apply to precision bred plants and animals, and food and feed derived from them, which are produced in or imported into England. This means that it would be possible to place them legally on the market in Wales if they can be marketed lawfully in England as a result of this Bill and the delegated legislation to be made under it.
14. In Wales the Genetically Modified Organisms (Deliberate Release) Wales Regulations 2002 (SI 2002/3188) regulate the deliberate release of GMOs and prevent their marketing without the consent of Welsh Ministers. However, these Regulations will not be applicable to precision bred organisms moved into Wales from England, as long as those organisms satisfy the requirements set out in the Bill. The practical effect is that precision bred plants and animals from England will be marketable in Wales, and Welsh law will be irrelevant for those particular precision bred plants and animals. Essentially these provisions are made for a purpose which is within the legislative competence of the Senedd as it will be possible to market the products in Wales despite PBs falling within the definition of GMO, and subject to more stringent regulations in Wales.
15. Food and animal feed containing, consisting of, or produced from genetically modified organisms are regulated under retained Regulation (EC) No. 1829/2003 on genetically modified food and feed. This Regulation prevents the marketing of genetically modified food or feed in each GB territory without prior authorisation granted by the 'appropriate authority' for the territory (in relation to Wales, the Welsh Ministers). Regulations made by the Secretary of State under Part 3 of the Bill will need to amend Regulation 1829/2003 to exclude PBOs from the scope of that Regulation to the extent it applies in relation to England. The effect of the Bill and UKIMA means that precision bred food and feed products

authorised under the new England regime could be lawfully marketed in Wales without being authorised (by the Welsh Ministers) under Regulation 1829/2003. This means there will need to be two different regulatory regimes for food and feed in operation in Wales – the new regime as proposed by the Bill and the existing Welsh regime. This could increase further should the EU change its regulatory approach, which would then apply in Northern Ireland

16. Furthermore, without a provision in the Bill mandating labelling or traceability of precision bred organisms or products, Welsh Ministers' ability to monitor, control or regulate the marketing of these products in Wales will be severely limited.
17. The lack of labelling of PB Goods will place enforcement authorities in Wales in a difficult position as they will be unable to identify relevant products which are in breach of Welsh laws or which are not in breach of English authorisation and, therefore, by virtue of UKIMA must be accepted in Wales.
18. The devolved areas of policy in scope of this Bill are: genetically modified organisms; plants; animal health and welfare; and food and feed. In particular, the Genetically Modified Organisms (Deliberate Release) Wales Regulations 2002 (SI 2002/3188) and retained Regulation (EC) No. 1829/2003 on genetically modified food and feed will not apply to precision bred organisms produced or imported into and England and moved into Wales. The Annex sets out specific provisions where the effect of UKIMA can be clearly seen, although these provisions interact with the entirety of the Bill.

UK Government view on the need for consent

19. The UK Government disagrees that consent may be required for any part of the Bill.

The Welsh Government's position on the Bill

20. The Welsh Government has concluded that it is unable to recommend to the Senedd that it gives consent to the Bill as currently drafted. We are recommending withholding consent on the following grounds:
 - a. The Welsh Government was not involved in the development of the Bill and the impacts of the Bill on Wales have not been properly considered. The current legal position in the UK stems from a ruling of the European Court of Justice in 2018, which stipulated that gene editing is considered a form of genetic modification. The Welsh Government has not completed its own assessment of the UK Government's scientific and economic rationale for deregulating precision bred organisms and so cannot yet agree with the position of the UK Government.

- b. The effect of the Bill as a whole will have detrimental effects on the devolution settlement. It creates a whole new regulatory framework for precision bred organisms that will have implications for Wales. The effect of the Bill, by virtue of the UK Internal Market Act, is that Welsh law relating to GM will be irrelevant for certain precision bred organisms moved into Wales from England. Precision bred plants and animals from England will be marketable in Wales without the authorisation of Welsh Ministers.
- c. The Bill does not require precision bred organisms to be labelled as such. This means Welsh consumers purchasing precision bred organisms and food derived from them will not necessarily know what they are purchasing. The Welsh Government wants to protect Welsh consumers' rights to choose whether to purchase food products which contain precision bred ingredients. Further, without a labelling or traceability requirement, Welsh Ministers' ability to monitor, control or prevent the marketing of precision bred organisms and products in Wales is greatly limited. It also makes it practically challenging to enforce Welsh Regulations, where they apply.
- d. The Welsh Government is also concerned about the effect that the Bill will have on trade with key markets, like the EU, where PBOs are regulated as GM organisms. Although the EU is considering deregulation of gene edited organisms, indications are that this will be restricted to plants and there will be a labelling or traceability requirement. As such, there may be increased barriers to trade for Welsh businesses looking to export precision bred products, and these barriers could be compounded by a lack of labelling or traceability.
- e. Key parts of the Bill, including Part 3 relating to the regulation of precision bred animals, are to be set out in secondary legislation. This makes it difficult to ascertain how the powers will be exercised and the potential effects that the related provisions will have for Wales and our devolution settlement. For example, it is not yet known what welfare standards will be put in place for precision bred animals that will be marketable in Wales. Animal welfare is a devolved area of competence. As the regulatory framework will be set out in secondary legislation, we are also concerned with the lack of scrutiny they may be subject to.

21. As such, the above reasons for recommending that consent is withheld apply across the Bill as a whole, as the effects of the Bill will impact the devolved areas of plant health, animal health and welfare, and food and feed.

22. It is Welsh Government's view that the Bill is a relevant bill as it makes relevant provision in relation to Wales as a result of the UK Internal Market Act 2020. The effect of the requirements in UKIMA mean that the provisions in this Bill will in essence allow the sale and marketing of PBOs in Wales, which currently Welsh legislation does not allow. It is therefore, the Welsh Government view that the provisions in the Bill, by virtue of UKIMA, are made for a purpose which is within the legislative competence of the Senedd.

Financial implications

23. Early analysis shows that there will be financial implications for Wales as result of the Bill. This is because there will be at least two different regimes operating in Wales with respect to precision bred products. Businesses will be required to operate lawfully in these environments, and there will be costs associated with enforcing two different regimes.

Conclusion

24. As outlined above and in the Annex, the overall effect of the Bill is of constitutional concern to the Welsh Government given the impact on the Welsh position on PBOs and enforcement of the same, by virtue of the provisions of UKIMA. In its present form the Welsh Ministers do not consider the Bill makes appropriate provision and would not recommend the Senedd provides consent.

Lesley Griffiths MS

Minister for Rural Affairs and North Wales, and Trefnydd

8 December 2022

Annex 1 Provisions of the Genetic Technology (Precision Breeding) Bill for which consent is required.

Under SO 29.1(i) for clauses which make provision in relation to Wales for any purpose within the legislative competence of the Senedd:

Clause 1 – Precision bred organism

Clause 3 – Restrictions on release of precision bred organism in England

Clause 4 – Release of precision bred organism: notification requirements

Clause 5 - Restrictions on marketing of precision bred organism in England

Clause 11 - Application for precision bred animal marketing authorisation

Clause 20 – Monitoring and inspection of Part 2 obligations

Clause 26 – Regulation of food and feed produced from precision bred organisms

Clause 28 – monitoring and inspection of Part 3 obligations

Clause 31 – meaning of “relevant breach” etc

Clause 32 – Enforcement

Clause 38 – Costs

Clause 41 - Consequential amendments of the Environmental Protection Act 1990

These provisions engage section 107(6) of the Government of Wales Act 2006 which provides that the UK Parliament will not normally legislate with regard to devolved matters without the consent of the Senedd. The effect of these provisions impacts on the devolved matters of genetic modification and the release of genetically modified organisms, plant health, animal health and welfare and food and feed, and the Senedd’s ability to legislate in these areas. Therefore, the consent of the Senedd is required.

Clause 1 provides the definition of a precision bred organism. It sets out that the conditions under which an organism will be considered precision bred. Wales has yet to define a precision bred organism yet. The definition of genetically modified organism in Wales encompasses precision bred organisms. The effect of UKIMA will be that the Welsh definition of a GMO will not be applied to PBOs. Genetically modified organisms are a devolved policy area and, as such, only Welsh Ministers should be able to legislate to amend the definition in relation to Wales.

Clause 3 sets out requirements for a precision bred organism to be released into the environment in England. It sets out that either a “release notice” must be in place for the organism, or that the organism must be considered a marketable precision bred organism. Under Welsh domestic legislation (The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations

2002), precision bred organisms would be considered as genetically modified and require authorisation of Welsh Ministers to be released into the environment. However, under the Precision Breeding Bill, and because of the effect of the UK Internal Market Act, there may be circumstances in which these organisms are released into the environment in Wales, by virtue of complying with the legal requirements in England, as long as the requirements set out in Clause 3 are satisfied.

Clause 4 sets out the notification process for the release of a precision bred organism in England. Release of a PBO can have several meanings and as a result of UKIMA, it is possible that by complying with the notification process for the release of a PBO in England, that PBOs can be released in Wales due to the effect of UKIMA. This would be contrary to the law in Wales which requires a far more detailed process for the release of GMOs (of which PMO is one) which the Welsh Ministers currently regulate.

Clause 5 sets out when a precision bred organism can be marketed. It requires that a precision bred confirmation needs to be in place for the organism and, in the case of animals, a precision bred animal marketing authorisation must also be in force. Marketing occurs when a product is made available to someone else (whether for consideration or not) and the marketing of that product takes place in England. Under existing Welsh regulations PBOs could not be marketed in Wales (without the relevant GM authorisation process being followed). However, the effect of UKIMA means that clause 5 will effectively render the Welsh provisions regarding GMOs, into which PBOs currently fall, irrelevant and likely unenforceable. Wales would have to allow the marketing and delivery of those PBOs in Wales

Clause 11 sets out the application process for a precision bred animal marketing authorisation. There is no requirement for labelling or traceability if this PB marketing authorisation is subsequently granted. GMOs in both England and Wales currently require labelling. As PBOs are being removed from the GMO definition in England and due to effect of UKIMA, if a product has gone through the application process for a PB animal marketing authorisation and receives said authorisation, then it can be marketed in Wales – with no indication that it is PB.

Clause 20 provides that regulations may be made to allow monitoring and inspection of obligations outlined in part 2 of the Bill. It is not clear how these obligations will be monitored when they relate to the release and marketing of precision bred organisms in Wales.

Clause 26 provides that Regulations may make provision for regulating the marketing of food and feed produced from precision bred organisms. The clause provides that a marketing authorisation for food and feed products may be required, and traceability requirements may also be put in place. These regulations will apply only to England. Under existing Welsh regulations PBOs could not be marketed in Wales without the relevant GM authorisation process being followed. However, the effect of UKIMA means that regulations made under clause 26 will effectively render the Welsh provisions regarding

GM food and feed, into which PB food and feed currently falls, unenforceable in relation to PB food and feed produced in, or imported into England, and marketed in Wales.

Clause 28 provides that regulations may be made to allow the enforcement of obligations outlined in part 3 of the Bill. It is not clear how this enforcement will take place regarding precision bred food and feed products that are marketed in Wales.

Clauses 31, 32 and 38 relate to breaches of the Act, the enforcement of the Act and costs associated with enforcement. It is not clear how the Act will be enforced in Wales or how costs will be handled. It is recognised that these are only framework powers and the regulation making powers will provide the detail of the enforcement regime.

Clause 41 amends the Environmental Protection Act 1990 to exclude precision bred organisms from references to genetically modified organisms in relation to England. The effect of this is that, in England, precision bred organisms will not be treated as genetically modified organisms in England. Whilst this amendment to the Environmental Protection Act 1990 does not apply in Wales, the impacts of it will do, as by virtue of UKIMA these PBOs, now falling outside the GMO regime, would be marketable in Wales.