Department for Environment Food & Rural Affairs

Llywodraeth Cymru Welsh Government

Scottish Government Riaghaltas na h-Alba gov.scot

Date: 19th Oct 2021

Dear Plant Health Licence holder,

Plans for revising legislation relating to scientific licensing

On behalf of the GB Plant Health Services, we are writing to invite views on our proposal to make changes to parts of the legislation governing Scientific Licensing. The proposal can be viewed in appendix 1 and a list of current legislation applicable to this proposal along with links to view this legislation, can be found in appendix 2.

We welcome your views and comments on the proposal and any other comments on the scientific licensing process that you would like to share at this time. Please send comments to the Defra licensing team at Planthealth_licensing@defra.gov.uk by 14th December 2021.

Yours sincerely

The Defra licensing team

Defra Licensing team

Part of the Risk and Horizon Scanning team

Animal and Plant Health and Welfare

Defra

Planthealth_licensing@defra.gov.uk

Appendix 1
Proposed changes to Scientific licensing legislation
Background
Scientific licensing allows quarantine pests and other prohibited material to be imported into Great Britain for scientific research and other work. As such it is vital that we have a robust legislative framework to allow us to mitigate the risks of these introductions. Since the Smarter Rules for Safer (SRSF) Food legislation package was introduced in 2019 a number of deficiencies have been identified in the legislation governing scientific licensing, which are included in retained EU legislation. A full description of this legislation and links to access it can be found in appendix 2.

We aim to amend Delegated Regulation (retained EU law) 2019/829. This regulation contains the detailed requirements surrounding scientific licensing. The proposed amendments aim to address deficiencies in this regulation and remove unnecessary burdens for licensees, which do not aid biosecurity. Further changes to this regulation and others which impact on scientific licensing may be required in the future.

Proposed amendments to Delegated Regulation (retained EU law) 2019/829
1. Removal of Third country endorsements

At present the country of origin of the material being imported to GB must endorse the letter of Authority (LoA) prior to export. We plan to remove the requirement for endorsement as it serves no purpose in terms of biosecurity. The National Plant Protection Organisation (NPPO) of the country of origin is not involved in the authorisation process and therefore has no knowledge of the purpose of the export. As such they have no control or involvement in the material they are endorsing. In addition, several NPPOs have refused to provide endorsement since SRSF rules were introduced.

2. Changes to information gathered during the scientific licence application process

We plan to make changes to the information which must be supplied by the licensee as part of the application process for new licences or amendments to existing licences as specified in annex 1 of the Regulation:

i. We will no longer require the number of imports/consignments (sending's) to be specified in the application as this will often not be known in advance and does not affect biosecurity. The Plant Health Regulation (Article 62) requires the person responsible to keep records of this information for three years.

ii. We will no longer ask for full details including name, address, email address, and phone number of the consignor or provider for each type of material to be included on a licence during the application process. We feel this isn't practical and, in many cases, will not be known. The risk posed by an organism will in most cases not change based on location. As such, listing countries or geographical areas is enough for the assessment of the risk posed by a particular pest. The Plant Health Regulation (Art 62) requires that records are kept of material entering under licence including its place of origin. Keeping records of where material has actually come from rather than where an applicant expects to get it from has more value in terms of biosecurity.

2. All Letters of Authority will be valid for multiple introductions

Currently LoAs should be either for a single introduction or for multiple introductions of one type of material, from the same origin under the same conditions. Given the size and complexity of some licences this is not practical. To remove administrative burdens all LoAs will allow multiple introductions of all material on a particular licence from all authorised origins. Each LoA will continue to be time limited to 1 year.

3. Structure of the Letter of Authority

We plan to alter the content of the LoA to better reflect our licensing practices. The model LoA in annex 2 will be amended as follows:

i. Box 1 – will be changed to "place of origin" of material as full details will often not be known and one LoA may cover multiple organisms which may have multiple different origins. Listing the Plant protection organisation or competent authority of the place of origin is not necessary as they have no involvement with the LoA.
ii. Box 8 – we plan to delete the wording in the second column so it can be entered as free text i.e. if being transported as passenger baggage, courier company etc.
iii. Box 10 – we plan to delete the multiple sending yes/no option as all LoAs will allow multiple sending's. We plan to retain the date of issuance and reference number. The date the LoA is valid until will also be included in this box.
iv. Box 12 – the third country endorsement will be deleted as discussed above.
v. Box 14 – Appropriate computerised information management system reference will be deleted as there isn't a computer system reference as such so this will be amended to say licence number and version.
vi. A box will be added for the declared point of entry for material introduced from a third country. This is because material may enter through a different part of GB to its destination i.e. material entering under licence in Wales or Scotland will often enter through an English point of entry.

Appendix 2
Current legislation governing scientific licensing

1. Regulation (retained EU law) 2016/2031 on protective measures against plant pests, establishing lists of regulated pests and products in line with prescribed criteria based on phytosanitary principles ("the Plant Health Regulation") contains derogations which allow quarantine pests or plants, plant products and other material which may harbour these pests to be imported into or moved within Great Britain (GB) for official testing, scientific or educational purposes, trials, varietal selections or breeding (Scientific licensing). The Plant Health Regulation was made operable by The Plant Health (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1482). Specific articles which pertain to scientific licensing are article 8, 48, 60, 61, 62, 63 and 64.
   The Plant Health Regulation can be accessed at:
   https://www.legislation.gov.uk/eur/2016/2031/contents
   The Plant Health (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1482) can be accessed at:
   https://www.legislation.gov.uk/uksi/2020/1482/part/3/made

2. The Plant Health (Phytosanitary Conditions) (Amendment) (EU Exit) Regulations 2020 (SI 2020/1527) lists all of the prohibited and regulated material which may be imported or moved within GB under scientific licence. The regulation can be accessed at:
   https://www.legislation.gov.uk/uksi/2020/1527/contents/made

3. Delegated regulation (retained EU law) 2019/829 on protective measures against pests of plants, authorising the Competent Authority to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections or breeding. This regulation was made operable by The Plant Health (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1482). This regulation contains details of the requirements for assessing and administering scientific licences, referred to as authorisations.
   The regulation can be accessed at:
   https://www.legislation.gov.uk/eur/2019/829/contents/adopted
   SI 2020/1482, part 47 can be accessed at:
   https://www.legislation.gov.uk/uksi/2020/1482/regulation/47/made