UK Plant Sciences Federation

Regulation Working Group final report

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This report was produced by an independent working group convened under the UK Plant Sciences Federation. All views, unless otherwise noted, are those expressed at the working group meetings, and are not necessarily those of the convening groups.

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Background

The UKPSF report presents concerns from plant scientists that the EU regulatory environment creates significant barriers to innovation in several areas. In particular, these are:

- High costs, long timescales and commercial uncertainty with bringing GM crops to market in Europe.

- Legislation on access and benefit-sharing arrangements relating to the use of plant genetic resources could discourage rather than encourage the use and exchange of such resources.

- The change from a risk- to hazard-based approach to decisions on approval or withdrawal of plant protection products, threatens to reduce crop yields and increase production costs.

Key recommendation from UKPSF report:

- **Regulatory frameworks must be more evidence- and risk-based, transparent, and enabling of innovation**

Given the challenges associated with sustainable agricultural intensification, it is crucial that plant scientists, commercial plant breeders, industry and UK farmers are able to deploy all of the advancing knowledge, tools and technologies available. The UKPSF supports the need for an appropriate regulatory framework and science-based processes to determine the balance between benefits and risks of adopting new technologies, products and practices.

Working Group implementation plan

Summary

The Working Group carried out a scoping exercise to identify the major regulatory barriers and concerns for UK plant science, and opportunities for influencing regulatory improvement. This included consultation with individuals outside of the Working Group. The group focussed on regulations relating to the following four areas:

1. Access and benefit sharing of plant genetic resources.
2. Genetic modification and novel breeding techniques.
3. Plant protection products
4. Invasive species

In addition, the group established the following general principles, which could apply to any area of regulation:

- The assessment and management of risks should be evidence-based and proportional.

- Risk management should take into consideration the balance between the risks and benefits of doing something as well as the risks and benefits of not doing it.

- The precautionary principle is a useful concept in risk assessment where there are fundamental uncertainties. However, it has been applied inappropriately in the case of genetically modified organisms (GMOs) where there is a strong belief amongst many scientists that the *process* of genetic modification is no more hazardous than other modern plant breeding techniques that are excluded from GMO regulations. Also, the manner in which the precautionary principle has been applied to genetic modification (GM) does not consider the risks of *not* using the technology or the potential benefits of GM breeding to agriculture, human health and environment function.

- Timelines for applications and approvals processes should be defined and adhered to.

- The European Commission should seek to harmonise environmental risk assessments in different areas (e.g. plant health, plant protection products and genetically modified organisms) to resolve the discrepancies and inconsistencies that exist between them.

Part 1 – Access and benefit sharing (ABS) of plant genetic resources

Background:

The Nagoya Protocol of the Convention on Biological Diversity (CBD) governs the regulation of access to genetic resources and sharing of benefits derived from them. It covers utilisation of genetic resources after 12 October 2014 (the date the Protocol came into force).

The EU has passed a Regulation (511/2014) to implement the Nagoya Protocol. The UK is currently preparing a Statutory Instrument (SI) to implement the EU Regulation at the national level and is likely to nominate the National Measurements Office (NMO) as the National Competent Authority responsible for implementation.

Both the Protocol and the Regulation will have a big impact on plant science and in order to ensure that implementation of the Regulation in the EU and the UK is manageable and in line with the objective of facilitating access to genetic resources, UKPSF needs to be proactive in engaging with this process. The major difficulties with the Protocol and the Regulation are:

- Lack of clarity in the requirements for compliance with the Regulation's due diligence criteria, leading to uncertainty over procedures needing to be introduced and the cost thereof.

- Lack of clarity over what is in and out of scope of the Regulation, causing legal uncertainty. (E.g. what amounts to *utilisation* and what is covered by the definition of *genetic resources*?)

- The possibility of criminal sanctions being applied to non-compliance. Defra has proposed this for UK implementing legislation as a worst-case scenario but it is not yet known whether it will appear in the final legal text.

- No clearly defined cut-off point for onward transfer of ABS obligations.
- The need to improve traceability in users' internal tracking systems. Will users be able to recover any costs for this from the UK government?
- Complex dispute settlement arrangements.
- Potential extreme complexity of activities in some scenarios, including use of multiple accessions under different and separate access contracts.

The risk is that complexity, lack of clarity and cost may prove a deterrent to those wanting access, such that there will be no benefits to share.

Opportunities for UKPSF:

There is no scope now to change either the Protocol or the EU Regulation so the focus must be on achieving pragmatic and proportionate systems for implementation, monitoring and compliance, and helping users of genetic resources to understand and work with the requirements of the Protocol and the Regulation to promote the best chance of both instruments realising their objectives of facilitated access and equitable benefit sharing.

The immediate first step must be to get clarity on the key terms of the Regulations: what constitutes utilisation, what is a genetic resource, what exactly do the due diligence requirements amount to and how can different user groups most cost effectively amend their operating systems where necessary to comply?

UKPSF is uniquely placed in bringing together all users of plant genetic resources with a number of providers and, if there is a common position, it has the potential to be a strong voice in this area.

If a cross-federation position can be agreed, the Working Group recommends that UKPSF:

- Seeks to find alliances with other organisations that are similarly affected and share the same views (including organisations at the EU level) to see if it is possible to publish joint statements that can be used by all partners and Member Organisations (MOs) in direct campaigning – particularly at the EU level.
- Briefs MOs and other stakeholders who might be involved in the consultation on the implementation of Regulation 511/2014, providing them with the arguments and encouraging them to respond using model responses that they can adapt.
- Uses MOs who already have established contacts in this area as a campaign network, feeding them material and messages to pass onto their contacts on behalf of the Federation.

- Encourages MOs who are not already members of Defra's ABS stakeholder forum to join and take part in meetings and conference calls.[1]
- Meets with the NMO at an early stage to get clarity on key issues and influence sector standard setting for its members.
- Responds to any further Defra consultation on implementing the Nagoya Regulation, providing case studies of how the plant science sector uses genetic resources, the costs involved and the likely effect of new legislation on business and research.
- Hosts a visit by regulators to a genetic resource unit to show at first-hand how users and providers work together, the benefits that accrue and how both innovation and biodiversity will lose out if a solution is not found.
- Produces communications material on the same that can be used by all MOs and others in their direct campaigning.
- Develops guidance for members on implementation workflows and suitable practices.

Timescales

- The Defra implementation issue is expected to be active in the next 6–12 months.
- The timetable for EU secondary legislation is not yet known but should be anticipated to start within the next 12 months.

Part 2 – Genetic modification (GM) and novel breeding techniques (NBTs)

Background

The regulations covering contained use of GMOs have recently been revised and the latest version came into force on 1st October 2014. This legislation appears to be considered largely appropriate and workable by academic researchers.

Regulations covering environmental release of GMOs, both for research purposes and for commercialisation, have received criticism from the UK academic community[2] for:

- being process- rather than trait-based,

[1] Defra is the most direct route for UKPSF to influence the UK implementation. UKPSF members who are not already involved can email Julian Jackson (Julian.jackson@defra.gsi.gov.uk) to be added to the ABS Stakeholder forum and can then take part in stakeholder meetings in person or by phone. This will ensure the UKPSF voice is heard on upcoming negotiations on the draft statutory instrument being prepared to implement the EU Regulation and draft implementing legislation being prepared at the EU level.

[2] GM Science Update: A report to the Council for Science and Technology (March, 2014).

- engendering serious delays for political rather than scientific reasons,
- imposing unnecessary requirements for data, and
- creating uncertainty affecting commercial planning.

This places limitations on the progress that can be made towards translating plant genetic research into new crop varieties. The stringent legislative framework for GMOs, along with the significant negative attitude of many consumers and other stakeholders towards GM foods, makes the EU unattractive to any commercial company considering investment in the research, development and marketing of new transgenic crop varieties. This in turn has had a negative effect on model-to-crop translational research and on applied plant genetics.

Whether a new crop variety in the EU is considered a GMO or not, is currently defined by the process used to make it not the new traits it possesses. This creates inconsistencies for the regulation of traits that can be generated via either GM or non-GM breeding processes. It also generates uncertainty as new breeding methods are constantly developed.

The practical implementation of the GMO legislation in the EU has become highly politicised and applications for import or cultivation of a GM crop variety face considerable time delays and uncertainty at the European Commission.

The Advisory Committee on Releases to the Environment (ACRE) has discussed barriers to exploiting GM technology in the academic community, in the light of the decline in number of field trials in the UK. It concluded that there was a perception amongst academics that the application and authorisation process was very difficult and something they would not want to undertake.[3] The reality is that application to ACRE for small-scale research trials is not so onerous. Help is available and the application process should not be seen as a barrier.

There is currently no legal certainty in Europe as to whether several Novel Breeding Technologies (NBTs) including genome editing (broadly defined as the precise manipulation of specific genomic sequences) fall within the definition of a GMO.[4] Genome editing techniques such as CRISPR/cas (clustered regularly interspaced short palindromic repeats), TALENs (transcription activator like effector nucleases) and ZFNs (zinc finger nucleases) which can be used to insert, excise or edit DNA sequences at specific, pre-determined locations in genomes, represent powerful research tools for functional genomics and are already being used for plant breeding. These techniques can be used to make DNA changes that are indistinguishable from natural mutations or those resulting from technologies such as chemical- and radiation-induced mutagenesis, the products of which are not considered GMOs. The uncertainty over how genome editing technologies and other NBTs are regulated within the EU undermines investment and R&D commitment to these techniques.

The European Commission is currently preparing guidance on the scope of the legislation as it applies to NBTs; however there is no definite timetable for the publication and it seems likely that this guidance will not provide legal certainty.

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[3] Advisory Committee on Releases to the Environment: Annual Report 2013.

[4] BBSRC position statement on new techniques for genetic crop improvement (2014).

Opportunities for UKPSF

The EU has adopted a highly precautionary approach to the use of GMOs in agriculture. This is unlikely to change in the short to medium term and may actually help to garner trust and support from a sceptical public.

It would be very difficult for UKPSF alone to effect change so its influence might rather be through engagement in the debate and adding a strong voice to a general application of pressure. Positive steps might include the following:

- Encourage the European Commission to provide legal clarity over the classification of NBTs. This could include the development of a UKPSF position statement and encouraging others to adapt it for their own use.
- Communication to researchers that application to ACRE for Part-B research-scale field trials is not really so onerous and that help is available.
- Development of a central online resource for guidance through regulations, best practice in compliance and application procedures. Institutes/organisations with good risk-assessment and working practices in place could share their documents for easy implementation on other websites including the UKPSF and Society of Biology sites. Resources might include:
    - Guidance on acceptable measures for contained use of GMOs.
    - Exemplars of Part B applications for experimental release, from the Defra website.

Timescales

- Exemplars of Part B applications are available online and could be easily linked to further notes on the UKPSF web pages.
- The European Commission has given no indication of time scales for its guidance on NBTs so there is scope for the UKPSF to campaign for a consistent and evidence-based approach to the regulation of varieties produced through these technologies.

Part 3 – Plant protection products (PPPs)

Background

Two pieces of regulation relating to plant protection products are relevant to UK plant science:

- EU Regulation 1107/2009 concerning the placing of plant protection products on the market. This follows a hazard- rather than risk-based approach to regulation of PPP, in conjunction with application of the precautionary principle.

- Allied with Regulation 1107, the Sustainable Use Directive (SUD) on pesticides, 2009/128/EC sets a new policy direction for plant protection. In particular it is designed to promote use of Integrated Pest Management (IPM).

One of the major problems with the new policies is that pesticide products have been withdrawn from the market faster than sustainable alternative solutions can be put in place.

The SUD is clear in its policy direction and has many potential benefits in terms of making plant protection more sustainable. It also creates new opportunities for plant science – both academic research and in industry as there is a need for new, environmentally sustainable solutions for plant pests, based around an IPM approach. However, developing IPM programmes and getting them in place is challenging (scientifically, technically, economically and logistically) and progress – in the UK at least – will be hampered by a lack of investment in plant and related sciences over the past twenty or so years.

The main issue for the biopesticide industry is the time taken to bring products to market. The present regulatory system is designed for conventional chemicals (rather than biopesticides) which is causing problems, alongside the lack of appropriate expertise in the regulatory bodies. The EU was supposed to bring forward proposals for low risk products, which would speed up registration, in December 2014. However DG SANCO has delayed that to a date as yet unknown but believed to be 2016.

The European Commission has also failed to resolve the interplay between PPP regulation and GM herbicide tolerant plants, creating regulatory tension between the two areas. A process aimed at harmonising the end points of different types of risk assessment would help to alleviate such tensions.

Opportunities for UKPSF

The Regulation and SUD have set out the policy direction for the next decade or more. While they are already in place and unlikely to be easily changed, there is still opportunity to influence the way in which they are interpreted. This should be done impartially and with the aim of making factual information on the natural science evidence base available to policy makers.

Given the breadth of interests within the UKPSF, finding a common position could – in theory – be a challenge. However, the following areas could perhaps be agreed upon:

- Regulation of plant protection products should be risk- and evidence-based.
- A good body of literature around risk assessment already exists and can provide guidance in developing evidence-based assessments.
- Risk assessments should take into consideration the balance between the risks and benefits of not doing something as well as the risks and benefits of doing it.
- UKPSF could highlight the discrepancy and difficulties around how to do environmental risk assessments in different areas (e.g. plant health, PPP and GM). The European Food Safety Authority (EFSA) has a working group whose

objective is to harmonise these different areas of risk assessment. A consultation document is expected to emerge by June 2015.

Part 4 – Invasive species

Background

A new EU regulation on the prevention and management of the introduction and spread of invasive alien species was passed by the European Parliament in April 2014, and will come into force on 1st January 2015. Previously, growing and exchanging seeds from invasive plants was permitted but trading was prohibited. The new regulation will make it illegal to introduce, transport, market, keep, breed, grow or release listed species into the environment. Of relevance to the plant science community, plants and other organisms that are found on or in plants (e.g. soil-borne organisms) are included under the regulation.

Overall, the new EU regulation is likely to have positive environmental and economic impacts. However, there are concerns that it could cause problems for plant science in the following ways:

- Blacklisted plants will most likely be regulated at the species (rather than variety) level. Some plant species have both invasive and non-invasive varieties, of which the latter provide valuable genetic resources for breeding and crop development work. E.g. Certain species of *Miscanthus* are important bioenergy crops and are also used in the ornamental plant industry. Some cultivars of these species are more invasive than others so banning all varieties of a particular species would restrict the use of beneficial varieties.

- Lack of clarity over which plant taxa will be regulated. E.g. *Rhododendron ponticum* (sp.) is in the breeding line of various other ornamentals but it is not clear at what point in the breeding line something would fall under the regulation.

- There is a possibility that the regulation will inadvertently restrict biodiversity.

Opportunities for UKPSF

There are possible opportunities for UKPSF to work with UK authorities (the Non-native Species Secretariat (NNSS) at Defra) and Brussels, to influence which species are entered onto the EU list and/or to seek national derogation for particular species/varieties that are of importance to breeding etc. However, the Working Group is unclear about the extent at which the new Regulation is a concern to the plant science community as a whole, and how much opportunity there will be to influence the composition of the EU list of banned invasive species. **We recommend that UKPSF consults with additional experts before taking further action**.

Possible next steps could be to:

- Develop a set of common messages (through consultation with UKPSF members and other stakeholders) and produce communication materials that can be used by members and others.

- Use UKPSF members and associates who have already established contacts in this area as a campaign network by feeding them material and messages to pass onto their contacts on behalf of the Federation.

- Promote awareness of the importance of a high level of understanding of taxonomic/classification issues within the sector. The lack of understanding undermines the integrity of any initiatives (or legislation) whereby it is critical that a plant is correctly identified.[5]

- Engage in discussions with the Non-native Species Secretariat (NNSS) at Defra and directly with Brussels, if possible.

Timescale

- The EU legislation comes into effect on 1st January 2015 but presumably different species will be added to the list at different stages so there could be ongoing opportunities to influence this.

[5] HDC, HTA and the NFU plan to address this in the coming year so UKPSF should liaise closely with these groups to identify opportunities through which UKPSF can help publicise them.