HORIZON

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AHDB
AGRICULTURE & HORTICULTURE DEVELOPMENT BOARD

What will happen to **Plant Health and Plant Protection Product regulations** after Brexit

Contents

SCENE SETTING

In this edition of Horizon we will examine what the regulatory framework for plant protection products (PPPs) in UK agriculture and the wider supply chain might look like post Brexit.

The current regulatory framework is determined by the EU Commission with subsequent approval for use in Member States being decided locally. The UK has a huge legislative task ahead, replacing existing EU laws with equivalent UK ones in many areas. The regulation of pesticides is unlikely to be top of the agenda when it comes to considering changing regulation at the point of transition and it is, therefore, likely that the existing EU rules will be 'lifted and shifted' in the medium term, as part of 'The Great Repeal Bill', pending more fundamental reform in the medium to long term.

The idea is to 'lift and shift' as much as possible of the rules that have been passed by Brussels straight into UK law. There is a distinction between EU 'directives' and 'regulations', which is important in this context. Regulations are directly applicable EU laws, which means that the EU law applies in the Member States without further national implementing measures, as soon as it enters into force. Directives will not usually apply directly and will require to be converted into UK law by Acts of Parliament and so most Directives will already be on our Statute book (although there is no straightforward 'read-across' from a particular Directive to a corresponding piece of UK legislation). If no specific provision is made for the EU laws that are directly applicable, they will no longer apply in the UK as soon as the European Communities Act 1972 is repealed and so Regulations will require to be 'saved' until Government has decided what should be done with these laws. The plan is for the Great Repeal Bill to make provision for this although much of what is to be decided may depend on the outcome of the withdrawal negotiations and the UK's future relationship with the EU.

The process of giving effect in UK law to EU regulations is likely to be complex, especially where those regulations confer responsibilities on particular EU bodies, which will no longer have jurisdiction once the UK exits. One of the critical tasks being undertaken by civil servants at the moment is to work through the 'domestic consequences' and identify where policy choices will have to be made during the legislative process.

The report 'Joseph Owen and Robyn Munro: Whitehall's Preparations for the UK's Exit from the EU, Institute for Government (IFG), December 2016', highlights this issue, making the distinction between 'operable' and' inoperable' legislation. It states:

'The Department for Exiting the EU (DExEU) asked departments to identify EU legislation relating to each department as either 'operable' (that is, could be lifted into UK law without significant amendment) or 'inoperable' (in need of reform before it could be used in post-Brexit UK).

The operable laws will work with a direct 'lift and shift', but the inoperable laws may require significant policy decisions to be made.

Reviewing EU legislation will involve thousands of decisions like this in policy area as diverse as environmental legislation and data protection. We were told by departmental officials that it isn't clear who is expected to make those decisions or when. This is making drafting the Great Repeal Bill a bigger challenge than some initially expected.'

"Reviewing EU legislation will involve thousands of decisions like this in policy area as diverse as environmental legislation and data protection"

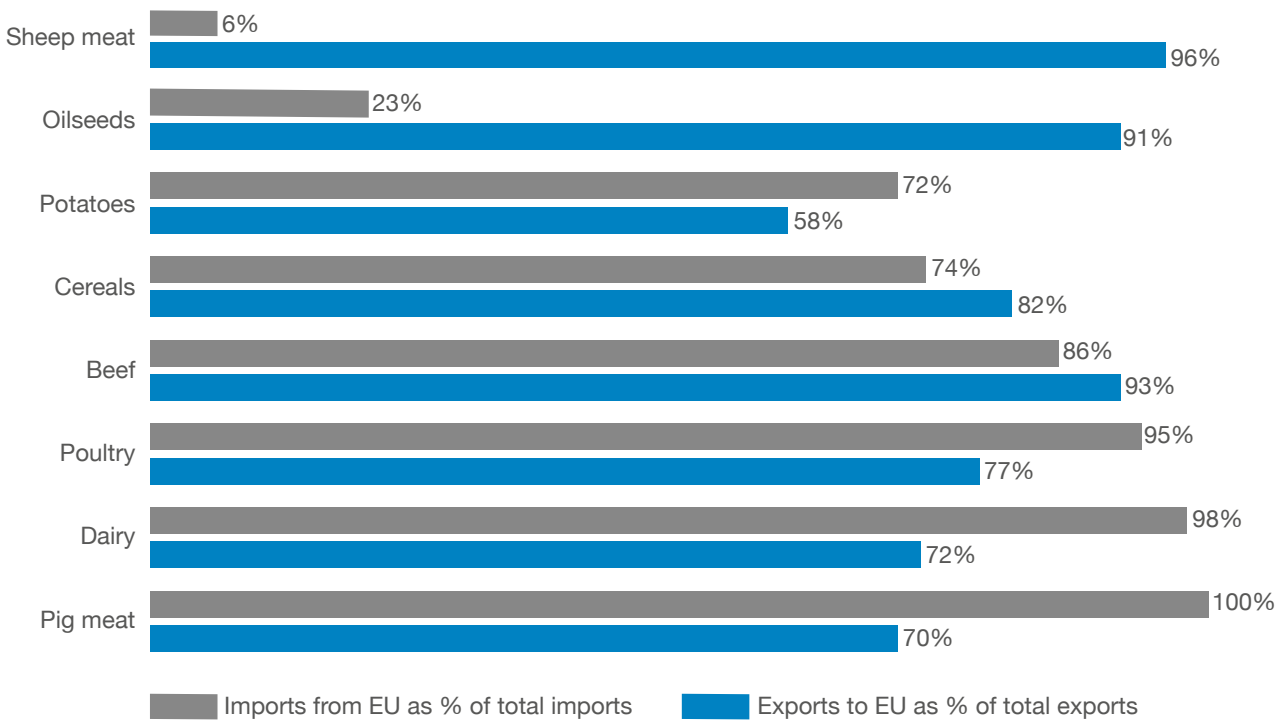
This is likely to place a significant burden on the department for the Environment, Food, and Rural Affairs (Defra). With the EU having focused much of its efforts on agricultural and fisheries policy, Defra is reckoned to have to deal with some 1,200 pieces of EU legislation, roughly a quarter of the total. The IFG report also highlights the capacity constraints faced by Defra and other departments. Defra is already in the middle of a massive organisational restructure, as it consolidates the work of 33 separate agencies. Its annual budget, as set by Resource Departmental Expenditure Limits (RDELs) is already 17 per cent smaller than in 2010 and is scheduled to have been reduced by 35 per cent by 2019.

Current PPP regulations are dependent on EU bodies, including the European Food Safety Authority (EFSA) and the Commission, for approval. Therefore, under the definition above, current regulations may be considered 'inoperable' and not eligible for a straight 'lift and shift', unless the UK Government chooses to align with the EU on current and future regulation.

Trade with the EU, and within Free Trade Agreements (FTAs) that the EU has agreed with third parties, is agreed on the basis of the current rules and regulations surrounding PPPs. Post-Brexit regulations will, therefore, be influenced by the future trade relationship the UK has with the EU. The importance of trade with the EU is highlighted in the chart below and is also discussed in more detail in our previous Horizon documents.
http://www.ahdb.org.uk/Brexit

Trade with countries outside the EU and outside current FTAs may be subject to different regulations and, therefore, provide an opportunity for greater regulatory flexibility. This document will examine possible alternatives to adopting EU regulatory policy and the effect each scenario may have on trade and the availability of PPPs.

UK agricultural trade wirth the EU[1]



Source: AHDB based on HMRC data

PPPs AND THE EU

Plant protection products (PPPs) are key to growing healthy, profitable crops, both arable such as wheat, barley and oilseed rape and higher-value crops such as potatoes and a wide range of horticultural crops including edibles and ornamentals. The availability and efficacy of PPPs are facing two main threats. First, new active substances failing to reach the point of authorisation, due to increasingly stringent controls and the need for greater amounts of supporting data and documentation. Secondly, uncertainty about the re-authorisation of key products required to go through the more stringent process at the end of their current approval period. A review of Maximum Residue Levels (MRLs) is also leading to actives being lost, as insufficient data is available to support the current or proposed MRLs, which are now often set at the limit of detection. Efficacy is also being squeezed by the growing resistance of pests, diseases and weeds to those products currently available.

The approvals process of active substances is currently harmonised throughout the EU, with active substances receiving general approval at a European level and specific national product uses controlled by the national regulatory authorities. However, the regulatory environment has become more challenging in recent years with the move from risk-based assessments under regulation 91/414 to hazard-based assessments under regulation 1107/2009. New criteria, such as endocrine disruption and the need to assess candidates for substitution and comparative assessment could also result in further losses or a decrease in the likelihood of actives being re-approved. For PPPs containing a number of active substances, Member States will be required to evaluate if they can be replaced (substituted) by other adequate, normally safer to humans and the environment, solutions (chemical and non-chemical).

In addition, water quality issues resulting from the implementation of the Drinking Water Directive mean restrictions or outright bans may be imposed on some PPPs that are particularly prone to contamination of ground or surface waters. A further pressure on use comes with the Sustainable Use Directive, which is intended to reduce the risks and impacts of the use of PPPs through the minimisation of use, or banning, in critical areas for environmental or health reasons. The UK is currently compliant with this regulation in that the principles of Integrated Pest Management are being adequately applied.

EU regulatory review overview
Loss of active substances by category

	No. AS	Approved	Not approved	Pending new AS
Herbicides	332	127	199 (60%)	6
Fungicides	313	155	143 (46%)	15
Insecticides	286	105*	172 (60%)	9
Others	354	116	232 (66%)	6
Total	1285	503	746 (58%)	37

Source: European Commission
* The most recent new active substance took 61 months for EU approval (vote)

AS loss from Dir 91/414 review

Further loss under Reg 1107/2009

THE SCOPE FOR CHANGE

The potential for regulatory reform may be seen by some as a way of reducing both unnecessary costs and the numbers or complexity of regulations. It may also be seen as an opportunity to look for the most effective and efficient ways of achieving regulatory outcomes, and to examine whether other policy instruments, such as voluntary approaches, could provide a better incentive for improved practices.

It also raises the issue of the regulatory process itself, as this could be an area of operations that the UK may have to take on should a decision be made to make this process independent of other countries.

So the two main issues are first, the use of plant protection products within the regulations ie using products so as to operate within the law, and secondly, the regulations and process surrounding the registration of the products themselves for use in the UK.

The UK has been keen to improve the use of evidence to support regulatory reform in many areas. UK Governments have, in the past, been less enthusiastic about the use, interpretation and application of the 'precautionary principle' than some other Member States, preferring an evidence-based, scientific approach. The precautionary principle (or precautionary approach) to risk management states that if an action or policy has a suspected risk of causing harm to the public, or to the environment, in the absence of scientific consensus (that the action or policy is not harmful), the burden of proof that it is not harmful falls on those taking an action that may or may not be a risk. The application of this will depend upon the level of risk that is judged to be tolerable and the use of evidence to support or refute a particular position.

Brexit offers an opportunity to join up the process of the setting of standards and the registration process, which is currently shared between the European Food Safety Authority (EFSA) and the Commission, to something similar to that used in the USA where the Environmental Protection Agency (EPA) has responsibility for the setting of standards, assessing compliance and final approval.

Brexit is seen by many as an opportunity to regain control of regulatory affairs, providing greater flexibility to set UK standards. However, regulatory standards play an important role in facilitating cross-border supply chains (eg livestock growth promoters, maximum residue levels for chemicals, genetically modified organisms, etc.) and, therefore, if the UK wishes to continue trading with the EU or with other countries requiring EU compliance, this flexibility may be limited. In addition, if UK standards were different or lower than current EU standards, it is possible UK produce would come to be associated, rightly or wrongly, with lower standards, (eg consumer safety or carbon footprints), which could affect demand for UK goods.

International commitments

Exiting the EU will not change all the laws that affect rural businesses. In many areas, the UK is bound by commitments as a signatory to international agreements such as the Bern Convention and Kyoto and Paris Climate Change Agreements. The Convention on the Conservation of European Wildlife and Natural Habitats (the Bern Convention) was adopted in Bern, Switzerland in 1979, and came into force in 1982. The UK Government ratified the Bern Convention in 1982. The obligations of the Convention is transposed into national law by means of the Wildlife and Countryside Act (1981 as amended), Nature Conservation (Scotland) Act 2004 (as amended), Wildlife (Northern Ireland) Order 1985 and the Nature Conservation and Amenity Lands (Northern Ireland) Order 1985.

All countries that have signed the Bern Convention must take action to:

- Promote national policies for the conservation of wild flora and fauna, and their natural habitats
- Have regard to the conservation of wild flora and fauna in their planning and development policies, and in their measures against pollution
- Promote education and disseminate general information on the need to conserve species of wild flora and fauna and their habitats
- Encourage and co-ordinate research related to the purposes of this Convention.

In addition, if the UK wishes to trade within the single market they will need to comply with the rules that underpin it.

CURRENT EU PLANT PROTECTION POLICY AND REGULATION

It is important to remember that UK businesses will remain bound by current EU regulation for up to two years after Article 50 is triggered or at such a time that the UK formally leaves the EU.

1) The pesticide approval process

Regulation 1107/2009 on the Placing of Plant Protection Products was introduced in June 2011 and replaced the earlier regulation 91/414.

Under the regulation, only authorised plant protection products can be advertised, sold, supplied, stored and used.

The EU authorisation system is two-tier:

- Approval of active substances
- Authorisation of formulated products

Approval of active substances

In the first stage, active substances are assessed at EU level for approval.

The process assesses:

- The impact on workers applying the product
- Consumers of treated produce
- Residents living adjacent to application sites and others who may be passing-by at the time of treatment
- Whether and how the pesticide might move throughout the environment once it has been applied
- The impact on the environment, in particular water bodies and wildlife
- Product efficacy.

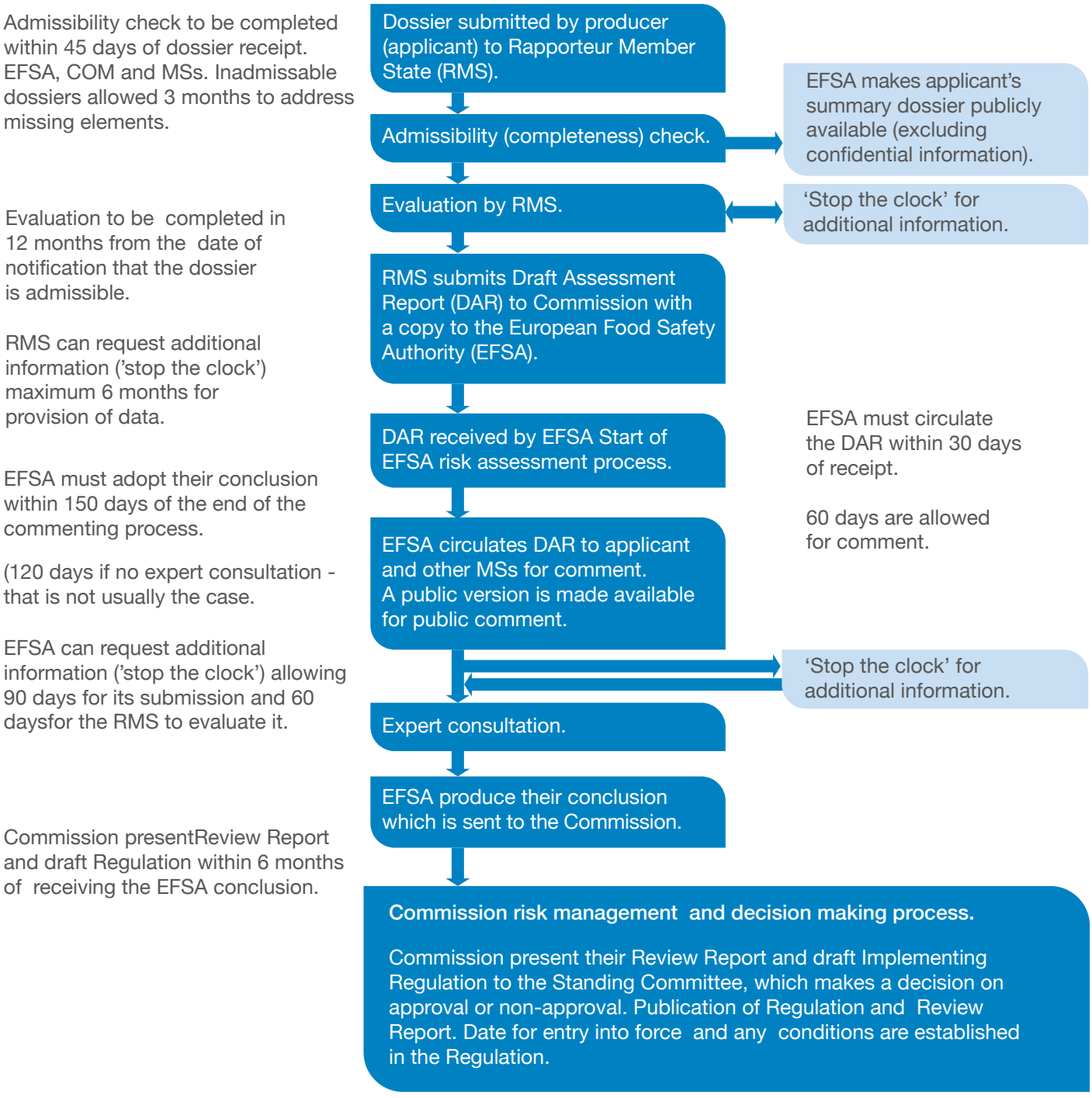
Active substances that have been shown to be without unacceptable risk to people or the environment are added to the list of approved active substances, which can be found on the EU database.

Various 'cut-off criteria' apply with approval not being granted if the active substance exhibits any of the following properties, which define it as hazardous:

- It is Carcinogenic or has Reproductive Toxicity (unless the exposure is 'negligible')
- It is an Endocrine Disruptor (ED)
- It is a Persistent Organic Pollutant (PoPs)
- It is a Persistent Bio-accumulative and Toxic (PBT) substance
- It is either a very Persistent or very Bio-accumulative (vPvB) substance

A key point about 1107/2009 is the move from a risk-based to a hazard-based approvals system. Under the previous rules (91/414), even if the properties of a pesticide deemed it to be classified as hazardous (eg carcinogenic), the way it was actually used would be looked at. Exposure when correctly used was considered, the risk was assessed and, if considered acceptable, the pesticide could be registered for sale. Under the new 1107/2009 rules, any level of exposure to a substance that is deemed as hazardous is considered unacceptable. It is the intrinsic properties of an active substance that are now key.

Regulation (EC) No 1107/2009. Overview of process for considering and application for approval of an active substance, safener or syngergist



Source: Health and Safety Executive

Regulation (EC) No 1107/2009. Overview of process for an active substance, process from publication of renewal regulation to production of renewal assessment report - total time 1 year with no stop the clock

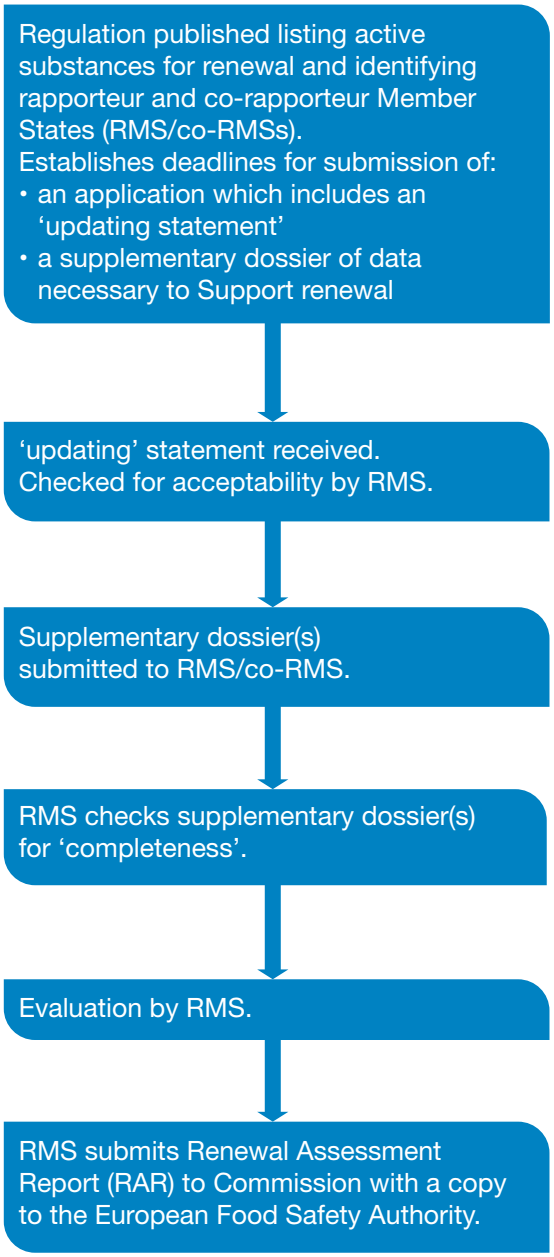
Co-RMS role is not defined - flexible to accommodate different approaches.

The updating statement Identifies the new data and assessments that will be provided a justification for the new data.Pre-submission discussions can occur in this period.

The supplementary dossier provides the new studies/information and updated risk assessments - necessary to reflect changes:

- in data requirements;
- in scientific & technical knowledge since first inclusion (approval) of the substance;
- to representative uses

RMS has 11 months to evaluate the submission and submit RAR. RMS can request additional information but there is no 'stop the clock'provision. Any additional information must be evaluated within the 11 month period.



Third parties (any person or Member State) can submit information that might contribute to the assessment (in particular of potentially dangerous effects). Must be done on or before the deadline for submission of supplementary dossiers.

RMS has 1 month from receipt to determine completeness. If elements are missing 14 days can be provided for the applicant to make the dossier complete.

Renewal of approval of active substances

Active substances are initially approved for a fixed period (usually 10 years). If they are to remain approved after that period, they must be re-assessed to ensure that they continue to be without unacceptable risk to people or the environment according to the latest standards of assessment.

Renewal of active substances is organised in phased programmes depending on the expiry date of the approval.

If active substances are not renewed, they are withdrawn and Member States must withdraw any plant protection products containing those active substances from the market.

If active substances are renewed, the approval period is extended and existing authorisations of plant protection products containing those active substances must also be renewed by the Member States where they are already authorised.

After approval of an active substance at EU level, companies can apply to Member States for authorisation to market formulated plant protection products (PPPs) containing that active substance. In the UK, the Chemicals Regulation Division (CRD) is the competent authority for PPPs approval. The CRD is an agency of the Health and Safety Executive and operates on clearly laid-out standards. The EU has made efforts to harmonise and streamline the product review process by creating three zones (north, central and south) within Europe, in which countries mutually recognise each other's approvals. This is known as 'Zonal Authorisation' and is intended to streamline and harmonise the registration and authorisation process.

Under EU rules, it takes up to 1.5 years from the date of application to the granting, amendment or withdrawal of an authorisation to market. This time varies depending on how complex and complete the application is and the type of application.

The authorisation states the situation (for example crops or areas) in which the product can be used. It will also contain conditions, such as:

- The amount of product that can be applied
- Timing of application and time which must elapse between treating and harvesting crops or allowing people into treated areas
- Any additional measures necessary for those responsible for applying the product to protect workers, residents and bystanders and the environment.

The conditions of authorisation are replicated on product labels. It is important that users understand and comply with the label.

There are different types of authorisations. Most typically, products are authorised for either professional (commercial) or amateur (home and allotment) use.

2) The Sustainable Use Directive

The EU sets rules for the sustainable use of pesticides to reduce the risks and impacts of pesticide use on people's health and the environment (Directive 2009/128/EC).

The main actions from the Sustainable Use Directive are:

- National Action Plans – EU countries adopt them, setting objectives and timetables to reduce risks and impacts of pesticide use
- Training – Professional pesticide users, distributors and advisors get proper training. EU countries establish competent authorities and certification systems
- Information and awareness raising – Member States take measures to inform the general public and put in place systems to gather information on acute poisoning incidents and chronic poisoning developments
- Aerial spraying – Aerial spraying is prohibited. EU countries may allow it under strict conditions after warning people
- Minimising or banning – EU countries minimise or ban the use of pesticides in critical areas for environmental and health reasons
- Inspection of equipment in use – All pesticide application equipment must have been inspected at least once by 2016 to grant a proper efficient use of any PPP.
- Integrated pest management (IPM) Promotion of low pesticide-input management including non-chemical methods. Professional users have to apply general principles of IPM from 1 January 2014.

3) The Water Directive

The Water Framework Directive (WFD) is EU legislation that requires all rivers, lakes, ground and coastal water to reach good ecological and chemical status. While the WFD does not directly address issues of pesticide pollution, it does require meeting standards laid down in existing EU legislation such as 91/414 and 1107/2000. In terms of the effect on pesticides availability, the WFD impacts in three main ways.

A small number of chemicals that have the biggest impact on water quality are identified at EU-level. Two categories of these are defined as:

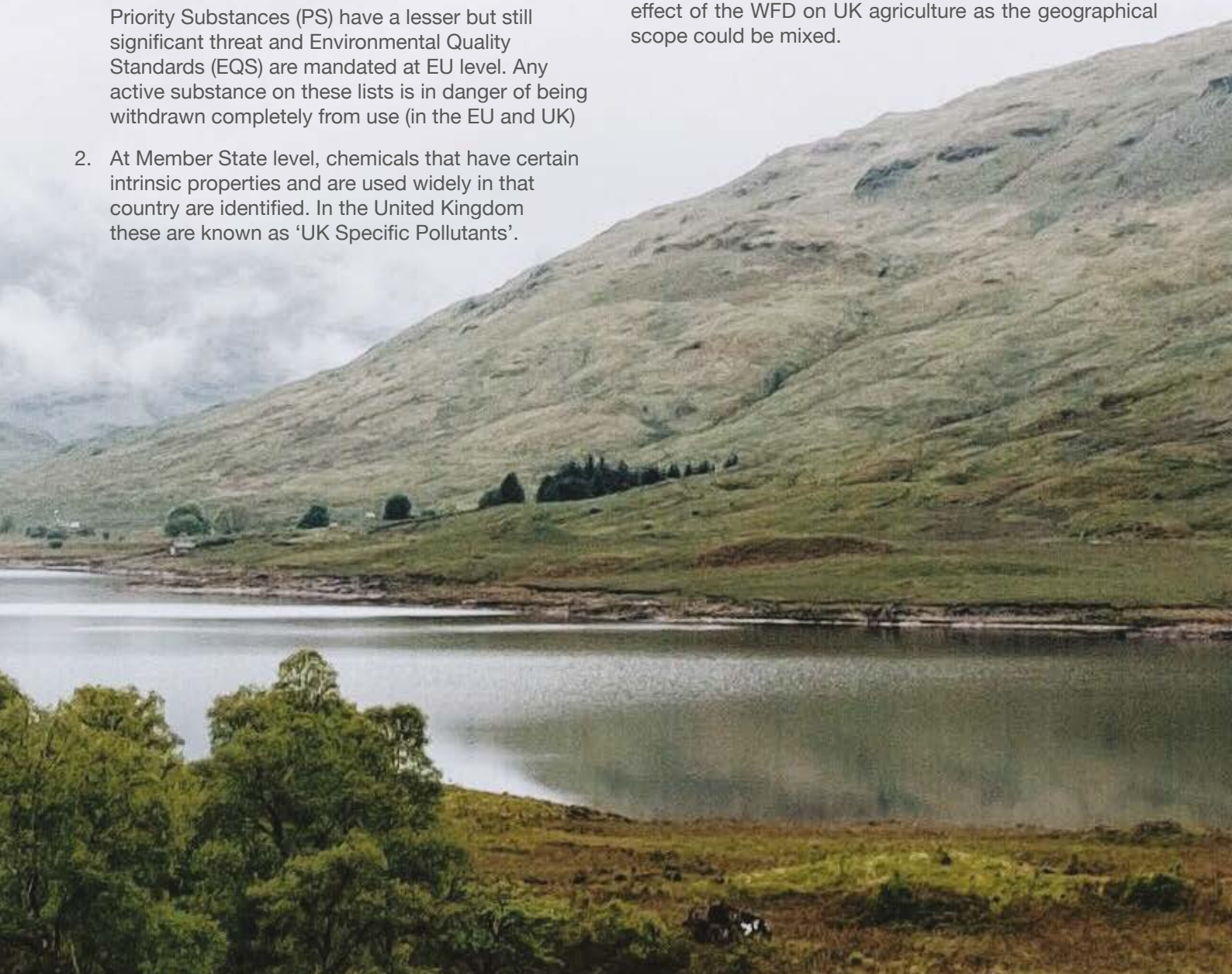
1. Priority Hazardous Substances (PHS) are deemed to have the greatest threat and are being phased-out.

   Priority Substances (PS) have a lesser but still significant threat and Environmental Quality Standards (EQS) are mandated at EU level. Any active substance on these lists is in danger of being withdrawn completely from use (in the EU and UK)

2. At Member State level, chemicals that have certain intrinsic properties and are used widely in that country are identified. In the United Kingdom these are known as 'UK Specific Pollutants'.

3. Article 7 of the WFD requires that the quality of water intended for drinking should not be allowed to deteriorate from a baseline level and thus require additional treatment.

Voluntary stewardship schemes have been adopted by the industry and agri-environmental schemes also contribute to water quality improvements. Should voluntary approaches not deliver the required results, then restrictions on the use of active substances may be imposed to meet rules on UK Specific Pollutants or Article 7 limits. There is unlikely to be a complete withdrawal across the UK. Restrictions could be implemented only in catchments or in Drinking Water Protected Areas where there was an identified problem. These are more likely to take the form of limits on timings, dose rate or crop area use rather than an outright ban. This makes it somewhat difficult to model the possible future effect of the WFD on UK agriculture as the geographical scope could be mixed.



4) Plant health regulation

The current EU plant health regime enshrined in Regulation 882/2004 has recently undergone a full review and the new version is likely to come into force in the period leading up to the exit of the UK from the EU. The review was driven by a number of considerations including the expansion of the EU, the continued expansion of globalisation of trade, shrinking public services and specialist expertise and criticism of the current review by some EU countries. The review of 882/2004 covers plant and animal health, plant reproductive material and co-funding of activities by the Commission.

The new proposal tightens plant health at a number of levels, which would generally be welcomed within the UK. It introduces clearer rules so third countries can understand requirements and, in relation to exports, how EU internal controls operate. There is greater recognition of international standards, improving the ability to trade, and improvement to biosecurity at borders through pre-entry assessment for new trades in high-risk commodities.

At the border itself, there will be improved use of existing databases, allowing better tracking of products, the introduction of quarantine stations and the removal of passenger baggage concessions, which will close a small but significant hole in the biosecurity defences. All these activities are targeting pre-border action i.e. preventing problems arriving into the EU.

The changes to within-EU trade relate to improved plant passporting (which could result in additional costs to industry), the development of contingency plans, intensified surveys and eradication programmes.

The text was provisionally agreed by Parliament and Council negotiators in December 2015, endorsed by the Council in July 2016 and has now been given a green light by the Parliament (October 2016) at the early second reading. It will enter into force 20 days after it is published in the EU Official Journal. The regulation becomes applicable 36 months thereafter, so it may or may form part of UK legislation going forward.

SUMMARY

The current issues surrounding PPPs come from a variety of sources.

The approvals process at the EU level (1107/2009)

Various additional policies in specific areas such as the neonicotinoid seed treatment ban, endocrine disruptors, candidates for substitution, Sustainable Use Directive, maximum residue levels, national authorisations process etc.

The implementation of the Water Framework Directive and Drinking Water Directive at the national level

UK regulatory framework post 2020 - what do we know?

Following Theresa May's announcements at the Conservative Party Conference in October, it appears likely that the UK will transfer current EU legislation across to the UK, where practicable, without making any immediate changes. However, CAP rules and regulations are unlikely to be included in the transfer of EU legislation into UK law under the 'Great Repeal Bill', according to UK environment secretary Andrea Leadsom.

If farm payment is linked more strongly to environment, as has been suggested in the past by the UK Government, there could be a move towards 'softer' crop protection measures which lead UK crop production toward more stringent control of pesticides. This would be wholly consistent with the objectives of the Sustainable Use directive but could put pressure on certain actives.

In relation to agricultural regulation, Andrea Leadsom has stated at a meeting with the NFU during the Conservative party conference that: "We will be nationalising EU regulations, although CAP is likely to be an exception." The question then, is how will a post-Brexit UK agricultural regulatory policy differ from the existing framework?

Defra's Farming Minister George Eustice, has said: "A precautionary approach is the right thing to do but it should be based on realistic assessments of risk and not just theoretical hazards." (The Guardian, 25 May 2016).

In the Government's review of competencies (2014), it was stated: "The Government agrees with the argument made by respondents that the system for approvals of pesticides should be harmonised as far as possible across Europe to ensure equal access to products for all European farmers, and that the approvals process should be based on likely field risk."

All of the above would appear to indicate that a move to an evidenced-based risk assessment approach away from the current hazard-based approach, is a distinct possibility.

Possible options for post-Brexit PPP regulation

Whichever direction post-Brexit PPP regulation takes, the key question of 'equivalence' will determine the impact on trade both with the EU and on global markets.

Article 20 of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism. In addition, there are two specific World Trade Organisation (WTO) agreements dealing with food safety and animal and plant health and safety and with product standards in general. Both try to identify how to meet the need to apply standards and at the same time avoid protectionism in disguise.

A separate agreement on food safety and animal and plant health standards, the Sanitary and Phytosanitary Measures (SPS) Agreement sets out the basic rules.

It allows countries to set their own standards but it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. They should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. When they do, they are unlikely to be challenged legally in a WTO dispute. However, members may use measures which result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary. They can to some extent apply the precautionary principle, a kind of 'safety first' approach, to deal with scientific uncertainty. Article 5.7 of the SPS Agreement allows temporary precautionary measures.

The SPS Agreement recognises that there may be varied ways of ensuring food safety or animal and plant protection in different countries but provides that WTO members should accept each other's regulations as equivalent whenever the same level of human, animal or plant health protection is achieved.

The agreement still allows countries to use different standards and different methods of inspecting products. So how can the UK be sure the practices it applies to its products post-Brexit are acceptable in an importing country?

The WTO states that if an exporting country can demonstrate that the measures it applies to its exports achieve the same level of health protection as in the importing country, ie are equivalent, then the importing country is expected to accept the exporting country's standards and methods.

Mutual recognition agreements acknowledging the equivalence of health protection measures enforced by different approaches are negotiated on a bilateral or regional basis. These negotiations may be lengthy and have the potential to impact current trade arrangements, at least in the short term, which have been agreed on the basis of an EU regulatory framework and the equivalence of that framework to domestic policy in importing countries.

Below are four key options which the UK may be considering post-Brexit. This is by no means an exhaustive list, but outlines some of the key issues to be considered when determining a UK regulatory framework.

OPTION 1 – Align with the EU

This scenario could be potentially straightforward. The UK continues to accept the EU registration process and the setting of maximum residue levels (MRLs). This assumes that the EU is happy to work with this model. However, this would mean that the precautionary principle would continue. In addition, as the UK would no longer be a member of the EU, it would have no influence over the approval process which may become more restrictive under the influence of remaining EU members.

Trade with the EU would not be affected by additional barriers relating to PPP. However, the availability of PPPs may continue to decline significantly with the continuation of a highly precautionary approach to active substance assessment.

OPTION 2 – Align with the US

The Chemicals Regulation Division (CRD) could work in partnership with US agencies. The US follows a risk-based approach, which is favoured here in the UK. This may mean more actives would be available to the UK industry, greater numbers of registrations for biological products and better availability of products for speciality uses, as the UK would become part of a much bigger market for PPP manufacturers. The UK would retain the power of veto for use of certain products here in the UK if required.

Again, registration and use of PPPs would have to be acceptable to the UK's trading partners. Despite the WTO rules outlined above, any move away from the EU PPP framework has the potential to disrupt trade if not seen as 'equivalent' to the current regulations.

Adoption of the US risk-based approach to regulation may result in pressure groups reacting to more permissive crop protection policy regimes.

In addition, the different climate and geography of the US may mean that actives may be geared towards US production systems and may be less suitable for use here in the UK, in particular for smaller 'niche' crops. It would be necessary to ensure that data packages were relevant to UK growing conditions, which could be achieved by using data generated in areas of the Pacific North West which are climatically similar.

OPTION 3 – Adopt OECD global standards regulation

The OECD (Organisation for Economic Co-operation and Development) has 35 member countries and provides a forum in which governments can work together to share experiences and seek solutions to common problems. They also set international standards on a wide range of things, from agriculture and tax to the safety of chemicals.

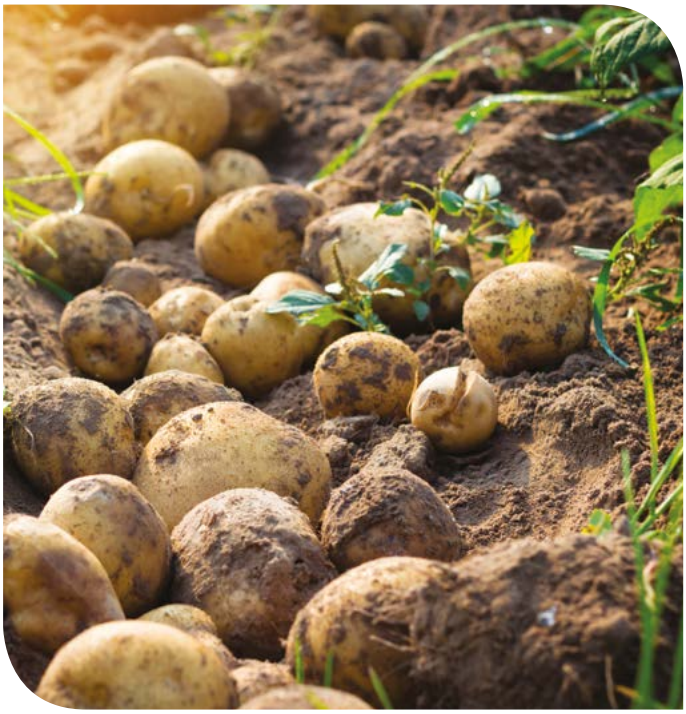
On 22 March 2012, the Council of the OECD adopted the Recommendation of the Council on Regulatory Policy and Governance. The Recommendation is the first international instrument to address regulatory policy, management and governance as a whole-of-government activity that can and should be addressed by sectoral ministries, regulatory and competition agencies. The mandate of the Regulatory Policy Committee is to assist members and non members in building and strengthening capacity for regulatory quality and regulatory reform. The Regulatory Policy Committee is supported by staff within the Regulatory Policy Division of the Public Governance and Territorial Development Directorate. The goal is to help countries build better government systems and implement policies at both national and regional level that lead to sustainable economic and social development.

The OECD recommendation states that Governments should consider basing their regulatory approaches on relevant international standards and more generally take into account their international obligations, for example under the World Trade Organisation (WTO) agreement and the General Agreement on Tariffs and Trade (GATT). In particular, governments must ensure that their regulations accord foreign products and services treatment no less favourable than like products and services of national origin or those originating in any other country.

Adopting the OECD recommendation may place the responsibility for registration entirely on the UK. However, there may be scope for harmonised submission via globally agreed and available PPPs data dossiers. This would enable sharing of information thus reducing costs and reducing the administrative burden on the CRD.

A risk-based approach is used by the OECD, with the UK in full control over which actives can be used within the UK industry. MRLs could be adopted from the Codex Alimentarius of international food standards. The Codex Alimentarius or 'Food Code' was established by the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization in 1963 to develop harmonised international food standards, which protect consumer health and promote fair practices in food trade.

More actives should be available as a result of switching from hazard to risk-based approach. Also, with Governments working together, risks can be evaluated more quickly and thoroughly as costs are shared. This could speed up the process of approving new, safer pesticides and removing higher-risk products. Theoretically, this could be the case if working together were perfectly efficient. However, this doesn't seem to happen across the board yet, although there are some specific collaborations that are well established and seem to work fairly well (e.g. Canada and USA; Australia and New Zealand). At present, there are not very many global joint reviews with three or more Governments involved as these tend to be very complex. This could be a possible direction for future developments but in practice it seems that there are major challenges involved in achieving efficient collaborations of multiple Governments. In this scenario the UK would also still need to establish a set of methodologies for assessment as these are not provided by the OECD, although perhaps the most straightforward would be to use those of the EU system.



OPTION 4 - Formulate a UK policy

This would place the responsibility for registration of PPP entirely on the UK, placing a significant administrative burden on the Chemicals Regulation Division (CRD). However, it would be possible to have a phased review of products so not everything would need to be done at the same time. The UK would have full control of the approvals process and a risk-based approach could be adopted. There may be opportunities to speed up the approvals process for low risk substances, such as biopesticides. This might potentially enable everything in the 'toolbox' from biologicals to gene editing, RNA interference (RNAi), and genome editing (CRISPR) to be used, using domestic crop scientists.

With regard to trade, registration and use of PPPs and resulting MRLs would have to be acceptable to the UK's trading partners.

A change to a risk-based approach for product approvals would, in theory, result in more actives being available in the UK. However, in practice, it may be that the UK is deemed too small a market for companies to go to the expense of registering products for approval. This may leave the industry with even fewer actives available for use, unless the Government subsidises the cost of registration.

Should the Government decide to use farmer subsidy payments to encourage environmental benefits, Brexit could see UK-adapted versions of the EU water-related legislation potentially rewarding farmers for greater use of beetle banks, pollinator strips, physical barriers or field margins to manage soil and pesticide run-off.

This could specifically support the greater adoption and approval of upgraded sprayers and nozzles (effectively a further implementation of the Sustainable Use Directive) and the deployment of digital farming systems.

Issues arising from a change in the regulatory environment

As has been previously highlighted, any change from the current EU PPP regulatory framework has the potential to disrupt existing trade arrangements which have been agreed on the basis of the current framework. In particular, if the UK wishes to continue to trade with the EU, it is likely that adherence to current standards, at least for those products entering EU markets, would be required.

Any move away from the precautionary principle, currently used by the EU, towards a risk based approach could be interpreted as a relaxation of standards and by inference, an increased risk to human health and to the environment.

Any changes would have to be acceptable to the public, to government and to customers, such as retailers. Given current retailer and consumer demands for blemish free produce and lower and lower residue levels, on the face of it, this seems unlikely.

There is also the issue of multiple standards. Any crops grown for export to a specific market may need to be grown to different protocols, potentially adding costs and complexity to the production process. However, many growers already produce to a number of specifications either within the UK or in different countries to supply different processors and retailers.

Opportunities arising from a change in the regulatory environment

Key areas for potential change include;

1) Regulation EC no. 1107/2009 – the placing of Plant Protection Products (and refit of 1107/2009)

2) Endocrine Disrupter criteria

3) Sustainable Use Directive

4) Water Framework Directive

5) Drinking Water Directive

6) Comparative Assessment

A shift towards a risk-based approach could help resolve issues where, through the application of the precautionary principle, MRL thresholds have been based on the limit of detection and as technology has improved, the ability to detect residues has improved. It could also address the issues surrounding the lack of actives to manage resistance problems in the industry, since the costs and benefits of the approval or loss of a substance could contribute to the risk assessment and decision-making process.

More broadly, changes in the regulatory framework and the approvals process could result in a loosening of the use of biotechnology, especially GM approaches and gene editing. Examples include developing blight-resistant potatoes and producing GM sterile insects for pest control. This would, however, result in tensions between the devolved governments as both Scotland and Wales have declared that they are GM-free countries. Adoption of higher standards in terms of pesticide regulation could help develop a niche for sale of crops and produce into premium markets.

The continued refinement and adoption of precision use of PPPs and investment in alternative approaches are important in maintaining and improving the competitiveness and profitability of the industry going forwards and could also contribute to greater longevity of actives as they could slow the development of resistance and reduce environmental impact.

CONCLUSION

Exiting the EU will not change all the laws that affect rural businesses. In many areas the UK is bound by commitments as a signatory to international agreements such as the Bern Convention and the Kyoto and Paris Climate Change Agreements. In addition, future trade arrangements and consumer sentiment will be key determinants of post-Brexit regulatory policy.

However, the industry should be preparing for change in the regulatory framework in the medium term. While changes in the regulation of PPPs may not be a top priority for Government within the wider context of Brexit, they will come under scrutiny once the UK leaves the EU.

Since a policy needs to be in place at the point of exit, it would appear likely that the vast majority of PPP regulations will be 'lifted and shifted" as part of 'The Great Repeal Bill'. However, following this, change is possible and the industry needs to think ahead regarding what it wants and needs to compete effectively in a changing global trading environment, as well as satisfying consumer preferences in a domestic market.

The four possible outcomes outlined in this report include aligning with the EU, aligning with the US, adopting OECD global standards regulation or formulating a UK policy. Other policy options are also possible, and the final outcome will depend on a number of factors including, probably most importantly, the UK's trading relationship with the EU post-Brexit and the issue of 'equivalence' of PPPs, UK agricultural policy and the UK's obligations under international agreements. At present it is not clear which approach the UK Government will adopt, as each have associated pros and cons. This is something that AHDB will be monitoring closely and we will be keeping our levy payers informed of future developments.

Continuing to protect human and environmental health is of fundamental importance but without a supply of safe and nutritious food, human health will also be impacted.

It may transpire that the regulatory burden might not be reduced as much as farmers might hope and in any event would probably take a number of years to achieve. It is also likely that environmental, conservation, consumer and public health lobbies will continue to be influential and to exert pressure for more stringent regulation of agriculture and plant protection products in particular. Achieving the right balance between regulation and productivity in all areas is an age-old challenge and that is no less true of the position the country finds itself in now.

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NOTES

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