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Regulation of Plant Protection Products in the UK after Brexit

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Executive summary

The Crop Protection Association (CPA) has requested an analysis to support their discussions with Government over the shape of the UK regime for the authorisation of plant protection products (ppp) after the UK leaves the EU.

The following scenarios have been considered:

1) Ongoing adoption of all new EU developments (in parallel with potential loss of influence over their development). This would include all EU timelines, decisions and new guidance for risk assessment.

2) Reversion to an entirely risk based assessment. That is removing the human health and environmental hazard based criteria and/or the groundwater limit.

3) A system without candidates for substitution and comparative assessment.

4) More flexibility in decision making and timelines including more rapid decision making, provisional authorisations, non-time limited authorisations, a data call in procedure for maintaining authorisations and a more systematic application of new risk assessment guidance.

This report presents the analysis requested by CPA.

A range of options are open to the UK post Brexit in relation to regulation of plant protection products. A primary driver to the feasibility of any of these options will be the overarching agreement negotiated with the EU. However there would appear to be scope even within a close arrangement to deal with some of the acknowledged flaws with Regulation 1107/2009 and with its implementation, including decoupling the UK from the effects of the lack of application of legally binding provisions on the part of many EU Member States.

Even with a close arrangement agreed there are risks in remaining tied to the EU position when the UK is not a Member State due to the divergence of the EU approach away from the globally accepted approach of risk assessment.

In the case of a more open high level relationship with the EU there is significant scope to develop a more flexible policy with a better balance between pre- and post- authorisation measures. The EU regime in its current form will inevitably lead to significant loss of crop protection products in a largely unmanaged way, without necessarily improving environmental or human health.

In relation to trade with the EU, the EU policy on imports of commodities containing residues of product not permitted on the EU market is neither clear, nor tested (such as through a WTO case). However there is a potential barrier to trade in treated produce with the EU. The significance of this barrier depends on the commodity, its trade with the EU and the possibilities for the supply chain to differentiate between commodities destined for domestic and export markets.

Scenarios 2, 3 and 4 are not mutually exclusive. They all present opportunities to retain what is good in the EU regime, and to which the UK has contributed very significantly over the whole implantation period, but to deal with those issues that are widely acknowledged to not work well. None of the scenarios outlined would be detrimental to human health or the environment in the UK compared to the EU if correctly implemented.

1. Introduction

The Crop Protection Association has requested an analysis to support their discussions with Government over the shape of the UK regime for the authorisation of plant protection products (ppp) after the UK leaves the EU.

Following a discussion with the CPA team on 29 March 2018, and based on Exponent Report 1710541.UK0 – 0095, the following scenarios were selected for further development:

1) Ongoing adoption of all new EU developments (in parallel with potential loss of influence over their development). This would include all EU timelines, decisions and new guidance for risk assessment.

2) Reversion to an entirely risk based assessment. That is removing the human health and environmental hazard based criteria and/or the groundwater limit.

3) A system without candidates for substitution and comparative assessment.

4) More flexibility in decision making and timelines including more rapid decision making, provisional authorisations, non-time limited authorisations, a data call in procedure for maintaining authorisations and a more systematic application of new risk assessment guidance.

2. UK approach to Brexit

The following outline arrangements have been described by UK officials involved in preparing the chemical control regimes for Brexit[1]:

- The Withdrawal Bill will transfer wholesale the EU legislation into UK domestic law
- Certain so called 'inoperabilities', that is those provisions that involve EU institutions or Member States, will be fixed by subsidiary legislation to ensure that from March 2019 chemicals regulation continues to function in the UK.
- These processes do not allow for changes in 'policy'. Changes in policy will be developed and implemented in the 'usual' way, through consultation, Ministers and Parliamentary legislation, where required.
- 'Policy' would appear encompass the basic requirements, timelines, guidance and procedures.
- Given the challenge of simply fixing the inoperabilities before March 2019, it is almost certain that substantive policy development will not begin until after that date.

It is also clear that any future role that the UK might play in EU evaluations (for example as a rapporteur) is heavily dependent on the high level post Brexit

[1] For example Dave Bench's presentation at the ECPA Conference, Brussels, March 7-8, 2018

relationship that is agreed with the EU. More widely the following ambitions have been articulated for this:

- to maintain an effective regulatory system for managing and controlling chemicals to safeguard human health and the environment, responding to emerging risks and allowing trade with the EU that is as smooth as possible[2].

- a time-limited implementation period was endorsed by the European Council on 23 March 2018[3].

- During the implementation period, it is expected that HSE will not be able to act as a 'leading authority' to conduct certain assessments under the Plant Protection Products, Biocides and REACH regulations[4]. Steps are being taken to hand over UK applications to other MS[5].

- Having regulations that are not necessarily identical but achieve the same outcomes[6].

- To explore with the EU, the terms on which the UK could remain part of EU agencies such as those that are critical for the chemicals, medicines and aerospace industries: the European Chemicals Agency, the European Medicines Agency and the European Aviation Safety Agency[7]. The European Food Safety Authority (EFSA), the key EU agency for plant protection products was not mentioned as part of this. It is unclear whether this was a deliberate omission or not.

It is therefore clear that under the arrangements intended to apply during the implementation period the UK will not be acting as a competent authority within the EU framework irrespective of any future longer term arrangement.

3. EU Regulation

Two EU Regulations fall within scope of this analysis:

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[8].

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC[9].

[2] Virtually all public statements include this or something similar
[3] Council agreement – March 2018
[4] EU Draft withdrawal agreement – 19 March 2018 TF50 (2018) 35 – Commission to EU27)
[5] Draft reg renewal programme voted at Standing Committee March 2018
[6] Prime Minister – Mansion House speech 2nd March 2018
[7] Prime Minister – Mansion House speech 2nd March 2018
[8] OJ L309/1, 24.11.2009
[9] OJ L70/1, 16.03.2005

An overview and commentary on the legal provisions in both these Regulations is given in Appendix 1 and 2.

Irrespective of the UK approach to Brexit, Regulation 1107/2009 includes a range of provisions which are:
- basic legal provisions one would expect to see in legislation of this type or;
- those provisions generally established and considered to be desirable in principle, if not in all details of the EU implementation.

These provisions include:
- basic criteria for protection of human health and environment.
- basic risk based criteria for authorisation.
- conditions and restrictions on authorisations.
- derogations for research and development work.
- derogations for plant health emergencies.
- keeping information and reporting of potentially harmful or unacceptable effects.
- those for voluntary withdrawal.
- grace periods.
- those for minor uses.
- avoiding duplication of vertebrate studies.
- confidentiality of commercial and personal details.
- rules on packaging, labelling and advertising.
- controls, enforcement and penalties.
- those to deal with emergencies.

There is scope for improving the practical application of these provisions but they do not present major policy choices.

Cost recovery through fees is also a long established UK approach. Within reason, a properly resourced and experienced regulatory authority remains a necessity.

With respect to the MRL legislation virtually all of the provisions in the MRL Regulation 396/2005 relate to the definition of MRLs and the procedures by which they are set or their control, monitoring or enforcement (all matters for the EU or EU Member States). In the context of this exercise, the relevance of these provisions is the implications for export of treated produce from the UK to the EU should the UK authorisation regime diverge from that of the EU.

3. Methodology

Following an analysis of the main provisions of the two EU regulations in scope (see Section 2), a number of scenarios were chosen for further development. Each has been considered for its impact on the following:

- Potential for continued regulatory collaboration with the EU regime.
- Possible global regulatory collaboration.
- Time to market for new active substances and products in the UK compared to the rest of the world.
- Cost of product registration in the UK.
- Active substance availability for UK farming.
- Trade issues related to export of produce from the UK market to the EU (and globally).
- Consideration of alternative arrangements (e.g. WTO) and impact on current trading practices.
- Environmental and human health protection in the UK.

A number of assessments have been made of the impact of EU regulation for plant protection products during its development and subsequent implementation. These have been conducted by various bodies. They have not however been considered in relation to Brexit. These have been used to provide information on the potential impacts.

4. Analysis

4.1 Ongoing adoption of all new EU developments

4.1.1 Scenario description

In this scenario it is assumed that no 'policy' changes would be made in the UK and that all EU timelines, decisions, data requirements and guidance for risk assessment would be applied. The key change would be that the UK would potentially have no influence over these developments.

Appendix 4 contains a list of the key technical guidance documents that have been 'agreed' (see Section 4.1.2.5). In addition, however, there are a significant number of ongoing EU guidance documents in development or envisaged. The European Food Safety Authority (EFSA) has recently consulted or intends to consult on the following risk assessment guidance:

Recently closed consultations on guidance documents
Guidance of EFSA on Risk Assessment for Birds and Mammals (closed 18/12/17) – identification of areas for updating
Draft EFSA/ECHA Guidance on Endocrine Disruptor identification (closed 31/01/18)

Announced future consultations (with expected date of launch)

Draft guidance of EFSA on risk assessment for amphibians and reptiles (01/06/18)
Draft guidance document on harmonisation of human and ecological risk assessment of combined exposure to multiple chemicals (01/07/18)
Revised SC scientific opinion on the TTC (Threshold of Toxicological Concern) (01/09/18)
Draft EFSA scientific report on the "FOCUS surface water repair action" (01/01/19)
Draft EFSA Guidance Document on completing risk assessment for active substances of plant protection products that have isomers and for transformation products of active substances that may have isomers (01/01/19)

There are additionally two guidance documents adopted by EFSA (those for bees[10] and definition of residues for consumer risk assessment[11]) which have not been accepted by the European Commission and Member States for use due to significant concerns over their practicality and impact in terms of resources required for their implementation, the capability of established test methods to meet the requirements set out and outcomes in terms of product availability. EFSA have taken the unilateral decision to use the bee guidance document irrespective.

More widely there are a number of 'ambitions' described in Regulation 1107/2009 that are not due to be implemented until accepted methodology has been developed including:

- cumulative and synergistic effects (Article 4)
- assessment for coastal and estuarine waters (Article 4)
- assessment for biodiversity and ecosystems (Article 4)
- common rules for adjuvants. (Chapter IV)

Finally the EU regime is currently under review as part of the EU Regulatory Fitness and Performance (REFIT) programme. This could potentially lead to a simplification of the EU regime although the EU track record in this respect is not good. Simplifications proposed by the Commission in the proposal for what became Regulation 1107/2009 (such as non-time limited approvals) were not accepted by the Council and the Parliament during the Co-decision negotiation[12] and the major part of the proposal to reduce regulatory burdens was a zonal system for product authorisations. Experience strongly suggests that this objective has not been met[13].

With respect to timelines there is currently a significant mismatch between the legally binding timelines in Regulation 1107/2009 and those being routinely delivered by most Member States. The EU Commission itself has stated:

[10] EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) EFSA Journal 2013;11(7):3295
[11] Guidance on the establishment of the residue definition for dietary risk assessment EFSA Journal 2016;14(12):4549
[12] Rob Mason – participation in negotiation
[13] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3

The majority of Member States fail to use the zonal authorisation system as envisaged in the Regulation and fail to comply with almost all legal deadlines under the Regulation, by significant margins in many cases. As a result, there is delayed or reduced access to new pest control tools for growers. In addition, the re-evaluation of plant protection products already on the market, in light of new scientific and technical knowledge, is delayed. Finally, delays in processing requests for authorisation also contribute to more emergency authorisations being granted by Member States, without a full evaluation being performed[14].

Appendix 8 uses graphics from the Commission Report referenced above to illustrate this. These conclusions are further supported by other reports on the functioning of the EU regime such as that published by the European Parliamentary Research Service on the Implementation of 1107/2009 [15]. The same experience is reported by industry applicants (Appendix 9).

Since a high proportion of the work in the Central EU Zone is currently being handled by the UK[16] (e.g. 37 % of zRMS for AIR 3 containing products (batch 1-6) and 21% zRMS AIR 3 batch 7-9 and group 4) and based on recent UK performance as audited by the European Commission and the internal CPA members survey[17], it is assumed that in this scenario the UK would keep to the timelines in the Regulation and that other Member States would continue to perform as to date. In reality the EU situation could deteriorate without the UK direct contribution.

4.1.2 Analysis

4.1.2.1 Potential for continued regulatory collaboration with the EU regime.

Under this scenario there would be clearly be no barrier at a process and technical level to regulatory collaboration with the EU regime. The same regulatory standards and timelines would be applied. It would also be expected that the same documentation formats would be retained.

The key barrier would be the legal status of the UK in relation to the EU post Brexit. This would determine the possibility for the UK to participate as a rapporteur for active substances or products. At present this is not finalised and will not be determined in relation to ppp alone. As set out in Section 2 during the implementation period, it is expected that HSE will not be able to act as a 'leading authority' to conduct certain assessments under the Plant Protection Products, Biocides and REACH regulations and steps have been taken to hand over UK applications to other Member States. This seems potentially contradictory to the aim also set out in Section 2 to 'explore with the EU, the terms on which the UK could

[14] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3
[15] European Parliamentary Research Service, European Implementation Assessment, Regulation 1107/2009, April 2018 ISBN: 978-92-846-2734-9
[16] See Appendix 11 Proportion of products allocated to the UK for renewals
[17] See Appendix 7 CPA survey CRD performance figures

remain part of EU agencies such as those that are critical for the chemicals……' although as also mentioned in Section 2, EFSA, the key EU agency for ppp was not mentioned as part of this.

It is also the case that, with the current arrangements for the implementation period, the UK could be excluded from the EU procedures for that period but, subject to any longer term agreement, participate once again at some point after that.

4.1.2.2 Possible global regulatory collaboration.

Under this scenario the same barriers present themselves to global regulatory collaboration as currently apply to the UK as part of the EU. The EU system has diverged from the rest of world in some significant areas, in particular hazard based regulation. The EU legal timelines are also an issue and have been a reason for the lack of EU participation in OECD Global Joint Reviews subsequent to the implementation of Regulation 1107/2009. New developments such as the guidance on definition of residues further reduces this potential for global collaboration such as the setting of global MRLs through the UN Food and Agriculture Organisation/World Health Organisation, Joint Meeting on Pesticide Residues procedure (JMPR). The EU already does not accept a high proportion of Codex MRLs where they differ from those intended in the EU and this is increasingly likely to be the position if the EU (and in this scenario the UK) continue to set different residues definitions.

Appendix 15 gives more detail on the numbers of Codex MRLs refused by the EU.

4.1.2.3 Time to market for new active substances and products in the UK compared to the rest of the world.

An overview of time to market in some key countries globally is at Appendix 10. In this scenario the UK would be largely dependent on the EU timetable and would have potentially less flexibility than is available now to improve the timelines in particular for new active substances.

Currently where the UK acts as Rapporteur Member State (RMS) there is the possibility that the UK can deliver more quickly than the EU legal deadlines. Since it is expected that the UK will no longer act as RMS, this part of the procedure will be dependent on other EU RMSs for delivery of the initial evaluation. Since, in this scenario the UK will follow all EU decisions, there is no benefit in the UK independently evaluating a substance in parallel to the EU procedure. Given the proportion of the EU work undertaken by the UK there is clearly the potential for the EU evaluation to suffer further delays when the UK resource and pragmatism is removed. As now the subsequent steps are dependent on EFSA and the European Commission for decision making.

For national product authorisations more flexibility exists even within this scenario, subject to the EU approval of the active substance initially. Although in principle evaluations are carried out on a zonal basis as outlined in Section 4.1.1, the applications are required to be made to each Member State where an authorisation is

required and many Member States (the UK included) apply additional national approaches to the assessment. Therefore there would be a choice of whether to wait for the EU zonal RMS to report (potentially well after the legal deadline based on current performance) or to evaluate the application in parallel and make an independent decision. The only further consideration would be if an MRL was required to accommodate a new use then the UK authorisation would again be bound into the EU timetable.

The approach taken would have implications for the resource requirements in the UK evaluating authority (currently CRD). However it can be roughly assumed, given the high proportion of zonal applications handled by the UK and resource savings through not participating in EU active substance evaluations, and in the zonal system for products. that a similar level of resources to those deployed today would be required if the approach of an independent UK product evaluation were followed.

Overall, within this scenario, no change would be expected to the current situation where the time to the market in the EU for a product containing a new active substance is significantly longer than many other places in the world. However for product authorisations there is scope within this scenario for the UK to deliver new products more rapidly that the EU system (subject to the active substance being EU approved) or to make the timelines significantly longer by relying more or less entirely on the EU zonal evaluation.

4.1.2.4 Cost of product registration in the UK.

In this scenario no account is taken of active substance data generation or authority fees. In addition no change would be envisaged to the costs for minor changes to products.

With respect to major product evaluations (new products or major changes) CRD's current fees and resource requirements are outlined in Appendix 12. The fee for acting as a zonal RMS could be roughly calculated to be £18,000. No UK specific study requirements are envisaged in this scenario although it is assumed that study costs overall will rise as new requirements and guidance are introduced across the EU.

Costs for individual applications will be highly dependent whether the UK chooses to conduct an independent product evaluation or follow that of the EU zonal RMS. With the first choice an increase in costs for major evaluations would be expected. With the second a reduction in costs would be expected. However the second approach would also introduce significant uncertainty around the sustainability of CRD as an organisation, assuming that cost recovery from industry remains the policy, with sufficient specialists to deal with UK specific issues in an expert and pragmatic way.

4.1.2.5 Active substance availability for UK farming.

In this scenario it would be expected that the numbers of active substances on the UK market will reduce in line with that in the EU. The trend since 1993 is given in

Appendix 6 and all the indications to date are that this will continue. A significant and increasing number of decisions on the renewal of approved active substances are currently pending with the European Commission and it is known either publically[18] or based on initial indications from the Commission to the applicants involved that a significant proportion of these are envisaged to be non-renewals. It is also evident that in a number of cases the delays are as a result of the Commission being unable to establish a qualified majority of Member States either in favour of approval or in favour of non-approval indicating a significant practical disagreement about the way the regime is being implemented and the results that are being delivered.

Appendix 5 is an analysis of the numbers of active substances and product types approved in the EU, including those new to the market since the implementation of the harmonised EU rules in 1993, compared to those on the market in the UK. The numbers authorised in the UK are roughly between 60-70% of those available in the EU as whole, probably reflecting more than anything else differences in production needs. It should also be noted that 'new' active substances considered early in the EU regime are being considered for renewal and some may not themselves be renewed[19].

It should also be noted that the full effect of the hazard based approval criteria in Annex II of Regulation 1107/2009 has not yet been realised with many substance evaluations ongoing and the definitive criteria for endocrine disruptors only recently agreed and the associated guidance still under discussion.

In addition significant new guidance is planned as outlined in Section 4.1.1 and given previous experience it can be expected that these will be more precautionary. The EU does not have a good track record in assessing the impact of new guidance before implementation (for example the bees guidance document is being applied by EFSA despite not being agreed by Member States). Appendix 13 gives an overview of some of the concerns identified with ongoing guidance in development. Examples of new guidance developments that could make passing risk assessments significantly more challenging include the EFSA bee guidance document (currently blocked by Member States), new guidance for non-target plants, including protection of in field weeds and more precaution for off-field plants, developing guidance on non-target arthropods and changes in testing for high dose effects related to human health classification[20].

Indicative of the increasing regulatory challenges in the EU is the decreasing proportion of global R&D that is targeted to the EU. The agrochemical industry invests around 4bn Euros globally on R&D each year. The proportion of spend on developing new products for the EU market has fallen from 33% in the 1990s, to 7% by 2014[21]. A graphical illustration is given in Appendix 14.

[18] Published agendas for the Standing Committee on Plants, Animals, Food and Feed – European Commission website and WTO, Technical Barriers to Trade (TBT) notifications by the European Commission.
[19] Rob Mason – based on knowledge of ongoing substance evaluations
[20] Phil Botham – ECPA conference 2018, Brussels
[21] R&D trends for chemical crop protection products and the position of the European Market Phillips-McDougall September 2013, Available on the ECPA website

Various studies have been performed during the negotiation of Regulation 1107/2009 and since looking at potential impacts on active substance availability and the agronomic, financial and economic consequences. Many of these studies build on the earlier ones. Some are UK focussed but most look at the EU as a whole. However since determining impacts is by its nature imprecise, the EU studies still have value in considering the potential impacts in the UK.

Notable studies include

1) **Revised assessment of the impact on crop protection in the UK of the 'cut-off criteria' and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market.** PSD, December 2008[22]

   This assessment prepared by the UK regulator looked at the vulnerabilities of active substances on the UK market to the developing criteria for substance approval. Based on the position finally adopted the following conclusion is probably the most valid from this report:

   'The loss of active substances from the Common Position, as detailed in Annex 2A, as previously identified (PSD 2008) would have serious implications in both agriculture and horticulture. Notably the potential loss of triazole compounds would remove the foundation-stone of control programmes on wheat against Septoria with potential for substantive yield losses. Similarly, on oilseed rape the removal of a range of fungicides would not leave any fully effective compounds for the major diseases of rape. There were significant implications for minor crops such as carrots, parsnips and onions because the majority of currently approved herbicides may no longer be available. There was potential for up to 100% yield loss on carrots. Insecticide losses are of limited impact.'

   It should however be noted that since this report was prepared the EU harmonised classification procedure (based on hazard and to which the approval criteria in Regulation 1107/2009 refer) has been increasingly precautionary as mentioned above.

   The PSD also makes some important points about alternatives and the fact it did not cover the so called EU 'List 4' substances (those covered by EU Regulation 1112/2002[23]) which included biological substances and 'natural' products such as plant extracts. It states '*This list includes some compounds that can provide a useful contribution to pest control, particularly in the insecticide arena, with substances such as* Bacillus thuringiensis*, nicotine fatty acids and pyrethrins. There are also insecticidal substances such as pheromones for moth control and fungi for aphid control. However they generally do not deliver the level, persistence or consistency of control delivered by conventional chemistry. As such they are commonly used in conjunction with conventional chemistry (to ensure populations are reduced sufficiently) or in partnership with biological control*

[22] Available on the National Archive version of the CRD website
[23] OJ L168/14 27.06.2002

agents in protected situations (where control by introduction of parasites and predators can be more reliable due to the more consistent environmental conditions). Whilst an increase in frequency of their use might lead to higher levels of control of some pests, this would lead to increased problems with resistance, present already for many of these substances. In the herbicide and fungicide area, the diversity of list 4 compounds is much more limited and (with the exception of sulphuric acid widely used for potato haulm desiccation and ethylene as a PGR) they only provide a small contribution to the control of weeds and diseases, or have very specific and limited application."

The report also makes the points that '*it is clear that it is not simply the percentage or absolute numbers of substances that might be lost which is the most important factor, but the particular substances concerned.'*

2) **What price protection? An Economic Assessment of the Impact of Proposed Restrictions on Crop Protection Substances.** Séan Rickard, Cranfield University School of Management, September 2008[24]

This assessment does not state who it was commissioned by. It is an economic analysis of the consequences of the PSD impact assessment described above which were elaborated by ADAS in terms of yield impacts.

It concludes that all other factors remaining equal, the experts' assessed reduction in yields would make a large proportion of the Community's arable farms unviable, resulting in the loss of livelihood for many farmers and further job losses throughout the food chain. Of course other factors are unlikely to remain unchanged, most notably the prices of arable crops would rise and the increase would be likely to be significant. It is impossible to say by how much prices would rise as much would depend on the availability and prices of alternative supplies – not subject to the same restrictions – imported from outside the Community. However, it is possible to demonstrate that the price of cereals, potatoes and vegetable brassicas would need to rise by more than 100 per cent under the more severe proposed crop protection restrictions if arable farm margins are to be protected.

3) **Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD.** WRC January 2013[25]

This assessment was commissioned by the UK Regulator, Chemicals Regulation Directorate, of HSE, examined differing proposals for the definition of endocrine disruptors.

Overall, the study considered 98 active substances for toxicological assessment and 20 for ecotoxicological assessment. The findings for each group were summarised in the report. These assessments indicated that a number of

[24] Available on the National Archive version of the CRD website
[25] Available on Defra R&D Reports website

agronomically important active substances would be eliminated as being more likely to pose a risk, whilst others might also be eliminated despite being less likely to pose a risk, depending upon the final criteria adopted. Additional data (predominantly mechanistic data) would have to be generated and evaluated before the status of a significant number of "potential" endocrine disrupters determined.

4) **Simplification of the EU Pesticides Regulatory Regime.** Biointelligence Service, September 2013[26]

This assessment was commissioned by Defra. It considered a number of policy options as follows:

- the introduction of new cut-off criteria for plant protection product active substances replacing the current hazard-based approach with a risk-based one and the introduction of criteria for substitution based on comparative assessment among possible substitute substances;
- the scope of the Regulation in terms of protection goals and its implementation;
  data requirements promoting a more flexible and cost-effective implementation of the Regulation, including a move towards more integrated testing needs and the possibility of using extensively novel approaches to data collection including the TTC approach, read-across and computational tools such as QSARs and PBPK models for active substance and metabolite toxicity assessment.
- the zonal approach to authorisation of active substances and plant protection preparations
- data requirements for biological substances and biopesticides
- data protection issues

In relation to each of these the following conclusions are drawn:

- A risk-based approach for the assessment

  Implementation of a risk-based approach for AS substance assessment is feasible assuming that more focus will need to be given on actual exposure compared to the sole assessment of intrinsic toxic potency of the active substances for hazard assessment (today's paradigm). A number of studies addressing general, farmer/applicator and consumer exposure to pesticides in Europe have been funded over the last decade from the European Commission RTD Framework Programmes and from EFSA (in more targeted form). The information drawn from these initiatives should be collated and put to use for exposure assessment purposes within the regulatory framework, effectively supporting the widespread implementation of a risk-based assessment process. Some experts have argued that such a move would increase regulatory complexity. However, the current experience from the pesticide programme

[26] Available on Defra R&D Reports website

of the US EPA and from the REACH Regulation in Europe shows that implementing a risk-based approach does not result in overburdened regulatory processes if done properly. The benefit towards rationalisation of the assessment process and cost-efficiency of the assessment could be significant. Additional benefits would include a spur of industrial innovation in terms of both pesticide manufacturers and agricultural industry. The economic benefits would in this case not be coupled to increased risks to environmental and human health. An adequately informed risk assessment process would protect appropriately both the natural ecosystem and public and consumer health.

It has been suggested that targeted case studies could be funded to provide specific evidence on the actual environmental and health burden from the introduction of specific cut-off criteria. This would be beneficial, of course, by means of providing a robust scientific basis for making the regulatory change. It is not expected, however, to result in any significant difference compared to the savings estimate given in the study, namely between 415 and 820 M€.

The information/data requirements for a comprehensive risk assessment would need to be regularly reviewed and adapted to reflect scientific progress and knowledge enhancement with regard to both the toxicity mechanisms and the fate of active substances and formulations in the environment and the human body. Such revisions would need to be accompanied by the necessary guidance to both industry and the regulatory competent authorities. Such reviews should only be done during pre-determined intervals (e.g. every 5 or, better, 10 years) in order to ensure cost-effectiveness and the smooth operation of both the market and the overall farming system.

Removal of the current requirements for comparative assessment of active substances and of the criteria for substitution of the authorised pesticides would encourage industrial and farming innovation. Coupling this to a more efficient risk-based assessment approach would ensure the adequate protection of people and the environment at a very low cost of implementation.

- Scoping the protection goals

Setting priorities in the protection goals of the Regulation including both environmental and health aspects would also improve the efficiency of the overall system, allowing everyone to focus resources on the most important issues. This change bears the potential for significant savings to the overall agricultural/farming system while protecting adequately the environment and human health. In doing that, however, care must be taken to consider not only the ecosystem goods and services that people gain from the environment, but also the structural and functional features of ecosystems in order to ensure their long-term sustainability. In this context, there is a need for clarification of monitoring needs in order to render the monitoring system more cost-effective. Analysis of the relative distribution of species sensitivity to

pesticides and consideration of potential synergistic effects of persistent and bioaccumulative substances would need to be included in the new monitoring regime.

- Targeted and prioritised data requirements

  More dramatic recommendations such as the reduction and streamlining of the tests considered necessary under the current (hazard-based) regulatory regime would seemingly meet opposition at the European Parliament. This notwithstanding, a re-evaluation of the necessity of each test should be considered, especially if we move towards a more risk-based approach. Certain expensive and time-consuming tests might not be necessary if manufacturers can prove that environmental or human exposure to the substances in question is negligible. This, however, would have to be reviewed in the framework of an integrated testing strategy, which would couple exposure and toxic potency considerations to ensure adequate protection of human and ecosystem health. It has to be noted that such an overhaul would bear very significant benefits to the cost-effectiveness of the overall risk assessment and management system.

  Environmental data requirements could be linked to the scale of use of active substances, resulting in significant enhancement in terms of cost-efficiency of the risk assessment process (this modification would be perfectly compatible with a move towards a risk-based assessment process, since scale of use could act as a first proxy of exposure). However, in this case, specificities such as due consideration of possible impacts on more sensitive population subgroups or ecosystem functions would have to be taken into account in drawing these links. Data requirements for impurities and active substance metabolites could be evaluated based on QSARs used on a case by case basis to support toxicological evidence. This would create savings to industry without jeopardising environmental and human health protection.

  It is possible to display an acceptable risk based on a small dataset if the calculated RAC (regulatory acceptably concentration) is sufficiently high. This modification is in agreement with the use of assessment factors accounting for data uncertainty in the current Biocides regulatory regime. The change would bring financial savings to industry and time saving to the MS regulatory authorities for risk assessment completion. No increase in environmental risk is expected.

  For acute toxicity testing, it is recommended to adopt the ILSI/HESI revised testing scheme. This would decrease significantly the number of laboratory animals necessary, resulting in significant benefits to both industry and regulatory authorities while protecting adequately human health and the environment.

- Zonal approach

  Generalising the zonal approach and rendering it obligatory for authorisation is a key change that would bring about significant cost reductions to industry and regulatory authorities, as well as resulting in ultimate environmental benefits from the coherent implementation of assessment results.

  In relation to the zonal approach, a potential way to simplify procedures would be to establish a 'one-stop-shop' in the risk assessment process that is followed in the implementation of the authorisation procedure. EFSA could play this role, much like ECHA's role in the risk assessment and authorisation or restrictions procedures followed in the chemical safety legislation (REACH Regulation). Establishing a single interlocutor for the pesticides industry with whom to discuss the scientific/technical aspects of product authorisation could significantly reduce the financial burden both for industry and for MS competent authorities. At the same time, this option would simplify the overall system. Mutual authorisation would no longer be required since the whole procedure would be technically managed by EFSA.

  The opinion expressed by EFSA could be developed with the assistance of a risk assessment expert committee, comprising MS experts. The discussions in the committee would be of scientific/technical nature, focusing on the evaluation of the product compliance with the requirements set by the Regulation regarding authorised use of the product.

  Clearly, individual MS could maintain the right to restrict or even ban the use of AS or of commercial preparations sold as PPPs in their territory (much like the current legislation foresees). This could be done on the basis of considerations regarding special agro-climatic characteristics of the national territory, or even on the basis of need to protect public health taking into account the social-economic conditions of the country (i.e. taking into account the realistic PPP application and use practices as per the experience of the national competent authority) and the ways in which the latter influence population exposure.

  Final authorisation or restriction decisions would still have to be made on the basis of a common decision (i.e. through a MS committee). This committee, however, would be expected to act on the basis of political considerations and, if necessary, national sensitivities with regard to exposure to PPPs. It would not be expected to question the EFSA opinion.

  The advantage of the system proposed above is that it follows a relatively simple line in the flow of information and the decision-making processes involved in the authorisation of PPPs to enter the internal market. It resembles the corresponding procedure foreseen under REACH; thus, the PPP community would benefit from the experience acquired in REACH in order to streamline any operational efficiency issues.

In order for such a system to function, industry would have to provide the Agency with the complete AS/PPP dossier, thus allowing the expert committee(s) of the Agency to efficiently review and assess the respective risk profiles. If the submitted dossier were not complete, the timeline of the authorisation procedure would have to be paused until industry complements the missing information.

To summarise, a clear possibility to streamline Article 9 of the Regulation is provided if a one-stop procedure is applied for each dossier application. In particular, if as proposed above, EFSA (or a similar Community body) were responsible for the management of the risk assessment process, then the only communication line necessary for admission of the application would be between the Agency and the applicant. Until the application is accepted for further consideration by the Agency, no exchange of information with other MS authorities or the Commission are necessary. In this way, red tape is limited to the minimum and all interested parties are aware of the fact that they have to consult the Agency for information concerning PPPs applications.

- The specific case of biological substances

  In the case of biological substances and biopesticides separate data requirements accompanied by the provision of adequate guidance on use would be needed to ensure a cost-effective regulatory regime. Even though developing separate data requirements would entail administrative costs the significant efficiency gains expected from the implementation of these requirements would be expected to reduce the net cost to minimal levels. Thus, such a development is highly recommended.

- Data protection issues

  Data protection is considered an issue that is way too sensitive to be left to industry alone to handle. Some level of involvement of the competent authorities in the MS is deemed necessary to ensure that no unfair market advantage is gained by specific market actors while maintaining the quality and quantity of the data necessary for adequate human and ecosystem health protection.

  Overall, there is a number of possible modifications to the current structure and scope of the Regulation that are widely considered plausible by the experts consulted in this process and by the project team. Effectiveness, feasibility and cost-benefit aspects have been considered in this assessment. Based on these high-level criteria several of the policy options studied were dropped because they were either difficult and/or unfeasible to implement, or they would incur excessive costs to industry and/or regulatory authorities in such a way that the costs would outweigh the potential benefits. Such options include removal of efficacy data and replacement by an approach similar to the one used in the US (“let the market decide”); and revision of limit concentrations of active substances in groundwater based on the outcome of a

risk assessment and/or the WHO safety guidelines, i.e. dropping the current threshold (0.1 μg/L) as unreasonably precautionary. In both cases, more detailed cost-benefit analysis needs to be undertaken on the basis of specific case studies, which would help forge a feasible regulatory change.

In conclusion, the bundle of policy modification options outlined above are considered as parts of a feasible restructuring of the current regulatory regime in order to enhance the cost-effectiveness of the system without jeopardising the protection to human and ecosystem health. The overall cost of implementation of the policy options described above is reasonable - the potential benefits both with regard to streamlining and simplification of the regulatory process and with regard to spurring innovation in plant protection product manufacturing and farming in Europe clearly outweigh the investment cost. Furthermore, the time required for implementation is reasonable; all changes in the Regulation could be brought about within the normal regulatory review period. The development of the necessary guidelines for the implementation of some of the novel aspects proposed herein should not take exorbitant amounts of time. Thus, the whole regulatory simplification procedure would not take more than twelve to eighteen months.

5) **The Effect of the Loss of Plant Protection Products on UK Agriculture and Horticulture and the Wider Economy.** The Andersons Centre; 2014[27]

This assessment was commissioned by the Agricultural Industries Confederation, the National Farmers Union, and the Crop Protection Association in the UK. This report draws the following conclusions:

- At present, no definitive list of ppp under threat from the various policies exists, in part due to uncertainty in the way regulations will be defined and interpreted. This project identified that 87 of the 250 active substances currently approved in the UK could be threatened by the cumulative effects of these policies.
- In practice, there is a sliding scale of threat. It has been assessed that 40 active substances are highly likely to be lost or restricted. This includes 10 insecticides, 12 fungicides, 16 herbicides and 2 molluscicides. The active substances deemed likely to be withdrawn or restricted include important products for UK crop production.
- Loss or restricted use would make control of weeds, disease, and pests in key UK crops far more difficult. Furthermore, as reliance is on fewer PPP, resistance build-up will become more likely.
- Loss of PPP will result in lower overall yields. Predicted yield decreases range from 4-50% in the crops studied, based on the effect of losing PPP classified as 'high' likelihood of being restricted or not gaining reauthorisation.
- UK cropping patterns would change, with an increase in spring cropping, fallow and temporary grass. Overall food output from UK farming and horticulture would decline. Although it is assumed that the global market

[27] Available on the NFU website

would offset the shortfall, the effect would be to make the UK more reliant on food imports and so reduce self-sufficiency.

- Domestic production of some 'iconic' British foods such as frozen peas, apples and fresh carrots would be severely curtailed.
- The structural change in UK crop production would alter farming costs as seed, fertiliser and PPP uses all shift and greater reliance is placed on mechanical and hand weeding.
- A reduction in home-grown cereal output would lead to rising livestock feed costs.
- Modelling all the changes sees UK agriculture's Gross Value Added (GVA) fall by *ca*. £1.6bn per annum – a drop of 20% on the 5-year average (2009-2013).
- UK farming profit (Total Income from Farming) drops by £1.73bn in monetary terms, which equates to a 36% drop in overall profits. These figures are based on a realistic assessment of the risks of losses of PPP, not a worst-case scenario.
- Declining profitability will cause further structural change. In general, less efficient producers will exit the sector and farming operations will, on average, become fewer and larger.
- The impact of losing key PPP goes wider than agriculture. Farming provides the raw materials for the wider agri-food sector which makes up over 7% of the total UK economy. As a result, the food processing and manufacturing sector would decline over time and potentially lose around £2.5bn of GVA. The impact on the associated workforce would be job losses of 35,000 to 40,000.
- The agricultural supply industry, including wholesalers would be hit hard with a loss of £0.28bn in GVA and job losses of 3,500-4,000.
- The UK's role as a major centre for PPP research and development is threatened by legislative uncertainty. This not only means that better and safer alternatives are not being developed, but it also threatens investment in this high-tech sector of the UK economy.
- As the UK is a relatively wealthy country, purchased imports could make good any shortfall in domestic production. However, food costs are likely to rise for consumers. While not popular with most of the UK population, it would seriously affect up to a fifth of the population who already suffer food poverty.
- There is a moral question of imposing rich-world production standards when some 842 million people globally do not have enough to eat. There is a strong argument that Europe, with its favourable soils and climate, should be optimising output (sustainable intensification).
- Alternative production systems and technologies are often cited as ways of ensuring sufficient food production with less (or no) reliance on PPP. Whilst making useful contributions, these cannot fully replace PPP at the current time.
- The conclusion must be that the current direction of policy in the area of PPP is likely to lead to considerable economic and social losses, with the gains, at best, uncertain or minimal.

- Any policies should be science-led, and the assessment of risks undertaken on a proportionate basis. This will ensure a thriving agricultural sector and safe food for the UK population in future.

6) **Impact Assessment. Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation**, Commission Staff Working Document, July 2016[28]

This assessment prepared by the European Commission does not address the impact of implementing endocrine disruptor criteria since the decision had already been taken that it should apply (the baseline case being retaining the interim criteria) but addresses the impact of differing definitions, including one involving risk assessment.

The assessment concludes that all options offer the same high level of protection of human health and the environment. A total of 108 substances are identified in according the WHO/ IPCS definition as either ED or suspected ED with 26 of those substances identified as ED. The overall conclusion is that the impacts on all aspects on sectorial competitiveness are related to the number of substances identified as ED.

7) **Cumulative impact of hazard-based legislation on crop protection products in Europe** Steward Redqueen, July 2016 [29]

This assessment, commissioned by the European Crop Protection Association. This study examined the current value of 75 substances for European agriculture. It focuses on seven staple crops at the EU level and 24 specialty crops across nine EU member states, representing 49% (in crop value).

The key findings were:

1. Use of the 75 substances identified for the production of seven key staple crops in the EU (potatoes, barley, wheat, sugar beet, rapeseed, maize and grapes) contributes to 96 million tons or €15bn in crop value:
- Barley, wheat, rapeseed and maize could face 10-20% lower yields, while potatoes and sugar beets might decrease by up to 30-40%; grape yields by up to 20%;
- At the current speed of technological progress, it would take 15-20 years to make up for this loss;
- Higher yields and lower production costs for these crops support farmer income by €17bn (i.e. €15bn additional revenue, €2bn lower costs);
- With the 75 substances, overall farm profitability is 40% higher (€17bn of a total of €44bn);
- In value, wheat benefits the most with €4bn of value, while sugar beet shows the largest profitability surplus (+100%);

[28] SWD(2016) 211 final – available on European Commission website
[29] Available on the ECPA website

- The seven staple crops correspond to 1.2m direct jobs. Of these, 30% face a medium or high risk of job loss due to relatively 'thin' margins for these crops.

2. The 75 substances are crucial for the economic viability of the 24 specialty crops covered in the scope of this study:
- The supported yields range from 40-100%, a total of 12 million tons;
- The size of the crop protection toolbox of many specialty crops is already limited and is the key driver of the high potential for yield losses;
- These 24 specialty crops relate to 300,000 direct jobs, of which almost 60% are at high risk of job loss due to relatively large loss of margins.

3. At current crop demand, the 75 substances support the EU's self-sufficiency for wheat, barley, potatoes and sugar beets, while limiting the import levels of rapeseed and maize:
- In contrast to the current situation with a positive trade balance, without these 75 substances, the EU is likely to depend on imports for more than 20% of its staple crop demand;
- Meeting the demand for staples with imported crops entails risk of selling crops on the European market produced with non-EU standards;
- Meeting the demand for specialty crops seems even more challenging as sufficient import amounts are not always readily available;
- An additional 9 million ha farmland might need to be integrated to feed Europe. This is equal to half of the total currently used agricultural area of the UK;
- This would increase the carbon emissions by up to 49 million t CO2-eq (i.e. 10% EU agriculture, 1% of EU, similar to the total emissions of Denmark11 or twice the international aviation emissions of Germany12), putting the CO2 aims of European legislation at risk;
- In monetary terms, these increases could mean additional emissions to the value of €500 million.

4. Mediterranean crops analysed benefit from using the 75 active substances for protecting against a wide range of pest diseases. Most of these are specialty crops that currently benefit of a limited number of registered active substances:
- The supported grape yields would decrease by 20% (22% in France, 13% Spain, 20% Austria and Italy even 30%) and overall farm profitability would be 11% lower;
- The EU is currently self-sufficient for grapes. Losing the active substances will require the EU to import some 4m tons of grapes from third countries;
- Yields are expected to decrease by 92% in carrots, 60% in apples, 65% in pears, 40% in olives, 36% in tomatoes, 36% in citrus fruits and 15% in cherries.

5. Smaller local crop supply will also affect EU value chains with higher costs and less jobs:
- Primary crop processors in the EU could run into difficulties with their supplies, e.g. if tomatoes become economically unviable to be cultivated locally, the long-term perspective for the processors is uncertain;
- Effects are likely to trickle down the value chain to the consumer but also to affect EU trading partners.

For the UK specifically the study reports:
the results represent only the loss of the 40 substances at high risk (i.e. excluding medium risk) and are based on the Andersons Centre' study. The British production of five key staple crops is currently 4 Mt higher and generates €1.1 billion more value per year than if the 40 substances were removed from the farming toolbox.
In addition, the economic viability of the production of speciality crops such as peas would be challenged.
Further impacts include:
- Wheat, barley, sugar beets, potatoes and oilseed rape would face 10-20% lower yields;
- Variable production costs for the staple crops would increase by about 15% per hectare;
- Speciality crop peas would be affected to a similar extent;
- Wheat would be most affected with €0.4bn of value loss;
- British crop agriculture provides 500,000 fulltime jobs of which 283,000 rely on the crops discussed in this study.

6) **Broader impact of criteria for endocrine disrupting properties for crop protection products in Europe,** Steward Redqueen, March 2017[30]

This assessment was commissioned by the European Crop Protection Association. It focusses on 16 substances which may be captured by the EU criteria for endocrine disruptors and on seven staple crops at the EU level and selected crops across five EU member states, representing 47% of crop value produced in the EU28 and 53% of harvested volume of these crops.

The assessment is stated to lead to the following quantitative insights:
- Use of the 16 substances in the cultivation of seven key staple crops in the EU (potatoes, barley, wheat, sugar beet, rapeseed, maize and grapes) contributes to between 34 and 69 million tons or between €4.1 and €8.3bn of crop value:
- Wheat, barley, maize could face 1-7% lower yield if the 16 substances were no longer available;
- Yield for rapeseed, potatoes, sugar beets and grapes might decrease by between 5% to 31% if the 16 substances were no longer available;
- If these substance were no longer available, the EU's trade balance could be negatively affected: the volumes imported into the EU could quadruple: from currently 7 Mt of maize, OSR and sugar beet to some 28 Mt
- At the current speed of technological progress, it would take 5-8 years4 to make up for this loss;
- Higher short-term yields for these crops support farmer income of between €4.1 and €8.3bn;
- With the 16 substances, overall farm profitability is up to 20% higher (€8.3bn of a total of €44bn);

[30] Available on the ECPA website

- In value, grapes and wheat benefit the most with between €0.8 and €1.9bn revenues from using the 16 substances, while oilseed rape and sugar beet have the largest profitability surplus (between 10 and 100%);

This current report is not in itself an assessment of the impact of the EU regulatory regime. However the assessments that have been conducted give a broadly consistent picture of the potential significant impacts of the EU regulation resulting from the loss of plant protection products. There is also a low expectation that alternative approaches will fill these gaps in either an effective or timely manner. Should the UK apply the EU rules then impacts as described can be expected due to a significantly lower availability of plant protection products to growers.

4.1.2.6 Trade issues related to export of produce from the UK market to the EU (and globally).

Trade with the EU should not be affected since common standards are being applied. However there is a potential issue with MRLs where the UK has the critical GAP for the EU MRL. In principle this will require an import tolerance to be established to facilitate the UK GAP.

There is however a potential vulnerability for the UK to a WTO case being brought due to import restrictions being based on an EU hazard assessment. No cases have yet occurred where the EU has taken action against MRLs and/or import tolerances due to the withdrawal of an active substance based on hazard criteria so the procedure has not been tested. However the European Commission have previously indicated that this is their intention and to do anything different for a substance withdrawn due to failure of a human health hazard criteria would be entirely inconsistent in policy terms. However to do so is entirely incompatible with both the risk based approach set out in Regulation 396/2005 for setting MRLs and the WTO Phyto-Sanitary (SPS) agreement rules. ECPA have prepared a paper setting out the details of this[31]. There appears to have been some very recent recognition of this vulnerability by the European Commission and this was indicated in a recent presentation by Klaus Berend at the San Francisco 2018 MRL Harmonisation Workshop[32]. The presentation made it very clear that there was no barrier to making an application for an import tolerance for a compound which met the cut-off criteria and a risk assessment would be made by EFSA. Whilst not explicitly in the slides, Mr Berend made the comment that to date, in this situation, no import tolerance application had received a positive recommendation from EFSA. The UK alone is potentially significantly more vulnerable to a WTO challenge than the EU as a whole if actions on import tolerances follow those of the EU and are not risk based. This would also be at a time when the UK will be seeking wider trade agreements post Brexit.

[31] Import tolerances in the European Union Can Import Tolerances be set for active substances impacted by the EU hazard-based criteria? ECPA May 2017

[32] EU Legal Framework for Pesticides and Residues, Klaus Berend, Head of Unit, European Commission. 2018 MRL Harmonisation Workshop, San Francisco, USA. 30-31 May 2018. http://specialtycrops.org/mrlworkshop.html

Two extensive reports are available related to agricultural imports from outside the EU.

1) **Estimation of Potentially Affected Agricultural Imports Due to Hazard-Based Criteria in the EU Regulation of Plant Protection Products Part I, Analysis by Region and Product Group** Bryant Christie Inc October 2017[33]

2) **Potentially Affected Trade from World Agricultural Exporters with European Union Regulation of Endocrine Disruptors 2017 Update: Part II, Country Data** Bryant Christie Inc October 2017[34]

These reports were commissioned by CropLife International and the ECPA. The analysis suggests that agricultural imports with a total value of €70 billion in 2016 might be adversely affected by a loss of MRLs resulting from hazard-based non-approval of 58 active substances. This represents over 60 percent of the estimated total value of all agricultural imports to the EU in 2016.

4.1.2.7 Consideration of alternative arrangements (e.g. WTO) and impact on current trading practices.

This impact is considered above in Section 4.1.2.6.

4.1.2.8 Environmental and human health protection in the UK.

At one level it can be argued that removal of substances from the market will improve environmental and human health protection. This certainly the position taken by many NGOs and politicians, who often cite 'the precautionary principle'. A full analysis of all the issues is clearly outside the scope of this report however it is clear that in reality the situation is more complex. Wider issues that should be taken into account include:

- with respect to hazard assessments risk based assessments are designed to ensure human health and environmental protection, with significant precautionary elements built in in both the hazard and exposure parts. Hazard based assessments do not in themselves improve this and the EU has diverged from the global norm in taking this approach.
- 'acceptability' is often presented as a scientific decision whereas in reality it is a political choice. Ppp by their nature have impacts, as do many other forms of human activity, and the choice is whether these impacts are 'acceptable' against the benefits that they bring.
- no account is taken of what alternative pest control measures, such as increased mechanical intervention, will be required and their impact on human health and the environment.
- issues of food supply and, for example, affordable fresh fruit and vegetables.
- exporting production to other countries with lower levels of control.

[33] Available on the ECPA website
[34] Available on the ECPA website

The EU system as it stands is very focussed on pre-market control through the authorisation regime. There is also very limited risk/ benefit consideration possible in contrast to EU regulations of general chemicals through REACH[35] and of biocides[36]. Whether this will change as a result of the REFIT procedure remains to be seen but given the political environment around ppp this seems unlikely. However this does seem to a lost opportunity to provide a better balance between pre-and post-market control approaches.

4.2 Reversion to an entirely risk based assessment.

4.2.1 Scenario description

In this scenario it is assumed that the UK would apply all the EU rules except those that are hazard based. That is removing the human health and environmental hazard based criteria and/or the groundwater limit.

4.2.2 Analysis

4.2.2.1 Potential for continued regulatory collaboration with the EU regime.

Since the EU regime contains two components, hazard and risk, the potential for collaboration on the risk assessment part remains. Although the EU requirements for active substance evaluation specify that a first step should be evaluation against the hazard criteria[37], in reality evaluations are not halted at this stage in case of an envisaged failure because it is never that clear cut. Additionally there are two possible derogations (negligible exposure and necessity to control a serious danger to plant health (Article 4(7)) which also come into play at this point. The use of hazard criteria is a risk management decision for which the UK Government could make different choices

Not applying the groundwater limit of 0.1 µg/L would require some additional risk assessment, in particular for the active substance where the limit is an absolute cut off but does not preclude collaboration between the UK and the EU since this can be applied locally.

As outlined in Section 4.2.1.1 collaboration is also heavily dependent on the wider agreement reached on the future UK relationship with the EU.

4.2.2.2 Possible global regulatory collaboration.

By not applying the hazard criteria there is a possibility of substances being commercialised in the UK that would not be introduced in the EU. Since it is highly unlikely that substances would be developed for the UK alone then there is clear

[35] Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No 1907/2006, OJ L 396, 30.12.2006
[36] Regulation (EU) No 528/2012, OJ L 167/1, 27.6.2012
[37] Article 11(2), Regulation 1107/2009

scope for global collaboration on the evaluation of these substances, either following an evaluation and authorisation by another country/ region or jointly from global dossier submission. In the past CRD was a relatively enthusiastic participant in OECD Joint Global Reviews and there is no reason why this approach could not be taken in future. Application of different risk management was accommodated in the OECD procedures. The remaining barrier would be the EU timelines but since this evaluation would not be relevant to the EU different timelines in these circumstance would be possible.

4.2.2.3 Time to market for new active substances and products in the UK compared to the rest of the world.

This scenario in itself does not impact on timing since hazard criteria are not a process issue but a decision making step. As indicated above in Section 4.2.2.2 it could be envisaged for substances not submitted in the EU that different timelines could apply to those for substances being evaluated in the EU.

4.2.2.4 Cost of product registration in the UK.

For products containing active substances which will not be approved elsewhere in the EU then regulatory fees for those applications, which will involve a complete active substance dossier, will be substantial and can be assumed to be the same order as when CRD acts as an active substance RMS. The compensation would be earlier entry into the market. Costs for product authorisations should be affected only as indicated in Section 4.1.2.4.

4.2.2.5 Active substance availability for UK farming.

To date no decisions have been taken in the non-approval of an active substance solely on a hazard basis in the EU. Key issues in relation to this have been a lack of definitive criteria for endocrine disruptors, a mismatch in the timing between the ppp approval process and the European Chemicals Agency (ECHA) classification procedure to which the ppp hazard assessment is linked and an ongoing debate in what constitutes negligible exposure. This is anticipated to change as ECHA reach decisions on classification and the endocrine disruptor criteria apply.

However it can envisaged that increasingly conservative and precautionary risk assessment schemes are an equal threat to product authorisations and whilst not applying hazard criteria will probably permit some substances to remain on the UK market compared to those in the EU, ongoing adoption of EU risk assessment guidance is likely to result in, if not the loss of entire active substances and products, significant restrictions on their use and loss of specific crop uses.

4.2.2.6 Trade issues related to export of produce from the UK market to the EU (and globally).

Trade issues with respect to hazard criteria are explored in Section 4.1.2.6. Whether the UK has a trade issue with the EU will depend on the eventual stance taken by the EU in setting import tolerances for substances which fail the hazard criteria, see

Section 4.1.2.6. However in this scenario the UK would be in line with the risk based approach taken globally.

4.2.2.7 Consideration of alternative arrangements (e.g. WTO) and impact on current trading practices.

Use of Codex MRLs as trading standards would be an alternative approach to use of EU MRLs or import tolerances. This may already have been recognised by CRD who participated in the 2018 Codex Committee on Pesticides Residues in April 2018[38] after many years of non-attendance in this forum. This would make the possibility of legal challenge under WTO rules (in relation to MRL decisions based on hazard criteria) less of a threat to the UK specifically since they still maintain their own dietary exposure models and MRLs could be refused where an unacceptable theoretical exposure could be demonstrated i.e. refusal of a trading standard on risk assessment grounds which is permissible. However, it has to be recognised that the comparatively few Codex MRLs would results in large gaps for crop/compound combinations. In addition, less onerous import tolerance mechanisms could be implemented such as that used by the APVMA[39] or proposed in the APEC region[40] – basically, a notification system based on the MRL in the exporting country accompanied by an independent exposure assessment carried out by the regulatory authority. CRD has always fostered collaborative working practices but the level of trust required in the abilities of other regulatory authorities without independent assessment of data by CRD may be too much of a political challenge, even though this mechanism has the potential to deliver a large number of import tolerances for a modest personnel requirement to maintain this system.

4.2.2.8 Environmental and human health protection in the UK.

Apart from the potential impact of endocrine disruptor criteria for the environment a general conclusion is that in most (although not all) cases substances that fail the environmental criteria (POP, PBT, vPvB) do not pass a risk assessment and have either already been withdrawn or not developed[41]. Therefore not applying the hazard triggers will have minimal impact with the regard to environmental protection.

The same arguments apply as set out in Section 4.12.8 with respect to general protection of human health. An appropriate risk assessment should be protective of human health and is the standard global approach.

[38] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-50%252FREPORT%252FFINAL%252520REPORT%252FREP18_PRe.pdf
[39] http://specialtycrops.org/pdfs/mrl_2017/wednesday/04.pdf
[40] https://www.apec.org/Publications/2016/08/Import-MRL-Guideline-for-Pesticides
[41] CRD impact assessment

4.3 A system without candidates for substitution and comparative assessment.

4.3.1 Scenario description

In this scenario candidates for substitution would not be identified and consequently comparative assessment will not be required.

4.3.2 Analysis

4.3.2.1 Potential for continued regulatory collaboration with the EU regime.

Since comparative assessment and substitution is a Member State national responsibility not following this element of 1107/2009 would not impact significantly on EU collaboration.

4.3.2.2 Possible global regulatory collaboration.

Again since comparative assessment and substitution is a Member State national responsibility not following this element of 1107/2009 would not impact significantly on wider global collaboration.

4.3.2.3 Time to market for new active substances and products in the UK compared to the rest of the world.

This proposal will have no impact on time to market for new active substances but could reduce the time and resources required to prepare product dossiers by applicants, and for their evaluation by the regulatory authority, when a comparative assessment does not need to be submitted or evaluated.

4.3.2.4 Cost of product registration in the UK.

For those substances identified as candidates for substitution there will be a cost saving with each application both in preparation of the comparative assessment by the applicant (estimate £15 -20,000 per use [42]) and CRD fee.

4.3.2.5 Active substance availability for UK farming.

Since to date no substitutions have been made and given the procedure nor are they likely in the future no change is anticipated. The principle of comparative assessment and substitution is attractive but in practice is fraught with difficulty. As an approach it might have worked in the past when there were significantly more active substances available but with reducing pest control measure available each product or technique has its own benefits and drawbacks making a comparison

[42] Exponent estimate

complex and performing one of sufficient weight to support a substitution close to impossible.

4.3.2.6 Trade issues related to export of produce from the UK market to the EU (and globally).

Since comparative assessment and substitution is a Member State national responsibility not following this element of 1107/2009 would not impact on trade since products are likely to remain authorised within the EU.

4.3.2.7 Consideration of alternative arrangements (e.g. WTO) and impact on current trading practices.

See Section 4.3.2.6 above.

4.3.2.8 Environmental and human health protection in the UK.

Given that no substitutions have been made to date and each product authorised has to pass a risk assessment, not applying comparative assessments and substitution will have no impact either way on environmental or human health protection. The procedure as it stands involves costs for no benefit.

4.4 More flexibility in decision making and timelines

4.4.1 Scenario description

A wide range of issue have been identified[43] [44] with the current EU rules, some rooted in the legislation and some in the capacity and capability of Member States and EU agencies and institutions to implement the (unrealistic) ambitions set by the legislators.

Issues that have been raised include more rapid decision making (at least keeping to the legally defined timelines), provisional authorisations to allow new active substances onto the market pending EU decisions, non-time limited authorisations, a data call in procedure for maintaining authorisations and a more systematic application of new risk assessment guidance.

The completely unrealistic and widely disregarded timetable for renewal of product authorisations set out in Article 43 of Regulation 1107/2009 is also widely cited.

In this scenario options are explored for the UK to adopt more realistic and pragmatic procedures

4.4.2 Analysis

[43] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3

[44] Examples – Portugal and Czech Republic presentations ECPA Conference 2018, Brussels

4.4.2.1 Potential for continued regulatory collaboration with the EU regime.

Over time this is likely to limit the potential for EU collaboration if the UK is operating to significantly different timelines, or different procedures to those in the EU. Some issues that might arise with the ideas mentioned above:

- a data call in procedure is a completely different approach to that taken by the EU. Implementation would have consequences for timelines and outcomes.

- non-time limited authorisations would in principle lead to fewer review cycles for each active substance. However in reality it is likely that a review outcome in the EU (withdrawal of a substance or new end points) would trigger a re-evaluation in the UK.

- more systematic application of new guidance could lead to the application of differing risk assessment guidance in the EU and UK.

It can be anticipated that some of these ideas might be accepted in the EU as a result of the REFIT programme. Earlier introduction in the UK might be an opportunity to influence the EU to manage some of the processes acknowledged to be flawed in a more systematic way.

As for the other scenarios, future collaboration is also heavily dependent on the wider agreement reached on the future UK relationship with the EU.

4.4.2.2 Possible global regulatory collaboration.

With increased national flexibility it is possible that the barriers to global collaboration could be removed, or handled more flexibly depending on the circumstances.

4.4.2.3 Time to market for new active substances and products in the UK compared to the rest of the world.

The ability to issue provisional authorisations ahead of an EU decision could lead to a substantially more rapid introduction of new active substances and products in the UK. The actual timeline would depend on the procedure adopted and the point at which the UK chose to makes its own independent decision. Alternative scenarios would be (assuming this was an application submitted to the UK at the same time as the EU and the UK authorities would need around 6 months to assess the EU documentation and take a decision):

- a completely independent UK evaluation (1 - 1.5 years)
- a UK evaluation based in the EU Draft Assessment Report (2 years)
- a UK evaluation based on the EFSA Conclusion (3.5 years)

Since the introduction of 1107/2009, and by March 2018, 57 substances had been submitted, 22 have been approved but only eight had been authorised in a product at

least one Member State. The average delay since the necessary MRL entered into force is 15 months[45]. Therefore even a procedure that kept to the EU timeline (that is the third bullet above) would be a practical improvement in time to market for new active substances UK compared to the EU and bring the timelines into closer alignment with those globally.

At present 26 new substances are pending decisions in the EU according to the analysis at Appendix 5.

4.4.2.4 Cost of product registration in the UK.

Depending in the approach taken costs of product authorisation could increase with UK specific processes (such as data call in) or parallel evaluation to the EU evaluation for new active substances. These costs however are likely to be offset by more rapid market access for new substances and more predictable regulatory outcomes.

4.4.2.5 Active substance availability for UK farming.

The measures in this scenario will not in themselves change the availability of substances in the UK overall but could have the following effects:

- more rapid availability of new substances.

- avoiding the temporary loss of substances through inadequate approaches to the application of new guidance meaning that decisions are taken without adequate time for new data to be provided, or even when new data are available.

4.4.2.6 Trade issues related to export of produce from the UK market to the EU (and globally).

Potential trade issues in relation to a divergence between active substance availability in the UK and EU is considered in Section 4.2.2.6.

4.4.2.7 Consideration of alternative arrangements (e.g. WTO) and impact on current trading practices.

This is considered at Section 4.2.2.7.

4.4.2.8 Environmental and human health protection in the UK.

As mentioned under Section 4.4.2.5 the proposals under this scenario will not in themselves change the overall outcomes in terms of substance availability but could change the timings of certain decisions. However implementation of new knowledge into a regulatory system is always a judgement between its importance and the rights of applicants to an opportunity to respond to new developments, such as with the

[45] Martyn Griffiths, ECPA Conference, March 2018, Brussels

provision of new data. These principles are recognised in Regulation 1107/2009, such as in Article 36(1) requiring use of guidance available at the time of application. Correctly managed none of the proposals in this scenario will impact on environmental and human health protection in the UK.

5. Conclusions

A range of options are open to the UK post Brexit in relation to regulation of plant protection products. A primary driver to the feasibility of any of these options will be the overarching agreement negotiated with the EU. However there would appear to be scope even within a close arrangement to deal with some of the acknowledged flaws with Regulation 1107/2009 and with its implementation, including decoupling the UK from the effects of the lack of application of legally binding provisions on the part of many EU Member States.

Even with a close arrangement agreed there are risks in remaining tied to the EU position when the UK is not a Member State due to the divergence of the EU approach away from the globally accepted approach of risk assessment.

In the case of a more open high level relationship with the EU there is significant scope to develop a more flexible policy with a better balance between pre- and post-authorisation measures. The EU regime in its current form will inevitably lead to significant loss of crop protection products in a largely unmanaged way, without necessarily improving environmental or human health.

In relation to trade with the EU, the EU policy on imports of commodities containing residues of product not permitted on the EU market is neither clear, nor tested (such as through a WTO case). However there is a potential barrier to trade in treated produce with the EU. The significance of this barrier depends on the commodity, its trade with the EU and whether it is possible for the supply chain to differentiate between commodities destined for domestic and export markets.

Scenarios 2, 3 and 4 analysed above are not mutually exclusive. They all present opportunities to retain what is good in the EU regime, and to which the UK has contributed very significantly over the whole implantation period, but to deal with those issues that are widely acknowledged to not work well. None of the scenarios outlined would be detrimental to human health or the environment in the UK compared to the EU if correctly implemented.

Appendix 1 Abbreviations

APVMA	Australian Pesticides and Veterinary Medicines Authority
CRD	Chemicals Regulation Directorate
Defra	Department for Environment, Food and Rural Affairs
EFSA	European Food Safety Authority
HSE	Health and Safety Executive
MRL	Maximum Residue Level
ppp	plant protection product
RMS	Rapporteur Member State
WTO	World Trade Organisation

Appendix 2 Main provisions of Regulation 1107/2009

Reg Article		Main provisions	Comments
CHAPTER I – GENERAL PROVISIONS			
1	Subject matter and purpose	Safeners and synergists, adjuvants and co-formulants	
		High level of protection human health and environment	High level aim – highly likely to be followed
		Harmonisation of rules	
		Precautionary principle	
2	Scope		
3	Definitions	Substances of concern – cross reference to other legislation	Established definitions.
		Non-chemical methods - cross reference to other legislation	
		Vulnerable groups	
		Professional user – cross reference to SUD	
		References to Member states	
CHAPTER II - ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS			
SECTION 1 – Active substances			
Subsection 1 - Requirements and conditions for approval			
4	Approval criteria	No harmful effects human or animal health	The basic criteria are well established and reflect pre Directive 91/414 UK policy. Extended criteria (cumulative and synergistic effects, coastal and estuarine waters, biodiversity and ecosystems) are not yet implemented in the EU due to lack of methodology
		Cumulative and synergistic effects	
		Groundwater	
		No unacceptable effect on the environment	
		Analytical methods for relevant residues	
		No unacceptable effects – plants or plant products	
		No unnecessary suffering vertebrates	
		Fate in environment – including coastal and	

Reg Article		Main provisions	Comments
		estuarine water	Groundwater criteria are clearly non-risk based
		Impact on non-target species including ongoing behaviour	
		Impact on biodiversity and the ecosystem	
		Representative use for approval	
		No human data allowed	
		Derogation for serious danger to plant health	
5	First approval	10 year approval	Not relevant to UK post Brexit unless a national 2 tier system is implemented
6	Conditions and restrictions	Minimum purity	Standard restrictions
		Maximum impurities	
		Other restrictions	
		Type of preparation	
		Conditions of application	
		Confirmatory data	
		Categories of user	
		Specific use areas	
		Risk mitigation and monitoring	
Subsection 2 - Approval procedure			
7	Application	Application submitted to MS	EU related processes – see Articles 63 and 59 for confidentiality and data protection
		RMS and Co-RMS	
		Request confidentiality	
		List of tests and studies and claims for data protection	
		RMS may consult EFSA	
8	Dossiers	One or more 'representative use'	EU requirement related to 2 tier system
		Active substance data study summaries	Basic dossier requirements
		Product data study summaries Approval may be restricted if range of representative uses is limited	

Reg Article		Main provisions	Comments
		Justification for vertebrate studies	
		Checklist	
		Justification of necessity of studies	
		Copy of MRL application	
		An assessment of all information submitted	
		All study reports required	
		No studies on humans	Could be reviewed
		Format of dossier to be established by Standing Committee	EU process
		Data requirements to be adopted by Regulation	
		Open literature to be included	
9	Admissibility of application		
10	Access to the summary dossier	EFSA to make available	EU process
11	Draft assessment report	RMS to prepare DAR	EU processes
		Independent, objective and transparent assessment in light of current scientific and technical knowledge	
		If approval criteria not met shall be confined to those parts only	
		Six months for additional data	
		DAR format to be determines by Standing Committee	
12	Conclusion by the authority	EFSA to circulate DAR	EU processes
		60 day public consultation	
		Expert consultation	3rd countries can make comments
		120 days to adopt conclusion (plus 30 days if an expert consultation) using GD available at the time of the application	
		90 days for applicant to supply additional	

Reg Article		Main provisions	Comments
		information plus 60 days for RMS to evaluate	
		Can consult a Community Reference Lab	
		In a format determined by EFSA	
		Link to MRL Reg 396/2005	
13	Approval Regulation	Commission within 6 months	EU processes
		Applicant can submit comments	
		Regulation adopted approving, not approving or amending approval	Confirmatory data provision could be more flexible
		Time limit for confirmatory information to be submitted and evaluated	
Subsection 3 - Renewal and review			
14	Renewal of approval	Application required	EU Processes
		Shall be renewed if Art 4 satisfied	
		15 years	Routine review was an established UK approach pre 91/414
		Except 5 years for Art 4(7) approval	
15	Application for renewal	Required 3 years before expiry	EU processes
		Applicant to identify new data and necessity, and timetable for ongoing studies	For confidentiality and data protection see Articles 63 and 59
		Identify info to be kept confidential and data protection claims	
16	Access to the information for renewal	EFSA to publish	EU processes
17	Extension of the approval period for the duration of the procedure		
18	Work programme	Including timetable, RMSs	
19	Implementing measures	For renewal programme	
20	Renewal regulation	Regulation for renewal or non-renewal	
		For non-renewal periods of grace unless an immediate concern	
21	Review of approval	Commission can review at any time	EU processes

Reg Article		Main provisions	Comments
		New scientific or technical knowledge	The principle of a review when new info. is available is well established
		Can aske MS and EFSA for opinion	
		Approval can be withdrawn	
Subsection 4 - Derogations			
22	Low risk active substances	Approval 15 years	
		Point 5 Annex II	
		Low risk substances identified separately	
23	Approval criteria for basic substances	Unlimited approval	Similar concept existed in the UK pre Directive 91/414 as commodity chemicals
		Criteria	
		Not predominately used for ppp	
		Other evaluations may be taken into account	
		Application can be submitted by any interested party	
		EFSA opinion in 3 months	
		Article 6 – 13 apply	
		Commission can review at any time	
24	Candidates for substitution	Criteria – Point 4, Annex II	EU concept
		Approval 7 years	
		Listed separately	
SECTION 2 - Safeners and synergists			
25	Approval of safeners and synergists	Must comply with Art. 4	New EU requirements – not yet fully implemented
		Same procedures apply	
		Similar data requirements through regulatory procedure	
26	Safeners and synergists already on the market	Regulation to adopted with work programme for gradual review	
SECTION 3 - Unacceptable co-formulants			
27	Co-formulants	Not acceptable for use in ppp where harmful effects on humans and unacceptable effects	New EU requirements – not yet fully implemented

Reg Article		Main provisions	Comments
		on the environment	
		Unacceptable co-formulants included in Annex III	
		Procedures to be developed	
CHAPTER III - PLANT PROTECTION PRODUCTS			
SECTION 1 - Authorisation			
Subsection 1 - Requirements and contents			
28	Authorisation for placing on the market and use	Shall not be placed on the market or used unless authorised	Standard permitting provision
		No authorisation required for: - basic substances - R and D - production etc. intended for another MS or third country - with a parallel trade permit	Similar concepts existed in the UK before Directive 91/414 and Reg 1007/2009 For parallel trade see Article 52
29	Requirements for the authorisation for placing on the market	Follow the Uniform Principles	Mostly standard requirements for product authorisation
		Active substance, safener or synergist approved	
		From a different source to be acceptable	
		Co-formulants not in Annex III	
		Technical formulation to reduce risks without compromising functioning	
		Complies with Art 4(3)	
		Appropriate methods of analysis for active substance and impurities	
		Appropriate methods of analysis for residues	
		Acceptable phys chem for use and storage	
		MRLs set	
		Applicant shall demonstrate requirements	

Reg Article		Main provisions	Comments
		met	
		Using official or officially recognised tests	
		Uniform Principles copied from 91/414 and subsequently amended by Standing Committee	
		Interaction between active substance and coformulants to be taken into account	
30	Provisional authorisations	Can authorise a product containing an as not yet authorised provided evaluation deadline has been exceeded, dossier was admissible, MS is concludes that authorisation requirements met and MRLs established	The provision has never been used
		Must inform other MS and Commission	
		Applicable until June 2016	
31	Contents of authorisations	Define plants, plant products or areas and use of ppp	Standard authorisation requirements
		Requirements at a minimum to comply with active substance approval	
		Shall include classification	
		Shall include where applicable dose, PHI and number of applications	
		May include: - restrictions on use and distribution - obligation to inform neighbours - indications on IPM - user categories (professional/ non-professional) - approved label -interval between applications - withholding interval for plant product - re-entry period	Optional elements for authorisation

Reg Article		Main provisions	Comments
		- packaging	
32	Duration	1 year after approval	
		May be shorter to synchronise evaluation	
Subsection 2 - Procedure			
33	Application for authorisation or amendment of authorisation	Apply to each MS where authorisation required	EU processes
		Application to include: - list of intended uses in each zone - a proposal for MS to carry out evaluation - copy of authorisation - any conclusion on equivalence	
		Application to be accompanied by: - product data - as data - justification vertebrate data - necessity of studies - copy of MRL application - draft label	
		Request confidentiality – MS to decide on confidentiality in the event of a request for info.	
		Data protection claims	
		Official language	
		On request samples to be provided	
34	Exemption from the submission of studies	Exemption if MS has study and access demonstrated or protection expired	Application of data protection
		Applicant still has to provide: - data on identification of ppp and as - data to show comparability	
35	Member State examining the application	MS proposed by the applicant unless another MS agreed	EU processes – operation of the zonal system

Reg Article		Main provisions	Comments
		MS to cooperate to ensure fair workload	
		Other MS within zone to not evaluate pending MS evaluation	
		More than one zone MS to cooperate on non-zonal data	
36	Examination for authorisation	Independent, objective and transparent	
		In light of current scientific knowledge	
		Using GD available at the time of application	
		MS in zone can submit comments	
		Apply uniform principles	
		Format of report established by Standing Committee	
		Concerned MS shall grant or refuse authorisation based on the conclusions of MS examining the application	
		Derogation to apply specific risk mitigation measures	
		If risks cannot be controlled by mitigation measures can refuse if due to specific environmental or agricultural circumstances and substantiated reasons	
		Must immediately inform applicant and Commission with reasons	
		MS shall provide an appeal mechanism	
37	Period for examination	12 months from receipt	
		Additional information 6 months maximum	
		Additional information not received – application inadmissible	
		Time limits suspended if equivalence check required	

Reg Article		Main provisions	Comments
		For new AS evaluation to start when DAR is received and for representative product to be completed 6 months after approval	
		Concerned MS to decide in 120 days	
38	Assessment of equivalence under point (b) of Article 29(1)	Different source to be considered by substance RMS	EU process for active substance equivalence
		Equivalence report 60 days to Commission, MS and applicant	
		Disagreement – shall inform Commission, MS and applicant	
		Applicant can submit comments	
		No agreement in 45 days refer to Commission for Standing Committee. EFSA may be consulted	
		Standing Committee can develop detailed rules	
39	Reporting and exchange of information on applications for authorisation	MS shall compile a file with: - application - evaluation - decision - label	EU process for information exchange
		On request make available to MS, Commission and EFSA	
		On request applicant to send copy of application to MS, Commission and EFSA	
		Detailed rules may be established by Standing Committee	
Subsection 3 - Mutual recognition of authorisations			
40	Mutual recognition	Authorisation holder can apply for same product, same use under same conditions to another MS if	EU processes

Reg Article		Main provisions	Comments
		- reference MS is in same zone - reference MS in different zone provided not used for further MR - use in greenhouses, empty storage or seeds	
		Official or scientific bodies can apply with consent of authorisation holder or on public interest grounds	
41	Authorisation	MS shall authorise under same conditions	
		Derogation – may authorise if: - from a different zone - contains a candidate for substitution -a provisional authorisation - an essential use approval (Art 4(7))	
42	Procedure	Application to include: - copy of reference authorisation - statement that product is identical - dossier when requested - assessment of reference MS	
		MS to decide in 120 days	
		Submit in official language	
Subsection 4 - Renewal , withdrawal and amendment			
43	Renewal of authorisation	Renewed on application provided criteria still met	EU processes for renewal
		Within 3 months or renewal of approval holder to submit: - copy of authorisation - new info required - evidence of necessity of new data - info. to demonstrate approval conditions met - monitoring data	

Reg Article		Main provisions	Comments
		MS to check compliance with approval conditions	
		Zonal RMS to coordinate compliance check	
		Guidance can be adopted by Standing Committee	
		MS to decide on renewal 12 months after approval decision	
		No decision can extend expiry date	
44	Withdrawal or amendment of an authorisation	MS can review authorisation at any time if indications conditions no longer met or if water framework objectives may not be met	MS processes for review of authorisation
		If intending to withdraw or amend authorisation holder can comment	
		MS shall withdraw or amend: - if conditions no longer met - false information was supplied - a condition of authorisation not met - manner or use or amounts can be modified - the holder fails to comply with obligations	
		MS shall immediately inform holder, MS, Commission and EFSA.	
		Other MS in zone to follow unless a derogation has been applied	
		Grace periods apply	
45	Withdrawal or amendment of an authorisation at the request of the authorisation holder	May be withdrawn at holders request	Voluntary withdrawal
		Grace periods apply	
46	Grace period	MS may grant a grace period for disposal, storage, placing on the market and use of existing stocks.	Grace periods

Reg Article		Main provisions	Comments
		6 months for the sale and distribution and additional 1 year for disposal, storage, and use of existing stocks	
Subsection 5 - Special cases			
47	Placing on the market of low-risk plant protection products	Where all as in product are low risk and product does not require mitigation authorised as a low risk product. - does not contain substance of concern - if effective - no unnecessary suffering for vertebrates - complies with Article 29	Provisions for Low risk products
		Applicant to make application	
		MS 120 days to decide	
		6 months maximum for additional d	
48	Placing on the market and use of plant protection products containing a genetically modified organism	Written consent under Directive 2001/18/EC before it can be authorised	
49	Placing on the market of treated seeds	MS shall not prohibit treated seeds if use authorised in a MS	Provisions for treated seeds
		If risk cannot be managed Commission can take action through Standing Committee	
		Seed labelling requirements	
50	Comparative assessment of plant protection products containing candidates for substitution	Required for products containing candidate for substitution	Comparative assessment
		Shall refuse or restrict where: - a safer alternative exists - no economic or practical disadvantage - chemical diversity for resistance management is preserved	

Reg Article		Main provisions	Comments
		- account for minor uses	
		MS can apply even if product does not contain candidate	
		Can be authorised with comparative assessment to gain experience of use – 5 years only	
		Comparative assessment at least at renewal or amendment	
		If withdrawn or amended take effect after 3 years	
51	Extension of authorisations for minor uses	Holder, official or scientific bodies or users can ask for minor use extension	EU processes for minor uses
		MS shall extend provided: - use is minor - conditions satisfied - in public interest - data submitted	
		MS may take measures to facilitate minor uses	
		Can be extension or separate authorisation	
		Request holder to add to label. If declined include in an official publication	
		Liability for person using the product	
		Can also apply by mutual recognition	
		MS to establish and keep list of minor uses	
		Commission to present minor uses report by 14/12/11	
52	Parallel trade	Ppp authorised in one MS can, with a parallel trade permit, placed on the market in another if determined to be identical to a	Single market measure

Reg Article		Main provisions	Comments
		ppp already authorised	
		Simplified procedure 45 working days	
		MS to respond to requests within 10 working days	
		Criteria on identicality	
		Requirements for application	
		Rules can be amended or adopted by Standing Committee	
		Specific control requirements to be adopted	
		Permit valid for period of authorisation of reference product	
		Not applicable to emergency authorisations or R and D permits	
		Public info. to be made available	
Subsection 6 Derogations			
53	Emergency situations in plant protection	Derogation 120 day authorisation Limited and controlled use Danger cannot be contained by any other reasonable means	EU processes for plant protection emergencies
		MS concerned shall immediately inform others	
		Commission may consult EFSA who shall respond with 1 month	
		Can be referred to the Standing Committee	
54	Research and development	Derogation for trials permit	Derogations for R and D
		Limitation on quantity and use including entry into food chain	
		Possible to issue a general permit	
		Not applicable to GMO	
		Detailed rules can be adopted by Standing	

Reg Article		Main provisions	Comments
		Committee	
SECTION 2 – Use and information			
55	Use of plant protection products	Proper use	Standard permitting provision
		Application of good pp practice and IPM	
		Following authorisation and label conditions	
56	Information on potentially harmful or unacceptable effects	Holder to notify immediately new information which suggest no longer complies with criteria	EU information provisions – expected basic provisions
		In particular harmful effects	
		Holder to keep records of harmful effects	
		Include international developments	
		Notification to include assessment of implications of information	
		Zonal RMS will evaluate info. and inform others where it considers conditions no longer met	
		Holder to report unexpected efficacy annually	
57	Obligation to keep information available	MS to keep available: - authorisation holder -trade name - type of preparation - name and amount of active substance - classification - authorised uses - reasons for withdrawal - list of minor uses	
		Readily accessible and updated every 3 months	
		Information system can be set up by Standing	

Reg Article		Main provisions	Comments
		Committee	
CHAPTER IV - ADJUVANTS			
58	Placing on the market and use of adjuvants	Not placed on the market or used unless authorised	Adjuvants – not yet implemented
		Detailed rules to be developed by Standing Committee	
		Until rules adopted MS can apply national rules	
CHAPTER V DATA PROTECTION AND DATA SHARING			
59	Data protection	Test and study reports to benefit from data protection	Data protection is MS by MS rather than EU harmonised
		Must be: - necessary - GLP/GEP	
		Where protected may not be used for other applicants	
		10 years from first authorisation 13 years low risk products	
		3 month extension for minor uses applied for with 5 years to 13 or 15 years total	
		Renewal data 30 months protection	
		Unless letter of access or data protection expired	
		Data protection has to be claimed	
60	List of test and study reports	Active substance RMS to prepare and make list available	
		Each MS to prepare lists for product authorisation	
61	General rules on avoidance of duplicative testing	Those intending to seek an authorisation shall check authorised products and	EU rules on data sharing and duplicative testing

Reg Article		Main provisions	Comments
		protected studies	
		Prospective applicant to provide evidence of intent	
		MS shall facilitate contacts	
		All reasonable steps shall be taken to share data	
62	Sharing of tests and studies involving vertebrate animals	Vertebrate testing only where no other method available	
		Duplication shall be avoided	
		MS shall not accept vertebrate studies for classification where 'conventional methods' could have been used	
		Every effort shall be made to share data	
		If no agreement shall inform the MS who shall not be prevented from using the study	
		The authorisation shall have a claim for the costs – binding arbitration or litigation	
CHAPTER VI - PUBLIC ACCESS TO INFORMATION			
63	Confidentiality	Confidentiality request supported by evidence	Confidentiality – expected basic provisions
		Following information normally considered confidential - method of manufacture - specification other than relevant impurities - batch data - methods for impurities - links between producer, applicant and holder - complete composition of product - persons involved in vertebrate testing	
CHAPTER VII - PACKAGING, LABELLING AND ADVERTISING OF PLANT PROTECTION PRODUCTS AND ADJUVANTS			

Reg Article		Main provisions	Comments
64	Packaging and presentation	Avoid being mistaken for food or drink	Packaging, labelling and advertising - expected basic provisions
		Products available to the general public to contain components to stop consumption	
		CLP applies	
65	Labelling	CLP applies	
		Standard phrases to supplement CLP copied across from Directive 91/414/EEC	
		MS can require samples	
		If MS identify additional phrases they shall inform MS and Commission for consideration for inclusion as standard phrases	
66	Advertising	Not authorised – no advertising.	
		Include standard phrase	
		No misleading statements. Low risk ppp can be described as such	
		Restriction on certain media	
		No representation of dangerous practice	
		Draw attention to warning phrases and symbols	
CHAPTER VIII - CONTROLS			
67	Record-keeping	Producers, suppliers, distributors, importers, and exporters to keep records for 5 years	Record keeping – expected basic provisions
		Professional users to keep records for 3 years	
		To be available to competent authority on request	
		Competent authority shall provide access	
		Producers to undertake monitoring at request of competent authority	
		Holders to provide sales data according to statistics legislation	

Reg Article		Main provisions	Comments
		Implementing measures by Standing Committee	
68	Monitoring and controls	MS to carry out official controls and report to Commission annually	MS control measures – expected basic provisions
		Commission shall carry out general audits	
		Regulation on controls by Standing Committee	
CHAPTER IX - EMERGENCIES			
69	Emergency measures	Clear problem not controllable by MS – Commission to take immediate measures through Standing Committee. Can consult EFSA	Emergency measures – expected basic provisions
70	Emergency measures in cases of extreme urgency	Commission can adopt measures without Standing Committee and refer within 10 days	
71	Other emergency measures	MS can adopt interim measures	
		Commission to refer to Standing Committee in 30 days	
CHAPTER X - ADMINISTRATIVE AND FINANCIAL PROVISIONS			
72	Penalties	MS to lay down penalties	Penalties
73	Civil and criminal liability	Regulation without prejudice to general liability	
74	Fees and charges	MS can recover costs	
75	Competent authority	MS to designate Competent Authority	Provisions only relevant to EU
		Suitably staffed	
		Commission to keep list	
76	Expenditure by the Commission	Commission can incur expenditure contributing to the aims of the legislation	
77	Guidance documents	Guidance documents to be noted. EFSA can prepare or contribute	
78	Amendments and implementing	Gives implementing measures to be adopted	

Reg Article		Main provisions	Comments
	measures	via Standing Committee	
79	Committee procedure	EU comitology	
CHAPTER XI - TRANSITIONAL AND FINAL PROVISIONS			
80	Transitional measures	Transitional measures from Directive 91/414/EEC	Redundant transitional and implementing measures
81	Derogation for safeners and synergists, co-formulants and adjuvants	Derogation for MS pending EU rules	
82	Review clause	Commission to report on functioning by 12/14	
83	Repeal		
84	Entry into force and application		
ANNEX –I - Definition of zones for the authorisation of plant protection products as referred to in Article 3(17)			
ANNEX II - Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II			
1	Evaluation	RMS and EFSA to cooperate with applicant	
		Evaluation to be based on scientific principles and with expert advice	
		MS and EFSA to take account of guidance documents	
2	General decision-making criteria	One safe use for approval	Relevant only to EU 2 tier system
		In exceptional cases confirmatory information can be submitted after approval	
		Approval may be subject to restrictions	
3	Criteria for approval of an active substance	Dossier shall be sufficient: - to establish reference doses - define residues of concern - predict residues in food - set MRLs - estimate fate in environment and impact on non-target species	Expected basic requirements

Reg Article		Main provisions	Comments
		Efficacy to be demonstrated	
		Relevance of metabolites established	
		Composition of active substance	
		Methods of analysis - validated - sufficiently sensitive-	
		Impact on human health - Reference doses established with at least SF 100 - not M Cat 1A or 1B - not C Cat 1A or 1B (unless negligible exposure) - not R Cat 1A or 1B (unless negligible exposure) - not ED (unless negligible exposure) ED criteria to be adopted – until then interim criteria apply	Human health hazard criteria
		Fate and behaviour in the environment - not POP - not PBT - not vPvB	Environment (mostly) hazard criteria
		Ecotoxicology - acceptable risk - not ED (unless negligible exposure) - negligible exposure or no unacceptable effects on honey bees	
		Residue definition for risk assessment and enforcement	Expected basic requirement
		Groundwater – active substance or (relevant) metabolites below 0.1 µg/L	EU groundwater provision
4	Candidate for substitution	Shall be a candidate for substitution:	

Reg Article		Main provisions	Comments
		- low reference doses - two PBT criteria - critical effects - significant proportion of non-active isomers - C, R or ED and not otherwise excluded	
5	Low-risk active substances	Not - CMR - Sensitising - very toxic or toxic - explosive - corrosive - P or B - ED - neurotoxic or immunotoxic	
ANNEX III - List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27			
ANNEX IV - Comparative assessment pursuant to Article 50			
ANNEX V - Repealed Directives and their successive amendments as referred to in Article 83			

Appendix 3 Main provisions of Regulation 396/2005

Reg Article		Main provisions	Comments
CHAPTER I - SUBJECT MATTER, SCOPE AND DEFINITIONS			
1	Subject matter	Provisions on MRLs	EU scope and definitions
2	Scope	Products of plant or animal origin in which residues may be present	
		Does not apply to: - non-food products - sowing or planting - testing	
		Does not apply to exports to 3rd countries for plant health treatments	
3	Definitions	GAP	
		Critical GAP – gives rise to highest acceptable residue	
		Residues	
		MRL – upper legal limit	
		CXL – Codex	
		LOD	
		Import tolerance required due to product not authorised in EU or requires higher MRL	
		Proficiency test – quality test for labs	
		ARfD	
		ADI	
4	List of groups of products for which harmonised MRLs shall apply	Annex I lists	
5	Establishment of a list of active	Annex IV	

Reg Article		Main provisions	Comments
	substances for which no MRLs are required		
CHAPTER II - PROCEDURE FOR APPLICATIONS FOR MRLS			
SECTION 1 Submission of applications for MRLs			
6	Applications	Where MS envisages a product authorisation shall consider whether MRL needs to be modified	EU application procedures
		If necessary request application according to Article 7	
		All parties demonstrating a legitimate interest can also submit	
		Where MS considers a change to MRL is necessary shall compile and evaluate an application	
		Import tolerance to be submitted to active substance RMS or at the request of applicant	
7	Requirements relating to applications for MRLs	Application to include -applicant - presentation of application - overview of literature - relevant data	
		MS can use public domain data, Reg 1107/2009 evaluation, CXL evaluation and justify using or not using	
		MS can request applicant to provide supplementary information. Time limit not to exceed 2 years	
8	Evaluation of applications	MS shall forward application to Commission and EFSA and draw up evaluation report without delay	
		To be evaluated to Uniform Principles	

Reg Article		Main provisions	Comments
		MS evaluating the application can be changed by agreement	
9	Submission of evaluated applications to the Commission and the Authority	MS to Commission who will send to EFSA	
		Authority will acknowledge receipt	
SECTION 2 - Consideration of applications concerning MRLs by the authority			
10	The Authority's opinion on applications concerning MRLs	EFSA to give a reasoned opinion to include: - assessment of analytical method - LoD - risk of ADI and ARfD being exceeded	EU assessment procedure
		EFSA to send to Commission and MS and make public	
11	Time limits for the Authority's opinion on applications concerning MRLs	Reasoned opinion 3 months after application	
		If more detailed required extended to 6 months	
		Supplementary info. required – timelines suspended	
12	Assessment of existing MRLs by the Authority	EFSA shall within 12 months of approval/non-approval submit a reasoned opinion: - existing MRLs - necessity of new MRLs - processing factors	
		For substances already approved before entry into force of Reg. reasoned opinion to be delivered within 12 months	
13	Administrative review	EFSA decisions can be reviewed by Commission	
SECTION 3 - Setting, modifying or deletion of MRLs			

Reg Article		Main provisions	Comments
14	Decisions on applications concerning MRLs	Upon receipt of reasoned opinion Commission to prepare regulation within 3 months	EU decision making procedure
		Account to be taken of: - scientific and technical knowledge - possible presence of residues from other sources and known cumulative and synergistic effects when methods available - potential risks to consumers with high intake and high vulnerability - results of decision to modify use of products - CXL or GAP implemented in 3rd country - other legitimate factors	
		Can request supplementary info. from applicant or EFSA	
15	Inclusion of new or modified MRLs in Annexes II and III	Regulation shall: - set new or modified MRLs - temporary MRLs for provisional authorisations	
16	Procedure for setting temporary MRLs in certain circumstances	Temporary MRLs: - in exceptional cases residues from contamination or emergency use - minor component of diet - honey - herbal infusions - essential use - new products in Annex I	
		Based on opinion of EFSA, monitoring data and acceptable risk assessment	
		Validity to be assessed every 10 years or when essential use expires	

Reg Article		Main provisions	Comments
17	Modifications of MRLs following revocation of authorisations of plant protection products	Can be deleted without seeking EFSA opinion	
CHAPTER III - MRLS APPLICABLE TO PRODUCTS OF PLANT AND ANIMAL ORIGIN			
18	Compliance with MRLs	Products in Annex I shall not contain residues exceeding: - MRLs in Annex II and II - 0.01 mg/kg where no MRL set unless difference defaults are set	EU control procedures
		MS shall not prevent placing in the market produce meeting MRLs	
		MS can authorise further to a post-harvest treatment with fumigant produce listed in Annex VII exceeding MRLs: - not intended for immediate consumption - controls are in place - MS and Commission informed of measures	
		For emergency and plant health situations derogation available	
19	Prohibition concerning processed and/or composite products	Processing or mixing for dilution purposes prohibited	
20	MRLs applicable to processed and/or composite products	Where MRL not set, MRLs for relevant products apply with processing factor	
		Factors can be included in Annex VI	
CHAPTER IV - SPECIAL PROVISIONS RELATING TO THE INCORPORATION OF EXISTING MRLS INTO THIS REGULATION			
21	First establishment of MRLs	Existing MRLs to be incorporated within 12 months	Redundant transitional provision
22	First establishment of temporary MRLs	For substances with no decision on approval	
23	Information to be provided by the Member States on national MRLs	MS to provide Commission with info on national MRLs	

Reg Article		Main provisions	Comments
24	Opinion of the Authority on data underlying national MRLs	EFSA to provide opinion on: - temporary MRLs - active substances for Annex IV	
25	Setting of temporary MRLs	Temporary MRLs can be set	
CHAPTER V - OFFICIAL CONTROLS, REPORTS AND SANCTIONS			
SECTION 1 - Official controls of MRLs			
26	Official controls	MS shall carry out official controls	EU control procedures
27	Sampling	MS shall take sufficient samples to be determined by Standing Committee	
28	Methods of analysis	Methods to comply with rules	
		Laboratories shall participate in proficiency tests	
SECTION 2 - Community control programme			
29	Community control programme	Coordinated multiannual Community control programme	EU control procedures
SECTION 3 - National control programmes			
30	National control programmes for pesticide residues	MS to establish multiannual national control programmes	EU control procedures
SECTION 4 - Information by the Member States and annual report			
31	Information by the Member States	MS to submit annual report	EU control procedures
32	The Annual Report on Pesticide Residues	EFSA to prepare annual report	
33	Submission of the Annual Report on Pesticide Residues to the Committee	Commission to submit report34	
SECTION 5 - Sanctions			
34	Sanctions	MS to lay down sanctions	
CHAPTER VI - EMERGENCY MEASURES			
35	Emergency measures	Immediate action provision	
CHAPTER VII - SUPPORT MEASURES RELATING TO HARMONISED PESTICIDE MRLS			

Reg Article		Main provisions	Comments
36	Support measures relating to harmonised pesticide MRLs	Support measures shall be established at Community level	Administrative provision to support EU regime
37	Community contribution to the support measures for harmonised pesticide MRLs	Financial provision	
CHAPTER VIII - COORDINATION OF APPLICATIONS FOR MRLS			
38	Designation of national authorities	MS to designate authorities	EU administrative provisions
39	Coordination by the Authority of information on MRLs	EFSA shall coordinate with MS and Commission	
40	Information to be submitted by the Member States	MS to submit to EFSA	
41	Database of the Authority on MRLs	EFSA to develop a database	
42	Member States and fees	MS may recover fees	
CHAPTER IX - IMPLEMENTATION			
43	Scientific opinion of the Authority	Commission or MS can request	EU implementing provisions
44	Procedure for the adoption of the Authority's opinions		
45	Committee procedure	Comitology	
46	Implementing measures		
47	Report on implementation of this Regulation	10 years after entry into force	
CHAPTER X - FINAL PROVISIONS			
48	Repeal and adaptation of legislation		EU implementing provisions
49	Transitional measures		
50	Entry into force		
ANNEX I, II and III - MRLs			
ANNEX IV – substances not requiring MRLs			

Appendix 4 Key technical Guidance documents

'Agreed' guidance documents

Physical and chemical properties		
Guidance document on significant and non-significant changes of the chemical composition of authorised PPPs under Regulation 1107/2009	SANCO/12638/2011 Rev.2 20.11.2012	
Guidance document on the finalisation of the reference specification for technical active substances after the peer review	SANCO/6075/2009 Rev.3 00.07.2009	
Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009	SANCO/10597/2003 Rev.10.1 13.07.2012	
EFSA guidance on recurring phys/chem & analytical issues	EFSA 2017; EN-1221 08.05.2017	
Analytical methods		
Guidance document for generating and reporting analytical methods for technical material and formulations in support of pre- and post-registration data requirements.	SANCO/3030/99 Rev.4 11.07.2000	
Toxicology		
Guidance document for the setting of an Acute Reference Dose (ARfD)	7199/VI/99 Rev.5 05.07.2001	
Setting of AOELs	SANCO/7531 Rev.10 07.07.2006	
EFSA Guidance on Dermal Absorption	EFSA 2017; 15(6): 4873 30.06.2017	
Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products	SANTE-10832-2015 Rev.1.7 24.01.2017	
EFSA Scientific Opinion on Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment	EFSA 2012; 10(07): 2799 02.08.2012	

Residues		
Guidance on the establishment of the residue definition for dietary risk assessment	EFSA 2016; 14(12): 4549 22.12.2016	Not adopted (being used by EFSA?)
Analytical quality control & method validation for residues analysis	SANCO/11945/2015 Rev.0 01.12.2015	
Fate and behaviour		
Guidance document on persistence in soil	9188/VI/97 Rev.8 12.02.2000	to be superseded by EFSA 2017; 4982
Guidance document on the assessment of the relevance of metabolites in groundwater	SANCO/221/2000 Rev.10 25.02.2003	
Guidance document on Efate assessment for substances used on rice	SANCO/1090/2000 Rev.1 00.06.2003	
Working document on evidence needed to identify POP, PBT and vPvB properties for ppp's	SANCO 2012 09 25 Rev.3 25.09.2012	
Guidance Document for evaluating laboratory and field dissipation studies to obtain DT50 values in soil for active substances and their metabolites	SANCO/12117/2014 Rev. final 12.12.2014	
Guidance Document estimating Persistence & Degradation Kinetics from Efate studies	SANCO/10058/2005 Rev.2.0 00.06.2006	
EFSA Guidance on PEC soil setting 2017	EFSA 2017; 15(10): 4982 19.10.2017	
Guidance Document on emissions from protected crops	SANCO/12184/2014 Rev.5.1 14.07.2015	
Ecotoxicology		
EFSA Guidance on Risk Assessment Birds and Mammals	EFSA 2009; 7(12):1438 17.12.2009	
Terrestrial Ecotoxicology	SANCO/10329/2002 Rev.2 EFSA 10.2903/j.efsa.2017.4690	
Guidance Document on tiered risk assessment for ppp's for aquatic organisms in edge-of-field surface waters	SANCO/00080/2015 Rev_ 15.01.2015	

EFSA Guidance on Risk Assessment on Bees	EFSA 2013; 11(7):3295 04.07.2013	Not adopted but being used in part by EFSA

Recently closed consultations on guidance documents

Public consultation on the Guidance of EFSA on Risk Assessment for Birds and Mammals (closed 18/12/17) – identification of areas for updating
Draft EFSA/ECHA Guidance on Endocrine Disruptor identification (closed 31/01/18)

Announced future consultations (with expected date of launch)

Public consultation on the draft guidance of EFSA on risk assessment for amphibians and reptiles (01/06/18)
Public consultation of the draft guidance document on harmonisation of human and ecological risk assessment of combined exposure to multiple chemicals (01/07/18)
Public consultation on the revised SC scientific opinion on the TTC (01/09/18)
Public consultation on the draft EFSA scientific report on the "FOCUS surface water repair action" (01/01/19)
Public consultation on the EFSA Guidance Document on completing risk assessment for active substances of plant protection products that have isomers and for transformation products of active substances that may have isomers (01/01/19)

Appendix 5 EU approved active substances and those on UK market

The following analysis has been complied based on information from the European Commission EU Pesticides Database [46]

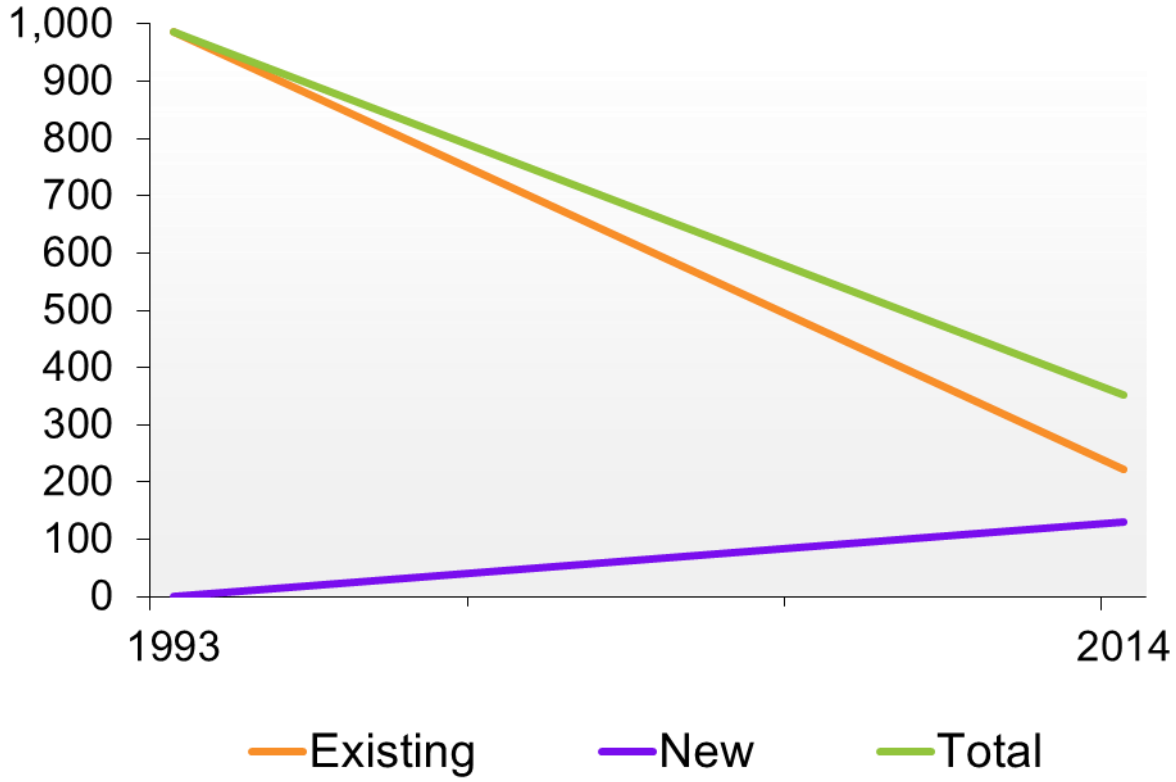
Note that for the purposes of this assessment all straight chain lepidotoran pheromones have been regarded as a single substance, as have fatty acids

	Number of as approved EU	Number of as pending EU	Number of as approved UK[1] (% EU)	Numbers biologicals approved EU	Numbers biologicals approved UK	Number basic substances EU	Number new active substances EU[2]	Number new active substances UK[2]
Total	436	26	278 (63%)	49	21	17	163	101
Herbicides[3,4]	139	6	103 (74%)	0	0		44	28
Insecticides[3,5]	105	8	60 (57%)	22	8		44	21
Fungicides[3]	132	10	96 (73%)	22	11		66	48
Other[6]	60	1	19 (32%)	5	2		9	4

1 excluding basic substances
2 substances approved since Directive 91/414/EEC was implemented (1993) – excludes pending substances
3 excludes basic substances since a function is not specified
4 includes plant growth regulators
5 includes acaricides and nematicides
6 attractants, repellents, rodenticides, elicitors, basic substances, fatty acids, molluscicides, plant activators

[46] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

Appendix 6 Numbers of as on EU market over time



Appendix 7 CPA CRD performance figures

Q 4 2017

Evaluations (applications in which issues arose during Q4 2017)
Applicants reported that:

- Following notification that the application was complete and had been passed to admin to arrange for the Authorisation to be issued, it now seems that the application is being looked at again by specialists even though CRD stated that it was complete.
- Authorisation issued without an acceptance letter received from CRD on a national application.

Historical stream tracking (applications completed or ongoing in Q4 2017)
Within the timeframe of the survey, respondents identified 27 admin applications, 2 no data applications, 2 data applications, and one MR that were completed in the following evaluation times (i.e. weeks to complete excludes weeks of 'stop the clock'):

- The mean evaluation time for admin applications was 6.6 weeks (min = 2.6 weeks, max = 17.6 weeks)
- The mean evaluation time for no data applications was 9 weeks (min = 7 weeks, max = 10.9 weeks)
- The mean evaluation time for data applications was 26.7 weeks (min = 21.4 weeks, max = 32 weeks)
- The evaluation time of the MR was 15.4 weeks.

At the time of the survey there were:

- 10 incomplete admin applications still being processed that had exceeded the mean processing time of complete admin applications, these were pending at 11, 14, 14, 15, 15, 15, 31, 31, 31, and 31 weeks past the date of acceptance.
- 13 incomplete data applications still being processed that had exceeded the mean processing time of complete data applications, these were pending at 28, 29, 32 37, 37, 39, 40, 47, 48, 61, 66, 66, and 76 weeks past the date of acceptance.
- 7 incomplete no data applications still being processed that had exceeded the mean processing time of complete no data applications, these were pending at 9, 19, 20, 21, 23, 23, and 27 weeks past the date of acceptance.
- 1 incomplete MR application still being processed that had exceeded the processing time of the complete MR application. This was pending at 65 weeks past the date of acceptance.

Data plus applications still being processed were reported at up to 50 weeks past the date of acceptance, although none were reported as complete in the timeframe of the survey.

Experimental permit applications still being processed were reported at up to 49 weeks past the date of acceptance, although none were reported as complete in the timeframe of the survey.

EAMU applications still being processed were reported at up to 26 weeks past the date of acceptance, although none were reported as complete in the timeframe of the survey.

No other application types were recorded as completed during the time period of the survey.

Q3 2017

Evaluations (applications in which issues arose during Q3 2017)
No issues were reported in Q3 2017.

Historical stream tracking (applications completed or ongoing in Q3 2017)
Within the timeframe of the survey, respondents identified 17 admin applications, 10 no data applications, and 4 data applications that were completed in the following evaluation times (i.e. weeks to complete excludes weeks of 'stop the clock'):

- The mean evaluation time for admin applications was 4.9 weeks (min = 0.4 weeks, max = 11.1 weeks)
- The mean evaluation time for no data applications was 20 weeks (min = 6.1 weeks, max = 26.3 weeks)
- The mean evaluation time for data applications was 20.5 weeks (min = 4.4 weeks, max = 27.1 weeks)

At the time of the survey there were:

- 3 incomplete admin applications still being processed that had exceeded the mean processing time of complete admin applications, these were all pending at 17 weeks past the date of acceptance.
- 8 incomplete data applications still being processed that had exceeded the mean processing time of complete data applications, these were pending at 16, 22, 23, 25, 34, 35, 53 and 63 weeks past the date of acceptance.

Data plus applications still being processed were reported at up to 37 weeks past the date of acceptance, although none were reported as complete in the timeframe of the survey.

Other reported ongoing applications did not exceed the mean processing time of completed applications of the corresponding type. No other application types were recorded as completed during the time period of the survey.

Appendix 8 MS performance against regulatory timelines – European Commission figures [47]

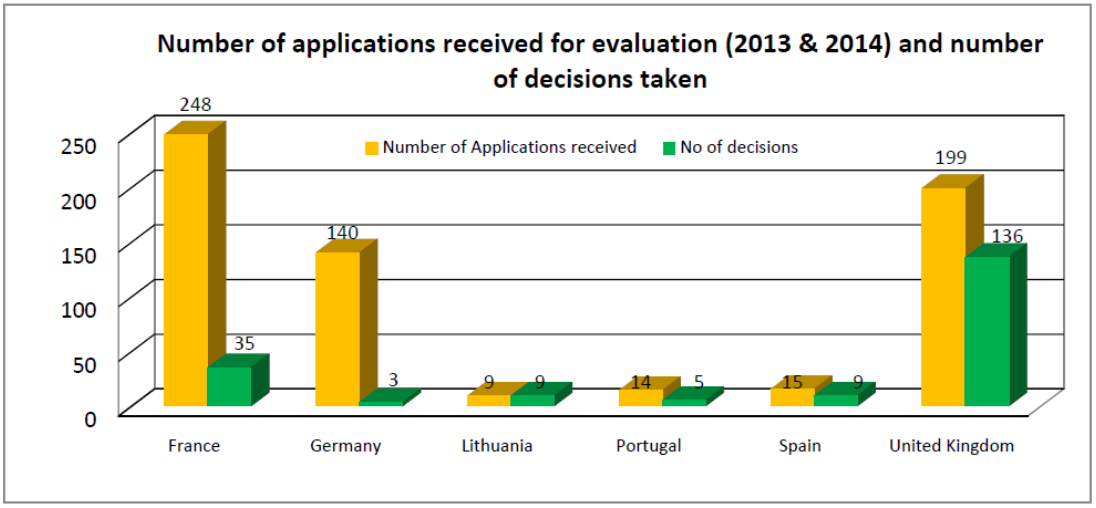


Chart 5 Number of applications received for evaluation (2013&2014) and decisions taken

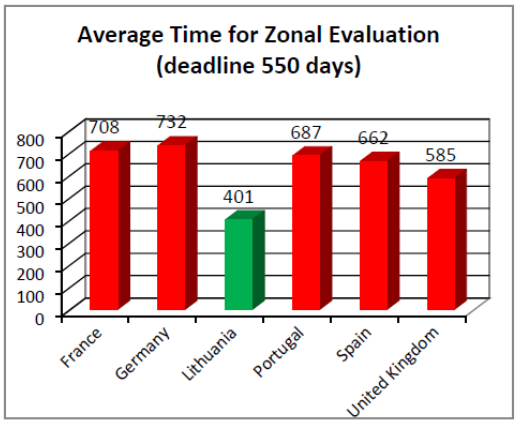


Chart 7 Average time for zonal evaluation

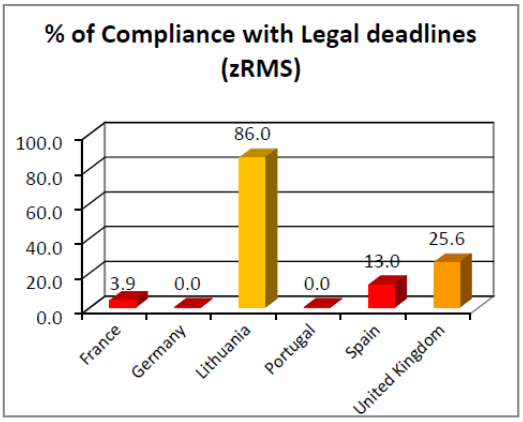


Chart 6 Percentage of compliance with legal deadlines (zRMS)

[47] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3

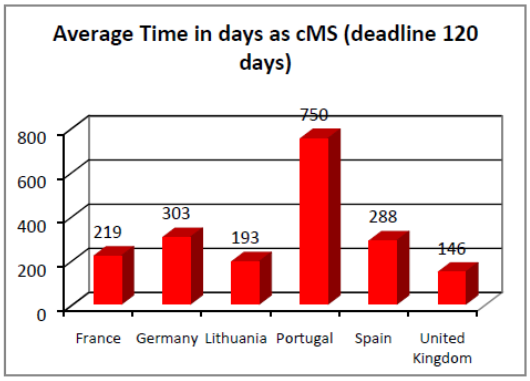


Chart 8 Average time (in days) as cMS

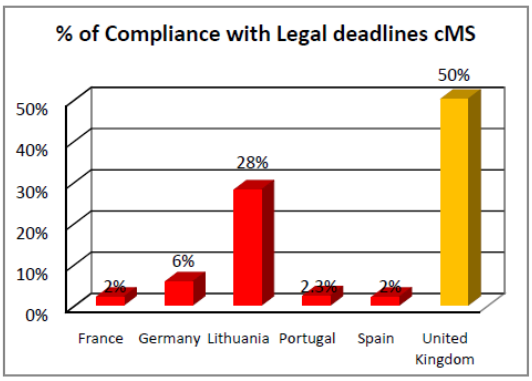


Chart 9 Percentage of compliance with deadlines as cMS

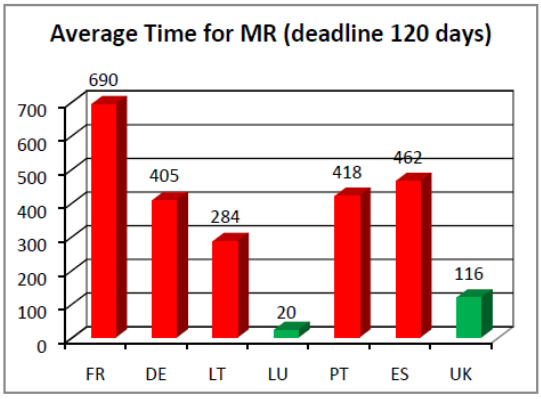


Chart 10 Average time for MR applications

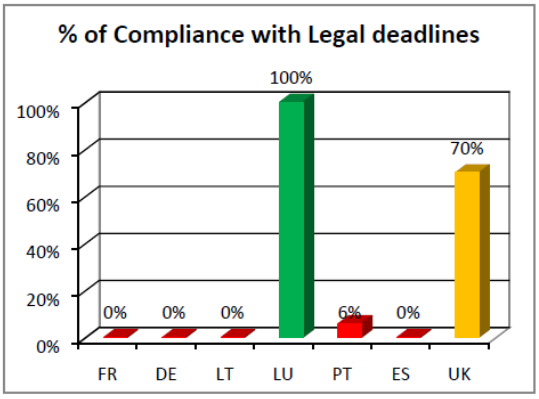
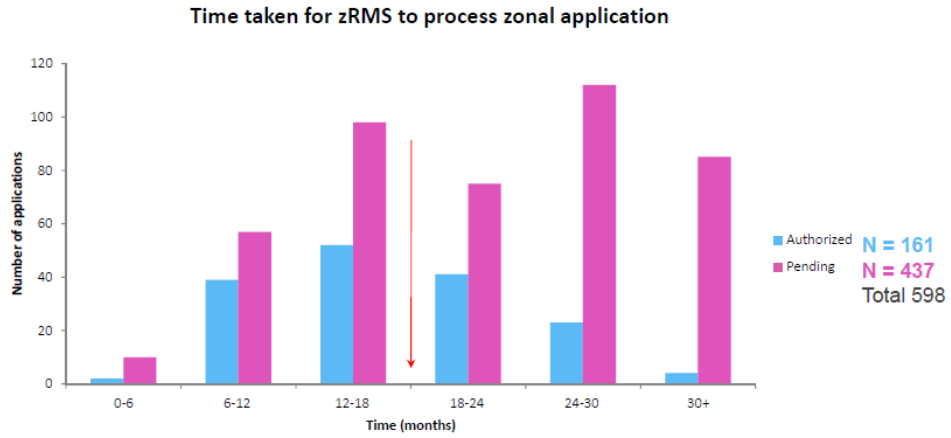


Chart 11 Percentage of compliance with deadlines (MR)

Appendix 9 MS performance against regulatory timelines – ECPA figures [48]

zRMS Registrations New Formulations

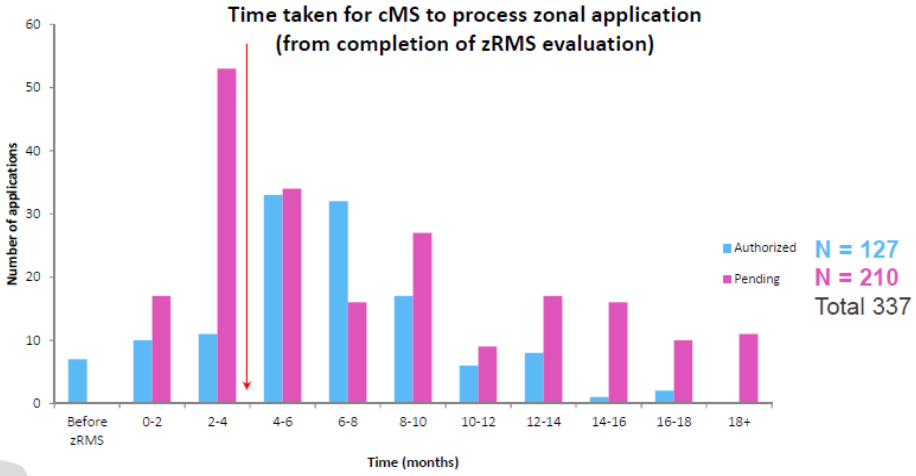
European Crop Protection



- Granted Zonal authorisations within 18 months or less = 21%
- Pending Zonal evaluations already exceeding 18 months = 62%

cMS Registrations New Formulations

European Crop Protection

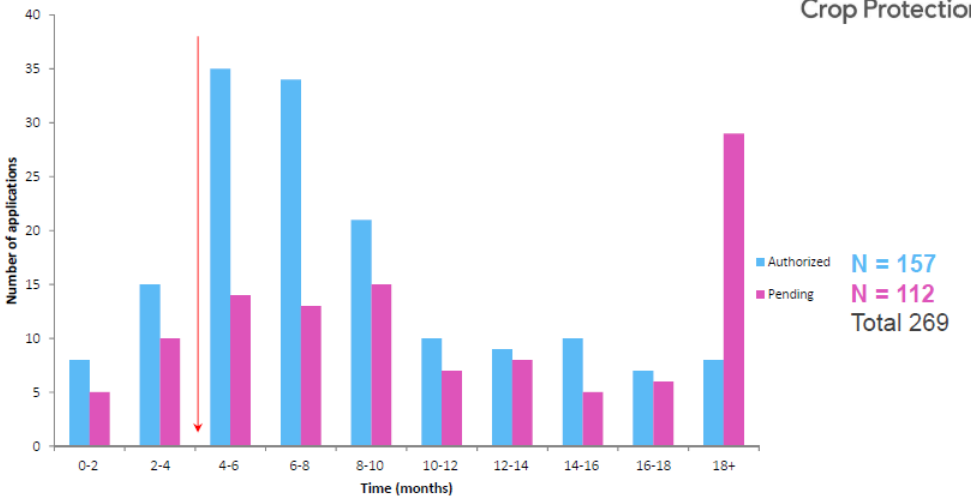


- Granted cMS authorisations within 4 months or less = 10%
- Pending cMS evaluations already above 4 months = 67%

[48] Jeanne Roederer presentation ECPA Conference 2018, Brussels

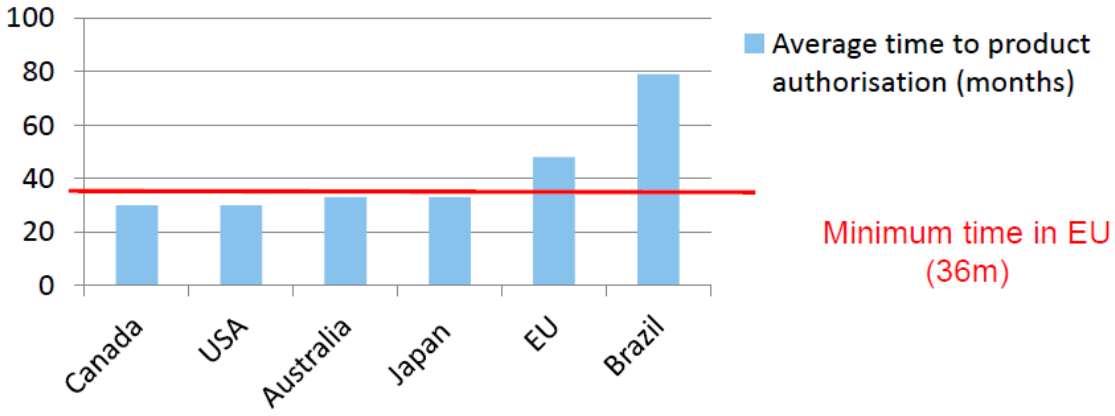
Mutual Recognition

European Crop Protection



- Granted MR authorisations — within 4 months or less = 9%
- Pending evaluations already — above 4 months = 84%
  above 8 months = 63%
  above 12 months = 43%

Appendix 10 Global time to market[49]

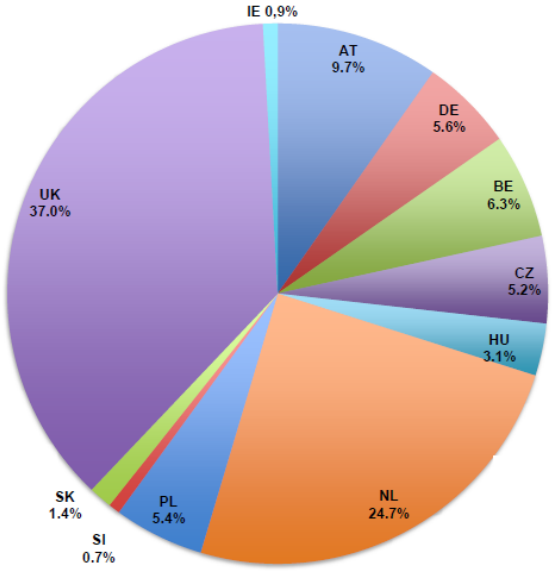


[49] Dr. Martyn Griffiths, Bayer SAS, Chairman, ECPA Regulatory Policy Team, ECPA Conference 2018, Brussels

Appendix 11 Distribution of work in the EU Central Zone

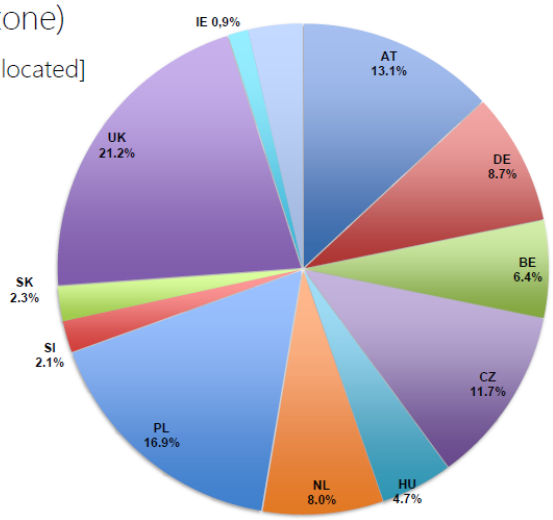
Allocation of zRMS

Distribution of zRMS for AIR3 containing products (batch 1 – 6), 578 products (central zone)



Distribution of zRMS for AIR3 containing products (batch 7 – 9 and group 4), 528 products (central zone)

[provisional, not all products allocated]



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[50] Christian Prohaska – AGES, Austria - ECPA Conference 2018, Brussels

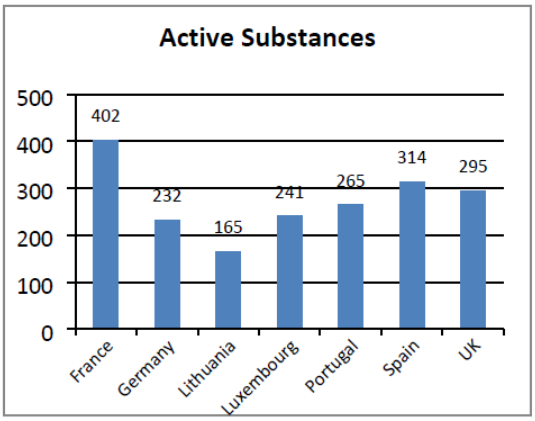


Chart 3 Number of Active Substances

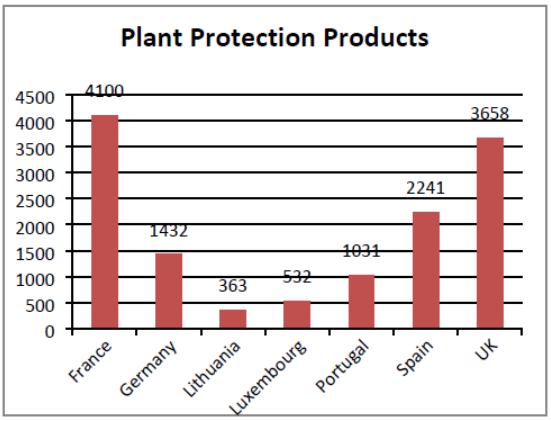


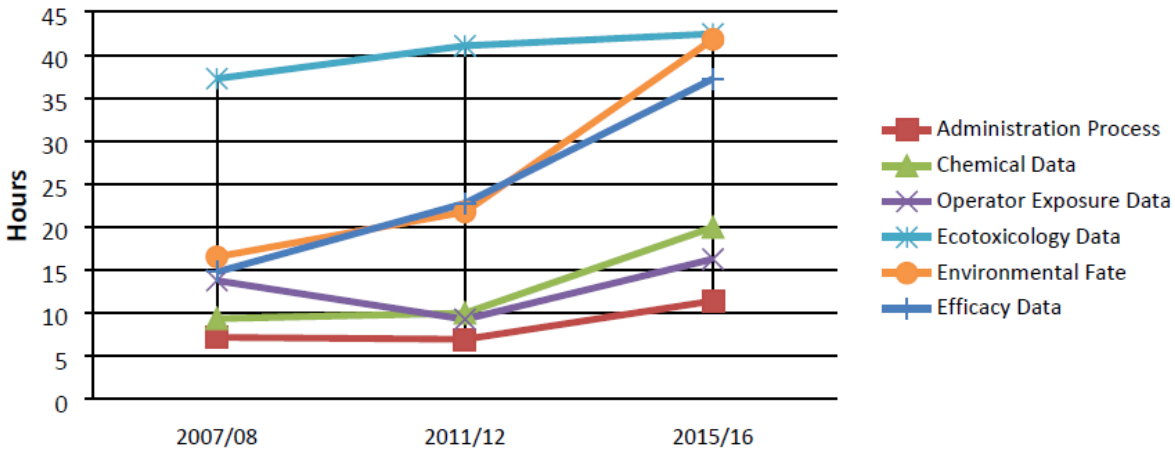
Chart 2 Number of Authorised PPPs

51

[51] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3

Appendix 12 CRD Resources and fees

CRD Resource requirements for application processing[52]



60 FTE days zRMS

CRD fees [53]

The following fees apply to individual application types and will be applied to applications received by CRD from 6th April 2016 . When you submit an application you will be invoiced for the appropriate total fee; where an application is subject to a detailed technical sift the fees applicable will be applied in stages reflecting the validation check, detailed technical sift and evaluation stage, although only one invoice will be issued. Additional fees may also be applied mid evaluation where additional data is required and accepted. The figures below are for information only.

Fees for Product Stream Applications	
Co-ordination	**Fee**
Withdrawal	£104
Sift	£229
Co-ordination – (all standard technical stream applications)	£1,872
Parallel co-ordination	£728

[52] DG Health and Food Safety Overview report Authorisation of Plant Protection Products ISBN 978-92-79-53017-3
[53] CRD website

Off - Labels - (Extensions of use applications submitted by growers or grower organisations. Applications submitted by the product authorisation holders will be charged the standard modular fees)	£1,768 (Charged per risk assessment based on crop groupings)
Administrative authorisations	£156
Task - (applicable to administrative blanket applications for identical changes which affect 15 or more products. A 'sift' fee and an 'Administrative approvals' fee is charged for the first product, a 'Task' fee is then charged for each subsequent product. For more information see (Change of Authorisation Holder link to CRD website))	£52
Administrative Trials Permit	£52
Commenting on draft protocols	£416
Pre-submission meetings for lead zone re-registration and new product applications	£5,200

Specialist Modules	**Fee**
Label check	£208
Parallel import verification (charged for each source and appeals procedure requested)	£208
Reasoned cases (all areas)	£416
Chemistry data	£780
Residues data	£780
Toxicology data	£780
Operator Exposure data	£780
Ecotoxicology data	£1,872
Fate & behaviour data	£1,872
Efficacy/crop safety data	£1,872
Zonal surcharge 1 (An additional charge for lead zonal re-registration and new product applications where the UK is the zonal RMS. This fee is in addition to co-ordination and specialists charges above and may be applied for applications where the UK has agreed to act as zonal RMS)	£7,800
Zonal surcharge 2	£15,600

(An additional charge for lead zonal re-registration and new product applications where the UK is the zonal RMS. This fee is in addition to co-ordination and specialists charges above and may be applied for applications where the UK has agreed to act as zonal RMS)	
Import Tolerance category 1	£16,224
Import Tolerance category 2	£6,760
Import Tolerance category 3	£2,028

Official Recognition	Fee
Initial inspection	£2,080
Renewal	£2,080
Re-inspection	£1,560

The appropriate Band will be determined following the resource estimate at the application sift.

Fees for New Actives Applications and EU Reviews	
Core Data (New Substances & EC Reviews)	**Fee**
Completeness Check	£5,200
Evaluation of core dossier	£114,400
Provisional approval (including efficacy)	£36,400
EFSA peer review (as either rapporteur or co-rapporteur Member State)	£36,400

Partial Dossier (New Substances & EC Reviews)	Fee
Band 1	£7,800
Band 2	£15,600
Band 3	£31,200
Band 4	£52,000
Band 5	£72,800
Band 6	£93,600
Band 7	£114,400

Biological & Pheromones (core)	Fee
Evaluation: Bio pesticides including Plant extracts	£23,400
Evaluation: Pheromones	£13,520
EFSA peer review (as either rapporteur or co-rapporteur Member State)	£7,800

Biological partial dossiers	Fee
Band 1	£5,720
Band 2	£11,700
Band 3	£17,680
Band 4	£23,400

Pheromone partial dossiers	Fee
Band 1	£3,380
Band 2	£6,760
Band 3	£10,140
Band 4	£13,520

Basic Substance dossiers (core)	Fee
Assistance with a full data package	£114,400

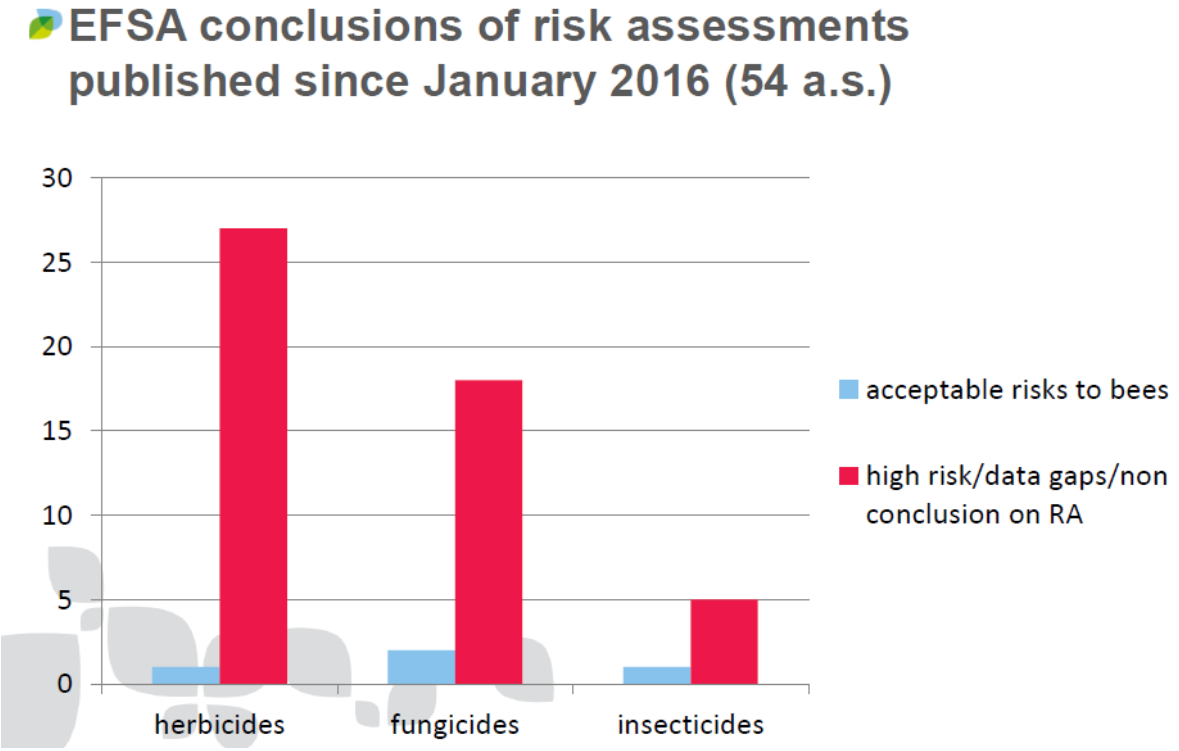
Basic Substances partial dossiers	Fee
Band 1	£7,800
Band 2	£15,600
Band 3	£31,200
Band 4	£52,000
Band 5	£72,800
Band 6	£93,600
Band 7	£114,400

Pre-submission meetings	Fee
Meeting before the submission of an application in support of new active substance, safener or	£5,200

synergist, biocontrol and pheromone applications

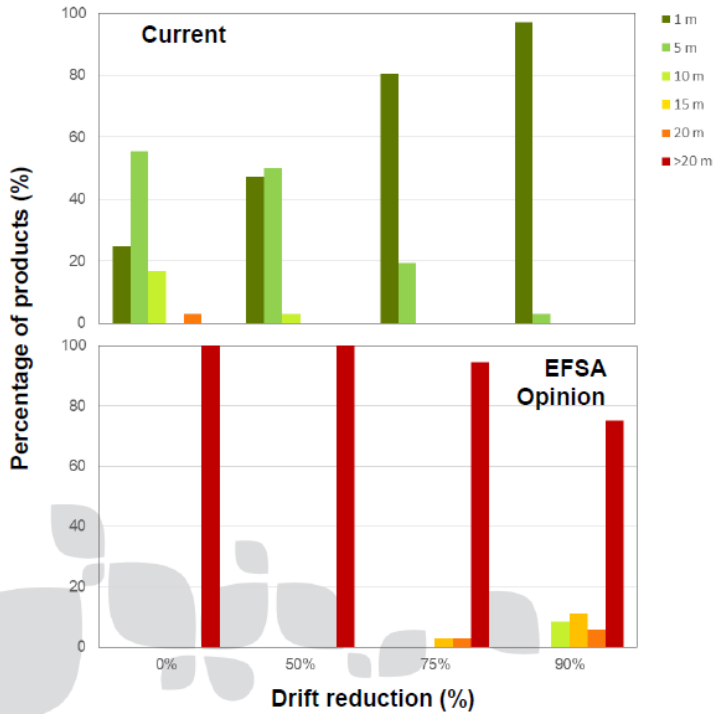
Appendix 13 Impact of Guidance Documents [54]

Bees



[54] Peter Campbell – ECPA Conference 2018

Impact of Reproductive Endpoint Introduction



Current

- All products are registerable with up to 20 m buffer and/or up to 90% drift reduction

EFSA Opinion

- 27 products require >20 m buffer & 90% drift reduction
- only 9 products are potentially registerable with 10 to 20 m buffer & 75% to 90% drift reduction

- **SPG - "small" effects on in-crop non- target arthropods**
- **Potential large increase in buffers**

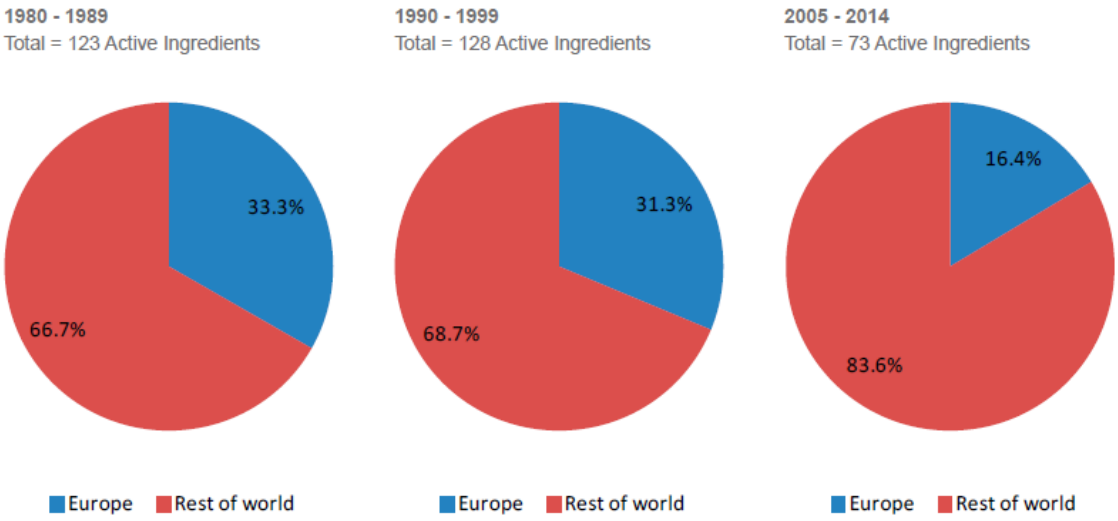
  Typical buffers of 5-10m will increase to 30-50m

  Buffer of 1m (with 90% drift reduction nozzles) will increase to 10-20m

- **Assuming a buffer size of 30-50 m in a square field:**
  - 2 ha field ~ 50 % loss of cropped area
  - 20 ha field ~ 15 % loss of cropped area

Are Insecticides registerable??

Appendix 14 Share of active substance development[55]



[55] R&D trends for chemical crop protection products and the position of the European Market Phillips-McDougall September 2013, Available on the ECPA website

Appendix 15 Codex MRLs refused by the EU

The European Commission gave reservations to the advancement of the following approximate percentages of proposed Codex MRLs
2016: 63%
2017: 44%
2018: 22%
This means that these MRLs would not pass directly into EU legislation

In 2018, the EU Commission also made 'comments' They were very clear to say that these were not reservations but that more work would be needed before the MRLs could be recognised in EU legislation. Although comments had been used at the 2017 meeting, it was to a much smaller extent. It is yet to be seen whether this additional work will take place to allow these MRLs to be adopted into EU legislation without further regulatory submission/input.

(figures collated from European Union Comments submitted to the annual Codex Committee on Pesticide Residues)