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Crop Protection European Regulatory Conference

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Crop Protection European Regulatory Conference

The 4th Crop Protection European Regulatory Conference was held in Brussels on 15-16 March. Organised by the European Crop Protection Association (ECPA) and the European Crop Care Association (ECCA) it again provided an ideal opportunity for the 441 delegates from 20 Member States (MSs) to discuss the challenges in the implementation and application of Regulation 1107/2009 and the regulatory issues facing the crop protection industry in the future. Martin Redbond, editor of *Crop Protection Monthly* (mredbond@aol.com), reports:

Introductory session

Welcome address

Jean-Philippe Azoulay, ECPA's new Director General welcomed the delegates to the 4th Crop Protection European Regulatory Conference. He said it was the first conference in the age of post-truth, the word of 2016 that describes a culture in which appeals to the emotions tend to prevail over facts. He said two topics, glyphosate and endocrine disruptors (ED), demonstrated how scientific studies and evidence were being replaced by emotions, political interest and social networking. He said we are lucky to be living in a Europe where we can access good quality and healthy food and where life expectancy is increasing by three months every year.

However, he said the zonal system is not working because too many national authorities choose to work in old-fashioned ways. As a result innovation and new approvals are being blocked. The industry understands that there is political pressure to reduce the use of pesticides and ECPA companies are using their intelligence, experience and resources to find modern solutions. However, industry wants to see progress on a science-based and efficient decision making system in Europe and an authorisation system which relies on trust between competent authorities. It also needs to increase the tool box so that farmers are able to supply good quality food while at the same time earning a living and helping to sustain the planet.

Update on the implementation of Regulation 1107/2009

Wolfgang Reinert, DG SANTE, gave an update on the Commission's REFIT evaluation of Regulation 1107/2009. He said it is a full and comprehensive review to ensure that the regulation meets the needs of citizens, businesses and public institutions in an efficient way. The review started in 2016 but suffered from administration delays before a road map was finally submitted to a 12 week public consultation in November. The Commission now has the green light to launch the tendering procedure.

Mr Reinert said the Commission was committed to improving low risk criteria. He said the new criteria were better explained and much clearer. The Commission's proposal, which again took longer to prepare than foreseen, was finalised in 2016 and is on the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) agenda for March 2017 for a vote. In the meantime the European Parliament adopted in January a Resolution on biological substances and the new criteria will be a central element of this.

The Plant Protection Products Application Management System (PPPAMS) is currently used for Article 53 applications and was developed by the Commission to enable users to create applications for PPPs and to follow their evaluation. Norway and 22 Member States (MSs) are already participating. In future Mr Reinert said all applications for new PPPs should be submitted through the PPPAMS. The Commission is providing additional resources, training and user support.

The European Parliament has asked the Commission to look at Annex III of the Regulation 1107/2009 which proposes a list of co-formulants that are not accepted for safety reasons. The process and criteria for compiling the list has been discussed between the Commission, the European Food Safety Authority (EFSA) and MS experts. To create a first list decisions will be based on existing information (REACH, CLP, open data) as there is no wish to generate new studies. Some products might need reformulating.

The European Court of Justice has ruled that studies used by regulators to assess the dangers of pesticides must be disclosed. It is argued that such research falls under 'information on emissions into the environment,' as defined under the Aarhus Convention and the EU law implementing this Convention. The Commission is currently exploring with MS experts the impact of the European Court of Justice ruling. Aarhus represents only part of the access requests that the Commission receives. In 2016 there were 91 requests, 20% to SANTE. Some 50% came from only 7 individuals. Thousands of documents can be involved in this exercise. Mr Reinert said that only rarely does the information get disseminated to the public.

Mr Reinert admitted there were several deficiencies in the implementation of the zonal system. The 120 days for zonal authorisation/ mutual recognition is often not achieved because the concerned MSs are refusing to authorise for reasons which are outside the scope of Article 36(3). He said they were not sufficiently exploring risk mitigation measures.

Mandates for the Post Approval Issues Group and Interzonal Steering Group are currently being revised with a view to better dovetailing the different 'post approval' processes.

Mr Reinert concluded by saying that decisions in 1107/2009 are often being taken according to comitology. The Commission presents a draft proposal and there is a vote. Distribution of votes is based on the size of the MS. A qualified majority is required. If not supported the decision goes to appeal. The Commission may then withdraw or adopt. Mr Reinert said a growing number of MSs were unwilling to support unpopular decisions.

Regulation 1107/2009 – challenges for today and the future

Dr Martyn Griffiths, Senior Regulatory Policy Manager (Europe-Middle East-Africa) with Bayer CropScience and chair of the ECPA Regulatory Policy Team, said genotoxicity is now a major issue in the EU with requirements for huge and extensive data packages. This is currently impacting on up to 20 substances. Three substances are already non-approved. The issues include the lack of endpoint setting after peer review, insufficient consideration being given to the weight of evidence (WoE) approach, no clear guidance on which studies to conduct and conflicting evidence since 2011 as well as animal welfare concerns about the additional studies being requested.

Since June 2011, almost six years since entry into force of Regulation 1107/2009, 49 new substances have been submitted. Of these 19 active substances have an approval vote, 17 have also an MRL vote. 15 have MRL regulations which apply. Only five have products authorised - halauxifen-methyl, benzovindiflupyr, COS-OGA, and Pepino mosaic virus, rescalure. It is clear that new process improvements are required in order for new innovative products to be made available to EU farmers.

To ensure efficient functioning of the legislation there needs to be better stakeholder engagement. While ECPA have regular bilateral meetings with DG SANTE, EFSA and MSs there is no platform where all parties can review the process and work together on solutions. Greater collaboration exists with all stakeholders for biocides and medicines. ECPA have welcomed the proposals by the Pesticides Steering Network (PSN) to review stakeholder participation in the peer review. An early dialogue with EFSA and with other MSs would help to readily clarify uncertainties about EFSA conclusions. ECPA companies would also appreciate a scientific dialogue with EFSA and MS together. Dr Griffiths said there is a need for another 'Dublin' type workshop for all parties to discuss all aspects of active substance evaluation. With regard to the review of the legislation the Commission is expected to report in 2018/19. Dr Griffiths referred to the DG SANTE 'road map' and said a consultant review is expected to start in Q2 2017. An important consideration will be the MS audits provided by Directorate F.

The agronomic consequences of the EU PPP legislation

Copa Cogeca was created in 1962, making it one of the biggest and most active lobby organisations in Brussels. Copa represents some 23 million European farmers and family members while Cogeca comprises around 22,000 European agricultural cooperatives. The organisation's vision is to ensure a viable, innovative and competitive EU agriculture and agri-food sector. 66 Member organisations and 34 Partner Organisations are involved covering 25 agricultural sectors.

César González, Copa-Cogeca Working Party on Phytosanitary issues, explained how the various pieces of PPP legislation impacted on their farmers and how extension of authorisation for minor use and emergency authorisations were critical in many crops. He also described the impact of Directive 2009/128/CE on the sustainable use of pesticides (SUD). This covers National Actions Plans (NAP) and Integrated Pest Management (IPM). He said it had been mandatory in Europe since 1st January 2014 to follow general IPM principles. The Directive also involved the testing of spraying equipment, training and certification of sprayer operators.

Mr González said IPM is not a new concept, it is based on good farming practices that have evolved over time. There are many different definitions but IPM means managing, in a given situation, populations of plant pests, diseases and weeds using a the combination of all appropriate agricultural practices in a holistic way that reduces crop damage to an acceptable level and at the same time ensures the protection of human health and the environment. Mr González concluded by calling on regulators to apply mandatory mutual recognition and to fast-track procedures for low-risk active substances. He also called on the industry to find alternative strategies where no PPPs are available and to develop chemical and non-chemical solutions that can be used according to IPM principles.

Active substance evaluation update

AS review programme

Wolfgang Reinert, DG SANTE, (substituting for Mark Williams) said the purpose of renewal was to bring assessments and decisions in line with the requirements of Regulation 1107/2009. Approvals can only be renewed if it has been demonstrated that the substance is not expected to have any harmful effects on human and animal health or any unacceptable effects on the environment. EU regulations outline the rules for timelines, responsibilities, submission of the dossier, assessment and decision making. Decisions on renewal of approval are taken in line with the approval criteria outlined in Regulation 1107/2009. There are now three work programmes: AIR 2 (29 substances), AIR 3 (146 substances), AIR 4 (204 substances). Mr Reinert said the status of the renewal work can be found at (http://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal_en).

Decisions have been taken for 20 of 29 AIR 2 substances; delays are mainly due to the need for additional processes. AIR 3 decisions have been taken for three substances and there are many pending. AIR 4 are active substances with expiry dates between 1 January 2019 and 31 December 2021. The work programme is prioritised into substances expected to fulfil the low risk criteria, substances expected to fail the 'cut-off' criteria and the remainder. Article 17 of Regulation 1107/2009 provides for extending the expiry dates of substances where a decision could not be taken before the current expiry date. The applicant must submit an application for renewal three years before the current deadline if they wish to renew approval. Only when an application is received will the Commission take action and extend the current approval period. If an application is not received, the current expiry date will remain.

Extensions are required for three main reasons: delays in the assessment, delays in decision making (there are often highly complex cases) and to facilitate the work programme. Extensions are subject to a vote in the SCoPAFF. Significant delays are being encountered due the volume of applications and the complexity. There is clearly insufficient resource available. The Commission has made it clear that delays cannot continue and remedial action should be taken. MSs can help to address the problem by ensuring that dossiers submitted and assessments are of high quality.

The criteria for approval are based on the 'one acceptable use' concept. The dossier submitted must show that the authorisation expected is for at least one representative use of at least one PPP in at least one MS. There are harmonised approval criteria (Article 4 and Annex II of Regulation 1107/2009) but there are various problems and blockers around 'cut off criteria', genotoxicity requirements, groundwater and metabolites. Future developments would include the alignment of Draft Assessment Report (DAR) and the Harmonised Classification and Labelling (CLH) report to ensure availability of harmonised classification and labelling at the time of decision. There is also an amendment to Regulation 844/2012 foreseen that will oblige MSs to submit a CLH dossier to the European Chemicals Agency (ECHA). A mandate on the assessment of genotoxicity, clarity on some

key areas to assist risk assessors and managers in the future, improvements to the peer review process and clarity on criteria for ED are other issues for the Commission to resolve.

EFSA update on active substance review

Benedicte Vagenende of EFSA's Pesticides Unit Co-ordination Team gave an update on the active substance review. She described the Unit's responsibilities and told delegates how co-ordination of the peer review of active substances includes providing conclusions and technical reports for single active substances to support the EU decision makers. She updated delegates on the Unit's outputs during 2016. EFSA has been mandated by the Commission to provide scientific assistance as to whether exposure of humans to active substances under realistic proposed conditions of use can be considered negligible. EFSA is to calculate the actual expected exposure values in absolute values and as percentage of the established toxicity reference values.

Ms Vagenende outlined an action plan for improving the EU peer review which had started with a PSN brainstorming session. A plan which included comments from a number of MSs was then drafted and after further discussion this will be implemented and published as a technical report and communicated to stakeholder in a webinar at the end of the year. Improvements in the peer review include new procedures for MSs commenting and increased transparency in the conclusions, especially in recording diverging views and the reasoning behind such divergence.

For Maximum Residue Levels (MRLs) new procedures are also in place for residue reviews under Article 12 of Regulation 396/2005. The list of Article 12 reviews planned for 2017/2018 will be published and updated on a quarterly basis on the EFSA website.

EFSA's work on guidance document development was also highlighted, with the finalisation in 2017 of work on dermal absorption, soil and endocrine disruption. Work will also be initiated on a guidance document on isomers and on a data collection exercise to support the birds and mammals guidance document.

MS challenges in AS review – can we improve?

Dr Luuk van Duijn of the Dutch regulators, Ctgb, spoke about MS challenges in the active substance review. He reminded delegates of the approval process and made some suggestions about how it could be improved. He said the notifier chooses a Rapporteur Member State (RMS) in the case of a new approval or an RMS is assigned by the Commission if a renewal. The RMS evaluates the dossier and prepares the Draft Assessment Report (DAR). The draft is then presented to EFSA who circulate it to the Commission and MSs and makes it available to the public for consultation. EFSA then organises a peer review and publishes the conclusions. The Commission prepares a report and a proposal for approval or non-approval is presented to the SCoPAFF Committee for voting. If no qualified majority is reached, an appeal procedure starts.

Up until 2016 the opinion of the RMS formed part of the background documents. However, the RMS has an in-depth knowledge of the dossier and due to a change in EFSA policy the opinion of the RMS is now represented in the body of the text.

Involvement of the notifier throughout the process is currently limited. During the procedure new insights are often presented or a new weighting of critical points takes place. How can a notifier reflect on these 'new issues'? The notifier builds their dossier and has a pre-submission meeting with the RMS before submitting it. Issues raised during the assessment will be discussed with the notifier. However, after that there is a period of silence before the Commission asks the notifier to comment on the finalised EFSA opinion. Dr van Duijn said that EFSA changes to the way it represents the opinion of MSs (most notably the RMS) is welcomed and will contribute to a better understanding. Creating a new 'loop' after the opinion is finalised will help if due to new insights or new weighing of criteria additional information is required. The notifier should then be given the opportunity to present this information so it can go through the EFSA evaluation process again.

For issues tabled in SCoPAFF that do not call for extra information a short 'loop' back to the notifier or RMS is recommended. The notifier should also be given the opportunity to attend a meeting where those issues are discussed. This could improve and even shorten the complex active substance discussions in SCoPAFF.

Impact of active substance conclusions on the re-approval and product re-registration processes

Panagiotis Theodoris, Department of Plant Protection and Biocides Products in the Greek Ministry of Rural Development and Food, provided a national perspective on the impact of the active substance evaluation on product availability at a country level. One key concern he highlighted was the need to provide a sensible and workable balance between the precautionary principle (applied at the EFSA/EU level) and the subsidiarity principle which allows MSs to put in place relevant measures. The precautionary approach at the EFSA/EU level leaves little scope to manage issues at the local level and Mr Theodoris gave a number of examples where the EFSA/EU assessment has not provided relevant options for local risk management and will likely lead to severe restrictions of important products. He noted that Greece is already heavily dependent on the emergency use derogation in Regulation 1107/2009 and this will continue to be the case with the unnecessary loss of many more substances.

Developments in human health risk assessment

Regulatory challenges in human health RA

Dr Carole Langrand-Lerche, Head of Regulatory Science for Europe-Middle East–Africa for Bayer CropScience, gave her presentation on behalf of the ECPA Toxicology Expert Group. Dr Langrand-Lerche said changes to regulatory policies, guidelines and testing methods are necessary and important. They allow new science and improved knowledge concerning human exposure and chemical hazards to be incorporated. Effective implementation of these changes, however, requires a process that allows for stakeholder collaboration and step-wise adoption. Implementations that lack a proper transition process often result in misinterpretation of the requirements and unnecessary testing. The scientific opinion for genotoxicity testing was updated in 2011 based on evolving test methodologies and experience with existing tests that raised scientific debate about their predictive potential. However, regulatory implementation was initiated without sufficient scientific collaboration regarding interpretation of data, the management of older data packages and use of weight of evidence (WoE). The result was a significant increase in testing without guidance on what is really needed. Data gaps based on genotoxicity can, of course, lead to non-approval.

Naturally evolving science results in evolving regulations and both are necessary to ensure that sustainable solutions are effectively and efficiently brought to the market. An example is the science of hazard and exposure characterisation which is evolving at a record pace. In silico/in vitro methods are available for adverse outcome pathway (AOP) and mode of action (MoA) determination as well as species differentiation, physiologically based pharmacokinetic (PBPK) modelling, exposure methodologies, epidemiology, biomonitoring, mixtures toxicity and cumulative risk assessment. Regulatory frameworks must be able to effectively incorporate new technologies to ensure that the best available science is used when assessing human and environmental health. Dr Langrand-Lerche said success is reliant on transparency gained from open communication and true collaboration. The current process of updating and implementing new regulations needs a more defined process that allows for stakeholder engagement, provides for WoE of existing data sets and defines the uncertainties with current and new technologies.

Member State view on challenges in human health RA

Roland Solecki, Head of the Pesticide Safety Department at the German Federal Institute for Risk Assessment (BfR), gave some views on the challenges in human health risk assessment. Some key points for further discussion, he said, were that agencies should exchange and harmonise best practices. He said it was very important that the regulatory system is transparent and that improvements do come forward. There should be better availability of documents from applicants. He suggested that open literature could be more useful for regulatory purposes. Some areas of risk assessment also merit further discussion. For example enhancing testing methodology of formulated PPPs, taking into consideration synergistic/cumulative effects. For co-formulants existing data (REACH and BP) should be used. He said the Commission should also support research on improved

safety testing and suggested that more coordinated research is needed to generate new data supporting the regulatory use of alternative methodologies.

He concluded that the regulatory system, overall, needs some improvements in order to create streamlined organisational processes and more transparency. More harmonised guidance is necessary for risk assessment of combined exposure to pesticides and other hazards. He stressed the need for urgent implementation of scientific criteria for the identification of EDs and one applicable guidance for them in the EU.

Opportunities for efficient testing strategies

Jarlath Hynes, a Toxicologist and Regulatory Science Adviser with the Humane Society International (HSI), told delegates that his organisation is present in Brazil and Latin America, US, Canada, Europe, India, Japan, Korea, Australia, and beyond. Its expert team covers toxicology, ecotoxicology, pharmacology, biochemistry, neuroscience, endocrinology, law and regulatory science. It works with research institutes, companies, government regulators and other stakeholders and is the leading international NGO working to advance non-animal safety testing and bioscience research worldwide.

He said Directive 2010/63/EU on the protection of animals used for scientific purposes represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To achieve that HSI seeks to facilitate and promote the advancement of alternative approaches. It also wishes to ensure a high level of protection for animals that still need to be used in procedures. The Directive should be reviewed regularly in light of evolving science and animal protection measures.

Mr Hynes said 1107/2009 should promote the use of non-animal test methods and other risk assessment strategies while animal testing is minimised and tests on vertebrates should be undertaken as a last resort. He said there should be rules laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. There should also be an obligation to allow access to studies on vertebrates on reasonable terms. Between 2012-13, EU authorities, industry and animal welfare groups (HSI and Eurogroup) cooperated on the revision of registration data requirements for pesticides and biocides achieving substantial reductions in animal test requirements by the removal of redundant in vivo study requirements.

Update on Endocrine disruption and classification issues

Endocrine disruption and guidance update

Dr Karine Nienstedt, DG SANTE, gave an update on the scientific criteria to identify endocrine disruptors (ED). She spoke about the draft criteria and their implementation. She said the objective had been to present and adopt the ED criteria by December 2013 however a decision was taken to carry out an impact assessment before presenting the proposal. In the meantime the European Court of Justice ruled that the Commission had breached EU law by failing to publish a definition for ED. The proposal was finally presented in summer 2016. Decision making was to be implemented through two draft acts, one for PPPs and one for biocide products, the impact assessment and several annexes.

The World Health Organisation (WHO) through its International Programme for Chemical Safety had proposed in 2002 a definition for ED. Those definitions have now reached wide consensus among scientists and the EFSA has endorsed these definitions in its scientific opinion on ED. The impact assessment was based on a road map that outlines four different options with regard to setting EU criteria. The impact assessment concluded that there were no preferred options based on the screening of substances carried out using Multicriteria Analysis (MCA). There was also a public consultation in which individuals and organisations could express their opinions on the 4 options which were: Option 1: Keep existing regulations as they are i.e. interim definitions for endocrine disruptors. Option 2: WHO definition, purely hazard based, Option 3: WHO definition, various categories defined and Option 4: WHO definition, incorporating the element of potency. There is consensus that the interim criteria are not fit for purpose, therefore it is proposed that there will be no transitional period.

Technical discussions on the ED criteria are now well advanced. Dr Nienstedt said the criteria are considered balanced, stable, and reflect a compromise between the originally different MS positions and are now supported by a majority of MSs. The Commission is now reflecting on the next steps for decision making on the criteria and in parallel they are getting ready for implementation. MSs have requested a transition period of six months and a review clause (every seven years). In parallel to the decision making EFSA and ECHA are developing a joint Guidance Document on implementation of the criteria and this is expected to be ready for public consultation in summer 2017.

Industry view on Endocrine disruption

Jean-Pierre Busnardo, European Regulatory Affairs Manager for DuPont Crop Protection, gave the industry's views on the proposed regulatory criteria for EDs. He said there was no regulatory or public health vacuum. He also referred to the Commission's impact statement that said the evidence related to endocrine mediated diseases does not show a link to exposure to ED substances.

While numerous elements of the proposed criteria are supported, the fact that the criteria remain hazard based is not. The use of the WHO definition along with a clear 'burden of proof' is a welcome part of the criteria but the fact that potency will not be considered is a major deficiency. Examples were presented which highlighted the impact of regulating without considering potency – with substances with very large margins of safety potentially being removed from the market unnecessarily.

With the criteria currently proposed, the actual impact is difficult to evaluate. But Mr Busnardo did highlight that the Commission's estimated loss of 8% of substances was unrealistically low. The final impact could be as high as 42% of substances depending on how the criteria are implemented and interpreted in the EFSA process.

Mr Busnardo concluded that ED effects are already highly regulated so the new criteria should be applied with great care. He said industry is opposed to the proposed criteria and supports shifting derogation to risk basis. Industry supports the Commission in their proposal to change from negligible exposure to negligible risk. It recommends bringing derogation back with criteria handled as a 'package.' Longer term industry believes that hazard criteria should be removed from chemicals legislation and there should be a return to a risk (and benefits) based framework.

Overview of the CLH process, emerging challenges and specific issues in the classification of pesticide active substances

Jonas Nygren of ECHA gave an overview of the Harmonised Labelling and Packaging (CLH) process and the emerging challenges and some specific issues in the classification of pesticide active substances. The CLH process is legally binding and has downstream consequences for a large number of legislations including PPPs. It is based on hazard only. He said the CLH process should take a maximum of 18 months and runs parallel to the PPP authorisation process. ECHA's Committee for Risk Assessment (RAC) will consider the comments received during the public consultation when developing its opinion on the CLH proposal. The European Commission takes into account the RAC opinion when it decides whether the proposal for harmonised classification and labelling is accepted. The Mode of Action (MoA) concept is important. If there is a positive result but no known mode of action the active substance will be classified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified. Mr Nygren said that ECHA receives both good and not so good data sets but there has been a considerable effort on behalf of applicants to establish best practice.

Product evaluation challenges

Evaluating the implementation of Regulation 1107/2009

Dara O'Shea, DG SANTE, said that Directorate F had been scrutinising the implementation of Directive 1107/2009. Since 2015 they had audited seven MSs - Germany, Lithuania, France, Austria, the UK, Luxembourg and Spain. The objective was to quantify the scale of the backlog of applications and to focus on finding the root causes. Since the beginning of 2013 Lithuania alone had managed to complete zonal evaluations within the 550 day deadline. The UK had given decisions on 197 applications out of the 285 it had received. With regard to mutual recognition where the deadline is 120 days the UK has averaged 116 days, Luxembourg 20 days, France 690 days. However, delays of two years were commonplace. The complexity of evaluations, the complexity of the administrative process, the failure of management, no long term planning and too many staff were the main reasons given for the backlog. Interpretation of national legislation is a barrier to the zonal system in some MSs. Guidance documents can help or hinder because sometimes they are considered to be too detailed or not to have enough detail. However, the zonal system is undermined by the lack of common approach to evaluation and risk management. In some MSs it is just a lack of willingness to make the zonal system work and to adhere to the timelines.

There has been a large increase in emergency authorisations due to the delays whereas mutual recognition can be successfully used when there are limited resources. Mr O'Shea pointed out that there is a big variation between MSs regarding generic PPPs. If you want to authorise a generic, he said, you should go to the UK. In fact the UK has carried out large volumes of work so Brexit will present a huge challenge for the Central Zone as no other MS is close. Directorate F intends to produce MS and overview reports. They will also follow up recommendations with the seven MSs and will contribute to the 1107/2009 review. However, Mr O'Shea said they had not yet worked out how to follow up a consistent breach of authorisation deadlines.

Zonal system and (inter) zonal co-operation – an update

Darren Flynn, Head of the PPP Active Substance Team in CRD (the UK regulators) and Chair of the Commission's Post Approval Issues Group, is a member of the Central Zone Steering Committee for zonal authorisations. He said the zonal system is one of the cornerstones of 1107/2009 which includes Articles 33-39 – applications for authorisation or amendment of an authorisation under the zonal system and Articles 40-42 – mutual recognition. However, five years on there are still significant issues affecting the smooth operation of the zonal system. MSs are not meeting legislative deadlines, they are not accepting assessments of other MSs and in addition there is an uneven distribution of the workload. He said that EU agreed endpoints were not being used, there are differences in risk assessment/mitigation measures and some MSs had national specific data requirements. Inconsistency in the application of new guidance can increase complexity and lead to re-assessment and delays.

Mr Flynn said there are still concerns over the capacity of some MSs to act as the zonal Rapporteur Member State (zRMS) for zonal applications. Mr Flynn said this was not surprising given all the other work going on - new actives, renewal of actives, Article 43 renewal of products and the increased complexity of the risk assessments involved. However, Article 75 (3) says that MSs shall ensure that all the competent authorities have a sufficient number of suitably qualified and experienced staff to meet the obligations laid down in the Regulation. Mr Flynn said all these issues had been identified and discussed previously in Dublin.

He said thus far there had been limited scope for real inter-zonal co-operation. The inter-zonal system (straight acceptance by all zones of an assessment carried out by one MS) is not really happening due to the need for environmental risk assessments. The Inter-zonal Steering Committee has not really been functioning as intended and needs reinvigorating.

Zonal independent parts of the assessment must be encouraged to make best use of resources. Article 35 says where an application has been made in more than one zone that MSs evaluating the application shall agree on the evaluation of data that are not related to the environmental and agricultural conditions. Zonal sharing of 'zonal independent' parts of the risk assessments has been recognised as something that must be encouraged but is still not really happening

Industry must identify products where inter-zonal work sharing is possible and must time their submissions to facilitate work sharing. MSs must share information on applications received and must accept assessments from other MSs. Mr Flynn suggested that reduced fees might encourage more uptake. He said five years in and clearly there are still issues with the zonal system not operating as smoothly as it should. Some progress has been made to improve the system and procedures have been reviewed and tightened up. There has also been further work on harmonisation of risk assessments but it is vital that MSs and applicants work together to make the zonal system a success.

Article 43 – where’s the silver bullet

Christian Prohaska, Austrian Agency for Health and Food Safety (AGES), said the first version of the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation 1107/2009 was noted at the Standing Committee in July 2015. It has undergone some amendments since but is to be further amended in 2017 in light of experience. In his presentation he was seeking the ‘silver bullet’ and covered a number of topics including zRMSs, equivalence/data match and mixed products. He said that allocation of AIR 2 containing products were product-based. As a consequence there are often different zRMS for even comparable products containing the same active. The issue is that it is possible that different conclusions might be reached for comparable products unless the zMSs do liaise. If the evaluation by the zRMS cannot be finalised in time (four months) all concerned MSs (cMSs) should be notified. AIR 3 containing products are allocated on the basis of active although not all MSs agree to this approach. Germany, Poland and Slovenia are considering acting as zRMSs only for products registered in their countries. Mr Prohaska said zRMS should be accepting product evaluations even if the products are not registered in their countries.

Mr Prohaska told delegates that a Central Zone secretariat should be established by 2017. This will hopefully speed up the renewal process. There are capacity issues but there is no excuse for not accepting the role of zRMS. Of concern is whether the UK will continue to act as a zRMS because of Brexit. Some applicants, he said, had already switched from the UK to alternative zRMSs.

South zone challenges

Dr José-Luis Alonso-Prados, Technical Director at the National Agronomic Research Institute (INIA) in Madrid, spoke about the importance of agriculture in the Southern Zone. He went on to describe how the MSs co-operate. He said work sharing started in 2004 and is still ongoing for the remaining re-registrations of PPPs according to Article 80.5. One MS acts chair of the steering committee which holds a teleconference every two months and an annual face to face meeting. Meetings with industry have been established too. The committee does not address questions on product specific risk assessments but exchanges knowledge and facilitates the harmonisation of risk assessment within the zone. It also discusses any general issues relating to the efficiency of the system and plays a role in the allocation of the zRMSs. To ensure transparency each RMS gives formal feedback on its work to the other MSs in the zone.

Regarding zonal evaluation Mr Alonso-Prados said the quality of documents was important and ongoing studies must be declared in the pre-submission meeting. To retain some flexibility the clock may be stopped before the period of comments. However, no additional studies may be submitted during or after the commenting period. The draft Registration Report (dRR) should be submitted within three months of the last Category 4 study being available.

Industry view on the key challenges in product authorisation

Dr Jeanne Roederer, Regulatory Strategy Expert at Adama and Chair of the ECPA Product Authorisation Expert Group, gave an industry view on the challenges in product authorisation. She said a survey of ECPA member companies had been conducted by TSGE. There were 13 participants - Adama, BASF, Bayer, Belchim, Dow AgroSciences, DuPont, FMC, ISK, Janssen, Nufarm, Oxon, Sumitomo, and Syngenta. Findings were based on company data regarding completed and ongoing evaluations for applications submitted from 1 January 2014 until end 2016. There were 598 zonal authorisation applications of which 21% were granted within 18 months. 62% were pending zonal evaluations and were already exceeding 18 months. It is believed that significant resources will be

required to complete those pending and there is concern that delays in zonal authorisations have a knock on effect on the concerned MS (cMS) assessments.

Mutual recognition (MR) shows a similar picture. 157 authorisations issued by cMS via Article 40. Average time is 8.3 months, more than twice the target. The percentage of granted authorisations within the prescribed timelines is 9%. Data appear to indicate that overall MR tends to be slow in the majority of cases except in some specific countries. Registration of new formulations in 18 months and the mutual recognition of existing registrations in four months can be achieved but in the vast majority of cases it takes longer. A high percentage remains pending for even longer than the legal timelines for authorisation. Delays are primarily caused by lack of EU harmonisation in the standards used for evaluations particularly in the environmental area and the risk mitigation measures. There are also difficulties with work sharing and a lack of trust between MSs. Dr Roederer said there are opportunities for improvement to ensure better functioning of the regulation. The implementation of a zonal secretariat, as discussed at the Dublin workshop, would help.

She concluded that despite noticeable efforts to improve harmonisation, zonal authorisation and mutual recognition systems are still slower than timelines laid out in the regulation. Improvements are possible within the framework of the current regulation. There are also proposals for further improvements to the Article 43 guidance document. A follow-up to the 'Dublin' workshop is recommended.

Legislative review

Introduction to a discussion on the review of 1107 and 396

Hans Mattaar, Technical Director of the European Crop Care Association (ECCA), said the challenge facing the industry was how to improve the regulatory system. Although a monstrous piece of legislation all parties are generally making work. However, it is necessary to identify the root causes of the problems that notifiers and regulators face. Today industry has to deal with 28 competent authorities plus EFSA, ECHA sometimes EPPO and OECD and occasionally the European Parliament. The number of players has grown incredibly so it is not surprising that decisions are often not possible within agreed timelines. An agreement on ED criteria is getting closer but discussions are only starting on guidance and this will be another consideration when making a decision. It currently takes 2.5 years if you are lucky but generally longer. A quicker decision might be possible but is likely to be negative. Adding a new loop to resolve any issues that might have arisen during the peer review will further lengthen the process putting the data submitted, maybe four years earlier, further out of sink with current science and technology, and new standards.

Data call-in system – what can we learn from Canada

Pierre Petelle, Acting President of CropLife Canada, said pest control products in Canada are registered under the authority of the Pest Control Products Act (PCPA) and are regulated nationally by the Pest Management Regulatory Agency (PMRA). If a proposed product has value and does not pose unacceptable risk to health or the environment it may be registered. Once registered products are subject to new standards, a 15 year re-evaluation or to special reviews. The PCPA authorises the PMRA to request additional information/studies when necessary. Notice is given to registrants who have 30 days to declare support (or not) and to provide a list of studies available and in progress. Data Call-In is based on a list provided by registrants. No new data will be considered except that requested by PMRA. New use applications are discouraged to avoid repeat of risk assessments. The process ends with a Re-evaluation Decision Document (RDD).

On the announcement of a special review PMRA will, if deemed necessary, require the registrant to provide information through a Data Call-In. Registration may be cancelled or amended at any time to deal with dangers to human health or the environment. In 2015 PMRA was criticised by the Auditor General for not conducting re-evaluations quickly enough. The PMRA responded that the process was slowed by extensive scientific debates with the registrant.

Registrants and Task Forces are submitting new data without a firm PMRA policy. When drafting a policy long timelines for re-evaluation should be considered. The US Environmental Protection

Agency (EPA) re-registration/re-evaluation process is similar to that of the PMRA but with an important difference. A Data Call-In results from discussions between the EPA and registrants regarding data gaps and protocols/timing for studies to address the data gaps. Generating new data may take one or several years but the results make for better scientific decision making.

Can we improve protection of the environment and streamline the evaluation process for PPPs

Johan Axeleman of the Swedish Chemicals Agency (KEMI) asked the question: can we improve environmental protection and streamline the authorisation process? Kemi's long term objective is to have more effective protection of the environment, more effective application handling and increased trust and confidence. The Swedish national environment goal is that levels of contaminants are so low that ecosystem functions, biodiversity and human health are not threatened. He said the specific effect of PPP use is difficult to distinguish from the effects of changed land use and it is even more difficult to distinguish the effect of a single pesticide. The true problem is not the individual components, however, they do become a problem when taken together. He suggested that to improve and streamline the regulatory process would require a holistic perspective, constructive dialogue and a legislative review.

The role of environmental protection goals to support the EU regulatory process

Kees Romijn, Global Head of Regulatory Policy and Issue Management at Bayer CropScience, is chair of the ECPA Environmental Expert Group (EEG). He presented his paper on the role of protection goals in Environmental Risk Assessment (ERA) to support the EU regulatory process. The approval criteria in Regulation 1107/2009 state that active substances should not have an unacceptable effect on the environment while uniform principles identify hazards, assess their significance and make judgement as to their likely risk in the environment.

Mr Romijn said that protection goals take account of the level of effect, magnitude, duration and the geographic size of the effect but do not take into consideration the frequency of effect. The risk likely to arise is not well addressed in current ERA. At present the main tool for decision making is the Risk Quotient (RQ), a method used to characterise risk quantitatively. However, used alone Risk Quotients are poor risk communication tools and do not allow for good decision making. Establishing good protection goals that address the acceptability and likelihood of effects is a way forward to improve ERA. There are some proposals on the table to improve the relevance of Risk Quotients for decision making. KEMI has proposed benchmarking RQ against what is currently on the market while ECPA – EEG has proposed calibrating Tier 1 quotients with higher Tier risk data thus replacing a theoretical approach with an empirical one.

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