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international news, comments, features and conference reports

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European Regulatory Conference 2018

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European Regulatory Conference 2018

The 5th European Regulatory Conference was held in Brussels on 7- 8 March. Organised by the European Crop Protection Association (ECPA) the conference was attended by over 500 delegates from 19 Member States who had gathered to listen to a wide range of presentations on the latest regulatory developments in crop protection. The delegates and the speakers representing Member State Competent Authorities, the European Commission, the European Food Safety Authority (EFSA) and industry also participated in some lively debate on the challenges that lie ahead.

SESSION 1 – OVERVIEW OF CURRENT CHALLENGES

Welcome address

In his welcome address the ECPA Director General Jean-Philippe Azoulay said working in the crop protection space was never boring. With the world population increasing and available arable land decreasing farmers will have to produce more food with fewer resources and in a sustainable way. He said there is intense political pressure on the crop protection industry and little or no trust in food production. The industry is very much on the defensive and must find a way to open the door to reconciliation. ECPA intends to invite dissenting voices to openly debate the issues.

Update on implementation of Regulation 1107/2009

Dr Klaus Berend, head of Unit E4 - Pesticides and Biocides - DG SANTE (European Commission - Directorate-General Health and Food Safety) reported on some of the key issues currently impacting on the industry. He said there had been a qualified majority in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) in favour of the criteria proposed by the Commission for the identification of active substances with endocrine disrupting properties. However, Parliament had rejected the criteria and the Commission had been unable to adopt them. As a consequence the interim criteria have remained in force. Interestingly neither Parliament nor the Council opposed the same criteria for substances used in Biocidal Products that were published in Delegated Regulation 2017/2100. Scrutiny of the revised criteria by Parliament and Council ends on 9 April 2018 and hopefully they will be adopted later this year.

In July 2017 the Commission's proposal for a 10 year renewal for glyphosate was finally reduced to five years by Member States (MSs) and was adopted on 27 November 2017, the last day before the approval expired. During the renewal process a European Citizen's Initiative (ECI) – 'Ban glyphosate and protect people and the environment from toxic pesticides' was submitted. This was only the fourth ECI to have gathered the required number of signatories (one million) from at least seven MSs. It had three aims: to ban glyphosate; to increase transparency in the assessment procedure and to achieve EU reductions targets for pesticide use that would ultimately achieve a pesticide-free future. The Commission's reply to the ECI organisers highlighted the need to involve more public authorities in the process of deciding which studies were needed, to enhance auditing of compliance with Good Laboratory Practice (GLP) principles, to publish full study reports to increase transparency while respecting confidential business information, and to exceptionally commission ad-hoc studies in specific cases. Following the concerns raised about the risks posed by glyphosate the European Parliament adopted a mandate that a special committee should be set up to review future policy on the registration of pesticides.

Based on EFSA opinion in 2013 the use of the neonicotinoids (clothianidin, thiamethoxam, imidacloprid) was prohibited on all outdoor plants that were considered attractive to bees. In 2016 EFSA identified further risks to bees from additional data submitted to confirm the safety for bees for the uses still allowed. EFSA has also evaluated data collected in an open call for the review of the 2013 restrictions. The deadline for this evaluation was postponed to February 2018 due to the amount of data to be assessed, the complexity of the request and to give MSs sufficient opportunity to comment on EFSA's draft conclusions. The EFSA conclusions on the risk assessment for the active substances clothianidin, imidacloprid and thiamethoxam were published on the EFSA website on 28 February 2018. The Commission and the MSs will examine these conclusions thoroughly and depending on the outcome of this analysis, the Commission may propose to further modify the conditions of approval.

Since 2013 several MSs have repeatedly granted emergency authorisations under Article 53 for the three restricted neonicotinoids for the same uses on large parts of their territories. The Commission has asked EFSA to assess whether the authorisations granted in 2017 fulfil the requirements in Article 53. EFSA has requested additional information from MSs using the Article 4(7) protocol for insecticides. EFSA opinion is expected in May 2018.

Potential low-risk active substances were prioritised under the renewal process (Annex I Renewal) AIR 4 through a Commission Implementing Decision issued in September 2016 (2016/C 357/05). The low-risk criteria were then amended by Regulation 1432/2017 which sets specific criteria for micro-organisms and for chemicals. Updated guidance on the zonal system and mutual recognition will include accelerated procedure for low-risk products. There is also a specific focus on low-risk and basic substance issues within the ongoing Regulatory Fitness and Performance (REFIT) evaluation.

Dr Berend said the objective of the REFIT evaluation is to ensure that the needs of citizens, businesses and public institutions are met efficiently and that the legislation is fit for purpose. The roadmap, content and scope along with the main evaluation criteria were published on 17 November 2016 and the study was to be carried out by an external contractor between July 2017 and June 2018. The first workshop involving a limited group of MSs and stakeholders was held in September 2017. Further evidence will come from surveys of the public, stakeholders, small and medium enterprises (SME) and MS Competent Authorities.

The overview report on the audits carried out in seven member states (MSs) revealed that legal deadlines are hardly ever respected regardless of the process and this results in delayed market access to products and the non-availability of appropriate tools for farmers. The delays and deficiencies in the authorisation process are also one of the main reasons for the high number of emergency authorisations. National requirements were being applied in six out of the seven MSs and this was not foreseen in the legislation. Dr Berend said it is an additional burden for applicants and hampers cooperation between MSs and leads to duplication of work. Re-evaluation also ignores the uniform principles, is not lawful and undermines the credibility of the work carried out by the zonal Rapporteur Member State (zRMS). Some good practices were detected during the audits including fee reduction for potential low-risk products and the enhanced scrutiny of emergency authorisations under Article 53 for the same use.

Regulation 1107/2009 – challenges for today and the future

Dr Martyn Griffiths, Bayer's senior regulatory policy manager for the Europe, Middle East and Africa (EMEA) region and chair of the ECPA Regulatory Policy Team, said genotoxicity had been a major issue since 2016 impacting on the approval of active substances. Regulation 1107/2009 was designed to decrease vertebrate testing but the genotoxicity issue has had the opposite effect. Five substances have been non-approved and seven more are pending. The issues include the lack of endpoint setting after peer review despite complete toxicology packages being available. Dr Griffiths said insufficient consideration has been given to the weight of evidence approach. There were no clear guidelines from EFSA at the time of submission as pre-submission meetings with it are not possible and the opinion comes at the end of the process.

Dr Griffiths said it is seven years since 1107/2009 came into force. During this time 57 new substances have been submitted, 22 substances have an approval vote and MRL EIF, only eight products have been authorised and a further 14 product applications are still pending. Average delay since MRL EIF is 15 months compared to the maximum six months given in Article 37.3. Under Directive 91/414 an average of 8.6 new substances had been approved every year. Under Regulation 1107/2009 an average of 3.3 substances have been approved each year and only 1.2 on average have been commercialised. After seven years only eight new active substances with product authorisations have been commercialised in a least one MS. Innovation is being hindered for both chemical and low-risk substances equally.

Dr Griffiths said ECPA continues to focus on improving the working of the current legislative framework. It supports REFIT and its key proposal is for a data call-in system that would ensure a predictable regulatory process. Other improvements proposed by ECPA and supported by the International Biocontrol Manufacturers Association (IBMA) and the European Crop Care Association (ECCA) include more realistic deadlines (current timelines are not achievable without increased resources at EU/MS level) and decoupling of the active substance and product reviews. It also calls

for harmonisation across EU chemical legislation – pesticides, biocides, REACH and cosmetics. It would also welcome an amendment to the General Food Law that introduces measures which allow for more transparency and scientific discussion. Bayer has itself set up a transparency website that gives increased access to its scientific data.

Main issues for national authorities in the AS and product evaluations

Ana Bárbara Godinho de Oliveira is head of the department in charge of authorising pesticides at the DGAV in Portugal. She suggested that after seven years Regulation 1107/2009 was perhaps itself a candidate for substitution. More seriously, however, she felt the industry should be seeking to strengthen the regulation because it has been proven to be useful and workable. 1107/2009 requires a comprehensive framework of procedures and timelines, a pragmatic approach, cooperation and good communication between MSs, trust, and harmonised risk assessment and decision making. She said dividing Europe into three zones had forced the MSs to improve cooperation and to build trust in each other. It has created a uniform and harmonised way of working where mutual recognition is important. The weakness, however, is that it still needs specialised and competent human resources, requires improved IT systems and a reduction in administrative workloads. As a result there was a loss of active substances and delays in the time taken for new active substances to come to market.

Opportunities to improve the legislation and implementation

Pavel Minar, head of the PPP Division at UKZUZ in the Czech Republic, said the REFIT evaluation was a rolling programme to ensure the regulatory scheme was fit for purpose, that regulatory burdens are minimised and all simplification options are identified and applied. Dr Minar presented some of the issues that the Central Zone MSs had put forward for the REFIT evaluation to consider. He called for more realistic timelines for most of the processes. He said 1107/2009 was a complex regulatory regime that required more complex assessments and that deadlines were being breached by most MSs. He argued for a conciliation committee and for EFSA to have an arbitration role such as the European Chemicals Agency (ECHA) has in the case of biocides and said there were more and more problems linked to data protection. Other issues that need to be considered include minor uses, stimulating low-risk products and Integrated Pest Management (IPM), taking into account socio-economic factors and a review of the overall toolbox of plant protection products.

During the panel discussion that followed the speakers discussed timelines, pre-submission meetings and centralisation. Dr Griffiths again called for a data call-in system that provides information about what needs to be submitted. Dr Berend said Parliament would not permit changes to timelines. He said some MSs were able to achieve 100% compliance and this was not a matter of applying more resources but better management. Barbara d'Oliveira proposed a centralised system to evaluate active substances but Dr Berend had doubts about the idea and said that a single zone would create even more problems. EFSA and MSs could, however, provide technical support and this might be of more value. Dr Griffiths said industry could be prepared to pay higher fees if there was more predictability and if authorisations were granted at the same time as in other parts of the world.

SESSION 2 – ACTIVE SUBSTANCE EVALUATION UPDATE

Active substance review programme

Mr Wolfgang Reinert, head of Pesticides Sector Unit E4 at DG SANTE, reminded delegates that the purpose of the AIR renewal process was to bring assessments and decisions in line with the requirements of 1107/2009. The fifth batch of renewals AIR 5 involves 66 approvals expiring in 2022, 2023 or 2024. There will, he said, be an overlap with AIR 4. The work programme for AIR 5 has been subject to public commenting in early 2018 and was due to be voted in March 2018. The legal basis for AIR 5 is laid down in Regulation 844/2012, Responsibilities, timelines and allocation of a Rapporteur Member State (RMS) are in Regulation 686/2012. Several substances have subsequently been reallocated in Regulation 2018/155 to take into account the impact of Brexit. Priority is given to active substances that are approved as candidates for substitution or those that might fail to satisfy the approval criteria. Expiry of approval will be extended if the assessment is delayed for any reason beyond the control of the applicant. This is monitored by the Commission and extension is kept to a minimum. In the case of non-renewal the extension period is reset.

Approvals of 325 active substances (around 62%) are due to expire between 2018 and 2024. In AIR 3 a review of 115 active substances is still ongoing. Most of these approvals expire in 2018 and it is

doubtful whether all decisions can be taken in time. In AIR 4 145 out of 163 substances are supported and there is a better spread of expiry dates. Issues impacting on the renewal process include the quality of dossiers, RARs and conclusions as well as insufficient joint dossiers and the general lack of resources. There is also growing political pressure that is hampering science-based decision making.

Member State challenges in the active substance review evaluation: improving cooperation between Member States and EFSA

Dr Luuk van Duijn, director of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) in the Netherlands, said the renewal of active substances was the cornerstone of the EU regulatory system. The implementation of 1107/2009 had meant the introduction of hazard criteria such as candidates for substitution and endocrine disruptors. New guidance had been updated and implemented, universal principles and data requirements were being followed more strictly. Political pressure on the approval and renewal process has increased, he said, and there is now more and more discussion on individual substances. It is clear that the number of active substances will decrease during the renewal process. Approval of new actives is now much slower and low-risk microbials do not fill the gaps quickly enough. Combined with climate change the impact on agriculture could be considerable. The challenge for Competent Authorities is to keep the system functioning within the current regulatory framework taking account of both the organisational and political environment.

The ECPA Conference in 2017 had considered how to align the tasks and responsibilities of EFSA and the MSs and how to improve the assessment process so that management decisions in SCoPAFF are supported effectively. Since then more and more discussion on the assessment report has taken place. There is an agreement that to improve predictability the first focus must be on the pre-submission phase. EFSA is willing to participate in discussions on the completeness of the dossier and possible issues which can arise. Final opinion will be discussed and will involve the RMS and those MSs actively participating in the peer review. A critical review of existing procedures and committees is necessary. Are they fit for purpose, are the right people attending meetings? Progress is being made but it needs to go a step further concluded Dr van Duijn.

EFSA update on active substance review

Dr José Tarazona, head of the EFSA Pesticides Unit, gave delegates an update regarding stakeholder involvement with the EFSA/ECHA guidance on endocrine disruptors (EDs). He said a scoping paper had been published in December 2016 and updated in January 2018. It covered the process for drafting the guidance and consultations to be carried out before the guidance was finalised and adopted. There are differences in the approach with ECHA involving stakeholders during guidance development and EFSA launching a public consultation on the draft. In total there had been 3100 comments and a significant amount of redrafting is required. All comments will be published as background documents to the guidance.

With regard to EFSA's Pesticide Steering Network (PSN) action plan for improving the peer review process, Dr Tarazona said it had been finalised and published as an EFSA Technical Report. Most of the actions included have been implemented. EFSA will support the RMS through the full process. The scope of the action plan covers all steps during the peer review process - preparation of the summary dossier by the applicant, preparation of the Draft/ Renewal Assessment Report (DAR/RAR), peer review and the finalisation of the EFSA conclusion. The aim of the actions is to enhance the overall quality of the process, to optimise different steps, to improve the efficiency and to facilitate the cooperation between EFSA and MSs. An ad-hoc working group will conduct the accordance /completeness check of the summary dossier, also an accordance check of the DAR/RAR. Similarly, it is aimed to agree on EU wide criteria for what is considered a good quality DAR/RAR in order to ensure sufficiently high level of details in the study summaries as well as to ensure comprehensive and transparent evaluation and presentation of the data.

The risk assessment output – what options for risk managers

Dr Martin Streloke of the BVL, which is responsible for authorising plant protection products in Germany, is an aquatic ecotoxicologist with special interests in regulatory risk assessment and management. He said there were three main processes under 1107/2009. These are EFSA (risk assessment), Commission/PAFF (risk management) and MS authorisation (risk assessment and risk management). The three processes are all connected and MSs are working in the EFSA and the

Commission processes. However, EFSA and the Commission have no or very little involvement in the MS process. He said the whole regulatory system would benefit from better connecting the EFSA and MS authorisation process. He said there are many active substances facing problems in the approval process. Examples were given of issues that EFSA concluded could not be finalised but where SCoPAFF agreed on renewal of approval with a request for confirmatory data. This creates problems for MSs either because there is no reason not to authorise the plant protection product (PPP) at national level when the active substance has been renewed, or the identification of a risk by EFSA results in no decision by the MS until the confirmatory information is assessed. The system would be better served if EFSA could quantify the risk and state if the risk can be managed. However, approval of active substances and subsequently authorisation of products should be possible if the various problems, often handed down to the national level, can be effectively managed.

Key hurdles from assessment to decision making

Jane West, head of Syngenta's EAME regulatory portfolio and a member of ECPA's Regulatory Policy Team, commented on the key hurdles to be overcome in moving from assessment to decision. She said some 20% of AIR 2 substances are still under review and 90% of AIR 3 substances. There are delays in the timelines and documents are often out of date. AIR 4 and 5 will overlap so AIR 5 needs to be delayed or MSs will be working on 4 and 5 while still working on AIR 3 in parallel. There is already a draft programme agreed for AIR 4.

The current EU review process is challenging for applicants and the outcome is increasingly unpredictable. The findings from the ongoing REFIT evaluation of 1107/2009 will be too late – an effective process is required now. There is a need to give serious consideration to a data call-in system which would provide applicants with some clarity on what is required and the regulators clarity on what exactly to review. It would also provide a mechanism for further data to be requested to address any open questions. Ms West said there are a number of short term solutions which do not require legislative change. These include pre-submission meetings involving EFSA in order to avoid issues only visible late in the process. Clarity on the use of the derogations and a harmonised classification process would be helpful too.

SESSION 3 – PRODUCT EVALUATION CHALLENGES

Article 43- where's the silver bullet?

Christian Prohaska, head of the department for Residue Behaviour at AGES in Austria, focused on Article 43, renewal of authorisations. He said allocation of AIR 3 containing products is active based if possible. It should be the same RMS or Co-RMS as for the renewal of the active. This avoids coming to different conclusions for comparable products. Not all MSs are happy with this approach because of the fee issue. For some active substances such as ethofumesate a high number of products will be allocated to one zRMS. The allocation of product evaluation is largely based upon the proposal from the applicant, but this may lead to increased discussions if Category 4 studies are identified.

A large number of AIR 3 containing products in the Central Zone are with the UK. Whether the UK will act as a zRMS in the future is doubtful and some applicants have already switched from the UK to other zRMSs. Further allocations to the UK will probably not be considered although the possibility of using UK assessment after Brexit is under consideration.

North Zone update

Vidbeke Moller, deputy head of the Pesticides and Biocides Division in the Danish EPA, said the North Zone was functioning well. Guidance for risk assessment and risk management was harmonised and close cooperation had been achieved through workshops, email groups and teleconferencing. The North Zone was also making best use of detailed planning and workload distribution and there was above all flexibility and commitment to make the system work. However, there had been a lack of progress at the EU level over issues such as the ED criteria, co-formulants, safeners, synergists and adjuvants. Decisions on the approval or re-approval of actives had been slow because issues that should be resolved at EU level have been transferred to the zonal/national level (eg confirmatory data and Category 4 data). There is also inconsistency in assessment and decision making and a lack of agreement at a scientific/EFSA level. Ms Moller said the development and adoption of guidance documents has been too slow.

South Zone update

Dr José-Louis Alonso Prados, technical director at the National Agronomic Research Institute (INIA), commented that agriculture in the South Zone is more diversified than in the other two zones. Therefore, there are a high number of authorisations and uses. He said the zonal system has helped all MSs in this zone to learn from each other with regard to assessments and authorisations. One MS acts as chair and another as co-chair. The chair always has the support of an 'experienced' MS. The MSs communicate every two months via a teleconference and meet face to face once every year.

Industry view on key challenges in product authorisation

Jeanne Roederer is Adama's regulatory strategy expert. She is also chair of the ECPA Product Authorisation Expert Group. Speaking on behalf of ECPA, she said the delays in granting mutual recognition and zonal authorisations were not necessarily related to insufficient human resources at the national authority level. She pointed to a lack of harmonisation for evaluation methodologies and the growing complexity of requirements. Repeated evaluations were delaying decision making and this can only be overcome by building greater trust between the MSs. Since previous regulatory conferences mutual recognition has increased but overall the zonal system is not working as efficiently as it should and this is in turn reducing the toolbox available to farmers. There has been more pragmatism on the acceptance of Category 4 data for Article 43 and improved alignment of process within the zones and, she said, emergency uses are working. She suggested that there should be a single evaluation for the three zones for draft Registration Report (dRR) sections that are not related to environmental or agricultural conditions. The outcome of zonal meetings should be shared, pre-submission meetings should be allowed and a zonal helpdesk would help too. Key messages to industry are - aim for excellence in dossier quality, use the Guidance Document (GD) valid at the time of submission and do not re-evaluate the data. Ms Roederer stressed the importance of agreeing the rules within the zones and effectively communicating them. She said for Article 43 the zonal steering committee (ZSC) or the inter-zonal steering committee (IZSC) should decide on the rules for mixtures and stick to them.

Challenges and focus of the Post Approval Issues Group

Darren Flynn, head of the PPP Active Substance Team at the UK's Chemical Regulation Division (CRD) and current chair of the Commission's Post Approval Issues Group, said the group is a working party of SCoPAFF and has been mandated to discuss particular issues. Its decisions and opinions, however, must go back to the Standing Committee for agreement. He outlined some of the deficiencies in the current regulatory system which the group was addressing and solutions they are implementing via new guidance. He focused on changes to the Renewal GD (Article 43) and the Zonal Evaluation and the Mutual Recognition GDs. Appendices have been deleted, updated and new ones included. Other GDs being updated are Technical Guidelines on the presentation of draft Registration Reports and the GD on Data Protection. All of the changes need to be noted, published and used, he said.

SESSION 4: SCIENCE UPDATE AND LEGISLATIVE REVIEW

Update on endocrine disruption and other scientific guidance issues

Karin Nienstedt works in the pesticide and biocide unit at DG SANTE. She opened session 4 of the conference. She said while the ED criteria for biocides will apply from 7 June 2018 to new and ongoing applications, for pesticides, however, the same criteria are still under the scrutiny of the European Parliament and Council until 9 April 2018. If not opposed they will be applicable from November 2018 onwards. The new scientific criteria will replace the interim criteria which were not fit for purpose. They are based on the three elements of the 2002 WHO/IPCS definition of an endocrine disruptor – endocrine mode of action, causality/correlation and adverse effects. The principles are all available scientific information (in-vivo, in-vitro and in-silico), animal evidence and weight of evidence. During the negotiations MSs requested a transition period of six months and a review clause (every seven years). In parallel to the decision making on ED criteria a joint EFSA/ECHA GD has been developed, with the involvement of the Joint Research Centre (JRC), on the implementation of the criteria. This is expected to be available by mid-2018. The GD was the subject of a workshop on its applicability held in February 2018 with MSs and stakeholders involved. An amendment to the implementation Regulation 844/2012 which applies to ongoing applications is also necessary. This provides a 'stop the clock' opportunity at the level of MS, EFSA or the Commission in order to obtain

and assess additional data for pending applications and to decide if the new criteria for EDs are satisfied or not.

Scientific developments likely to impact on regulatory implementation

Dr Gábor Tőkés is the deputy director of the NÉBIH Directorate of Plant Protection in Hungary and head of authorisation for pesticides and yield enhancers. He said Regulation 107/2009 Article 36(1) states that the MS examining an application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using GDs available at the time of application. He said GDs are the key links between science and decision making. They ensure that there is a uniform response by all parties to the legislation and that decisions are consistent and predictable. While Commission and EFSA guidance is generally produced in the form of GDs there are also EPPO standards for plant protection products published by the European and Mediterranean Plant Protection Organisation (EPPO). Additionally there are OECD guidelines and Environmental Protection Agency (EPA) guidance which can be used if there is no Commission/EFSA/EPPO GD available. All of this can sometimes be difficult to follow and can occasionally lead to 'information overload.' GDs require a considerable amount of expertise and lots of time to produce. The smaller MSs who rely on GDs are often unaware of their existence or need the help of experts to understand them. There can be contradictions between the documents and sometimes there are parallel papers such as scientific opinions and draft GDs in the system too. He said the Commission should encourage smaller MSs to have more expertise available. Articles 74 and 75 of the Regulation are not enough. The Commission and EFSA should also be carrying out sufficient training on how to interpret GDs.

Industry viewpoint on guidance documents under discussion

Dr Peter Campbell, Syngenta's head of Product Safety Research Collaborations, speaking for ECPA, gave an update on EFSA Environment guidance/opinions referring to bees, non-target terrestrial plants, non-target arthropods, soil, birds and mammals, and amphibians. He said the industry supported periodic updates of guidance based on new scientific developments. However, this should include an assessment of the strengths and weaknesses of current guidance and the proposed new guidance. He was critical of the Bee GD which he said was over conservative with regard to tier 1 because it fails all insecticides and is combined with new field study specifications which cannot be met. This has resulted in all insecticides being un-registerable. Also there are many data gaps and risks identified for herbicides and fungicides with no inherent bee toxicity. He said ECPA had drafted a revision proposal which is receiving interest from MS authorities.

Dr Campbell said EFSA expects Specific Protection Goals (SPGs) to be agreed by risk managers within two years of publication of the scientific opinion. Only then does work on a GD start. He said ECPA acknowledges that risk managers in the Commission and MSs should set the SPGs and guidance but he suggested there was a role for industry to say whether the proposals are feasible and practical to follow and to be able to communicate their potential impact.

Legislative Review

Euros Jones, a partner at ERM and formerly director of Regulatory Affairs at ECPA, introduced a panel discussion on legislative review. He said the findings of the REFIT evaluation should be available in June 2018 and there was also the proposed amendment to the General Food Law around transparency to look forward to later in the year. Additionally there are three groups looking at the authorisation of plant protection products. SAM (Scientific Advice Mechanism) is a high level group of seven scientific advisors to the European Commission who have replaced the EU's Chief Scientific Officer post. They intend to give an opinion on the 'Authorisation processes of plant protection products in Europe' from a scientific point of view. In addition to the Parliament's Environment Committee which is looking at the regulatory processes with a focus on 1107/2009 there is now a new 'special' Pest Committee. It was set up by Parliament recently in response to the concerns raised about the risk posed by glyphosate. This committee will address the recent European Citizens Initiative, conflict of interest and the ability of EU agencies to fulfil their obligations. It will report back to Parliament by the end of 2018. What will come out of these initiatives, what can be improved going forward and what can be improved within existing legislation is at present uncertain.

Dr Berend stressed the need to address societal concerns about the use of pesticides. Otherwise, he said, the future of the industry is bleak. He said the Commission follows Science but is then criticised by industry in the case of the neonicotinoids or by the other side in the case of glyphosate. REFIT he

said was not a proposal but should tell us what is working and what is not. Parliament will make the proposals and if the regulations are amended we do not know what we might get. Timelines are an issue because there is no time for compromise. There is also too much room currently for national divergence. There should also be much stronger co-ordination on how to use guidance.

Dr Tarazona added that all parties need to work together to ensure there are sufficient products and better products to support EU agriculture. On the subject of guidance, he said it was a map that covers everything. Science is complex and therefore it is not possible to produce a simple map for the EU. We also have to accept that there is real variability between MSs. EFSA, he said, is working on new guidance on public consultation and how to bring others into the consultation process.

Ian Wheals, head of EAME Regulatory Policy at Syngenta, said we need to safeguard EU agriculture. Resources should whenever possible be freed up in MSs to focus on innovation and to register new products such as the introduction of low-risk and biocontrol products. Much can be done within existing legislation. We need to decide at what level there should be changes and whether there is scope in the legislation to make improvements such as the introduction of data call-in. He said it will take lots of effort to build trust and develop common approaches.

Conclusions & close

There were some clear messages from the conference. The renewal workload is much bigger than the system is able to cope with and although zonal cooperation is improving, national requirements keep slowing things down. In 2018 the Commission's REFIT evaluation as well as the new European Parliament's Pest Committee will look carefully at how Regulation 1107/2009 is functioning.

Jean-Philippe Azoulay drew the conference to a formal close. He thanked all those who had contributed to its success with particular reference to the chair Coralie van Breukelen-Groenveld of Bayer and Rivka Benatar who was retiring from her role at ECPA. He said there had been much progress regarding the regulation of pesticides but progress is still too slow. There was a lot of commitment to improve but there were still many challenges ahead. Science, he said, needs dialogue and while perception is considered to be reality dialogue can help to take us beyond perception. He said everyone should be searching together for solutions and there should be no more blaming each other. Listening to opposing views opens new perspectives. Mr Azoulay also took the opportunity to introduce ECPA's new Regulatory Affairs director Peter Day. He also informed the conference delegates that the 2019 European Regulatory Conference would be held in Ghent from 22-23 May. It will be organised in co-operation with the 14th IUPAC International Congress of Crop Protection Chemistry and will be hosted by Ghent University at the International Convention Centre (ICC).

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