

# NEWSLETTER

SCC Newsletter Vol. 15, No. 6, October 2015

## LAST TIME IN BARCELONA – AgChem Forum 2015

### SPECIAL EDITION

#### Dear Subscribers,

This edition of the Newsletter comprises a detailed report on the last CIR Conference in Barcelona focused on the AgChem Forum.

A review of selected presentations on regulatory frameworks is given for your convenience.

Well, it is time to say good-bye to Barcelona...  
... the next CIR conference will be held in Nice / France from 7-8 September 2016.

However, in the fast-moving world of regulation, SCC is ready to keeping its customers on a successful course. Regardless of whether your needs are in scientific and regulatory support for agrochemicals and biopesticides, biocides, chemicals, cosmetics, archiving solutions or Task Force management, SCC can provide you with high quality service and consulting.

Furthermore, we appreciate your feedback and comments regarding the SCC Newsletter. Please drop us an E-mail at

[newsletter@scc-gmbh.de](mailto:newsletter@scc-gmbh.de)

Finally, all of us here at SCC would like to wish you a nice fall and an opportunity for some recreation before the next challenges coming up ahead of us.

Dr. Friedbert Pistel

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## AGROCHEMICALS



### AgChem Forum, Barcelona 23 - 24 September 2015

In this year's AgChem Conference in Barcelona from 23rd to 24th September, Dara O'Shea of the Food and Veterinary Office (FVO) of DG SANTE was giving the first keynote lecture. The office is based in Ireland and is obliged with controlling and monitoring through audits various aspects of the legislation. They are doing approximately 220 audits per year, of which 75% are within the EU, and 25% in third countries. The audits result in reports with re-recommendations. Corrective actions are also followed up by the office.

He recalled what Regulation 1107/2009 is intended for quoting from the recitals:

- to establish a high level of protection of both human and animal health and the environment
- to safeguard the competitiveness of community agriculture, the free movement of goods
- to avoid any duplication of work
- to reduce the administrative burden

From his auditing experience he did not see these being implemented. Especially, with respect to mutual recognition he compared the EU with 28 independent kingdoms, instead of three zones. Is there mutual recognition ongoing? No, it is struggling was his observation. He identified national requirements as one point which is still up held in many Member States. Other problems are more systemic and all Member States are affected, such as shortage of staff. He referred to the Dublin workshop in June 2015, where such issues have been addressed. Nevertheless, he observed huge delays, significant administrative burdens, a lack of co-operation, and in his assessment the current workload will increase.

He feared there will be continuous delays in the authorisation process but asked, what, if any, consequences Member States have to face that consistently breached legal deadlines with respect to authorisations? The office will also contribute with its audit experience to the Regulation 1107/2009 review.

The office is also auditing the different enforcement system of the Member States, which is very important because otherwise non-compliance undermines the regulatory system itself. The audits address all participants in the market from manufacturers, re-packer, importers, distributor and retailers to farmers and non-farm and users. With respect to formulation analysis it was his observation that approximately 10% of all Plant Protection Products are illegal. He criticised that most Member States are content to check the level of active substance in a formulation, but do not check the composition. The speaker emphasised that we are not content with authorising the level of active substance, but the whole composition!

Details of their reports on Member States and an overview report can be viewed on their homepage: [http://ec.europa.eu/food/food\\_veterinary\\_office/index\\_en.htm](http://ec.europa.eu/food/food_veterinary_office/index_en.htm)

The second keynote speaker was Bénédicte Vagenende from the Pesticides Unit of EFSA. She emphasised that the vision of EFSA is openness, transparency, and scientific-based approaches. The pesticides unit supports the scientific panel for pesticides with opinions, Guidance Documents, and ad-hoc mandates. Co-ordinates the peer reviews of active substances and providing conclusions for the EU decision makers. Last but not least EFSA supports the maximum residue level system with reasoned opinions and annual reports.

EFSA has published 40 conclusions and 40 technical reports in 2014. As well as health assessment of chlorpyrifos, aquatic risks of imidacloprid, the bee study protocols and a risk of neonicotinoids in foliar uses to bees. Currently ongoing is a data call-in for the risk assessment of bees with respect to neonicotinoids. An assessment of flumioxazin needs to control serious dangers to plant health. New elements to the EFSA conclusions within the peer review system will be the assessment of cut-off criteria, for which EFSA will co-operate with ECHA on the classification and labelling proposals.

The literature search requested in Regulation 1107/2009, which calls for a detailed review of scientific peer-reviewed literature, is also detailed in an EFSA Guidance Document. It is to ensure an exhaustive review with a minimised bias, which is then to be incorporated into the dossier and assessed. The intention is to improve the assessment of an active substance with contribution from the scientific community.

The endocrine disrupting effect assessment of active substances has already been done by EFSA on the basis of the current preliminary criteria. Since 2014 EFSA has published 15 conclusions on new active substances and 23 on renewals that explicitly summarise the assessment of potential endocrine effects since the entry into force of Regulation 1107/2009, 23 EFSA conclusions were published, where no endocrine disrupting concerns and no data gap with respect to ED assessments were identified, 2 where no endocrine concerns were identified, however data GAPS with respect to ED were identified and 13 conclusions, where concerns have been identified with respect to the endocrine disrupting properties.

MRL applications should be seen as part of the active substance dossier, but the conclusion reached from that dossier must be a stand-alone document. EFSA foresees that there will be two GAP tables in future dossiers, one detailing the representative use and a second one covering all MRL applications.

EFSA is currently planning a database for updated lists of endpoints from conclusions and reasoned opinions following the EFSA assessment. It is expected that the database will become available at the end of 2016.

The Guidance Documents EFSA issues covered those aspects where the science is well established and focused on risk assessor's needs. They should be concise and practical. Wherever possible, they should be supported by a calculator.

EFSA is working currently on a number of projects one of them being a Guidance Document on the residue definition which is expected to be finalised by mid-2016. In the area of environmental fate and ecotox a landscape, pan-European risk assessment is currently being thought about.

The major tasks for the pesticide steering network activities, as seen by the speaker, are to plan and monitor the risk assessment process, to integrate risk assessment and MRL setting to coordinate with the European Chemicals Agency (ECHA) and to give advice on the prioritisation and risk assessors needs in the development and the updating of risk assessment Guidance Documents.

The rest of the day's presentations were dedicated to issues of the zonal authorisation starting with Anne-Marie Dillon from the Irish Authorities. She reported from the EU Workshop on this issue in Dublin from 2 - 4 June 2015 in which the Commission, 26 Member States, and the Industry Associations IBMA, ECPA, ECCA, and EFSA participated. One of the issues raised were national data requirements still in place in many Member States. The speaker emphasised that the Member States need to reflect on these requirements.

There is an obligation for them to report back to their zonal steering committees by the end of 2015 as to why they do have and need to keep these data requirements. Furthermore, the workshop was also reflecting on mutual recognition and the speaker advertised the advantage of mutual recognition for the Member States in saving work. With respect to Article 43 re-authorisations an amendment of Regulation 1107/2009 would have been the preferred way. As this was not possible, Guidance Document SANCO/13169/2010 was developed and noted in the standing committee of July 2015. The final report of that workshop will be published on the Commission homepage.

In assessing Plant Protection Product applications she emphasised that the harmonised endpoints must be used unless there is need to change, to get a safe risk assessment. The upcoming EFSA database on endpoints will be extremely helpful in this respect.

Christian Prohaska from the Austrian Authorities was elaborating on some of the issues raised in the previous presentation. He was detailing the workload capacities and timelines that are being spent by the Authorities. Every Member State has failed and will continue to fail to keep the deadlines prescribed in the legislation. He asked to consider the additional workload with respect to the comparative assessment, Article 43 applications and the renewal programme of the active substances. While welcoming pre-submission meetings, he clearly emphasised that Member State Authorities cannot be seen as consultants, answering all open questions. Contrary to the previous speakers, his assessment is that more experts in the Authorities might not solve all the problems. It is more important that Member States might reflect on the organisation within their territory. Secondly priority setting is important for national Authorities, as well as work sharing within the zone and between the zones. But of utmost importance is the harmonisation of all data requirements. Austria has no national data requirements left.

Within the Central Zone it is an agreement that no new studies are accepted during the commenting period, although some Member States, such as Austria, Germany and Poland, are required by their national laws to do so. With respect to new active substance data in the product assessment, he was in full agreement with the previous speaker, not to review such data.

Harmonisation is being brought forward. The speaker quoted a number of workshops which were particularly addressing this issue with respect to toxicology, ecotoxicology and fate and behaviour.

The draft registration report (dRR) is designed to be a stand-alone document with no reference to other dRRs or national assessments with the exception of:

- Amendments of authorisations such as new use
- Article 34 applications
- EFSA conclusions
- D(R)AR
- EFSA reasoned opinions

Mutual recognition (Article 40) is, according to the speaker, a good way of saving a lot of work for the Authorities. According to legislation such registrations must not be refused on efficacy grounds only. But he also conceded that this is not true in practice. Some Member States refuse applications, if the efficacy is not assessed in the corresponding EPPO zone. The speaker advised the Authorities not to reopen the file in a mutual recognition process, but to trust the assessment of the previous Authority doing the risk assessment allowing only an adaptation for national risk mitigation measures. He conceded that, within mutual recognition, data protection has become an issue with regard to the referenced product in the Member State.

A feedback from the Southern Zone Member States was delivered by José Luis Alonso-Prados of INIA in Spain. He quoted data from Eurostat 2015 on the sales of Plant Protection Products, underlining that the Southern Zone, with 59% of the total sales, is using most of the Plant Protection Products in Europe. With 37% of total of sales, the Central Zone is second and the Northern Zone, with only 4% of the total, is last. Also, the application rates in kg/ha are significantly higher in the South with an average of 4.68, versus 2.64 and 1.26 in the Central and Northern Zone, respectively.

The southern Steering Committee is currently working mainly on the allocation of zonal Rapporteur Member States, as well as the refinement of the risk assessment on birds and mammals, a dRR for major label extensions, a dRR for Article 51 applications and the allocation of the zonal Rapporteur Member State under the Article 43 workload.

During the evaluation of an application for authorisation no additional studies will be accepted during the commenting period. A stop of the clock is only possible before the commenting period. On-going studies must be addressed before the submission and the applicant has to declare as to when they will be submitted.

Mutual recognition in the Southern Zone is possible and has significantly increased in number, also when the original evaluation was not done under Regulation 1107/2009, but under the uniform principles, mutual recognition is possible. Nevertheless, this creates problems as no proper RR is available.

Currently there are Guidance Documents under preparation to as addressed the comparative assessments. As this is necessarily a national issue, these Guidance Documents are prepared by the Member States.

For a mutual recognition to be acceptable to Spain the Authorities need Part A of the original RR, as that contains the final conclusion by the Member State.

An industry feedback was provided by Monica Teixeira from Syngenta. She observed that of the nine Member States in the Southern Zone only seven are acting as zonal Rapporteur Member States. Also there is a big discrepancy between the individual Authorities. For evaluations of new formulations as well as mutual recognitions the evaluation timelines prescribed in the legislation are exceeded in significant numbers by the Authorities. She analyses that this is due to a lack of resources, although Article 75 of the Regulation stipulates the necessity for adequate resources. In addition, a lack of harmonisation is observed. She then rhetorically asked, whether agriculture is important for the Southern Member States? And: whether it is possible to develop a competitive agriculture without agrochemicals?

Industry proposes that draft Guidance Documents should be tested prior to noting them. Furthermore, clear timelines should be set for the implementations of Guidance Documents in the zone and to set up workshops on dRR preparation to improve their quality.

Finally, Claudio Mereu of fieldfisher was addressing the zonal process from a more legal perspective. He clearly stated that the zonal process is at the core of Regulation 1107/2009. The rationale behind this kind of assessment goes even deeper than the Regulation, as it is already enshrined in the treaty, which requests the free movement of goods. In addition, at avoidance of duplications of work, co-operation and trust are also important. He emphasised that the zonal evaluation is the rule and everything else deviating is derogation. The derogation, he felt the need to emphasise again, cannot, as the word is already implying, be the rule itself, although current observation seems to imply exactly that. After running through the shortcomings of the Member States, he also gave some advice on how to dispute decision. It is important to identify exactly where and when such a dispute arose and to keep detailed written records of it. Information or complains can then be filed with either DG SANTE, the zonal Steering Committee or the Community in general. He indicated that usually there are also administrative possibilities within each Member State, such as the "recours gracieux" in France. Of course, court proceedings are also possible as a final resort. He referred to the biocide situation were ECHA actually has a board of appeal which has both, technical and legal staff to address complains by applicants. Giorgos Georgiannakis of DG SANTE presented the Plant Protection Products application management system

(PPPAMS), which is intended to improve the evaluation system of products. It is required by the Regulation, in particular Articles 39, 57 and 76, the last of which has been superseded by Article 36 of Regulation 652/2014. The database is expected to improve information flow to all sides involved. Industry is to submit their information on applications to the zonal system into the database and, subsequently, the Member States are to use that entry and to complete it with their evaluation. The database will not contain full dossiers, but the GAPs, classification and labelling, as well as the authorisation will be included. The latter will also be available to the public. It is intended that all types of applications are to be included, eventually. The system will send out emails to the users, which are classified as message for information (MFI) or message for action (MFA). Details, training and further information is available from the homepage:

[http://ec.europa.eu/food/plant/pesticides/authorisation\\_of\\_ppp/pppams/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams/index_en.htm)

The southern Member States' feedback was given by Thierry Mercier presenting Léa Riffauts' slides (both ANSES). The southern Member States now have decided on their zonal Rapporteur Member States for Article 43 applications. They have identified, after having deleted clone and duplicate entries, 338 products that need to be re-authorised under this procedure. Of these, glyphosate is for example present with 127 products. To economise on the evaluation the Authorities will apply the risk envelope between individual applications. Currently France has accepted 40%, followed by Italy with 23%, Spain with 22%, Greece with 8%, Portugal with 5% and Croatia with 1% the role as zonal Rapporteur Member State. The focus in the evaluation will be the applicant's justification for CAT 4 missing studies according to Article 43 (6). Also the technical and scientific justification that the conditions of Article 29 are still met is important.

Aurélié Dhaussy speaking on behalf of the ECPA was reviewing many aspects of the product authorisation, but started out with approval assessments. All 29 AIR2 substances' RARs are available, but only few voted upon. Any extension of approval until June 2016 has already been granted. It is important to note that the old data requirements for Plant Protection Products apply to re-authorisations related to these re-approvals. For all AIR3 substances, of which the review is currently ongoing, the new product data requirements will apply. For all substances which are evaluated subsequently, i.e. which have an expiry date starting with January 2019, nothing has been settled yet and, in addition, it will be a very extensive programme. With respect to the AIR2 substances, she stated, that unrealistic timelines were assumed, as the complexity of Regulation 1107/2009 was underestimated. She emphasised, that we are in the process of renewal of active substances which have been through the same system of evaluation before and

have been approved as safe. An extension of product authorisation should therefore be possible and no products should be removed from the market for administrative reasons.

Classification and labelling is coming into focus, as it has consequences on the evaluation of active substances. With the policy shift intended, it seems that the Commission is willing to not approve active substances, rather than to ask for confirmatory data. According to ECPA's assessment 1 of 3 active substances will be affected. Another critical area is the interim criteria of endocrine disruption. Again, the Commission decision should be based on the ECHA evaluation rather than on EFSA's. The Commission currently seems to be willing to rather withdraw the approval for an active substance based on these interim criteria, than to wait for confirmatory data as already stated above.

Product re-authorisation is certainly associated with very challenging timelines. It is the assessment of ECPA that they will not and cannot be met. ECPA is asking that mixed products are to be reviewed only once and that the focus of the assessment should be new information which must be evaluated on the standards of Guidance Documents in force at the time of submission. The evaluation must be risk-based, not hazard based! She called upon Member States to handle Article 43 with pragmatism.

Important points were addressed in the subsequent question and answer session. An application is needed for each product after each active substance re-approval, also from mixed products. Mixed products re-approvals, which are within one year, can be dealt with in one dossier at the latest date of re-approval. This one year difference should be based on the original expiry dates prescribing the timelines for the re-approval. If there is a delay the applicant of the product should not be held responsible. Under Article 43, full dRRs must be submitted with all points properly address. The new information is to be highlighted.

With respect to comparative assessment Ireland stated that it is sufficient to receive the necessary data at the time when Ireland will do the evaluation, i.e. if Ireland is a concerned Member State the data should be available when the concerned Member States start their evaluation.

The second day started off with a "confrontation" on the subjects of candidate for substitution and comparative assessment. Maarten Trybou of the Belgian Authorities was taking a pro stand on the motion, while Gordon Rennick of the Irish Authorities and Markus Kruse of DuPont were arguing against. Maarten Trybou first quoted the recitals of Regulation 1107/2009 to elucidate the intentions of the legislators, which were to achieve a high level of protection and, at the same time, safeguard

community agriculture. He conceded that there is a need for Plant Protection Products to grow our crops and, if there were enough safe Plant Protection Products available, a substitution of those which were not as desirable as the majority would be pertinent. He immediately clarified that in Europe, and particularly in Belgium, there are not enough such products available today! And thus substitution should be kept for the exceptional cases where a clear benefit for society is given.

He then described the Belgian approach. Substitution, as he clearly stated and was confirmed by all other speakers, is strictly a national issue. Belgium has a Guidance Document, as well as an application form. If there is minor use for a product, no substitution will be implemented. This will already cover 90% of all products on the Belgian market. No comparative assessment will be done for duplicate products or parallel trade permits, which will be evaluated together with their reference product. As comparative assessment is dealt with use by use, the alternative uses have to score better on all aspects, i.e. have to have less risk mitigation. As the UK, Belgium also clearly stated that non-chemical measures are in general not considered to be suitable substitutes for professional uses; substitution might occur for the non-professional uses. As to optional comparative assessments, also addressed in Regulation 1107/2009, Belgium will not authorise products that are less safe than already existing products, i.e. a powder formulation will not be authorised, if a liquid formulation is already on the market.

As the biggest advantage of comparative assessment he stated political issues. The Authorities will be able to address the public, by clearly stating that the available products have been checked and there are no alternatives available. In his view this will increase the awareness of the necessity of the authorised products.

Gordon Rennick of the Irish Authorities was against the motion, by quoting that Directive 91/414 already removed 800 "old" active substances from the market. Since 1991 less than 200 new active substances were introduced and even less progress has been made with new modes of action. He, although conceding that substitution is related to nationally authorised uses, criticised the inflation of Guidance Documents. There are EU, EPPD and individual Member State Guidance Documents. He then presented many examples, from Ireland, where in many crops and many pests, resistance has occurred. For him, very clearly, the comparative assessment is a complete waste of time for the Irish Authorities, which would be much better spent on mutual recognition and thus introducing new and more effective products into the Irish market. Finally Markus Kruse of DuPont declared the comparative assessment to be completely unnecessary, as all the

authorised Plant Protection Products are, by having been assessed in the system, of low risk and acceptable. He completed the examples of Gordon Rennick with a detailed description of a big case study in Germany, *Phytophthora infestans* in potatoes. Although, there are a total of 60 products on the market and 15 products of those cover 94% of the treated areas, with only 13 different modes of action. He then detailed how at different stages of the growth of the potato different products have to be applied and cannot be substituted by the general description of use in potatoes. The farmer has many different reasons to choose a given product and his assessment of the situation, depending on growth states, weather conditions, field conditions etc. are much too complex to be assessed by the regulators and thus in a comparative assessment. He clearly calls upon the Authorities not to implement additional assessment.

Following this "controversy" about the comparative assessment was a presentation by Jean-Pierre Busnardo of DuPont who assessed the nature and extend of science in the review of crop protection active substances. He, too, also started by reminding us of the more than 1000 active substances before the implementation of Directive 91/414. In his assessments more than 50% of those were not supported by industry and thus lost. Of those supported by industry, approximately 71% were approved under Directive 91/414. Under AIR1 all substances called upon were reapproved. Currently, no decisions are available on the AIR2 substances, but it is expected that 9 out of 10 might not be renewed, based on the available EFSA conclusions. Main points for this non-approval are, to his assessment, the cut-off criteria, operated and work exposure, consumer risk assessment, groundwater and non-target species issues. What has changed with respect to the evaluation are the approval criteria and the evaluation standards. Also, approximately 60% of the active substances have a harmonised classification with a CMR component. EFSA is revisiting all CMR classes and considers that 41% of all active substances meet the C, M or R criteria. For EFSA human relevance is assumed by default as well as biological relevance. Thus a very high level of conservatism is the standard approach and a growing reluctance to consider higher tier information and thus an increasing number of non-save-use conclusions by EFSA. The speaker coined the phrase that cumulative conservatism does not lead to conservative but to unrealistic output! Assumptions are made on risks that cannot occur and which will lead to the loss of products, as well as a significant increase of animal testing by industry to anticipate all possible criticism during the evaluation process.

Peter A. Watson gave the industry perspective on the MRL Regulation. He reminded us that an MRL (maximum residue level) is a maximum concentration of a residue legally permitted in or on food or feed of plant or animal origin. MRLs are solely established as trading standards, they are not safety.

MRLs relate to the authorised (registered) GAPs. They are set at default values in the EU (0.01 mg/kg), unless superseded by data derived values. They are collected in a positive list system. Within the AIR projects many issues are to be resolved between the setting of MRLs and the registration of active substances. One particular concern is the different residue definitions that might be deduced in the different procedures.

Other than MRLs, import tolerances are established based on GAP outside the EU. They become necessary, if the commodity is not produced or produced to a lesser GAP in the EU. With respect to the timeframe the speaker showed that some of the assessments are not associated with a legally set timeframe, such as the assessment by the evaluating Member state. According to the statistics of ECPA this time period usually takes 12 month. The subsequent timeframes, such as EFSA reasoned opinion, vote in the committee and publication of the MRL in the official Journal are kept more or less as required by the legislation.

A complaint is that import tolerances now will only be assessed and dealt with by EFSA, if and authorisation of the respective product is available from the third country. The speaker though emphasised that this will be a significant delay of up to 2 years banning the import of such product into the EU. This gives rise to trade restrictions, particularly where no safety issues exist and threatens the global food chain security and sustainability.

Lesley Earl of ENVIGO was trying to give Guidance for the conduct of studies in the absence of official Guidance Documents. She has assessed 14 different dRRs on a variety of issues, such as endocrine disrupting properties. In 20 of these dRRs since 2013 no mention was made of endocrine disruption. In 3 dRRs planned studies were described or studies already conducted were presented.

An important issue is the presentation of a structure activity relationship, for which a good mechanistic basis is needed. It is eminent to build a weight of evidence approach. In referring to legislation the speaker emphasised that tests or studies should not be rushed, as it is required by said legislation to discuss the particularities first with the Authorities.

The subsequent speaker, Bernd Brielbeck of SCC, elaborated on biopesticides. He asked the question, whether biopesticides do exist in EU legislation. After comparing the legislations of OECD, FAO, the USA, Canada, China and Brazil, all of which approach biopesticides differently, he returned to assess the European situation examining basic substances and low risks substances as possible biopesticide. A definition of biopesticides, which he considered a top-down approach, only exists in detail in the US law. Nevertheless, many exceptions to the defini-

tion required a case to case assessment. All other countries, including the European legislation, do have a bottom-up approach, defining desirable or undesirable properties of active substances, which are then prioritised or not in their assessment. Thus, he concluded that, although the word biopesticides is well understood and present in every day regulatory speech, it nevertheless is not defined in EU legislation. The speaker favoured the bottom-up approach, *i.e.* defining desirable properties and prioritising active substances having them, in contrast to a definition, which would be a top-down approach.

Markus Griesser of BASF was assessing endocrine disruptors and asked the question: risk or hazard - how to regulate EDs? He quoted the example of Biocides and Plant Protection Products, where hazard assessment is currently the basis for endocrine disrupter's evaluation, while the REACH Regulation is risk-based. He then strongly emphasised the positive approach of a risk-based assessment. He drew the attention to the endocrine activities of Vitamin D3, which, nevertheless, is recommended for such vulnerable groups as babies, young children and pregnant women. Also, the US EPA is doing exclusively risk-based assessments. He criticised that the Commission roadmap, in spite of all the diversity and possibilities it contains, does not allow for a fully risk-based assessment as an option.

The public consultation started by the Commission on the endocrine disrupting properties yielded 27087 responses. It is important to note that more than 25000 responses were submitted exclusively via two external NGO websites with pre-filled in questionnaires. The second largest number of returns came from farmers. None of the replies of the public consultation were favouring option one, which is to retain the interim criteria. It seems that the final criteria are to be based on the WHO criteria and must also consider elements of hazard characterisation.

ECPA upholds that endocrine disruption is a mode of action and cannot be categorised in similarity to the CMR classification. Mr. Griesser expects that the first study which is a screening of 700 substances by Commission will be completed in the first quarter of 2016. The second study, a socio-economic assessment, could be completed in the fourth quarter of 2016.

It is ECPA's assessment that 35 to 45% of active substances in the market can be affected by the endocrine disrupting properties definition. This could result in a loss of yield of 10 to 20% in average and up to 50% in difficult years. The speaker also questioned, whether it will not lead to trade barriers, as the WHO has clearly stated that any measures leading to a change of MRL should be based on risk and not on hazard! The US system of data call in and compensation is much superior to the EU system of a pseudo data call in and

data protection was the opinion of Mike Carroll of Dow AgroSciences. He criticised that currently in the EU there is no data protection for Annex I inclusion, but only for Member State Plant Protection Product authorisation. With the European system, companies tend to over-compensate the conduct of studies in order not to fail via a data gap. In the US, the Authorities clearly state which data are needed and in which time all applicants have to provide this data to the Authorities. Similar systems are in place in Canada and Australia.

Hans Mattaar, Technical Director of ECCA, was looking at data protection from an opposite angle. He emphasised that before looking abroad it would be worthwhile to look within the EU, where other systems have already been established, such as REACH and Biocides. He agreed with the previous speaker that a full data call in system is much better and applies available resources much more effectively. The necessary data for the call-in are published, for example in the European Journal, and represent a “shopping list”. That time all authorisation holders are at the same starting point and it is their free choice to join a task force or not, to generate and provide the data. Furthermore, such a system gives clear and feasible deadlines for everyone participating.

The second day of presentations was wrapped up with a panel discussion chaired by Paul Leonhard of BASF and Anthea McIntyre, Member of the European Parliament, Angel Martin of Dow AgroSciences and Adrian Bell, a journalist by training, of Whisper.pr as panelists. The MEP gave a speech on the project “Horizon 2020” which would provide research money to practical applications. She indicated that public suspicion was certainly a problem in the industry, but quoted the recent VW scandal as a reason for such suspicion. She conceded that not only the plant protection industry, but also politicians have a PR problem. She defends Plant Protection Products not for the gain of the industry, but for the small farmers that feed the people in her country. Angel Martin of Dow analysed the tactics of the NGO which is to isolate the industry from society and demonise it. The NGO’s campaign is purely emotion driven, but, nevertheless, they are an industry too, which is very sophisticated, well organised and networking very cleverly. He presented survey of the European Parliament conducted by ECPA in which the question was asked “are pesticides a part of a sustainable agriculture?”. Of all MEPs in the Parliament 56% agreed and 36% disagreed with that sentence. If asking the same question to the MEPs active in the agricultural committee, *i.e.* specialists in agriculture, the agreement went down to 44% and disagreement up to 52%!

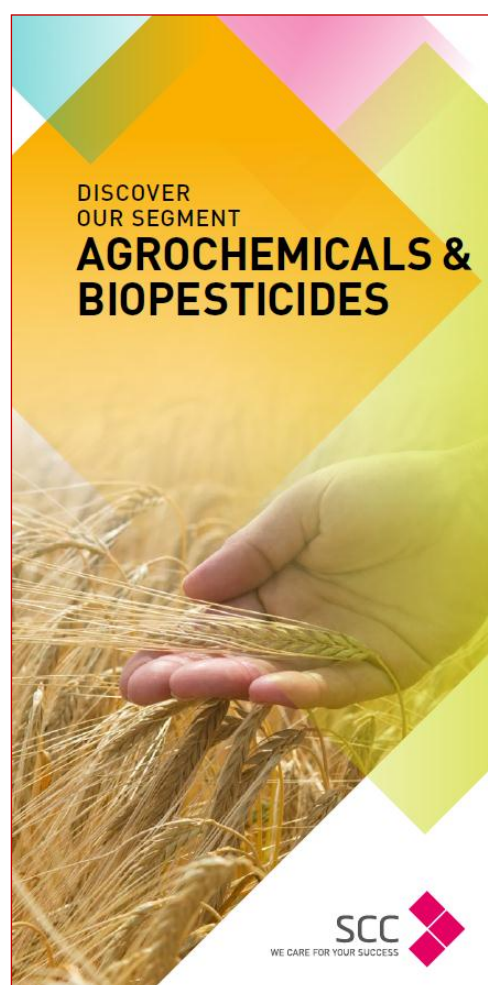
Adrian Bell was giving a similar view and noted the dilemma that industry cannot say that Plant Protection Products are safe, but is only allowed to say that they have negligible effects on, for example, non-target arthropods when used as directed. He, too, conceded that

the NGOs argue emotionally, but are using a general public chemophobia - anything that is “chemical” must be bad. As a positive effect and advertising tool, he strongly proposes to use the positive image that farmers still hold in UK public opinion. Also, the facts are actually speaking for the industry; in 1960 the farmers could feed two people per hectare, while today (2015) five people are fed per hectare.

The subsequent very lively debates between panelists and the plenum were concluded by Paul Leonard observing that industry is fighting a hard and difficult battle against the NGOs which are well-established within all political and public areas.



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Access our website at

<http://www.scc-gmbh.de/downloads-scc/brochures>



CALENDAR



**Biocides Europe 2015 - 18th Annual Conference,  
25-26 November 2015, Vienna, Austria**

This Conference highlights legal issues and trade aspects of Biocidal products. A pre-summit workshop (24 November) provides a practical introduction to the Biocidal Product Regulation. Furthermore, some half-day workshops on 27 November offer a more in-depth and hands-on study of several topical issues. Dr. Martina Galler, Senior Manager Regulatory Affairs Biocides, and Dr. Stefan Nave, Manager Regulatory Affairs Biocides, will attend this conference and will be available to talk to you about your regulatory needs regarding biocidal active substances and biocidal products.

For further information on Biocides Europe 2015, please refer to:

<http://www.europeanbiocides.net/>

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Do you have any comments, questions or suggestions? Drop us an E-mail at [newsletter@scc-gmbh.de](mailto:newsletter@scc-gmbh.de).

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