

# NEWSLETTER EXTRA

SCC Newsletter Vol. 18, No. 3, May 2018

## EU-ED CRITERIA, REACH REGISTRATION OBLIGATIONS AND AGRICULTURAL ISSUES

Dear Subscribers,

On a short track we inform you about several important issues concerning Agrochemicals, Chemicals/REACH, and Regulatory Science.

### AGROCHEMICALS



#### New EU Code on agricultural data sharing

The new “[EU code of conduct on agricultural data sharing by contractual agreement](#)” was signed on 23 April by the 9 agro-food chain organisations and associations CEETTAR, CEJA, CEMA, Copa and Cogeca, ECPA, EFFAB, ESA, FEFAC and Fertilizers Europe (see below).

In recent years, the rise of precision/digital farming systems led to a huge increase in agri-food chain data available to be processed, shared and analysed. Considering the current scientific and technical progress and the envisaged uses of precision/digital farming methods (e.g. [CAP-reform](#)), a further tremendous increase is to be expected in the years to come.

To fully deploy the benefits of precision/digital farming systems, data access and sharing has to be regulated and transparent rules have to be implemented

for a huge variety of data on land, livestock, machines, climate, compliance and finance and different data sources such as farm data incl. agronomic, compliance and livestock data, machine data, agri-supply data (e.g. on fertilisers or plant protection products) or agriservice provider data. The new, non-binding code of conduct provides respective guidance especially taking into account data ownership and farmer’s needs, collection, access, storage and usage of data as well as the further development of precision/digital farming systems.

Annex 2 of the Code of Conduct includes case studies for different situations of data ownership considering different data sources and types including for example pest alert systems or agricultural contractors.

Besides [Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data](#), Annex 3 of the Code of Conduct also provides further information on the relevant EU regulatory frameworks concerned.

For further information on the new Code of Conduct see also the websites of the organisations and associations involved:

CEJA (European Council of Young Farmers):

[www.ceja.eu](http://www.ceja.eu)

CEETTAR (European Organisation of Agricultural, Rural and Forestry Contractors): [www.ceettar.eu](http://www.ceettar.eu)

CEMA (European Agricultural Machinery):

[www.cema-agri.org](http://www.cema-agri.org)

COPA (Committee of Professional Agricultural Organisations): [www.copa-cogeca.be](http://www.copa-cogeca.be)

COGECA (General Committee for Agricultural Cooperation in the European Union): [www.copa-cogeca.be](http://www.copa-cogeca.be)

ECPA (European Crop Protection Association): [www.ecpa.eu](http://www.ecpa.eu)

EFFAB (European Forum of Farm Animal Breeders): [www.effab.info](http://www.effab.info)

ESA (European Seed Association): [www.euroseeds.eu](http://www.euroseeds.eu)

FEFAC (European Feed Manufacturers' Federation): [www.fefac.eu](http://www.fefac.eu)

Fertilizers Europe: [www.fertilizerseurope.com](http://www.fertilizerseurope.com)

## Commission publishes new rules on transparency and sustainability of the EU risk assessment in the food chain

In April, Commission published its proposal for a new regulation to improve the transparency and sustainability of EU risk assessments for plant protection products, GMOs (cultivation, food/feed uses), feed additives, food contact materials, food additives, food enzymes and flavourings, novel foods and smoke flavourings ([COM\(2018\) 179 final](#)). The new Regulation is a follow-up of the fitness check of the General Food Law Regulation ([Regulation 178/2002](#)), initiated in 2014, and the Commission's reply to the European Citizens Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides'.

The aim of the proposal is to ensure more transparency on safety related information used for risk assessments for substances and products used in the food production chain (regulations to be amended see below) by:

- Ensuring for public access to all relevant information
- Establishing a common European Register of commissioned studies for all regulatory frameworks in the food chain
- Possibility for additional studies to be requested by EFSA and financed by EU budget
- Consultation of stakeholders and the public on studies submitted in the registration process
- Increase Member States' involvement in the European Food Safety Authority's (EFSA) governance structure and scientific panels
- Strengthening risk communication to citizens

Confidentiality of studies/information provided in the registration process will be maintained. The new Regulation will contain a positive list of confidential

items to safeguard commercial interests of applicants.

As the fitness check on the General Food Law Regulation has also shown, that the approval/authorisation procedures for several sectors are long-lasting and thus slow down the market entry process of the respective products a closer involvement of EFSA, for example in the pre-submission procedure may contribute to a faster and more streamlined registration process.

Vytenis Andriukaitis, the European Commissioner for Health and Food Safety called for a fast entry into force of the new Regulation, i.e. early 2019, whereat for specific issues, such as the expansion of the Management Board specific timelines are set in the Regulation.

### Amended Regulations/Directives:

- [Regulation 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- [Directive 2001/18/EC](#) on the deliberate release into the environment of genetically modified organisms (GMOs)
- [Regulation 1829/2003](#) on genetically modified food and feed
- [Regulation 1831/2003](#) on additives for use in animal nutrition
- [Regulation 2065/2003](#) on smoke flavourings used or intended for use in or on foods
- [Regulation 1935/2004](#) on materials and articles intended to come into contact with food
- [Regulation 1331/2008](#) establishing a common authorisation procedure for food additives, food enzymes and food flavourings
- [Regulation 1107/2009](#) concerning the placing of plant protection products on the market
- [Regulation 2015/2283](#) on novel foods

## European Parliament adopts new regulation on Europe's organic agriculture

On April 19th European Parliament has adopted the new legislation on EU organic farming rules thus repealing [Regulation 834/2007](#). The new regulation, initiated in 2014, was adopted with 466 votes against 124.

As the organic farming sector has hugely grown in the last years, organic managed farms covering 6.7 % of Europe's agricultural area (2016, EU-28), the new Regulation tries to adapt the regulatory framework for organic farming to these new circumstances and establish the basis for the further growth of this farming sector.

Advancement of organic farming is already well established in different political and regulatory frameworks, such as the Common Agricultural Policy (CAP) or the Directive for sustainable use of pesticides (SUD 2009/128). To further boost organic farming in EU the new Regulation allows for a mixed production of organic and conventional food on one holding and simplifies the certification for small farmers (group certification) to encourage conversion.

Furthermore, the new Regulation implements strict, risk-based checks along the organic supply chain and phases out the current "equivalence" rules for imports of organic goods within five years after entry into force.

In regards to plant protection, *"the new rules are not very different from the current legal situation"* says rapporteur MEP Martin Häusling. Main focus is to avoid contamination from chemical pesticides or synthetic fertilisers. In order to further improve respective standards, a new set of measures is implemented by the Regulation. Effectiveness of these new EU anti-contamination rules and national thresholds will be checked four years after entry into force of the new regulation and if need be the Commission is to come up with a draft law to harmonise them. For further information on pesticide residues in organic food see also the supporting publication by European Food Safety Authority, 2018: *Monitoring data on pesticide residues in food: results on organic versus conventionally produced food*. EN-1397. [Click here](#) to view EFSA's publication.

Read also the [Provisional Edition of the European Parliament legislative resolution of 19 April 2018 on the proposal for a regulation](#).



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## CHEMICALS/REACH



### Commission clarifies its position on registration obligations regarding cease of manufacturing before the 2018 deadline

In SCC's last newsletter we reported about the Commission's position on phase-in status after May 2018 with a special focus on Commission's interpretation of registration obligations.

In April, the Commission provided a clarification on its statement. The intention of the statement was to confirm that, regardless of whether a manufacturer or importer of a phase-in substance ceases to manufacture or import after the deadline, he will have to register. This differs from the scenario described by the Germany CA which focuses more on the scenario before the registration deadline.

Consequently the commission modified the wording of its statement as follows:

"[...] the Commission wishes to clarify that if a manufacturer or importer of a phase-in substance, who has pre-registered that substance, exceeds the 1 tonne per year threshold in 2018, based on the 'three-year average' rule in Article 3(30), but has ceased the manufacture or import of that substance before the final registration deadline on 1 June 2018, then he will not be required to register after the deadline has passed unless he subsequently restarts the manufacture or import of the substance and the conditions of Article 6 of REACH are met."

Taking this updated statement into account the Commission's interpretation is in-line with the interpretation of the national helpdesk, ECHA's F&Q and the ECHA guidance documents.

We would like to point out that one should closely monitor the manufacturing / import of substances until the deadline in order to ensure that no import or manufacturing takes place after 31 May 2018 which results in an overall tonnage above 1 tpa. Please keep in mind that the time point for import is the arrival of the shipment at the European customs clearance.

In case you have any questions or need further support, please get into [contact](#) with us.

## EPA Interim Science Policy for the Replacement of Animal Testing for Skin Sensitisation

On 04/10/2018, EPA published a draft of an Interim Science Policy to reduce animal testing for skin sensitization, which can be found [here](#). The draft of the Interim Science Policy is open for public comment until June 9, 2018.

The draft document states that the Office of Pesticide Programs (OPP) and Office of Pollution Prevention and Toxics (OPPT) will immediately begin to accept submissions as described in the draft Science Policy.

It lists OECD test guidelines that will be accepted in submissions to the Agency for single chemicals. For the time being, alternative testing will be accepted only for pesticide active and inert ingredients, but not yet for formulations. However, the agency states that it expects expansion of this interim policy in the near term to include some pesticide formulations or other mixtures evaluated by OPPT.

In contrary to the situation in Europe where a clear guidance for the regulatory interpretation of the alternative method is still pending, EPA has defined clear criteria how the results of the alternative test methods should be handled.

The two following defined approaches (DA) will be accepted by EPAs as alternatives to the LLNA for regulatory submission:

- Adverse Outcome Pathway (AOP) "2 out of 3"
- Key events (KE) 3/1 sequential testing strategy (STS)

The first DA was initially submitted to OECD by BASF and reflects the current approach used for the non-animal test strategy in the scope of EU REACH (SCC Comment: The "2 out of 3" approach is not yet officially confirmed by ECHA): At least two studies need to be conducted in order to assess two different key events. If these studies provide discordant results, a study for a third key event needs to be performed. The overall result is based on the two concordant findings. In case two positive findings are revealed this leads to a conclusion as sensitizer.

The second DA reflects a simple decision tree that requires only two studies. The first study investigates the key event 3 (Dendritic cells). If the response is positive, the test substance is classified as a sensitiz-

er. If a negative result is obtained from a key event 3 assay, an assay for key event 1 (covalent interaction with skin proteins) is conducted. A negative study for key event 1 confirms that it is a non-sensitizer and a positive result for key event 1 leads to a finding of sensitizer.

A project proposal was submitted to OECD jointly by the US, EU, and Canada to develop a new performance-based test guideline (PBTG) for defined approaches for skin sensitization. As part of the work on the future OECD PBTG guideline, refinements and updates to some of the defined approaches are expected in the near-term (until end of Q4 2018).

*SCC's conclude the following: In case companies already generated data for skin sensitisation for chemicals subjected to registration under REACH using the "2 out of 3", these data will be accepted by EPA and thus additional animal studies do not need to be conducted in order to comply with US data requirements in the near future.*



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## REGULATORY SCIENCE



### Endocrine Disruption

#### Regulation update:

**Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties**

The European Union is the first region and regulatory system worldwide to define scientific criteria for endocrine disruptors (EDs). Under EU's Biocidal Products and Plant Protection Products Regulations (EU No 528/2012 (BPR) and EC No 1107/2009 (PPPR)), an active substance, which is considered as having ED potential will not be approved unless the risk from exposure is negligible (BPR), unless exposure is negligible (PPPR), or there is evidence that it is essential to prevent or control serious pests or it is required on socioeconomic grounds (BPR).

The ED-criteria for plant protection products (EC No 1107/2009) have been under scrutiny of the European Council and the European Parliament (EP). The initial regulation was rejected by the EP in October 2017. The new proposal taking into consideration the claims of the EP (the criteria contain no more the specific provision for the so-called "growth regulators") was adopted by a narrow Qualified Majority during the Standing Committee on Plants, Animals, Food, and Feed (PAFF) meeting dated 12-13 December 2017. The final adoption by the Commission has been recently performed in April 2018.

The corresponding Regulation (EU) No 2018/605 dated 19 April 2018 defines the scientific criteria to determine ED properties of active substances, safeners and synergists and amends Annex II of Regulation (EC) No 1107/2009.

The criteria to identify adverse effect to humans and adverse effect on non-target organisms are very similar. An active substance, safener or synergist shall be considered as having endocrine disrupting properties if:

- (1) *it shows an adverse effect in /an intact organism or its progeny/non-target organisms,*
- (2) *it has an endocrine mode of action (altering the function(s) of the endocrine system)*
- (3) *the adverse effect is a consequence of the endocrine mode of action.*

In point 3.6.5/3.8.2 of Annex II to PPPR the corresponding paragraphs will be added after the fourth/sole paragraph regarding the ED criteria.

#### Identification of a substance as endocrine disruptor (ED)

The identification of an active substance, safener or synergist as having ED properties that may cause adverse effect in humans or in non-target organisms is based on a procedure using all available relevant scientific data.

These data shall be assessed based on a weight-of-evidence (WoE) approach in order to consider if the criteria set out are fulfilled.

The WoE shall be used to investigate the putative link between the adverse effect(s) and an endocrine mode of action.

Of note, *"adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor."* (Commission Regulation (EU) 2018/605).

Referring to the new Commission Regulation (EU) 2018/605, the European Commission is of the opinion that *"The criteria for the determination of endocrine disrupting properties reflect the current state of scientific and technical knowledge and allow identifying active substances having endocrine disrupting properties more accurately. The new criteria should therefore apply as soon as possible, while taking into account the time necessary for Member States and the Authority to prepare for applying those criteria. Therefore, from 20 October 2018, those criteria*

*should apply except where the relevant Committee has voted on a draft Regulation by 20 October 2018. The Commission will consider the implications for each procedure pending under Regulation (EC) No 1107/2009 and, where necessary, take appropriate measures with due respect for the rights of the applicants. This may include a request for additional information from the applicant and/or for additional scientific input from the rapporteur Member State and the Authority."*

**Thus, the new criteria to identify ED will apply as of 20 October 2018 to all on-going and future evaluations of active substances used in plant protection products.**

With regard to biocides, in a first step the new ED-criteria for biocidal products (EU No 528/2012) were approved in November 2017. These very similar ED-criteria will apply from 7th June, 2018, to all new and on-going applications for biocides. Furthermore, a draft guidance document for identification of EDs in the context of BPR and PPPR was published for public consultation in 2017/2018. Meanwhile, ECHA and EFSA are in the process of finalizing this technical Guidance document to implement the identification of EDs in the context of the BPR and the PPPR which is planned to be published in June 2018.

#### Consequences for on-going and future evaluations of active substances from 20 October 2018 onwards

Based on the setting of these scientific criteria for substances used in plant protection, the causal link between an endocrine mode of action and adverse health effects is crucial for the reliable identification of endocrine disruptors. Since current methodology for the assessment of (eco)toxicological hazards is largely based on endpoints indicative for altered biological function, the distinct identification of an endocrine mode of action and of a causal link to adverse health effects is considered to represent a major new challenge in hazard identification.

Even with the enforced EU ED criteria and the ED guidance on hand, expert work and judgement will be needed to evaluate the putative ED properties of

compounds in the forthcoming process, especially in cases where the scientific evidence is ambiguous or contradictory.

SCC has a wide spectrum of expertise in the assessment of potential endocrine disruption. This allows us to successfully anticipate regulatory challenges and confidently guide our clients through the difficulties in developing target-specific strategies. To keep up to date with every new requirement, we continuously monitor the current regulatory and scientific developments in this field, both in the EU and worldwide.

Our expertise covers the entire range of methods that can be used in the development of an appropriate assessment strategy, including mode of action (MoA) analyses and adverse outcome pathway (AOP) concepts as well as weight of evidence (WoE) approaches.

SCC will serve you as a dedicated and highly experienced partner when it comes to assembling the lines of evidence.

We will support you in gathering, evaluating and putting together all relevant information required for establishing whether the ED criteria are fulfilled.



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#### **16th International Fresenius Conference "Food Safety and Dietary Risk Assessment", 17 – 18 April 2018, Mainz/Germany**

In the 16th International Fresenius Conference the focus was on cumulative risk assessment, assessment of metabolites, acute dietary risk assessment, and the setting of MRLs.

In May 2018 the draft EFSA guidance on risk assessment of combined exposure to multiple chemicals will be presented, in June 2018 public consultation, in December 2018 adoption of the draft guidance by the Scientific Committee, in spring 2019 a workshop pre-

senting the guidance document is foreseen. In the guidance the conceptual framework for human, animal and ecological risk assessment of chemical mixtures will be covered, but aggregate exposure is not a topic of this guidance.

OECD is developing guidance on consideration for assessing the risks of combined exposure to multiple chemicals, which is near to completion. EuroMix will prepare practical guidance on how to use the EuroMix tools in the context of the OECD development. EFSA is also developing further assessment groups for pesticides (CAGs) and will consider how to utilise these in risk assessments.

Currently the COM has established a working group concerning the decision taking.

It was discussed that the cumulative risk assessment is intended to be applied by 2020 for the enforcement as well as for the MRL product registration.

Regarding the guidance on residue definition the Commission is concerned about the implementation of the guidance only on EU level, therefore discussions with international organisations are on-going. Thus, it might be that the OECD Guidance Document on the definition of the residue will be updated considering the outcome of the current EFSA Guidance Document. In this context ECPA proposes changes of the approach proposed by EFSA.

Regarding the short term dietary exposure of pesticide residues the French authorities have done further impact assessments with the proposed revised IESTI equation. According to this assessment the impact on existing MRLs is limited. Also the JMPR have done further impact assessments. However, in the CCPR meeting 2018 no final decision has been taken whether the new approach will be used and the outcome of further assessments will be awaited.

Regarding the import tolerances the following is under discussion: If an active substance fulfils the cut-off criteria, no import tolerance will be granted for actives which are not approved according to the criteria (health based only), for actives which fulfil the criteria and for which derogation is applicable. Thus MS receiving an application for setting an import tolerance should refuse the application. For actives, which may fulfil the criteria but are not yet reviewed, import tolerances could be granted. Important points in the discussion are the cases where for an active

substance a decision about the cut-off criteria is not yet available and the implications on the global trade (e.g. implications during the SPS notification, acceptance of CXL for a "cut-off" substance). Even court cases either at WTO or at the Court of the European Union could not be precluded.



## Segment REGULATORY SCIENCE



## CALENDAR



**International Fresenius Biocontrol Conference: Biopesticides – Biofertilisers – Biostimulants in Mainz, Germany**  
**5 - 6 June 2018**

Please meet

**Dr Lars Huber**, Senior Manager Regulatory Affairs, Head of Biostimulants, Fertiliser, IMP at the international Fresenius Biocontrol Conference, taking place in Mainz in June 2018. Lars looks forward to meeting you and discussing your registration needs for biorationals and any other regulatory or scientific issue you might want to address.

The upcoming Fresenius conference aims at promoting an active exchange among professionals as well as updating the participants on the latest EU and international developments in the regulatory field of biopesticides, biofertilisers and biostimulants. For more information, please visit [the event website](#).

**Chemspec Europe 2018 in Cologne, Germany**  
**20 - 21 June 2018**

We are exhibiting at the 33rd International Exhibition for Fine and Speciality Chemicals, taking place at Koelnmesse in Cologne on 20 - 21 June 2018. For more information on the event, please visit [Chemspec's official website](#).

Meet us on **stand K146 / Hall 8** to talk about any regulatory or scientific issues you would like to address.

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