EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis
F3 - Plants and organics

Grange,
SANTE.F3 [redacted]

BACK-TO-OFFICE NOTE

SUBJECT: **Crop Protection European Regulatory Conference**
LOCATION: **Hotel Le Plaza, Brussels**
DATE: **16 March 2017**
ATTENDANCE: [redacted] **(DOS) and** [redacted] **(GGL)**

The European Crop Protection Association (ECPA) and the European Crop Care Association (ECCA) organised the 4th Annual Regulatory Conference on Wednesday 15th and Thursday 16th March 2017. The programme focused on the main regulatory challenges within the framework of Regulation 1107/2009. Presentations included developments on regulatory issues such as endocrine disruption, [redacted]

[redacted]

The conference attracted a high number of participants from the industry, consultants, NGOs and competent authorities.

On the second day of the conference, presentations were divided into three blocks: EDs, [redacted]

Endocrine Disruptors

[redacted] explained the state of play of the development of ED criteria. An impact assessment was conducted in March 2016 which included screening of substances aimed at indicate how many and which active substances including co-formulants, may be identified as EDs. Consideration was given to different models to be used for defining criteria for hazard identification of EDs. Two draft legal acts (one for PPPs and one for biocides) were released in June 2016 establishing the criteria for EDs which contained elements of the World Health Organisation definition of an ED. The main regulatory consequences (via Member State (MS) voting) for an active substance identified as an ED are: not being approved, or approved with restrictions on time and use, with no possibility to grant mutual recognition authorisations. It is expected that restrictions

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related to ED criteria will have an impact on the approval of this type of active substance, and consequently in the authorisation of PPPs.

In the decision making process, the next step is to discuss and vote in the SCPAFF, and then submit the draft regulations for the scrutiny of the European Council and the European Parliament before adoption and entry into force of the criteria. In parallel EFSA and ECHA are working to develop a guidance document on the implementation of the criteria.

Authorisation challenges

Legislative review

[redacted]

Conclusion:

[redacted]

(Signed)

[redacted]

cc: