



ESA NEWSLETTER

January 2009

External Meetings (selected)

- **12.02.2009**
EU experts meeting on ABS in CBD, Brussels
- **24.-25.02.2009**
Eurofins International GM Seminar Paris, France
www.eurofins.fr
- **18.03.2009**
European Seed Conference on Better Regulation Brussels

Dear Members,

2009 started off well for the European seed industry! Following intensive discussions between European Parliament, Member States and Commission, an agreement was reached on the new legislation for the authorization and conditions of use of plant protection products in the EU. The new Regulation that will replace the old Directive 91/414/EC now contains a strict mutual recognition principle within defined groups of Member States with similar agro-climatic conditions (so-called 'zones') and –most importantly for ESA- an EU-wide mutual recognition of authorisations for seed treatments combined with a free marketing of treated seed. Further improvements of existing provisions facilitate the extension of authorisations for minor uses and safeguard the availability of products where no alternative crop protection solutions are (yet) available. It is the nature of compromises that no party is entirely happy with them; and here as well, there are still concerns that the 'cut-off criteria', i.e. the criteria that determine whether an active substance / PPP may at all be considered for authorization, could prove too strict for some important crop-pest problems.

Still, as seed industry, we can be very content with what has been achieved as well as how we have worked over the past 24 months to achieve it. This lobbying campaign was a success! Not only because of its positive final outcome, but mainly because it may serve as an example how an organisation as ESA can effectively work with its widespread membership to effectively address EU decision makers at both EU and national level and what is the role of Secretariat, responsible ESA body, national associations and individual companies in such a lobbying effort.

In this Newsletter you will find a more extensive overview on the new legislation as well as our ESA lobbying campaign and we will prepare a detailed ESA info and guidance document in the coming months that may help to get familiar with the new Regulation and its provisions. But may I use this Newsletter to once again express my thanks to all those that have helped in this campaign and specifically the ESA STAT Working Group chaired by Jan-Willem Breukink, the national associations and companies that have worked with their respective contacts in Member States and Isabelle Klopstein from the ESA Secretariat in charge of the management of ESA STAT.

There are new and important challenges ahead of us: the Better Regulation initiative for the seed marketing legislation, the evaluation of the plant health regime and the GM legislative framework to name but a few. And we will be facing these challenges under a new EU Treaty and working with a new European Parliament and a new Commission. But if we work together with the same dedication and in the same spirit as we have done in our seed treatment campaign, I am convinced that the voice of the European seed industry will be heard loud and clear – in Brussels and in the whole EU!

With best regards, yours

Garlich v. Essen, Secretary General



- **The European Parliament adopts the EU Pesticide Package**

The new legislative package on plant protection products (PPP) was adopted by the European Parliament (EP) on 13 January 2009. Both the Framework Directive and the Regulation will have to be formally adopted by Council (Spring 2009). The vote in the European Parliament concluded with success the ESA Seed Treatment (ST) Lobbying Campaign initiated in 2006 with the release of the Commission's legislative proposals.

ESA Meetings

- **03.02.2009**
WGBR
- **12.02.2009**
CPVO - quality requirements DUS
- **17.02.2009**
WGB
- **18.02.2009**
CRLA
- **19.02.2009**
CIPR
- **27.02.2009**
CPVO AC / CIPR

**All meetings at the
ESA Office unless
indicated otherwise.**

**Further information
available from the
Secretariat**

- **Placing on the market: New EU Regulation (replacing Directive 91/414)**

The new Regulation covers the authorisation, use and control of PPP and notably introduces major procedural improvements for the authorisation of PPPs in Europe. The approval system for active substances (AS) will remain centralised at EU level and each Member State will continue to be responsible for the authorisation of PPP to be used on their own territory. A general compulsory mutual recognition of authorisations for PPP within the three authorisation zones (north, south and central) will avoid duplication of work and lengthy procedures for approval. The new zonal approach should significantly reduce the fragmentation of the EU market and European seed industry, farmers and growers will benefit from a more harmonized availability of PPPs within the European Union.

Most importantly, the new Regulation finally addresses the long standing gap between the EU seed marketing and crop protection rules by introducing specific provisions for an EU-wide mutual recognition of PPP authorized for use as seed treatment (ST) and for the free marketing of seed treated with PPP authorized in the EU.

The new Regulation also aims to improve the availability of crop protection solutions for minor crops by facilitating the submission of small-scale applications: professional users (e.g. seed and coating companies) will be allowed to file application for an extension of authorisations for minor uses. Furthermore, the creation of a European fund for minor uses is envisaged within two years following proposal from the European Commission. A specific derogation is also foreseen for the use of non-authorized PPP in research and development projects.

On the other hand and despite clear improvements, the introduction of a hazard based approach and the establishment of more stringent health and environmental criteria for the approval of AS could significantly reduce the range of PPPs available and potentially damage European agricultural production, including seed production. The new cut-off criteria would however apply after the Regulation enters into force and should not affect the authorization of AS already on the market.

- **Sustainable use: The Framework Directive**

Next to the authorization of AS and PPPs, their actual use by farmers has also been addressed. The Framework Directive on Sustainable Use of PPPs forms the second pillar of the PPP legislative package and aims to reduce the risks and impacts of pesticide use on human health and the environment. The implementation of this Directive at national level is also likely to impact the seed industry, in particular with the setting up of quantitative objectives and targets in National Action Plans (NAP), training for professional users and a related certification system, and technical inspections of pesticide application equipment etc..



For more information:

- Positions of the European Parliament adopted in second reading (13 January 2009)
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0011+0+DOC+XML+V0//EN&language=EN> (Regulation)
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0010+0+DOC+XML+V0//EN&language=EN#BKMD-11> (Directive)
 - Q&A on Plant Protection Products:
<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/8&format=HTML&aged=0&language=EN&guiLanguage=en>
- **The Seed Treatment Lobbying Campaign - A success for ESA!**

The proposed revision of the EU regulatory framework on plant protection products (PPP) was defined as essential to the European seed industry by the ESA Board. It finally offered the opportunity to re-establish an effective EU harmonised market for treated seed and end the lack of coherence and consistency in Member States' application of Directive 91/414. The campaign also provided a platform to raise awareness of the benefits of seed treatment application technology and thus promote its further development. As neither Directive 91/414 nor the original Commission's proposal mentioned seed treatment, it was a major challenge for ESA to change it for the better. Additional financial contributions from the ESA budget as well as ESA members were specifically assigned for the ST Campaign in order to finance external consulting services to support the ESA Secretariat.

Alignment of seed marketing Directives and crop protection product legislation to facilitate ST authorisations and assure a free marketing of treated seed had thus been defined as a priority for ESA STAT (Seed Treatment and Technology). STAT (Chaired by Jan Willem Breukink) is composed of seed companies, the crop protection industry and seed treatment companies. STAT significantly increased its capacity throughout the Campaign to reach a number of 20 representatives from both companies and national associations.

Seed treatment was originally not at all considered as an issue by Commission, Council and Parliament. The active involvement and sustained communication efforts of STAT members ensured that it would be considered in the overall debate. With the support of the ESA Secretariat, STAT members and national associations have managed to achieve great progress for the whole seed industry in discussions with Member States and Members of European Parliament (EP).

STAT members regularly met to fine-tune the lobbying strategy, elaborate positions and discuss activities in coordination with the ESA Secretariat. In total, more than a dozen STAT meetings were held in the years 2007-2008. In addition, regular conference calls were held for updates and feedback. Multiple lobbying materials (papers, flyer, letters, explanatory notes, etc) were jointly developed with or prepared by the ESA Secretariat for further national actions. STAT members were also regularly updated about development of the discussion at EU level by the ESA Secretariat, specifically on the continuous meetings with Member States' representatives and MEPs. The successful outcome of the campaign is to a significant part due to these regular contacts/meetings and the good coordination of actions between members at national level and the ESA Secretariat in Brussels. External meetings were held in parallel at both levels to present and explain the ESA position. It was thus possible to cover a wide range of officials and defend a



clear and uniform position throughout the adoption process. Communication at all levels was very efficient and the messages of the seed industry clear and consistent. The seed industry was able to make use of all possible channels to put forward its views so as to ensure that the necessary legislative adjustments would be considered and taken over in the new legislation.

Regular consultations and contacts with other sectors, in particular farmers and crop protection industry, also helped raising awareness of a wider audience for more active participation and support. Such collaboration with COPA (farmers) and ECPA (crop protection) notably materialized with the organization of a joint industry workshop in Spring 2008 where over 100 experts gathered to analyze the potential impact of the new legislative proposal on availability of PPP. Farmers, crop protection and seed association repeatedly called upon EU legislators to acknowledge the need for a sufficiently wide range of crop protection solutions to take account of the increasingly diverse production of Europe's farmers and growers.

- **New PPP legislation – next challenges for the seed industry**

The ESA Secretariat and ESA STAT members will now focus their activities on the implications of the new legislative framework for the seed industry. An ESA explanatory guide is being developed to the attention of ESA members. Some uncertainties still remain with regards to the practical implementation at EU and national level, the transitional provisions and practical use of the new provisions by the crop protection industry and other relevant actors. The ESA STAT will closely monitor the application of the Regulation and the implementation of the Framework Directive in the Member States. The latter may also have significant impact on the use of specific application techniques in defined areas (sensitive areas, playgrounds, recreational areas, etc). Similarly, the potential influence of NAP on the effective availability of workable PPP solutions will require a continued scrutiny.

- **OECD meetings**

On January 28 the OECD Technical Working Group on variety Identity and Purity met in Paris followed by the annual meeting of the Extended Advisory Group (EAG). In total 48 experts participated from 26 countries. It was the first meeting for Mrs. Katarina Djermanovic who replaces Bertrand Dagallier in the OECD Secretariat. The EAG discussed the action plan in relation to the OECD strategy and agreed on proposals in relation to effective implementation of the Schemes, communication, the enhancement of policy awareness through better linkages to seed related issues, institutional and technical developments as well as to enlarge participation in the Schemes. In addition the EAG agreed to address the introduction of a special category in relation to seeds of varieties not yet listed, comparable to the provision for orange labels within the EU. ESA supported the proposal as this would clearly improve the export of seed of not yet listed varieties to especially eastern European countries. The issue of VCU was discussed following an intervention by Canada and it was agreed that the OECD Secretariat will list the conclusions of the discussion in 2008 before taking any further initiatives. The OECD Annual Meeting is scheduled for in Paris in the first week of July 2009. (BS)

- **ESA Secretariat meets Seed Unit DG SANCO**

The ESA Secretariat met with the Seed Unit of DG SANCO on 23.01.2009 for its regular exchange on the work programme and planning of the Commission on seed related matters. Main items of discussion were the ongoing



evaluations of the seed marketing Directives (Better regulation), the plant health regime and the GM food/feed legislation as well as the future role of the CPVO. Further information on these specific issues is given in separate articles.

In the framework of the so-called 'mobility principle' for leading Commission staff, M. Flueh, currently Head of Unit E 1 in SANCO will leave his position on 01.03.2009 and take over the Unit E 3 in SANCO which is responsible for Chemicals, Pesticides and contaminants. As of 01.03.2009, the biotech and plant health unit (responsible for seed legislation) will be headed by Deputy Head of Unit Dorothée André. When and by whom the position of Head of Unit will be filled will be decided only following a Commission internal call for candidatures and selection process which might last several months. (vE)

- **The European Seed Conference on 18.03.2009 - next step of the Better Regulation process for seed marketing legislation**

The European Commission will hold a high level seed conference on 18.03.2009 to present the conclusions and final report of the evaluators on the Better regulation initiative for the seed marketing legislation. Next to an extensive overview on the BR process and the findings by the evaluator, the programme will include presentations from representatives of Member States, third countries, the European Parliament, farmers and seed industry. Registration to the conference which will be open to the public is via a dedicated website and processed on a first come – first served base.

If you are interested to attend the conference, please go to the following link:

http://ec.europa.eu/food/dyna/seed_conf/index.cfm

The ESA Secretariat will also inform all Members about the open registration by e-mail and we urge members to make use of the opportunity to be present at this important event.

- **Yet another evaluation - EU GMO legislation under scrutiny by Commission's DG ENVI and SANCO**

Next to the Better Regulation initiative for the seed marketing legislation and the evaluation of the EU's plant health regime in which we reported in our last Newsletter, the Commission is starting to conduct yet another evaluation of its seed related legislation: both the legislation governing the deliberate release of GMOs into the environment (Directive 2001/18 and associated implementing measures) as well as the Regulation on the placing on the market of GM food and feed (Regulation 1829/2003) are up for an overall Commission review. While the first will be carried out by DG ENVI, the latter is in the responsibility of DG SANCO. Both DGs have set up a joint Steering Group in order to keep each other updated and in view of the obvious links between the two sets of regulations. Unlike the Better Regulation exercise, the GM evaluation will not involve member States in a formal Steering Group but rather at the level of expert meetings on specific aspects of the legislation. Here, a Working Group dealing with the definition of GMOs and specifically with the classification of (novel) breeding techniques must be mentioned. National experts and Commission are currently discussing which techniques may or may not fall under the existing or a potentially revised legislation. ESA has set up a specific Working Group Breeding Technologies (WGBT) to provide input to both Commission and Member States and a formal consultation has been agreed upon already with DG ENVI to this effect.