

# crop protection monthly

international news, comments, features and conference reports

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## CONTENTS

### LEAD ARTICLE

SCIENTISTS APPEAL TO ANTI GM CAMPAIGNERS	2
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### EUROPEAN NEWS AND MARKETS

GOWAN TO DEVELOP SDS RICE HERBICIDE IN THE EU	3
POLAND PLANNING TO IMPOSE BAN ON MONSANTO'S MON 810	3
EU AND FAO SUPPORT DISPOSAL OF OBSOLETE PESTICIDES	3
CROP PROTECTION INDUSTRY INTENSIFIES WATER PROTECTION	4
UK SCIENTISTS DISCOVER NEW CHEMICAL SIGNALS IN MAIZE	4

### AMERICAN NEWS AND MARKETS

BAYER INTRODUCES NEW POTATO SEED TREATMENT	5
GOWAN TO MARKET NISSO'S SOYBEAN INSECTICIDE IN THE US	5
MONSANTO OFFERS CUCUMBERS WITH IMPROVED DISEASE RESISTANCE	5
PHC AND MANA TEST HARPIN TECHNOLOGY WITH FUNGICIDES	5
DUPONT STEPS UP INVESTMENT IN PLANT GENETICS RESEARCH	6
BASF SUBMITS ITS REGISTRATION APPLICATION FOR ENGENIA	6
NICHINO AMERICA APPOINTS ENGAGE AGRO FOR PRODUCTS IN CANADA	6
GOWAN TO MARKET OTSUKA MITICIDE IN CANADA	6
EPA DECLARES 2, 4-D TO BE SAFE	6
BAYER RECEIVES EPA APPROVAL FOR TWINLINK TECHNOLOGY IN COTTON	7
MONSANTO EXPANDS ROUNDUP READY PLUS	7

### OTHER NEWS AND MARKETS

BAYER AND KWS TO DEVELOP WEED CONTROL SYSTEM FOR SUGAR BEET	8
DUPONT FORMS DISTRIBUTION ALLIANCE IN INDIA	8
INCOTEC AND KEYGENE COLLABORATE ON SNP TECHNOLOGY	8
SYNGENTA AND NOVOZYMES COLLABORATE ON PHOSPHATE UPTAKE	8
SYNGENTA FIRST QUARTER SALES INCREASE BY 9%	9
BAYER FIRST QUARTER SALES UP 15.6%	9
BASF REPORTS A 7.9% INCREASE IN SALES FOR Q1	10
FMC SALES INCREASE BY 32% IN FIRST QUARTER 2012	10
CHEMTURA'S FIRST QUARTER SALES UP 13%	10
AMERICAN VANGUARD Q1 SALES UP 32%	11

### CONFERENCES AND FEATURES

INSECT DECLINE	12
REGISTRATION OF AGROCHEMICALS IN EUROPE	14

### BOOK DISCOUNTS

## LEAD ARTICLE

### SCIENTISTS APPEAL TO ANTI GM CAMPAIGNERS

Crop scientists at Rothamsted Research, a government funded agricultural research centre in the UK, have appealed to anti GM protesters not to destroy a field trial of genetically modified wheat at a day of action due to take place on 27 May. The researchers who have taken a gene from a peppermint plant and inserted it into wheat, have both written to the campaigners and recorded a video plea in an attempt to save their experiments.

The video says: "We know we cannot stop you taking the action you are planning to take, but please reconsider before it is too late and before several years of work to which we have been devoting our lives will be destroyed forever." The video goes on to invite protesters to discuss their objections instead of uprooting the trial. The anti GM lobby group *Take the Flour Back* claims that the Rothamsted GM wheat trial poses a 'contamination' threat to the local environment and to the UK wheat industry.

While the Rothamsted scientists have put forward a very strong science-based case for the experiment, the campaigners currently have no plans to cancel the raid. Professor Maurice Moloney, director and chief executive of Rothamsted Research, said: "This is a critical experiment that begins Rothamsted's investigation of second generation GM technologies which focus upon naturally occurring deterrents of pests and diseases. We believe that using GM as a tool to emulate natural defence mechanisms provides a unique and world-leading approach that will also benefit the environment."

The scientists at Rothamsted have been seeking novel ecological solutions to overcome the problem of aphids in wheat. One approach has been to use an odour, or alarm pheromone, which aphids produce to alert one another to danger. This odour, (E)- $\beta$ -farnesene, is also produced by some plants as a natural defence mechanism and not only repels aphids but also attracts the natural enemies of aphids such as ladybirds.

The scientists are using biotechnological tools to genetically engineer a wheat plant which produces high levels of this aphid repelling odour, which could help promote sustainable and environmentally friendly agriculture. Rothamsted says that the work, sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC), is not for commercial gain. It forms part of a wider scientific strategy for Rothamsted Research to meet the challenge of increasing food and energy production in a more environmentally sustainable way.

The Society of Biology has strongly endorsed Rothamsted's approach to engaging in debate. It said: "We support the use of GM technology when properly regulated and tested. Trials such as this are essential if we are to determine whether specific GM crop varieties are effective. Tight regulations control GM research to ensure there are no safety risks resulting from the trials, and we therefore support the field testing of GM crops. We believe the results have potential value for food security around the world."

The BCPC (British Crop Production Council) commented on the planned day of action by saying: "This is a general attack on scientific advances that are aiming to meet one of the world's biggest challenges - providing safe and nutritious food for a growing global population, whilst reducing the environmental impact of production."

*Take The Flour Back* claims to be a broad coalition of people - bakers, farmers, school workers. It has responded to Rothamsted's invitation saying: "We would welcome the opportunity to engage with you in a public debate over the forthcoming weeks, so that both sides have an equal chance to hear and understand each other's perspectives. To this end we invite you to join us on neutral ground, with a neutral chairperson, for an open exchange of opinions and concerns."

Calling on campaigners publicly not to destroy crops and appealing on the basis of the environmental credentials of GM crops is a relatively new tactic for scientists, and was deployed with some success by the Sainsbury Laboratory in Norwich, UK last year. Protests were held under the banner *Take the Spuds Back*. However, no attempt was made to destroy the site where a trial with a GM potato, modified to resist potato blight, was carried out.

## EUROPEAN NEWS AND MARKETS

### GOWAN TO DEVELOP SDS RICE HERBICIDE IN THE EU

SDS Biotech KK has extended its exclusive evaluation agreement with Gowan for the herbicide benzobicyclon so that it includes key rice growing areas in the EU. Benzobicyclon controls sedges, grasses and broadleaf weeds in flooded rice. It is already one of the largest selling rice herbicides in Asia and will be introduced into the Californian rice market in the very near future. "Gowan welcomes the opportunity to bring this molecule to Europe," said Keith Holmes, the benzobicyclon product manager. "The new mode of action in rice, combined with good crop safety and outstanding control of a wide range of weeds will make it an excellent tool for European rice producers."

Herbicide resistance in key rice weeds has become one of the major hurdles to rice producers around the world say the two companies. Benzobicyclon offers a new mode of action to control rice weeds that have developed resistance to older chemistries. Under the agreement, Gowan, in cooperation with SDS, has initiated an extensive development and registration programme, with the goal of delivering new weed management tools to rice growers throughout the Southern EU.

### POLAND PLANNING TO IMPOSE BAN ON MONSANTO'S MON 810

Polish Agriculture Minister, Marek Sawicki, recently announced that the Polish Government was planning to impose a ban on Monsanto's MON 810, the insect resistant maize crop. This is the only GM food crop that can be cultivated in the EU. The announcement followed a protest by environmental lobby groups. The justification for a total ban of MON 810 is that pollen from the crop could have a harmful effect on bees. Mr Sawicki said: "European law forbids any discrimination against genetically modified crops, but it allows for a national ban, provided the ban is justified."

If Poland implements a ban it will follow in the footsteps of Austria, France, Germany, Greece, Hungary and Luxembourg, which have all banned the cultivation of MON 810 at different stages, saying it threatens biodiversity. France has recently re-imposed a temporary ban having had the ban it put in place in 2011 overturned by the European Commission. Some reports suggest that a ban imposed by Poland on legal grounds could also be rejected by the European Commission. Mr Sawicki however believes that the Polish justification has a greater chance of being accepted.

Polish law forbids the trading of GM seeds, but the cultivation of the seed is permitted. Many Polish farmers therefore purchase the seeds in neighbouring countries and cultivate them in Poland. It is reported that some 3000 fields have been planted with MON 810.

### EU AND FAO SUPPORT DISPOSAL OF OBSOLETE PESTICIDES

A programme is to be implemented over the next four years, to help Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan to manage the disposal of stocks of obsolete pesticides. The EU is contributing €6 million to the initiative, and FAO, which will be the operating agency, has allocated €1 million.

It is estimated that nearly half the world's stockpiles of obsolete pesticides, amounting to around 200,000 tonnes, can be found in the 12 countries. The stocks are believed to be located in tens of thousands of unprotected sites, and pose a serious threat to the health of the people in the vicinity and to the environment. The project is also intended to avoid the build-up of additional stockpiles in future, and to set in motion activities to reduce risks from all pesticides used in agriculture.

José Graziano da Silva, director-general of FAO ([www.fao.org](http://www.fao.org)), commented: "Pesticides may be an important input for farming, but they need to be used responsibly while protecting human health and the environment from their adverse effects. In our quest for sustainability and to meet the challenge of feeding a growing population while preserving our environment, we also need to take a good look at the different options we have to protect crops and improve productivity. This includes using natural means to protect and improve crop yields through sustainable crop intensification, or 'save and grow' techniques as we call it at FAO." In addition to helping to organise the disposal of stockpiles, the programme will also aim to help establish local capability in legislative reform, pesticide registration processes, the promotion of alternatives to the most hazardous chemicals in use and the development of communication strategies to raise awareness among farmers and the public.

## CROP PROTECTION INDUSTRY INTENSIFIES WATER PROTECTION

Safeguarding water is one of the thematic areas that ECPA (European Crop Protection Association) is working on as part of its *Time to Change* initiatives. One of the projects, TOPPS prowadis (Train Operators to Promote best Practices and Sustainability), is currently run in collaboration with seven EU member states and fourteen different partners. The crop protection industry plans to expand the TOPPS prowadis ([www.topps-life.org](http://www.topps-life.org)) initiative going forward to all EU member states. To this end some 90 delegates representing research institutes, national authorities, farmer associations, water industry and the crop protection industry recently gathered in Brussels. The workshop's objective was to exchange views and discuss practical solutions for professional pesticide users on how to best mitigate water contamination from diffuse sources.

"What we describe as diffuse sources is pesticide run-off and drift at field level," explained Philippe Costrop, project chairman of the initiative. "As diffuse sources are often the main cause of water contamination, we want to offer concrete recommendations to farmers to protect water. As part of the TOPPS prowadis projects we have been preparing best management practices, training materials and information for farmers with tools on how to reduce losses of crop protection products to water bodies."

"Studies have proven that with simple risk mitigation measures and best management practices 80% of water contamination can be prevented," said Friedhelm Schmider, director general of ECPA. "Minor modifications applied by the farmer can have a significant impact on water quality. The understanding that it can be markedly improved by knowledge transfer to the field has been driving all of our efforts. We plan to reach out to 350,000 farmers and their advisors, land managers and pesticide operators in key European agricultural markets, addressing main European water protection issues and the new pesticides legislative requirements."

## UK SCIENTISTS DISCOVER NEW CHEMICAL SIGNALS IN MAIZE

Scientists funded by the Biotechnology and Biological Sciences Research Council (BBSRC) have discovered that maize crops emit chemical signals which attract growth-promoting microbes to live amongst their roots. This is the first chemical signal that has been shown to attract beneficial bacteria to the maize root environment. The study was led by Dr Andrew Neal of Rothamsted Research in Hertfordshire and Dr Jurriaan Ton of the University of Sheffield's Department of Animal and Plant Sciences. Their research could be particularly useful in the fight against soil-borne pests and diseases. By breeding plants that are better at recruiting disease suppressing and growth promoting bacteria the scientists hope to reduce agricultural reliance on fertilisers and pesticides.

Dr Neal said: "We have known for a while that certain plants exude chemicals from their roots that attract other organisms to the area. In fact, the environment around a plant's roots teems with microorganisms and populations of bacterial cells can be up to 100 times denser around roots than elsewhere. Simple compounds such as sugars and organic acids are attractive to these microorganisms as they are a good source of energy; however other more complex chemicals were not known to serve as attractants because they were typically thought of as toxic. Now we have evidence that certain bacteria - we studied a common soil bacterium called *Pseudomonas putida* - use these chemical toxins to locate a plant's roots. The plant benefits from the presence of these bacteria because they make important nutrients like iron and phosphorous more available and help by competing against harmful bacteria around the root system."

The roots of young maize plants exude large quantities of chemicals called benzoxazinoids or 'BXs' which are known to play a role in helping the plant defend itself against pests above the ground in its stem and leaves. Dr Neal and Dr Ton found that a number of bacterial genes that are associated with movement responded to one of these BX chemicals, encouraging *Pseudomonas putida* to migrate towards the plant. They also found that the presence of the bacteria accelerated the breakdown of BX molecules suggesting that the bacteria have evolved the ability to detoxify the root environment, perhaps even using BX molecules as an energy source. Dr Ton added "Our study has opened up exciting new opportunities for follow-up research. One interesting lead suggested that the BX chemicals not only recruit the bacteria to the root surface, but they also activate processes in these bacteria that can help to suppress soil-borne diseases. This is really exciting as it would mean that the plant is not only recruiting beneficial microbes but also regulating how they behave."

## AMERICAN NEWS AND MARKETS

### BAYER INTRODUCES NEW POTATO SEED TREATMENT

Bayer CropScience is introducing *Titan Emesto*, a liquid insecticide and fungicide potato seed treatment for protection against major insect pests and diseases. The product features a new coloured formulation that ensures growers can uniformly and safely apply it to potato seed to maximise pest control and yield potential. The company says the product gives good Fusarium protection, superior seed-borne Rhizoctonia control, good activity on silver scurf and insect control.

“*Titan Emesto* is a combination-pack of *Titan* (clothianidin), the broad spectrum potato seed treatment insecticide, and *Emesto Silver* (penflufen + prothioconazole), a new fungicide with two new modes of action that protects against major diseases,” says David Kikkert, portfolio manager for horticulture. “Growers will benefit from the outstanding protection provided by *Titan Emesto* against Fusarium tuber rot including current resistant strains, seed-borne Rhizoctonia, silver scurf, Colorado potato beetle, leafhopper, aphids and flea beetle, and reduces the damage caused by wireworms.”

“To achieve optimal disease and insect control, growers must ensure good uniform coverage,” says Andrew Dornan, responsible for field development in Eastern Canada. “Our coloured formulation is a unique feature making it easy for growers to see and experience the difference *Titan Emesto* makes.” Products from the *Emesto* family are expected to be granted approval in more than 40 countries, in particular in the growing markets for seed treatments in Latin America and Asia.

### GOWAN TO MARKET NISSO’S SOYBEAN INSECTICIDE IN THE US

Gowan Company and Nisso America have announced that the insecticide *Justice* has been approved by the Environmental Protection Agency (EPA) for use on soybeans in the US. Gowan will have exclusive rights to the premix formulation which contains a neonicotinoid for aphid control and acetamiprid and bifenthrin for fast knockdown of insect pests. “*Justice* will be marketed as a liquid oil flowable formulation that allows both active ingredients to remain in their most biologically active form,” says Gowan. The foliar-applied insecticide is used at rates ranging from 2.5-3.0 fluid ounces per acre (0.18-0.24 litres/ha) It has a 30 day preharvest interval, a 12 hour restricted entry level, and a zero plant back interval for soybeans, and a 30 day plant back interval for all other crops.

### MONSANTO OFFERS CUCUMBERS WITH IMPROVED DISEASE RESISTANCE

Monsanto’s Seminis brand will be offering cucumber growers in the US and Canada two hybrids that increase harvestable yield potential and enable the growers to reduce the number of sprays needed to control downy mildew. “This disease is a significant problem globally and affects the yield and quality of many crops, including cucumbers,” said Ronnie Blackley, Monsanto’s Cucurbit Technology Development lead. “We are very excited to be able to offer cucumber growers a new defence against this damaging disease, which was previously limited to fungicides.” The effective disease resistance has been developed through conventional breeding and a new donor. The two downy mildew resistant cucumber varieties, SV3462CS and SV4719CS, will be offered exclusively with *FarMore F1400 Cucumber Technology* from Syngenta Seed Care. Monsanto says that this proprietary seed protection system provides superior fungal disease and insect control while working to maximise cucumber production value by enhancing performance and quality.

### PHC AND MANA TEST HARPIN TECHNOLOGY WITH FUNGICIDES

Plant Health Care (PHC) ([www.planthealthcare.co.uk](http://www.planthealthcare.co.uk)) and Makhteshim Agan North America (MANA) have signed an agreement that will combine PHC’s dry formulated *Harpin*  $\alpha\beta$  protein technology with selected MANA technologies for corn, soybeans, and dry beans in the US. In 2012 the two companies will test market combinations of PHC’s yield enhancing protein technology with MANA’s foliar fungicides *Bumper* (propiconazole) and *Incognito* (thiophanate-methyl). This programme follows the same model that will result in an estimated three million acres (1.1 million ha) of soybeans being treated with *Harpin* seed treatment in 2012.

The US foliar corn fungicide market exceeded \$135 million in grower value in 2011 but more than 80% of spend was on strobilurin-based fungicides, classified as high risk for developing fungal resistance. The use of *Harpin* protein in combination with non-strobilurin-based fungicides mitigates the development of strobilurin-based fungicide resistance, and represents a new opportunity for an effective replacement to be introduced in situations where strobilurin-based fungicides may no longer be effective. John Brady, CEO of PHC, said: “The three years of field results achieved in corn with

*Harpin* plus fungicides led to our test marketing agreement with MANA, and validates our belief that *Harpin* can be used effectively to improve the performance of foliar fungicides in these crops."

## **DUPONT STEPS UP INVESTMENT IN PLANT GENETICS RESEARCH**

DuPont has opened a \$40 million plant genetics research facility at Beaver Creek in Iowa, US. The company has indicated that the research and development activity, to be housed in a new state-of-the-art building, will lead to the creation of around 400 new jobs. Paul E Schickler, president of DuPont's Pioneer Hi-Bred business, said: "Beaver Creek will take DuPont's research and development efforts in seed and plant genetics to the next level and ensure we are consistently providing new solutions and products to farmers and communities around the world." Research groups will include scientists with expertise in plant physiology, molecular biology and bioinformatics. The focus will be on plant breeding and the development of new transgenic products. Pioneer has increased its workforce by 1,400 positions during the last five years. DuPont is projected to be spending \$10 billion by the end of 2020, in research and development dedicated to the food, agriculture and nutrition sectors.

## **BASF SUBMITS ITS REGISTRATION APPLICATION FOR ENGENIA**

BASF Crop Protection has now submitted its registration application for the herbicide *Engenia* to the regulatory agencies in the US. The product is a technologically advanced dicamba formulation. Farmers will be able to use *Engenia*, in combination with other herbicides and agronomic practices, in a weed control system enabled by dicamba-tolerant crops currently in development. "Farmers fighting against herbicide resistance have an important new tool in *Engenia* which, field research shows, will offer excellent weed control and crop safety, as well as low volatility characteristics for improved on-target application," said Paul Rea, vice president, US Crop Protection, BASF.

*Engenia* will deliver broad-spectrum burndown of more than 100 annual broadleaf weeds, including tough, glyphosate-resistant weeds like Palmer amaranth, waterhemp, marestail, velvetleaf, morning glory and giant ragweed. Field research demonstrates that *Engenia* is more effective than 2, 4-D on many problem weeds, such as velvetleaf, marestail, giant ragweed and morning glory. "Farmers have only a few post-emergence herbicide options in soybeans," Mr Rea said. "*Engenia* offers an additional site of action for post-emergence control, and can also be used pre-emergence in dicamba-tolerant soybeans, giving farmers maximum application flexibility to target key weeds." BASF anticipate a registration decision will be received in parallel with the commercialisation of a dicamba-tolerant soybean system in around 2015. Cotton, corn and canola will follow.

## **NICHINO AMERICA APPOINTS ENGAGE AGRO FOR PRODUCTS IN CANADA**

Nichino America has announced an agreement with Engage Agro ([www.engageagro.com](http://www.engageagro.com)), which will expand its US business into Canada. Under this agreement Engage Agro will register, market, and sell fenpyroximate, flutolanil, tolfenpyrad, and buprofezin products. "This is the first opportunity for Nichino America to expand its business outside the US and is an exciting alliance for us. We have a product portfolio of excellent chemistry, and this agreement will allow us to offer crop protection solutions in the Canadian marketplace," says Jeffrey Johnson, President of Nichino America. With current development activities underway, Engage Agro anticipates the first commercial launches in 2014.

## **GOWAN TO MARKET OTSUKA MITICIDE IN CANADA**

Otsuka AgriTechno, Japan and Gowan have recently signed a memorandum for exclusive distribution of Otsuka's product *Acaritouch* in Canada. The distribution agreement will be preceded by a period of evaluation and later registration in Canada to position the product according to market needs. *Acaritouch* is a novel contact miticide, is environmentally friendly and used in Integrated Pest Management programmes in registered countries. It also has mildewicidal properties.

This is the first such agreement between the two companies and is for all uses in Canada. "Gowan Canada is excited to be involved in the *Acaritouch* project", says Garth Render, business manager for Canada. "The product is a new tool for mite control in a wide range of crops from orchard and vine to greenhouse vegetables and ornamentals. *Acaritouch* will be a welcome addition to Gowan Canada's new line of green crop protection products."

## **EPA DECLARES 2, 4-D TO BE SAFE**

The US Environmental Protection Agency (EPA) recently ruled on a petition filed in 2008 by the Natural Resources Defence Council (NRDC) environmental group which had sought the cancellation of all 2, 4-D product registrations and the revoking of all tolerances. The Agency declared, based on studies addressing endocrine effects on wildlife species and the adequacy of personal protective

equipment for workers, that the science behind the current ecological and worker risk assessments for 2,4-D is sound and there is no basis to change the registrations.”

In 2005, EPA completed a review of the registration and the safety of the tolerances for 2,4-D. It determined that all products containing 2,4-D are eligible for reregistration, provided certain changes were incorporated into the labels and additional data was generated and submitted to the EPA for review. EPA's statement on 9 April, having evaluated all of the data cited by NRDC including new studies submitted in response to the reregistration decision, said: “This study and EPA's comprehensive review confirmed EPA's previous finding that the 2,4-D tolerances are safe.” Included in the studies is a reproduction study providing an in-depth examination of 2,4-D's potential for endocrine disruptor, neurotoxic, and immune-toxic effects.

## **BAYER RECEIVES EPA APPROVAL FOR TWINLINK TECHNOLOGY IN COTTON**

Bayer CropScience has received registration from the US Environmental Protection Agency (EPA) for its *TwinLink* technology for cotton in the US. The EPA registration completes the federal regulatory authorisation. *TwinLink* combines dual insect resistance for effective management of a number of caterpillar pests and tolerance to *Liberty* (glufosinate ammonium). When commercialised, the technology will be offered to US cotton growers in combination with *GlyTol*, which imparts tolerance to glyphosate herbicides. The stacked product will combine dual insect resistance with dual herbicide tolerance, allowing farmers to manage the pests and weeds that reduce yields and fibre quality, as well as prevent or postpone the onset of weed and pest resistance.

It is anticipated that the first cotton varieties with the *TwinLink* and *GlyTol* stacked traits will be available in the US from 2013 onwards, pending additional regulatory approvals in key import countries. *TwinLink* has now been approved in Australia, New Zealand, Brazil, Canada and the US.

## **MONSANTO EXPANDS ROUNDUP READY PLUS**

Monsanto has expanded its popular *Roundup Ready Plus Weed Management Solutions* platform to include two more post-emergence herbicides for use in soybeans. These additional options are highly effective on tough to control weeds, such as waterhemp and Palmer amaranth pigweed. According to Dr Rick Cole, weed management technical lead for Monsanto, Midwestern soybean growers are becoming increasingly aware of the threat of weed resistance to various herbicides, and the best way to manage resistance is to use residual herbicides.

“Farmers need to be proactive in taking steps now to manage establishment of tough to control weeds, including those resistant to glyphosate or other types of herbicide chemistries,” Dr Cole says. “This is true whether they have experienced weed resistance or not.” The additional post-emergence herbicides for *Roundup Ready Plus* in 2012 include *Cobra* (lactofen) and *Flexstar* (formesafen). *Cobra* is claimed to be an excellent fit for northern states due to its activity on waterhemp, while *Flexstar* will be offered for use in the Mid-South region of Arkansas, Mississippi and west Tennessee because of its efficacy against Palmer amaranth pigweed.

Dr Cole said: “We listened to our customers, who were concerned about what options farmers might have to fall back on if there wasn't sufficient rain to activate our pre-plant and pre-emergence residual herbicides. In the event of dry conditions, growers will now have more post-emergence residual herbicide options in soybeans.” Developed in conjunction with leading academics, agronomists and other industry partners, the *Roundup Ready Plus* platform offers recommendations and incentives for control of glyphosate-resistant and other tough weeds, such as those that are resistant to multiple herbicide chemistries. Monsanto's *Roundup Ready Plus Weed Management Solutions* platform offers financial incentives to soybean growers of up to \$10 per acre to use selected pre-emergence and post-emergence residual herbicides.

## OTHER NEWS AND MARKETS

### BAYER AND KWS TO DEVELOP WEED CONTROL SYSTEM FOR SUGAR BEET

Bayer CropScience and KWS SAAT AG have signed an agreement to jointly develop and commercialise an innovative system of weed control in sugar beet for the global market. The technology is based on the breeding of sugar beet varieties that are tolerant to broad spectrum herbicides in the Acetolactase Synthase (ALS) inhibitor class. This will give farmers a new opportunity to make sugar beet cultivation easier, more flexible in its timing and more environmentally friendly.

“We started work on this innovative system 11 years ago. It will significantly improve the competitiveness of sugar beet and enable our customers to cultivate sugar beets more successfully in future,” explained Dr Peter Hofmann, head of the sugar beet division at KWS. The new sugar beet plants have a naturally occurring change in an enzyme involved in the biosynthesis of essential amino acids. During the development, sugar beets with this spontaneously changed enzyme were specifically selected and used for further breeding. As such, these varieties are not considered to be products of genetic modification. “There have been no new active ingredients for weed control in sugar beet for many years. The new system will make it possible in future to use new active ingredients in sugar beet and to control major weeds with low dose rates of product and reduced number of applications,” said Christophe Dumont who is responsible for Bayer’s business strategies in soy, corn, cotton, sugarcane, sugar beet and for the herbicides portfolio.

### DUPONT FORMS DISTRIBUTION ALLIANCE IN INDIA

DuPont Crop Protection (DCP) India recently signed a memorandum of understanding for a distribution alliance with the Punjab State Cooperative Supply and Marketing Federation Limited (Markfed), a federation of more than 3,000 societies in Punjab State. Markfed represents the interests of more than a million farmers in the state. This means that DCP products will be sold through the distribution network of Asia’s largest marketing cooperative. “This alliance with Markfed is one more step in our commitment to finding new ways to collaborate with local partners to address the challenge of food productivity. It also fits well with our strategy to rapidly expand our reach in India and will allow DuPont access to one of India’s largest crop protection markets,” said Balvinder Kalsi, former president for DuPont South Asia. “Reaching the farming community through this agency with more than 3,000 cooperatives will be easier now,” said Ram K Mudholkar, director for DCP South Asia and ASEAN (South East Asia). “We see a huge potential for growth and aim to facilitate this growth with quality products.”

### INCOTEC AND KEYGENE COLLABORATE ON SNP TECHNOLOGY

Incotec, an independent seed processing company, and KeyGene, a leading agro biotechnology company specialising in molecular plant genetics, are to collaborate on DNA based Single Nucleotide Polymorphisms (SNP) technology. The two companies will develop, identify and select SNPs from a number of crops and use them for testing hybrid purity and variety verification. For each crop a proprietary set of SNPs will be developed that will be tested on germplasm collections originating from all over the world. Both companies will make these unique SNP sets available for a broad range of seed companies. Development and commercialisation will be phased. The SNP sets will be developed for vegetables as well as field crops such as corn, sunflower and cotton. Incotec will promote services using these SNP sets worldwide through its global affiliates, with the actual testing of varieties and determination of hybrid purity performed centrally by the company in the Netherlands. Managing director of Incotec Analytical Lab Europe BV at Zwaagdijk, the Netherlands, Rob Pronk, said: “With the new services we are offering, a broad range of companies can now increase their quality control and improve their product development.”

### SYNGENTA AND NOVOZYMES COLLABORATE ON PHOSPHATE UPTAKE

Under a global agreement Syngenta will commercialise Novozymes’ technology *JumpStart*, a seed-applied biological which increases phosphate solubility in the soil. The two companies will jointly develop the market for *JumpStart* in combination with Syngenta’s Seed Care portfolio on crops including cereals and corn. The agreement extends the geographic potential of *JumpStart*, currently sold mainly in North America, to the rest of the world.

Phosphorus is an essential macronutrient for the healthy growth of young plants. *JumpStart* is based on a unique fungus, *Penicillium bilaii*, which increases phosphate uptake into the plant through the root system. The market potential for seed-applied technologies to increase phosphate efficiency is estimated at over \$100 million. John Atkin, COO Syngenta, said: “We are pleased to enter into this



agreement with Novozymes ([www.novozymes.com](http://www.novozymes.com)) which marks a further addition to our growing range of bioactives. Our Seed Care portfolio already offers best-in-class control of insects and disease together with crop enhancement benefits. With the addition of *JumpStart*, growers will now gain the added advantage of improved phosphate efficiency.”

### **SYNGENTA FIRST QUARTER SALES INCREASE BY 9%**

Syngenta sales in the first quarter of 2012 increased by 9% at constant exchange rates. Volumes were up 5% with a further 4% contribution from price. Reported sales were 7% higher at \$4.3 billion. In Europe, Africa and the Middle East sales increased by 14% at constant exchange rates compared with the same quarter in 2011. In France, a strong underlying performance by *Callisto* (mesotrione) on corn and in fungicides was augmented by a shift in sales from the fourth to the first quarter following a change in the law on credit terms. Eastern Europe continued its growth trajectory, with sales up by more than 25% helped by a broadening of the crop protection range and strong demand for spring crop seeds; in Ukraine, seeds sales doubled to exceed \$100 million. In North America sales were up 13%. Syngenta says that crop protection sales reflected an early start to the season and recognition of the company’s capabilities in resistance management and crop enhancement. There was also strong demand for Syngenta’s enhanced corn seed portfolio, in particular the *Agrisure Viptera* trait. Sales of soybean and vegetable seeds, however, were lower.

In Latin America, at the end of the season, an increase in second season corn in Brazil partly offset the effect of drought in Argentina and southern Brazil. Seeds sales continued their rapid expansion, with growth of over 40% and market share gains in both corn and soybean. Growth in Asia Pacific was also led by seeds, notably corn; crop protection sales were slightly lower owing to cold and wet conditions in Australasia and to range rationalisation in India and Japan. China and the emerging ASEAN markets showed strong growth across the business.

Mike Mack, CEO, said: “After a strong year in 2011 sales momentum continued in the first quarter, with an excellent start to the season in both Europe and North America. The implementation of our integrated strategy is proceeding rapidly and we are already seeing benefits in the leverage of our portfolio and the commercial organisation. This underpins our confidence that we will continue to outperform an expanding market. In 2012, although we face the anticipated headwind from currencies and raw materials, we expect to achieve a further increase in earnings before interest, tax, depreciation and amortisation margin (EBITDA) at constant exchange rates and to sustain strong cash generation.”

### **BAYER FIRST QUARTER SALES UP 15.6%**

Bayer CropScience’s crop protection business has reported that its sales increased to €2,610 million (\$3,400 million) in the first quarter of 2012, up by 15.6% (14.4% on a currency-adjusted basis) against the same quarter in 2011. Earnings before interest and tax (EBIT) of CropScience rose strongly in the first quarter of 2012 from €219 million to €851 million. Special charges amounted to €10 million (Q1 2011: €405 million) and were incurred for restructuring at Crop Protection. EBIT before special items improved by 38.0% to €861 million, while EBITDA before special items advanced by 31.7% to €981 million. The Crop Protection segment posted growth in all product groups and regions. While seed treatment products showed a moderate increase, the other business units registered double-digit growth rates. Sales of insecticides rose by 16.7% to €336 million, benefiting from the company’s rejuvenated portfolio. The herbicides business remains the largest category, with sales up by 21% to €848 million, mainly driven by the company’s corn portfolio, especially the *Adengo* (isoxaflutole + thiencazuron-methyl) group of products. Fungicide sales increased by 11.5% to €554 million. The strongest growth was achieved in North America and Asia / Pacific.

Sales of crop protection in Europe rose by 6.0% (Fx adj) to €903 million. The herbicides, fungicides and insecticides businesses showed solid growth, while seed treatment products were down from the high level of the prior-year period. Growth was driven by the Eastern European countries, particularly Ukraine, along with Italy. In central Europe the company posted a slight increase. Business on the Iberian Peninsula dropped noticeably due to an ongoing drought. Crop Protection sales in North America advanced by a substantial 25.4% (Fx adj) to €432 million. This was the result of an early start to the season and generally favourable market conditions in the US, where the company nearly doubled sales of herbicides due to a balanced portfolio. Insecticides business benefited from the rejuvenation of the portfolio, led by *Movento* (spirotetramet) for fruit and vegetables. Fungicides matched their performance in 2011.

Sales in the Asia / Pacific region achieved double-digit growth rates in all business units and grew by a substantial 24.6% (Fx adj) to €298 million. The products for rice and cereals were especially successful. Sales in the Latin America / Africa / Middle East region moved forward by 14.1% (Fx adj) year on year to €304 million. Growth in Latin America was driven by herbicides, insecticides and seed treatment products. The herbicides business expanded across the entire portfolio and in all important crops. Insecticides developed particularly well in Brazil and Argentina in the major crops of soybeans and cotton. By contrast, demand for fungicides was impaired by drought. Business developed positively overall in Africa and the Middle East.

The company says it expects market conditions for its CropScience business to remain favourable in 2012, and predicts above market growth. The continuing high prices for agricultural commodities are likely to stimulate growth, particularly in Asia / Pacific, Eastern Europe and Latin America.

### **BASF REPORTS A 7.9% INCREASE IN SALES FOR Q1**

BASF reports that its Agricultural Solutions segment got off to good start to 2012. Sales were up 7.9% to €1,327 million (\$1,730 million) in the first quarter of 2012. Sales growth was driven by higher sales volumes (3% up) and prices (3% up). Currency effects also had a positive impact on sales (2% up). EBITDA increased 19.5% to €459 million, and EBIT rose by 22.2% to €419 million.

The company says that the early start to the season in North America due to weather conditions led to an improvement in sales, particularly for herbicides. The season also began positively in Europe. Higher sales prices also contributed to sales growth, and the company continued to strengthen its business in the growth markets of Eastern Europe. BASF posted a slight decline in sales in Asia as higher demand in China was not able to fully compensate for the weaker season in Japan. Increased sales in South America contributed to strong demand for insecticides based on the active ingredient fipronil. However, sustained drought in the southern regions had a negative effect on sales development. The company's business with products for plant health also developed well.

### **FMC SALES INCREASE BY 32% IN FIRST QUARTER 2012**

FMC's Agricultural Products increased sales by 32.2% to \$454.2 million in the first quarter of 2012, driven by broad-based growth in Latin America, North America and Asia. "Our first quarter 2012 results provided a very strong start to what we expect will be another record year for FMC," commented Pierre Brondeau, president, chief executive officer and chairman of FMC. Earnings of \$129.7 million increased 29.1% compared to first quarter 2011 driven by the sales growth, partially offset by higher spending on targeted growth initiatives. The company said sales gains were achieved in all regions.

In North America, sales increased significantly driven by strong demand for pre-emergence herbicides, growth from new products and the shift of some sales to earlier in the year reflecting an early start to the 2012 season due to favourable weather conditions and high crop prices. In Latin America, sales also increased significantly, driven by a strong finish to the crop season, particularly in sugarcane and cotton segments, and sales from the company's new market access joint venture in Argentina. In Asia, sales gains reflected continued strong demand across the region and growth from new products. In Europe, sales increased driven by volume gains in herbicides and fungicides.

FMC says it is confident that sales will increase for the rest of the year. "For the full year, our Agricultural Products segment expects to achieve its ninth straight year of record earnings, up 10-15% reflecting increased volumes in all regions, particularly Latin America, North America and Asia. This is due to strong market conditions and growth from new and acquired products," said Mr Brondeau. "For the second quarter of 2012, we expect segment earnings to be up approximately 5% reflecting growth in all regions partially offset by a shift in some sales in North America to the first quarter and higher spending on targeted growth initiatives.

### **CHEMTURA'S FIRST QUARTER SALES UP 13%**

Chemtura AgroSolution's sales increased 13.3% to \$85 million in the first quarter of 2012. This was the result of a higher sales volume (\$ 10million) and in higher selling prices (\$2 million), offset by \$2 million from unfavourable foreign currency exchange. Increases in sales volume benefited from new products and registrations with growth in revenues in all regions except Southern Asia. North America had the benefit of a mild winter and a warm start to spring. European sales still grew despite the harshest winter in a number of years. Operating income increased \$8 million reflecting the benefit of a \$3 million increase from sales volume and product mix changes, \$2 million from higher selling prices,

\$1 million from lower raw material costs and \$3 million from lower manufacturing and distribution costs, only partly offset by a \$1 million impact from unfavourable foreign currency exchange. Chemtura expects stronger performance this year from its AgroSolutions segment due to its new products, registrations and improved distribution and from Consumer Products as a result of the additional volume it has gained compared to the 2011 season.

### **AMERICAN VANGUARD Q1 SALES UP 32%**

Eric Wintemute, chairman and CEO of American Vanguard, reported: "Our first quarter 2012 business performance reflects positive conditions in the US agricultural sector and was driven largely by the growing demand for our portfolio of granular soil insecticides. Net sales increased 32% to \$87.3 million, compared with \$66.0 million in 2011. Gross profit margins rose to 43% as we achieved improved overall factory utilisation. Operating expenses as a percentage of sales were held to 26%, despite higher regulatory expenses and freight costs that kept pace with our expanding export business. Stronger sales, improved gross margins and operating expense management enabled us to improve our bottom line significantly."

He continued: "We are seeing renewed demand for the use of granular soil insecticides in the US corn market, as growers combat strong pest pressure from both primary and secondary insects. The use of our corn soil insecticides in conjunction with genetically modified seeds as part of an integrated pest management programme provides the most comprehensive defence against the full range of soil insects and can enhance harvest yields. American Vanguard has the largest offering of corn soil insecticides along with the most advanced closed delivery equipment for safely and efficiently dispensing these products." Mr Wintemute concluded: "Our performance during the quarter serves to validate our long-standing belief that conventional chemistry is an essential part of integrated pest management."

## CONFERENCES AND FEATURES

### INSECT DECLINE

*The Society of Chemical Industry's (SCI) BioResources Group ([www.soci.org](http://www.soci.org)) held a one-day conference titled Insect decline: the causes and the role of agriculture in mitigation at Rothamsted Research, Hertfordshire, UK, on 25 April 2012, which brought together ecologists, agronomists and crop protection specialists to discuss this topical issue. Dr Alan Baylis reports for Crop Protection Monthly.*

#### Current situation

Professor David Goulson (University of Stirling) focused on the decline of bumblebees in the UK. More than 250 species of bumblebees are known worldwide, with 25 in the UK. They contribute significantly to the pollination of many crops and wildflowers. Three main factors believed to be involved in bumblebee decline were discussed. Firstly, changes in farming systems which have undoubtedly played an underlying role, reducing sources of nectar. For example, the area of unimproved grassland in the UK, with its diversity of flowering species, has reduced from seven million ha to only 250,000 ha. In more intensively managed grassland, the use of clover has largely been abandoned and there has been a move from hay to silage.

A second factor may relate to the use of commercial bumblebees and the introduction of diseases. *Bombus terrestris dalmatinus* is distributed to 60 countries from hives in Southern Europe. In the UK they are used in the pollination of tomatoes and soft fruit. They are often infected with 'honeybee diseases' including *Nosema ceranae* and Deformed Wing Virus. There is also strong evidence that non-native pathogens have spread with commercial bumblebees in North and South America, devastating natural populations.

Thirdly, neonicotinoid insecticides have been widely implicated and banned in some countries such as Italy. In the UK, clothianidin is most extensively used, followed by thiamethoxam and imidacloprid, with lesser use of thiacloprid and acetamiprid. The main use of these insecticides is as seed treatments for oilseed rape, with other uses as sprays on top fruit and soft fruit, and as soil drenches to turf, as well as garden use. Levels of 0.6 – 28 ppb found in pollen and nectar do not pose any practical lethal threat as massive amounts would need to be consumed to even start to approach the LD50. However, there is evidence from recently published studies of behavioural effects related to navigation when foraging, and ultimately to hive reproduction rates. Another study found that leaching of the water soluble neonicotinoids may have resulted in the high levels found in the pollen and nectar of dandelions in field margins, potentially increasing the exposure to bees.

Professor Goulson concluded that there was no single cause of bumblebee decline and that banning neonicotinoids was not the answer, given their benefits in crop production. Means of boosting numbers of natural populations of bumblebees should be encouraged.

Richard Harrington (Rothamsted Research) presented some findings from more than 40 years of monitoring of insect populations by the Rothamsted Insect Survey. Light traps are used to gather data on moths and suction traps for other insects. Only aphids are monitored routinely from the latter, but samples are retained for analysis of all species by other organisations when funding allows. While moths have generally declined, this is not the case with aphids where there has been no overall change. However, aphid species generally have more than one discrete migratory phase each year, so annual totals may not reflect changes of practical importance. Comparisons of the total insect biomass collected in traps from the east of England with those from the west, have implicated the intensification of arable farming as a factor in decline. In the west, where intensification came later, there has been a significant decline in biomass from a higher starting point in the early years of the survey. One example of an increase in abundance is that of *Culicoides* midges which can be vectors of animal disease. This is possibly associated with a warmer climate. Fecundity and mobility traits in insects probably determine the resilience or success of populations under changing scenarios.

Nick Sotherton (Game and Wildlife Conservation Trust) described how the monitoring of 100 cereal fields in the south of England for the past 40 years has recorded the demise of the Grey Partridge (*Perdix perdix*). Numbers of this species, which has its habitat in arable crops, declined by 90% over the period 1967-2008. Chicks of this species rely on insects as food. These insect species do not have any particular role as pollinators, but are simply weed feeders. They are not very mobile and disperse from elsewhere to re-colonise only slowly. Increasingly successful weed control from the

1970s has broken the food chain. Other contributing factors have been the move from spring barley to winter wheat, less grassland and more monoculture in large blocks of fields. The use of conservation headlands around field margins in which herbicides are used more judiciously has been associated with an increase in numbers of Grey Partridge. On farms with gamekeepers, predator control has also been beneficial. The keys to success were summarised as habitat, food and predator control.

A similar problem of early-life food supply was discussed by Jeremy Thomas (University of Oxford). Three quarters of butterfly species in the UK have declined over recent decades principally because of the elimination of larval food plants. Warming of the climate has shown some benefit for many UK butterfly populations.

Simon Leather (Imperial College, London) illustrated the importance of habitat. He said that the area of tree cover in the UK has quadrupled over the past 100 years. In woodlands, surveys such as the Rothamsted Insect Survey have shown that moth species, for example, show no signs of declining.

### **Progress in encouraging insect biodiversity**

Syngenta was the only agrochemical major to present at the conference. Environmental stewardship manager Peter Sutton discussed the management of farmland biodiversity under intensive arable farming. Under the EU Common Agricultural Policy, farmers have the option of participating in Agri-Environmental Schemes with an emphasis on the management of field margins to improve biodiversity while being practically compatible with growing high yielding crops. The LINK Farm4Bio project has investigated the management of field margins on 28 100 ha sites on UK farms growing 50% winter wheat and 25% oilseed rape. Two types of sown habitats proved to be more reliable in increasing biodiversity than simply establishing grass strips or game cover. A perennial wildflower mix including species such as red clover, various broadleaves and less competitive grasses provided 'flowers over summer', and food and habitat for various arthropod communities all year round. The winter birdseed mix comprised cereals, millet, quinoa, linseed, radish and kale to provide 'seeds over winter' and also a summer habitat for invertebrates.

Reducing spray drift on to field boundaries as a means of mitigating possible adverse effects of crop protection products was addressed by Paul Miller (Silsoe Spray Applications, NIAB-TAG). Marked improvements in the accuracy of spraying have been made by the introduction of better nozzles, especially air-induction designs which combine large droplets less liable to drift with better adhesion to targets, thanks to the 'cushioning' effect on contact provided by the air bubbles within the spray droplets. Also, controlling the height of very wide sprayer booms to operate close to the top of the crop canopy reduces drift. Advances in image capture and analysis with precise nozzle control are meaning that already large weeds in young row crops can be specifically targeted for spot spraying. New perspectives on selective weed control, sparing less competitive species useful in supporting biodiversity may be possible in future.

Claire Robinson (UK National Farmers Union) rounded-off the conference on a practical note. In order to engage farmers to work to promote biodiversity, there must be a single environmental message of direct relevance to each farm. This must be adequately supported by advice and resources from all the various stakeholders.

## REGISTRATION OF AGROCHEMICALS IN EUROPE

*Developments in the registration of plant protection products were discussed at the recent Informa conference Registration of Agrochemicals in Europe held in Brussels on 17/18 April. Peter Chapman from JSC reports on the main topics presented including feedback from European Food Standard Authority (EFSA) and the European Commission, active substance renewal, zonal authorisation and comparative assessment.*

In opening the conference the chairman, Terry Tooby, a regulatory consultant, suggested that the current situation regarding the implementation of the new Regulation 1107/2009 was reminiscent of when Directive 91/414 was introduced. At the time there were insufficient resources available and a lack of clarity in how the legislation was to be implemented. He said there is a real danger that the lessons learned then were not being heeded. He was hopeful that the conference presentations would prove him wrong, particularly as this would be his last conference as chairman.

### EFSA feedback

The head of EFSA's Pesticides Unit, Herman Fontier, gave an overview of the Unit's activities during 2011 and plans for 2012. All resubmissions under Regulation 33/2008 had been completed by the end of 2011. Conclusions on 'green track' substances from Stage 4 of the EU review had been progressed with 34 substances out of 59 approved; the rest would be completed in 2012. Fewer than expected new active substances had been peer reviewed because most have had additional information submitted by the applicant. As far as future work was concerned the major task was the peer review of new active substances. With delays occurring as a result of clock stopping, the number of conclusions will be lower than the 47 originally anticipated. In addition the remaining Stage 4 'green track' substances will be completed along with peer review for three basic substances and at least three confirmatory data evaluations. EFSA is proactively trying to ensure that scientific staff in the Pesticides Unit have the necessary skills to work across the whole range of work in order to better manage shifts in workload and to be able to cope with the possibility of a reduction in staff numbers.

### Regulation 1107/2009

Francesca Arena, head of the Pesticides Sector, DG SANCO reported on progress with implementing Regulation 1107/2009 and the lessons learnt. Decisions following the evaluation of confirmatory data were proving a considerable workload, post-approval, that had not previously been envisaged. Legal opinion was being sought on whether a second company could take over submission of confirmatory data where the original company no longer supported the active. Amendments to approval were subject to the same rules and timelines as a new application. The procedures for amendments and confirmatory data were separate.

Ms Arena explained that there were a number of implementing measures that the Commission was committed to undertake in 2012 and 2013. These include: voting on revision of data requirements expected in June 2012; a report to Council and Parliament on funding for minor uses to be published by end of June 2012; and, guidance documents on parallel trade, seed treatment emergency use (Article 53) and basic substances. An expert meeting was due to be held in late April to discuss the setting of criteria for POPs (Persistent Organic Pollutants) and PBTs (Persistent Bioaccumulative and Toxic) and to integrate decisions taken with other Commission services and the European Chemicals Agency (ECHA). By mid-December 2013 the Commission is also due to provide draft proposals for the establishment of criteria for determining endocrine disrupting substances and a list of candidates for substitution.

DG SANCO is also expecting to reduce staff numbers by 10% in the period 2013-2018 and as a result will be initiating a project to establish 'negative priorities' in order to achieve cost savings and prioritise work. In addition to the already high workload there is expected to be a challenge by the EU Ombudsman on the Commission's lack of use of Article 21 of the Regulation to initiate ad hoc reviews of approvals.

### Active substance renewals

Jeroen Meeussen from DG SANCO provided an update on the latest developments in the renewal programme. The key principles for the next phase of renewals (AIR-3) were that the applicant should provide an application and updating statement no later than three years before the end of the approval period with the dossier submission two and a half years before the expiry. The revised data requirements will apply to all substances and the starting date for submissions will be 1 January 2014. For the first group of 40 substances (expiring before 14 June 2014) it will be necessary to extend the

deadline. Within this group five priority substances have been identified. There will be a single regulation describing the general procedure for the renewal of active substances. Further extensions to expiry dates will be done stepwise as required. Extensions will be based on the condition that the application and dossier have been submitted to ensure that there are no extensions granted for substances that are not being supported. All of the current 27 member states are expected to act as rapporteurs (RMS) or co-rapporteurs (co-RMS). Final agreement on which countries take which active substance is expected in June 2012; where possible company and member state preferences will be taken into account. However, as a rule the RMS will be a different one from the first review and if appropriate the RMS and co-RMS will be from a different zone.

Martyn Griffiths, EU regulatory strategy manager for Bayer CropScience, raised concerns on behalf of industry about the pressure on resources in EFSA, the Commission and member states, in completing the work in accordance with the regulatory timelines. One particular point of concern was the fact that the final step before approval was confirmed by the Standing Committee had no timeline, which will put pressure on the renewal procedure that has to be completed within 12 months of renewal of approval.

### **Comparative assessment and substitution**

Gunilla Ericson from the Swedish Chemicals Agency provided some comments on how the comparative system might work. A stepwise approach is proposed following a flow chart, starting with agronomical aspects of use of the product. The intention is that the procedure can be terminated at any stage once the product/use was determined ineligible for substitution. It was important to document the steps taken. Ms Ericson expressed the view that although the concept as set out in Article 50 of the Regulation is a risk-based approach at product level, it was also important to take into account the assessment of the candidate substance. The likelihood was that very few products would fulfill all the criteria for substitution so no major impact on crop protection was envisaged in Sweden.

An industry view was given by Jean-Pierre Busnardo, DuPont's European regulatory affairs manager, representing ECPA. He suggested that 41% of the 220 active substances currently approved in the EU could be classed as candidates for substitution, this in turn equated to some 50% of authorised products. It was also likely that 27% of active substances would trigger the PBT criteria in the Regulation. There was real concern that the list of candidates for substitution would be misunderstood and misused by some stakeholders and that industry may also try and seek a competitive advantage. It was important that pragmatism and robust scientific principles are applied when conducting comparative assessment and that necessary measures should be taken to minimise workload and the number of substitutions.

Carolyn Thomas, regulatory manager at Syngenta, gave an industry view on the practical implementation of comparative assessment. In practice there had already been a significant reduction in the number of products available to farmers. If not handled properly comparative assessment had the potential to further reduce the competitiveness of European agriculture. It was important to bear in mind that all the relevant criteria should be met before substitution occurs. Guidance would need to be regularly updated as additional experience was gained.

### **Other issues**

Darren Flynn from the UK's Chemicals Regulation Directorate (CRD) highlighted a number of issues around timelines and consistency of approach regarding zonal authorisations. In some member states the inability to meet deadlines was an organisational issue where often it was possible to complete the technical assessment in time but the subsequent administrative process of granting authorisations took too long. It was apparent that an inconsistent approach was being taken in a number of aspects. In relation to mutual recognition, where all authorisations are now deemed to be granted under Regulation 1107/2009, some countries have been applying 91/414 procedures and time lines. There is also some confusion over whether applications should be submitted at zonal or national level. Delegates were advised that in principle any application for a new product should be considered via the zonal procedure even where authorisation is sought in a single member state, in order to allow the possibility of mutual recognition at a later date. For certain applications the Regulation is considered overly onerous. These include back-to-back products, changes in pack size, minor formulation changes and other applications where no technical assessment is required. In such cases 'lighter touch' procedures are being developed.

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