BiologicaI 2019
An analysis of corporate, product and regulatory developments in 2018/2019
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At the time of the publication of Agrow’s 2018 review of the biologicals sector, the competitive landscape within the crop protection industry as well as biologicals was being redefined. At this time last year, the last (Bayer/Monsanto) of the three mega deals (including Dow/DuPont and ChemChina/Syngenta) was on the verge of completion. The year following that has witnessed further changes in the competitive landscape. There has also been some progress in the regulatory process of biological products as well as an increasing recognition of the need for faster and easier approval process for such products.

The completion of the Bayer/Monsanto deal has had a two-pronged effect on the biologicals landscape. Firstly, as part of divestment conditions for Bayer’s acquisition of Monsanto, BASF acquired some of Bayer’s Crop Science division assets, which included Poncho Votivo (Bacillus firmus + clothianidin) seed treatment. The second major impact was that of the coming together Bayer’s portfolio of biopesticides with Monsanto’s inoculants developed in conjunction with Danish company Novozymes through the BioAg Alliance.

Since then, the shape of the Alliance has changed. The BioAg Alliance ended on that exclusive basis although Novozymes and Bayer continue their joint commercialisation of the BioRise 2 technology for upstream maize application and the co-development of next-generation upstream maize inoculant strains with a co-funded R&D model. Bayer will be Novozymes’ distributor for downstream microbial products for soybean and pulse crops, except in the Canadian market, with both companies having the possibility to engage with other parties. Novozymes began pursuing multi-partner set ups with UPL and US-based chemical distributor Univar Solutions through its BioAg business.
In the meantime, another big acquisition, that of Platform Specialty Products’ agrochemical business, Arysta LifeScience, by UPL, made further changes to the competitive landscape. That was by enhancing the geographical reach of the biostimulant offerings of Arysta, which was one of the early entrants to the sector.

What has been the impact of the mega-M&As on the biologicals sector?

**Syngenta** points out that while the mega-M&A’s have not specifically impacted the sales or adoption of biologicals in the market, the biological portfolio of select major multinationals has expanded. “Driven by grower demand and improved technology, the emphasis of biologicals remains a high priority for the mega-ag companies and is driving growth in this important segment,” says the company’s head of biologicals and Syngenta Ventures, Corey Huck.

**BASF** expects the growth in demand for biologicals-based products to endure. The company will continue to develop biologicals-based solutions for seed, foliar and soil applications in the developing marketplace.

US company **Marrone Bio Innovations** (MBI) founder and CEO, Dr Pam Marrone, feels that the mergers have slowed the large companies in the areas of licensing, the launch of new active ingredients and the acquisition of biologicals.

**Dr Marcus Meadows-Smith** agrees. “There will be more opportunities for niche biological companies to enter the market based on licence and distribution agreements due to increasing and short-term needs for innovative biological solutions, which often are being invented by smaller enterprises,” says Bayer’s global segment manager biologics, Karl Muenks.

**BASF** concurs with the view. Niche biologicals specialist companies will continue to have an important role with the development of biologicals – continuing to focus on developing new technologies and implementing use in specific high-value markets, the company says. It points out that products with consistent performance from these companies at marketable pricing will be of interest to BASF.

**MBI’s** Dr Marrone negates the view that niche biologicals companies will find it harder to operate following the big consolidation. “The farmers still want to try new, effective biologicals offerings that offer them added ROI [return on investment]. These can come from small or large companies,” she points out.

**BioConsortia’s** Dr Meadows-Smith agrees. “The mega companies will want to launch the best products and likely will be agnostic as to whether it is discovered internally or by a third party,” he says. Dr Meadows-Smith points out that large companies find it harder to operate following the post-M&A scenario?

**Bayer** points to increased opportunities for niche biological companies. “There will be more opportunities for niche biological companies to develop the market based on licence and distribution agreements due to increasing and short-term needs for innovative biological solutions, which often are being invented by smaller enterprises,” says Bayer’s global segment manager biologics, Karl Muenks.

**FMC** foresees a scenario of further acquisition of niche biological companies. “As larger companies will be looking to de-risk R&D activities by licensing and acquiring, niche biological companies may well be a target and so could cease to be independent,” says FMC’s head of plant health global R&D and director of EMEA [Europe, Middle East and Africa] R&D, Duncan Aust. Consolidation of several niche payers is a potential, he points out.

**Syngenta** says that the efficacy of biological products is often influenced by the local environment, and the success of niche biological companies is driven by their ability to properly position their technologies into local environments. “Those who focus on the needs of the grower and positions their biological products where the grower experiences the best return on investment will be the most successful in the market,” points out Mr Huck.

**Biopesticides in the EU**

In July 2018, the European Commission issued a list of 57 ais approved under old EU agrochemical laws that may potentially be classified as “low-risk” under the EU agrochemical registration Regulation (1107/2009). That was partly because of pressure from the European Parliament, which has made numerous calls for measures to speed up approvals for low-risk ais.
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Up to today, Zhongshan chemical has became world second largest Triazine producer next to Syngenta, our new products range expands to fungicide & insecticide include cyproconazole, pyraclostrobin & trifloxystrobin. All these efforts made us can better serve customers from almost every region of the world and support the agriculture with complete crop protection solution.

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BENTAZONE
MESOTRIONE
FLORASULAM
ISOXAFLUTOLE
PROTHIOCONAZOLE
Regulation 1107/2009 introduced the low-risk category, which grants benefits such as a longer 15-year approval period. Last year, new criteria for identifying such ais came into force. The 57 ais included 30 micro-organisms and 27 naturally derived substances. However, the sought-after impact of faster approvals did not seem to be on the cards because the Commission pointed out that neither the ais nor products containing them could be considered as low-risk until they had been fully evaluated.

Furthermore, the list did not include ais being considered for new approvals. The International Biocontrol Manufacturers Association (IBMA) has been calling upon the Commission to set up by the end of 2020, a “bioprotection-specific” body that will have developed and implemented a “short and precise” evaluation process for biocontrol ais and products. This should involve evidence-based procedures and tailored data requirements.

Syngenta says that biopesticides are not automatically registered as low-risk products within the EU. Information needs to be provided which supports their classification as low-risk, and this is obviously part of the registration process. “Theoretically the registration process should be faster as, (1) less information is required (compared with traditional crop protection products) for an approval decision; (2) a lot of information is also already available in the public domain and this can be used to support the registration of a biopesticide and; (3) for a low-risk ai, member states should make a registration decision (on the product), within 120 days,” points out Mr Huck.

“However, our experience is that the whole process is still taking approximately the same amount of time as for a traditional product,” he adds.

Bayer points to a high degree of unpredictability in terms of data requirements, mainly in the area of efficacy trials and registration timelines.

FMC says that the process for microbials is less complex insofar that the data requirements (and thus the level of complexity) are clearly reduced for microorganisms. However, the company points out that low-risk status will always depend on the individual properties of the micro-organisms - so it is not a given.

“The active registration has a potential to be faster (less amount of information to be worked through), but allocated timelines are the same,” says Mr Aust. He adds that the timing will “highly depend” on who is the RMS [rapporteur member state] and if the authority has competent personnel who understand microbials.

MBI’s Dr Marrone feels that registration of biopesticides has not become any easier within the EU, but a way seems to be evolving, which is somewhere between the US EPA process and the EU chemical process. “Meanwhile, growers are left without tools and chemicals are removed and biologicals are not coming to market fast enough,” she complains.

Biostimulants in the EU

In May, EU Ministers adopted proposals that will harmonise the regulation of plant biostimulants and bring them under the scope of revised laws on fertilisers. The proposals will create a European Economic Area (EEA)-wide market for biostimulant products by laying down rules on the labelling of biostimulants with a European conformity CE (Conformité Européenne) marking for free movement and marketability within the EU. CE marking is a part of the EU’s harmonisation legislation and indicates conformity with health, safety, and environmental protection standards for products sold within the EEA.

The proposals also include a formal definition of biostimulants: “Plant biostimulant means a product containing any substance or micro-organism stimulating plant nutrition processes independently of its nutrient content, or any combination of such substances and/or micro-organisms, with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

• (nutrient use efficiency;)
• tolerance to abiotic stress;
• quality traits;
• availability of confined nutrients in soil or rhizosphere.”

Syngenta says that the standardisation of the information required means that plant biostimulants will meet the high standards European growers expect, and address the increasing challenges of sustainable agriculture under more adverse growing conditions. With the access to the European Single Market, for the first time, all farmers across the EU will have access to the same and growing product innovation platform to meet their needs, says Mr Huck.

But the company views the move as being somewhat of a mixed bag in terms of outcomes for the industry. “Regarding the timelines, on the whole we think that they won’t be significantly shorter as, in the past, many member states granted registrations in a matter of only weeks/months, though some were much longer,” says Mr Huck. However, he says that it will now be possible to gain EU wide registration as “EU fertilising product”, whereas before this was not possible. Mr Huck points out that the information requirements have been standardised, which will mean that the applicants will know exactly what they are required to submit, which is a positive development. However, the requirements have increased over what was previously required in most countries, he adds.

FMC says that it should get easier in EU member states. “But we need to clarify how to expand the micro-organism category definition (CMC 7 in Annex II), which currently only lists Azobacter spp, mycorrhizal fungi, Rhizobium spp and Azospirillum spp,” says Mr Aust. He stresses the need to have at least Bacillus spp added, and says that it is currently not clear how that is going to work. “We think we will have to go through national approvals for a few more years,” he says. Mr Aust adds that member states still have the option to regulate through national legislation and that the new EU regulation does not harmonise in the same way as Regulation 1107/2009.

Bayer expects that the move will gradually lead to a separation of “wheat from the chaff” and, thereby, higher transparency for growers leading to better decisions and better return on investments when using biostimulants for improving yield and/or quality.

MBI views the harmonisation as a good thing. Having one unified definition and process improves transparency and predictability, says Dr Marrone.

“Meanwhile, we all got a surprise in the US as the EPA put out a notice to regulate certain biostimulants,” she adds.

BioConsortia’s Dr Meadows-Smith hopes that the move will bring some credibility to
the products that gain the new registration and reduce the number of products with dubious and highly inconsistent efficacy that get to the market under individual country processes.

**Biostimulants in the US**

In December last year, the US Agriculture Improvement Act of 2018, known as the 2018 Farm Bill, led to some long-sought certainty for biostimulants by providing the first statutory language regarding plant biostimulants in any law in the US.

In April, the US EPA sought public comments on a draft guidance document that aimed to clarify which products under growing categories of products generally known as plant biostimulants would (or not) be subject to regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as plant regulator pesticides, and what kinds of claims could be made for them. The Agency anticipates that this guidance may reduce confusion, in the regulated community as well as regulatory agencies, as to whether specific products are or are not subject to registration as a pesticide under FIFRA.

**Syngenta** views the publication of the Farm Bill in 2018 by the USDA as paving the way for legislation to be developed for the regulation of biostimulants. “As such, we think that this can only been seen as a positive step forward, and it should provide a boost to the biostimulant market,” says Mr Huck. However, he points out a problem in that the definition of biostimulants and that of plant growth regulators (PGRs - regulated by the EPA under the FIFRA) overlap and this is creating some uncertainty within industry and for other stakeholders. The EPA has recently published a guidance document (for public consultation) on the definition of PGRs, but unfortunately, some open points remain, he adds.

**FMC** feels that the problem with biostimulant registration in the US lies in the fact that they are out of the purview of the FIFRA. “Without US EPA input on the process, every state has its own rules and regulations regarding the registration of biostimulants,” says Mr Aust. He thinks that based on the draft proposal, the Agency appears not to intend to move biostimulants under FIFRA but to define what biostimulants are and what they are not. “More specifically, they are looking to outline what claims can and cannot be used with biostimulant materials”. Some current biostimulant materials in the marketplace have terms that potentially would place them into the plant growth regulator realm and thus require EPA FIFRA registration, Mr Aust adds.

**Bayer** feels that certain products that could be marketed under the fertiliser regime would have to be evaluated under the FIFRA regime. “That means more data requirements, higher registration costs and longer time-to-market,” says Mr Muenks.

**MBI** feels that the draft guidance could increase regulations on certain types of biostimulants. “The BPIA [Biological Products Industry Alliance] has asked for and received more time to comment on these proposed new rules, which could have serious implications for seaweed extracts and humic and fluvic acid types of products,” says Dr Marrone.

**Syngenta** sums up the industry view on the registration of biologicals in various jurisdictions around the world. “For biologicals, the development of legislation should be positive as in the past there was little/outdated regulation, and industry requires a stable environment, with clear requirements, if it is going to invest significant resources in developing products that can take many years to get to the market,” says Mr Huck. However, the legislation for biologicals should not merely be a ‘cut and paste’ from existing legislation for traditional crop protection products, he adds. “Such legislation should be drawn up in conjunction with a risk-based approach with clear and transparent requirements, timelines and decision-making process.”

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**Formulation improvements**

**Bayer** points to BioAct as an example of taking formulation quality for fungal strains to a new level. “Bayer achieved a shelf life of minimum two years at a storage temperature of 20°C or minimum six months at constant 30°C,” says Mr Muenks.

**FMC** mentions several convenient-to-handle liquid systems, which have been developed, as well as granule and powder formulations.

**MBI** highlights a bioherbicide that it has been working on, in which the company has used new formulation technology to increase the shelf life and field residual life. “The rest of our products already have three plus years of shelf life and are easy to use,” claims Dr Marrone.

**BioConsoritia** says that products in its pipeline have at least a two-year stability in the package, and further can have up to two years life on seed for seed treatments. “We have reduced shelf life (one year) for crops and markets where that is appropriate, such as wheat and soybean seed treatments, as these crops are not stored from one season to the next,” says Dr Meadows-Smith.

**Eden** says that the core of its technology offering is a micro-encapsulation system suitable for biologicals. “Indeed, it was the discovery of this system that enabled the use of our actives, which are volatile compounds derived from botanical extracts,” says Mr Smith. “Through the use of our ‘Sustaine’ system, we are able to improve efficacy, reduce phytotoxicity and provide stable formulations with ease of use and shelf lives comparable to conventional formulations,” he adds.
Trends

Syngenta says that many of the new technologies awaiting approval will be solo biological products. “However, we expect to increasingly incorporate tank mix and IPM-based rotation recommendations with conventional synthetic chemistries,” adds Mr Huck.

Bayer feels that better formulated plant extracts will become a highly regarded alternative and addition for conventional growers to chemical pest and disease management products. “Virus products or plant extracts for combating lepidopteran pests will be supplementing conventional products, in particular in horticulture, mainly driven by resistance development and lack of new mode of actions,” says Mr Muenks.

BASF points out that biologicals will continue to be an element of what agriculture needs and what it can offer. How the products can be used with chemical products, either in separate or combination approaches, will develop further, the company adds.

FMC sees good opportunities for combining biological and synthetic solutions. “Further R&D activities, more money invested and some clarified/reduced regulatory requirements will ensure that new and more effective products will seek and gain approvals,” says Mr Aust.

BioConsortia emphasises the need for biologicals with superior efficacy and higher levels of consistency across all locations and growing conditions. “Biologicals with the current level of efficacy are unlikely to have value to move forward to registration; another “me-too” will receive very low market share and hardly be worth the investment to develop,” says Dr Meadows-Smith. He feels that combination products of chemical and microbial a.i.s are less likely to be registered because that would require a chemical pesticide registration, which is long and costly, and usually this can be achieved as tank mix or rotational spray programmes. “Also, combo products would not get the benefits of residue management or organic status,” Dr Meadows-Smith adds.

STK expects continued double-digit growth in the use of botanical-based biopesticides. The company also sees “big growth” in the use of “hybrid products” incorporating chemical and biological a.i.s. “These hybrids are easy-to-use pre-mixes, so they will be tried by many current non-users of biological products,” the company says.

Eden views combination products as an inevitability. “Eden is actively working on the development of formulations pairing conventional active ingredients with its own plant-derived active ingredients,” says Mr Smith. These combinations can provide equivalent efficacy with reduced amounts of conventional actives while avoiding pesticide resistance.

MBI says that the biggest trend is “finally” momentum behind integrated programmes. Dr Marrone points out that chemicals and biologicals used together provide greater ROI than either alone. She foresees continued launches of stacked biological and chemical seed treatments and new launches of all-biological seed treatments. Dr Marrone also expects tightening of regulations on biostimulants in the US.
Biologicals-related mergers, acquisitions and deals in 2018-19

Monthly-wise listing of the mergers, acquisitions and deals from January 2018 until April 2019.

JANUARY 2018
- Japanese company Mitsui & Co’s US biopesticide subsidiary, Certis USA, entered into a global licensing agreement with the Hungarian University of Szeged for a novel, patented biopesticide strain, Bacillus mojavensis strain R3B.
- US biopesticide company Marrone Bio Innovations agreed an exclusive Philippine distribution deal with national agricultural inputs supplier Great Harvest Agri Chemicals Corporation.
- UK crop enhancement company Plant Impact and Belgian research institute VIB agreed a research and development collaboration on VIB891, a newly identified molecule and its analogues proven to increase plant biomass.
- The US biological pesticide and fertiliser company, Vegelab US, exercised an option to acquire US company The Agronomy Group.

MARCH 2018
- US biological crop protection company Omnia agreed to acquire the Cayman Islands-based biologicals business of Oro Agri. The deal was completed in June.

APRIL 2018
- The US biopesticide company, Marrone Bio Innovations (MBI), agreed a deal with Israeli crop protection supplier Lidorr Chemicals to distribute MBI’s portfolio in Israel.

JUNE 2018
- Swiss biopesticide company Andermatt Biocontrol and German biologicals company Trifolio-M became shareholders in Polish biologicals company Biocont Poland.
- FMC agreed a five-year extension to its collaboration with Danish bioscience company Chr Hansen to develop and commercialise biopesticides.
- Brazilian biologicals company Santa Clara Agrociencia signed a deal with Brazilian public sector bodies to develop plant extract-based nematicides.
- Sipcam-Oxon acquired the Swiss biopesticide company, Sofbey.

JULY 2018
- UK-based enabling technology company Exosect licensed its Entostat technology to Monsanto for use with certain “agricultural biologicals” as seed treatments.

SEPTEMBER 2018
- French crop protection company De Sangosse acquired Spanish biostimulant companies Biologicas Canarias and Biotecnologia del Mediterraneo and created a new company, Biologica Nature.
- Dutch bioproducts company Kappert Biological Systems agreed to acquire the biological crop protection activities of Dutch company Horticoop with effect from November 1st.
- The US biopesticide company, Marrone Bio Innovations (MBI), entered into an agreement with the Vietnamese Hop Tri Investment Corporation to introduced three MBI biopesticides to Vietnam and Cambodia.

OCTOBER 2018
- UK company Eden Research entered into an exclusive distribution agreement with Sipcam-Oxon for Eden’s biofungicide, 3AEY, in Australia and New Zealand.

NOVEMBER 2018
- The Canadian company, Bee Vectoring Technologies, entered into a global technology sharing agreement with Belgian biological pest control company Biobest.
- The US biopesticide company, Marrone Bio Innovations (MBI), signed an exclusive distribution agreement with the Turkish agricultural inputs supplier, AMC-TR, covering two MBI biopesticides.
- The US agricultural technology development investment company, TechAccel, entered into a biopesticide research collaboration with US agricultural biotechnology company AgroSpheres.

DECEMBER 2018
- Belgian biological pest control company BioBest acquired a stake in the Australian pest management company, Bugs for Bugs.
- Belgian biological pest control company BioBest’s German affiliate, IVOG, acquired a majority stake in Turkish pest control company BKS from its parent company, Antilson.
**Herbicides**

- 2,4-D 406 g/L + Picosulfuron 103 g/L SL
- 2,4-D, 98% TC, 806 g/L SL
- Clethodim, 37% TK, 240 g/L EC
- Dicamba•Glyoxyphosate, 40% SL
- Ethoxysulfuron 10% + Penoxsusam 20% WDG
- Ethoxysulfuron, 95% TC, 15% WDG
- Glufosinate, 95% TC, 200 g/L SL
- Glyphosate, 96% TC, 41% AS
- Mefenacet 60% + Ethoxysulfuron 10% WDG
- Metamitrom 98% TC, 700SC, 75% WDG
- Metsulfuron-methyl, 98% TC, 60% DF
- Picosulfuron TC
- Rimexyl 98% TC, 25% WDG

**Fungicides**

- Carbendazim, 500 g/L SC, 98% TC
- Chlorothalonil 40% + Thiophanate-methyl 35% WP
- Difenconazole 15% + Azoxystrobin 15% SC
- Ipbenfenos, 95% TC, 50% EC, 50% EW
- Picoxytrobin 20% + Propiconazole 10% SE
- Picoxytrobin 20% + Tebuconazole 10% SC
- Picoxytrobin, 98% TC, 95% TC
- Propiconazole, 98% TC, 41.8 EC
- Tebuconazole 20% + Azoxystrobin 10% SC
- Tebuconazole, 98% TC, 430g/L SC

**Plant Growth Regulators**

- 4-Indol-3-ybutoxylic acid 0.85% + 1-Naphthyl acetate 0.2% AS
- Cyanamide, 50% AS
- Forchlorfenuron, 98.0% TC, 0.8% SL
- Paclobutrazol, 98% TC, 240g/L SC

**Bacillus Subtilis**

- Bacillus subtilis, 1x10^6 CFU/g WP, 8x10^5 CFU/g SC
• Sipcam-Oxon exercised its option to distribute UK company Eden Research’s first biofungicide, Mevalone, based on the terpene active ingredients, eugenol, geraniol and thymol, in several markets.

JANUARY 2019
• Corteva Agriscience agreed a deal to market Canadian biological crop care supplier Stoller’s Brazilian subsidiary, Stoller do Brasil’s, biofungicide, Rizotec (Pochonia chlamydospora strain PC-10).
• US agrochemical company Gowan acquired the Colombian bioproducts company, EcoFlora Agro, and created a new biologicals business unit to be built around the EcoFlora brand.
• Portuguese agricultural company Sapec Agro Business’ nutrients supplier, Tradecorp, acquired Brazilian biologicals business Microquimica.
• Italian biostimulants company Valagro agreed a deal with Hungarian distributor Malagrow for the exclusive distribution of Valagro’s products in Romania and Slovakia.

FEBRUARY 2019
• US bioproducts supplier Agrinos agreed a deal with Mexican crop protection company Seferssa to distribute a portfolio of its plant nutrition products in Mexico.
• French co-operative group InVivo’s biologicals business, Bioline, and Spanish biocontrol company Bicolor launched a joint venture, Bioline Iberia.
• Japanese company Mitsui & Co subsidiary Certis Europe and Portuguese company CEV agreed an exclusive sales and distribution deal for CEV’s BLAD polypeptide-based biofungicide, Problad.
• Nufarm acquired the nematicide seed treatment, Trunemco (cis-jasmone + Bacillus amyloliquefaciens strain MBI 600) from BASF.
• Israeli biopesticide company STK Bio-ag Technologies agreed a deal with Sipcam-Oxon for the distribution of its biofungicide, Timorex Gold (Melaleuca alternifolia extract), in Spain.

MARCH 2019
• ChemChina subsidiary Adama and Israeli biopesticide company STK Bio-ag Technologies agreed an exclusive distribution deal for two STK Melaleuca alternifolia extract-based biofungicides in Colombia.

APRIL 2019
• US-based biologicals company Bio-Cat Microbials and South African company Omnia Holdings agreed an exclusive deal to develop microbial strains to be added to Omnia’s portfolio of crop science products.
• US biopesticide company Marrone Bio Innovations appointed Canadian crop inputs supplier Terralink to distribute its biofungicide, Regalia Maxx (Reynoutria sachalinensis extract) in western Canada.
• US biopesticide company Marrone Bio Innovations appointed the Canadian horticultural products supplier, Plant products, to distribute its biofungicide, Regalia Maxx (Reynoutria sachalinensis extract) in eastern and central Canada.
• Danish company Novozymes added UPL and US-based chemical distributor Univar Solutions as partners in its BioAg business.
• Israeli plant biotechnology company PlantArcBio and Israeli specialty fertiliser company ICL Innovation agreed to collaborate on the development of crop productivity enhancers for agriculture.
• Israeli biopesticide company STK appointed the Sumitomo Corporation/ Ishihara Sangyo Kaisha joint venture, Summit Agro USA, as exclusive distributor in the US.

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Imidasol 20% SL
Difenconazole 250 g/l EC
Dithiocarbamate + Cyromazine 35% SC
Azoxystrobin + Chlorothalonil 480 g/l SC
Kasugamicin + Tricyclazole 13% WP
Tebufenozide + Emaproct 34% WP

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France | Germany | Spain | UK | USA | Canada
New active ingredients registered or launched in 2018 and the first four months of 2019

<table>
<thead>
<tr>
<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
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<tbody>
<tr>
<td><strong>2018</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>AgBiTech</strong></td>
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<td><em>Chrysodeixis includens</em> nucleopolyhedrovirus isolate 460 Soja (with <em>Helicoverpa armigera</em> nucleopolyhedrovirus ABA-NPV-U)</td>
<td>Soybeans</td>
<td>Approved in Argentina as Surtiva isolate 460 Soja (with <em>Helicoverpa armigera</em> nucleopolyhedrovirus ABA-NPV-U)</td>
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<td><strong>Andermatt BioControl</strong></td>
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<td>Fruit, vegetables, herbs, spices &amp; ornamentals</td>
<td>Approved in Canada as Helicovex</td>
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<tr>
<td><strong>BASF</strong></td>
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<td><em>Beauveria bassiana</em> strain PPRI 5339</td>
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<td>Approved in Canada as Velifer</td>
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<td><em>Bacillus amyloliquefaciens</em> strain MBI 600</td>
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<td>Proposed approval in Canada as Serifel</td>
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<td>Proposed approval in Canada as Velifer</td>
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<td><em>Bacillus amyloliquefaciens</em> strain QST 713</td>
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<td>Approved in Australia as Serenade Opti</td>
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<td><strong>Brandt iHammer</strong></td>
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<tr>
<td>methyl-alpha-D-mannopyranoside [plant growth regulator]</td>
<td>Fruit, vegetables, herbs, spices &amp; ornamentals</td>
<td>Proposed approval in US as iH026a</td>
</tr>
<tr>
<td><strong>De Cuester</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>pepino mosaic virus</em> strain CH2 isolate 1906 [virus defence]</td>
<td>Fruit, vegetables, herbs, spices &amp; ornamentals</td>
<td>Proposed approval in Canada</td>
</tr>
<tr>
<td></td>
<td>Fruit, vegetables, herbs, spices &amp; ornamentals</td>
<td>Proposed approval in US</td>
</tr>
</tbody>
</table>
Smithers Viscient recently presented posters and platform sessions at two major European events. Scientists from Harrogate, UK and Wareham, US presented information on a variety of current environmental topics:

- Higher Tier Testing-When Reality Does Not Meet Expectations: A Tale of Two Copepods
- The Biodegradability of Acetaminophen Using Multiple OECD 301 Guidelines and the OECD 307 Guideline
- Fish Extended One Generation Reproduction Test: A Comparison Between Medaka and Fathead Minnow
- Aquatic Plant Exposures - The Complexities of Higher Tier Testing
- Evaluations of In-Vitro Plant Metabolism as a Tool to Aid Identification of Metabolites from Crop Metabolism Studies
- Comparison of Soil Photolysis in Dry and Moist Soil Layers
- The Effects of the Deepwater Horizon Oil Spill on Marine Microalgae - A Comparison of Species Sensitivity
- Comparison of EPA and ECHA Guidance on Characterization of Non-Extractable Residues (NER) in Degradation Assessment

To request copies of the poster and platform presentations, please contact us at info@smithersviscient.com and we will send you copies www.smithersviscient.com
<table>
<thead>
<tr>
<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Envera</strong></td>
<td><em>Bacillus amyloliquefaciens</em> strain ENV503 [biofungicide]</td>
<td>Proposed approval in US as ENV503</td>
</tr>
<tr>
<td></td>
<td>Fruit, vegetables, vine crops, herbs, spices &amp; grasses</td>
<td></td>
</tr>
<tr>
<td><strong>FMC</strong></td>
<td><em>Bacillus subtilis</em> strain FMCH002 + <em>B. licheniformis</em> strain FMCH001 [biofungicide/nematicide]</td>
<td>Proposed approval in Canada as F4018-4</td>
</tr>
<tr>
<td></td>
<td>Crops including maize, soybeans &amp; sunflowers</td>
<td></td>
</tr>
<tr>
<td><strong>Gowan</strong></td>
<td><em>Swinglea glutinosa</em> extract [biofungicide]</td>
<td>Approved &amp; launched in US as EcoSwing</td>
</tr>
<tr>
<td></td>
<td>Outdoor &amp; greenhouse food &amp; non-food crops</td>
<td></td>
</tr>
<tr>
<td><strong>Koppert Biological Systems</strong></td>
<td><em>Metschnikowia fructicola</em> strain NRRL Y-27328 [biofungicide]</td>
<td>Proposed approval in US as KM1110 WDG</td>
</tr>
<tr>
<td></td>
<td>Fruits &amp; berries</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stone fruit, strawberries &amp; grapevines</td>
<td>Approved in EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marrone Bio Innovations</strong></td>
<td><em>Bacillus amyloliquefaciens</em> strain F727 [biofungicide]</td>
<td>Approved in Canada as MBI-110 EP</td>
</tr>
<tr>
<td></td>
<td>Cucurbits, legume vegetables, potatoes, grapevines, canola &amp; sunflowers</td>
<td></td>
</tr>
<tr>
<td><strong>Monsanto (now Bayer)</strong></td>
<td>lipochitoooligosaccharide SP104 [plant growth regulator]</td>
<td>Approved in US as Acceleron B-360 ST</td>
</tr>
<tr>
<td></td>
<td>Maize &amp; canola</td>
<td></td>
</tr>
<tr>
<td><strong>OmniLytics</strong></td>
<td><em>Xanthomonas citri</em> subsp citri bacteriophage [bactericide]</td>
<td>Approved in US as AgriPhage-Citrus Canker</td>
</tr>
<tr>
<td></td>
<td>Citrus trees</td>
<td></td>
</tr>
<tr>
<td><strong>Phyllom Bios</strong></td>
<td><em>Erwinia amylovora</em> bacteriophage [bactericide]</td>
<td>Approved in US as AgriPhage-Fire Blight</td>
</tr>
<tr>
<td></td>
<td>Apples &amp; pears</td>
<td></td>
</tr>
<tr>
<td><strong>Syngenta (owned by ChemChina)</strong></td>
<td><em>Pasteuria nishizawae</em> Pn1 [bionematicide]</td>
<td>Approved in EU</td>
</tr>
<tr>
<td></td>
<td>Sugar beet</td>
<td></td>
</tr>
<tr>
<td><strong>Verdesian Life Sciences</strong></td>
<td>calcium salts of phosphorous acid/calcium phosphate [fungicide/systemic acquired resistance activator]</td>
<td>Proposed approval in US as Fungi-Phite Ca</td>
</tr>
<tr>
<td></td>
<td>Fruit, vegetables, trees, nuts, ornamentals &amp; turf</td>
<td></td>
</tr>
<tr>
<td><strong>2019</strong></td>
<td><em>Bacillus amyloliquefaciens</em> strain MBI 600 [biofungicide]</td>
<td>Proposed approval in Australia as Serifel</td>
</tr>
<tr>
<td></td>
<td>Strawberries</td>
<td></td>
</tr>
<tr>
<td>Company &amp; active ingredient</td>
<td>Use</td>
<td>Status</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>--------</td>
</tr>
<tr>
<td><strong>Beauveria bassiana</strong> strain PPRI 5339 [bioinsecticide/acaricide]</td>
<td>Protected tomatoes, sweet peppers, aubergines, cucumbers &amp; ornamentals</td>
<td>Approved in EU</td>
</tr>
<tr>
<td><strong>Belchim Crop Protection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trichoderma atroviride</strong> strain SC1 [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in Italy as Vintec</td>
</tr>
<tr>
<td><strong>BioHerbicides Australia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lasiodiplodia pseudothebromae strain NT039 + Macrophomina phaseolina strain NT094 + Neoscytalidium novaehollandiae strain QLS003 [bioherbicide]</td>
<td>Grazing land</td>
<td>Approved in Australia as Bi-Bak Parkinsonia</td>
</tr>
<tr>
<td><strong>Exosect</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Beauveria bassiana</strong> strain IMI389521 [bioinsecticide]</td>
<td>Post-harvest storage facilities</td>
<td>Proposed approval in EU</td>
</tr>
<tr>
<td><strong>FMC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus subtilis strain FMCH002 + B. licheniformis strain FMCH001 [biofungicide/nematicide]</td>
<td>Maize, soybeans &amp; sunflowers</td>
<td>Approved in Canada as F4018-4</td>
</tr>
<tr>
<td><strong>Nufarm</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cis-jasmone [bionematicide]</td>
<td>Cotton, soybeans &amp; maize</td>
<td>Proposed approval in US as Trunemco (with Bacillus amyloliquefaciens strain MBI 600)</td>
</tr>
<tr>
<td><strong>Otsuka Pharmaceutical</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xylella fastidiosa bacteriophage [bactericide]</td>
<td>Grapevines</td>
<td>Approved in US as XylPhi-PD</td>
</tr>
<tr>
<td><strong>Phyllom Bios</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus thuringiensis subsp galleriae SDS-502 [bioinsecticide]</td>
<td>Turf &amp; ornamentals</td>
<td>Approved in Canada as GrubGONE!, strain GrubHALT!, BeetleGONE! &amp; BeetleJUS!</td>
</tr>
<tr>
<td><strong>Task Force AB-IT 56 (Jouffray Drillard/Danstar Ferment)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saccharomyces cerevisiae strain DDSF 623 [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in EU as ABE-IT 56</td>
</tr>
</tbody>
</table>

**PESTICIDES FOR AGRICULTURE**

- **INSECTICIDE**
  - Bifenthrin
  - Cyfluthrin
  - Beta-cyfluthrin
  - Lambda-cyfluthrin
  - Cypermethrin
  - Beta-cypermethrin
  - Deltamethrin
  - Lambda-cypermethrin
  - Acephate

- **ACETAMIFID**
- Chlorfluazuron
- Hexaflumuron

- **HERBICIDE**
  - Dicamba
  - Glyphosate
  - Haloxyfop-P-methyl

- **FUNGICIDE**
  - Fluazinam
  - Propiconazole
  - Carbendazim
  - Thiram
  - Thiopeptate-methyl
  - Difenconazole
  - Pyraclostrobin

- **PLANT GROWTH REGULATOR**
  - Trinexapac-ethyl
  - Thifurazon

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Europe’s political and legislative framework on pesticides – slow move towards sustainability

by Dr Lars Huber, Senior Manager Regulatory Affairs, Head of Biostimulants, Fertiliser and IPM, SCC GmbH

Regulations within the EU have focused on chemical pesticides and the move towards sustainable and low-risk solutions has been at a slow pace. This article traces the evolution of EU regulations and the gradual move towards sustainability.

On February 12th 2019, the European Parliament adopted a resolution on the implementation of sustainable use of pesticides by 546 to 39 votes. It was strongly critical of the lack of progress in the implementation of the EU sustainable pesticide use Directive (2009/128) and the economic loss of the added value of sustainability.

The resolution was one of several adapted in the recent past on the use and registration process for pesticides in the EU. Feedback and public discussions on these resolutions as well as recent related documentation suggest that the EU’s general political and legislative framework on pesticides is often not considered in its full scope, focusing mainly on the EU agrochemical Regulation (1107/2009) and its implementing regulations. This article aims to give a brief introduction on the EU’s general legal and political frameworks governing the use and the bringing onto the market of pesticides.

The basic concepts that triggered the need for a registration process for pesticides date back to the Paris Summit in 1972, in which the protection of human health and the environment became an integral part of European politics and established the general framework for the Community Action Environment (CAE). The CAE and inter-related legal acts established the long-term activities, which also govern pesticides, such as establishment of the European Environment Agency (EEA), the European Environment Information and Observation Network (EIONET), and, in later years, the European Food Safety Authority (EFSA).

In parallel, the legal basis for the long-time monitoring and further development of community actions was established by various means such as Directive 91/692,
<table>
<thead>
<tr>
<th>HERBICIDE</th>
<th>SAFENER</th>
<th>FUNGICIDE</th>
<th>INSECTICIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glufosinate-ammonium</td>
<td>Diuron</td>
<td>Cloquintocet-mexyl</td>
<td>Pyriproxyfen</td>
</tr>
<tr>
<td>Flumioxazin</td>
<td>Fluometuron</td>
<td>Isoxadifen-ethyl</td>
<td></td>
</tr>
<tr>
<td>Clodinafop-propargyl</td>
<td>Chlortoluron</td>
<td></td>
<td></td>
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<tr>
<td>Picloram</td>
<td>Linuron</td>
<td></td>
<td></td>
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<tr>
<td>Clopyralid</td>
<td>Propyzamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluroxypyr-meptyl</td>
<td>Cyclanilide</td>
<td>Epoxiconazole</td>
<td></td>
</tr>
<tr>
<td>Triclopyr-acid</td>
<td>Isoproturon</td>
<td>Difenconazole</td>
<td></td>
</tr>
<tr>
<td>Triclopyr-butoyl</td>
<td>Tebuteiuron</td>
<td>Iprodione</td>
<td></td>
</tr>
<tr>
<td>Diquat</td>
<td>Bensulfuron-methyl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pinoxaden</td>
<td>Pyrazosulfuron-ethyl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flufenacet</td>
<td>Nicosulfuron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difluufenican</td>
<td>Quinclorac</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mefenacet</td>
<td>Napropamidine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxadiazon</td>
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<td></td>
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</tr>
</tbody>
</table>
which standardised and rationalised reports on the implementation of certain Directives relating to the environment. That was published in the same year as the first Directive concerning the placing of plant protection products on the market, Directive 91/414, or the subsequent EU State of Environment Reports (SOER; 1995-2020).

Besides introducing the general principles and data requirements for placing of active substances and plant protection products on the market, Directive 91/414 introduced IPM, although for decades to come, the implementation of IPM was restricted to few areas and, in general, did not get much attention in the regulatory process. However, the definition of IPM, termed “integrated control” in Directive 91/414, did not vary much from the definition applicable under the sustainable use Directive (SUD) 2009/128.

One of the reasons for introducing IPM in 1991 was the onslaught of red spider mites after World War II in European agriculture. For many years, red spider mites were regarded to be the major pest for various crops, triggering extensive use of acaricides, especially in viticulture and pomiculture. Realisation that the red spider mite epidemic was due to the use of pesticides damaging their natural enemies, mainly predatory mites, led to the IPM requirement for plant protection active substances and products not to be harmful to these predators. Currently, conservation biological control of red spider mites is an integral part of Good Agricultural Practice in all EU member states.

After the entry into force of Directive 91/414, it was amended many times and many guidance documents were published. But all of those, including Regulation 396/2005 on the maximum residue levels of pesticides, were focused on chemical active substances. In regard to the registration of biopesticides, sustainable use of pesticides, IPM and related topics, nothing substantial happened in the two decades after entry into force of Directive 91/414.

Regulation 1107/2009, which entered into force in 2011, introduced the new pesticide grouping of low-risk substances. It also introduced basic substances, which comprise those substances that can be used in plant protection but cannot be formulated or sold as plant protection products. But, as with Directive 91/414, apart from mentioning sustainability or IPM as general requirements in crop production, Regulation 1107/2009 itself did not directly establish the regulatory framework to sufficiently foster the developed EU sustainability goals.

However, Regulation 1107/2009 was not published as a single legislative act but was part of a legislative package. The legislative package contained another three legislative acts (see left hand column of Fig 2a):

1. Regulation 1185/2009 concerning statistics on pesticides;
2. Directive 2009/127 on machinery for pesticide application and especially;

But following the publication of the legislative package, a similar situation occurred as during the years 1991-2009, with no movement towards making the registration
of biopesticides easier. This was especially true in relation to data requirements. For micro-organisms, for example, the “new” data requirements published in 2013 (Regulation 283/2013 for active substances and Regulation 284/2013 for plant protection products) stayed unaltered.

Even the “new” low risk criteria published in 2018 under EU Regulation 2017/1483 have not changed the status for micro-organisms. For micro-organisms, the criteria defined sound straightforward: “An active substance which is a micro-organism may be considered as being of low risk unless at strain level it has demonstrated multiple resistance to antimicrobials used in human or veterinary medicine”. Vice-versa, this seems to imply that all micro-organisms not showing multiple resistance to antimicrobials are classified as low risk. However, as recent approvals for microbial active substances have shown, this is not the case and, according to the Commission, extensive guidance on low-risk criteria is under preparation.

Furthermore, similar to the 20 years under Directive 91/414, a multitude of general legislative acts pertaining to community action were adopted without much influencing the registration process for pesticides. One example is the establishment of the so-called Ecological Focus Areas (EFAs) in the framework of the Common Agricultural Policy (established by Regulation 1307/2013), in which the use of plant protection products is banned in certain productive EFAs.

In regard to pesticides, the added value of sustainability in general, as well as sustainable agriculture and pesticide use in particular as major driving forces for EU economy, are focal points of interest. This is especially evident, for example, in the respective EU actions on bioeconomy, circular economy (for instance, the draft EU fertiliser Regulation), environment and climate action (LIFE; Regulation 1293/2013), sustainability, innovation and economic development, harmonised risk indicators for pesticides (draft Directive; Ares 2018), transparency and sustainability of the EU risk assessment in the food chain (proposal for regulation COM(2018) 179) or greening (draft CAP regulations).

The SUD was originally introduced to align these EU actions and programmes to the registration requirements and procedures for pesticide registration and use. But, as only very little has happened in regard to the sustainable use of pesticides and IPM since 2009, the clear voting results and the strong criticism of the European Parliament is not surprising. Also, the time of adoption of the respective parliamentary resolutions is not surprising since Article 4 of Directive 2009/128 already includes the requirement of the Commission reporting to Parliament on the Directives goals, such as the implementation of IPM or National Action Plans (NAPs) for sustainable pesticide use, the deadline for which was December 14th 2018.

The Parliament is likely to take action to assert a more thorough implementation of the SUD in the near future. This will also affect the registration process for pesticides as the parliament clearly stated that, inter alia,

- “the current practices of the Commission and the member states regarding the approval of active substances and authorisation of plant protection products are not compatible with the objectives and purpose of the directive [SUD],”

- “these current practices impede attaining the highest possible level of protection and achieving the transition to a sustainable agricultural sector and a non-toxic environment”,

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- MCPA 95% TC
- MCPA-2-ethylhexyl 93% TC
- Glyphosate 96% TC
- Fenoxaprop-P-ethyl 97% TC
- Glyphosate-ammonium 98% TC
- Glufosinate-ammonium 95% TC
- Quinalofop-P-ethyl 97% TC
- Tribenuron-methyl 97% TC

Insecticide
- Imidacloprid 95% TC, 97% TC
- Fipronil 95% TC, 97% TC
- Cartap 98% TC
- Lambda-cyhalothrin 97% TC
- Chlorpyrifos 97% TC
- Phosalone 95% TC
- Pirimicarb 95% TC
- Dichlorvos 94% TC

Fungicide
- Kresoxim-methyl 96% TC
- Carbendazim 98% TC
- Thiophanate-methyl 97% TC
- Flusilazole 95% TC

Formulation processing
- Glyphosate 30% SL, 41% SL,
  62% SL, 540 g/L SL, 75.7% GR,
  77.7% GR, 88.8% GR

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- Nicosulfuron

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- Flumazine 98% TG; Flumioxazin 96% TG
- Indexacarb 95% TG;

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- 2 billion PLB/ml Unclear polyhedralosis Virus SC

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Confirmed speakers include
- Julie Girling (Member of European Parliament (MEP) for the South West of England and Gibraltar)
- Robert Shearsby (Agricultural Industries Confederation)
- Guy Smith (National Farmers Union (NFU))
- Dr Tina Barsby (National Institute of Agricultural Botany (NIAB))
- Dr Mike Carroll (TSG Consulting)
- Dr Martyn Griffiths (Bayer AG)
- Prof Lin Field (Rothamsted Research)

DATE
19-20 November 2019

LOCATION
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PRICE
£700 + VAT (Early bird rate)
(Full rate £800 from 1 August)

CONFERENCE LANGUAGE
English

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• “that the implementation of the directive is not sufficiently aligned with related EU policies in the field of pesticides, agriculture and sustainable development, notably but not exclusively the common agricultural policy (CAP) and the plant protection products regulation”,

• “the current regulatory framework, including data requirements, was designed for the assessment and management of chemical PPPs [plant protection products], and is thus ill-fitting for low-risk biological active substances and products; whereas this ill-fitting framework is significantly slowing down the market entry of low-risk biological PPPs, often deterring applicants; whereas this hinders innovation and hampers the competitiveness of EU agriculture”,

• “the lack of availability of low-risk PPPs, including biological ones, hinders the
The formula of valuable solution for agriculture

HERBICIDES

Flumioxazin
Isoxaflutole
Mesotrione
Pinoxaden
Penoxy sulfam
Diclosulam
Clorsulam
Flumetsulam
Florasulam
Imazethapyr
Imazamox
Imazapic
Imazapyr
2,4-D
2,4-DP-p
Dicamba
Sulfentrazone
Carfentrazone
Amicarbazone
Flu carbazone
Diflufenican
Glyphosate
Glufosinate
Bentazon
Clomazone
Fluroxypyr
MCPA
MCPB
MCPP-p
Clompyralid
Picolram
Diuron
Triclopyr
Bromacil
Hexazinone
Clothodim
Metribuzin
Fomesafen
Oxyfluorfen
Atrazine
Diuron
Bispyribac
Propanil
Benazolin
Acethlor
Metazachlor
Metolachlor
S-Metolachlor
Cyhalofop
Clodinafop
Fenoxaproprop
Quinoxalofop
Haloxynop

INSECTICIDES

Thiamethoxam
Clothianidin
Dinotefuran
Chlorfenapyr
Methoxyfenozide
Indoxacarb
Pymetrozine
Bifenthrin
Lufenuron
Profenofos
Flicamid
Chlorpyrifos
Imidacloprid
Acetamiprid
Ethiprole
Fipronil
Diafenthiuron
Pyriproxyfen
Methomyl
Oxamyl
Abamectin
Emamectin
Spirodiclofen
Lambda-cyhalothrin

FUNGICIDES

Azoxystrobin
Pyraclostrobine
Trifloxystrobin
Picoxy strebin
Prothioconazole
Cyproconazole
Difenconazole
Epoxiconazole
Fluazinam
Bosalid
Fludioxonil
Fluazinam
Tebuconazole
Propiconazole
Prochloraz
Dimethomorph
Benomyl
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Propanocarb
Spiroxamine
Captan
Chlorothalonil
Mancozeb
Propineb

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development and implementation of integrated pest management (IPM)
• “the observed sharp decline in insect numbers has negative impacts on the entire ecosystem and on biological diversity, but also on the agricultural sector and its future economic wellbeing and output”
• “Europe currently stands at a crossroads that will determine the future of the agriculture sector and the Union’s possibilities of achieving a sustainable use of pesticides, most notably through the reform of the CAP; whereas reforming the CAP brings with it a substantial potential to strengthen the streamlining and harmonisation of policies as well as the implementation of the Directive, and to facilitate the transition towards more environmentally sustainable agricultural practices”.

Furthermore, in its resolution, the Parliament calls on the Commission and member states to
• “complete the implementation of the Directive without further delay”,
• “adhere to the established timelines for delivering revised NAPs; urges those member states that have not yet done so to deliver without further delay, this time with clear quantiative targets and a measurable overall objective of an immediate and long-term effective reduction in the risks and impacts of pesticide use, including clearly defined annual reduction targets”
• “propose an ambitious EU-wide binding target for the reduction of pesticide use”,
• “further develop guidance on all the IPM principles and their implementation”,
• “establish guidelines on the establishment of criteria for measuring and assessing the implementation of IPM in the member states”,
• “place greater emphasis on the promotion of the development, research, registration and marketing of low-risk and biological alternatives, including by increasing funding opportunities within Horizon Europe and the Multiannual Financial Framework 2021–2027 [...]

The Parliament explicitly recalled
• “the importance of the added value of ecologically sustainable and safe plant protection techniques,
• “to submit, before the end of its current mandate, a specific legislative proposal amending Regulation 1107/2009, outside of the general revision in connection with the REFIT initiative, with a view to adding a definition and a separate category for ‘naturally occurring substances’ and ‘nature-identical substances’, the criterion for which would be the existing presence and exposure of the substance in nature, as well as to establishing a rigorous fast-track evaluation, authorisation and registration procedure for low-risk biological pesticides, in line with Parliament’s resolutions of 15 February 2017 on low-risk pesticides of biological origin and 13 September 2018 on the implementation of the plant protection products regulation”.

Furthermore, the Parliament highlighted that “the potential of using intelligent technology and precision farming as means to better administer PPPs and to prevent the dispersion thereof in areas where they are not needed, for instance by means of drone or GPS precision technology; stresses, moreover, that the uptake of such solutions could be improved in member states if better incorporated into training courses and certification schemes for pesticides users in the NAP”.

It is, however, important to note that the Commission’s communication and EU parliamentary resolutions issued in 2018/19 have not been about greening and sustainability at all costs. On the contrary, a closer focus, for example, on risk reduction is also demanded, “as extensive use of low-risk substances might be more harmful than limited use of high-risk substances” (P8_TA-PROV(2019)0082). Also, as often implied, an excessive influence of NGOs is not the reason for all of these recent EU actions but the more than 40 years of scientific research, screening, monitoring and adoption of legislation that resulted in sufficient knowledge to bring IPM and sustainable pesticide use within the regulatory registration process.

It is essential to consider that definition of IPM according to the SUD highlights that integrated pest management means careful consideration of all available plant protection methods - mechanical, physical, biological and chemical - to keep the use of plant protection products and other forms of intervention at levels that are economically and ecologically justified. It is these combinations of all available plant protection methods that would make IPM an economically and ecologically valuable future farming tool.
Preparations for the International Exhibition for Fine and Speciality Chemicals are well under way. From 26 – 27 June 2019, the 34th edition of Chemspec Europe provides a powerful and well-known industry platform to explore bespoke solutions, new approaches and innovative substances as well as to discuss the latest market trends, technical innovations, business opportunities and regulatory issues in a rapidly changing market.

On a record net exhibition space of some 6,300 m², more than 370 exhibitors from 27 countries represent an excellent cross-section of the fine and speciality chemicals industry, with strong participation from Germany, France, Great Britain, Switzerland, China, India and the USA. Amongst its exhibitors, Chemspec Europe will host a fair number of global market leaders, but also many small and medium-sized companies. The international event brings together manufacturers, distributors, regulators, equipment suppliers, raw materials suppliers, traders, agents and consultants, covering the full spectrum of fine and speciality chemicals for various applications and industries: agrochemicals, pharmaceuticals, polymers, food and feed ingredients, flavours and fragrances, pigments and dyes, paints and coatings, household and cleaning chemicals, adhesives and sealants, petrochemicals, leather and textile chemicals, electronic chemicals and many others.

Amongst exhibiting companies are Albemarle, AizChem Trostberg GmbH, BASF SE, CABB AG, Chemical Industries Association, Dottikon Exclusive Synthesis AG, ESIM Chemicals, IVICT Europe GmbH / Mitsubishi Corporation, Johnson Matthey, Lanza Ltd, Robinson Brothers Limited, Saltigo GmbH, Siegfried AG, SOCMA, SOLVAY, Sumitomo Chemical Europe SA/ NV, Vertellus, WeylChem and many more. This remarkable line-up of exhibitors underlines the show’s unique position as the premier specialised trading and networking event for the fine and speciality chemicals industry in Europe.

**Online Show Preview 2019**
“Visitors of Chemspec Europe 2019 have the chance to explore specific ingredients and custom-made solutions in direct exchange with renowned industry experts”, says Liljana Goszdziewski, Exhibition Director of Chemspec Europe, on behalf of the organisers, Mack Brooks Exhibitions. The official Show Preview offers a first glimpse of Chemspec Europe 2019. Visitors can create a customised show preview with detailed summaries of exhibitors as well as their products and services. The Show Preview can be found on the Chemspec Europe 2019 website: www.chemspeceurope.com
Extensive two-day conference programme alongside the exhibition

“The accompanying workshops and conferences offer plenty of additional opportunities to exchange industry know-how and form international relations with peers and business partners”, Liljana Goszdziewski continues. An outstanding two-day seminar programme will provide further knowledge and insights into major industry developments as well as key strategies adopted by industry leaders to succeed and grow. All visitors and exhibitors of Chemspec Europe 2019 are invited to attend, free of charge. The full conference programme is published on www.chemspeceurope.com and will be updated continuously:

• **The Chemspec Agrochemical Outlook Conference**, sponsored by AGROW, deals with challenges and opportunities facing the industry in 2019.

• **The Pharma Lecture Theatre** is dedicated to the trends, challenges and outlook of the pharmaceutical industry and provides first-hand information on ongoing R&D projects and exchange with leading industry experts.

• The ever popular **Abou-Gharbia Lecture** by Dr Magid Abou-Gharbia of the Moulder Center for Drug Discovery Research in Philadelphia explores new strategies by pharmaceutical companies aimed at restoring public trust and confidence, addressing declining productivity and cutting cost while ensuring steady stream of innovative therapeutics to patients.

• **The Pharma Panel** will discuss approaches to developing global outsourcing strategies, identifying outsourcing partners, identifying approaches to mitigate risks, and addressing challenges associated with outsourcing and how to effectively manage partnerships.

• **The Regulatory Services Conference**, organised by REACHReady, gives support and advice on regulatory and chemicals management issues from exhibitors and topical presentations delivered by experts offering insights and practical advice.

• **The RSC Symposium 2019**, organised by the Royal Society of Chemistry, is a two-day international symposium on reducing environmental impact. It presents a programme of internationally acclaimed speakers, mostly from industry and from companies making pioneering advances in science, understanding and development of new approaches to sustainability.

• **The Chemspec Careers Clinic**, organised by Chemical Search International, offers executives from the fine and speciality sectors at all levels the chance to discuss their career aspirations with a specialist professional search firm on a discreet and completely free basis.

• For the third time Chemspec Europe and BCNP Consultants bring young companies, their innovations and the topic of chemistry founding on stage. The program of **Innovative Startups** includes a keynote lecture, presentations by founders of chemistry start-ups and a panel discussion.

Visitor information

Ticket registration is now available on the exhibition website. Online tickets for Chemspec Europe 2019 are free of charge. On-site, a ticket will cost 60 CHF. The tickets are valid for both exhibition days and include free access to the conferences on-site.

Chemspec Europe 2019 will take place from 26 – 27 June 2019 in hall 1.0 of Messe Basel, Switzerland. The Basel region is one of Europe’s major hubs for the fine and speciality chemicals industry and borders three of Europe’s strongest countries in this sector. Visitors can sign up for the free newsletter to receive updates and notifications prior to the show. Further information is available on www.chemspeceurope.com.
US EPA seeks comments on draft guidance for biostimulants

The US EPA is seeking public comment on a draft guidance document entitled “Guidance for plant regulator label claims, including plant biostimulants”.

In recognition of the growing categories of products generally known as plant biostimulants (PBS), the draft document gives guidance on which products are (and are not) subject to regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as plant regulator pesticides, and what kinds of claims can be made for them, the EPA says. The draft guidance provides examples of each.

The Agency anticipates that this guidance may reduce confusion, in the regulated community as well as regulatory agencies, as to whether specific products are or are not subject to registration as a pesticide under FIFRA. Reducing uncertainty may reduce costs of bringing a product to market. The Agency points out that in some situations, uncertainty could deter firms from developing products. The guidance will reduce the effort firms expend to determine the appropriate regulatory path.

The EPA points out that statutory definitions for PBS currently do not exist in the US or overseas and there is no applicable regulatory definition under the FIFRA. Nonetheless, to help provide guidance and clarity, the Agency has provided a description of a PBS, which reflects its current understanding and views: “A plant biostimulant is a naturally occurring substance or microbe that is used either by itself or in combination with other naturally occurring substances or microbes for the purpose of stimulating natural processes in plants or in the soil in order to, among other things, improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve the physical, chemical, and/or biological characteristics of the soil as a medium for plant growth.”

The EPA clarifies that the draft guidance does not address or attempt to provide a regulatory definition for PBS. The Agency is seeking comment on whether it should develop a definition for PBS, noting that the development of such a definition would require rulemaking.

In developing the draft guidance, the EPA considered whether a PBS product physiologically influences the growth and development of plants in such a way as to be considered plant regulators by the Agency and thereby triggering regulation under the FIFRA as a pesticide. FIFRA section 2(u) includes plant regulators, defoliants, desiccants, and nitrogen stabilisers in its definition of a pesticide, so they are subject to federal registration as pesticides under the law. In addition, FIFRA section 2(v) defines plant regulator and explains which substances are excluded from the definition.

Based on the plant regulator definition contained in FIFRA section 2(v), many PBS products and substances may be excluded or exempt from regulation under the law depending upon their intended uses as plant nutrients (for instance, fertilisers), plant inoculants, soil amendments and vitamin-hormone products. Other PBS products will not involve EPA oversight because they do not fit within the specific FIFRA definition of how a plant regulator functions. A key consideration is what claims are being made on product labels. This draft document is intended to provide guidance on identifying product label claims that are considered to be plant regulator claims by the Agency, thereby subjecting the products to regulation under the FIFRA as pesticides. Examples are provided of claims that are considered plant regulator claims as well as those that are not considered plant regulator claims.

Comments must be received on or before May 28th.

2018 Farm Bill
The US Agriculture Improvement Act of 2018, known as the 2018 Farm Bill, led to some long-sought certainty for biostimulants by providing the first statutory language regarding plant biostimulants in any law in the US. Signed into law on December 20th 2018, the Bill describes a plant biostimulant as “a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield”.

The 2018 Farm Bill includes language that requires the Secretary of Agriculture, EPA administrator, states and relevant stakeholders to provide a report to Congress that identifies any potential regulatory and legislative recommendations, including the appropriateness of any definition for plant biostimulants. The intent of this report is to facilitate the development a regulatory framework for plant biostimulant products and to ensure the efficient and appropriate review, approval, uniform national labelling, and availability of these products to agricultural producers.

EU regulation
Last week, the European Parliament voted through a proposal for a regulation laying down rules that would help harmonise EU rules on biostimulants and create a European Economic Area (EEA)-wide market for them.
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