Biologicals 2018
An analysis of corporate, product and regulatory news in 2017/2018
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In this instalment of Agrow’s annual biologicals sector review, we begin by examining the impact on the sector of the mega mergers and acquisitions involving the biggest players in the crop protection industry.

Biologicals, especially biopesticides, occupied centre stage during the first half of the current decade when the bigger players started acquiring niche biopesticide companies in a bid to quickly establish their presence in the sector. But from 2015 onwards, the limelight shifted to huge deals between the major companies themselves. With the last (Bayer/Monsanto) of the three mega deals (including Dow/DuPont and ChemChina/Syngenta) almost on the verge of completion, it is time to examine the impact in the years to come on the biologicals sector.

Syngenta says that consolidation among the multinationals could be good news on the innovation side for biologicals as more R&D efforts, technologies and resources could be deployed to discover and enable breakthrough technologies, which could bring biocontrols to a higher level of efficacy and reliability.

BASF expects the demand for biologicals-based products to continue to grow. “BASF will continue to develop biologicals-based solutions for seed, foliar and soil applications in the growing marketplace,” says BASF’s vice-president, global marketing for its Functional Crop Care division, Alyson Emanuel.

Once the agreed acquisitions from Bayer have expanded BASF’s business, the company says that it will be more committed than ever to best-in-class agricultural innovation, including continued investments in expanded R&D and production for biologicals.

Platform Specialty Products agrochemical business Arysta LifeScience expects the impact on the biologicals sector to be minimal in the short term as the mega-M&As are focused on seed genetics and chemical crop protection.

Israeli biopesticide company STK feels that the large-scale M&As create opportunities in the short as well as medium term. In the short term, they will provide opportunities for the biological sectors to more deeply integrate into conventional agriculture and offer its solutions to the channel, it says. In the medium to longer term, the
multinationals will continue to look for technologies and solutions to widen and improve their offering to farmers through diverse types of collaborations. “Mega mergers could also help to soften farmers’ initial reluctance to biosolutions by having a stronger supplier company,” points out STK’s chief executive officer, Guy Elitzur.

Will niche biological companies find it harder to operate in the post-M&A scenario?

Syngenta’s head of biologicals R&D, Matthias Brandl, points out that opportunities will increase to collaborate with multinationals and benefit from their development capabilities and global market presence. He adds that following portfolio rationalisation after the mega-M&As, there may be an increased appetite for external innovation, which would benefit smaller players.

BASF points out that niche companies will continue to have an important role in product development. “We believe niche biologicals specialist companies will continue to have an important role for development of biologicals – continuing to focus on developing new technologies and implementing use in specific high-value markets,” says Ms Emanuel. She points out that products with consistent performance from the niche companies at marketable pricing will be of interest to BASF. “We will be best placed to exploit new technologies for global market penetration,” she adds.

Arysta concurs with the view of a positive scenario for specialist companies. “If anything, it may be easier as the new mega-companies focus on integration, while the trend towards increased biologicals use continues to grow,” says Arysta’s global marketing director, biostimulants & innovative nutrition, Neil Stapensea.

STK points towards a scenario of mergers within the sector. “In general, we think the biological sector will mature over time and we will see niche biological companies merged with others to get wider and sustainable businesses, and then they will show up on the radar of the first to third tiers of the companies,” says Mr Elitzur. But he adds that one negative impact of this development is to block market access of the smallest players.

What about acquisition opportunities for biologicals-based companies and products?

Syngenta says that consolidation of multinationals will continue to create broader market access opportunities for innovative smaller biologicals companies, which may take the form of smaller companies being acquired or getting into partnerships.

DowDuPont says that it remains open to exploring partnerships and acquisitions that will complement its current portfolio of biological technologies.

Arysta concurs, saying that consolidation in the biologicals sector will continue as in other agricultural sectors, particularly with the strong continued growth of the sector, as players strive to establish critical mass, global footprint, and a dominant position in the market.

STK points out that the biologicals sector is becoming more mature. “We will experience more M&As within biological companies and we’ll see bigger and more diversified biological companies in the next years,” says Mr Elitzur.

Product launches and pipeline

Syngenta launched the disease resistance activators, Bastide/Blason (COS-OGA), in France in 2017. It highlights the products as differentiated and effective solutions against downy mildew and powdery mildew in high-value crops such as grapevines and greenhouse vegetables. As part of the deal agreed in 2017, the company is about to launch STK’s biofungicide, Timorex Gold (Melaleuca alternifolia extract), in Australia and New Zealand. It will be focused on grapevines and vegetables against powdery mildew and Botrytis spp.

BASF received approvals from France and the UK for its biofungicide, Integral Pro (Bacillus amyloliquefaciens MB1 600), as a seed application for oilseed rape. The company has begun marketing it through seed companies in France. Registration is pending in several other European countries.

In the US, the EPA approved the company’s B subtilis strain BU1814-based Velondis biofungicidal seed treatments for use on soybeans, small-grain cereals and maize. Pending regulatory approvals, Velondis will first be launched in the US as a component in Vault IP with Velondis Plus in the 2019 season. The company also plans to offer Velondis in South America in coming years.

In 2017, BASF expanded marketing of the biofungicide, Serifel (B amyloliquefaciens strain MB1600), with additional uses in the US (mushrooms) and Thailand (speciality crops). During the remainder of 2018 and into 2019, Serifel will be launched in key European countries including Italy, Spain, Greece, Turkey, Australia and Mexico. Regulatory approval is pending in France.

During 2017 as well as 2018, BASF’s bioinsecticide, Velifer (Beauveria bassiana strain PRRI 5339), was registered for emergency use in potatoes against wireworms in Austria and Germany. In March 2018, Velifer was registered in Canada for greenhouse use, vegetables and ornamentals. From 2019, Velifer will be launched in key European countries, the US and Australia.

In 2017, BASF France agreed to distribute the disease resistance activator, Romeo (cerevisane), for specialty crops (in particular grapevines) in France.

During 2017/18, Bayer received further marketing authorisations and the approval of expanded uses for the biofungicide, Serenade ASO (Bacillus amyloliquefaciens strain QST 713), in various countries. It combats diseases such as Botrytis spp, bacterial infections, black sigatoka (bananas) as well as soil-based syndromes. A new formulation of Serenade developed specifically for soil applications has been submitted to the US EPA, Bayer says.

The bioinsecticide, Contans WG (Coniothyrium minitans), was launched in 2017 in South Africa.

The biofungicide, BioAct Prime DC (Paecilomyces lilacinus 251), was launched in Greece in 2017. Regulatory approval for the product was granted in 2018 in Spain and further approvals are expected. The launch in Spain is scheduled for the second half of 2018.

DowDuPont says that as it creates its agricultural division, Corteva Agriscience, its combined R&D product pipeline is strong and growing through its own efforts and
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collaborations. “We have agreements in place for distribution of various biological products, and continue to grow our natural product offerings that are currently on the market including the spinosad and spinetoram actives, which are sold under the brands of Entrust, Delegate and Radiant.”

Arysta launched various forms of seaweed extract in Asia and the EU. One of these products, Raze, a new formulation targeted at row crops, is being launched in the US. An amino acid biostimulant is being launched in Asia to be followed soon in the EU.

STK launched Timorex Gold in Brazil, Australia, New Zealand, and expanded into 40 states in the US. The “hybrid” biological and chemical fungicide, Regev (M alternifolia extract + difenoconazole), was launched in Serbia, Dominican Republic, Guatemala, Argentina, Colombia and Peru. The biofungicide, Aviv (Bacillus subtilis strain AB/BS03), was launched into 26 US states, including California.

Global market development

Syngenta says that the market for biologicals is growing in all continents. “But the expected lift-off is still not visible in the absence of technologies able to rival with synthetic chemistry based on performance, spectrum and costs,” points out Mr Brandl.

BASF says that in value terms, the biggest increases were seen in North America and Europe. “However, percentage growth is equally strong in South America and Asia,” adds Ms Emanuel.

Bayer looks at the macro picture and predicts that the environment for the world seed and crop protection market will remain volatile in 2018. Growth stimuli are expected to come from Latin America, and the Asia/Pacific region and eastern Europe, it says. In North America and western Europe, on the other hand, the pace of growth will presumably lag behind global development, the company points out. Overall, Bayer anticipates a slight recovery in the market as a whole, and biologicals will benefit from this trend.

Arysta says that Central and South America continue to lead growth, particularly in biostimulants, while the EU continues to lead in biocontrol growth.

STK sees China adopting biological solutions most rapidly from grower acceptance to adopting regulations. “We see more biological products are being applied and used in conventional programmes across China at a growing pace,” says Mr Elitzur. Use of biological products in the US is also growing strongly and “we are looking for future growth from the EU as well”, he adds.

Standalone biologicals vs combination products

Syngenta says that the used of standalone biologicals or combinations with synthetic chemistries will be driven by farmers’ needs for sustainable production, when technologies become available. “Besides residue reduction, product performance, resistance management opportunities and costs will continue to be key criteria for selection of either technology, says Mr Brandl.

BASF says that benefits for biocontrols include options for growers to extend the window of protection, flexible working practices for re-entry and pre-harvest intervals, and support for resistance management. The company points out that while chemistry will always be more relied upon due to the typically wider spectrum of control and efficacy under most environmental conditions, it sees biologicals continuing to grow to be an important factor in coming years.

“We see that most often biocontrols will be used along with and to complement chemistry-based solutions in IPM programmes, though circumstances may arise where a biocontrol can address a need for which there is no chemistry-based solution available,” says Ms Emmanuel. She gives the example of Serifel, which can be effective in managing specific disease strains that have known resistance to traditional chemistry. “We are also demonstrating that biologicals in combination with chemistry can extend performance in terms of pest and disease targets.”

Ms Emmanuel sums up by saying that biological products extend BASF’s portfolio. They are not substitutes for BASF chemical crop protection products, but rather are complementary, she points out. “BASF research directions include development of combinations of biological and chemistry, and we have such commercial offers on the market.”
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Bayer says that there is no “one solution fits all”. In general, Bayer regards biologicals complementary to chemicals rather than stand-alone solutions since there are many segments in agriculture where biologicals are unlikely to fully replace chemicals, for instance, when the pest is too aggressive or immediate and curative effects are needed. The company says that its objective is to offer growers customised agronomic solutions, which would be “smart” combinations of chemicals and biologicals that help to maintain growers’ expectations in effective and cost-efficient pest and disease management.

DowDuPont believes that farmers will continue to demand effective products while also valuing products with favourable environmental profiles. “We view biological technology as another tool to help answer farmers’ needs across production systems and an important part of our complete product offering.”

Arysta feels that both standalone and combination products will be used in integrated programmes to meet environmental and food safety needs.

STK expects to see more integration due to its belief that, at the grower level, the solutions must be integrated into one, more complete product. It points to its product Regev as providing the best of the two worlds. “Having said that, we will see more technology biological companies entering the space since more money will be injected into it,” says Mr Elitzur. “There will still be standalone products,” he adds.

Formulation innovation
BASF’s investment in formulation technology for biologicals is ongoing and includes characteristics that can enhance performance and ease of use. “Our pipeline includes development of new formulations that will be released to the market in due course,” says Ms Emanuel.

Arysta says that formulation advances continue to be made for efficacy as well as shelf life as the sector evolves. “We see this as a key area for many of these technologies, and have had significant success in research to address stability-of-living and extract-based active substances and the compatibility of these substances with conventional chemistry,” explains Mr Stapensea.

STK has decided to focus its research in plant extracts pointing out that oil is robust and can be mixed in all types of formulations with good shelf life. “Nevertheless, we are also bringing to market a state-of-the-art Bacillus subtilis formulation, Aviv biofungicide, which also has a lot of benefits over the standard,” says Mr Elitzur.

Regulatory hurdles
Syngenta says that there has been nothing noticeable in terms of regulatory developments in spite of some expressed political willingness to continue to support the growth of the biologicals market.

Bayer says that it is active in various industry associations to advocate globally harmonised regulations and data requirements adapted to biologicals (biocontrols as well as biostimulants). Talking about ongoing activities, it highlights the OECD, through its Expert Group on Biopesticides (EGBP), which is developing a harmonised approach specific to biopesticide registration through numerous projects. The Joint UN FAO/WHO Meeting on Pesticide Management has recently drafted a new guidance document for biological pest control agents, which covers micro-organisms, botanicals and semiochemicals. Also, the EU Working Group on Biopesticides is developing a guidance document on metabolites of micro-organisms.

Arysta says that new regulatory developments, particularly for biostimulants, are pending in the EU as well as the US. These may not necessarily make it easier, but may better define the regulatory environment while validating the technologies.

STK says that regulations in the EU are still crawling behind and have not adapted themselves to the needs of the food chain. “We do see China changing its regulation to adopt to the first world standard,” says Mr Elitzur.

Conversations about regional regulatory systems
Agrow sought views on the approval process for biologicals from industry associations in the EU, US and Brazil.

US: Comments were sought from Keith Jones, executive director, Biological Products Industry Alliance, who provided the following answers:

How different is the approval process of a biopesticide compared with a chemical ai?
New biopesticide active ingredients can be reviewed and a decision made in just over a year, while new conventional registrations are reviewed and a decision made in about two years. The fundamental process of making an application to the EPA’s Biopesticide and Pollution and Prevention Division (BPDD) is the same as for a conventional chemistry.
However, there are usually less data or studies needed to support a biopesticide application than required for a conventional pesticide. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that the data and risk assessments address the same primary toxicity concerns as conventional pesticides but a reduced data set is justified by the preliminary requirements that the biopesticide must either be microbial or a biochemical with a non-toxic mode of action and a history of safe use. For instance, caffeine would not be accepted as a biopesticide with a reduced data set because it has a toxic mode of action. It would have to reviewed as a conventional product.

The process can get complicated depending on the product and the results of the data. If there are issues in the data or because of a lack of data, it may trigger the requirement for more studies or may not be able to pass the risk assessment. In that case, the EPA may not be able to make a safety finding for a biopesticide registration.

How many biopesticides are currently approved in the US? How many were approved in 2017 and first four months of 2018? According to the EPA, there are 410 registered biopesticide active ingredients. In 2017, nine new biopesticide ais and eight new uses were registered.

What are the BPIA’s recommendations for the registration process for biopesticides? The EPA has three divisions responsible for regulatory activities: Antimicrobial Division (disinfectants and sanitisers), Registration Division (conventional) and the Biopesticide and Pollution Prevention Division (BPPD). The independent unit was developed in 1996 to facilitate the registration of low-risk biopesticides. The BPPD also has reduced timelines and fees compared to conventional pesticides. The BPIA’s recommendation is that the EPA continues to facilitate biopesticide registration and use science-based decisions that are commensurate with the risks and not unnecessarily complicate the process.

Brazil: Comments were sought from Amalia Piazentim Borsari, executive director of the Brazilian association of biological control companies, the ABCBio, who provided the following answers:

How different is the approval process of a biopesticide compared with a chemical ai? Was there any change in the last year? Biological products have their distinct registration process based on specific regulations classified into three categories: microbiological control agents, biological control agents and biochemicals. If there is a product that does not fit into these categories, all the requirements and studies contained in the legislation of pesticides in general, regardless of their nature, will be required. Another important differentiation is the product registration by biological target, allowing its use in any crop, unlike with agrochemicals. The registration process for biological products is prioritised due to their low toxicity and danger to users.

However, despite these advantages over agrochemicals, the Brazilian environmental agency, the Ibama, a little more than a year ago, banned research on exotic organisms under the precautionary principle, considering that invasive species are considered the second largest cause of biodiversity loss in the world. Currently, ABCBio is mediating the resolution of this impediment until the establishment by the Ibama of criteria for risk assessment. Another major ongoing change is the new toxicological and labelling reclassification under the GHS (Globally Harmonised System of Classification and Labelling of Chemicals) model, which is expected to be implemented in 2018.

How many biopesticides are currently approved in Brazil? How many were approved in 2017 and first four months of 2018? There are 166 commercial products approved with 30 biological control assets (biological agents and microbiological agents). There were 37 products approved in 2017 and nine approved in 2018 (up to May 7th).

What are the ABCBio recommendations for the registration process for biopesticides? The companies requesting registration must obey the following laws: Law 7.802/1989, Decree No 4.074 / 2002, INC 2 (biological agents), INC 3 (microbiological agents) and INC 32 (biochemicals). These Joint Normative Instructions (INC) are available on the ABCBio website: (http://www.abcbio.org.br/conteudo/legislacao/). It is important to emphasise that the protocols to be adopted for the tests of the physico-chemical properties of the products based on micro-organisms be the same ones adopted for chemical products. These internationally accepted protocols are available from the OECD and the EPA.
Biologicals-related mergers, acquisitions and deals in 2017

A monthly listing of the mergers, acquisitions and deals in 2017, with links to the original articles.

JANUARY
• US biostimulant company Agrinos entered into a distribution partnership with US distributor Van Diest Supply Company.
• Monsanto and Danish company Novozymes’ BioAg Alliance granted exclusive distribution rights in the US and Canada for its biofungicide, Taegro 2 (Bacillus subtilis var amyloliquefaciens strain FZB24), to Italian agrochemical company Isagro’s US business, Isagro USA.
• The Canadian company, Bee Vectoring Technologies, entered into formal agreements with several leading US strawberry growers to conduct large-scale commercial demonstrations of its proprietary growing system for its bee-delivered biofungicide, Vectorite with CR-7 (Clonostachys rosea strain CR-7).
• Nufarm and US biopesticide company Marrone Bio Innovations (MBI) agreed to develop MBI’s bioinsecticide/acaricide, Grandevo (Chromobacterium subtsugae strain PRAA4-1T), for Australia and New Zealand.

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• Spanish biological pesticides company Symborg agreed a deal with Japanese CBC group’s European subsidiary, CBC Europe’s bioproducts company, Biogard, for distribution rights in Italy for Symborg’s biofungicide, MycoUp (Glomus iranicum var tenuihypharum).
• The US biopesticide company, Vestaron, entered into a marketing agreement with US greenhouse and nursery specialist OHP for Vestaron’s peptide-based bioinsecticide/acaricide, Spear-O (GS-omega-Hxtx-Hv1a – trade-marked as Versitude), for use on greenhouse ornamentals.

MARCH
• Dutch bioproducts company Koppert Biological Systems, Brazilian pest management company ISCA Technologies and Dutch remote sensing firm TEC-1B joined forces on a project to control red palm weevils (Rhynchophorus ferrugineus) on date palms in the Middle East.
• Israeli biopesticide company Stockton entered into an agreement with New Zealand distributor Grosafe Chemicals to sell Stockton’s biofungicide, Timorex Gold (Melaleuca alternifolia extract), in the country.

MAY
• The US biopesticide company, Marrone Bio Innovations, and US agrochemical and specialty chemical company Albaugh’s Mexican distributor, Agri-Star, agreed a distribution deal in Mexico.

MAY
• Marrone Bio Innovations entered into a distribution agreement with US company Jet Harvest covering the latter’s fungicide/bactericide/algaecide, Jet-Ag (hydrogen peroxide + peroxyacetic acid).

JUNE
• Japanese company Mitsui & Co’s US biopesticide subsidiary, Certis USA, acquired the US biopesticide business, LAM International.
• The US biopesticide company, Marrone Bio Innovations, engaged the US investor relations firm, M Z Group, to manage a strategic investor relations and financial communications programme across all key markets.

JULY
• DuPont seed subsidiary DuPont Pioneer entered into a multi-year collaboration with Israeli biotechnology company Evogene on the development of microbiome-based biostimulant seed treatments for maize.
• Israeli biopesticide company Stockton and Spanish biopesticide firm Seipasa entered into an agreement to introduce a Bacillus subtilis-based biofungicide/bactericide into the US.
• Italian biostimulants company Valagro signed a global agreement with Syngenta to supply biostimulants for seed treatment.

AUGUST
• Bayer’s Crop Science division entered into an exclusive global distribution deal with Italian biostimulants producer Sicit 2000.
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Bayer’s Crop Science division agreed to collaborate with US not-for-profit company Citrus Research and Development Foundation on developing solutions to the bacterial citrus greening disease (*Candidatus liberibacter*).

The Israeli biopesticide company, Stockton, granted Syngenta (owned by ChemChina) exclusive rights to commercialise and distribute Stockton’s biofungicide, Timorex Gold (*Melaleuca alternifolia* extract), for use on edible crops in Australia and New Zealand.

### SEPTEMBER

- Bayer’s Crop Science division started a five-year research collaboration with the Greek Institute of Molecular Biology and Biotechnology to discover insect control solutions.
- US biopesticide company Marrone Bio Innovations agreed to collaborate on a pilot project with US agricultural technology company AgShift to assess the impact of the use of biopesticides on the quality of fresh produce.
- US biopesticide company Marrone Bio Innovations formed a partnership with Swiss technology transfer company Elephant Vert to distribute two biopesticides in North Africa.
- The US agricultural technology development investment company, TechAccel, awarded $60,000 to the Donald Danforth Plant Science Center to further the development of a sprayable RNAi-based biopesticide for the control of diamondback moths (*Plutella xylostella*).
- Italian biostimulants company Valagro and French crop protection and home garden group SBM Company agreed a distribution deal covering Europe and the US.

### OCTOBER

- The US biopesticide company, Marrone Bio Innovations, agreed an exclusive distribution deal with Kenya Biologics to deliver its products in Kenya and Tanzania.
- Israeli biopesticide company Stockton and Israeli chemical distributor Lidorr Chemicals built a new biological manufacturing unit at Lidorr’s sister contract manufacturing company Liad Agro’s facility in Jerusalem, Israel for the production of Stockton’s new products.

### DECEMBER

- The Australian biotechnology company, Bio-Gene Technology, entered into an extended research collaboration with the Australian state of Queensland’s Department of Agriculture and Fisheries to assess Bio-Gene’s β-triketone-based insecticide, Flavocide (flavesone), against grain storage pests. It also entered into an extended collaboration with the Australian research organisation, the CSIRO, to develop improved manufacturing systems for Flavocide.
- UK biopesticides company Biotechnica agreed a distribution deal with Chinese company Dyacare Bio-Tech for Biotechnica’s organic certified seaweed extract concentrate, Algaflex, in mainland China.
- Japanese company Mitsui & Co’s US biopesticide subsidiary, Certis USA, entered into an agreement with the Colombian Corporation for Agriculture Research, Corpoica, to develop a viral bioinsecticide for the control of fall armyworms (*Spodoptera frugiperda*).
- Indian company Coromandel International agreed to acquire its parent company EID Parry’s biopesticides business as well as its wholly owned subsidiary, Parry America.
- Dutch bioprocess company Koppert’s Brazilian subsidiary, Koppert do Brasil Sistemas Biológicos, acquired Brazilian biologicals enterprise BUG Agentes Biológicos.
- US biopesticide company Marrone Bio Innovations (MBI) agreed an exclusive distribution deal with Guatemalan agricultural inputs supplier Disagro for MBI’s biofungicide, Regalia Maxx.

### JANUARY

- 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 R38.
- US biopesticide company Marrone Bio Innovations agreed an exclusive Philippine distribution deal with national agricultural inputs supplier Great Harvest Agri Chemicals Corporation.
- The US biological pesticide and fertiliser company, Vegelab US, exercised an option to acquire US company The Agronomy Group.

### MARCH

- US biological crop protection company Omnia agreed to acquire the Cayman Islands-based biologicals business of Oro Agri.

### APRIL

- 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.
- Israeli biopesticide company STK (previously Stockton) and BASF agreed a distribution deal in Brazil for STK’s biofungicide, Timorex Gold (*Melaleuca alternifolia* extract).
## New active ingredients registered or launched in 2017

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<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
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<td><strong>AgBiome Innovations/SePRO Corporation</strong></td>
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<tr>
<td><em>Pseudomonas chlororaphis</em> strain AFS009 [biofungicide]</td>
<td>Food crops, turf &amp; ornamentals</td>
<td>Approved in US as Zio &amp; Howler</td>
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<tr>
<td><strong>Arysta LifeScience (Platform Specialty Products)</strong></td>
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<tr>
<td><em>Beauveria bassiana</em> strain 147 [bioinsecticide]</td>
<td>Ornamental palm trees</td>
<td>Approved in EU</td>
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<tr>
<td><em>Beauveria bassiana</em> strain NPP111B005 [bioinsecticide]</td>
<td>Bananas &amp; ornamental palm trees</td>
<td>Approved in EU</td>
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<td><strong>BASF</strong></td>
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<tr>
<td><em>Beauveria bassiana</em> strain PPRI 5339 [bioinsecticide/acaricide]</td>
<td>Protected horticulture</td>
<td>Approved in Australia as Broadband OD &amp; proposed approval in Canada as Velifer</td>
</tr>
<tr>
<td><em>Bacillus subtilis</em> strain BU1814 [biofungicide]</td>
<td>Vegetables &amp; field crops</td>
<td>Proposed approval in US as Velondis Flex, Velondis Plus &amp; Velondis Extra (both with <em>B amyloliquefaciens</em> strain MBI 600)</td>
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<td><strong>BASF/Agrauxine</strong></td>
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<tr>
<td>cerevisane [disease resistance activator]</td>
<td>Grapevines</td>
<td>Approved in France as Romeo</td>
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<tr>
<td><strong>Bayer Crop Science</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus firmus</em> [bionematicide]</td>
<td>Cotton, maize &amp; soybeans</td>
<td>Approved in Brazil as Oleage</td>
</tr>
<tr>
<td><em>Bacillus amyloliquefaciens</em> strain QST 713 [biofungicide]</td>
<td>Grapevines</td>
<td>Proposed approval in Australia as Serenade Opti</td>
</tr>
<tr>
<td><em>Coniothyrium mimitans</em> strain CON/M91-08 [biofungicide]</td>
<td>Oilseed rape, lettuces, cucumbers, beans &amp; sunflowers</td>
<td>Approved in EU</td>
</tr>
<tr>
<td><em>Paecilomyces lilacinus</em> strain 251 [bionematicide]</td>
<td>Fruit &amp; vegetables</td>
<td>Approved in Greece as BioAct Prime</td>
</tr>
<tr>
<td><strong>Consume em Verde</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BLAD (Banda de <em>Lupinus albus</em> doce) [biofungicide]</td>
<td>Stone fruit</td>
<td>Approved in Australia as Problad Plus</td>
</tr>
<tr>
<td><strong>Eden Research</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eugenol/geraniol/thymol [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in France &amp; Portugal as 3AEY &amp; Mevalone</td>
</tr>
<tr>
<td>Company &amp; active ingredient</td>
<td>Use</td>
<td>Status</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----</td>
<td>--------</td>
</tr>
<tr>
<td>Ihara</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus amyloliquefaciens</em> strain D747 [biofungicide]</td>
<td>Various</td>
<td>Launched in Brazil as Eco-Shot</td>
</tr>
<tr>
<td>Marrone Bio Innovations</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus amyloliquefaciens</em> strain F727 [biofungicide]</td>
<td>Various including grapevines, leafy greens, potatoes, carrots &amp; onions</td>
<td>Approved in US as Stargus</td>
</tr>
<tr>
<td>MosquitoMate</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Wolbachia pipientis</em> ZAP strain [bioinsecticide]</td>
<td>Mosquitoes</td>
<td>Approved in US as ZAP Males</td>
</tr>
<tr>
<td>National Machinery Traders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cedarwood oil [repellent]</td>
<td></td>
<td>Proposed approval in Australia as Nature's Botanical Crème (with rosemary oil)</td>
</tr>
<tr>
<td>Novozymes BioAg</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Streptomyces lydicus</em> strain WYEC108 [biofungicide]</td>
<td>Vegetables, turf &amp; ornamentals</td>
<td>Approved in Australia as Actinovate</td>
</tr>
<tr>
<td>Nufarm</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Aureobasidium pullulans</em> strain DSM 14940 + A pullulans strain DSM 14941 [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in Australia as Botector</td>
</tr>
<tr>
<td>Simbiose Agro</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Trichoderma harzianum</em> strain Cepa Simb-T5 [biofungicide]</td>
<td></td>
<td>Launched in Brazil</td>
</tr>
<tr>
<td>Stockton</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Melaleuca alternifolia</em> extract [biofungicide]</td>
<td>Cucumbers &amp; courgettes</td>
<td>Approved in Spain as Timorex Gold</td>
</tr>
<tr>
<td>Syngenta (owned by ChemChina)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pasteuria nishizawae</em> [bionematicide]</td>
<td>Soybeans</td>
<td>Approved in Brazil as Clariva PN</td>
</tr>
<tr>
<td>Valent USA (subsidiary of Sumitomo Chemical)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus amyloliquefaciens</em> strain PTA-4838 [bionematicide]</td>
<td>Soybeans</td>
<td>Launched in US as Aveo EZ</td>
</tr>
<tr>
<td>Vitae Rural Biotecnologia</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Spodoptera frugiperda</em> multiple nucleopolyhedrovirus [bioinsecticide]</td>
<td>Maize</td>
<td>Launched in Brazil as CartuchoVIT</td>
</tr>
</tbody>
</table>
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  - Global supply/demand, country balances and trade flows analysis with history dated back to 1980
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   - Authenticate and connect to our API
2. **Call**
   - Call the API as described in the API documentation
3. **Collect**
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4. **Consume**
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New biological active ingredients registered or launched in 2018

<table>
<thead>
<tr>
<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BASF</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Beauveria bassiana</em> strain PPRI 5339 [bioinsecticide/acaricide]</td>
<td>Greenhouse ornamentals &amp; vegetables</td>
<td>Approved in Canada as Velifer</td>
</tr>
<tr>
<td><strong>Bayer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus amyloliquefaciens</em> strain QST 713 [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in Australia as Serenade Opti</td>
</tr>
<tr>
<td><strong>Brandt iHammer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monsanto</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>lipochitoooligosaccharide SP104 [plant growth regulator]</td>
<td>Maize &amp; canola</td>
<td>Approved in US as Acceleron B-360 ST</td>
</tr>
<tr>
<td><strong>Verdesian Life Sciences</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>calcium salts of phosphorous acid/calcium phosphite [fungicide/systemic acquired resistance activator]</td>
<td>Fruit, vegetables, trees, nuts, ornamentals &amp; turf</td>
<td>Proposed approval in US as Fungi-Phite Ca</td>
</tr>
</tbody>
</table>
The formula of valuable solution for agriculture

### HERBICIDE

<table>
<thead>
<tr>
<th>Flumioxazin</th>
<th>Imazethapyr</th>
<th>2,4-D</th>
<th>MCPA</th>
<th>Clethodim</th>
<th>Acethlorsulfuron</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoxaflutole</td>
<td>Imazamox</td>
<td>2,4-DB</td>
<td>MCPB</td>
<td>Metribuzinsulfonyl</td>
<td></td>
</tr>
<tr>
<td>Mesotrione</td>
<td>Imazapyr</td>
<td>2,4-DP-p</td>
<td>MCPP-p</td>
<td>Fomesafen</td>
<td>Metolachlor</td>
</tr>
<tr>
<td>Butoxydim</td>
<td></td>
<td>Dicamba</td>
<td>Clopyralid</td>
<td>Oxyfluorfen</td>
<td></td>
</tr>
<tr>
<td>Penoxsulam</td>
<td>Sulfentrazone</td>
<td>Glyphosate</td>
<td>Picloram</td>
<td>Atrazine</td>
<td>Cyhalofop</td>
</tr>
<tr>
<td>Diclosulam</td>
<td>Carfentrazone</td>
<td>Glufosinate</td>
<td>Diuron</td>
<td>Ametryn</td>
<td>Clodinafop</td>
</tr>
<tr>
<td>Cloransulam</td>
<td>Amicarbazone</td>
<td>Bentazone</td>
<td>Triclopyr</td>
<td>Bispyribac</td>
<td>Fenoxyprop</td>
</tr>
<tr>
<td>Flumetsulam</td>
<td>Flucarbazone</td>
<td>Clomazone</td>
<td>Bromacil</td>
<td>Propanil</td>
<td>Quizalofop</td>
</tr>
<tr>
<td>Florasulam</td>
<td>Mesosulfuron</td>
<td>Fluroxypyr</td>
<td>Hexazinone</td>
<td>Flufenacet</td>
<td>Haloxyfop</td>
</tr>
</tbody>
</table>

### INSECTICIDES

<table>
<thead>
<tr>
<th>Thiamethoxam</th>
<th>Methoxyfenozide</th>
<th>Lufenuron</th>
<th>Imidacloprid</th>
<th>Diaphenthiuron</th>
<th>Abamectin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clothianidin</td>
<td>Indoxacarb</td>
<td>Profenofos</td>
<td>Acetamiprid</td>
<td>Pyriproxyfen</td>
<td>Emamectin</td>
</tr>
<tr>
<td>Dinofuran</td>
<td>Pymetrozine</td>
<td>Acephate</td>
<td>Ethiprole</td>
<td>Methomyl</td>
<td>Bifenazate</td>
</tr>
<tr>
<td>Chlorfenapyr</td>
<td>Bifentrin</td>
<td>Chlorpyrifos</td>
<td>Fipronil</td>
<td>Oxamyl</td>
<td>Lambda-cyhalothrin</td>
</tr>
</tbody>
</table>

### FUNGICIDES

<table>
<thead>
<tr>
<th>Azoxystratin</th>
<th>Prothioconazole</th>
<th>Fluazinam</th>
<th>Tebuconazole</th>
<th>Benomyl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyraclostrobin</td>
<td>Cyproconazole</td>
<td>Bosalid</td>
<td>Propiconazole</td>
<td>Carbendazim</td>
</tr>
<tr>
<td>Trifoxystrobin</td>
<td>Difenconazole</td>
<td>Fludioxonil</td>
<td>Isoprothiolane</td>
<td>Pyrimethanil</td>
</tr>
<tr>
<td>Picoxystratin</td>
<td>Epoxiconazole</td>
<td>Cyprodinil</td>
<td>Dimethomorph</td>
<td>Spiroxamine</td>
</tr>
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Biopesticides · Biostimulants · Fertilizers
Efficacy of low-risk substances and micro-organisms

by Dr Lars Huber and Dr Joachim Kranz, SCC Scientific Consulting Company GmbH

The updated criteria in the EU for low-risk substances (Regulation 2017/1432) more or less clearly define the characteristics of these substances in regards to certain physical-chemical, toxicological, ecotoxicological and environmental fate properties. With the exception of the very vague criteria given for micro-organisms, these low-risk requirements can be applied to any type of substance, setting the framework for registration strategies in these subject areas for each individual substance.

In addition, the criteria fixed for these subject areas also set the framework for possible incentives to foster the registration and availability of low-risk substances and products, for example, in regards to residue exemptions, reduced study requirements, reduced evaluation time-lines and, in some member states, lower authority fees.

With respect to economisation of the time and cost consuming efficacy studies and data requirements for a product authorisation, the low-risk criteria for active ingredients according to Regulation 2017/1432 offer no starting points.

As a basis for data/study requirements for low-risk product authorisations, the European and Mediterranean Plant Protection Organization (EPPO) published standard PP1/296(1) on the “Principles of efficacy evaluation for low-risk plant protection products” in 2017 (the Standard).

The new standard also includes micro-organisms, in case they are of low-risk, and thus supplements EPPO standard PP1/276(1) of 2012 on the “Principles of efficacy evaluation for microbial plant protection products”.

In general, EPPO standard PP1/296(1) describes the framework for the minimum data requirements for demonstration of efficacy and crop safety for low-risk products. The Standard clearly does not substitute any of the EPPO standards in effect for non-low-risk plant protection products. On the contrary, the Standard makes reference to the existing applicable standards (see https://gd.eppo.int/) and emphasises consistently that there should not be a difference between the principles of efficacy evaluation for low- and non-low-risk products. The Standard ascribes possible differences in study conduct, testing strategy, trial programme, description and evaluation of results by authorities between low- and non-low-risk products solely to scientific reasons, based on the special characters of the individual low-risk ais. Even without considering different functions or modes of actions, the huge variety of low-risk ais is evident from the examples of the (very few) low-risk ais already authorised (12 substances) as well as the possible candidates identified in the ai renewal programme (64 substances);
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- Zineb
- Propineb
- Cymoxanil
- Metam-sodium
- Difenconazole
- Azoxystrobin
- Fosetyl-Al
- Chlorothalonil
- Mancozeb

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- INDONACARB
- IMIDACLOPRID
- LAMBDA-CYHALothrin
- Lufenuron
- METHOMYL
- METHOXYFENozIDE
- PYMETROZINE
- PYRPROXYfen
- TEFLUFENZURON
- THIAMETHoxAM

FUNGICIDE
- BOSCALID
- CYPRODINIL
- EPOXYCONAZOLE
- FAMONABONE
- FLUAZINAM
- FLUACONOMIL
- FLUOROXYMETHYL
- MANCOZEB
- PICONYSTROBIN
- PROTHIOCONAZOLE
- PYRACLOSTROBIN
- TRIFOXYSTROBIN
- REGULATOR
- ETHERPHON

HERBICIDE
- 2,4D ACID/AMINE SALT
- ACIFLUORFEN
- ATRAZINE
- BISPYRIMIC SODIUM
- BROMACIL
- CARPENTRAZONE-ETHYL
- CHLORIMIVURON-ETHYL
- CLODINAFOP-PROPARGYL
- DICAMBA
- DICLOSlAM
- DIFLUFENIC
- FLOPENSLAM
- FLOXIGNAZIN
- FOMESEN
- GLUFOSINATE AMMONIUM
- GLYPHOSATE
- HEXAZINONE
- ISONAZOLE
- MEMBRINE
- MEFENZURON
- NICOSULFURON
- OXASULFURON
- PROPYLAMINE
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Contact Person: Mr. Dennis Lu / Ms. Michael Lu
SAN-TE-2016-10616–rev 8 of October 2017). These 76 substances comprise biologically very different groups of microorganisms – even from different domains and kingdoms – viruses, botanicals, inorganic salts, fatty acids, plant hormones, proteins, plant oils, gases, minerals and basic chemicals. Thus, the scientific, “more specialised”, approach to efficacy testing chosen by EPPO (“Good quality data and science are essential”) is reasonable and to be applauded in general.

For implementation of this scientific approach, certain principles are to be considered:

- Diversity of low-risk ais and products.
- General requirement for scientific explanations and justifications of claims.
- Flexibility of the efficacy evaluation in regards to the level of effectiveness where the Standard defines the primary criterion of acceptable efficacy as “results that are significantly superior to those recorded in the untreated control, i.e., that the use of the product is better than no use”. In the case of the use of a chemical product as reference product, the Standard highlights that the reference product is to be used to establish the validity of the trial and not for comparison of the level of efficacy.
- Use of lab trials and relevant published data as “important and valid source of information”.
- Acceptability of non-GEP data if scientifically sound.
- Further possible benefits of low-risk products, for example, regarding resistance management or suitability for IPM or special cultivation systems such as organic farming, that is the contribution of low-risk products to agricultural sustainability, are to be considered in the evaluation.
- Especially considering the level of effectiveness and the acceptable efficacy of low-risk plant protection products, the Standard highlights that the principle of relevant benefit applies, i.e., the effectiveness should be compared to untreated control and not a possible (chemical) reference product either stand alone or in a programme (for instance, IPM). In addition, for the evaluation of the contribution of the use of low-risk products to agricultural sustainability and additional benefits such as short or no pre-harvest intervals, reduced or no residues, lower or no probability of resistance, less side-effects, for example, on non-target organisms or the unnecessity of risk mitigation measures are to be considered.

As key topics to be used in the scientific approach, the Standard mentions:

- Mode of action (MoA) where the Standard also defines categories of low-risk plant protection products, for which general scientific argumentation is possible. The categories are (bio)chemicals and substances derived from animals, botanicals, minerals, extracts from micro-organisms and synthetic substances with direct or indirect MoAs as well as micro-organisms with direct or indirect MoAs and semiochemicals including pheromones. In addition, the Standard acknowledges, that some ais belong to more than one category.
- Conditions and situations of minimum, optimum and maximum performance of low-risk ais and products such as, in the case of micro-organisms, biological/physiological parameters regarding survival, reproduction, colonisation and competition.
- Crop biology and physiology.
- Environmental conditions.

Considering the huge variety of (possible) low-risk substances and their special characters, the commitment to a scientific approach in regards to efficacy evaluation itself is a huge benefit for applicants. Furthermore, the scientific case-to-case approach, with certain exceptions, renders additional efficacy or crop safety guidance for low-risk ais types as unnecessary. For low-risk substances, a reduction of the financial burden in the efficacy area is of special interest, not only as many applicants are SMEs. First and foremost, as many of these substances are able to control diseases and pests in crops of lower economic importance or situations for which no pest control method is available until now but for which big investments in efficacy trial programmes are not justified.
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**Matthew Burns:** Matt brings extensive experience in Plant Protection regulation from his career with the HSE, where he took the lead on substance review and assessment under the EU review programme.

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Based on the scientific approach, economisation of efficacy data/study requirements is also considered in the present standard on the “Principles of efficacy evaluation for low-risk plant protection products” to a huge extent.

The Standard sets the minimum number of fully supportive direct efficacy trials required for an area of similar conditions as six for a major pest on a major field crop, four for a major pest under protected conditions and three for other uses. At first glance, this is quite similar to the minimum requirements for plant protection products given in EPPO standard PP1/226(2) which, of course, is already a clear reduction of studies required. But in addition, the numbers of efficacy trials given in The Standard do not only apply for a single pest or crop, but to pest and crop groups where The Standard explicitly refers to the existing extrapolation possibilities for minor uses as described in EPPO standard PP 1/257(2) as well as the relevant extrapolation tables developed by EPPO (refer to: https://www.eppo.int/PPPRODUCTS/minor_uses/minor_uses.htm) and the use of these extrapolation possibilities not only for minor but also for major uses.

Furthermore, depending on the characteristics of the individual ais/product for example, an extrapolation from worst-case circumstances to intermediate or less-critical conditions is considered feasible by EPPO. Similar for extrapolation between agro-climatic zones as – considering the special characteristics of many low-risk ais – comparable conditions do not depend on climatic factors only but also on edaphic and agronomic factors, crop biology, pest/crop interrelationships, soil conditions, application and cultivation techniques. Due to the huge variety of low-risk ais, extrapolation outside EPPO PP 1/257(2) may also be possible for low-risk products.

In addition, the Standard establishes possibilities for exemptions from the requirement of dose justification field trials, for example, based on MoAs as well as minimum effective dose trials. For reproducing micro-organisms, the minimum effective dose approach is considered difficult or not appropriate. Instead, the Standard proposes that a range of doses should be provided which reflects the scientific and practical facts. A similar approach applies for semiochemicals. In case of selectivity/phytotoxicity trials EPPO concludes that even for special low-risk herbicides and plant growth regulators appropriate analysis of the effectiveness trials may be sufficient, given that no phytotoxicity symptoms are observed in these trials. The same is the case for effects on plant parts used for propagation or side effects on succeeding or adjacent crops.

As evident, full implementation of the possibilities and benefits of the EPPO standard PP1/296(1) on the “Principles of efficacy evaluation for low-risk plant protection products” in the registration strategy for a low-risk product obliges applicants to use a completely different (new) approach to efficacy testing and dossier preparation. In addition, standard PP1/296(1) requires in-depth knowledge of applicants not only in regards to their individual low-risk ais and products, but also on crop biology and physiology, environmental and agricultural conditions, application and cultivation techniques such as IPM.

As practical experiences with the implementation of the new principles for efficacy evaluation for low-risk plant protection products is currently very limited, there are several open questions on the future impact of this standard. The two key points are: (i) whether applicants are willing and able to provide a scientifically sound dossier [Biological Assessment Dossier (BAD) and dRR], scientifically explaining and justifying their claims and (ii) whether authorities are willing and able to follow the scientific approach, accepting the special character of many low-risk substances and the study/data reduction approach.

If these two points can be met, EPPO standard PP1/296(1) represents a valuable incentive for plant protection product authorisation applications, fostering the availability of low-risk plant protection products on the market. This may, in future, even include possibilities to fully exploit the potential of low-risk ais including their use against abiotic stresses or in the scope of IPM programmes for which an efficacy testing guideline would be much needed.
Taking place from 20 to 21 June 2018 in Cologne, in one of the central hubs of Germany’s chemical industry, Chemspec Europe 2018 will once again present the full spectrum of custom, fine and speciality chemicals for many different applications and industries, including pharmaceuticals, agrochemicals, polymers, additives, advanced intermediates, food and feed, oil and gas mining, pigments, dyes, electronics, fragrances, household chemicals, bio-based chemicals and many more. The broad exhibition portfolio is completed by a range of analytical, production and processing equipment, as well as regulatory services and products.

In this complex and competitive market, Chemspec Europe offers a highly diversified yet specialised business platform that allows purchasing, sourcing, R&D and process management professionals to get hold of innovative solutions, products and services. The coming event will feature some 350 suppliers from 27 different countries, with the majority of exhibitors coming from Germany, plus a substantial European line-up headed by the United Kingdom, France, Belgium, Switzerland, the Netherlands, the Czech Republic and Spain. The USA and various Asian countries will also show a strong presence, with India and China being Asia’s most prominent participants.

**New Partnering Programme to create smart networking opportunities**
Promoting networking has always been a major part of Chemspec Europe. At this year’s show, visitors have the opportunity to use a new matchmaking service, the Chemspec Europe 2018 Partnering Programme, to connect and do business with people of complementary interests. A compatibility function will help attendees find the perfect match and organise private meetings in dedicated on-site meeting spaces.

“Chemspec Europe is blessed with a top-class range of highly qualified trade visitors offering a huge pool of industry knowledge and business contacts. By introducing the new Partnering Programme, we want to help attendees capitalise on this potential by offering an...
innovative matchmaking technology that is easy to use and extremely targeted”, explains Liljana Goszdziewski, Exhibition Director of Chemspec Europe, on behalf of the organisers, Mack Brooks Exhibitions. “The idea is to add a third level of networking in addition to the activities on the exhibition stands and around the conference sessions. The new Partnering Programme will help visitors meet people from similar industries or interests in the easiest way possible, adding true value for attendees. Visitors can save time, extend their network beyond already existing contacts, and use modern technology to make networking a less daunting task.”

Interested visitors can already sign up to participate via the official show website www.chemspeceurope.com.

**Extensive conference programme and educational content**

Chemspec Europe provides an extensive educational programme of lectures and conference sessions on-site. In four designated lecture theatres, industry experts will hold talks and discussion rounds on chemical supply chain knowledge, ongoing R&D projects and regulatory issues. All conferences and seminars are free to attend and will partly be organised by renowned partner organisations:


- The Pharmaceutical Update conference organised by Chemspec Europe, including “The Pharma Outsourcing Best Practices Panel session on global outsourcing strategies” and “The Abou-Gharbia Lecture on drug discovery and the road to personalized medicine”, both held and chaired by Dr Magid Abou-Gharbia, Moulder Center for Drug Discovery Research, School of Pharmacy, Temple University, Philadelphia, PA, USA.

- **The Regulatory Services Conference**, organised by REACHReady: Covering the range of regulatory challenges facing those in the global chemical supply chain.

- **The RSC Symposium**, organised by the Royal Society of Chemistry: Two-day symposium on advances in the science, understanding and development of new additives to enhance product performance.

- **The Chemspec Careers Clinic**, organised by Chemical Search International: Chance for executives from the fine and speciality chemical sectors to discuss their career aspirations with a specialist professional search firm.

Further details on the latest programme and speakers are published on www.chemspeceurope.com

Cologne – a key location in the “chemical belt” of Germany

Chemspec Europe is held annually at different locations in Europe. For 2018, the show will occupy Hall 8 of Koelnmesse in Cologne, Germany. The region around Cologne, also called the “chemical belt” of Germany, boasts large-scale chemical sites and chemical parks with a vast number of production plants where diverse chemical products are manufactured, from fuel for modern engines to highly complex active agent molecules for life science applications.

Koelnmesse can easily be reached by plane via Düsseldorf Airport or Cologne-Bonn Airport, with international and domestic flight connections. The venue is also well-connected to Cologne’s public transport system and a number of motorways.

**Show Preview available in print and online**

The Chemspec Europe Show Preview has just been published. The bilingual brochure contains over 200 exhibitor profiles and a detailed overview of the product and services portfolio which will be presented at the show. It also includes the detailed conference programme, the exhibitor list and industry news. Visitors can order their print copy via the visitor enquiry form on www.chemspeceurope.com

The official show website is updated regularly and offers the latest exhibitor list and detailed information on the exhibition and conferences. The Chemspec Europe Newsletter, available via the show website offers its subscribers the latest news about the upcoming exhibition as well as short reports on markets, products and trends. Chemspec Europe is also on Social Media:

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Progress needed to characterise the active agent in biologicals

by Dr Oni Oluwatobi

In recent decades, biopesticides have attracted significant attention in pest management, evidenced by valuations of the biopesticide market close to $3 billion in 2016 and for some $6.6 billion by 2022. The increasing global popularity of biopesticides in crop protection compared with their synthetic counterparts can partly be put down to their lower development cost, suitability for use in sustainable agriculture and as an additional tool to manage resistance in integrated pest management schemes.

The US and Canada has made the registration of biopesticide products more efficient through the development of modified test methodologies and clear guidance documents. However, in the EU, biopesticides are still registered under the same regulatory framework as chemical pesticides. The EU’s registration process is complex with limited guidance on key areas of biopesticide risk assessment. The EU is encouraging the registration of more plant protection products of biological origin through “low-risk” categories. However, challenges still lie ahead in the registration processes that hinder safe and successful commercialisation of novel biopesticides.

There are three generic categories of biopesticides in the EU: (i) microbial pesticides – pesticides with microorganisms (bacteria, virus or fungi) as the active ingredient; (ii) biochemicals – such as secondary metabolites produced by plants to deter insects from feeding on them; (iii) semiochemicals - chemical signals produced by one organism to cause a change in the behaviour of another organism of the same or different species. Most biopesticides on the market are microbial pesticides. Bacteria-based pesticides (mainly *Bacillus thuringiensis*-based products) are the most common form of microbial pesticides. Bacteria (especially *Bacillus* strains) are relatively easier and cheaper to produce through fermentation in comparison to fungal biological control agents, thus attracting commercial development of bacterial strains for use in biological control.

To ensure the safe use of bacterial strains, it is necessary to conduct a thorough assessment of hazard and risk to humans and the environment. Similar to synthetic chemical pesticides, the first and perhaps most vital step in the risk assessment of a bacterium are its taxonomic identification and characterisation. The EU, according to Regulation 283/2013 (part B) requires that each microbial active substance be...
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identified, characterised and named at the strain level. Identification and characterisation of bacterial species with potential for biological control at strain level is necessary to distinguish them from closely-related pathogenic variants. Unlike synthetic chemical pesticides, there is limited guidance in the EU on the characterisation of micro-organisms. The only guidance document recently released, caters to the characterisation of micro-organisms used as feed additives. However, none so far have been adapted for the same purpose with micro-organisms used as active ingredients in plant protection products.

Citing literature reports on bacterial strains similar to the biocontrol agent is a common approach but may be insufficient and misleading in drawing physiological and pathogenic comparisons. This is because a few base pair differences in the genetic sequences of diagnostic marker genes from micro-organisms of the same species or strains may be enough to result in pronounced differences in physiological (for example, metabolite profiles) or pathogenicity traits. Besides, reports describing and characterising the reference strain may be inaccurate as the strains may have been falsely assigned to certain taxonomic groups. This is particularly common in bacterial groups with a tight assemblage of closely-related species or strains, for example, the *B subtilis* complex, *B cereus* group or *Burkholderia cepacia* complex that harbours strains with significant potential for use as biological control agents. Clearly, better methods of characterisation or ways of interpreting data from existing methods are required. Currently, significant progress is being made through advanced gene technologies and a substantial foundation of prior knowledge to help designate novel members of these bacterial strains to the correct taxonomic groups and clearly distinguish them from very closely-related pathogenic strains. However, unequivocal strain level identification and characterisation of bacteria is still a challenging process. This is particularly problematic for novel strains from taxonomic groups about
which not much is known about cultured reference strains.

A handful of genetic methods for strain typing currently exist and have been widely applied by industries and contract research laboratories to identify and characterise novel bacterial strains for use in biological control. Examples of available methods include:

- **Pulsed-field gel electrophoresis (PFGE):** a fingerprinting technique that involves electrophoretic separation of DNA fragments produced from the use of restriction enzymes to digest DNA. The resultant genetic information in highly definitive patterns can be compared with those of reference strains.

- **Multi-locus sequence typing (MLST):** one of the most commonly used techniques for strain typing. It characterises microbial species by identifying small variations on fragments (400-500 base pairs) of multiple housekeeping genes.

- **Multi-locus variable number tandem repeats analysis:** a DNA fingerprinting technique which involves amplification and sequencing of multiple regions of the genome where nucleotides are arranged in tandem repeats. The number or length of repeats is variable in different microbial strains, thus forming a pattern characteristic of the analysed strain.

- **Repetitive sequence-based polymerase chain reaction (rep-PCR):** exploits the variation in the arrangement of repetitive consensus sequences between different bacterial strains. Primers complimentary to the repetitive sequences enable their amplification via PCR. Amplicons of varying sizes are generated and separated by electrophoresis. The resulting fingerprint, specific for each bacterial strain can be compared.

- **PCR-ribotyping:** relies on the polymorphism of the 16S and 23S rRNA genes. It involves amplification and partial sequencing of the 16S and 23S rRNA genes as well as the intergenic space between them. The amplicons generated are digested by restriction enzymes. The resulting DNA fragments are fractionated by electrophoresis and visualised using fluorescent dyes.

The techniques described above are generally based on PCR and restriction digests. They can be prone to bias arising from the choice of primers or restriction enzymes. The methods can also produce varying results for the same strain or bacterial isolate analysed. For example, a limitation of MLST was recently highlighted in a study in the journal, Scientific Reports. MLST failed to fully represent phylogeny from whole genome sequencing for many tested bacterial strains. Such discrepancies in results from different strain typing techniques may complicate taxonomic assignments of bacterial strains. This makes the delineation between pathogenic and biocontrol bacterial strains challenging, requiring expert assessment.

The ideal way to definitively characterise a microbial strain is to sequence the whole genome. The cost of sequencing an entire microbial genome is much cheaper nowadays and has become a more practical option for microbial strain characterisation due to the advent of next-generation sequencing technologies. A bottleneck is still the analysis and interpretation of the huge amount of data generated from such highly sophisticated
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sequencing techniques. With rapid developments in the field of bioinformatics, powerful software is now being developed to accurately annotate genomes within a very short time. Alternatively, using a combination of different strain typing techniques can also serve as a valid way to identify and characterise novel bacterial biological control agents and distinguish them from pathogenic variants with a high degree of certainty. Nevertheless, expert opinion on the choice of methods for unambiguous strain-level characterisation of novel biological control strains will be needed. The biopesticide industry should also expect relevant expertise from competent authorities to agree and interpret the outcomes from suitable technologies for proper strain identification to facilitate the regulatory process and hence promote biopesticides to the European market.

In summary, regulatory guidance has not kept pace with scientific progress in the characterisation of bacterial strains used as biocontrol agents. It is arguable that guidance is voluminously produced in other areas of pesticide regulation in the absence of adequate scientific validation and the limited progress for biocontrol characterisation is hampering the regulatory process and consequently the rate of appearance of new products on to the market.

Sources:
2. EFSA guidance on the characterisation of microorganisms used as feed additives or as production organisms. https://doi.org/10.2903/j.efsa.2018.5206.
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US still leads the way in biopesticides, as EU rules remain complex

By Alan Bullion

The following article is an extract from the Informa Agribusiness Intelligence Global Biopesticide Regulations 2017 report.

A plethora of different scientific, regulatory and commercial definitions of the term ‘biopesticide’ exists, so there is no single internationally-agreed designation. From a regulatory perspective, the precise terminology and scope can vary considerably between different countries.

In its broadest sense, the sector covers a wide spectrum of biologically-based agents used for pest control. Major product categories comprise microbials; biochemicals; semiochemicals, and macrobials. Some countries also include genetically modified plants that express introduced genes conferring protection against pest or diseases, such as ‘Plant Incorporated Protectants’ (PIPs).

There are a number of regulatory ‘grey’ areas. Examples include biostimulants, biofertilisers and some bioinoculants that claim to deliver plant protection effects as well as nutritional and plant health benefits. Others areas of uncertainty include new genetic technologies such as RNA interference, mutagenesis and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), particularly in the EU.

Market size

Estimates of market size vary but there is broad agreement that the biopesticide market has shown remarkable growth over the last 15 years. Global biopesticide sales have increased from around US$0.6 billion in 2003 to around US$ 3 billion today and are projected to reach US$11 billion by 2025. With a Compound Annual Growth Rate (CAGR) of 16-17%, biopesticides are currently the fastest growing sector in the crop protection market sector.

North America and Europe together account for two thirds of the total market but Latin America is the fastest growing region and seems set to overtake Asia Pacific as the third largest regional market by 2025.

The value and growth rate of different product categories varies by region but overall, microbials constitute the largest and most rapidly growing segment and are expected to make up almost 60% of the market by 2025.

Bioinsecticides and biofungicides currently dominate the market but bionematicides are growing rapidly with a spate of new products entering the market and others in development. The bioherbicide sector remains very small with no significant or successful products to date.

Key drivers of growth include political and societal pressure for greener, safer and more sustainable crop protection technologies; food retailer and consumer demands for low or no residues on food crops; an increasingly tough regulatory climate for chemical products; resistance development to existing conventional chemical pesticides and a lack of novel chemistry.

Biologicals can offer effective solutions to many of these issues through multiple and novel modes of action to combat pest resistance; reduced residues on food crops; greater worker safety and flexibility, along with reduced regulatory costs and timelines. Additionally, technology advancements have improved product efficacy and reliability and increased confidence among growers and input suppliers.

The sector is characterised by a large and diverse membership with a high proportion of small and medium-sized enterprises (SMEs) and many start-up companies. It has attracted considerable attention from the major multi-national agrochemical companies over recent years that recognise clear opportunities for using biologicals in portfolio management and business growth.

Recent years have witnessed multiple R&D and commercial agreements as well as a number of mergers and acquisitions. These developments have significantly improved market access and expansion for biopesticide products through faster product commercialisation, increased R&D investment and more effective technology transfer to growers.

US leads the way

Registration is widely perceived to be the single most important barrier to successful commercialisation of biopesticide products. In many countries, the regulatory system has been designed for conventional chemical pesticides and has difficulty in responding to the different properties and characteristics of biological products.

The registration process is further complicated by different regulatory frameworks, most notably in the key markets of North America and the European Union. Additionally, there are
An overview of the draft guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

Last December the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) issued a joint, harmonized, draft guidance document: Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. The guidance laid out the scientific criteria necessary to evaluate the endocrine disrupting potential of plant protection products (PPP) and biocidal products (BP). The guidance is limited to humans and non-target vertebrates (mammals, fish, birds, amphibians and reptiles) and only covers estrogen, androgen, thyroid and steroidogenesis (EATS) modalities. This webinar will discuss key aspects of the guidance document, including new key phrases like EATS mediated parameters and sensitive to but not diagnostic of EATS mediated parameters, new considerations like maximum tolerated concentrations in ecotoxicology studies, relevant OECD tests and potential strategies for assembling and collecting the necessary data for assessment. We will also walk through the assessment strategy flow chart using the new terminology and understanding where and how to use some of the proposed test methods.

Conduct of plant metabolism and translocation studies with crop protection products – An examination of case studies

Plant metabolism studies including confined rotational crop studies, are an important component of the registration of plant protection products. The USA, EU and Japan all require such testing as required by the following guidelines of the U.S. EPA Residue Chemistry Guidelines, OPPTS 860.1300: Nature of the Residue – Plants, Livestock. The OECD 501 (Metabolism in Crops) and OECD 502 (Metabolism in Rotational Crops) guidelines satisfy the requirements of the EU regulation EC 1107/2009 and the data requirements for active ingredients (EU 283/2013) and in Japan, the Ministry of Agriculture, Forestry and Fisheries of Japan (12-Nousan-No. 8147, 2-4-1, 2000) are followed. Similarly, translocation studies in plants have also become increasingly important in the safety assessment of these products, especially in relationship to pollinator insects. During this webinar, case studies will be presented to demonstrate the functional conduct of such studies from planting to dosing and to harvesting and analysis. Selected results of the case studies using tomato plants and other crops will be presented and their potential impact on risk assessment of plant protection products discussed.

For further details on how you can attend these webinars please contact: marketing@agri.informa.com
significant inconsistencies between the rules for products destined for organic and conventional agricultural production.

At a global level, OECD’s Expert Group on BioPesticides (formerly known as the BioPesticides Steering Group) is leading efforts to promote a harmonised and proportionate approach to biopesticide regulation, develop guidance documents and facilitate communication and information exchange across a wide range of stakeholders.

Other key players include the United Nations Food and Agriculture Organisation (FAO) and World Health Organisation (WHO), the International Organization of Biological Control (IOBC), the European and Mediterranean Plant Protection Organisation (EPPO) as well as Global BioProtection, the worldwide federation of biocontrol and biopesticides industry associations.

At a regional level, the picture is mixed with some countries clearly leading the way while others are lagging behind.

In North America, the US Environmental Protection Agency (EPA) has established itself as the world leader in biopesticide regulation. It has pioneered the simplification of the registration process for biopesticide products through the development of modified test methodologies with reduced data requirements that have significantly lowered registration costs and timescales. The success of this approach is reflected in the fact that today there are over 430 biopesticide active ingredients and 1,320 products available to US growers.

Canada’s biopesticide registration requirements are closely aligned with those used by the US and the two work closely together to promote biopesticide registration in both countries through joint review, work share and other regulatory processes.

### EU complexity

In the EU, microbial, biochemical and semiochemical biopesticides are registered under the same regulatory framework as chemical pesticides although some special provisions have been developed. The legislation provides for measures that favour the registration of products defined as ‘low risk’ (most of the biopesticides) but the process has not worked well in practice.

The EU regulatory process remains complex and cumbersome; registration timescales can be at least twice as long and double the cost of registration elsewhere. This situation is discouraging product developers from applying for registration in Europe. Proposals to improve the situation were approved by the European Parliament earlier this year but there are real concerns that implementation could be delayed for several years because of the ongoing EU REFIT exercise, which aims to simplify existing regulation.

Nevertheless, there are some clear examples of regulatory innovation at Member State level, most notably in the Netherlands, the UK, France and Hungary. In addition, the EU is leading the way in clarifying the regulatory boundaries between biopesticides and plant biostimulants. It is widely anticipated that the revised Regulation (EC) on Fertilising Products could set the benchmark for a more appropriate and harmonised approach to biostimulant regulation elsewhere.

### Industrial standards

The main challenge facing regulators is to develop predictive and efficient regulatory processes that ensure product safety and consistency without inhibiting commercialisation. This is especially vital for the many small and medium enterprises in this sector where lengthy registration delays and disproportionate data demands can have a major impact on their willingness and ability to submit products for regulatory review.

However, an extensive body of regulatory and industry experience around biopesticides is already in place. It identifies some clear examples of regulatory innovation as well as good regulatory practice.

Examples include creation of a dedicated specialist regulatory team with expertise in different biopesticide categories; the development of biopesticide-specific guidance documents and training for regulators and applicants; the use of pre-submission meetings between applicants and regulators to identify potential issues early in the process; reduced data requirements and a flexible approach to interpreting data needs; a predictable and transparent review process and timeline; priority review for low risk biopesticide products; and reduced or subsidised fees and creation of fora for sharing experience and best practices.

A common theme in the key North American and European markets is that data requirements continue to become ever more demanding. Regulators are requesting new ‘non-standard data’ requirements, often late in the registration process, making the timelines longer and unpredictable. Additionally, increasing numbers of biopesticide registrations coupled with less staff and resources in the regulatory agencies are leading to slower review processes, a challenge also being seen for conventional agrochemical registrations.

As the biopesticides market matures, so these challenges will grow, leading to calls for greater coherence and harmonisation across the world.
福华通达农药科技有限公司
FUHUA TONGDA AGRO-CHEMICAL TECHNOLOGY CO., LTD.

Sichuan Leshan Fuhua Tongda Agro-Chemical Technology Co. Ltd, specializes in glyphosate and glufosinate manufacturing, with current annual Glyphosate 95% Tech production capacity of 120,000Mt (glycine route) and Glufosinate 95% Tech capacity of 10,000Mt. It is the largest producer in China and the second largest worldwide. Fuhua is projecting Dicamba and 2,4-D in capacity of 5,000Mt/a each in the next two years by fully utilizing the advantages of its integrated industrial production chain involving phosphorus, brine, glyphosate and silicone, making it to be the most competitive agro-chemical products producer in the field. The factory is located in Leshan city, Sichuan Province, an area with extensive resources for Agro-chemicals manufacturing, and the international sales offices are located in Shanghai and Singapore. Fuhua exports to America, Asia, Africa, Oceania and Europe, with over 2500 employees around the world.

SUSTAINABLE SUPPLY OF HIGH QUALITY GLUFOSINATE AND Glyphosate

CORE PRODUCTS
- Glyphosate 95% TECH
- Glufosinate 95% TECH
- Dicamba
- 2,4-D

OTHER PRODUCTS
- Acetamiprid
- Atrazine
- Bisulfate
- Chlorpyrifos

CHEMICALS
- Cebuzidim
- Cyhalofop-Butyl
- Cyproconazole
- Difenoconazole
- Fluroxypyr
- Imidacloprid
- Mesotrione
- Metribuzin
- Monosulfate
- Propiconazole
- S-Metolachlor
- TEBUCONAZOLE
- Thiamethoxam
- Tricyclazole
- Melamine 99.8%
- Methionine
- Hexamine
- Soda Ash
- Ammonium Chloride
- Triple Superphosphate
- DAP
- NPK
- MAP
- Urea

2018 CAC:
Booth No.N1G01
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