Latin America 2018

INCLUDING:
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Date: 16-18 October, 2018

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**HERBICIDE**
- Glyphosate
- Glyphosate Isonicotinamide Salt
- Glyphosate Ammonium Salt
- Glyphosate Potassium Salt
- Glyphosate Dimethylamine Salt
- Glyphosate Dicamba
- Glyphosate +2,4-D
- Glyphosate-MCPA
- Glyphosate,Glufosinate
- Glyphosate-Oxynifuran
- Duro
- Quinclorac
- 2,4-D
- Glufosinate-ammonium
- Parquat
- Atrazine
- Nicosulfuron
- Caethin
- Oxylufuron
- Methabenzthiazuron
- Dicamba
- Isoproturon
- Propanil

**FUNGICIDE**
- Carbendazim
- Thiaconazole-methyl
- Myclobutanil
- Azoxyrodin
- Fosetyl-Al
- Tetraconazole
- Mancozeb
- Chlorothalonil
- Procymidone
- Pyraclostrobin
- Cyproconazole
- Propiconazole

**CHEMICAL PRODUCT**
- 3,4-Dichloroaniline
- 1-Chloro-2-nitrobenzene
- O-Phenylenediamine
- 3,4-Dichlorophenyl isocyionate
- Sodium pyrophosphate
- 4-Chloro-3-bromobenzaldehyde
- O-Dimethyl Phosphate
- Phosphorus Trichloride
- Phosphorus Oxychloride
- Sodium tripolyphosphate
- Methyl chloride

**Flame Retardant**
- Tri(2-Chloroethyl)Phosphosphate (TCP)
- Tri(2-Chloroethyl)Phosphate (TCP)
- Isopropylate Triphenyl Phosphate (IPP)

**Agrochemical Adjuvants**
- Agricultural organosilicon adjuvants: XHG-248 Silicone Surfactant

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Brazilian regulators are boosting pesticide registrations while debate is raging on how to go further.

A 2017 study claimed that the deficit in the registration of pesticides in Brazil was growing at a rate of 45% per year. That compared the amount of registrations with the number of new applications entering the process. That study also highlighted that new active ingredient approvals were in single digits.

However, Brazil’s Ministry of Agriculture reported early this year that it had granted a record 326 registrations for new active ingredients, generic ais, and formulated products in 2017. That came after a four-fold increase the previous year to a then record of 277 registrations.

The registration system has been a thorny issue for the industry. Process times are typically longer than in many other countries, including neighbouring nations. That concern has reached government and political debate, culminating in parliamentary moves to liberalise the approval process.

Approval process liberalisation
In June, the Brazilian lower house of Parliament’s agriculture select committee approved draft legislation seeking to amend
The Ministry of Agriculture has thrown its support has come from industry, while the tentative human and animal health, along with several civil society groups. Tentative backing behind the proposals.

The Anvisa has since published alternative proposals. It is seeking to approve rules later this month to speed up the toxicological evaluation of pesticides in the approval process. The agency has issued a “service orientation” (OS) notice to adopt UN FAO recommendations to its risk analysis procedures.

The Anvisa says that the draft legislation would effectively withdraw the agencies’ competent status in carrying out the toxicological and environmental assessments and reassessments for agrochemicals. There would be only a “homologation” of evaluations from applicant companies. The proposals would undermine work carried out to international guidelines such as those in use in the EU, it reckons.

The Ministry says that the draft bill aims to modernise terms and procedures, with a view to improving the efficiency of registration of these products. It reckons that the current system diminishes the competitiveness of Brazilian farmers and their ability to sell at home and abroad.

The Anvisa has also hosted a parliamentary debate on a national pesticide use reduction policy. A special commission of the lower house of Parliament is analysing a draft bill, PL 6670/16, for the policy, Phara. Meanwhile, the Senate’s committee of social affairs has approved a draft bill to ban the aerial application of pesticides. Draft Bill PLS 541/2015 would also prohibit the registration of products based on the herbicides, glyphosate and lactofen, and the insecticides/acaricides, carbofuran and phosmet.

Among the most trenchant critics were two of the competent authorities whose roles are potentially under threat. The Anvisa and the Ibama reiterated their position following the positive vote at the select committee. They have been followed by the Brazilian health scientific commission, the CCVISA, a regulatory body set up six years ago as an aid to the Anvisa's board to help evaluate the safety of products to human and animal health, along with several civil society groups. Tentative support has come from industry, while the Ministry of Agriculture has thrown its backing behind the proposals.

The Anvisa has already been registered in the reference country, it is assumed that the safety, efficacy, quality and risk aspects are acceptable at that location, and it is up to the country in which the product registration is sought to evaluate only if the conditions approved are similar and can be considered valid for the national scenario.

This approach would apply extrapolation methods for pesticide risk assessment and be relatively less complex. It would also require fewer staff than a full evaluation. The guidance proposal calls for the use of two reference authorities rather than just one, and makes provision for the processes that do not meet the requirements for this evaluation to be analysed in full.

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Brazilian reassessments

Early this year, the Brazilian Anvisa issued new criteria for the reassessment of approved pesticide ais that present signs of changes to risk to human health. The criteria and procedures for toxicological reassessment come in Anvisa board resolution RDC 221/2018 and revoke those of RDC 48/2008.

One of the most important points of the new standard is the definition of criteria for the selection of the ais that should be submitted for re-evaluation. The resolution foresees the publication of a list of the ais selected for re-evaluation in order to give greater predictability to society, the agrochemical industry and to pesticide users. A re-evaluation programme

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covering 14 ais since 2008 has yet to be completed and the experience led to calls for change with proposals submitted for comment last year.

From the reassessment programme, the agency ordered a six-month phase-out of the carbamate insecticide/acaricide/nematicide, carbofuran, late last year for use on bananas, coffee and sugar cane. That ended this year. All other uses were immediately banned. The agency also ordered a three-year phase-out of the herbicide, paraquat, in September. But, in December it issued a resolution to “amend the ban” on paraquat. That followed a Ministry of Agriculture report that the Anvisa had U-turned and reapproved the herbicide for three years. Nevertheless, grower groups welcomed the amendments as the original order limited use of the herbicide to growers who had already bought supplies, meaning a de facto immediate withdrawal. In August last year, it was revealed that the reassessment of glyphosate was not expected to be completed until 2019.

Sales of paraquat herbicide in Brazil are being registered in a computerised system from this year. The aim is to guarantee the restrictions that the agency imposed on the product. A draft bill in the national Parliament contests last year’s phase-out resolution.

The Anvisa also sought comments on four proposals to changes governing the regulation of agrochemicals in Brazil. They cover proposals on: required toxicology labelling on agrochemicals and non-crop pesticides; on criteria for the evaluation and toxicological classification of agrochemicals and their components; criteria for dietary and occupational risk assessment resulting from human exposure to agrochemicals and related substances; and a potential “Normative instruction [NI]” to set and publish the list of non-active components of pesticides and related substances that are considered evaluated and the list of unauthorised components for use in agrochemicals and related products.

Several Brazilian states extended the emergency controls against earworms for 2018. In December, the government went a step further and approved the insecticide, emamectin benzoate, for the control of the pest on cotton, maize and soybeans. Previously, emergency controls allowed the temporary import and use of emamectin benzoate against the major agricultural pest in Brazil for the last few seasons. It has since approved the sale and use of Syngenta’s emamectin benzoate until July 2019. The order allows the sale of the ai for companies authorised to import and market the insecticide in Brazil. Six states have approved the ai to control earworms (Helicoverpa armigera) under emergency rules.

**Argentina**

Argentina is simplifying processes for amended approvals of agrochemicals and biological products. Earlier this year, the plant and animal health inspection service, the Senasa, shortened procedures within its agrochemical and biological directorate. That includes required processes for changes to approvals from amending the commercial product name to name of registrant company or transferring products from one company to another among other measures.

Professionals will no longer be required to evaluate approvals. Rather, affidavits may be presented in which the company undertakes to respect the sought-after changes. Existing information on already approved labels would be maintained.

Late last year, councillors in Argentina’s third-largest city, Rosario, approved a draft bill to ban the sale and use of glyphosate. The bill called for ban of all uses. It was presented in the days after the UN’s International Agency for Research on Cancer (IARC) classification of the herbicide as “probably carcinogenic”.

The Argentine plant and animal health inspection service, the Senasa, has banned the import, marketing, and use of two insecticide/acaricide ais, subject to a 180-day phase-out. Resolution No 149/2018 extends the prohibition to the production, post-harvest use, transport, handling, and use in grain and tobacco storage facilities. The phase-out of trichlorfon and dichlorvos runs from May 8th.

Earlier this year, the government issued a decree (No 134/2018) that brings into force Law 27.279 on minimum budgets for the management of empty pesticide containers in Argentina. It defines the procedures for the proper application of the “integrated management system” for pesticide containers, including recycling and waste control. The law on management of empty pesticide containers was passed last year.

**Uruguay**

Uruguay banned all agricultural uses of the herbicide, atrazine, from March. The Ministry of Agriculture withdrew commercial registration of the herbicide last year.

The Uruguayan Ministry of Agriculture has issued a resolution setting EU and US agrochemical competent authority as a reference point for outstanding national residue limit approvals. Resolution DGS No 75/2018 allows the setting of MRLs for all those pesticides without them either in the country or by the UN’s Codex Alimentarius Commission.
Brazil comfortably remained the second major adopter of genetically modified crops globally in the most recent planting season. Sowing of GM crops increased by 2.2% and topped 50 million ha with an adoption rate of 94%. That included 33.7 million ha of soybeans, 15.6 million ha of maize and 940,000 ha of cotton.

The value of the GM seed market at the ex-manufacturer level in Brazil was $3.8 billion in 2017, according to Phillips McDougall. That was an increase of 6.9% over the previous year.

Brazil was followed by neighbour, Argentina, with a 100% adoption rate for GM crops, despite a slight dip in plantings to 23.6 million ha in 2017. The decline was due to a 3% drop in the area of GM soybeans to 18.1 million ha and a 38% decline in GM cotton to 250,000 ha. GM maize plantings rose by 10% to 5.2 million ha.

Phillips McDougall pegs the GM seed market in Latin America in 2017 at $5.3 billion. That accounted for some 18% of the global market of $21.4 billion.

A world first came in Brazil earlier this year. GM insect-resistant Bt sugar cane has been commercially planted for the first time. Some 400 ha of Brazilian company and Bt cane developer Centro de Tecnologia Canavieira (CTC - Piracicaba) cane borer (Diatraea saccharalis)-resistant sugar cane have been planted. The national technical commission for biosafety, the CTNBio, approved the commercial use of CTC’s GM line last year.

**Approvals**

Approvals of GM crops have maintained a healthy pace, and even accelerated in some countries. However, in Mexico, bans on GM trials approvals remains in place while a moratorium on planting in Peru remains in force.

The Brazilian CTNBio recommended the approval of ten GM crops in 2017, along with four other non-plant products. Approvals reached a high of 14 in 2015. Last year’s approvals included two for cotton, four for maize, three soybean lines and the first for sugar cane. In the first half of this year, the CTNBio has recommended approvals for a stacked Monsanto GM soybean line, insect-resistant and herbicide-tolerant Intacta 2 Xtend (MON87751xMON87708xMON87701xMON89788) soybeans. There were also authorisations for Dow's stacked herbicide-tolerant and insect-resistant DAS24236xDAS21023xSYNIR102xDAS81910 cotton, and two from DuPont Pioneer: the herbicide-tolerant and fatty acid modified Plenish (DP305423) and the stacked...
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herbicide-tolerant and fatty acid modified (DP305423xMON4032) soybeans.

Argentina authorised three GMOs in late 2017, and has followed that up with five more approvals for commercial planting so far this year. The six have included: three stacked GM maize, one each for Dow, Monsanto and Syngenta; a stacked GM soybean for Bayer CropScience and the country’s first approved GM alfalfa, Argentine Bioceres group’s affiliate, Indea’s, stacked herbicide-tolerant and altered content alfalfa, HarvXtra (MON179xMON101).

Uruguay approved eight unnamed GM crops late last year. They were the country’s first such approvals since 2014.

Intacta payment disputes
Soybean growers in Brazil filed a lawsuit late last year seeking to cancel Monsanto’s patent on its GM Intacta RR2 Pro soybean technology. The Mato Grosso (state) soybean growers’ association, the Aprasoj, makes several claims against the patent registration. That was followed early this year with Brazil’s industrial property agency, the INPI, finding that Monsanto’s patent for its Intacta RR2 Pro soybean technology should be declared void. The attorney general’s office has since filed a petition requesting that the patent be declared void. The patent runs until 2022.

In July this year, a Brazilian court ruled that Monsanto deposit royalties on its Intacta RR2 Pro soybean technology into an escrow account. The money is to be deposited until the outcome is known of the case brought against Monsanto’s royalty charges by the grower groups. Monsanto is mulling whether to contest the order.

However, Monsanto has won a legal dispute concerning the technology this year. A Brazilian judge ruled that Monsanto’s collection of royalties for saved seed of its Intacta RR2 Pro soybean technology including on saved seed is legal. The company’s victory came after a plaintiff sought a refund of the amount paid in the post-planting of saved seeds that are reserved for their own use.

Disputes around payments for the technology are unresolved in Argentina. Last year, Monsanto called for Argentine legislation guaranteeing its royalty rights, while it remained in discussions with the government over rights for its soybean technology. The company sought a regulatory framework for it to launch its latest technology, the stacked Intacta RR2 Pro soybeans. The Argentine government had promised a grain shipment inspection programme to identify the presence of Monsanto technology, and it reported hitting 90% control levels last year.

A seed law remains unsanctioned in Parliament. It seeks to resolve the issue of intellectual property rights of GM seed.

Biotech promotion in Argentina
The Argentine government has issued a decree this year to regulate the 2007 promotion of modern biotechnology law. Decree No 50.2018 was signed in February to regulate Law No 26.270, aiming to “promote the development and production of modern biotechnology”, the Ministry of Agroindustry says.

The stated aim of the Law is to bring a series of tools to facilitate those who want to invest, research or develop biotechnology. It provides a financing fund for new ventures, and tax benefits for projects submitted by established national biotechnology companies (the Law states that the promotion will be by project, not by sector).

Monsanto licence in Mexico
Late last year, the Mexican food quality and health service, the Senasica, has revoked a Monsanto licence to plant GM soybeans in seven states. The move followed the reported detection of the GM soybean in unauthorised areas, and a Supreme Court decision to revoke company licences in two states. Monsanto is contesting the withdrawal of licences.

It is the latest blow to biotechnology in the country. In 2013, a Mexican judge ordered the Ministries of Agriculture and of the Environment not to grant further authorisations for trials, pilot planting (an intermediate stage of extensive area trials) and commercialisation of GM maize. A class action against the order failed last year.

Brazil
Two months ago, the Brazilian Senate’s environment committee approved the support of a Senator to a parliamentary bill to remove a warning label on foods containing GMOs. The move was to back the lower house of Parliament bill PLC 34/2015 that seeks to remove labels marked with a “T” in a yellow triangle. The T stands for “transgenicos” – or GMOs. PLC 34/2015 will go to a plenary session of the Senate.

The Brazilian public prosecutor’s office, the MPF, filed a civil action to suspend the commercial use of GM glyphosate herbicide-tolerant crops. The targets include products that had been approved by the national technical biosafety commission, the CTNBio, while the national health surveillance agency’s, the Anvisa’s, toxicological reassessment of the herbicide had yet to be concluded.
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LUFENURON
 METHOMYL
 METHOXYFENOZIDE
 PYMETROZINE
 PYRIFLUNITRON
 TEFULOBENZURON
 THAMETOXAM

FUNGICIDE
BOSCALID
CYPRODINIL
EPICONAZOLE
FAMOXADONE
FLUZANAM
FLUOXONIL
KRESOXIM-METHYL
MANCOZEB
PICONYSTROBON
PROTHIOCONAZOLE
PYRACLOSTROBIN
TRICLOSTROBON

REGULATOR
ETHEphon

HERBICIDE
2,4D ACID/AMINE SALT
ACHLOROPHEN
ATRAZINE
BISPYRIBAC-SODIUM
BROMACIL
CARFENTRAZONE-ETHYL
CHLORIMURON-ETHYL
CLODINAPROP-PROPARGYL
DICAMB
DICLOSULAM
DIFLUENTAN
FLURASULAM
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A scan of existing market conditions in Brazil as well as the latest financial results of major companies indicates that the Brazilian market is likely to come out of a three-year slump in 2018.

First-half financial results of companies including Adama, Arysta, BASF, Bayer, FMC and Syngenta indicate higher volumes of agrochemicals, especially insecticide and fungicides, sold in Brazil. Furthermore, the glut of inventory in the distribution channel that had been one of the main causes of declining sales is showing signs of normalising.

Sales of insecticides in Brazil for the control of maize leafhoppers (*Dalbulus maidis*) have shot up by 85% for the present season compared with the same time last year. The estimates by a market study point to a rise from $9.2 million in 2016/17 to $17.1 million in sales of those insecticides. Revenues from the active ingredients targeting the pest represent some 94% of business within the foliar insecticide segment. The study also indicates strong growth in sales of neonicotinoids, organophosphates and pyrethroids.

Detections of Asian soybean rust (*Phakopsora pachyrhizi*) in Brazil are up 17% on the same point early last year. The finding came from figures across ten states from monitoring carried out by the

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales ($ million)</th>
<th>% change</th>
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<tr>
<td>2017</td>
<td>12,664</td>
<td>-4.7</td>
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<tr>
<td>2016</td>
<td>13,287</td>
<td>-14.4</td>
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<tr>
<td>2015</td>
<td>15,525</td>
<td>-3.7</td>
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<tr>
<td>2014</td>
<td>16,122</td>
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<tr>
<td>2013</td>
<td>14,203</td>
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</table>

Source: Phillips McDougall.

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**Key Products**

- Propiconazole
- Pyrimethanil
- Zineb
- Propineb
- Cymoxanil
- Metam-sodium
- Difenoconazole
- Azonxystrbin
- Fosetyl-Al
- Chlorothalonil
- Mancozeb

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---

**Herbicides**

- 2,4-D + Picloram
- 2,4-D
- Clethodim
- Dicamba + Glyphosate
- Ethoxysulfuron + Penoxsulam
- Ethoxyfuron
- Glufosinate
- Glyphosate
- Mefenacet + Ethoxyfuron
- Metamitron
- Metsulfuron-methyl
- Picloram
- Rimulfuron

**Fungicides**

- Carbendazim
- Chlorothalonil + Thiophanate-methyl
- Difenoconazole + Azonxystrbin
- Iprobenfos
- Picocystrobino + Propiconazole
- Picocystrobino + Tebuconazole
- Picocystrobino
- Propiconazole
- Tebuconazole + Azonxystrbin
- Tebuconazole

**Bacillus Subtilis**

- Bacillus subtilis

**Plant Growth Regulators**

- 4-Indol-3-ylbutyric acid + 1- 
- Naphthyl acetic acid
- Cyanamide
- Forchlorfenuron
- Paclobutrazol

**Insecticides**

- Abamectin
- Acephate
- Buprofezin
agricultural research corporation, the Embrapa’s, co-ordinated anti-rust consortium (Consorcio Antiferrugem). Researchers noted that weather conditions favourable to the disease and the fungus that causes it.

### Market figures

During 2017, sales in Latin America declined by 5% to $12,664 million, according to Phillips McDougall. The drop was largely attributable to Brazil which, despite decreasing for a third consecutive year, remained the largest single country market globally for crop protection sales. The decline was driven by: reduced pest and disease pressure; the rise in adoption of Monsanto’s genetically modified insect-resistant and herbicide-tolerant Intacta RR 2 Pro soybeans impacting insecticides; high levels of inventory at the dealer level, which is keeping the lid on prices despite the increase in the price of ais originating from China.

The decline began in 2015 and continued for three consecutive years taking in 2016 and 2017. Strong growth of 13.5% in 2014 was followed by a 3.7% reduction. The market shrank by a much higher 14.4% during 2016.

### Brazil

Phillips McDougall estimate that the Brazilian agrochemical market fell by 8.3% to some $8,763 million in 2017. That was the third consecutive year of falling sales in the country. The market peaked at $11,736 million in 2014, rising by 15.2% over the previous year. The year 2015 witnessed a 5.7% decline followed by a more substantial 13.6% decrease in 2016. The market lost more than a quarter of its value between 2014 and last year.

### Argentina

The market in Argentina displayed a somewhat different trend to Brazil and the Latin American market. The country saw a mostly positive trend with a decline being recorded only during 2016. But the somewhat substantial reduction of 22.9% in 2016 saw the market dropping from almost $2,140 million to under $1,650 million. A 6% rise during 2017 led the market to around $1,750 million.

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**Brazilian crop protection market 2013-17**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales ($ million)</th>
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<tr>
<td>2013</td>
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Source: Phillips McDougall.

**Argentine crop protection market 2013-17**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales ($ million)</th>
<th>% change</th>
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<td>2014</td>
<td>2,046</td>
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</tr>
<tr>
<td>2013</td>
<td>1,747</td>
<td>na</td>
</tr>
</tbody>
</table>

Source: Phillips McDougall.
HUAXING CHEMICAL
Established in 1984  GLP Registration Dossier Support
Certified under ISO 9001 and ISO 14001

Herbicide
- Nicosulfuron 97% TC
- MCPA 95% TC
- MCPA-2-ethylhexyl 93% TC
- Glyphosate 96% TC
- Fenoxaprop-P-ethyl 97% TC
- Glyphosate-ammonium 98% TC
- Glufosinate-ammonium 96% TC
- Quizalofop-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

Related formulation in all package size is available

ANHUI HUAXING CHEMICAL INDUSTRY CO., LTD
Head Office: No 6. Hongfeng Road, Hefei City, Anhui Province, P.R. China P.C.: 230008
Factory: Wujiaqia Town, Hixian County, Anhui Province, P.R. China P.C.: 238251
Tel: 0086-551-65848120/65848156 Fax: 0086-551-65848133
E-mail: wx@huaxingchem.com trade@huaxingchem.com http://www.huaxingchem.com

Kqiao
Shandong Kangqiao Bio-technology Co., Ltd.
The Leading Manufacturer of Pyraclostrobin, Spirodiclofen and Spiromesifen, Registration Support with GLP Data!

ISO 9001:2015 Accreditation

TECHNICAL
Pyraclostrobin 98% Min. TC  Spirodiclofen 98% Min. TC  Spiromesifen 98% Min. TC  Thifluzamide 96% Min. TC

FORMULATION

INSECTICIDE
- Spirodiclofen 240 g/L SC
- Spiromesifen 240 g/L SC
- Abamectin 5% EC

FUNGICIDE
- Pyraclostrobin 25% SC
- Pyraclostrobin 250 g/L EC
- Pyraclostrobin 25% WDG
- Pyraclostrobin 5% + Metiram 55% DF
- Pyraclostrobin 8.7% + Dimethomorph 12% WDG
- Pyraclostrobin + Bosalid 25% WDG
- Pyraclostrobin 12.6% + Thifluzamide 12.6% SC
- Pyraclostrobin 20.7% + Epoxiconazole 14.3% EC
- Pyraclostrobin 133 g/L + Epoxiconazole 50 g/L SC
- Pyraclostrobin 15% + Difenconazole 25% SC
- Thifluzamide 240g/L SC

HERBICIDE
- Clethodim 24% EC
- Cyhalofop-butyl 100 g/L EW
- Flucarbazone-sodium 10% OD
- Fluoroxydifen 10% EC
- Fomesafen 250 g/L SL
- Glyphosate-ammonium 85% SP
- Glyphosate-isopropylammonium 41% SL
- Imazapic 240 g/L SL
- Mesosulfuron-methyl 30g/L OD
- Mesotrione 5% + Atrazine 20% OD
- Nicosulfuron 40 g/L OD
- Nicosulfuron 2.5% + Atrazine 22.5% OD
- Quizalofop-p-ethyl 10% EC

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Qingdao office: A-903, Yintai Center, No. 2 South Heilongjiang Road, Qingdao City, Shandong Province, China.
Tel: +86-532-85624097 Fax: +86-532-85699108 E-mail: kangqiaobitech@163.com

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14 / Agrow | Latin America 2018 www.agrow.com
Latin America-related mergers, acquisitions and deals in 2017

JANUARY
- BASF and Brazil-based start-up facilitator ACE launched the second edition of its programme to aid start-up companies delivering agricultural products and services in Latin America.

MARCH
- US agrochemical and specialty chemical company Albaugh’s Brazilian operation, Albaugh Brasil, signed a distribution deal with fertiliser supplier PH Soluções to commence sales of its products in the north-east region of Brazil.
- Bayer CropScience and Brazilian co-operative Cooperativo Coprossel set up a partnership for the installation of industrial seed treatment machines at the co-operative’s seed processing unit.
- Bayer CropScience established a partnership with the Sao Paulo Federal Institute of Education, Science and Technology, the IFSP, in Brazil to back education and develop technologies for agriculture.
- Bayer CropScience and Brazilian seed multiplier Plantar formed a partnership to provide precision farming in the Brazilian Parana state.
- Brazilian agrochemical company Ourofino Agrociencia agreed a tie-up with start-up company Perfect Flight to supply pesticide application tools.

APRIL
- Brazilian agrochemical company Ourofino Agrociencia signed a partnership deal with the Brazilian Ministry of Science’s innovations funder agency, the Finep, to fund formulation improvements and an industrial facility for water-dispersible granule formulations.

MAY
- Brazilian fertiliser supplier Grupa Vittia acquired an 80% stake in Brazilian biopesticide company Biovalens.
- 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.

JULY
- Bayer’s Crop Science division and Israeli company Netafim agreed to co-operate on supplying a drip chemigation system in Mexico.
- Dow Chemical agreed to sell a portion of Dow AgroSciences’ hybrid maize seed business in Brazil to the Chinese CITIC Agri Fund for $1.100 million. The sale was completed in December.
- US agrochemical company Gowan’s affiliate, Gowan Crop Protection, completed the acquisition of the Chilean company, Agrotechnology, after purchasing a majority stake in the business in 2011.

AUGUST
- US agrochemical company American Vanguard subsidiary Amvac Mexico acquired certain selective herbicides and contact fungicides sold in Mexico from Syngenta (owned by ChemChina).

SEPTEMBER
- US chemical distribution company Univar’s wholly owned subsidiary, Univar Brasil, acquired Brazilian agrochemical custom formulation and packaging services company Tagma Brasil.
- UPL acquired a 33.3% stake in Brazilian seed company Serra Bonita Sementes from its Brazilian parent company, SinAgro Produtos Agropecuarios.

DECEMBER
- Bayer’s Crop Science division signed a research deal with the Brazilian Federal University of Viçosa aimed at improving production in tropical region agriculture.
- Dutch bioproducts 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.
The formula of valuable solution for agriculture

HERBICIDE

Flumioxazin
Isoxaflutole
Mesotrione
Butoxydim
Penoxsulam
Diclosulam
Cloransulam
Flumetsulam
Florasulam
Imazethapyr
Imazamox
Imazapic
Imazapyr
2,4-D
2,4-DB
2,4-DP-p
Dicamba
Sulfentrazone
Carfentrazone
Amicarbazone
Flucarbazone
Mesosulfuron
Glyphosate
Glufosinate
Bentazon
Clomazone
Fluroxypyr
MCPA
MCPB
MCPP-p
Clopyralid
Piloram
Diucon
Triclorpyr
Bromacil
Hexazinone
Clothodim
Metribuzin
Fomesafen
Oxyfluorfen
Atrazine
Ametryn
Bispyribac
Propanil
Flufenacet
Acythllo
Metazachlor
Metolachlor
S-Metolachlor
Cyhalofop
Clodinafop
Fenoxaprop
Quinalofop
Haloxyfop

INSECTICIDES

Thiamethoxam
Clothianidin
Dinotefuran
Chlorfenapyr
Methoxyfenozide
Indoxacarb
Pymetrozine
Bifenthrin
Lufenuron
Profenofos
Acephate
Chlorpyrifos
Imidacloprid
Acetamiprid
Ethioprole
Fipronil
Diafenthiuron
Pyriproxyfen
Methomyl
Oxamyl
Abamectin
Emamectin
Bifentafate
Lambda-cyhalothrin

FUNGICIDES

Azoxystrobine
Pyraclostrobine
Trifloxystrobine
Picoxyystrobine
Prothioconazole
Cyproconazole
Difenconazole
Epoxiconazole
Fluazinam
Bosalid
Fludioxonil
Cyprodinil
Tebuconazole
Propiconazole
Isoprothiolane
Dimethomorph
Benomyl
Carbendazim
Pyrimethanil
Spiroxamine
Captan
Chlorothalonil
Mancozeb
Propineb

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Latin America-related mergers, acquisitions and deals in 2018

JANUARY
- Platform Specialty Products’ agrochemical business, Arysta LifeScience, and Italian agrochemical company Isagro agreed a deal for the distribution of Isagro’s fluindapyr-based fungicide mixtures for use in soybeans and other row crops in Brazil.
- FMC agreed a partnership with Brazilian agriculture data analysis company Agronow.

FEBRUARY
- Bayer’s Crop Science division and Chilean precision agriculture company LB-Track agreed to co-operate on the development of methods for the detection of herbicide-resistant weeds.
- Monsanto reportedly acquired a holding of some 5% in Argentine seed and agrochemical supplier Bioceres group.
- Syngenta (owned by ChemChina) has agreed to acquire Brazilian digital agriculture management firm, Strider.

MARCH
- Bayer’s Crop Science division and the Brazilian Chapadao Foundation agreed to promote a research collaboration.
- Monsanto agreed to collaborate with the US charitable group, 2Blades Foundation, to discover new sources of resistance to Asian soybean rust (Phakopsora pachyrhizi). 2 Blades aims to deliver resistance gene in partnership with the UK Sainsbury Laboratory and the Brazilian Universidade Federal de Viçosa.

APRIL
- Israeli biopesticide company STK (previously Stockton) and BASF agreed a distribution deal in Brazil for STK’s biofungicide, Timorex Gold (Melaleuca alternifolia extract).
- Brazilian biologics company Santa Clara Agrociencia signed a deal with Brazilian public sector bodies to develop plant extract-based nematicides.

MAY
- DowDuPont’s agriculture division, Corteva Agriscience, and the Brazilian agricultural research corporation, the Embrapa, agreed to collaborate on genomics research to improve crop tolerance to pests and drought.
- Monsanto agreed to collaborate with the US charitable group, 2Blades Foundation, to discover new sources of resistance to Asian soybean rust (Phakopsora pachyrhizi). 2 Blades aims to deliver resistance gene in partnership with the UK Sainsbury Laboratory and the Brazilian Universidade Federal de Viçosa.

JUNE
- BASF signed a distribution deal with Brazilian seed company Biotrigo Genetica for its non-genetically modified herbicide-tolerant Clearfield wheat in Brazil.
- Platform Specialty Products agrochemical business Arysta LifeScience’s Chilean operation and soft drinks manufacturer PepsiCo are collaborating on a potato production project aimed at cutting waste and impacts on the environment.
- Syngenta and Brazilian start-up company Perfect Flight (São João da Boa Vista) have extended co-operation using the latter’s digital technology for precise aerial applications of agrochemicals.
The BCPC Congress 2018
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David Esdaile (Citoxlab)
Euros Jones (ERM)
Jean-Pierre Busnardo (DowDuPont)
Nick Pyke (FAR, NZ)
Chris Hartfield (NFU)
Ludovic Bonin (ARVALIS, Institut du végétal)
Hans Mattar (ECCA)
Mike Carroll (Arysta LifeScience)
Johan Axelman (Swedish Chemicals Agency)
Selwyn Wilkins (Fera Science Ltd)
Dave Bench (Chemicals at Health and Safety Executive)
Professor Mark Cronin (Liverpool John Moores University)
Dr Martyn Griffiths (Bayer Crop Science)
Dr Gerco Hoogeweg (Waterborne Environmental, Inc)

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New active ingredients registered or launched in Latin America in 2017

<table>
<thead>
<tr>
<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUNGICIDES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayer Crop Sciences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bixafen</td>
<td>Cotton, barley, sunflowers,</td>
<td>Approved in Brazil as Fox Xpro (with prothioconazole &amp; trifloxystrobin).</td>
</tr>
<tr>
<td></td>
<td>soybeans, wheat, canola &amp;</td>
<td>Launched in Argentina as Cripton Xpro</td>
</tr>
<tr>
<td></td>
<td>chickpeas</td>
<td>(with prothioconazole &amp; trifloxystrobin)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ihara/Sumitomo Corporation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>metominostrobin</td>
<td>Soybeans, maize, cotton, rice,</td>
<td>Launched in Brazil as Fusão EC</td>
</tr>
<tr>
<td></td>
<td>wheat &amp; kidney beans</td>
<td></td>
</tr>
<tr>
<td>Syngenta (owned by ChemChina)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>benzovindiflupyr</td>
<td>Cereals</td>
<td>Launched by DuPont in Brazil as Vessarya</td>
</tr>
<tr>
<td>(trade-marked as Solatenol)</td>
<td></td>
<td>(with picoxystrobin)</td>
</tr>
<tr>
<td>mandipropamid</td>
<td>Potatoes</td>
<td>Launched in Argentina &amp; Chile as Revus Top (with difenoconazole)</td>
</tr>
<tr>
<td>pydiflumetofen</td>
<td>Soybeans</td>
<td>Launched in Argentina as Miravis Duo</td>
</tr>
<tr>
<td>(trade-marked as Adepidyn)</td>
<td></td>
<td>(with difenoconazole)</td>
</tr>
<tr>
<td><strong>INSECTICIDES/ACARICIDES/NEMATICIDES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BASF/Nihon Nohyaku</td>
<td></td>
<td></td>
</tr>
<tr>
<td>metaflumizone</td>
<td>Various</td>
<td>Approved in Brazil as Verismo</td>
</tr>
<tr>
<td>Gowan/SDS Biotech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>benzbicyclon</td>
<td>Rice</td>
<td>Approved in Colombia as Avanza 400 SC</td>
</tr>
<tr>
<td><strong>BIOPESTICIDES &amp; OTHERS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayer Crop Science</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bacillus firmus</em></td>
<td>Cotton, maize &amp; soybeans</td>
<td>Approved in Brazil as Oleage</td>
</tr>
<tr>
<td><em>Bacillus amyloliquesciens</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>strain D747 [biofungicide]</td>
<td>Various</td>
<td>Launched in Brazil as Eco-Shot</td>
</tr>
</tbody>
</table>
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in the RIGHT Place
at the RIGHT Time

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## New active ingredients registered or launched in Latin America in 2018

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<td><strong>Use</strong></td>
<td><strong>Status</strong></td>
</tr>
<tr>
<td>Simbiose Agro</td>
<td><em>Trichoderma harzianum</em> strain Cepa Simb-T5 [biofungicide]</td>
<td></td>
</tr>
<tr>
<td>Syngenta (owned by ChemChina)</td>
<td>metominostrobin</td>
<td>Soybeans, maize, cotton, rice, wheat &amp; kidney beans</td>
</tr>
<tr>
<td>Syngenta (owned by ChemChina)</td>
<td><em>Pasteuria nishizawai</em> [bionematicide]</td>
<td>Soybeans</td>
</tr>
<tr>
<td>Vitae Rural Biotecnologia</td>
<td><em>Spodoptera frugiperda</em> multiple nucleopolyhedrovirus [bioinsecticide]</td>
<td>Maize</td>
</tr>
<tr>
<td><strong>Company &amp; active ingredient</strong></td>
<td><strong>Use</strong></td>
<td><strong>Status</strong></td>
</tr>
<tr>
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<tr>
<td>Bayer Crop Science</td>
<td>bixafen</td>
<td>Cotton</td>
</tr>
<tr>
<td><strong>INSECTICIDES/ACARICIDES/NEMATICIDES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adama (owned by ChemChina)</td>
<td>fluensulfone</td>
<td>Maize, soybeans, cotton &amp; other crops</td>
</tr>
</tbody>
</table>
Brazilian Min
Agriculture backs
draft agchem bill

by Sanjiv Rana

The Brazilian Ministry of Agriculture has given a positive appraisal of proposed legislation to amend the pesticide regulatory system including the approval process that has won the backing of a major parliamentary committee.

Draft bill PL 6299/02 would replace existing legislation governing the use of agrochemicals in the country. It along with related bills gained the approval of the lower house of Parliament’s select committee on agriculture last month.

The Ministry says that the draft bill aims to modernise terms and procedures, with a view to improving the efficiency of registration of these products. The comments are in marked contrast to those of the other two regulatory agencies that govern pesticide approval processes in the country. The environmental agency, the Ibama, and the national health surveillance agency, the Anvisa, are opposing the proposed reforms going through Parliament.

The Ministry believes that the current system diminishes the competitiveness of Brazilian farmers and their ability to sell at home and abroad.

Today there are more than 35 new active ingredients in the processing queue, which “are generally more efficient and less harmful to health and the environment” than products that are already on the market, the Ministry notes. The current method of evaluation and registration does not allow for predictability for Brazilian farmers to estimate when they would have access to these new technologies, “already available in several countries”.

The Ministry defends the bill, claiming that in current legislation and in the new proposal, a pesticide could only have its marketing approval if it were approved by the Anvisa and the Ibama – as well as the Ministry of Agriculture - participating in the registration of these substances. Thus, the proposal to amend Law 7802/89 would not alter the system of registration
nor allow products that have already been restricted or banned for health and environmental reasons to automatically come back onto the market, it claims.

In such cases, only a new decision by the registrant bodies, including the health and environmental authorities, would allow a banned product to be re-registered, it says. The Anvisa says that the draft legislation would effectively withdraw the agencies’ competent status in carrying out the toxicological and environmental assessments and reassessments for agrochemicals. There would be only a “homologation” of evaluations from applicant companies (Agrow ibid).

The Ministry calls for specific reforms that are advanced in the bill. It highlights trade agreements that focus on risk assessments, and calls for legislation to give more priority to such a system. It wants definitions to be replaced so that biological products are not classified as “agro-toxic products” as pesticides are referred to under existing legislation. The Ministry also complains about the use of the term “agrotoxico”, and advocates the equivalent to the English word, pesticide “to align with international practice”.

Brazil Anvisa to back alternative agchem rule changes

The Brazilian national health surveillance agency, the Anvisa, is seeking to approve rules later this month to speed up the toxicological evaluation of pesticides in the approval process. It has issued a “service orientation” (OS) notice to adopt UN FAO recommendations to its risk analysis procedures.

The OS No 49 provides for two forms of evaluation: by analogy and integral. Registration by analogy, according to the FAO, is a basic approach to registration in which a comparison is made between a product submitted for evaluation and a similar product already approved in one or more reference countries. Once the product has already been registered in the reference country, it is assumed that the safety, efficacy, quality and risk aspects are acceptable at that location, and it is up to the country in which the product registration is sought to evaluate only if the conditions approved are similar and can be considered valid for the local scenario.

This approach applies extrapolation methods for pesticide risk assessment and is relatively less complex, the Anvisa says. In addition, it requires fewer human resources than a full evaluation. Although analogy registrations present uncertainties on efficacy and risk under local use conditions, the OS guidance proposal calls
for the use of two reference authorities rather than just one, the agency notes. It also makes provision for the processes that do not meet the requirements for this evaluation to be analysed in full. There is also the forecast of monitoring and revision of the standard and its effects after 365 days of its publication.

The implementation of the analogy evaluation methodology has the potential to significantly reduce the time for analysis of the technical products of active ingredients not registered in Brazil that have already been registered in other countries, the Anvisa says. The adoption of this strategy will not reduce health and safety requirements, it insists. In addition, it will favour the insertion of technological innovations in the market, which may reduce toxicity and risk to human health by substituting substances of higher toxicity.

The proposed measure comes at a time when MPs are mulling the adoption of new rules governing the use and registration of agrochemicals. That would potentially relegate the Anvisa’s role, as well as that of the environmental agency, the Ibama.

The chief executive of the Anvisa, Jarbas Barbosa, says that the proposal includes include label changes based on standards in other countries and a “positive list” that would seek to streamline analyses of products that are already approved abroad, national media report. He also notes that the agency supports measures such as cutting deadlines as outlined in proposed legislation to a year or less. Recently, the lower house of Parliament’s agriculture committee backed draft legislation PL 6299/02 from Luiz Nishimori MP and a group of draft bills on a similar theme, such as PL 3200/15. The bills should subsequently pass to a plenary sitting of the House. If enacted, they would replace Law 7802/09.

Mr Barbosa reportedly rates the proposed bill in Parliament as outdated. He says that it would remove the current regime’s focus on registering products that are less toxic than existing ones.
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72  New biological active ingredients registered or launched in 2018
Bio-pesticides

Agri Life, is a research based agri-biotech manufacturing enterprise based in Hyderabad, India. The Company is focused on bio solutions for crops and soils, Agri Life manufactures BioPesticides, BioFertilizers, BioStimulants and other Agri inputs. The enterprise is promoted by technocrats having experience in similar agri-biotech industry.

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- Comprehensive data gap analysis
- Task force management
- Study commissioning and monitoring
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- Project Management of AIR renewal programmes
- Preparation of biological assessment dossiers (BAD)
- Data matching and technical equivalence applications
- Literature searches
- Classification and labelling advice

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Consultancies & other advisory bodies

APC provides global regulatory services to the agrochemical, biocide and chemical industries.

Our worldwide team can help you achieve national, European and international registrations and maximise your regulatory product portfolio and associated sales potential. We deliver timely, cost-effective solutions in all aspects of the regulatory process.

Our strengths include:

- **Scientific expertise** – We have a team of highly skilled and experienced specialists from government, industry and CRO’s.
- **Regulatory** – Each member of APC's worldwide team has extensive knowledge and expertise in their market sector and of country specific and regional regulatory requirements.
- **Strategic and project managers** – Our regulatory experts have professional knowledge coupled with business acumen and hands-on experience.

**EU Services**

APC provides a complete range of regulatory services to support active substance approval, product registration/re-registration and active substance renewal:

- Assistance with strategy development
- Data Gap Analysis (DGA)
- Data Matching Evaluations (DME)
- Preliminary Risk Assessment (PRA)
- Coordinating multi company task forces
- Monitoring of regulatory studies and field trials
- Preparation and submission of dossiers for new and existing active substances and products
- Preparation of Biological Assessment Dossiers (BAD) and Comparative Assessments (CA)
- Literature searches/study summaries
- MRL/Import tolerance applications
- Technical Equivalence submissions

**International Services**

APC can also offer a complete service for development and product registrations in many key countries throughout Asia, Australasia, Eastern Europe and South America.

We take pride in providing an excellent level of support to our clients throughout the entire regulatory process.

Whatever your regulatory needs, APC can assist you.
Since 1988, CSI has been specialising in regulatory and scientific consultation to the crop protection, biocides, cosmetics and chemicals industry.

CSI's services include agrochemical, biostimulant, biocide, chemical and cosmetic registration, hazard assessment (including QSAR and GHS CLP), exposure assessment (including modelling), risk assessment (including for human and veterinary medicines, and relating to endangered species), study monitoring, data compensation evaluations, and M&A regulatory due diligence.

In the EU, CSI can assist with Member State (including Mutual Recognition) or pan-EU regulatory compliance (e.g. via zonal authorisations) with key Regulations, e.g. EC 1107/2009 (Plant Protection), EC 528/2012 (Biocides) and EC 1907/2006 (REACH). CSI can also provide support for global regulatory strategies (including under the OECD Joint Review Process for Pesticides).

CSI’s staff combine a wealth of experience, derived from regulatory authorities, industry and CROs, to provide quality consultancy services to both new and our many repeat customers around the world.
With more than 20 years experience, DHD-Consulting GmbH offers full scientific and regulatory services for Agrochemicals, Biopesticides, Biocides and Fertilizer in Europe. From initial completeness check to dossier submission and registration monitoring, our clients benefit from our quality, flexibility and reliability:

- **Data gap analysis** including budget estimates
- **In-depth evaluation** for indication of **endocrine disruption (ED)**
- **Study monitoring** from quotations to careful auditing of study plans, test conductance, results, and reporting
- **Modelling and risk assessments** of environmental, ecological, and toxicological exposure
- **Literature research** according to EFSA guidance
- **Dossier preparation** for zonal and EU procedures
- **Placing, design, monitoring, and assessment of efficacy trials**
- **Preparation of Biological Assessment Dossiers (BAD)**
- **Comparative Assessments** for products containing Candidates for Substitution
- **Regulatory Affairs** by specialized staff (incl. e-application in Germany)
- **Expanded CADDY capacity**

Client focus and service quality are our foundations for enduring relationships.

Dextra International is a leading strategic consultancy firm specialized in the crop protection business at an international level.

Our target focuses on our client’s international growth, starting with a deep analysis of the product portfolio and the definition of new potential markets. Dextra strategies are based on detail market analysis and cost-effective registration processes.

Dextra provides you with country-basis market survey to take the right decision on registration investment and distribution channels. Our Regulatory consultant advice you on the strategic registration decision and oversee the whole process, from dossier preparation fulfilling local requirements until registration obtaining.

Our main Markets are Europe and Americas, giving all our services from our Headquarters in Spain or from our branches in Colombia and United States.

Dextra provides Due diligence services, and strategic advice on new acquisitions.

Dextra International is the right key for your internationalization.
Consultancies & other advisory bodies

Exponent International Ltd
The Lenz, Hornbeam Business Park
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Tel: +44 (0) 1423 853203
Email: npear@exponent.com
Contact: Nicholas Pear
www.exponent.com

Exponent International’s regulatory specialists have extensive European expertise gained with the regulatory agencies, independent consultancies, contract research organisations and industry. Our expertise is in all technical aspects relating to the regulation of plant protection products, biocides and industrial chemicals, including regulatory strategy and project/task force management. We can assist clients with the preparation of dossiers for both EU and national registrations, support discussions on regulatory documents, import tolerance applications, submissions to panels such as JMPR & JMPS, classification and labelling and study monitoring. We are also able to manage all aspects of REACH, including data review, SIEF discussions, generation of CSRs and IUCLID dossiers, as well as manage consortia.

EBRC Consulting GmbH
Raffaelstrasse 4, 30177 Hanover, Germany
Tel: +49 511 898389 0
Fax: +49 511 898389 10
Email: tg@ebrc.de
Contact: Torsten Grewe
www.ebrc.de

EBRC is a privately-owned consulting organisation based in Hannover, Germany, providing consulting services with a focus on chemical, biocidal and agrochemical industries. Specialised scientific experience is available in all key disciplines relevant for product safety with respect to human health and environment. Task force management and coordination of industry consortia is another important aspect of our work.
Environmental Resources Management (ERM) is one of the world’s leading providers of EHS and sustainability management, technical consulting and IT implementation services, with considerable experience in providing global product stewardship services. Global product stewardship (GPS) is positioned within ERM as a strategic growth initiative with a strong focus on agrochemicals and biocidal products. ERM offers integrated product services across all divisions within the company. ERM has more than 200 professionals with extensive specific GPS experience located at various offices worldwide.

Our Regulatory services team, which includes the acquired experts at JSC International, provide advice in the development of regulatory strategies for the agrochemical, biocide and chemical industries. We have a successful track record and extensive experience in developing strategies for agrochemical active substance renewals and product authorisations for agrochemicals and biocides. Same people, same service, greater reach!

Kerona Scientific Ltd

Kerona Scientific is an award winning regulatory consultancy headquartered in Ireland and with offices in Spain.

Our experience spans all areas from plant protection products to plant biostimulants, fertilisers, and agronomic additives at European and Member State level, working equally with chemical, microbial and low risk active substances.

Our services include:

• Strategic advice on product development programmes
• Comprehensive data gap analysis
• Task force management
• Study commissioning and monitoring
• Preparation of full zonal dRR dossiers and national addenda including all necessary risk assessments
• Project Management of AIR renewal programmes
• Preparation of biological assessment dossiers (BAD)
• Data matching and technical equivalence applications
• Literature searches
• Classification and labelling advice

Our native English, German, Spanish, Lithuanian, Polish and Arabic speakers can assist with registrations across the Middle Eastern and all European regions.
Consultancies & other advisory bodies

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Fax: +41 61 906 8509
Email: lkc@lkc-ltd.com
Contact: Dr. David Kane
www.lkc-ltd.com/EU-services.html

For almost 20 years, Phillips McDougall has worked with all the major crop protection companies and the investment community, by providing independent and accurate agrochemical and seed industry business intelligence.

Phillips McDougall is unique in linking global industry analysis with market research, providing unsurpassed knowledge and experience to answer questions and fulfil clients’ consultancy needs. Services range from the broadest global analysis delivered through a new, intuitive platform, to consultancy around specific issues at the individual, crop and country level.

With a team of analysts based in the UK and the US - and a combined industry experience of almost 150 years - Phillips McDougall work closely with the wider Agribusiness Intelligence group, which also publishes Agrow.

For more information and to take a FREE demo of any of the services, visit: www.phillipsmcdougall.co.uk
SCC – Scientific Consulting Company
Am Grenzgraben 11
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Germany
Tel: +49 671 298 460
E-mail: info@scc-hq.de
Contact: Dr. Albrecht Heidemann
www.scc-gmbh.de

Redebel Regulatory Affairs (RRA) offers you a highly qualified international team of experts who can support you in a various range of premium quality services.

- Preparation, redaction and submission of PPP, REACH and Biocides dossiers in the European Union
- Preparation of National addenda in all Member states
- Contact and organize meetings with competent authorities through the European Union
- Monitoring of the regulation
- General regulatory support and advice
- Consortium Management

Through its wide EU network of partners, REDEBEL is able to provide following services:

- Drafting of files from A to Z
- Expertise in ecotoxicology, toxicology, EFATE, etc.
- Flexibility
- Contact with all EU Members competent authorities
- Confidentiality
- Close working relationships and communication with the client

SCC is a privately owned and independent regulatory consulting company. Since 1989, we have been supporting our international customers with cost-efficient solutions for their scientific and regulatory needs. Our expertise extends over a broad range of areas, including agrochemicals and biorationals, chemicals and biocides, feed and food additives, food contact materials, cosmetics and consumer products as well as pharma pre-clinical.

Our long-standing expertise includes defence of more than 90 chemical and biological active substances under Directive 91/414/EEC and Regulation 1107/2009, compilation of plant protection product dossiers (> 500), filing of more than 600 LEAD dossiers for phase-in and non-phase-in substances, submission and defence of numerous dossiers for biocidal active substances and products, preparation of more than 50 reauthorisation dossiers for feed additives as well as management of more than 30 task forces.

SCC stands for meeting every single deadline: we are the experts for regulatory challenges – large and small. More than 130 highly skilled, team-focused employees, mostly academics, form the backbone of our company.

SCC has 2 offices in Germany – the headquarters in Bad Kreuznach and an office in Berlin, and runs SCC Japan K.K. in Tokyo.

We care for your success

www.agrow.com
Consultancies & other advisory bodies

Staphyt Regulatory is a consulting company specializing in chemical regulatory affairs. Operating in the agro chemistry, biologicals, biocides and chemical sectors, our mission is to keep manufacturers informed about the regulations that apply to their business. We help our clients to achieve the smooth entry to the market of their substances and products in compliance with national and European regulations. Our expertise covers all areas related to chemical risk assessment: physico-chemistry, analysis, toxicology, ecotoxicology, residue, biological efficacy, etc. Our team brings together the expertise of scientific and regulatory experts, and we can rely on a network of consultants to cover the whole of Europe.

**Plant Protection & Nutrition expertise:**

We can assist you in all regulatory procedures required to obtain active substance approval and/or product authorisation for both conventional and biological products (EC 1107/2009, EC 2003/2003...).

**Benefits of working with us:**

Both agronomic experimentation and regulatory affairs expertise gathered in one service company!

We offer you real added value by taking charge of your projects from the earliest stage all the way through registration.

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23 Rue De Moeuvres
62860-Inchy En Artois
France
Tel: 00 33 3 21 21 45 21
Fax: 00 33 3 21 21 45 19
Contact: Fanny Vanel (Marketing Manager)
Email: fvanel@staphyt.com
www.staphyt.com/regulatory

TSG Consulting provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting has offices in the UK, France, Germany, Spain, the USA and Canada. TSG is a Science Group (AIM:SAG) company.

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Contact: David Bakes, Amy Burrows, Bruce Callow, Stefanie Humpert, Philippe Kuenemann, Anna Rowbotham, María Jesús Fernández Villamil, Iain Watt
www.tsgconsulting.com
Contract research organisations

Agrolab is the leading CRO in the EU North Zone, with facilities in Denmark, Sweden, Latvia and Lithuania. Agrolab provides an independent and confidential service of the highest quality.

First established in Denmark in 1984, Agrolab has more than 30 years of experience as a CRO. Since 2007, our activities have expanded to Sweden (2007), central Sweden (2011), Latvia (2012) and Lithuania (2016). Agrolab has been GLP-certified since 1989 and GEP-certified since 1996. Our regulatory team specialises in the EU North Zone requirements and the 1107/2009 directive. Agrolab is a highly qualified partner for planning the registrations of your PPPs in EU, with extensive experience in all parts of the dRR for application.

ANADIAG is one of the leading CROs in Europe and provides a wide range of services for the registration of existing or new Plant Protection Products.

With nearly 30 years experience in the agricultural business market, more than 50 field trial stations all over Europe and in-house regulatory experts and laboratories, ANADIAG is the most reliable choice to lead your registration projects to success.

**Your project – Our services**

**Field Experimentation Services**
We own one of the largest European GEP and GLP certified field networks which provide efficacy, residues and development trials for registration as well as marketing trials.

**Laboratory Services**
We manage complex studies in analytical chemistry, physical measurements, environmental fate, residue analysis and methods development under GLP and other accepted industry test protocols.

**Regulatory Affairs and program handling**
We are managing a regulatory group with excellent connections at EU and National level and can arrange the preparation and submission of your EU Annex II and Annex III dossiers as well as National applications, equivalence/specification dossiers.

**YOUR PRODUCT REGISTRATION – OUR SUCCESS**
Contract research organisations

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04827 Gerichshain
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Tel: +49 (0) 34 292 863 10
Contact: Gernot Renner, Friedbert Maul
Email: gernot.renner@biochemagrar.de
friedbert.maul@biochem.de
www.biochemagrar.de

As an independent and GLP/GEP compliant CRO we offer expertise and capabilities to conduct studies for product registration of agrochemicals and chemicals. Our services include a broad range of regulatory testing on laboratory, semi-field and field scale at different sites in Germany and Europe.

We provide you with studies necessary for registration including but not limited to Ecotoxicology (Aquatic organisms, Non-target arthropods, Honey Bees/Pollinators, Soil organisms, SMO, Non-target terrestrial plants), Field trials (residues inclusive processed crops, crop rotation, soil dissipation/accumulation, variety evaluation, efficacy, fertilizer, demonstration trials) and Analytical chemistry (plants, soil, water, bee relevant matrices).

AGROBLU BUL OOD
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EIK/BULSTAT BG202997647
Contact: Stefano Cassani
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Contact: Gospodin Kolev
Email: gospodin.kolev@agroblu.com
Contact: Albena Stoyanova
Email: albena.stoyanova@agroblu.com
website www.agroblu.com

It is the latest of six companies of the AGROBLU Group for PPP and Biocides Registration consultancy and GEP and GLP field studies. Funded in Sofia in 2014 under the thrust of the Greek and Romanian staff, which have collected the technical know-how, AGROBLU BUL has two locations: one in Plovdiv (South) and the other in Veliko Tarnovo (North), which has been the ancient and beautiful capital of Bulgaria. Despite his young age, he has already achieved the GEP certification and is implementing the process of GLP certification. Bulgarian staff has been carefully selected among highly experienced technicians and has nothing to envy to the more established companies of the AGROBLU Group in Europe. The staff is fully operative and started to archive the first tens studies.
We are an independent and privately-owned company for agricultural field research with GLP and GEP certification. Since 1990 we have developed a strong experience in efficacy and selectivity studies as well as in residue, soil dissipation, rotational crop and DFR studies. We provide service for the development of agricultural chemistries, bio-pesticides, fertiliser and biostimulants.

Our trials are carried out in all agricultural and horticultural crops and in orchards, vineyards, ornamentals, forests and non-agricultural land in Northern and Southern Germany as well as in collaboration with global partners in different European countries.

We offer the whole project management from planning trials to the preparation of the biological assessment dossier for the Central and South European Registration Zone (zone B and C).

For further information, please contact us: contact@croptrials.com

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Fax: + 49 5139 27095
Email: contact@croptrials.com
Contact: Dr. Paul Reh and Kirsten Heitsch
www.croptrials.com

CEMAS is a GLP-compliant contract research organisation established in 1989 that specialises in multi-site residue studies, pesticide residue analysis, analytical method development, method validation, livestock feeding studies, agrochemical product and biocide analysis, elemental analysis, formulation support for a range of solid and liquid formulation types, 5-batch analysis and bee studies. Human risk assessment studies are also performed including operator exposure, worker re-entry, bystander exposure, dislodgeable foliar residues and drift monitoring. Experience in agrochemical research in the company is extensive and includes soil dissipation and accumulation studies, analytical and environmental sciences, product chemistry, formulation work, soil characterisation and the generation of regulatory dossiers. Experienced personnel and state-of-the-art equipment allow CEMAS to generate quality data on time for all of our clients.

www.cemas.co.uk/Home/Contact-Us

Modern, Laboratory established in 2013 near Milano, carry out official Studies for determining the efficacy of Biocide Products, any kind of formulation. Prof. Luciano Süss (already Director of the Institute of Entomology of the University of Milan) manages and develops Research activities on Biological and Integrated pest Management for Crop Protection, Stored Products, Food Productions and Food Distribution. Studies on food packaging are also included. A peripheral facility of this Laboratory has been established in Fondi, Central Italy, where under the direction of Dr. Giuseppe Carbone, bred Parasites and Useful species of insects (Beneficial) for Laboratory and Field Studies.

ENTOMOLOGIA APPLICATA collaborate with governmental Institutes, Universities and Private Laboratories on Studies of International en/or mutual interest. The Personnel of this Laboratory support by consultancy all the 9 AGROBLU Facilities in Europe.
Contract research organisations

Field Research Support
Max-Planck-Str. 5
D–31515 Wunstorf
Germany
Tel: +49 5031 5166999
Email: zoellner@frs-trials.com
Contact: Helmut Zöllner
www.frs-trials.com

Field Research Support (FRS) was founded in 1997 as a local operator for Europe-wide multi-site studies for agricultural field trials. Since then, FRS obtained GEP recognition in 1997, as well as GLP certification in 2000. The company now offers GLP and GEP field studies in southern, middle and eastern Europe under GLP and GEP recognition by the national authorities.

Field studies are conducted by the company’s experts in all main arable crops and a wide range of vegetables, fruits, vines, ornamentals and industrial crops in open field or greenhouses. From 2005 onwards, Field Research Support began a registration and dossier preparation service.
AGROBLU is a privately, owned and independent Service Company that provides consultancies on the Registration of PPP, Research and Field Studies in all the Regions of Greece and even Cyprus by facilities and technicians located in the most important Agricultural areas of the Countries. AGROBLU HELLAS has professional and ownership connections with the facilities in Italy, Romania, and Bulgaria. GLP and GEP certified AGROBLU HELLAS has been designed to enable smart, swift and effective communication with clients, wherever their location, and between scientists and Consultants of the Company. Over 2000 Trials in 23 years on 98 crops, 238 Active ingredients and 540 formulated products tested, no complain by the clients are the number that make AGROBLU HELLAS tip of the AGROBLU organization diamond.

Innovative Environmental Services (IES) Ltd is an independent and privately owned GLP-certified contract research organisation (CRO) which performs environmental fate, metabolism, aquatic and terrestrial ecotoxicology, and analytical chemistry testing to support the development, registration and stewardship of pharmaceuticals as well as agrochemical, biocidal and chemical products in a prompt, flexible and cost-efficient manner.

At IES Ltd, we cooperate with authorities, research institutes and clients on a regular basis to improve existing test systems and guidelines, and to develop alternative and more cost-effective studies to satisfy the stringent and demanding regulatory requirements. Participation in ring-testing, scientific working groups and workshops is an integral part of our company philosophy.

IES’ GLP testing facilities and equipment are state of the art. All laboratories, incubation rooms, growth chambers, cooling and freezing facilities are temperature and, if required, humidity controlled. Our outdoor facilities consist of greenhouses, crop metabolism areas and agricultural land.
WORLDWIDE LOCATIONS

North America

With the acquisition of EAG Laboratories, a highly advanced portfolio of services is offered in North America to include all field studies, eco-toxicology studies, e-fate and metabolism studies and crop biotechnology & development in the lab and field. State of the art residue laboratories are dedicated to GLP residue and metabolism analytical services.

In addition, our public health department provides a full range of services on mosquitoes and other pests.

Regional contact: Phil Sarff
psarff@eag.com Tel: +1 (573) 777-6108

South America

In South America, EAS can offer a broad portfolio of services including field residue and efficacy studies; field and lab ecotoxicology studies; e-fate and crop residue analysis; method development and validation; stability studies.

Regional contact: Marcos de Ferran
MarcosFerran@eurofins.com Tel: +55 1921075500
Europe

Europe is home to a highly developed network of Eurofins field facilities and laboratories. All field and laboratory services for development, registration, and post-registration support can be provided in the European zone. Animal health and public health services are also available and rapidly growing.

General contact for:

- Regulatory: Vincent Dreze
  VincentDreze@eurofins.com Tel: +33 (0) 6 44 11 71 41
- Consumer safety & biological assessment (efficacy and screening): David Clark
davidclark@eurofins.com Tel: +44 1332864800
- Environmental safety, product chemistry & animal health:
  Jeffrey Kolman
  JeffreyKolman@eurofins.com Tel: +31 622489680

Asia

With facilities in Thailand, India & the Philippines, and partners in Vietnam and Indonesia, EAS Group conducts GLP field trials to test crop protection compounds for bio-efficacy, selectivity, vigour and residual activity. In addition to field trials, public health services, resistance monitoring and ecotoxicology studies are offered throughout the region.

Regional contact: Jean-Louis Allard
Jean-LouisAllard@eurofins.com Tel: +66 929925666

Australia and New Zealand

EAS has a large network of field and laboratory facilities throughout the ANZ region which offer a full range of CRO services to the crop protection and animal health industries. The laboratories provide pesticide and veterinary medicine residue testing. The public health portfolio in ANZ is comprehensive.

General contact for:

- Field: Michael Cave
  MichaelCave@eurofins.com Tel: +61 263624539
- Analytical: Susan McKeen
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- Animal Health: Sally Colgan
  SallyColgan@eurofins.com Tel: +61 406 066 026
- Regulatory: Kathryn Adams
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Since 1984, Oxford Agricultural Trials (OAT) has been a leading contract research organisation specialising in agrochemical field trials: residue (crop residue and rotation, soil dissipation and accumulation) efficacy, crop safety, variety evaluation, fertiliser and demonstration. Our fully equipped main base in Oxfordshire includes access to land for specialist studies, whilst our regional bases in England and Scotland including Devon, Wiltshire, Essex, Yorkshire, Nottinghamshire, Gloucestershire, Lincolnshire, Leicestershire and Angus ensure products are tested under a variety of environmental conditions. There is close co-operation with research organisations in Europe for many projects.

The company has an excellent reputation for providing a service which is independent, confidential and of the highest quality. Residue trials are conducted in accordance with Good Laboratory Practice (GLP) guidelines and OAT has been an “Officially Recognised Efficacy Testing Facility” (ORETO certificated) since 1998.

Mambo-Tox is a GLP-compliant CRO specialising in terrestrial ecotoxicological studies. Now part of the larger Cawood Scientific Group, we offer a comprehensive list of services for evaluating the effects of pesticides on non-target arthropods, soil invertebrates and pollinators. Studies following internationally-accepted guidelines are carried out under laboratory or semi-field conditions, utilising our extensive controlled-environment and glasshouse facilities. We also conduct field trials to assess effects on NTA populations in arable crops.

Mambo-Tox understands the importance of delivering to tight deadlines and can offer a rapid turnaround for urgent projects. We have been expanding our laboratory facilities and our team of scientific staff during the present year.

Since 1984, Oxford Agricultural Trials (OAT) has been a leading contract research organisation specialising in agrachemical field trials: residue (crop residue and rotation, soil dissipation and accumulation) efficacy, crop safety, variety evaluation, fertiliser and demonstration. Our fully equipped main base in Oxfordshire includes access to land for specialist studies, whilst our regional bases in England and Scotland including Devon, Wiltshire, Essex, Yorkshire, Nottinghamshire, Gloucestershire, Lincolnshire, Leicestershire and Angus ensure products are tested under a variety of environmental conditions. There is close co-operation with research organisations in Europe for many projects.

The company has an excellent reputation for providing a service which is independent, confidential and of the highest quality. Residue trials are conducted in accordance with Good Laboratory Practice (GLP) guidelines and OAT has been an “Officially Recognised Efficacy Testing Facility” (ORETO certificated) since 1998.

Since 1976, Peracto is the leading Australasian agricultural contract research organisation with a growing international client base. We provide superior design and conduct of GLP and efficacy studies in all crops grown in Australia and New Zealand (tropical to cool temperate). Our focus is on quality and timeliness of reports for our clients. Experienced and fully qualified staff bring a wealth of national and international experience with the company offering out-of-season opportunities for northern hemisphere clients. With continuing growth of our business we welcome enquiries from those wishing to discuss opportunities to work with us. For more information visit www.peracto.com

Since July 2016, Peracto has been part of the Staphyt company.
Since 1988, we turn your ideas into value

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Tel: +32 71 85 33 92
Email: info@redebel.com
Contact: CEO Ir Tanguy Dumont de Chassart
www.redebel.com
www.flora-west-europa.eu

For more than 30 years REDEBEL is a leading company in the EU in the following areas:

- Field trials (GEP, demo platform, R&D)
- Resistance to herbicides trials
- Study monitoring of trial programs
- Study direction throughout the EU
- Residue trials GLP:
  - Non Target Plant (NTP) Trials
  - DFR Trials
  - Drift Trials
  - Soil Sampling...

Through its wide EU network of partners, REDEBEL is able to provide following services:

- Act as a global Study Director for-EU GLP residue programs
- Act as Study Monitor for-EU efficacy & selectivity GEP programs
- Carry out all types of Residue, Efficacy & Selectivity trials
- Provide clients with high quality platform, R&D & demo programs

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Tel: +40 (787) 809 275
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AGROBLU ROMANIA benefits of the 25 years experience in the Mediterranean Countries such as Italy, Spain, Greece and Bulgaria.

Operating in Romania since 2014 for PPP Registration Consultancy and GEP field Studies. AGROBLU ROMANIA can count on an extended net of 59 reliable farmers growing the most typical crops of the Central Zone of Europe.

The company is GEP certified, and its shared experience with AGROBLU EUROPE leads to high level demo and launch trials.

Besides 3 peripheral operating units – each located within big farm – spread in the most strategic areas of the Country, AGROBLU ROMANIA can count on an extended net of 59 reliable farmers growing the most typical crops of the Central Zone of Europe.

The convenient vision of AGROBLU ROMANIA, as it is in all Europe is to provide the Sponsor client with high quality data, passionate observations by personnel trained to analyse the reaction of the Nature broad-spectrum to any action onto the Crops.
Contract research organisations

SGS Seed & Crop Services provides a global network of R&D facilities with more than 600 experts in 28 countries for client research and product development programs in Europe, North America, Latin America, Africa and Asia-Pacific.

Globally, our experienced team provides project, program, and GLP study management services to support the development of new pesticides, fertilizers, biostimulants and seeds, as well as seed treatment solutions. With many years of experience in the fields of R&D, analytical chemistry and project management, SGS processes laboratory and field studies within the scope of regulatory testing, such as efficacy, crop tolerance, residue, environmental, operator and consumer safety, along with bio safety and nutritional/compositional testing of new seeds. SGS Trait Genetics provides molecular breeding services for plants. Testing is based on international guidelines, including EPPO, OECD, EPA and SETAC, and in compliance with GLP (Good Laboratory Practice) or GEP (Good Efficacy Testing).

SGS is the world’s leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 offices and laboratories around the world.

SynTech Research delivers a competitive advantage to our clients by providing expert product development, specialized testing and registration services for agrochemicals, biocides and seeds.

This is based on the company’s agronomic knowledge and technical expertise in field, greenhouse and laboratory studies.

Operating in over 30 countries worldwide, we conduct field and laboratory studies for over 200 clients, in efficacy, environmental chemistry, biotechnology, and ecotoxicology, in strict adherence to GLP/GEP standards.

SynTech Research also provides or contributes to creation and submission of registration dossiers to EPA, EU, PMRA and South America authorities.

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Smithers Viscient provides environmental and consumer safety contract research and regulatory services for the crop protection, pharmaceutical, industrial chemical, and the consumer product industries.

Smithers Viscient has performed standard guideline and higher-tiered environmental studies for over 45 years. We conduct studies to satisfy all regulatory requirements globally. We continue to expand our facilities, locations, and capabilities to provide the most comprehensive environmental safety solutions.

Offerings include environmental fate, plant and animal metabolism, aquatic and terrestrial ecotoxicology, honeybee and pollinator testing, avian toxicology, residue, analytical, and product chemistry, mammalian toxicology, endocrine testing (including in vivo toxicology and in vivo ecotoxicology), and regulatory risk assessment.

For the crop protection industry we offer a variety of services to support regulatory submissions in:

- The United States (Federal Insecticide, Fungicide, and Rodenticide Act – FIFRA)
- Europe (Regulation (EC) No 1107/2009 concerning the placing of Plant Protection Products on the market)
- Canada (Pest Control Products Act and Regulations)
- Japan (Agricultural Chemicals Regulation Law)

We have the capacity and expertise to test difficult materials and confirm exposure levels in the low parts per trillion range in a variety of sediment, soil and aquatic matrices. We support the pharmaceutical, veterinary medicine, personal care, and household product industries through:

- Environmental assessment testing
- Endocrine disrupter studies
- Consulting services
- Advanced analytical instrumentation and novel study designs

For the human pharmaceutical and animal health industries, we offer testing and regulatory services to support product registrations in:

- The United States under FDA Regulations in 21 CFR Part 25
- In Europe under Directive 2001/83/EC relating to Medicinal Products for Human Use
- In Europe under Directive 2001/82/EC relating to Veterinary Medicinal Products
- In Europe and the US under the VICH guidance (International Cooperation on harmonisation of Technical Requirements for Registration of Veterinary Products)

For the chemical and biocidal product industry, we conduct testing to support regulatory submissions in:

- The United States, Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Canada, under the Canadian Environmental Protection Act (CEPA)
- Europe, under the REACH and the BPR

Smithers Viscient has worked with many of the chemical industry task forces, trade associations, and product working groups over the decades to solve unique exposure and testing requirements for different chemistries.
Contract research organisations

Staphyt provides reliable solutions and high level of expertise to agro-chemical, bioproducts manufacturers and plant breeding companies for the development, registration and promotion of their products. The strength of our network combined within the expertise of our people guaranteed the success of the studies, in complete safety and within the time limits allowed.

These key points show our commitment to provide the best quality and to succeed in your trials, their management and registration issues:

• 30 years experience
• over 400 team members
• Access to all crops all over Europe, Australasia (Peracto), in Americas through partners.
• GEP, GLP certified and CIR Agreement

From screening to registration, Staphyt offers the most complete area of expertise:

• GEP trials (efficacy & dose response, crop safety, practical value, rotational, drift studies...)
• GLP studies (residue, OPEX, soil dissipation and accumulation, DFR...)
• Screening trials in field and glasshouse
• Biologics screening/testing and consulting (Bioteam)
• Sales support and development trials
• Seed variety testing on all crops, including silage & compositional analysis
• Processing laboratory (+100 different processes available)
• Ecotox field & tunnel studies for honey/ bumble bees
• Research studies (rain fastness...)
• Fungi resistance monitoring for pre and post registration purpose

Staphyt regulatory & consulting provides support for registration of chemicals, biologicals, fertilisers, growth media and adjuvants:

• Consulting and strategy
• Pan-European registration program
• Active substance (CA) and preparation (CP) dossier’s (study management, write up of dossier’s according to dRR format including Risk Assessments and BADs)
• Mutual recognition, Bis application, Second trade name...
• Direct contact with National Authorities in Europe
• Trial permits
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The founder of AGROBLU European group, active since 1993 as European Regulatory Consulting and Test facility for GEP and GLP field Studies. AGROBLU has long and deep experience in coordinating European projects of Regulatory, Efficacy and Selectivity Studies, GLP Studies including Environmental Fate, Exposure and Magnitude Residues.

All studies – over 2000 in 25 years – have been conducted in a wide range of crops for testing Chemicals, Natural and Biological Crop Protection Products. AGROBLU has established and developed its own laboratories for conducting sponsored researches of Entomology and Microbiology for conducting sponsored researches along the food production chains, from crop protection to packaging and distribution.

In this respect AGROBLU breeds a range of Insects parasites and Beneficials to implement IPM studies. In parallel, owns a collection of diseases to test solutions on plants and cultures inoculated.

Vigna Brasil is a 22 year-old CRO that works as a facilitator in Brazil rendering services as “one stop shop”. We’re a full services provider, offering any kind of support regarding to the segments below, since the establishment of a legal entity in Brazil; company licenses and products registrations (Regulatory Affairs); strategic operational issues and market intelligence studies (Business Advisors); field trials research and development for crop protection, fertilizers, inoculants and GMO (Field Management) and then keeping the company and products in full operation.

We also offer services for products and/or dossiers hosting and importation in most of segments attended by the Group, through our local company called PROPHYTO. We are able to attend companies interested in the following segments: Crop Protection, Biopesticides, Adjuvants, GMO, Fertilizers, Inoculants, PCO, Public Health, Household, Lubricants, (Bio)Remediator, Wood Preservatives, Home&Garden, Aquatics, Food, Beverages and Food Additives.

We provide business facilitator services, helping your company to reduce bureaucracy or operational barriers for starting up and maintaining your operations in Brazil.

Vigna Brasil is also able to work in other Latin-American countries as your focal point, intermediating with local confident consultants and CROs in order to register products and execute R&D projects in each country.
IQV (Industrias Químicas del Vallés, S.A.) founded in 1935 is a recognized world leader in copper fungicides, the 1st world producer of Bordeaux mixture and the 2nd of Copper Oxychloride. IQV is involved in the development, production, commercialization and distribution of Plant Protection Products to provide safer products for healthier crops worldwide. IQV has focused, basically but not only, on the development of Copper salts and mixtures thereof as fungicides for crop protection. Other products, sectors, activities, new production facilities, subsidiaries and markets abroad, partners and customers make up for the actual presence of IQV in all continents.

IQV offers full toll manufacturing and logistic services. Certified according to ISO 9001, 14001 and EMAS; IQV has been approved by many multinationals and is proud to have them among its customers or partners.

IQV produces active ingredients, develops and improves recipes, formulates and conditions both liquid and solid pesticides, and offers purchase of packaging and raw materials, warehousing and distribution services. IQV listens to customers’ need and is completely flexible regarding processes. In its two manufacturing units, IQV deals with more than 100 active ingredients, produces more than 30,000 mt of the different TG copper salts and more than 26,000 mt of ready-to-use formulations.

IQV owns around 450 registrations worldwide, mostly straight copper products, mixtures thereof and Metalaxyl-based fungicides.

IQV’s most well-known trademarks (Caldo Bordeles Vallés®, Bordo®, Cuprosulf®, Cupertino®, Curenox®, Vitra®, Americop®, Armetil® and Mevaxil®) are our cover letter in many countries.

At the EU level, IQV has defended Copper (the three main Copper salts: Bordeaux mixture, Oxychloride and Hydroxide) as member of the European Copper Task Force and Metalaxyl on its own. Both are now included in Annex I. Copper and Metalaxyl are IQV’s present and near future bets, while opportunities of new active ingredients are always welcome.
Croda is a global company with operational locations specifically chosen to facilitate close customer working. We are constantly investing in our existing markets and expanding into emerging markets to give our customers the best, most responsive service.

Our unique formulation expertise helps crop protection customers get the best performance out of their active ingredients, enabling farmers to get the best yields for their crops.

Our adjuvants and formulation aids under the renowned brands, Atplus™ and Atlox™, are well known in the industry as high performance, reliable products. Our value adding technology helps our customers achieve more complex, efficient, safer formulations that minimise impact on our environment.

Our partners in agrochemicals value our role in the industry as influential contributors applying scientific expertise from the bench top to the field to support unmatched innovation.

Applications include emulsifiable concentrates (EC), microemulsions (ME), suspension concentrates (SC), concentrated aqueous emulsions (EW), soluble liquids (SL), suspoemulsions (SE), water dispersible granules (WG), wettable powders (WP), oil dispersions (OD) and seed coatings.

Exwold Technology Ltd is a contract processing and formulation company dedicated to servicing the Crop Protection & Speciality Chemical markets.

We are recognised as specialists in the formulation and supply of low pressure extruded granules primarily for use as WDGs in the agrochemical market & have an established capability in high potency herbicide formulation. We also supply a wide range of powder and granule processing technologies including granule impregnation and coating, compaction granulation and powder blending.

We provide a trusted, fast and flexible service to companies around the world. With our pilot facilities, we are able to support our customers through product development and finding solutions and are proud to be partners in chemical processing.
SBM-FORMULATION is a leading European toll formulation company providing an extended range of sophisticated technologies, including WG using fluidized bed or extrusion (basket granulator), RB or GB by wet process, EW, SE, SC, for fungicides and insecticides.

In 2019, 2 new lines will be implemented, one for sticks (compression) and one for CS.

SBM offers a full formulation and packing service from early development stage and is certified ISO 9001, ISO 14001 and OHSAS 18001.

Iris, sister company of SBM-Formulation is specialized in toll packing for small packs for CPP or Home and garden Business, formulation of biocontrol herbicides, as well as rodenticides (paste and cereals).

SBM group also operates a plant for CPP and Home and Garden products in Pasadena, Texas.
As the leading research specialist in agriculture, Kynetec helps companies around the world understand the dynamics of the industry, turning research into business opportunities and enabling clients to create winning strategies.

We have expertise in all major categories needed for keeping operations running smoothly, including crop protection, seeds, soil treatment, plant nutrition, farm machinery, water management and amenity. We conduct tracking studies for monitoring market trends, perform customized research for answering unique business challenges and provide market forecasts to support the long-term vision.

Everything we do is delivered by a team of more than 650 specialists who understand the challenges impacting the agriculture industry. Our coverage extends to major and niche sectors of our industry, where we regularly undertake research projects in more than 70 countries. With our international team of experts located around the world, no matter where you are, we can help.

Dextra International is a leading strategic consultancy firm specialized in the crop protection business at an international level.

Our target focuses on our client’s international growth, starting with a deep analysis of the product portfolio and the definition of new potential markets. Dextra strategies are based on detail market analysis and cost-effective registration processes.

Dextra provides you with country-basis market survey to take the right decision on registration investment and distribution channels. Our Regulatory consultant advice you on the strategic registration decision and oversee the whole process, from dossier preparation fulfilling local requirements until registration obtaining.

Our main Markets are Europe and Americas, giving all our services from our Headquarters in Spain or from our branches in Colombia and United States.

Dextra provides Due diligence services, and strategic advice on new acquisitions.

Dextra International is the right key for your internationalization.
For almost 20 years, Phillips McDougall has worked with all the major crop protection companies and the investment community, by providing independent and accurate agrochemical and seed industry business intelligence.

Phillips McDougall is unique in linking global industry analysis with market research, providing unsurpassed knowledge and experience to answer questions and fulfil clients’ consultancy needs. Services range from the broadest global analysis delivered through a new, intuitive platform, to consultancy around specific issues at the individual, crop and country level.

With a team of analysts based in the UK and the US - and a combined industry experience of almost 150 years - Phillips McDougall work closely with the wider Agribusiness Intelligence group, which also publishes Agrow.

For more information and to take a FREE demo of any of the services, visit: www.phillipsmcdougall.co.uk
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Friedbert Maul
Managing director
Friedbert Maul has more than 35 years experience in Finance and administration, therof more than 20 years as CFO in international based companies. He joint BioChem in 2017. He works as Managing Director Administration responsible for BioChem agrar and the whole BioChem Group since March 2018.
Redebel Regulatory Affairs (RRA) offers you a highly qualified international team of experts who can support you in a various range of premium quality services

- Preparation, redaction and submission of PPP, REACH and Biocides dossiers in the European Union
- Biostimulants, biopesticides and fertilizers products experts
- Preparation of National addenda in all Members States
- Contact and organize meetings with competent authorities through the European Union
- Monitoring of the regulation
- General regulatory support and advice
- Consortium Management

Through its wide EU network of partners, REDEBEL is able to provide following services:

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- Expertise in ecotoxicology, toxicology, EFATE, etc
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- Contact with all EU Members competent authorities
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- Close working relationships and communication with the client

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REDEBEL is a leading company in the EU in the following areas:

- Field trials (GEP, demo platform, R&D)
- Resistance to herbicides trials
- Study monitoring of trial programs
- Study direction throughout the EU
- Residue trials GLP:
  - Non Target Plant (NTP) Trials
  - DFR Trials
  - Drift Trials
  - Soil Sampling ...

Through its wide EU network of partners, REDEBEL is able to provide following services:

- Act as a global Study Director for EU GLP residue programs
- Act as Study Monitor for EU efficacy & selectivity GEP programs
- Carry out all types of Residue, Efficacy & Selectivity trials
- Provide clients with high quality platform, R&D & demo programs

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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.

Israel 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 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 biologicals 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 MBI 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 MBI600), with additional uses in the US (mushrooms) and Thailand (specialty 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 PPRI 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 mimitans), was launched in 2017 in South Africa.

The bioinsecticide, 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 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.

Standalone biologicals vs combination products
Syngenta says that the used of stand-alone 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 Emanuel 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.”

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, Biopesticide 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 Prevention Division (BPPD) 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) (biologically based pesticides). The Agency is unique in the world in that it developed a regulatory group that specialises in biopesticides. 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). TheseJoint 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.

• Israeli biopesticide company Stockton agreed a long-term, non-exclusive distribution deal for its Melaleuca alternifolia extract-based biofungicide, Timorex Gold, with Chinese company Chongqing Shurong Crop Science.

• 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-Hv1α – 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-IB 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.

• 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.
• 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 Lidad 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 biostimulants 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 bioproducts company Koppert’s Brazilian subsidiary, Koppert do Brasil Sistemas Biológicos, acquired Brazilian biologics 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.

Biologicals-related mergers, acquisitions and deals in 2018

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

### New active ingredients registered or launched in 2017

<table>
<thead>
<tr>
<th>Company &amp; active ingredient</th>
<th>Use</th>
<th>Status</th>
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<tbody>
<tr>
<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>
</tr>
<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>
</tr>
<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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<tr>
<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 Velonis Flex, Velonis Plus &amp; Velonis Extra (both with <em>B amyloliquefaciens</em> strain MBI 600)</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td><strong>Bayer Crop Science</strong></td>
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<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 minitans</em> strain CON/M/91-08 [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>
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<tr>
<td><strong>Consume em Verde</strong></td>
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<tr>
<td>BLAD (Banda de <em>Lupinus albus</em> doce) [biofungicide]</td>
<td>Stone fruit</td>
<td>Approved in Australia as Problad Plus</td>
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<tr>
<td><strong>Eden Research</strong></td>
<td></td>
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<tr>
<td>eugenol/geraniol/thymol [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in France &amp; Portugal as 3AEY &amp; Mevalone</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Ihara</strong></td>
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<tr>
<td><em>Bacillus amyloliquefaciens</em> strain D747 [biofungicide]</td>
<td>Various</td>
<td>Launched in Brazil as Eco-Shot</td>
</tr>
<tr>
<td><strong>Marrone Bio Innovations</strong></td>
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<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><strong>MosquitoMate</strong></td>
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<tr>
<td><em>Wolbachia pipientis</em> ZAP strain [bioinsecticide]</td>
<td>Mosquitoes</td>
<td>Approved in US as ZAP Males</td>
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<tr>
<td><strong>National Machinery Traders</strong></td>
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<tr>
<td>cedarwood oil [repellent]</td>
<td></td>
<td>Proposed approval in Australia as Nature’s Botanical Crème (with rosemary oil)</td>
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<tr>
<td><strong>Novozymes BioAg</strong></td>
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<tr>
<td><em>Streptomyces lydicus</em> strain WYEC108 [biofungicide]</td>
<td>Vegetables, turf &amp; ornamentals</td>
<td>Approved in Australia as Actinovate</td>
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<tr>
<td><strong>Nufarm</strong></td>
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<tr>
<td><em>Aureobasidium pullulans</em> strain DSM 14940 + <em>A pullulans</em> strain DSM 14941 [biofungicide]</td>
<td>Grapevines</td>
<td>Approved in Australia as Botector</td>
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<tr>
<td><strong>Simbiose Agro</strong></td>
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<tr>
<td><em>Trichoderma harzianum</em> strain Cepa Simb-T5 [biofungicide]</td>
<td></td>
<td>Launched in Brazil</td>
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<tr>
<td><strong>Stockton</strong></td>
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<tr>
<td><em>Melaleuca alternifolia</em> extract [biofungicide]</td>
<td>Cucumbers &amp; courgettes</td>
<td>Approved in Spain as Timorex Gold</td>
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<tr>
<td><strong>Syngenta (owned by ChemChina)</strong></td>
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<tr>
<td><em>Pasteuria nishizawai</em> [bionematicide]</td>
<td>Soybeans</td>
<td>Approved in Brazil as Clariva PN</td>
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<tr>
<td><strong>Valent USA (subsidiary of Sumitomo Chemical)</strong></td>
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<tr>
<td><em>Bacillus amyloliquefaciens</em> strain PTA-4838 [bionematicide]</td>
<td>Soybeans</td>
<td>Launched in US as Aveo EZ</td>
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<tr>
<td><strong>Vitae Rural Biotecnologia</strong></td>
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<td></td>
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<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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New biological active ingredients registered or launched in 2018

New active ingredients registered or launched in 2018.

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<thead>
<tr>
<th>Company &amp; active ingredient</th>
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<tbody>
<tr>
<td><strong>BASF</strong></td>
<td></td>
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</tr>
<tr>
<td>Beauveria bassiana 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>
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<tr>
<td>Bacillus amyloliquefaciens strain QST 713 (biofungicide)</td>
<td>Grapevines</td>
<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>Fruits, vegetables, peanuts, bulb &amp; root crops, turf &amp; ornamentals</td>
<td>Proposed approval in US as iH026a</td>
</tr>
<tr>
<td><strong>Monsanto</strong></td>
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<tr>
<td>lipochitooligosaccharide SP104 (plant growth regulator)</td>
<td>Maize &amp; canola</td>
<td>Approved in US as Acceleron B-360 ST</td>
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<tr>
<td><strong>Verdesian Life Sciences</strong></td>
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<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>
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 120,000 Mt (glycine route) and Glufosinate 95% Tech capacity of 10,000 Mt. It is the largest producer in China and the second largest world-wide. Fuhua is projecting Dicamba and 2,4-D in capacity of 5,000 Mt/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 65% TECH
- Digma
- 2,4-D

OTHER PRODUCTS
- Acetamiprid
- Atrazine
- Bisulfate
- Chlorpyrifos

CHEMICALS
- Caustic Soda Flakes / Pearls
- Sodium Tripolyphosphate (STPP)
- Glycine (Industrial Grade)
- Paraformaldehyde

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