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SynTech Research in 2010

In 2010, SynTech Research celebrated its rapid growth over the last 10 years. From its origins in California, we are all proud to have built SynTech Research into a leading global independent research company, providing agricultural product development and regulatory service.

Today the Company operates from permanent field stations and satellite facilities in 26 countries, in the Americas, Europe/Africa and Asia/Pacific. This year SynTech Research has updated its strategy to be focused on providing its customers with a menu of expert services which will give them competitive advantage.

As you can see from our new website www.syntechresearch.com, we have launched a new corporate identity, which I feel reflects our development and professionalism - and more importantly, illustrates the extent of our presence and offerings. I hope that you will find this, teh following brief summaries of our progress in the Regions, and articles on current "hot" topics of interest and I wish you a very successful year of business in 2011.

Dr. Khosro Khodayari, President and CEO

SynTech Research

New sites and services in Europe

It was very gratifying to see a strong year's performance in 2010, with increased business taking up all our trials capacity – and driving double-digit sales growth, particularly in Italy, Hungary, the UK and Portugal, and we have responded to the demand with expansion of our facilities.

In Hungary, we established satellite stations at Kaposvar (south), Szeged (east) and Eger (north), which along with the headquarters at Szombathely (west) now provide trials capability throughout the country.

In the UK, we have initiated satellite sites at Sutton Bridge, Lincolnshire and Frome, Somerset, With our main station at Hopton, Suffolk, these provide even greater ability to conduct a range of horticulture work and cereal trials with high probability of disease - see www.syntechresearch.com/operations-worldwide

This year we have introduced a system of EU Project Managers to act as and be the key link with clients for monitoring and reporting on EU-wide GLP and GEP programs. We will be increasing our Project Manager resource in 2011 – and they will be supported by EU-wide introduction of Syntech's Trials Progress Information System ("InSite") allowing visibility of key events – initiation, treatment,

Expanding SynTech Research in Asia Pacific

2010 has been a year of fast expansion of SynTech's capability in the Region, and we have established seven locations covering a wide geographic spread. These are now supplying high quality, reliable and cost effective crop safety/efficacy field trials as well as regulatory support services to clients.

From 2011, we will be conducting GLP field studies in Japan. In Korea our partnership has official recognition to do Registration trials and residue analysis, whilst in Taiwan and the Philippines we focus on providing "out-of-season" and early stage testing on Japanese/Korean and global crop/targets - particularly rice, fruit & vegetable crops.

Our new operations in India include crop protection field testing (non-regulatory) as well as traditional and GM seed trials on a range of crops in both the north and south of the country. In Australasia we have established a partnership to provide all necessary support activities for Product Development. We have also formed a "mobile" unit to do trials in countries where we do not have a resident team.

Contract Research in Asia/Pacific is often different from the US or Europe, since many countries require registration data to be generated by recognised official institutes or universities, so in many countries assessment and reporting, and so rapid responses to customer queries.

In 2011 we will start to see the first impacts of the new EU regulation. For a summary of the key provisions see the article by our Biological Assessment Dossier manager, Isabelle Rety-Guignon, in this newsletter. In principle, the new Zonal arrangements will reduce the number of bioefficacy trials required for regulatory submission. But we believe that the option for Member States to require National Addenda, and the continued need for territorial data for country technical support and marketing, will still mean that high quality efficacy trials will be needed in all territories.

Dr Colin Ruscoe, Regional Director, Europe & Africa

Adding Aquatoxicology to the SynTech Research Ecotoxicology offering

SynTech 's Ecotoxicology offer has grown rapidly, and in 2010 it greatly increased its capabilities by establishing a new Aquatoxicology laboratory at its research station in Nimes, France. The range of organisms includes aquatic plants, algae, fish, Daphnids, and various other non-target organisms. These have already been used extensively in customer's testing programmes in 2010.

The terrestrial Ecotoxicology labs are based at our research stations in Macon, France and Sanger, California, and we run semi-field and field studies worldwide. The Study Directors are specialized on NTAs/soil organisms, bees, aquatic organisms and NTPs. Our full offer on terrestrial Ecotoxicology, includes: laboratory tests, semi-field and field

we are not called on to provide Registration trials support. But we have a Regionally-based Registration expert who can help customers understand the data requirements needed to achieve registrations in the different countries.
For more information on our Asia/Pacific capabilities, contact Paul French:
pfrench@syntechresearch.com

The new EU Plant Protection Products Regulation (EC 1107/2009)

The new legislation for the Plant Protection Products (PPP) (Authorization) – Regulation (EC1107/2009) will apply from 14 June 2011. Member States must bring in national laws to implement the Sustainable Use Directive 2009/128/EC by 14 December 2011. The key points of the procedures which will apply under EC 1107/2009 are summarized in the full document at ……. with particular reference to the new Zonal system and Efficacy Data (Section 7) for formulated products. The key points of this section are:
National aspects kept to a minimum: The aim is to include as much information in Core/zonal dossiers rather than as national addenda: if a Zonal Rapporteur MS (ZRMS) evaluates efficacy for uses outside their normal area of expertise he can call upon the expertise of regulatory and other specialists within other MS.
Official Methods and standards: Data generated according to EPPO guidelines will be accepted so the ZRMS should therefore only need to determine

studies on many terrestrial non-target organisms including bees, soil organisms, NTAs and NTPs are now well recognized by clients.
With the new Aquatoxicology facility on-stream, SynTech can now provide a full Ecotoxicology package for submission of chemical or GMO regulatory dossiers, worldwide. The full list of studies and species can be seen at: www.syntechresearch.com/wp-content/uploads/2010/07/SynTech-Ecotoxicology-4pp-web-v2-Oct.pdf.
Eric Ythier, Ecotoxicology, Global Lead

North and South Americas region

In 2010, SynTech mounted a major expansion of its GMO testing services in both North and South America. We have now established field GMO capability in California, Iowa, Illinois, Indiana, New York and Alabama. In February, we became the first foreign CRO to obtain a GLP-OECD license in Brazil, we are the first CRO to offer GMO trials in several Latin American countries under USDA/APHIS regulation (see associated article on Global GMO Study Capabilities and Services)
During the year we also increased our US Ecotox laboratory and field offerings at the main US technical center in California, where three new glasshouses were completed. New operations were established in Indiana and Illinois.
In Latin America, SynTech built its regional regulatory organization, lead by Magdalena Zingoni and located in Argentina. We also secured new sites in Brazil, Argentina and Chile for early stage

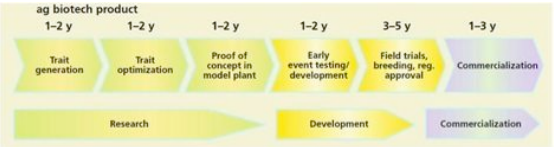
compliance of the studies with EPPO standards.Specific country test methods e.g. the France CEB should only apply to trials conducted in that specific Member State e.g. the inclusion of specific commercial standards. So, in theory, a maximum 3 Biological Assessment Dossiers (BADs) are needed (one per zone) for a formulated product, as it will not be necessary for applicants to submit any National BAD in addition to a zonal dossier – dependant on the results of the harmonization of data requirements.

Numbers of Trials: It is accepted that there will be recognition of data according to EPPO zones across regions and acceptance of data from other regions/sources as long as relevant scientific justification provided in the data package, however the impact on the number of trials to be generated will be clearer only when the guidance documents per zone become available.

Isabelle Rety-Gutton, EU BAD Manager

agrochemical testing. Along with our South East Asia facilities, our Entomology and Nematology capabilities in the Region now complement North America/Europe, by providing 2-3 lab/field tests within one year, to accelerate the development of new products.

Dr. Khosro Khodayari, President and CEO



Global GMO Study Capabilities and Services

Since prehistoric times, improvements in agricultural production have been based on improving crops through “crossing and selection”. As the advancement of molecular biology allowed the identification of plant genetic sequences, or plant markers which correlate with desired attributes, a new whole generation of plant breeders has emerged. These use molecular plant markers from plant genetic sequences to improve the plant selection process, ensuring the homogeneity of populations and, most importantly, decreasing the time required for improvement and obtaining better crops.

A key qualitative leap occurred in the 1980s as new techniques in molecular biology and genetic engineering allowed the incorporation of genes from other species into the plant breeding process Once identified, a gene associated with an attribute of interest (e.g. herbicide or stress tolerance, insect resistance) can be introduced into crops, regardless of their origin, not by sexual crossing, but by the transformation of plants - the hallmark of GMOs.

The process of obtaining a commercially valuable GMO takes about ten years and can be divided into different functional phases: see above

From a technical standpoint, developing a new GMO involves five phases of development. using molecular biology, tissue culture, greenhouse tests,

field trials The phases are gene discovery, proof of concept, transformation and phenotypic testing, conversion and pre-release. Regulatory studies for the release authorization of the crop are performed during phases four and five.

During initial stages of development, the trials are normally managed by sponsors, but in advanced stages and the “regulatory approvals phase” sponsors use external service providers.

Commercialisation usually requires that trials (environmental impact, phenotype environment interaction, NTOs, etc.) performed in the countries where the crop will be introduced. As companies normally plan the release of crops simultaneously in major markets, it becomes necessary to perform trials globally within a set period of time.

To provide such services, a CRO requires secure sites and the capacity to manage varied crops in different locations, complying with a myriad of regulations. Quality stewardship (QC and QA) and experience in USDA/APHIS as well as EPA/FDA and GLP regulations are all essential for effective delivery of such studies worldwide.

SynTech Research now provides these in an integrated package of technical development trails (Blue boxes in the diagram above), in different countries and through a single service contract.

Our GMO studies are based on our locations in the United States (especially California, Iowa, Illinois, Indiana, New York and Alabama) as well as Chile, Argentina, Brazil, Spain and the Philippines. Our California, Chile and Argentina are particularly good locations for ***drought tolerance*** trials, where we use purpose-built irrigation systems specifically for these difficult studies.

Dr> Carlos Perez (Argentina), Dr. Chuck Doty and Gary Schultz (USA)

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