Staphyt

empower science together

EXPERTS IN CHEMICAL & BIOLOGICAL REGULATORY AFFAIRS

GLOBAL SOLUTIONS,
LOCAL FOCUS

ABOUT US

Staphyt was initially established in 1989 as an agricultural field trials organisation. Over the years, we have grown and extended our services in field services, laboratory services and regulatory affairs consultancy, in the sectors of:

- Plant protection
- Plant nutrition
- Biocides
- Industrial Chemicals (REACH)
- Pharmaceuticals

Working side-by-side to define your regulatory strategy and guide you to successfully bring your products to market.

Staphyt Regulatory Affairs department has grown from a small team to be a significant player in the regulatory consultancy world. This expansion has come from direct recruitment of experienced individuals, plus the acquisition of other well regarded consultancy department companies. We are currently 120+ experienced employees and we continue to expand our regulatory team internationally.

Achieve international registrations and maximise your global sales potential

We help our clients to meet all aspects of their chemical and biological regulatory obligations, to achieve authorisation for the production, marketing and sale of their new or existing substances or products in their target countries. We offer complete management of your registration projects, from understanding data requirements, managing data generation, producing the relevant dossiers and supporting the post submission.

Skills, experience and geographical coverage are three essential assets to enable our clients to achieve their regulatory affairs objectives.

OUR SERVICES

	Plant Protection Reg. (EU) 1107/2009	Plant Nutrition Reg. (EU) 2019/1009 (EC) 2003/2003	Biocidal Products Reg. (EU) 528/2012	Industrial Chemicals (REACH) Reg. (EC) 1907/2006
Chemicals	✓	✓	✓	✓
Biologicals	✓	✓	✓	✓
Strategic advice	✓	✓	✓	✓
Compliance audit (Plant Nutrition Products)	•	✓	•	•
Data Gap Analysis	✓	•	✓	•
Preliminary Risk Assessment	✓	•	✓	•
Study commissioning & monitoring	✓	✓	✓	•
Literature search	✓	✓	✓	•
Dossier preparation (all types)	✓	✓	✓	✓
Initial risk assessment	✓	✓	✓	•
Higher tier risk assessment	✓	•	✓	•
Technical equivalence applications	✓	•	✓	•
Biological Assessment Dossier (under Reg. EU 1107/2009)	✓	•	•	•
Comparative Assessments	✓	•	•	•
Derogation 4.7	✓	•	•	•
MRL Application preparation	✓	✓	•	•
CLH Dossier preparation	✓	•	✓	•
Only Representative Services (REACH)	•	•	•	✓
Task Force Support	✓	•	•	•
Consortium Support	•	•	✓	✓
SDS preparation	✓	✓	✓	✓
Submission support for EU Countries	✓	✓	✓	✓
Submission support for UK	✓	✓	✓	✓
International submission support	✓	✓	✓	✓

PLANT PROTECTION

Chemicals - Biologicals - Adjuvants

We have worked with a wide variety of clients, varying in sizes and levels of experience in the regulatory landscape.

We support you in all the regulatory procedures required to obtain approval of both chemical and biological active substances and products, including adjuvants.

Our larger clients include many of the top 10 agrochemical companies worldwide, but we also work with smaller companies, many of which are developing new and novel products in response to the need for greener and more sustainable solutions to pest control. The following is an outline of some of the more challenging activities that we have supported our clients with in recent years:

- Higher Tier Risk Assessments
- Biological Assessment Dossiers (BADs)
- Comparative Assessment (CAs)
- Derogation under Article 4.7
- Combined Field and Regulatory Services for Crops
- New chemical active substance
- New novel microbial active substance
- Renewal dossiers to support botanical active substances and register products

BioTeam

Member of IBMA

Our « Bioteam » is a cross functional group of experts created in 2011 from both of our Regulatory and Agroscience teams, specializing in biological products. They have:

- Strong experience in biopesticides (botanical extracts, microbials, semio-chemicals).
- Expertise in designing studies and conducting tests to identify the technical active, to prove effectiveness and to define the mode of action of substances.

PLANT NUTRITION

Fertilisers- Biostimulants - Growing media

We started supporting clients with fertiliser and biostimulant registration in France in 2012. Our team has built up considerable experience since then, assisting clients of all sizes and for all aspects from start ups notification, mutual recognitions or even full registration in almost all EU countries.
We provide strategic support to clients by helping them to refine their European registration strategies by advising on the fastest and most effective routes to market.

We have worked on several types of microbial and organic substances, representing the main biological fertilisers and biostimulants on the market today.

We have been closely involved in the work of BN Ferti, influencing the standard approach that is used for biostimulants registration in France, under the Fertilising Products Reg. (EU) No. 2019/1009. Our long established involvement in a 'mirror group' means that we already have a good understanding of current thinking on how the legislation will be applied at a practical level. This long standing experience enable us to better assist our clients, by advising on the regulatory positioning to consider for their product, taking account of the nature of the compounds and the supported uses.

BioTeam

The value of Biostimulants is becoming better defined and recognized all over the world. Increasing plant vigor and improved management of abiotic stress indirectly helps plants to fight against other types of stress.
At Staphyt, we started working on the mode of actions of biostimulants and their regulatory positioning in 2011.

We have an excellent understanding of the feasibility of registration strategies. Our team has direct experience of working closely with Regulatory Authorities to look beyond the legal texts and better identify the authorities' expectations regarding novel substances. Along with our laboratory and field offer, we can help you understand the mode action and identify the effects so that you can have confidence in your label claims.

A PROJECT MANAGEMENT APPROACH

Regulatory Managers support and guide you through the full regulatory process

Our experienced teams are drawn from regulatory authorities, CROs and consultants. We help you by:

- Identifing the most appropriate regulatory strategy
- Liaising with Regulatory Authorities on your behalf through pre-submission and post-submission meetings, including the defense of your substances or products
- Coordinating the full package of work across the wider team, through a project management approach
- Keeping you informed on progress and communicating any questions during the mission

Regulatory Strategy Advice

Data Gap Analysis Risk Assessment

Study Monitoring

Active substance & Product Registration preparation

Dossier Submission & Follow up

TASK FORCE & CONSORTIA MANAGEMENT

We support clients who wish to work with other companies in task forces or consortia through the sharing of data, strategy and costs.

If you are considering working together with other actors in the sector, we can help you set up the appropriate legal and financial framework. We can also provide, if necessary, a dedicated chairperson who will facilitate discussions, help find solutions and REACH agreements in the group.

If you are interested, do not hesitate to contact us to discuss your needs and expectations.

PRINCIPAL CONSULTANT

GARTH DRURY

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SCIENTIFIC & TECHNICAL EXPERTISE

Our highly qualified and experienced team provides comprehensive support in all sections of the dossier

PHYSICAL CHEMISTRY

TOXICOLOGY

ENVIRONMENTAL FATE

EFFICACY

ANALYTICAL METHODS

RESIDUE CONSUMER RISK

ECOTOXICOLOGY

- ✔ Commission scientific studies on your behalf
- ✔ Manage and monitor the studies through to completion
- ✔ Prepare study summaries and undertake the risk assessment
- ✔ Advise you on options if problems are identified, and if needed, undertake any higher tier risk assessment
- ✔ Support you on all scientific aspects during the evaluation process and post-submission

Higher Tier support includes:

- QSAR
- Dislodgeable Foliar Residue Studies
- Endocrine Disruption Assessment
- Refinements to Bird and Mammal Risk Assessment
- Study Monitoring support for Ecotoxicology Field Studies
- Modelling refinements for Environmental Fate risk assessment and field studies
- Preparation of Position Papers or Waivers across all areas

A COMPREHENSIVE OFFER IN AGROSCIENCES

For plant protection and plant nutrition clients, we can fully manage all of the work for you as a single project, in combination either with Staphyt's Field and Laboratory divisions, or in conjunction with our network of trusted external partners. We can help reduce the burden and keep you informed at all stages, allowing you to focus on other priorities.

TAILOR-MADE SERVICE

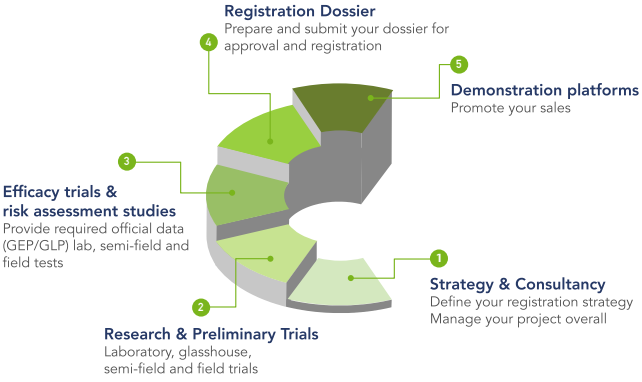
We adapt our service to your requirements, supporting you comprehensively or only on specific aspects. We agree with you upfront on how you want us to work together with as much flexibility as possible.

CURRENT AND EMERGING ISSUES

We closely monitor regulatory developments to ensure that we are providing you with accurate advice and guidance at all times.

PROFESSIONAL EXPERTISE

We are committed to developing our team and ensuring that they continue to maintain their professional expertise in their respective field.



BIOCIDES (BPR)

Our team can advise and support you in all the regulatory procedures required for an approval of a biocidal active substance and/or authorization of a biocidal product, in Europe as per Regulation (EU) No.528/2012 or at national level as per local regulations.

Our expertise covers all scientific areas related to regulatory requirements for biocidal active substances / products: Physico-chemistry, analysis, toxicology, ecotoxicology, efficacy, risk assessments, etc.

We offer a complete range of services to successfully register your substances and products, in order to achieve fast and optimal placement of product on the market.

- → **Regulatory and strategic advice**
- → **Active substances approval, products and family products registration dossiers**
- → **Human, animal, environmental, consumer Risk Assessments**
- → **Annex I listing and simplified procedure dossier**
- → **Transitional registration in all Europe and internationally**
- → **Contact with Authorities**
- → **Trial testing strategy and monitoring of GLP studies (chemistry, toxicology...) and efficacy**
- → **Poison Centre notification (PCN)**

CHEMICAL (REACH/CLP)

Our Team can help you achieve regulatory compliance for chemical substances and products you wish to place on the market in Europe and the United Kingdom.

Our team has extensive experience of working with the REACH Regulation (EC) 1907/2006 and CLP Regulation (EC) 1272/2008, delivering a broad range of projects, including CLP classification, SDS preparation, REACH registrations (for Lead registrations and joint submission member registrations) and Chemical Safety Report preparation.

We are experts in UK REACH, and with teams based in the EU and UK, we also provide Only Representative services under both EU REACH and UK REACH.

Our services include:

- → **REACH compliance audit and strategy**
- → **REACH registration**
- → **Only representative services**
- → **Chemical Safety Report (CSR)**
- → **Human, environmental, PBT/vPvB and POP Risk Assessments**
- → **CLP classification, SDS and label preparation**
- → **GLP study monitoring**
- → **Poison Centre, PIC, SCIP Notifications**
- → **Nanomaterials conformity**
- → **QSAR Modeling**

INTERNATIONAL REGISTRATION

The expertise of our in-house team is supplemented by a network of external business partners providing local agronomic, regulatory, and scientific knowledge as well as established relationships with the associated regulatory bodies, local distributors, CROs, universities and research stations.

We provide cost-effective regulatory solutions and outstanding client care in over 40 countries worldwide.

Our team is continually growing and should you require assistance in a country where we do not have yet an established partner, we can still do the groundwork for you.

CONTACT US:

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