



knoell

worldwide  
registration

CLASSIFICATION CHALLENGES

# BORDERLINE PRODUCTS

PLANT PROTECTION | BIOCIDES | FERTILISERS | BIOSTIMULANTS

## Let's grow together

Some products, due to their mode of action, composition and marketing positioning do not always fit neatly into a given regulatory regime. Placing such products on the EU market requires in-depth analysis of the applicable regulatory frameworks and the myriad of available regulations, directives, delegated acts, etc.

For instance, biostimulants, whose function is to stimulate plant nutrition processes independently of the products nutrient content, encompass a wide variety of components, such as micro-organisms, amino acids, humic acids, fulvic acids, seaweed extracts, plant extracts, or synthetic substances. Some of which may also be authorised as active substances in accordance with the Plant Protection Products Regulation. Nevertheless, substances known to have a pesticidal or other plant protection effect may still be included in biostimulant products provided that the label claims remain within the scope of the Fertilising Products Regulation or National Applicable Frameworks.

The criteria for determining whether a product may or may not fall within the scope of an applicable regulation can be a complex decision.

Key considerations are:

- ▶ What are the intended uses and how is it applied?
- ▶ What are the claimed effects/benefits e.g. controlling a pest or influencing the life process of a plant?
- ▶ What is the mode of action?
- ▶ What are the known precedents that have already been set by other decisions?
- ▶ Which are the target markets for commercialisation of your products?
- ▶ What level of investment can your enterprise afford?

Efficient commercialisation of borderlines products requires in-depth knowledge of the various routes to market, in a constantly evolving regulatory landscape. Our experts can evaluate the appropriate regulatory framework for your product and develop a regulatory strategy that is tailored to your organisational needs. Once a strategy has been identified, we can prepare and submit high quality technical dossiers and manage your regulatory submission through to compliant commercialisation and beyond.

## Our services at a glance

- ▶ Development of cost-effective regulatory strategies to meet your commercialisation timelines.
- ▶ Identification and assessment of data gaps to efficiently address regulatory requirements.
- ▶ Technical and scientific support.
- ▶ Global regulatory services provided by local experts, to support your global commercialisation strategies.
- ▶ Submission and post submission support.
- ▶ Certification support for organic use.
- ▶ Workshops and seminars to meet your organisations training needs.

## knoell: your go-to partner for registration – worldwide

Think globally, act locally. Our strength is being where it matters: with sites in Europe, Asia, North America as well as a global network of co-operation partners, we combine global know-how with local experience and intercultural knowledge. Our dedicated teams support you in all phases of registration, from planning right through to the market launch of your product and beyond.

For further information on crop nutrition products and our services, please contact us:  
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