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Registration - a global competence

Registration is a demanding discipline which involves keeping the ball rolling right up to the finishing line.

Cheminova has many assets – production facilities, patents and human resources – and a very valuable asset which may be less conspicuous, our product registrations. These product registrations are the authorities' approvals which allow us to sell our products. It is therefore important that we continue to invest resources in maintaining and developing these registrations. Considerable sums are invested in obtaining and maintaining approvals, mostly in the EU and the USA.

Very strict registration authorities in the EU and the USA

Both in the EU and in the USA, strict quality requirements apply to crop protection products, and documenting the quality of the products must meet similarly strict requirements. Fortunately, Cheminova's competent employees can ensure that the company always supplies high-quality products. In the EU and the USA, extensive data concerning health and safety issues must be provided. The scientific questions which we must answer are comprehensive and focus on risk assessments. Here, Cheminova spends millions of kroner annually on scientific tests to measure the risk to people and the environment and the effectiveness of its products.

Many-sided tests

To assess the possible hazardous properties of the products, testing for side-effects is carried out on mammals, fish, birds and a large number of other organisms

which are exposed to the products one or more times and in some cases throughout their lives. Special studies are also required which provide a basis for assessing the risk of undesired effects on reproductive ability, the hormone system and foetal development.

Scientists from industry, the authorities, universities and private laboratories have for many years worked together to develop the best possible test methods, which means that new tests have been devised and that test standards are becoming increasingly complex.

The question of the extent to which farmers and consumers are exposed to pesticide residues is answered with reference to field tests involving, for example, the spraying of a vine field and measuring residual concentrations over a period of time. Residual concentrations can be determined in soil, water and crops, but also in urine samples from sprayer operators and field workers. In some cases, some of the analyses can be replaced by computer calculations based on approval models. Advances within analytical chemistry have meant that incredibly low levels of pesticide residues can be measured and used to determine safety thresholds.

Breakdown products included

Not only ingredients are included in the analysis. Sunlight, water and bacteria as well as enzymes in the sprayed plants break down the compounds. Consequently, assessments and measurements of breakdown products are also included



Field testing the environmental impact of new products.



Registrations



when assessing the risk profile for Cheminova's compounds. The general picture must be summarised to assess the potential risk posed by individual products. The standards applied by the registration authorities in the different countries vary.

Own experts rather than consultants

Cheminova can conduct the chemical analyses of the products at our own laboratories, but the rest of the investigations are left in the hands of external laboratories which are authorised by the authorities.

In the past, Cheminova has used consultants to monitor these investigations, but the Registration department has gradually taken on more scientific employees around the world so that we can now handle data development and risk assessments of our products, while the tests as such are still outsourced to competent laboratories.

Impossible to control everything, but efforts successful

The entire process is not only costly, it is also extremely time-consuming. Many investigations take a year or more. Sometimes problems arise which we cannot control, for example weather conditions which destroy the test fields, and the tests must be repeated. Planning and monitoring activities is therefore extremely important. Meeting deadlines in a complicated global test programme is decisive to being the first to market.

Our results so far from all the regions demonstrate the value of international collaboration, efficient communication and professionalism, and we can be rightly proud of the way in which our major investments in registration activities is administered.

Trials with midge larvae in mud samples.

