

ECOspray Ltd and Regulatory Approvals For Botanical Extract as Pesticides and Biocides.

This summary has been prepared to assist delegates in formulating questions on regulatory matters related to plant extracts and IPM technology.

1.0 Preliminaries

ECOspray Ltd is a UK based company formed in 1997 specialising in manufacture and research and development of garlic extracts for use in agriculture.

In 2005, ECOspray Ltd gained an approval under UK COPR for a garlic-based product to be used as a biocide against poultry red mite. This was followed in 2006, with Danish approvals for two other garlic-based products as insecticides for use against cabbage root fly in brassicas.

ECOspray Ltd has also completed the notification procedure for these and other garlic-based products under EU directive 91/414 and has submitted the dossier to also support these products as biocides under EU directive 98/8.

The review of the dossier to support ECOspray Ltd garlic based products under directive 91/414(stage 4 products) is now complete with DAR about to be circulated. ECOspray Ltd has been given to understand that recommendations for annexe1 listing have been made in the DAR. On the basis of the progress made with notifications, The Republic of Ireland has also recently issued labels for ECOspray Ltd garlic-based products for use as insecticides and nematicides.

With the body of data quickly developing around ECOspray Ltd garlic products, the company is now seeking to gain full 'on label' approval for a new nematicide that will hopefully compete with materials such as Temik and Vydate.

2.0 The regulatory review process.

The UK approvals have been conducted under the full conditions of the COPR regulatory framework, with data requirements being identical to those required for a new 'synthetic' active. The ongoing approvals process at national level in the EU is still for the most part using the existing data requirement frame works, although regulators appear now to be interpreting data requirements with a degree of latitude reflecting the increasing political will for less onerous review on intrinsically safer materials.

The experience of ECOspray Ltd as a 'test case' for regulating plant extracts as pesticides and biocides in the EU is now therefore very considerable and possibly unique, with the company able to relate the review process and data requirements to the actual effort and expense required to navigate through to successful outcome.

3.0 ECOspray Ltd and IPM

The company have designed numerous insect traps that are used to determine insect populations around crop plants. Introduction of these devices to the EU market has given ECOspray Ltd a very broad base of experience in IPM matters relating pest pressure to pesticidal interventions.

This experience is gaining considerable momentum in the organic sector, with numerous producers becoming increasingly confident in the value and implementation of sound IPM practices to increase efficiency and profitability.

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September 2006.