



### › Our undertakings:

- Personalised review of the manufacturer's application.
- Preliminary study of the dossier to determine the tests and evaluations necessary.
- Possibility of total compilation of the dossier through to its submission to the competent authority for market authorisation.
- Performance of tests set out in Directive 98/8/EC.
- Establishing deadlines and ensuring they are adhered to according to the work plan agreed with the manufacturer.
- Mobilisation of FCBA's multi-disciplinary skills and resources to ensure the dossier is a success.

Through our involvement in discussions and working parties on products assessment for the OECD, the European Commission and French Government (Ministry of Ecology, French Environmental Health Safety Agency), we are today able to provide you with top quality assistance to ensure the success of your marketing authorisation application.

### Contacts

#### Biological tests:

• Mycology:	Isabelle Le bayon	Tel. : +33 (0)5 56 43 63 68 isabelle.lebayon@fcba.fr
• Entomology:	Ivan Paulmier	Tel. : +33 (0)5 56 43 63 61 ivan.paulmier@fcba.fr
<b>Physico-chemical tests:</b>	Élisabeth Raphalen	Tel. : +33 (0)5 56 43 63 78 elisabeth.raphalen@fcba.fr
<b>Ecotoxicological tests:</b>	François Chastenet	Tel. : +33 (0)5 56 43 63 55 francois.chastenet@fcba.fr
<b>Initial technical support and compilation of the dossier:</b>	Gérard Deroubaix	Tel. : +33 (0)1 40 19 80 86 gerard.deroubaix@fcba.fr
	Éric Heisel	Tel. : +33 (0)5 56 43 63 37 eric.heisel@fcba.fr
	Dominique Ambrosi	Tel. : +33 (0)3 85 35 67 14 dambrosi@ambrosiconsulting.com

## DIRECTIVE 98/8/EC Market authorisation

### › A synergy of skills to deliver successful projects

- Initial technical support
- Tests (annexes IIA, IIB, IIA and IIIB)
- Compiling and supervision of market authorisation dossiers



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### › Your challenges:

Obtaining market authorisation for biocides and making applications for them is one of the major challenges facing the manufacturers of active ingredients, preservative products, termites-control products as well as wood coating products.

To meet the demands which these objectives entail, FCBA is offering the industry all its resources and skills throughout the process leading up to market authorisation. FCBA's approach is well-structured and perfectly tailored to suit your particular needs.

### › FCBA provides you with focus and support:

FCBA will help you meet this challenge and determine exactly what needs to be done to receive marketing authorisation. FCBA will offer you initial technical support – by objective study of your needs and analysis of your existing resources – which is designed to take stock of the situation, then to reach a joint decision on the actions to be taken through to submission of the dossier to the evaluation board.

As part of its support role, FCBA is willing to compile the dossier in its entirety, assembling all the documents required for its completion. FCBA can also, on behalf of the manufacturer applying for marketing authorisation, supervise the completion of the dossier by carrying out or outsourcing any missing tests, analysis and evaluations, particularly in terms of efficacy, but also with regard to the environment and health.



### › A complete range of tests at your service:

To receive market authorisation, the dossier must contain data resulting from a large number of tests as stipulated in the biocidal products directive. FCBA has the resources to perform most of these tests in its biology and ecotox-chemistry laboratories which are ISO 17025 certified and/or GLP approved.

#### • Biological efficacy tests:

These tests can be performed on active substances and biocidal products, and are carried out in accordance with the recommendations given in the Technical Guidance accompanying Directive 98/8/EC. Our biology laboratory is accredited by COFRAC (the French Accreditation Committee) for these types of test (insecticidal and fungicidal efficacy).

#### • Ecotoxicological tests:

The GLP-approved ecotoxicology laboratory performs all aquatic and terrestrial tests required by the directive: acute toxicity on fish and daphnie, growth inhibition tests, earthworm and terrestrial plants tests, microtox tests... Biodegradability test and fish embryo toxicity test are also proposed.

#### • Physico-chemical tests:

The tests outlined in annexes IIA, IIB, IIIA and IIIB can be performed by the chemistry laboratory, with in particular, development and validation of analysis methods. Though some tests may be carried out in partnership with other GLP laboratories, FCBA's chemistry laboratory will remain the main actor as far as the manufacturer is concerned. The laboratory can also perform tests measuring emissions from treated wood to different compartments (ground, water, air) using a variety of methods.

