eurofins | BioPharma Product Testing

Workshop

New insights of Biocide Product Regulation: strategies and perspectives of the authorization process

May 15th, 2018 – The Westin Palace, Milan

Speakers:

Raffaella Perrone
Ministry of Health (Italy)

Marcel Hulsmann
Account Manager Biocides - Ctgb (Netherlands)

An Vanden Bosch
Senior Project Scientist - Arche Consulting (Belgium)

Michele Cavalleri
GLP Facility Manager - Eurofins BioPharma Product Testing (Italy)

Anne-Laure Scelo
Environment Regulatory Expert - Staphyt Regulatory (France)

Andrea Drago
Entomology expert - Entostudio (Italy)

Daniela Romano
Project Manager of Biocidal Products - Eurofins BioPharma Product Testing (Italy)

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Introduction

Under the terms of the Regulation (EU) No. 528/2012, a biocidal product should contain active substances with a more favourable environmental and human health profile. To prevent undesired and harmful effects risk assessment for biocides has become a crucial part of the dossier for active substance approval as well as for biocidal product authorisation.

In addition efficacy data are required in order to ensure that the product is effective for the uses covered by the application and also that the risk to people and the environment is assessed and acceptable. The market claims submitted in connection with a product authorization must be supported by the necessary testing in order to assess whether the claims correspond to the results of the efficacy tests.

Companies must ensure that existing supply chain and biocidal products design are in compliance with the challenging regulatory framework.

After the remarkable success of the past edition, Eurofins BioPharma Product Testing Italy presents a dynamic and interactive Workshop with an enriched programme exploring regulatory aspects, risk assessment and efficacy testing of biocidal products.

This workshop represents a unique opportunity for participants to gain valuable insight from the significant experience of industry and regulatory experts that will provide key elements to determine a tactical and effective strategy implementation for the authorization process of biocidal products.

Who should attend

This workshop will be relevant to those in the biocidal products industry operating in the following departments: R&D scientists, Marketing Manager, Regulatory Affair Manager, formulators and all experts interested to enhance the learning experience on this topic.

Workshop language

The official workshop language will be English.

Benefits in attending

Be aware of the latest updates and perspectives of the BPR regulation.

Develop relevant risk assessment scenarios for the environment and human health in the context of the biocidal product authorization.

Understand the necessary and specific panel of efficacy testing to carry out in order to ensure safety and effectiveness of biocidal products.

Opportunity to bring your specific questions along to the workshop for discussion with industry leading authorities, experts and highly skilled consultants.

Programme

(9:00 - 9:30) Welcome address and introduction by Eurofins

Session 1: Regulatory update and risk assessment

(9:30 - 10:00) Experiences with BPR as eCA
Raffaella Perrone (Italian Ministry of Health)

(10:00- 10:30) Experiences with BPR as eCA
Marcel Hulsman (Ctgb)

(10:30 - 11:00) Coffee break

(11:00 - 11:30) How to manage the workload associated with large BPFs:
- Different strategies to reduce complexity
- Applying the risk envelope approach
- Case study on disinfectants

An Vanden Bosch (Arche Consulting)

(11:30 - 12:00) Environmental Risk Assessment for biocides: Latest development of guidance and guidance related documents
- Regulatory requirement for the environmental risk assessment under the BPR
- Latest updates about the effect assessment: PBT and endocrine disruptor issues
- Environmental exposure assessment: basic approach and challenges

Anne-Laure Scelo (Staphyt Regulatory)

(12:00 - 12:30) The ECHA Guidance on disinfection by-products: Risk assessment:
- Background on the disinfection by-products formation
- Product types relevant for the risk assessment
- Approach to the Human Health Risk Assessment
- Approach to the Environmental Risk Assessment

Daniela Romano (Eurofins BioPharma Product Testing Italy)

(12:30 - 14:00) Lunch break

Session 2: Efficacy Testing

(14:00 - 15:00) Efficacy testing within BPR:
- New trends in CEN TC 216 – Chemical Disinfectants and Antiseptics
- Insight on new guidance for tiered approach in order to differentiate active and non-active substances for BPR product authorization (CEN / ECHA joint approach)
- Focus on simulated use guidelines proposed for PT5 claims

Michele Cavalleri (Eurofins BioPharma Product Testing Italy)

(15:00 - 15:30) Efficacy test, procedures, guidelines and authorities:
- How testing should be performed to meet authorities requirements
- Available guidelines and their limits
- The importance of the product's claim

Andrea Drago (Entostudio)

(15:30 - 16:30) Efficacy study and specific claims:
- Insight on Laundry efficacy testing for PT2 products
- Insight on the new CEN airborne disinfection efficacy testing for PT2-PT4 products

Michele Cavalleri (Eurofins BioPharma Product Testing Italy)

(16:30 - 17:00) Q&A Session

Speakers

Raffaella Perrone
Italian Ministry of Health expert within the General Directorate for Medical Devices, Pharmaceutical Services and Safety in Healthcare.

Marcel Hulsman
With a degree in Chemical Engineering and a PhD in analytical chemistry gained experience as Laboratory Manager and Business Developing Manager. Since 2013 is covering the role of Account Manager Biocides at Ctgb, Dutch Board for the Authorisation of Plant Protection Products and Biocides.

An Vanden Bosch
She holds a degree in Bio-Engineering and a PhD in Medical Sciences. After several years in the crop protection industry as registration specialist, she moved to ARCHE Consulting in 2014, where she deals with the registration of active substances and products under the biocides and plant protection products regulations. Besides project management, her main focus lies on environmental exposure modelling and ecotoxicological risk assessments.

Michele Cavalleri
GLP Facility Manager of the Biocidal Products Division in Eurofins BioPharma Product Testing Italy. He has gained a solid expertise on efficay assessment of disinfectants. He is also member of the European Committee CEN TC 216 that establishes standardized methods of test and requirements for the antimicrobial efficacy of chemical disinfectants and antiseptics.

Anne-Laure Scelo
Agronomist with a PhD in environmental toxicology, has worked at Total Petrochemicals, INRA (French National Institute for Agricultural Research), CNRS (National Center for Scientific Research) and for 8 years has covered the role of scientist for Biocides and REACH-CLP regulations at ANSES (French Agency for Food, Environmental and Occupational Health & Safety). Within this framework, she was in charge of the exposure assessments and ecotoxicological risk assessments for substances and products. Since January she joined Staphyt Regulatory as a regulatory expert.

Andrea Drago
With a degree in Agricultural Sciences and a PHD in Public Health Sciences – Department of Parassitology – University of Rome "La Sapienza" he has gained a solid expertise in insecticides and repellents testing, field tests and protocol development for the control of pests. He is co-founder of Entostudio, entomologic laboratory specialized in consulting, pest control and insecticide and repellent testing.

Daniela Romano
Daniela holds a PhD in Biophysics and a Post Doc in medical research. She has joined Eurofins in 2003 and since 2013 she manages projects aiming to biocidal products authorisation. Her role focuses on supporting customers and risk assessors with data gap analyses as well as development of strategies for BPF.
Prior to her current position she has been in charge of stability studies and Chemical Laboratory Manager of the biocidal products division within Eurofins BioPharma Product Testing Italy.

Company profile

Eurofins BioPharma Product Testing, part of Eurofins Group, is the largest network of harmonised bio/pharmaceutical GxP product testing laboratories worldwide accross multiple industries. Our laboratories offer a broad range of methodologies under GMP and GLP authorization, ISO 17025 accreditation and ISO 9000 certification. We perform standard and customized efficacy tests on preservative and disinfectant products for all application areas.

Reservation Form (please complete in full):

Title, first name, surname _____

Company _____

Department _____

Adress _____

Phone _____ *Fax* _____

e-mail _____

Important: Please indicate your company's VAT ID Number

_____

If the bill-to-address is different please fill out here:

_____

_____

Registration fee:
Early bird: 200€ + VAT (if applicable) for submission within March 30th 2018 (extended).

Registration fee after March 30th 2018:
290€ + VAT (if applicable)
Discount rate for second participant: 250€ + VAT
Including: Workshop documentation, lunch and refreshment.
The registration fee is payable in advance.

A certificate of attendance for professional development will be given to each participant who completes the workshop.

General terms and conditions:

If you cannot attend the workshop you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- until 1 week prior to the conference 50% of the registration fee will be charged;
- less than 1 week prior to the conference full registration fee will be charged.

Eurofins BioPharma Product Testing reserves the right to cancel/alter the programme, the speakers, the date or venue. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Eurofins BioPharma Product Testing is not responsible for airfare, hotel or other costs incurred by registered delegates.

Terms of payment:

The registration fee is payable in advance.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
Only after we have received your payment, you are entitled to attend the workshop.

Date _____ Signature _____

Date:

Tuesday May 15th 2018, 09:30h - 17:00h
(Registration 08:45h-09:00h).

The Westin Palace, Milan
Piazza della Repubblica, 20, 20124 Milano
http://www.westinpalacemilan.com/
http://assets.westinpalacemilan.it/lps/assets/u/How_to_reach_us_palace-2.pdf

Registration:

Via the attached reservation form, by e-mail at:
FormazioneFarma@eurofins.com

Bank details:

UNICREDIT SPA
ABI: 2008 CAB: 20600 CIN: N
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We very much look to welcoming you on Tuesday May 15th 2018 in Milan.