

PROGRAMME

OECD Conference on RNAi based pesticides

10-12 April 2019

BACKGROUND INFORMATION

Externally applied double-stranded RNA (dsRNA) pesticides are based on an emerging technology. In 2015, the OECD Working Group on Pesticides (WGP) agreed to the establishment of an Ad Hoc Expert Group (EG) on RNA interference (RNAi)-based pesticides to examine if current assessment methodologies for conventional pesticides and biopesticides could be applied to them to a certain degree after they had been adapted accordingly. Since its formation the EG prepared a draft working document on “Environmental Risks from the Application of sprayed or externally applied dsRNA-Based Pesticides: Issues for Consideration” (conference’s background document), established the definition of the active ingredient/active constituent (AI/AC) for regulatory purposes and acquired funding from the OECD’s Co-operative Research Programme (CRP) to support the present conference.

ABOUT RNAi TECHNOLOGY

RNA interference (RNAi) is a biological process in which small ribonucleic acid (RNA) molecules inhibit gene expression, typically by causing the enzymatic destruction of specific messenger RNA (mRNA) molecules, which are the templates for the synthesis of proteins. This process is commonly referred to as post-transcriptional gene silencing (PTGS); that is, mRNA is transcribed from the DNA gene but before the message is translated into proteins by ribosomes, the mRNA is blocked or otherwise destroyed by an enzymatic process guided by a specific non-coding small interfering RNA (siRNA) or microRNA (miRNA).

In recent years, the application of RNAi-based technology has been investigated in human and animal therapies, and in the development of agricultural products. Using RNAi-based technology, plant protection against pests may be achieved among other ways by topical application (spraying) of dsRNA molecules (with a nucleotide sequence specifically developed to target a pest species) onto the plant. The dsRNA on the leaf surface may be directly ingested by feeding pests or, if the uptake of the dsRNA is facilitated in some way to aid penetration of the cuticle, the absorbed dsRNA molecules could possibly be processed to shorter siRNA molecules and distributed throughout the plant. The increasing development of these products has policy implications and guidance on regulating this technology is needed.

The OECD’s two and a half-day Conference will summarise the current state of knowledge and on-going developments that are relevant for the regulation of externally applied dsRNA-based products that are proposed for use as pesticides. Invited speakers include academic, industry and government experts in varying aspects of RNAi; presentations summarise environmental fate, exposure to externally applied dsRNA in non-target organisms, lessons gathered from human therapeutic use of dsRNA, and key points from previous regulatory reviews of dsRNA-based crop traits.

THE CONFERENCE STEERING GROUP

A steering group consisting of delegates nominated by OECD member countries has developed a balanced conference programme that is organised in three main sessions: i) Summary of the State of the Art: dsRNA-based Product Use in Agriculture; ii) Summary of Regulatory & Risk Assessment Experience with dsRNA-based Products; and iii) Discussion themes. The event will aim to provide a clearer understanding of the regulatory considerations raised by sprayable dsRNA-based products, aiming to favour a coherent policy approach to facilitate innovation involving RNAi technology.

THE CONFERENCE OUTPUTS

The Conference will provide participants with an update on the current status and future possibilities for the regulation of externally applied dsRNA-based products that are proposed for use as pesticides. The event will facilitate exchanges on their implications in health, environment, and regulation.

The main deliverable of the Conference will be a proceedings document comprised of a written version of each of the presentations. The publication of these proceedings is expected in 2020.

This conference will be followed by a meeting of the OECD EG RNAi-based pesticides that will discuss the outcome of the conference and draft recommendations that will be reviewed by the WGP. The WGP, formed by policy makers and stakeholders will decide on the following up steps.

Programme

OECD Conference on Regulation of Externally Applied dsRNA-based Products for Management of Pests

DAY 1 – 10 April 2019

9h30

Welcome by the OECD

Richard Sigman, OECD Environment Directorate

9h45

Welcome by the CRP and introduction to the Programme

András Székács, CPR Scientific Advisory Body

Session 1: Summary of the State of the Art: dsRNA-based Product Use in Agriculture

Chair: Achim Gathmann, Federal Office of Consumer Protection and Food Safety (BVL), Germany

This part of the first session will give some background on the molecular mechanism of RNAi and relevant related pathways, review the current understanding of cross-kingdom RNAi, examine the species-specificity of these dsRNAs on non-target species and discuss challenges related to the RNAi-efficiency in insects.

10h00

An introduction to RNAi technology

Petr Svoboda, Institute of Molecular Genetics of the ASCR, Czech Republic
(presentation: 25min; technical Q&A: 5min)

10h30

Potential for dsRNA-based management of plant diseases

Karl-Heinz Kogel, Justus Liebig University Giessen, Germany
(presentation: 25min; technical Q&A: 5min)

Tea/Coffee Break (11h00-11h30)

11h30

RNA interference technologies to control pests and pathogens

Steve Whyard, University of Manitoba, Canada
(presentation: 25min; technical Q&A: 5min)

12h00

RNAi as a novel technology in pest control: current status and challenges

Olivier Christiaens, Ghent University, Belgium

(presentation: 25min; technical Q&A: 5min)

Lunch break (12h30-14h00)

Chair: Dimitra Kardassi, European Food Safety Authority, EU

The following series of presentations will further discuss the research to date investigating the factors that affect insects' responsiveness to environmental dsRNA, cover approaches to assess biodegradation of dsRNA in different matrices and explore the role of RNA-Seq to predict genetic changes and impact the efficacy of RNAi products in target pests. They will also summarise the published literature related to dietary uptake of external dsRNA in humans and address the lessons learnt from human therapeutic use of dsRNA.

14h00

Variation in responsiveness to environmental dsRNA in insects

Ana María Vélez Arango, University of Nebraska, United States

(presentation: 25min; technical Q&A: 5min)

14h30

Potential for off-target effects in topically applied dsRNA-based products used for crop protection purposes

Gunter Meister, University of Regensburg, Germany

(presentation: 25min; technical Q&A: 5min)

15h00

Environmental dissipation of dsRNA in soil, aquatic systems and plants

Pam Bachman, Bayer

(presentation: 25min; technical Q&A: 5min)

Tea/Coffee break (15h30-16h00)

16h00

Validation of RNA interference by RNA-Seq: How to see the big picture

Brenda Oppert, United States Department of Agriculture, United States

(presentation: 25min; technical Q&A: 5min)

16h30

Dietary uptake of environmental dsRNA in humans and other vertebrates

Thais B Rodrigues, Greenlight Biosciences, United States

(presentation: 25min; technical Q&A: 5min)

17h00

Regulatory experience with antisense oligonucleotides for human use

Frank Holtkamp, Medicine Evaluation Board, The Netherlands

(presentation: 25min; technical Q&A: 5min)

17h30

Panel Discussion Session 1

Moderator: **Achim Gathmann**, Federal Office of Consumer Protection
and Food Safety (BVL), Germany

Reception: Salle Roger Ockrent (18h00-20h00)

Day 2 – 11 April 2019

Session 2: Summary of Regulatory & Risk Assessment Experience with dsRNA-based Products

Chair: Mike Mendelsohn, US Environmental Protection Agency

The second session will describe how problem formulation can guide risk assessments for spray applications of pesticides containing dsRNA, and consider potential pathways and testable risk hypothesis in the context of environmental risk assessment. It will also cover the experience gathered from the risk assessment of genetically-modified crop plants, which incorporate the machinery to synthesise RNA molecules specifically directed against a pest species feeding on the crop (so-called 'plant-incorporated protectants', or PIPs).

9h00

Problem formulation considerations for externally applied dsRNA-based products

Alan Raybould, Syngenta
(presentation: 25min; technical Q&A: 5min)

9h30

Ecological assessment of topically applied dsRNA-based products

Jörg Romeis, Agroscope, Switzerland
(presentation: 25min; technical Q&A: 5min)

10h00

Review of EFSA's activities on the risk assessment of RNAi-based GM crops

Nikoletta Papadopoulou, European Food Safety Authority, EU
(presentation: 25min; technical Q&A: 5min)

Tea/Coffee break (10h30-11h00)

11h00

The European perspective on regulatory aspects and experiences with dsRNA-based products

Achim Gathmann, Federal Office of Consumer Protection
and Food Safety (BVL), Germany

(presentation: 25min; technical Q&A: 5min)

11h30

Ecological Risk Assessment Considerations for in planta Expressed and Exogenously Applied dsRNA at the U.S. EPA

Shannon Borges, US Environmental Protection Agency, United States

(presentation: 25min; technical Q&A: 5min)

12h00

A perspective on risks associated with dsRNA-based products

Neena Mitter, Centre for Horticultural Science, Australia

(presentation: 25min; technical Q&A: 5min)

12h30

Panel discussion Session 2

Moderator: **Mike Mendelsohn**, US Environmental Protection Agency

Lunch break (13h00-14h00)

Session 3: Discussion themes

14h00

Background to the draft OECD Working Paper on 'Environmental Risks from the Application of dsRNA-Based Pesticides'

Les Davies, OECD consultant

14h30

Discussions themes

Environmental Fate of dsRNA

Facilitator 1: **Pam Bachman**

Tea/Coffee break (15h45-16h15)

16h15

Non-target Organism Assessment (Part 1)

Facilitator 2: **Shannon Borges**

Facilitator 3: **Joerg Romeis**

17h30

Summary of discussions

Facilitators 1-3

Day 3 - Discussion themes (Cont.)

9h00

Non-target Organism Assessment (Part 2)

Facilitator 2: **Shannon Borges**

Facilitator 3: **Joerg Romeis**

Tea/Coffee break (10h15-10h45)

10h45

Human Health Assessment

Facilitator 4: **Les Davies**

Facilitator 5: **Alan Raybould**

Lunch (12h00-13h00)

13h00

Summary of discussions

Facilitators 2-5

13h30

Wrap-Up and Leaving Address by the CRP

András Székács, CPR Scientific Advisory Body

13h45

Conference Results and next Steps

Mike Mendelsohn, US EPA

Dimitra Kardassi, EFSA

Achim Gathmann, BVL

Magda Sachana, OECD

14h00

Conference closes



For more information:

 ehs.contact@oecd.org

 oe.cd/rnai-pesticides

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