Industry perspective of the BPR Regulation (EU) No 528/2012

Dr. Irene McGrath
Managing Director
Kerona Scientific Ltd.
12th March 2020

Kerona Scientific Ltd.

- Regulatory consultancy
- Founded 2014
- HQ Ireland (Skerries)
- Office in Madrid, Spain
- Worldwide client base
- PPP, biocide, PB clients
- Multilingual multidisciplinary team
- www.kerona.ie

Dr. Irene McGrath

Kerona
Scientific Ltd.

- Over 26 years managing Regulatory Departments in industry and working as a consultant for the regulation of plant protection products, biocides, plant biostimulants and fertilisers in the EU
- B.Sc. Analytical Science, Ph.D. Chemistry
- Diploma in Project Management
- Founded Kerona Scientific Ltd in 2014
- Email: irene@kerona.ie

Our biocide projects

Kerona
Scientific Ltd.

- Representation with the MSCA
- Notifications in Ireland and other EU MS, registration in Turkey
- Study commissioning
- Additional product types (PT) for existing AS at EU level
- Complete BPR dossiers (IUCLID, product assessment report (PAR), SPC, R4BP3 submission)
- Risk assessments (human health, environment, ED assessment, higher tier risk mitigation)
- Biocidal Product Family (BPF) dossiers
- Task force representation
- Main product types (PT) 1-5, 7-9, 14/18/19
- Technical equivalence under the BPR
- Chemical and microbial AS

Main areas to be discussed

Kerona
Scientific Ltd.

- Industry obligations under the BPR:
  - Knowing the status of your AS at EU level
  - BPR submission deadlines
- Data requirements for BP authorisation under the BPR
- Data sharing: Article 95/Letters of access
- Biocidal Product Families (BPF)
- Same biocidal products (SBP)
- Union authorisation
- Simplified authorisation (Annex I substances)
- Endocrine disruption (ED assessment)

EU Status of an AS

Kerona
Scientific Ltd.

- AS is always approved in relation to one or more PTs
- Existing AS: on EU market on 14 May 2000 as an AS of a BP
- New AS: not on the market on 14 May 2000 as an AS of a BP
- Very few New AS: applications triggered by industry
- Existing AS: safety is evaluated via the Review Programme
- While AS is in review programme (pending an inclusion/non inclusion decision), BP can be marketed via national rules during the 'transitional period'
- AS approval date is the data submission deadline for BP re-authorisation dossiers

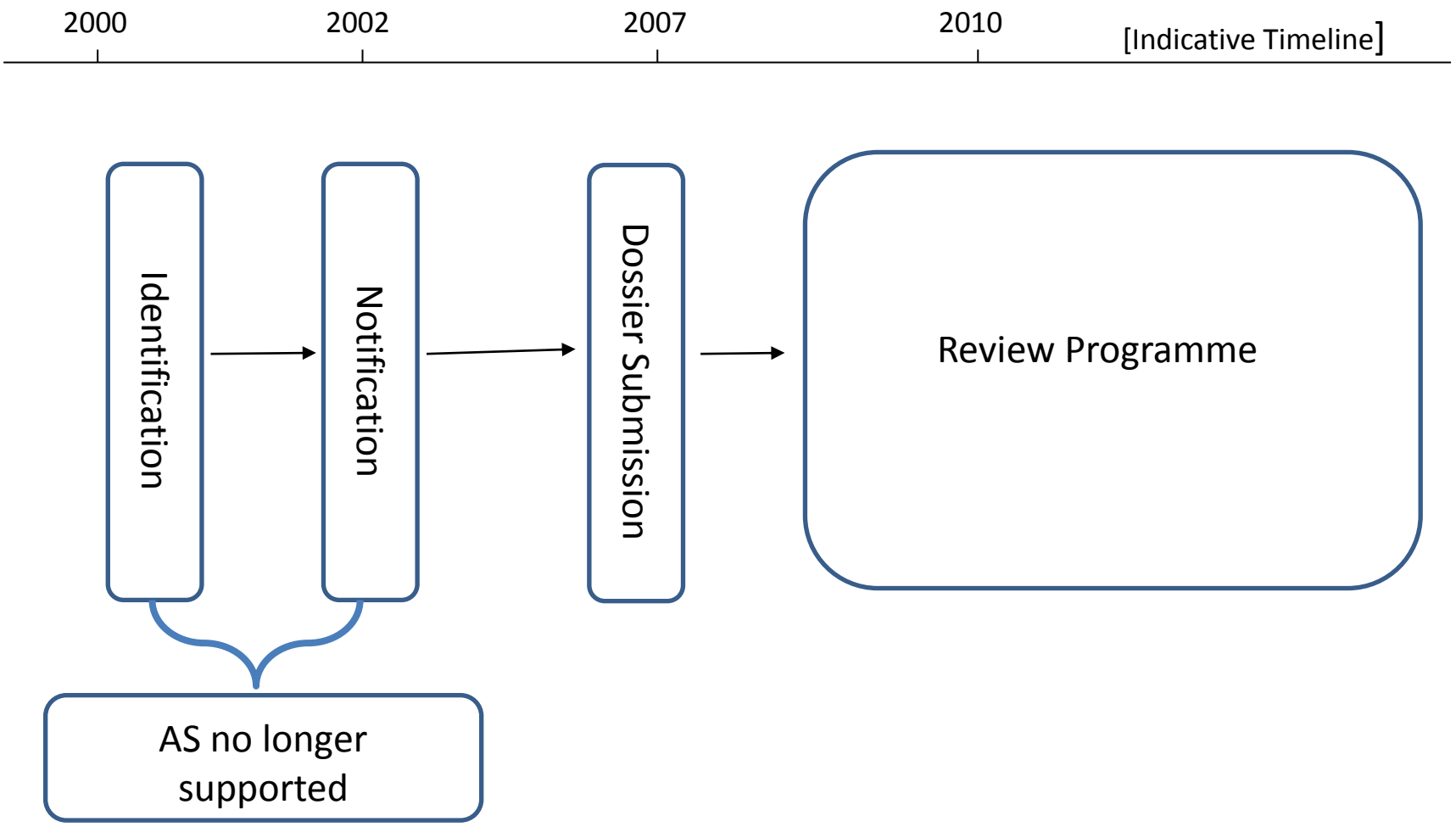
BPs – transitional measures

Kerona
Scientific Ltd.

- For BPs already authorised, the authorisation is still valid under the BPR until its expiry date or unless cancelled
- Many existing AS's still under evaluation in the Review Programme - will continue until at least 2024, until all AS evaluated
- BPs containing AS's under evaluation in the Review Programme can continue to be marketed in the EU according to MS national rules (varies by MS) provided Art. 95 requirements are met ('transitional period')
- Once the AS is included in the approved list at EU level for a certain PT, an application for authorisation of the BP of that PT must be submitted

Review of existing AS

Kerona
Scientific Ltd.



Time limits for evaluation of existing AS/PT's – Annex III of the Review Programme Regulation

Kerona Scientific Ltd.

Priority list	Product-types	Evaluation (submit assessment report)	Start BPC opinion	Progress (% evaluations finalised)
1	8, 14, 16, 18, 19, 21	31/12/2015	31/3/2016	77
2	3, 4, 5	31/12/2016	31/3/2017	30
3	1, 2	31/12/2018	31/3/2019	31
4	6, 13	31/12/2019	31/3/2020	24
5	7, 9, 10	31/12/2020	31/3/2021	15
6	11, 12, 15, 17, 20, 22	31/12/2022	30/9/2023	10

Status of the Review Programme

Kerona
Scientific Ltd.

- 253 AS/PT combinations finalised
- 474 combinations ongoing
- As of Feb 2020, 35% of programme completed
- Completion deadline: end 2024
- 95 decisions per year now needed to meet the deadline
  - Only 52 in the last three years!
- Drop in delivery of BPC opinions
- Delays from applicants & MS:
  - Redefined in-situ active substances – increased work programme
  - Assessment of endocrine disruptors – new criteria since Jun 2018

Sample timelines – chlorine based disinfectants

Kerona Scientific Ltd.

- AS's: NaClO, Cl_2, $Ca(ClO)_2$
- In situ generated AS – e.g. active chlorine released from calcium hypochlorite
- Two of the top three biocides based on production
- Task force/consortia set up with many companies taking part
- Three separate AS dossiers submitted under the BPR
- Supporting PT 1, 2, 3, 4, 5 (11 and 12)
- Dossiers submitted in 2007
- Final CA decision PT 1-5 in 2017, approval date 1/01/2019
- Final authorisations due in 2020 (PT 1 – 5)
- PT 11, 12 still under review

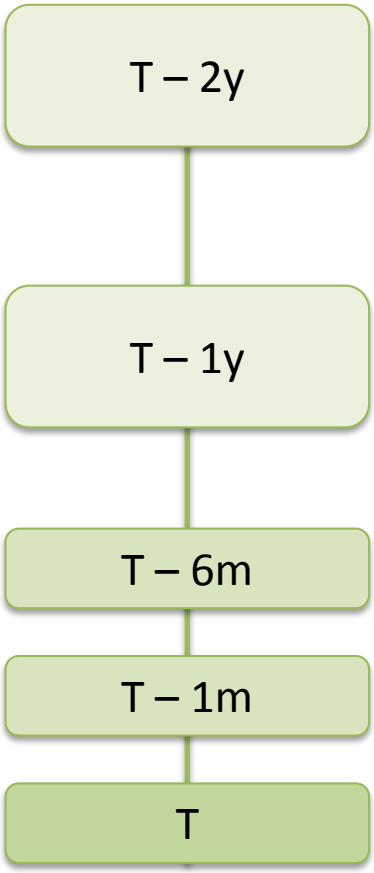
Case study - Sample AS approval – Chlorocresol (CMK) for PT13

Kerona Scientific Ltd.

- Biocidal Products Committee (BPC) meeting minutes 13-14 April 2016 – The BPC adopted by consensus the opinions for the approval of this AS/PT combination – see minutes published on ECHA website
- BPC opinion dated 13/04/2016 - published on ECHA website
- Assessment report dated April 2016 published on ECHA website
- Commission implementing Regulation (EU) No 2016/1931 published 4 November 2016 approving chlorocresol as an existing AS for use in BPs of PT13 – published on EUR-Lex
- **Date of approval in the implementing Regulation - 1 May 2018 for PT13**
- Product authorisation dossiers for chlorocresol containing BPs of PT 13 had to be submitted by 1 May 2018

Timeline - BP dossier preparation

Kerona Scientific Ltd.



Decide which product(s) you are supporting
Conduct data gap analysis, start ambient shelf-life study
Consider consortia formation early
Consider BPF strategy - efficacy/phys-chem testing

Get access to the active substance (LoA or other)
Preliminary risk assessments – based on actual use
Discuss approach with eMS
Create a draft PAR, IUCLID file, SPC

If using UA, deadline ECHA pre-submission (similar use)

Submit your dossier and payment

AS approval date = BP dossier submission deadline

Data requirements for BP

Kerona Scientific Ltd.

Data point	Title
1	**Applicant**
2	**Identity of the biocidal product**
3	Physical, chemical & technical properties
4	Physical hazards
5	**Methods of detection & identification**
6	Effectiveness against target organisms
7	Intended use & exposure
8	Toxicological profile for humans & animals
9	Ecotoxicological studies
10	Environmental fate & behaviour
11	Measures to protect humans & environment
12	Classification, labelling & packaging
13	Evaluation & summary

Product identity and detection

Data requirements for BP

Kerona
Scientific Ltd.

Data point	Title
1	Applicant
2	Identity of the biocidal product
3	**Physical, chemical & technical properties**
4	**Physical hazards**
5	Methods of detection & identification
6	**Effectiveness against target organisms**
7	Intended use & exposure
8	**Toxicological profile for humans & animals**
9	**Ecotoxicological studies**
10	**Environmental fate & behaviour**
11	Measures to protect humans & environment
12	Classification, labelling & packaging
13	Evaluation & summary

Data requirements for BP

Kerona Scientific Ltd.

Data point	Title
1	Applicant
2	Identity of the biocidal product
3	Physical, chemical & technical properties
4	Physical hazards
5	Methods of detection & identification
6	Effectiveness against target organisms
7	**Intended use & exposure**
8	Toxicological profile for humans & animals
9	Ecotoxicological studies
10	Environmental fate & behaviour
11	**Measures to protect humans & environment**
12	**Classification, labelling & packaging**
13	**Evaluation & summary**

Product assessment and use

Access to protected data

Kerona
Scientific Ltd.

- AS data is required for BP authorisation – LoA can cover this
- Letter of access gives the competent authorities permission to use data from one applicant for the benefit of another applicant
- LoA doesn't automatically provide a copy of the data to the applicant
- Each LoA is negotiated individually

Article 95 list

Kerona
Scientific Ltd.

- List of relevant substances and the respective substance and product suppliers - The list of 'accepted sources' of AS's that can be used in BP's
- To 'ensure the equal treatment of persons placing AS on the market'
- ECHA is responsible for publication of the list
- BP cannot be made available on the market unless either the substance supplier or the product supplier is included in the Article 95 list for the relevant product type
- AS must be sourced from companies on the list

Active Substance Name	EC number	CAS number	PT	Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
(3β,5Z,7E)-9,10-secocholesta-5,7,10(19)-trien-3-ol (Cholecalciferol)	200-673-2	67-97-0	14	BASF Agro B.V. Arnhem (NL) Freienbach Branch	Switzerland	Substance Supplier	New Active	24-Sep-14
(3β,5Z,7E)-9,10-secocholesta-5,7,10(19)-trien-3-ol (Cholecalciferol)	200-673-2	67-97-0	14	Bayer S.A.S	France	Substance Supplier	New Active	24-Sep-14
(9Z,12E)-tetradeca-9, 12-dien-1-yl acetate	Not allocated	30507-70-1	19	Aeroxon Insect Control GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
(9Z,12E)-tetradeca-9, 12-dien-1-yl acetate	Not allocated	30507-70-1	19	Gea srl	Italy	Product Supplier	Third Party Dossier	24-Sep-14
(benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)	244-445-0	21564-17-0	9	Laboratorios Miret, S.A.	Spain	Substance Supplier	Art.95 submission	26-Jun-15

Technical equivalence

Kerona
Scientific Ltd.

- Article 95 is not automatically linked to Technical Equivalence - they are different procedures
- Article 95 is necessary to use an AS in a product, while technical equivalence refers to the source of AS used in the BP
- Technical equivalence to a reference source is only possible for an approved AS
- Important at the level of product authorisation – often overlooked

Issues with BP dossiers

Kerona
Scientific Ltd.

- Lack of data (especially storage stability, shelf-life – 2 years)
- Efficacy testing – check label claims and species controlled
- Biocidal Product Family (BPF) – splitting of a product range
- Failing risk assessments
  - some BP have limited options for refinement in the exposure scenarios
  - need for higher tier data or risk mitigation measures
- MSCA availability
  - Notice period
  - Pre-submission meeting?
- Data access/Article 95
- Need for foresight and planning

Biocidal product family (BPF)

Kerona
Scientific Ltd.

A group of biocidal products with:

- Same AS
- Similar uses
- Similar composition within specified variations so that
  - Level of risk is not increased
  - Efficacy of the product is not reduced

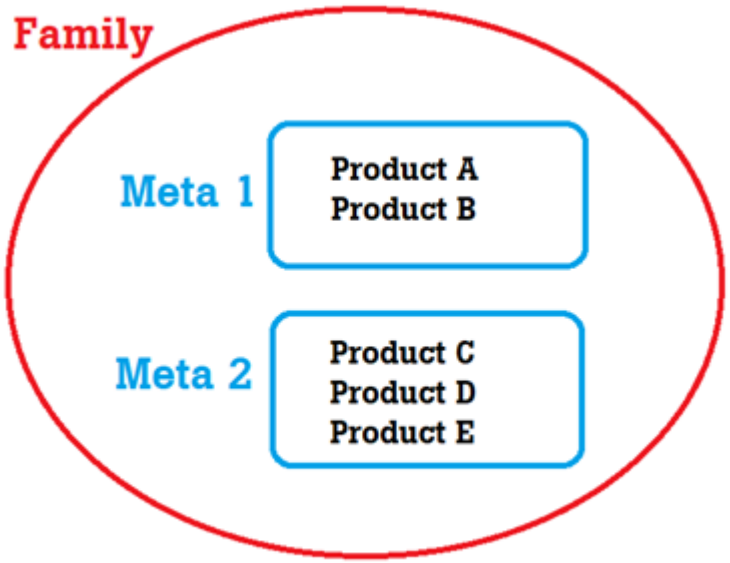
All products in BPF covered by one authorisation

Useful if many similar formulations with similar uses in the portfolio, and for product ranges that differ in e.g. AS concentration, colour/scent

Reduced administrative cost per product and burden in dossier management

Biocidal product family

BPs in family are defined by well-structured SPC (summary of product characteristics)



Meta-SPC: 3 levels of information

1. **Family**: General information that applies to all products
2. **Meta**: Formulation type, authorised uses, risk management measures and hazard and precautionary statements common to the products
3. **Product**: specific information at the product level

BPF - guidance

Kerona
Scientific Ltd.

- Note for Guidance on Implementing the BPF concept issued 2014
- New Note for Guidance: CA-July19-Doc4.2-Final
- Clarification of concept of similarity
- Addresses:
  - Best practice in pre-submission meeting
  - Assessment of similarity in BPF by applicants
  - Splitting of families for ongoing applications
- Once BPF established then draw up testing plan
  - Efficacy testing – lowest conc. in the meta grouping
  - Phys-chem – review each BP to determine testing
- Useful ctgb template for BPF structure: https://english.ctgb.nl/biocidal-products/documents/application-form-biocides/2017/05/11/product-family-structure

Union authorisation (UA)

Kerona Scientific Ltd.

- Authorisation is given by the Commission
- Access to entire EU market via single authorisation
- BPs with 'similar conditions of use across the Union'
- Not applicable to AS meeting the exclusion criteria
- Expensive: €80,000 ECHA fee per product (€150,000 per family) + MS fees (varies by MS) + annual fee of €10,000 (€20,000 per family)
- Fee reductions possible for SMEs
- Phased introduction by PT:

Product types	Introduction of UA
1, 3, 4, 5, 18, 19	From 1 September 2013
2, 6, 13	From 1 January 2017
7, 8, 9, 10, 11, 12, 16, 22	From 1 January 2020

Same Biocidal Product (SBP)

- Defined in Commission Implementing Regulation (EU) No 414/2013:
  - "… a product … which is identical to another single BP, BPF, or individual product of a BPF which has been authorised or registered in accordance with Directive 98/8/EC… or Regulation (EU) No 528/2012, or for which an application for such authorisation has been submitted (the 'related reference product' (RRP))"
- Official MS procedure for the authorisation of back-to-back products and marketing authorisations (letter of access must be obtained from authorisation holder of the RRP)
- Can apply for authorisation of a SBP where an identical BP (RRP) is already authorised or is under evaluation
- UA applications often include SBP

Same Biocidal Product (SBP)

Kerona
Scientific Ltd.

- Provision for SBP authorisation on a member of a BPF or the whole family
- As long as the formulations are the same, allows ‘same products’ to be formulated independently by individual companies
- Allows ‘same product’ companies to obtain non-active ingredients from alternative sources to those used by the lead
- Allows ‘same product’ companies to obtain AS from alternative sources to those used by the lead as long as they are included on the Article 95 list
- Fees for UA of a SBP - €2,000; fees also payable to eCA

Simplified authorisation

- ‘To encourage the use of products with a more favourable environmental or human or animal health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products’

- Product authorisation criteria
  - AS in Annex I
  - No substances of concern or nanomaterials in product
  - Product is sufficiently effective
  - No PPE is required for handling/use

- Authorisation procedure:
  - Application made to ECHA
  - One MS will evaluate
  - Product can be placed on market in all MSs – notify with no need for MR

Annex I categories

Kerona
Scientific Ltd.

Category	Description
1	Food additives (Reg. (EC) No. 1333/2008)
2	Substances included in Annex IV of REACH
3	Weak acids
4	Traditionally used substances of natural origin
5	Pheromones
6	Substances included in Annex I or IA to the BPD
7	Other

Exclusion & substitution criteria

Kerona Scientific Ltd.

Exclusion criteria:

- Carcinogens, mutagens and reprotoxic substances (1A or 1B)
- Endocrine disruptors
- Persistent, bioaccumulative and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)

Substitution criteria:

- Based on intrinsic hazardous properties in combination with the use and potential exposure

Endocrine disruptors

Kerona
Scientific Ltd.

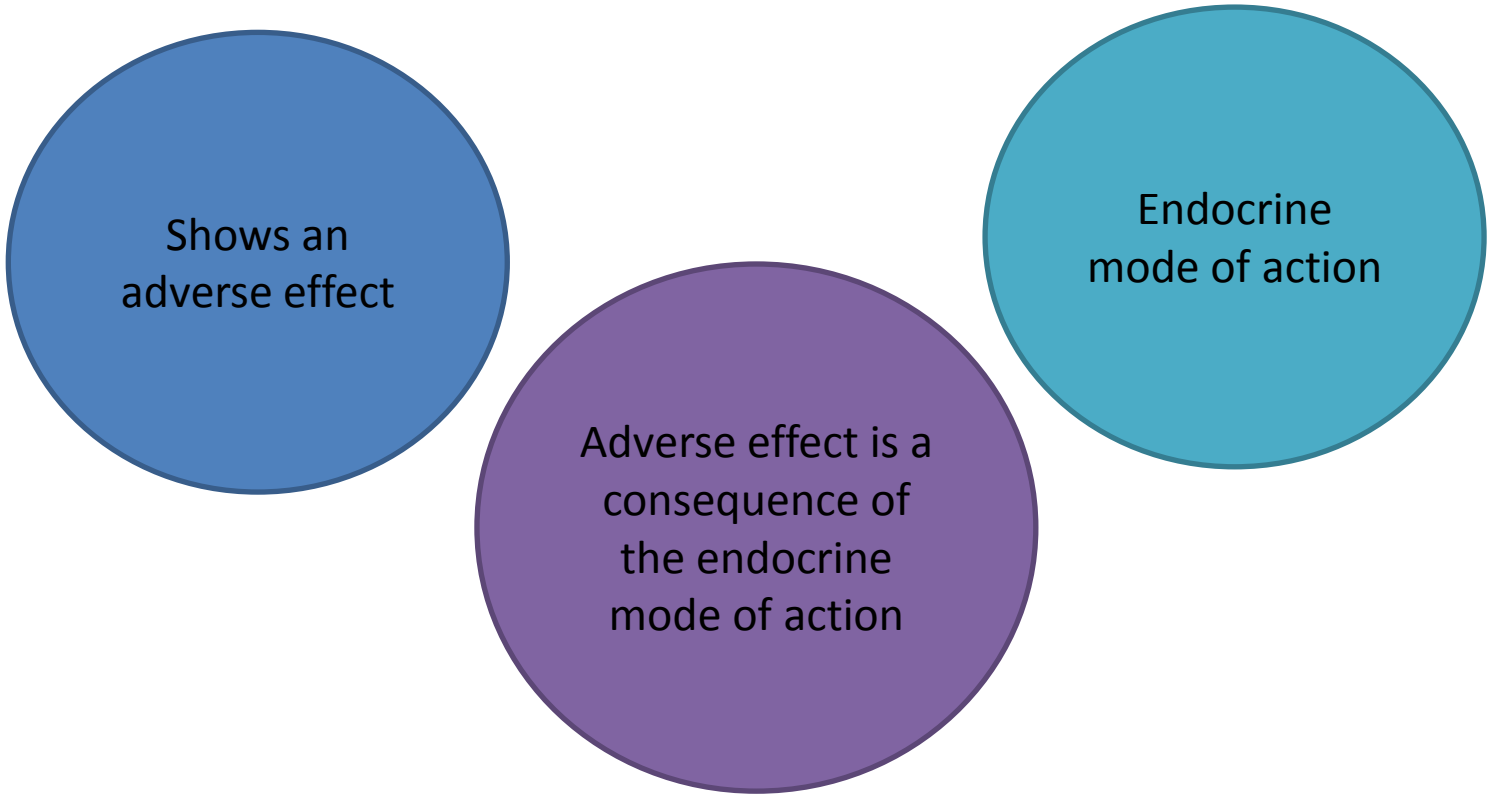
- Commission Delegated Regulation (EU) No 2017/2100
  - Scientific criteria for determining endocrine-disrupting properties pursuant to the BPR
  - Applicable from 07/06/2018

- Joint action by ECHA and EFSA
- Guidance document published 7/6/2018 EFSA Journal 2018;16(6):5311

ED criteria

Kerona
Scientific Ltd.

- Based on 2002 WHO/IPCS definition of an ED



Assessment of ED

Kerona
Scientific Ltd.

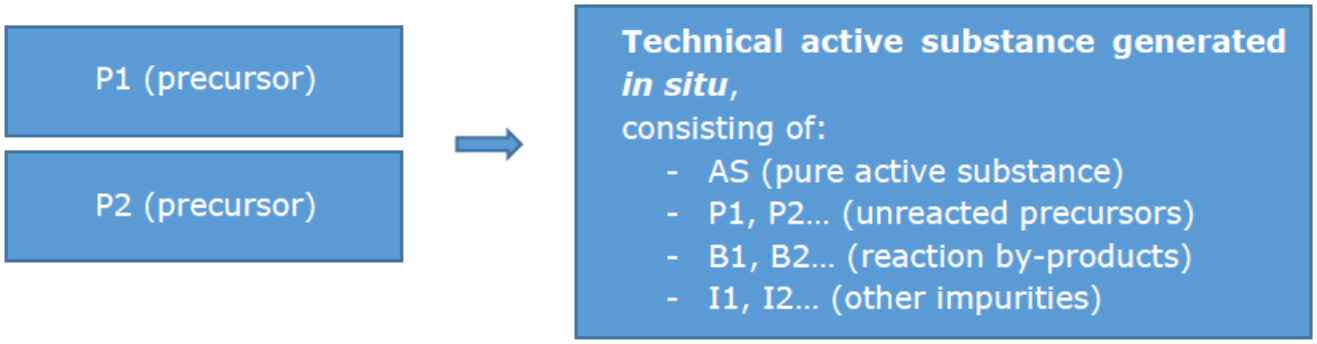
- *All available relevant scientific data* must be considered when determining ED properties
- Weight of evidence (WoE) approach for assessment of the data
- Strategy described in guidance document:
  - Gather all relevant information
  - Assemble and assess lines of evidence for endocrine activity and adversity
  - Initial analysis of the evidence
  - Mode of Action (MoA) analysis
  - Overall conclusion on the ED criteria
- Excel template for reporting the available relevant information

Treated articles

- ‘Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products’
- Treated articles do not need authorisation unless they have a primary biocidal function
- *Primary biocidal function* vs. *additional function:*
- Biocidal product = Antibacterial wipes
- Treated article = Socks with antibacterial function

In-situ generated AS

- AS generated from one or more precursors at the place of use
- Approval process involves the evaluation of the generated AS and the precursor(s) in the context of each product type



Examples:

Active chlorine generated from sodium chloride by electrolysis
Monochloramine generated from ammonia and a chlorine source
Peracetic acid generated from TAED and sodium percarbonate

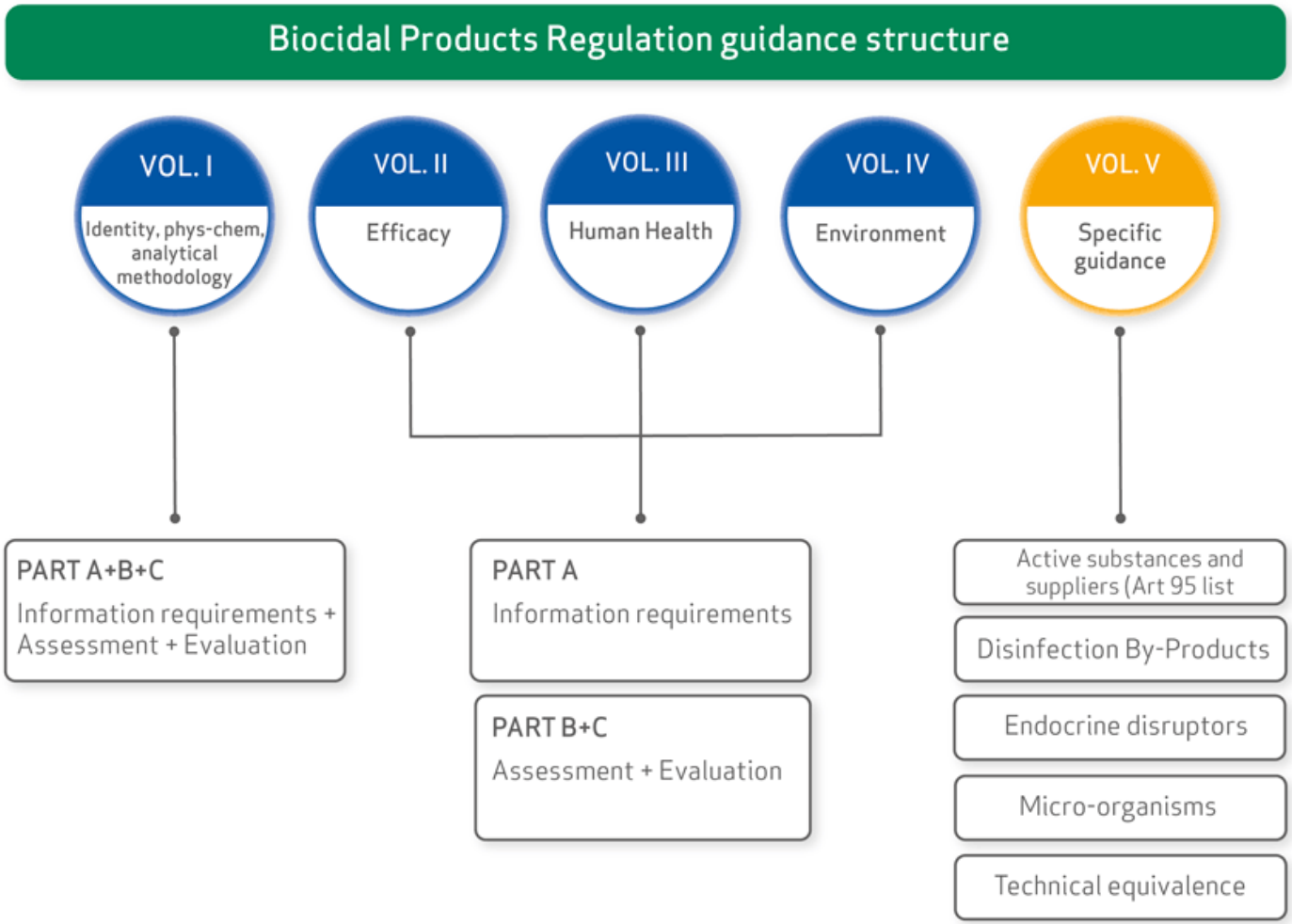
Differences to REACH

Kerona
Scientific Ltd.

- BPR considers products and AS (REACH - substances only)
- Under the BPR, every AS and BP is banned unless regulators give permission for marketing/use (in REACH only selected SVHC are banned unless authorised)
- Every BPR dossier is evaluated
- High regulatory cost of the BPR
  - No ‘fast-track’ system e.g. special consideration for low risk substances (e.g. microbials)
  - Adding additional PT
- Data requirements not tonnage dependent
  - Huge impact on SMEs
  - Discourages innovation - disincentive

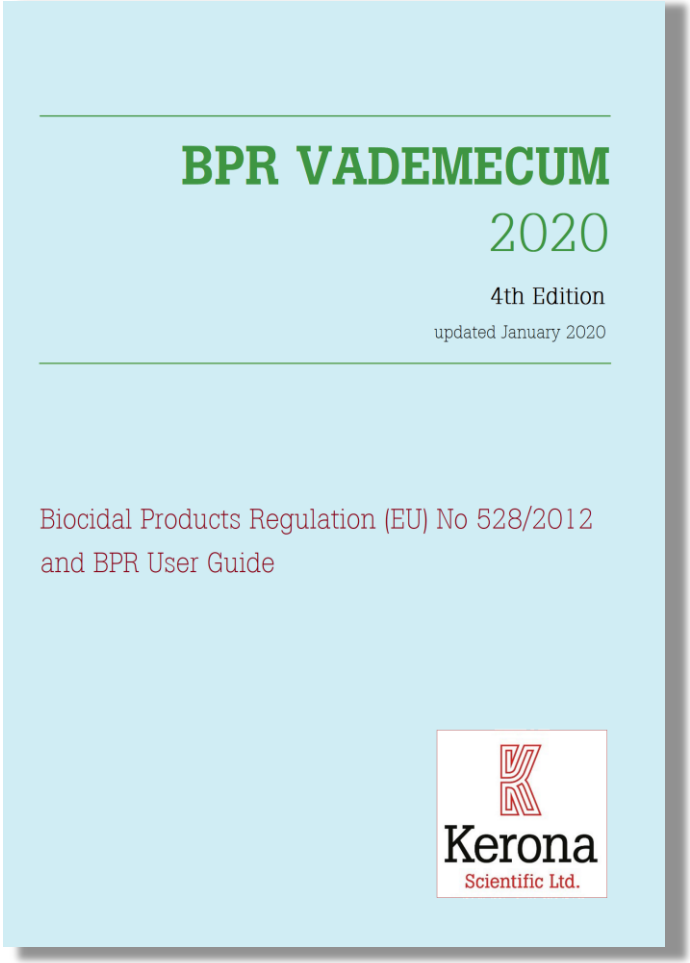
ECHA Guidance on BPR

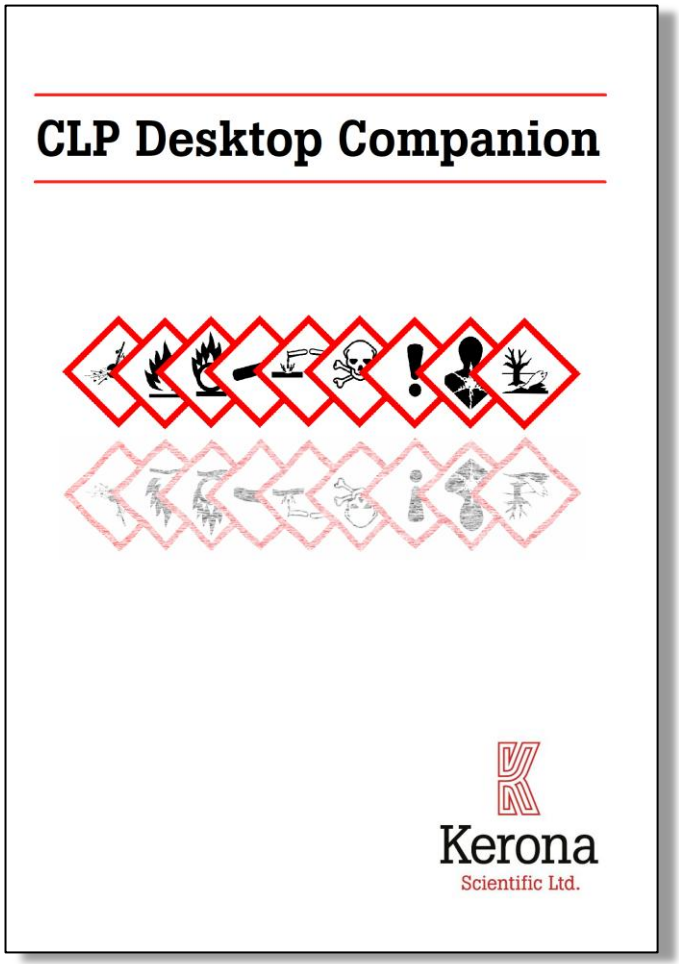
Kerona
Scientific Ltd.



Useful Publications

Kerona
Scientific Ltd.





Upcoming biocides training webinars

See www.kerona.ie/training

Kerona Scientific Ltd.

Free webinar

An introduction to technical equivalence under the BPR	13 May 2020

Biocides series

An overview of the BPR (Regulation (EU) No.528/2012	20 May 2020
Data requirements for biocidal products under the BPR	27 May 2020
Human health data requirements and risk assessment under the BPR	3 Jun 2020
Environmental risk assessment under the BPR	10 Jun 2020

Thank you – any questions?

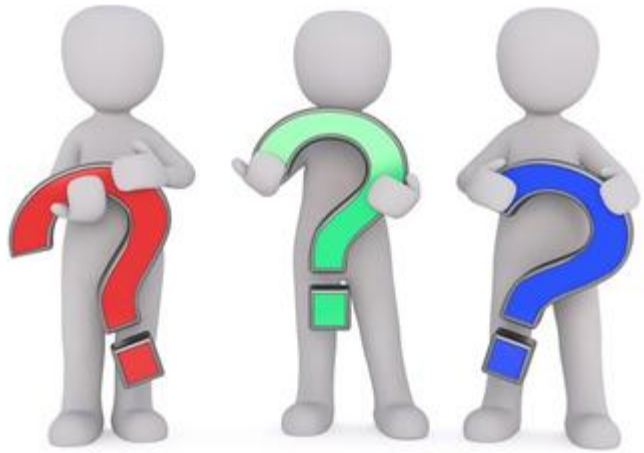
Dr. Irene McGrath

Managing Director

Kerona Scientific Ltd.

irene@kerona.ie

www.kerona.ie




Guiding you through the regulatory maze