US-FIFRA VERSUS EU-BPR
- An incomplete comparison
Diplomatic relations between the EU and the US date back to 1953.
Travellers’ trials and tribulations

[Images of various electrical plugs and adapters]
## Senior citizen versus 5-year old toddler

<table>
<thead>
<tr>
<th>US-FIFRA</th>
<th>EU-BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1947</strong></td>
<td><strong>2012</strong></td>
</tr>
<tr>
<td><strong>Data requirements</strong></td>
<td><strong>Information requirements</strong></td>
</tr>
<tr>
<td>Grouped in 5 categories, 4 use patterns plus 1 other. One is AF.</td>
<td>Essentially same for all 22 product types.</td>
</tr>
<tr>
<td><strong>United States</strong></td>
<td><strong>European Union</strong></td>
</tr>
<tr>
<td>= United States of America</td>
<td>≠ United States of Europe!</td>
</tr>
<tr>
<td>Federal system - Comprising 50 states</td>
<td>..., BUT... 28 EU Member States plus few other countries</td>
</tr>
<tr>
<td><strong>Not generally cause unreasonable effects</strong></td>
<td><strong>Precautionary principle</strong></td>
</tr>
<tr>
<td>Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications &quot;will not generally cause unreasonable adverse effects on the environment.&quot;</td>
<td>The purpose ... to improve the functioning of the internal market through the harmonisation of the rules ..., whilst ensuring a high level of protection of both human and animal health and the environment. ... underpinned by the precautionary principle, the aim ... safeguard the health of humans, the health of animals and the environment.</td>
</tr>
<tr>
<td>FIFRA defines ...: “...any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide,...”</td>
<td>Particular attention ... protection of vulnerable groups.</td>
</tr>
<tr>
<td><strong>Old and wise?</strong></td>
<td><strong>Young and reckless?</strong></td>
</tr>
</tbody>
</table>
United States of America ... Europe?

AI, MUP/EUP - Federal

MUP/EUP - States

AS - Union

BP - Member States
United States of America ... Europe?

AI, MUP/EUP - Federal

MUP/EUP - State

Limited information package
- State may set additional, stricter rules, requirements

AS - Union

BP - Member States
United States of America ... Europe?

AI, MUP/EUP - Federal

AS - Union

MUP/EUP - States

BP - Member States

No Union Authorisation for AF paints!

Mutual Recognition between MS, disagreement possible
Antimicrobial Policy and Guidance Documents

Efficacy Requirements for Antimicrobial Pesticides

Label Guidance for Specific Types of Pesticides

Antimicrobials used in fermentation of fuel ethanol -- cl

Implementation of the emerging pathogens and disinfec

Review process for the registration and use directions fo

Use of disinfectants and sanitizers in heating, ventilati

Guidance on Disinfectant Products Intended to Treat Drinking Water

Guidance on Whether Certain Claims Require Registration

- Determining if cleaning products are considered as pesticides under FIFRA

Contact Us to ask a question, provide feedback, or report a problem.

ICMCF Melbourne, Florida
<table>
<thead>
<tr>
<th>Guideline No.</th>
<th>Data requirement</th>
<th>Use pattern</th>
<th>Antifoulant coatings and paints</th>
<th>Wood preservatives</th>
<th>Aquatic areas</th>
<th>All other use patterns category</th>
<th>Test substance</th>
<th>Test note No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>850.2100</td>
<td>Acute avian oral toxicity</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>TGA1</td>
<td></td>
</tr>
<tr>
<td>850.1010</td>
<td>Acute freshwater invertibrates toxicity</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>TGA1</td>
<td></td>
</tr>
<tr>
<td>850.1075</td>
<td>Acute freshwater fish toxicity</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>TGA1</td>
<td></td>
</tr>
</tbody>
</table>

### Tier One Testing

**Avian Testing**
- 850.2200: Avian dietary toxicity
  - CR
  - CR
  - CR
  - CR
  - CR
  - CR
  - TGA1, TGA1
  - 4, 6

**Aquatic Organisms Testing**
- 850.1010: Acute freshwater invertibrates toxicity
  - CR
  - CR
  - CR
  - CR
  - CR
  - TEP
  - 2, 3, 5, 7

**Fish life-cycle**
- 850.1075: Acute freshwater invertibrates
  - CR
  - CR
  - CR
  - CR
  - CR
  - TGA1
  - TGA1

**Aquatic organisms, bioavailability, biomagnification, toxicity tests**
- 850.1710
  - CR
  - CR
  - CR
  - CR
  - CR
  - TGAI, PAI degrade
  - TGAI, PAI degrade
  - 11, 12

**Simulated or actual field testing for aquatic organisms**
- 850.1730
  - CR
  - CR
  - CR
  - CR
  - CR
  - TEP
  - TEP
  - 14, 15, 16

### Sediment Testing

- 850.1735: Whole sediment; acute freshwater invertibrates
  - CR
  - CR
  - CR
  - CR
  - CR
  - TGAI
  - TGAI

- 850.1740: Whole sediment; acute marine invertibrates
  - CR
  - CR
  - CR
  - CR
  - CR
  - TGAI
  - TGAI

### Insect Pollinator Testing

- 850.3020: Honeybee acute contact
  - NR
  - NR
  - NR
  - CR
  - TGAI

- 850.3030: Toxicity of residues to honeybees
  - NR
  - NR
  - NR
  - CR
  - TGAI

**Test note No.**
- 1
- 2
- 3
- 4
- 6
- 7
- 10
- 13
- 14
- 15, 16
- 17
- 19
- 20
- 21
Guidance on biocides legislation

The ECHA Guidance on biocides legis information requirements set by the Regulation (EU) 528/2012 (BPR) an assessments. It also explains the guid applications to be performed by the I.

In addition to the BPR guidance, Biod and other related documents are still submissions under the BPR in the prepar action. Furthermore these doc applications for active substances for product authorisation under the BPD the Co mission may have address in the Biocides competent authorities are advised to consult.

Related links
- Biocides competent authorities meetings documents
- Biocidal Products Directive Guidance and other relevant documents

Biocidal Products Regulation guidance structure

VOL. I
- Identity, phys-chem, analytical methodology

VOL. II
- Efficacy
- Human Health

VOL. IV
- Environment

VOL. V
- Specific guidance

PART A+B+C
- Information requirements + Assessment + Evaluation

PART A
- Information requirements

PART B+C
- Assessment + Evaluation

Active substances and suppliers (Art 95 list)
Disinfection By-Products
Endocrine disruptors
Micro-organisms
Technical equivalence
Antifouling-specific guidance

- Efficacy assessment for PT-21
- Dermal absorption antifoulings
- Manual of Technical Agreements
- Technical Agreements Biocides
- ...
- ...
- Excel calculation sheets for marinas – dd.13 Oct. 2017...

Dossier deadline most copper-containing antifoulings
Jan. 1st, 2018
Travellers’ trials and tribulations
Ease of decisionmaking process inversely proportional to parties involved

Actives and Products

Administrator

Actives

Standing Committee Biocides

Products

Member States - Competent Authorities

Outcome?

Mutual Recognition
... causes issues with legal deadlines - delays

PRIA
- registration categories
- deadlines (Congress!)
- fees

BPR
- registration categories
- deadlines (Challenge!)
- separate fees legislation (EU plus MS)
## Application categories

<table>
<thead>
<tr>
<th>EPA No.</th>
<th>New CR No.</th>
<th>Action</th>
<th>Application code</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>A530</td>
<td>84</td>
<td>New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix.</td>
<td>AS-ACC</td>
<td>Application for the inclusion in active substances and suppliers (Article 95) list</td>
</tr>
<tr>
<td>A531</td>
<td>85</td>
<td>New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.</td>
<td>AS-APP</td>
<td>Amendment to the conditions of an approved active substance</td>
</tr>
<tr>
<td>A532</td>
<td>86</td>
<td>New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite all data citation except for product chemistry; product chemistry data submitted</td>
<td>AS-RNL</td>
<td>Renewal of an active substance approval</td>
</tr>
<tr>
<td>A540</td>
<td>87</td>
<td>New end use product; FIFRA 62(mm) uses only</td>
<td>CC-APP</td>
<td>Classification of a change of a products</td>
</tr>
<tr>
<td>A560</td>
<td>88</td>
<td>New end-use product; uses other than FIFRA 62(mm); non-FQPA product</td>
<td>CS-APP</td>
<td>Chemical similarity check</td>
</tr>
<tr>
<td>A560</td>
<td>89</td>
<td>New manufacturing use product; registered active ingredient; selective data citation</td>
<td>RP-NOT</td>
<td>Notification to take over the role of participant / inclusion of Active Substance in the Review Programme</td>
</tr>
<tr>
<td>A570</td>
<td>90</td>
<td>Label amendment requiring data review</td>
<td>NA-APP</td>
<td>National authorisation of biocidal products</td>
</tr>
<tr>
<td>A572</td>
<td>91</td>
<td>New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

June 26th, 2018
JCMBF Melbourne, Florida
Product family – EU BPR

Products having similar uses,
the same active substances,
similar composition with specified variations,
similar levels of risk
and similar efficacy
BPR – hazard-based **exclusion** criteria for AS

- **Hazard** – based on intrinsic properties of a substance labelling classification, e.g. CMR
- **Risk** – about exposure versus safe levels
Risk assessment not only of the actives!

MUP/EUP - Federal

MUP/EUP - States

AS - Union

BP

Inerts!

Substances of Concern!
## From exclusion to exclusive use

<table>
<thead>
<tr>
<th>US-FIFRA</th>
<th>EU-BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exclusive use</strong></td>
<td><strong>Data protection</strong></td>
</tr>
<tr>
<td>“Exclusive-use” treatment for data means that the data may not be relied upon by other applicants or registrants to support FIFRA registration and reregistration actions without the permission of the data submitter. A 10-year period of protection for such data begins from the date of the original registration of the pesticide.</td>
<td>Data submitted for the purposes of BPD or BPR shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where the data protection limit has expired or a Letter of Access has been provided. The protection period for data submitted: 10 years for approval of existing actives substance = from approval decision, 15 years for new active substances.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Compensation</strong></th>
<th><strong>Data sharing/compensation – obligatory for vertebrate studies</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>After the “exclusive” use period has expired, the owner of the data may still be entitled to compensation. F.i. when data are within the 15-year compensatory period (period begins on the date the data were originally submitted to EPA). Applicants and registrants may not rely on data that retain compensation rights to support registration or reregistration unless they have first offered the data submitter compensation for the use of such data.</td>
<td>Where the data are still protected the prospective applicant may, or shall in the case of vertebrate studies, request from the data owner all the related scientific and technical data as well as the right to refer to these data. Prospective applicant and data owner shall make every effort. Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Cite-all or selective</strong></th>
<th><strong>Access to all or part of a dossier</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cite-All: The applicant cites to all the pertinent data in the Agency files for the requested registration action. Selective Method: The applicant selectively cites to individual studies, including the applicant’s own data. Letter of Authorization always necessary in Exclusive Use period.</td>
<td>The prospective applicant might not own the data but nevertheless has reached an agreement with the data owner that it can use the data for BPR purposes. Usage of the data will depend on the agreement with the data owner and could include a Letter of Access (by reference or physical access).</td>
</tr>
</tbody>
</table>
Notions and hopes for the future

- EU best boy in class or ‘world upside down’?
  - Risk perception toddler > risk perception senior citizen
- Senior citizen to take toddler by the hand
  - EU: “Don’t bite off more than you can chew”
- Toddler to inspire senior citizen
  - US: “Pesticide product families?”
- Connect!
QUESTIONS?

Annex3 | Consulting

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June 26th, 2018
ICMCF Melbourne, Florida
Mini-dictionaries

**A “new active substance”** is a substance which was not on the market on 14 May 2000, as an active substance of a BP for purposes other than scientific or product and process-orientated research and development (Article 3(1)(e) of the BPR).

**A “new active ingredient”** is an active ingredient that is not currently contained as an active ingredient in any EPA registered pesticide product.
BREXIT

- UK withdrawing from EU legislation
  - Effective withdrawal March 2019
- (New) approvals/authorisations
  - UK authority no longer available
- Future role of UK-HSE Competent Authority in EU-process unknown
  - Advisory?
- ECHA guidance for questions on BREXIT