Glyphosate AIR 2022

Pre-submission call - AGG

July 4, 2019
GTF2 Representation on the call

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Syngenta</td>
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<tr>
<td></td>
<td>Agria</td>
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<td>Agria</td>
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<td></td>
<td>Nufarm</td>
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<td>Brokden</td>
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<td>Helm Ag</td>
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<td>Sinon</td>
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<td>Bayer</td>
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<td></td>
<td>Albaugh</td>
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<td></td>
<td>POSTMON</td>
</tr>
<tr>
<td></td>
<td>Knoell Germany GmbH</td>
</tr>
</tbody>
</table>

* Representing Sinon; employed by Exponent
Remit of the teleconference

Agenda

- Introduction of GTF2 and AGG
- Align on high level procedural and practical aspects of the upcoming evaluation
- The Representative GAP
- Transparency
- Scope the pre-submission meetings
- Literature review
- What can the Task Force do to facilitate the process?
Task Force
Membership – 2019

Confirmed Associate members
Sinon Cziech Agria

Board
- Data package
- Representatives
- Decision vote

Associate
- No/little data
- Voluntaries
- Consulted

Lead Registrant
- Point of contact
# Task Force

## Membership – 2019 vs 2012

<table>
<thead>
<tr>
<th>2019</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adama Agan Ltd</td>
<td>Feinchemie Schwebda GmbH</td>
</tr>
<tr>
<td>Agria SA</td>
<td>Agria SA</td>
</tr>
<tr>
<td>Albaugh Europe SARL</td>
<td>Albaugh UK Limited</td>
</tr>
<tr>
<td>Arysta Lifescience SAS</td>
<td>Arysta Lifescience SAS</td>
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<tr>
<td>Barclay Chemicals Manufacturing</td>
<td>Barclay Chemicals Manufacturing</td>
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<tr>
<td>Bayer Agriculture bvba</td>
<td>Monsanto Europe SA</td>
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<tr>
<td>Brokden SLU</td>
<td>Brokden SLU</td>
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<tr>
<td>Ciech Sarzyna SA</td>
<td>Pinus TKI</td>
</tr>
<tr>
<td>Helm AG</td>
<td>Helm AG</td>
</tr>
<tr>
<td>Nufarm GmbH &amp; Co KG</td>
<td>Nufarm GmbH &amp; Co KG</td>
</tr>
<tr>
<td>Sinon Corporation</td>
<td>Sinon Corporation</td>
</tr>
<tr>
<td>Syngenta Crop protection AG</td>
<td>Syngenta Limited</td>
</tr>
<tr>
<td></td>
<td>Cheminova AS</td>
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<td></td>
<td>Agrotrade GmbH</td>
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<td></td>
<td>Agrichem BV</td>
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<td></td>
<td>Bros Polka</td>
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<td>Dow Agrosciences LCC</td>
<td>Excel Industries</td>
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<td></td>
<td>Industrias Afrasa SA</td>
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<td>ROTAM Agrochemical Europe Ltd</td>
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<td>Sapec Agro SA</td>
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<td></td>
<td>Société Financier de Potarlier</td>
</tr>
<tr>
<td></td>
<td>United Phosphorus Limited</td>
</tr>
</tbody>
</table>
Task Force

Bundeling data packages, expertise sharing cost

Board
- Budget approval
- Arbitration
- Monitor/Steer proces

Secretariat
- Treasurer

Public Affairs Group (PAG)
- Education and information to Stakeholders

Regulatory working Group (RWG)
- Regulatory Strategy
- Guidance to TWG
- Interactions with RMS
- Notif.-submission

Technical Working Groups (TWG)
- Technical compilation of dossier
- Studies – RA’s
- Literature reviews

 Consultant
Knoell Germany GmbH
## Task Force (GTF2)

### Contact

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman of the Board</td>
<td>Blacked out</td>
<td>(BCS- Brussels)</td>
</tr>
<tr>
<td>Secretary of the Board</td>
<td>Blacked out</td>
<td>(POSTMON- UK)</td>
</tr>
<tr>
<td>Chairman of the RWG</td>
<td>Blacked out</td>
<td>(BCS-Brussels)</td>
</tr>
<tr>
<td>Coordinator of the TWG</td>
<td>Blacked out</td>
<td>(BCS- Saint Louis)</td>
</tr>
<tr>
<td>Knoell Germany GmbH rep.</td>
<td>Blacked out</td>
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</tr>
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</table>

**Procedural topics**

**Back-up**

**Dossier technical topics-general**

**Back-up**

**Confidential data**
Task Force (GTF2)

Data sharing – data generation - data ownership & access

- All existing glyphosate studies owned by the membership are included in the joint submission
  - Ownership remains with original owner; access rights are granted
  - Study reports are not shared – included via Consultant
  - Data compensation is considered as necessary

All members are provided the right to refer to all studies in the data package in the context of the EU AIR and any product (re) authorization in the EEA

- New glyphosate studies are jointly developed/sponsored and co-owned
  - These studies can be used *ad libidum* globally

- Confidential data ((5-batch, sources of TGA etc) are NOT shared
  - Included in the dossier by the Consultant
  - EU reference specification is unknown to the membership
Alignment on procedural and practical aspects of the submission

Dossier & Application preparation - Evaluation

- **Application (< December 15 2019)>**
  - List of new studies
  - Updating Statement
    - Expectations
    - Special format requirements

- **Regulation 1141/2010 - Art 9 :Supplementary Dossier**
  - GTF2 intends to submit **full dossier**
    - All data (old & new) presented in line with latest requirements
    - Full weight of scientific evidence evaluated
  - How to make cross reference to studies already evaluated in 1998 - 2012?
    - OECD summaries vs tabular summaries

**Note**: Art 13 (third party submission) to be anticipated
Alignment on Procedural and Practical aspects of the submission (2)
Dossier & Application preparation - Evaluation

- Guidance, dossier and data requirements in force at time of submission
  - Will be used by GTF2 as basis for dossier preparation
  - Will be used by AGG/EFSA as the basis of evaluation

- Timelines

  - Pre-Submission (RMS EFSA)
  - Evaluation (RMS, Co RMS)
  - Peer Review (EFSA, COM, MS, Public, Experts)
  - Comitology SCoPAFF

- 2019
  - RMS assigned April 15
  - Application < December 15

- 2020
  - Dossier submission < June 15

- 2021
  - Preliminary checks to be anticipated?
  - ECHA submission / review?

- 2022
  - Renewal < December 15
Representative GAP

Demonstrating a safe and acceptable use concept

Setting the representative GAP: 2012

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Growth stage</th>
<th>#</th>
<th>Interval</th>
<th>Water</th>
<th>Dose rate</th>
<th>PHI</th>
<th>comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>All crops</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Pre-planting of the crop</td>
<td>1-2</td>
<td>21d</td>
<td>100-400L</td>
<td>0.36-2.16</td>
<td>N/A</td>
<td>Spring &amp; autumn after harvest (including stubble and seed bed preparation); max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>All crops</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post-planting pre-emergence of the crop</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.36-1.08</td>
<td>N/A</td>
<td>max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>Cereals (pre-harvest)</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Crop maturity &lt;30% grain moisture</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.72-2.16</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Oil seeds pre-harvest</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Crop maturity &lt;30% grain moisture</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.72-2.16</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Orchard crops, vines</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400L</td>
<td>0.72-2.88</td>
<td>N/A</td>
<td>Stone and pome fruit; olives; Applications made around the trunk of trees; seasonal application not to exceed 4.32 kg/ha;</td>
</tr>
<tr>
<td>Orchard crops, vines Spot treatment</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post emergence of weeds</td>
<td>1</td>
<td></td>
<td>0-400</td>
<td>0.72-2.88</td>
<td>N/A</td>
<td>Stone and pome fruit; olives; Applications made around the trunk of trees; seasonal application not to exceed 4.32 kg/ha; DL water = undiluted product;</td>
</tr>
</tbody>
</table>
Representative GAP

Demonstrating a safe and acceptable use concept (2)

Setting the representative GAP: 2020

1. Define major agricultural uses
   - Representing ~80% of volumes sprayed in the EU

2. Exclude uses sensitive to society
   - Exclude uses associated with (highest) residue levels
   - MRLs = LOQ
   - Exclude lawn & garden uses

3. Refine GAP based on weed type and GS
   - Annual weeds
   - Biennial perennial weeds in early vs advanced GS
   - Efficacy
   - WRM
   - More targeted and refined application approach
     (sustainability)

4. Include Risk Mitigation as part of the GAP
   - Drift reducing nozzles
   - Banded applications
   - PPE?
Representative GAP

Demonstrating a safe and acceptable use concept (3)

Setting the representative GAP: 2020 versus 2012

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Growth stage</th>
<th>#</th>
<th>interval</th>
<th>Water</th>
<th>Dose rate</th>
<th>PHI</th>
<th>comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>All crops</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Pre-planting of the crop</td>
<td>1-2</td>
<td>21d</td>
<td>100-400L</td>
<td>0.05-2.16</td>
<td>N/A</td>
<td>Spring &amp; autumn after harvest (including stubble and seed bed preparation); max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>All crops</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post-planting pre-emergence of the crop</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.36-1.08</td>
<td>N/A</td>
<td>max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>Cereals (pre-harvest) Desiccation + weed control</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Crop maturity &lt;50% grain moisture</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.72-2.16</td>
<td>7</td>
<td>max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>Oil seeds pre-harvest Desiccation + weed control</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Crop maturity &lt;30% grain moisture</td>
<td>1</td>
<td></td>
<td>100-400L</td>
<td>0.72-2.16</td>
<td>14</td>
<td>max 4.32 kg/ha in any 12 month period across use categories</td>
</tr>
<tr>
<td>Orchard crops, vines</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post-emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400L</td>
<td>0.72-2.58</td>
<td>N/A</td>
<td>Stone and pome fruit, olives, Applications made around the trunk of trees; seasonal application not to exceed 4.32 kg/ha; 0L water = undiluted product</td>
</tr>
<tr>
<td>Orchard crops, vines Spot treatment</td>
<td>Emerged annual perennial and biennial weeds</td>
<td>Post-emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>0-100</td>
<td>0.72-2.88</td>
<td>N/A</td>
<td>Stone and pome fruit, olives, Applications made around the trunk of trees; seasonal application not to exceed 4.32 kg/ha; 0L water = undiluted product</td>
</tr>
</tbody>
</table>
### Representative GAP

#### Crop, Pest, Growth stage, #, interval, Water, Dose rate (kg/ha), PHI, comment

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Growth stage</th>
<th>#</th>
<th>interval</th>
<th>Water</th>
<th>Dose rate (kg/ha)</th>
<th>PHI</th>
<th>comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 All crops</td>
<td>Emerged annual weeds</td>
<td>Pre-planting of the crop</td>
<td>1-2</td>
<td>21d</td>
<td>100-400L</td>
<td>0.72-1.08</td>
<td>N/A</td>
<td>Broadcast tractor mounted application; treatment 100% of field; Spring &amp; autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles</td>
</tr>
<tr>
<td>2a All crops</td>
<td>Emerged perennial and biennial weeds, <em>Weeds in early development stage (BBCH 13-21)</em></td>
<td>Pre-planting of the crop</td>
<td>1-2</td>
<td>21d</td>
<td>100-400L</td>
<td>1.08 - 1.44</td>
<td>N/A</td>
<td>Broadcast tractor mounted application; treatment 100% of field; Spring &amp; autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles</td>
</tr>
<tr>
<td>2b All crops</td>
<td>Emerged perennial and biennial weeds, <em>Weeds in advanced development stage &gt; BBCH 21)</em></td>
<td>Pre-planting of the crop</td>
<td>1</td>
<td>-</td>
<td>100-400L</td>
<td>1.44 - 2.16</td>
<td>N/A</td>
<td>Broadcast tractor mounted application; treatment 100% of field; Spring &amp; autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles</td>
</tr>
<tr>
<td>3 All crops</td>
<td>Emerged annual weeds</td>
<td>post planting / pre-crop emergence</td>
<td>1</td>
<td>-</td>
<td>100-400L</td>
<td>0.72-1.08</td>
<td>N/A</td>
<td>Broadcast tractor mounted application; treatment 100% field 75% drift reducing nozzles</td>
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<tr>
<td>4 All crops</td>
<td>Emerged perennial and biennial weeds</td>
<td>post planting / pre-crop emergence</td>
<td>1</td>
<td>-</td>
<td>100-400L</td>
<td>1.08 - 1.44</td>
<td>N/A</td>
<td>Broadcast tractor mounted application; treatment 100% field 75% drift reducing nozzles</td>
</tr>
</tbody>
</table>
Refinements

‘All crops’

- "All seeded and transplanted crops including but not restricted to root & tuber vegetables, bulb vegetables, stem vegetables (fruit vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, sugar & fodder beets; before planting fruit crops, ornamentals, trees, nursery plants etc."

- **Maximum annual application** rate per treated area: **2.88 kg/ha**
  
  - allows for instance combinations of:
    - pre-plant/pre-emergence annual weed treatment + perennial/biennial advanced development stage treatment
    - pre-plant/pre-emergence 2 applications targeting perennial/biennial early development stage
    - 1 Pre-plant pre-emergence + 1 post-plant pre-emergence application

  **In line with realistic and labeled treatment regimes**
Representative GAP

Demonstrating a safe and acceptable use concept (4)

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Growth stage</th>
<th>#</th>
<th>interval</th>
<th>Water</th>
<th>Dose rate (kg/orchard ha)</th>
<th>PHI</th>
<th>comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Orchard crops, vines</td>
<td>Emerged annual weeds</td>
<td>Post emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400L</td>
<td>0.36-0.54</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees - bands between tree rows left green (dose rate = 0.72-1.08 kg band ha treated orchard area = 50%); Ground-directed - Shielded (drift) sprayer</td>
</tr>
<tr>
<td>8 Orchard crops, vines</td>
<td>Emerged perennial and biennial weeds, Weeds in early development stage (BBCH 13-21)</td>
<td>Post emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400L</td>
<td>0.54-0.72</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1.08-1.44 kg band ha treated orchard area = 50%); Ground-directed - Shielded (drift) sprayer</td>
</tr>
<tr>
<td>7 Orchard crops, vines</td>
<td>Emerged perennial and biennial weeds, Weeds in advanced development stage (&gt; BBCH 21)</td>
<td>Post emergence of weeds</td>
<td>1-2</td>
<td>21d</td>
<td>100-400L</td>
<td>0.72-1.08</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1.44-2.16 kg band ha treated orchard area = 50%); Ground-directed - Shielded (drift) sprayer</td>
</tr>
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</table>
## Representative GAP

### Demonstrating a safe and acceptable use concept (5)

<table>
<thead>
<tr>
<th>Crop</th>
<th>Pest</th>
<th>Growth stage</th>
<th>#</th>
<th>interval</th>
<th>Water</th>
<th>Dose rate (kg/orchard ha)</th>
<th>PHI</th>
<th>comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 Orchard crops, vines Spot treatment</td>
<td>Emerged annual weeds</td>
<td>Post emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400</td>
<td>0.36-0.54</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees – bands between tree rows left green (dose rate = 0.72-1.08 kg band ha treated orchard area = 50 %); Ground-directed - Shielded (drift) sprayer Knapsack applicator (tbc)</td>
</tr>
<tr>
<td>9 Orchard crops, vines Spot treatment</td>
<td>Emerged perennial and biennial weeds Weeds in early development stage</td>
<td>Post emergence of weeds</td>
<td>1-3</td>
<td>28d</td>
<td>100-400</td>
<td>0.54-0.72</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1.08-1.44 kg band ha treated orchard area = 50 %); Ground-directed - Shielded (drift) sprayer Knapsack applicator (tbc)</td>
</tr>
<tr>
<td>10 Orchard crops, vines Spot treatment</td>
<td>Emerged perennial and biennial weeds Weeds in advanced development stage</td>
<td>Post emergence of weeds</td>
<td>1-2</td>
<td>21d</td>
<td>100-400</td>
<td>0.72-1.08</td>
<td>N/A</td>
<td>Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1.44-2.16 kg band ha treated orchard area = 50 %); Ground-directed - Shielded (drift) sprayer Knapsack applicator (tbc)</td>
</tr>
</tbody>
</table>
Transparency

Society urges for full transparency – GTF2 acts upon it!

GTF2 commits to pursue renewal ambitions in full transparency

- Pro-active application of new transparency provisions in the revised GFL
  - Register of studies – Consultation of third parties
  - Publication of study reports after completeness check

- Publication of all communication between GTF2 and AGG – EFSA–COM and other formal stakeholders in the renewal process
  - Letters
  - Minutes of meetings

- Publication of safety studies leading to 2017 renewal

- Exploring other options as a Task Force
Transparency

Notification of Studies

- GFL; Art 32b, Notification of studies
  - EFSA to establish a database of studies commissioned or carried out to support applications
  - Applicants must “…notify, without delay…the title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out by them to support an application …”

- GFL; Art 32c, Consultation of third parties

Public consultation on intended studies:
  - EFSA holds public consultation on intended studies
  - Based on comments received EFSA provides advice to Applicants on content of renewal application, as well as design of studies
# Transparency

## Notification of Studies - Adapted from ECPA format proposal (Excel spreadsheet)

### Ongoing studies

| Identified areas for which detailed re-evaluation is needed in dossier from applicant and in evaluation by RMS/GtRMS | Related data point | Dossier section | Study title (if available)/otherwise study purpose | Justification | Guideline or guidance document | GLP | CRO | Enlarged dates of study conducted | Vertebrate study | Confidentiality claims* | Notifier comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Identity / specification of TGal | Doc. J | Identity of the active substance | Analytical characterization of the batches of XY | Method validations | New batch analysis representing current commercial production | EU (2013) SANCO/30949/2013 (equiv. of TGal) | No | Yes | Public discussion only makes sense regarding already registered maximum putty and relevant impurities |
| Relevance of metabolites, Residue definition for MRL, setting and RA | MCA 5.8 | Metabolism in target crops | Metabolism in target crops | Changed policy on evaluation of metabolites | OECD Test Guideline 501: Metabolism in crops | Yes |
| Relevance of metabolites, Residue definition for MRL, setting and RA | MCA 6.2 | Metabolism in fish | Metabolism in fish (oral dosing) | New EU guideline SANCO/11187/2013 | Yes |
| Relevance of metabolites, Residue definition for MRL, setting and RA | MCA 8.7 | Residue definition for MRL, setting and RA | Changed policy on evaluation of metabolites, International harmonisation | OECD (2007), Guidance Document on the Definition of Residues, Environment, Health and Safety Publications, Series on Testing and Assessment No. 63 and Series on Pesticides No. 31 | Subsequent to MCA 5.1.1, 5.8 and 6.2 |

### New existing studies

<table>
<thead>
<tr>
<th>Dossier section/data point</th>
<th>Areas where today's requirements are not longer met by existing data</th>
<th>Study title (if available)</th>
<th>Justification</th>
<th>Guidelines</th>
<th>CRO</th>
<th>Date of Issue</th>
<th>GLP</th>
<th>Vertebrate</th>
<th>Notifier comment</th>
</tr>
</thead>
</table>
Transparency

Notification of Studies – How? – When?

- Applicant submits Register to EFSA after pre-submission meetings
- EFSA publishes on Website and opens for public comments

Note:
- Most studies have been completed or are ongoing
- Remit should be to inform before dossier submission
- Assess need for/suggestions for other studies

Questions
- Public comments: how long? – 30 days
- How will public comments be handled?
  - Non standard studies
  - Verification studies
- How to formally address/respond to comments/suggestions?
Transparency

Disclosure of study reports – How? – When?

- **Art 38, Making Public**
  EFSA shall make public (among other things):
  - “scientific data, studies and other information supporting applications”, (including supplementary information)
  - a summary of advice provided at pre-submission phase

- “without delay” once an application has been considered admissible

- EFSA publishes full dossier (except confidential sections) on Website after completeness check and opens for public comments
- GTF will make sanitized version of dossier available

**Questions**
- Public comments: how long? – 30 days
- How will public comments be handled?
Transparency

Disclosure of communication with authorities

- Applicant will make public all written exchanges with authorities
- RMS, EFSA, COM
- GTF transparency portal

Scope:
- Letters
- E-mails
- Minutes of meetings
- Elements submitted as part of dossier not in scope (GFL principles apply)
- Other elements?

Questions
- Agreement? Concerns?
Pre-submission meeting(s)

Scope: general

- Focus on technical/regulatory aspects of the dossier
  - Per Section: state of play (endpoints – conclusions)
  - Gaps identified by EFSA (2015)
  - New studies/new assessments – what-where-how-who-by when?
  - Representative GAP – Representative formulation
  - Methodology details of handling the literature review
  - Questions

- Practical set-up; logistics?
Pre-submission meeting(s)

Special attention to the following topics

- **Residues in Honey-Establishing MRL in Honey**
  - New EFSA requirement (to follow the new Guidance on the establishment of the residue definition for dietary risk assessment”)
  - Tunnel Study initiated
  - Protocol and use of monitoring date need to be explained

- **Toxicology**
  - Anses long term study
  - Revisit the ADI and the study it is based on
  - Need for phototoxicity testing
  - Genotoxicity of glyphosate based formulated products
  - Data presentation glyphosate genotoxicity/carcinogenicity

- **Eco-toxicology**
  - Acceptability of Vole population modelling
  - Higher tier refinement studies (Vole enclosure studies)
  - Endpoint selection for bird and mammalian risk assessment
  - Impact on biodiversity through trophic interaction

- **Analytical methods**
  - Extractability
Literature Review (EFSA 2092 - 2011)

Complete exhaustive literature review from 2012-2020

- 3 Phases
  - **Phase 1**: 2012-2018
  - 7,000+ new articles published
  - **Phase 2**: 2018 – present
  - **Phase 3**: present - 2020

- **Relevance assessment** which articles to include (content)
  - **In scope**: Articles relevant to risk assessments + articles with negative allegations/gaining popularity from activists/media

- OECD summaries and reliability assessment (criteria per section)
- Technical/regulatory positioning
- List of and link to recent (?) Regulatory Evaluation Documents
## Literature Review

### Part 1: Literature review from Jan 12 - Jan 18

<table>
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<tr>
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<th>STN search P1: Relevant articles subject for reliability assessment</th>
<th>STN Search P2 (Feb 18 - Jun 19)</th>
<th>STN Search P3 (Jul 19- Dec 19)</th>
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**Total:** 354
Questions

- What advice can AGG provide after this consultation and in what time frame?

- What advice/level of consultation to expect from EFSA?

- What can the Task Force do to facilitate the review?
Thank you!