Questions about the set up of the Transparency regulation for testing facilities

Background

On 27th January 2020, Redebel Regulatory Affairs SCRL (RRA) contacted EFSA on behalf of RRA and its sister company Redebel SA, regarding questions on the Transparency Regulation (Regulation (EU) 2019/1381 aka General Food Law) and its implementation. RRA is a consulting company acting in the field of Agrochemicals, Biocides and REACH regulations and Redebel SA is a GLP and GEP certified CRO company.

These questions concern how the General Food Law will be implemented for testing facilities and what will be their obligations (notification of studies, etc) as well as how it will impact the preparation and submission of active substance dossiers.

The questions are listed below.

Questions

Article 32b – Notification of studies

- How to notify a study for a testing facility? What will be the system being set up? When will it be set up? Will it be an online notification? To whom notify the studies conducted?

- What is the step of the study triggering the notification? The signature of the study plan? The signed quote? The first part experiment?
  What is the delay to notify a study after the trigger step?

- In the particular case of a residue study which contains a field part and an analytical part: is it only the Study Director of the entire study which needs to notify the study or have the Principal Investigators of each part (field and analytical) also to notify?

- If during a study, an amendment (which would modify the title or the scope of the study) is generated, will be it necessary to notify it?

- What about the notification of studies conducted before 27.03.2021 that will be submitted after 27.03.2021?

- Are the GEP trials also concerned by the notification?

- What about the studies intended to be presented in formulated PPP dossier? Should the testing facilities also notify them? What about the particular case of residues studies that are present in both active and product dossiers?

REDEBEL REGULATORY AFFAIRS SCRL
[Office] : +32 71 853 392
[Fax] : +32 71 853 618
[Email] : info@redebel.com
[Web] : www.rra.redebel.com
Rue de Chassart 4
B-6221 Saint-Amand
Belgium
T.V.A. : BE 0647.909.322 – RPM Charleroi

Article 39 f – Standard data formats

- What will be the standard formats for the active substances dossier and when will it be set up? Will it be IUCLID format?

General questions

If the answers of these questions are not yet definitive and still in progress, do you know if there will be any informative session for applicant and/or testing facilities in the near future?

We are looking forward receiving any updates and information from you regarding Regulation (EU) 2019/1381 and its implementation.

REDEBEL REGULATORY AFFAIRS SCRL
[Office] : +32 71 853 392
[Fax] : +32 71 853 618
[Email] : info@redebel.com
[Web] : www.rra.redebel.com
Rue de Chassart 4
B-6221 Saint-Amand
Belgium
T.V.A. : BE 0647.909.322 – RPM Charleroi