



SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT (REPRO)

3rd EFSA Technical Group on Notification of Studies Database

Meeting date: **27-28 January 2021**
Meeting hours: **14:00 – 17:00/ 09:00 - 12:30**
Meeting venue: **Microsoft Teams Teleconference**
Chair: **Karine Lheureux**
Admin: **Joy Duggins**

FINAL AGENDA

DAY 1

Time	No.	Topic	Documents & scope	Presenter
14H00	1	Welcome and Apologies for absences adoption of agenda		Karine Lheureux
14H10	2	Where we are today: status of progress of the TG	Present progress made since last meeting (October 2020)	Stefano Cappè
14H30	3	Summary on feedback received on reference list Q&A	Presentation	Davide Gibin
15H00	4	Accessing the database	Presentation	Sorina Puiu



15H15	5	<p>Case study 1: Enabling third party to notify on behalf of BO a study:</p> <ul style="list-style-type: none"> • Registration of third parties • Delegation of third parties • Notification of studies <p>Q&A</p>	Live demo	Sorina Puiu
16H00	<i>Coffee Break</i>			
16H15	6	<p>Case study 2: Third party notifies a study commissioned to a laboratory not registered in the system</p> <ul style="list-style-type: none"> • Notification of studies to a new laboratory • Invite of a new laboratory • Notification from laboratory 	Live demo	Sorina Puiu
17H00	7	Overall discussion on first day	Discussion	Karine Lheureux

DAY 2

Time	No.		Documents / scope	Presenter
09H00	1	Welcome second day		Karine Lheureux
09H10	2	Subject of application, test item and components	Presentation	Davide Gibin
09H20	3	<p>Case study 3: Specification of subject of application, test items and its components in pre-application-id and in study notifications</p> <ul style="list-style-type: none"> • Creation of pre-application-id • Notification of study on the subject of the application • Notification of a study with a test item different from the subject of the application <p>Q&A</p>	Live demo	Davide Gibin
09H50	4	Notification from laboratory	Presentation	Sorina Puiu



10H00	5	<p>Case study 4: Notification from a laboratory and its inclusion in a pre-application-id of a business operator</p> <ul style="list-style-type: none"> • Laboratory sends notification • BO adds notification to pre-application-id • BO reuse a notified study for other pre submission activities 	Live demo	Sorina Puiu
10H40	<i>Coffee Break</i>			
11H00	6	<p>Case study 5: Pesticides Renewals</p> <ul style="list-style-type: none"> • Joint applications renewals • List of intended studies for renewal according to article 32c1 • Adding new BOs • Notification according to article 32b <p>Q&A</p>	Presentation and live demo	Stefano Cappè
11H40	7	<p>Case study 6: Renewal procedures under tight timeline</p> <ul style="list-style-type: none"> • Notification 32c1 and 32b <p>Q&A</p>	Presentation and live demo	Stefano Cappè
12H00	8	Discussion of case studies and trainings	Discussion	Stefano Cappè
12H30	9	Second day wrap-up and conclusions		Karine Lheureux
12H30	End of meeting			