

Ad-hoc meeting GMO Representatives

Transparency Regulation Implementation

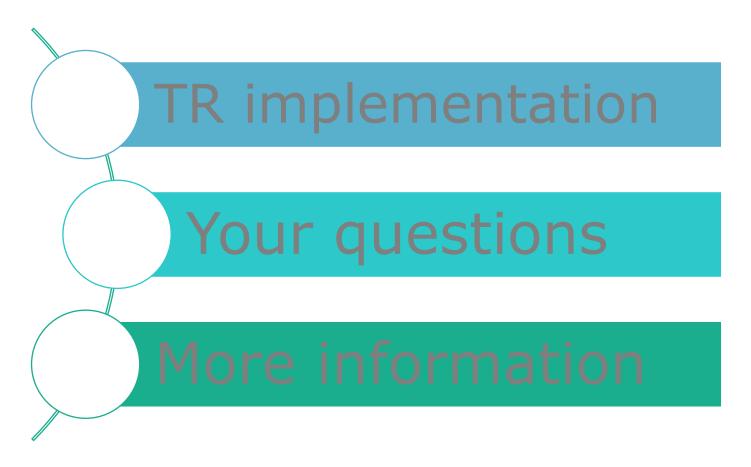
Karine Lheureux

HoU APDESK



Today's agenda







Statistics from Account Registration (21/06)

Applicants: 635

Laboratories: 404

Consultants: 278

Member States: 98

- Delayed account activation (by EFSA): counts as valid justification if any delay in NoS
- Number of members per organisation: increased to 6 / organisation as of end of June 2021
- Implementation of Two-way authentification

Authorisation of delegation to third parties



Update from Account Registration



This feature is in place since 30/04. New video under preparation.

Organisations playing multiple roles

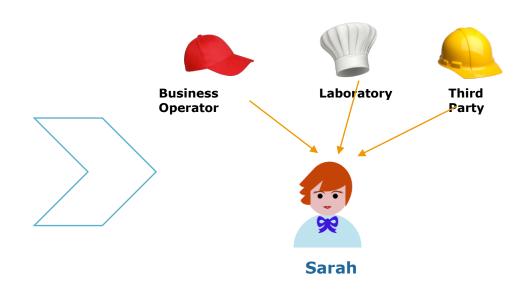


Update from Account Registration









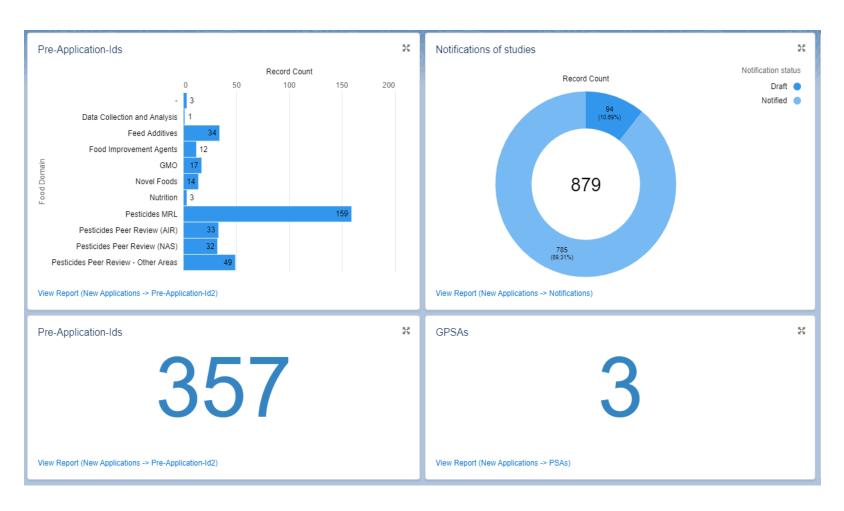
The implementation of this feature will require some adjustments to the user interface.

This feature will be in place from 30th June. New video under preparation.

Webinars: Webinar 16 February (here). Webinar 26 March (here).



Statistics from Connect.EFSA New applications (21/06)





Statistics from Connect.EFSA Renewals (21/06)





Statistics from E-submission ESFC (15/06)

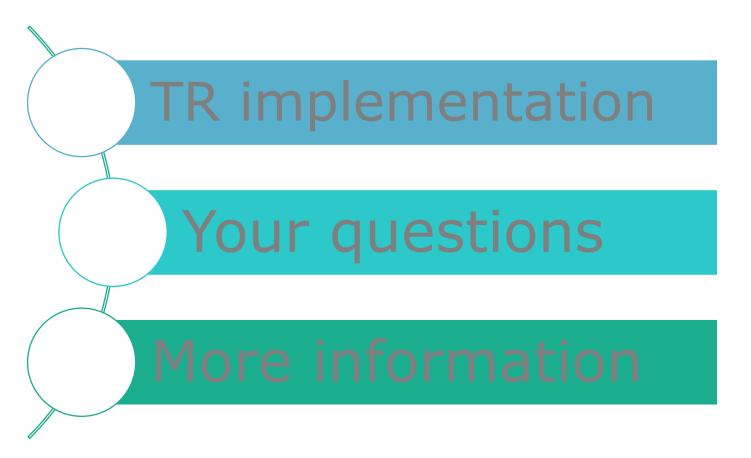
In EFSA - under Validity check	N*
Food Contact Materials – recycling processes	11
Novel Foods	1
Infant/Follow-on formula 1	
Total	13
Submitted to EC or MS	N*
Food Additives	1
Food Enzymes	1
Feed Additives	3
Health Claims	2
Novel Foods	11
Traditional Foods	3
Infant formulae-Follow on formulae	1
Food Contact Materials – recycling processes	4
Total	26

Solution Video Tutorials

User Guide

^{*} Captured on 15 June 2021



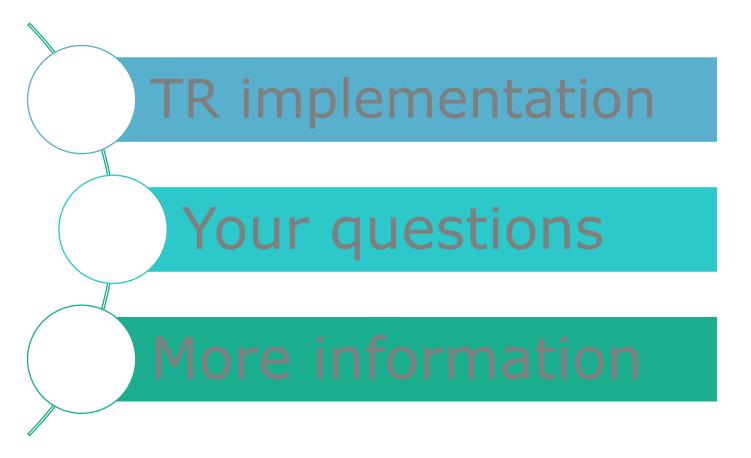


Your questions



Topics	Clarifications on	References
Notification of Studies	Type of justifications Steps workflow	PAs, Art.21, Art.22 EFSA Q&A, N42 EFSA ADM Guidance GMO
ESubmission Food Chain platform	ToC submission Connection with EFSA.connect portal	EFSA GMO ADM GD, chapter 2.14 ESFC User Guide EFSA Video Tutorials





Useful documents



<u>Legal documents:</u>



Transparency Regulation: Regulation (EU) 2019/1381



General Food Law: consolidated text of Regulation (EC) No 178/2002



<u>Practical arrangements on presubmission phase and public</u> consultations



<u>Practical Arrangements concerning</u> <u>transparency and confidentiality</u>



EFSA Practical Arrangement on Access to Document (March 2020)

Guidance/training materials:



Q&As on PAs: Questions and Answers on the EFSA Practical Arrangements



EFSA digital toolkit page

https://www.efsa.europa.eu/en/applications/toolkit



Updated administrative guidance for regulated products: <u>Administrative guidance for the processing of applications for regulated products</u> (update 2021)



Catalogue of services:

EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (update 2021)



Training material, including video introductions/tutorials and webinar recordings, are available under the dedicated section "Transparency Regulation Implementation Training Programme" on the EFSA website



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https://www.efsa.europa.eu/en/applications/abou t/services





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