

TG TOOLS – 4TH MEETING
15 APRIL 2024
FOLLOW UP FROM PREVIOUS
MEETING





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15 APRIL 2024

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Post-adoption Notifications

BACKGROUND INFO

Implementation of additional automatic notifications received via ESFC for **post-TR Applications for regulated products** (non-pesticides):

- EFSA Opinion **adoption**
 - EFSA Opinion **Pre-publication**
 - EFSA Opinion **Comments Response**, if applicable
 - EFSA Opinion **Publication Release**, if applicable
-
- Streamline of procedures and information flow
 - All the info in one unique place
 - Complement the set of automatic notifications received via ESFC (e.g., output publication)
 - **Complementary e-mail sent by EFSA to be dismissed** after the update of the Catalogue of support initiatives



WHERE WE ARE NOW?

- Update the **Catalogue of support initiatives during the life cycle of applications for regulated products** → [Catalogue updated](#) – 29 January 2024
- **Complementary e-mail** sent by EFSA to be **dismissed** after the update of the Catalogue of support initiatives → dismissed for all the Opinion adopted after **1st March 2024**



Thank you for your attention!





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Gunda Kriz
PORTALINO improvements

PORTALINO IMPROVEMENTS I

SUBMISSIONS WITHOUT CONFIDENTIALITY REQUESTS

Step 5/5: Data Submission * = Mandatory field

Zip files

How to use? ⓘ

Confidential version *

Public dissemination (Non-Confidential) version *

Data Submission

How to use? ⓘ

Please tick the box if your submission does not contain any confidentiality request related to confidential business information or personal data ⓘ



PORTALINO IMPROVEMENTS I CTD

SUBMISSIONS WITHOUT CONFIDENTIALITY REQUESTS

Step 5/5: Data Submission

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Zip files

How to use? 


Public dissemination (Non-Confidential) version

*

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Data Submission

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PORTALINO IMPROVEMENTS II

SKIPPING THE STEP OF DRAFT CONFIDENTIALITY DECISION

- **When?** Only in cases where **all confidentiality requests** are approved
- **Why?**
 - Article 39b(1)(c) of Regulation (EC) No 178/2002 (“inform applicant of intention to disclose”) - mandatory consultation period not applicable
 - Speeds up the confidentiality assessment and risk assessment process



PORTALINO IMPROVEMENTS II CTD

SKIPPING THE STEP OF DRAFT CONFIDENTIALITY DECISION

- How?
 - ✓ Final decision downloadable in Portalino
 - ✓ Email notification sent

Assessment initial

Final First Decision

Final decision.pdf (71.1KB)

11/04/2024 - 11:55

