



Euros Jones (ERM):

The notification of studies under the General Food Law

Training workshop on regulatory issues

Different but connected elements

1. Notification of **individual studies**
2. Notification of **renewal application**
(with list of studies to be submitted)

Notification of studies

Business operators to pre-notify EFSA of studies carried out to support an application

- EFSA to establish and manage a database of studies carried out to support an application
- Database will be visible in Q4 2020
- EFSA looking at range of 'fields' to be completed:

<ul style="list-style-type: none">• Study Title• Study Starting Date• Study Planned Completion Date• Business Operator(s)• Laboratory• Scope of study (e.g. pesticides)• Study type	<ul style="list-style-type: none">• Study quality (e.g. GLP, GMP, ...)• Study for renewal? ("Yes"/"No" value)• Ethical committee approval ("Yes"/"No value)• Study objective (description)• Study guidelines (e.g. OECD, EFSA guideline)• Study id (provided by notifier or lab)• Product name
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Issues to be considered

Notification of studies

Which studies should be pre-notified?

- All studies to be used for EU applications
- New studies starting after 27th March 2021

Penalties for non-notification

Additional considerations

- Alignment (internally and with CROs & consultants)
- Timing of notification (when start date agreed)

Renewal notification - third party consultation

- For AS renewals, applicant to pre-notify the submission to EFSA
 - Listing the studies it intends to perform to meet regulatory requirements
- After notification, EFSA to launch public consultation on intended studies
- Taking into account the public comments, EFSA shall provide advice on the contents of the application

Issues to be considered

Renewal notification

- Multiple notifications for same AS?
- Updated notifications needed based on new information?
- Role of EFSA/RMS in agreeing vertebrate testing?
- Start-date for the pre-notification process?
- Does not apply to new active substances!

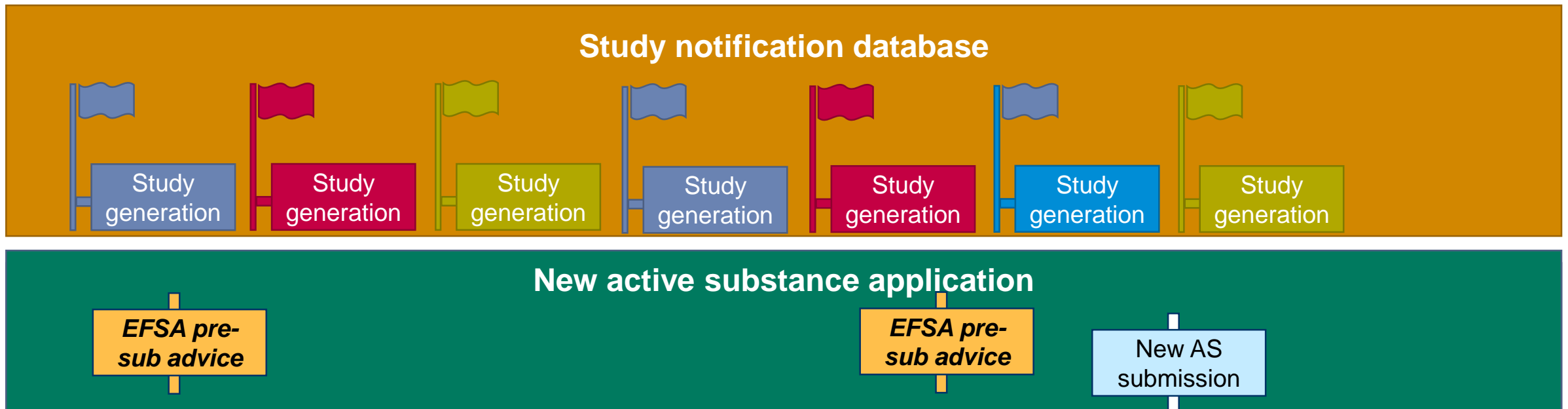
Notifications: [1] Individual studies and [2] Renewal notification (*current position*)

Notification of studies

- When studies are carried out to support an application

Renewal notification (& 3rd party consultation)

- Notification to EFSA of studies to be generated for renewal



Conclusion

New measures on:

- Notification of studies
- Pre-notification of renewal dossiers
(Consultation of 3rd parties)



**MORE
DETAILS**
Coming Soon!



Thank you!