TG NoS meeting

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Introduction to the Notification of Study Database

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Trusted science for safe food

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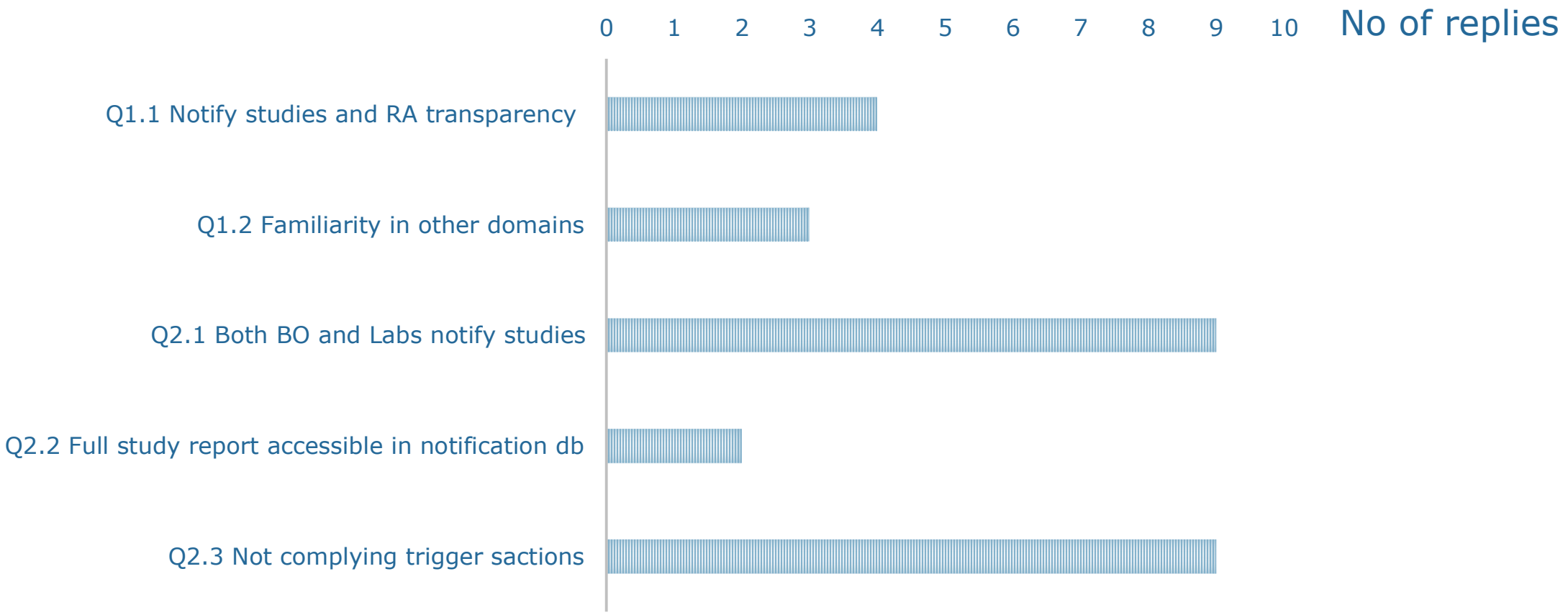
Summary

- ✓ Survey results
- Background
- Notification of studies
- Target of the meeting

Survey Results

Survey performed in advance of Technical Group with participants

Survey results summarising the positive answers



Survey Results (2)

- Question 3 – Main issues
  - Ensure data confidentiality
  - Link between notified studies and application
  - Legal obligations for laboratories under non-disclosure agreement
  - Reporting from non-EU laboratories
  - Duplication of public registries
  - Interference of other stakeholders in the application submission process
  - Easy system accessible both to applicants and laboratories allowing co-ordinated notifications
  - Link of notification of studies with intended studies for renewal
  - Link of notification of studies to the application validity and admissibility process

Summary

- Survey results
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Background

- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation)
- Notification of studies for application submission
  - Article 32b paragraphs 1-8
- Notification of intended studies for application renewal
  - Article 32c "Consultation with third parties", paragraph 1

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- Participants' questions
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Notification of Studies Supporting New Applications

Transparency in the generation and submission of studies in an application [Article 32b]

1. Pre-submission phase

Applicant

Labs and testing facilities

Notify studies

Database of Study Notifications

2. Submission of application

Validate if submitted studies were notified or justification provided

3. Validated application

Study notifications published with related studies

Notification of Studies Supporting Application Renewal

EFSA consults with third parties on the intended studies (and their design) proposed by applicants for application renewal [Article 32c]

1. Application renewal

Applicant

Intended studies and study design

Database of Study Notifications

2. Publication and public consultation

Provide advice

3. Notify studies

Applicant

What is a notification?

A notification is not a full study

- Title (Art 32b)
- Scope (Art 32b)
- Start date (Art 32b)
- Planned completion date (Art 32b)
- Business operator (Art 32b)
- Lab or testing facility (Art 32b)
- Study design only for intended studies for renewal (Art 32c)

Study information by Regulation

- Study identification
- Application identification (renewal)
- Product and components identification (New application)
- Notifier

Study interoperability and security information

No Study results

Confidentiality

The Notification of Studies are confidential

7. The Authority shall make public the notified information only in cases where it received a corresponding application or notification and after the Authority has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e.

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Target of the meeting

- Process of notification of studies by Business Operators (Article 32b(2))
- Process of notification of studies by Laboratories and Testing Facilities (Article 32b(3))
- Information to be notified
- Registration of organisation and users (only high-level information)

Notification of studies aspects not for discussion on the current meeting (1)

- Detailed information on organisation and user registration
- Access management to notifications
- Validity and admissibility of applications when supported by studies that have not been previously notified or valid justification is provided (Article 32b(4))
- Validity and admissibility of applications when studies that have been previously notified are not included in the application or valid justification provided (Article 32b(5))

Notification of studies aspects not for discussion on the current meeting (2)

- Detection, during the risk assessment process, of studies not submitted in full in the application (Article 32b(6))
- Publication of notified information (Article 32b(7))
- Practical arrangements (Article 32b(8))
- Submission of the list of intended studies for application renewal (Article 32c(1))

Aspects Outside this Technical Group

- Applications submission process
- Data formats for application submission
- Publication process
- Public consultation with third parties
- Pre-submission advice
- EFSA advice related to submission of the list of intended studies for application renewal
- EFSA confidentiality decision-making process

Questions?