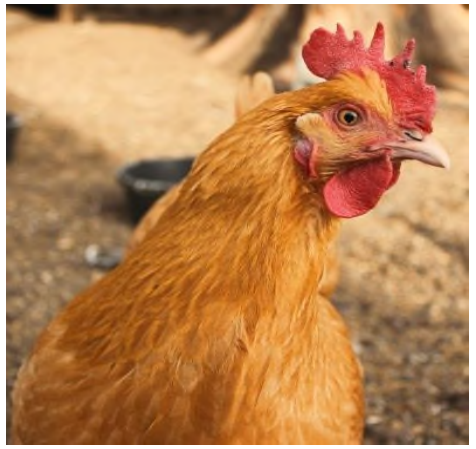
FEFANA

23 March 2023

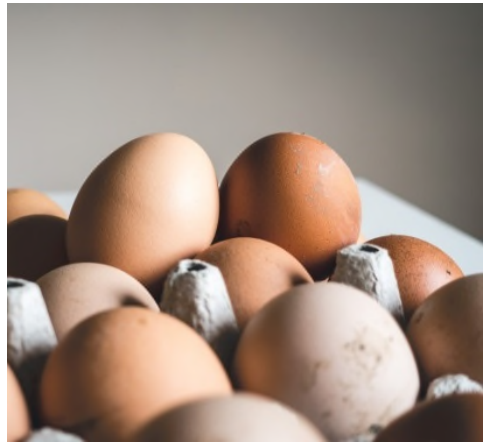
SUSTAINABILITY

INNOVATION



FEED SAFETY

ANIMAL HEALTH AND WELFARE



SAFE FOOD

EFSA TG tools – Second meeting

Feedback from TG members - FEFANA

Pre-submission phase

Notification of Studies with effect on dossier submission via ESFC

- According to the EFSA PA, the **internal study ID** is not a mandatory field when notifying a study.
- It emerges that in some cases the EFSA requested the Internal Study ID for each notified study when performing the **completeness check** of a dossier (no explanation given).
- In these cases, to avoid inconveniences and speed up the dossier validation process and considering that in most of the cases no “Internal Study ID” exists, a “pragmatic arrangement” put in place was to place the “EFSA study notification number” as the “Internal study ID”. => Should this be made a recommendation?

CALL FOR CONSISTENCY

If something is optional, it should not be made mandatory via RFI request.
If EFSA consistently want an internal study ID, the EFSA notification number might be used if no “internal study ID” is available. However, this should be communicated clearly.

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Submission phase

Management of published academic studies under ‘transparency rules’

On literature licenses, it was reported that the EFSA feedback depends on the officer responsible for the completeness check of the dossier.

Sharing copyrighted document without paying the proper license could expose companies to significant financial and legal problems.

CALL FOR a “Practical Arrangement”

Operators should be reminded about how to proceed in case of studies which are listed in their dossiers (*i.e.* supporting studies) but on which publisher property rights may apply. The intention should not be for the applicant to bear the financial burden for publication.

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Submission phase

Sanitisation of dossier may end up being extremely time consuming

Missing TOOL?

⇒ Currently, compliance with content sanitisation is being achieved in different ways by different operators:

- ⇒ Internally at company level
- ⇒ Via consultancy services
- ⇒ Via specific software where a fee is due either per page or via licensing.

Cost impact on SMEs!

⇒ Existing “paid software services” accurately perform the sanitation of application dossiers. Appropriate software utilities minimize the possibility of mistakes, secure sensitive data (and their handling) and significantly reduce operational time (up to about 80%).

CALL FOR an EFSA TOOL

Several EU SMEs would appreciate if the EFSA could explore the most appropriate way to offer an option to a recommended sanitising tool for companies who don't have an appropriate solution yet.

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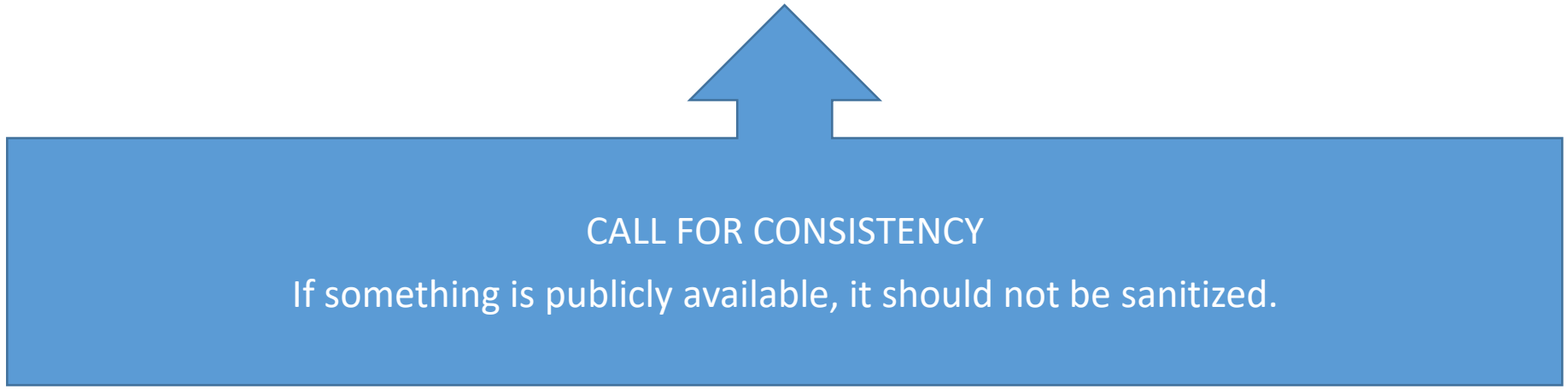
Submission phase

Personal information on publicly available documents

- European Union Reference Laboratory (EURL) reports publicly available on web should not be sanitized (especially if such missing sanitisation may generate delays). => Some operators have solved this problem by uploading the EURL report as a “Publication” with reference to the EURL webpage (of course “IPR not owned”). This worked out fine. Maybe the EFSA can make this a recommendation to prevent inconveniences.



RISK-ASSESSMENT phase

Validation of the application dossiers => current procedures should last no more than 30 days

- The validity check now takes substantially longer than before the transparency regulation came into force.
- Currently, EFSA requests are very often received on one of the final days of the review period.
- We acknowledge that reasonable questions may emerge last minute, but the issue was experienced regularly, by different companies.
- It was noticed that even if an RFI is clarified within the same day, it leads to an automatic extra 15 working days on the counter during validity check.

⇒Procedural suggestion: We would appreciate a first reaction within 15 working days.

CALL FOR PROPORTIONALITY

Possible EFSA Request For Information should be formulated within the 15 working days, as to avoid an otherwise mathematical delayed start of the risk assessment phase.

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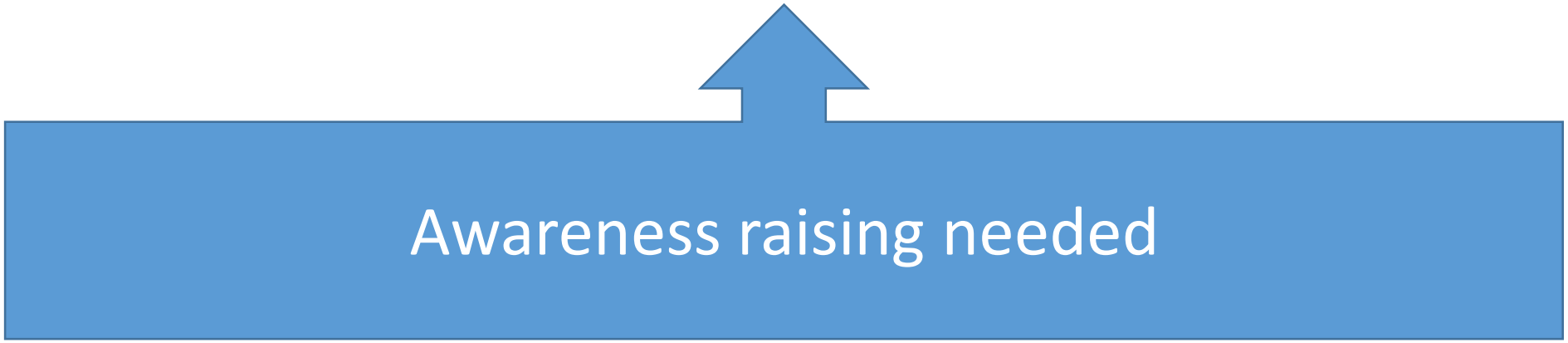
Appreciation

EFSA increased reactiveness

- ✓ EFSA tools continuous improvements being achieved
- ✓ Compared to the past, interaction with EFSA officers has significantly improved => in case of issues, a bilateral communication channel is possible
- ✓ Possibility to write to RAL@efsa.europa.eu / FDP@efsa.europa.eu for clarification!
- ✓ Technical support for EFSA.Connect works well



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THANK YOU!