30 June 2021

Ad-hoc meeting with industry representatives on smoke flavourings

Trusted science for safe food

efsa
European Food Safety Authority

Agenda

Time	No.	Item	
14:30	1	Welcome and scope of the meeting	EFSA
14:45		Transparency Regulation - Pre-submission activities	EFSA- APDESK
15:15	2	Questions and answers on the EFSA guidance for the preparation of applications on smoke flavouring primary products	EFSA Industry representatives
16:30		*Coffee break*	
16:45	2	Questions and answers on the EFSA guidance for the preparation of applications on smoke flavouring primary products	EFSA Industry representatives
17:30	3	Closing remarks	EFSA

In-house messages – some tips

Keep your **microphone muted and camera off** at all times unless specifically asked by EFSA

Use the **meeting chat box** only to **write questions** and **request the floor** (type: **"floor please"**)

When **taking the floor turn on your camera** (if possible). Please state your name and affiliation when introducing the question/comment

Use of headset recommended for better sound quality

If you have problems with the connection, exit the meeting and rejoin. If persist, write to: **Manuela.BUCALO@ext.efsa.europa.eu**

Scope of the *ad hoc* meeting

What?

- Initiative implemented by EFSA to **engage with its stakeholders** to **increase understanding** of its scientific risk assessment process (see EFSA Catalogue of supportive initiatives)
- **Set-up an open dialogue** and to **address any technical questions** that participants wish to discuss related to: i) **methodological** and procedural aspects, ii) **scientific requirements**, iii) approaches unique to the area of smoke flavourings
- This ad-hoc meeting is **not meant to provide any official scientific advice** to applicants for future submissions. This possibility is only foreseen under Article 32(c)1 of the GFL (Renewal Pre-Submission Advice), according to which EFSA can provide an advice on the design of the studies proposed by an applicant for renewal applications.

Participants

Who?

- **49 industry representatives** (applicants, CROs, consultants, associations, etc) in the area of **smoke flavourings**
- **10 scientific experts** from WG of the Panel on Food Additives and Flavourings (FAF) on Guidance Update on Flavourings
- **9 EFSA staff members**
- **11 Member States** representatives (AT, BE, ES, IE, NL, MT, NO, PT,)
- **2 EC DG-SANTE** representatives

Relevant links

- **Scientific Guidance** for the preparation of applications on smoke flavouring primary products (EFSA FAF Panel, 2021)

- **Administrative guidance** on the preparation of applications on smoke flavourings primary products (EFSA, 2021)

- **Q&A** on the EFSA's scientific guidance (link, minutes of the 22nd FAF Panel plenary meeting 4-6 May - pages 3 and 11-17)

Pre-submission advice and notification of studies

Remigio Marano

Applications desk (APDESK) Unit

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Summary

1. Recap on Transparency Regulation measures
2. Introduction on registration and pre-application ID
3. G-PSA
4. Notification of studies
5. List of intended studies for renewal and R-PSA

Renewal of smoke flavourings → Submit after 27th March 2021

- Transparency Regulation
  - EFSA PAs on pre-submission phase and public consultation
    - G-PSA Art. 32a
    - Public Consultation on submitted applications Art.32c(2)
  - EFSA PAs concerning transparency and confidentiality
  - Q&A on EFSA Practical Arrangements

TR provision	Study completed or ongoing* on 27th March	Study commissioned ON or AFTER 27th March
NoS 32b(2)(3)	NO	YES
List of int. studies 32c(1)	NO	YES (but)
R-PSA 32c(1)	NO	YES (but)

*Q&A #33 of PAs. […] In order to be considered an **ongoing** study on 27 March 2021, a study carried out by a potential applicant using its own test facilities must already have been started before this date. In the event that the relevant study is commissioned to an external laboratory or testing facility, the **study must have been commissioned before 27 March 2021** to be considered an ongoing study on this date.

Registration

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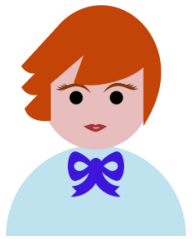
Registration Process



Sarah

Business Operator
Potential Applicant

John

Laboratories
Testing facilities

Martin

Third Parties

The public
(during PC or once studies are published)

1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

2. Third parties representing one or more entities shall also register in the Authority system supporting pre-submission activities …[1] and obtain the authorization by represented entities to act on their behalf

3. Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.[1]

[1]) Practical arrangements on pre-submission phase and public consultations

Pre Application Identification

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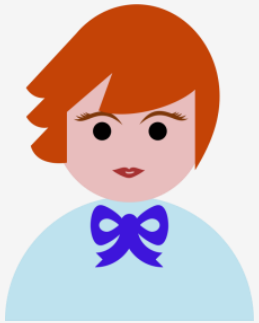
Pre-Application Identification for Renewal



Sarah

Requests
Pre-Application-ID
for Renewal

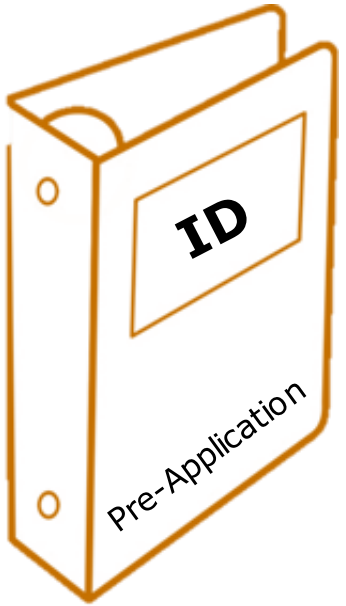
Additional features of Pre-Application Renewal

Former application ID +

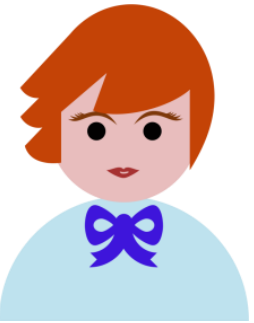
GPSA (If applicable) +

List of intended studies → Intended studies +

Is similar to ≈



Pre-Application Identification

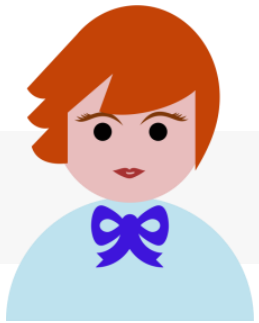


Sarah
Business Operator(s)

Subject of the application

Intended Area

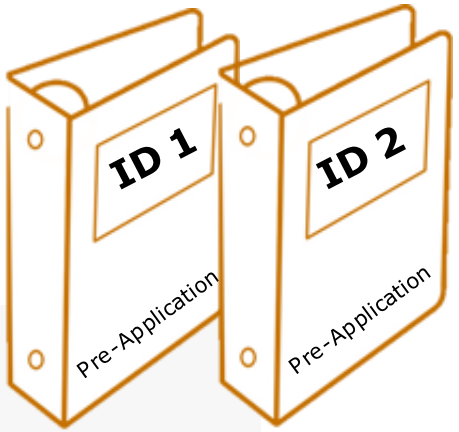
Pre-Application-IDs help in dossier validation



Sarah

Submits
the dossier

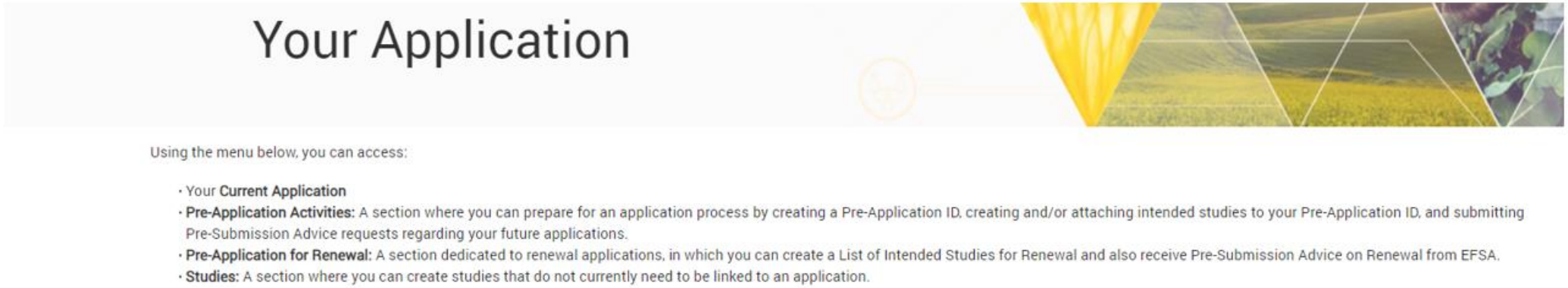
Reports
Pre-Application IDs



Finds
relevant
notifications

NoS-DB

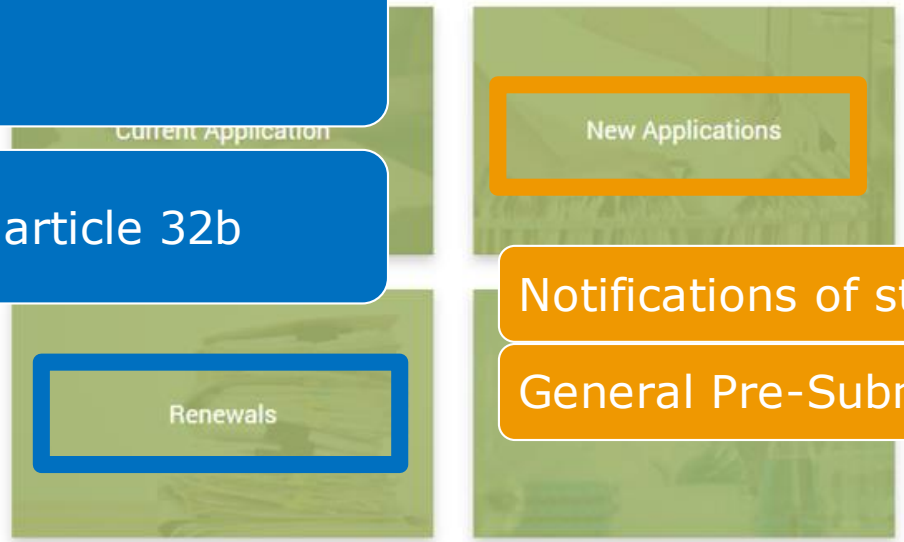
Your application sections



List of intended studies for renewal according to article 32c(1), PC and renewal PSA

General Pre-Submission Advice

Notifications of studies according to article 32b



Notifications of studies according to article 32b

General Pre-Submission Advice

General Pre-Submission Advice (G-PSA)

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Background

Transparency regulation Article **32a**

1. **Applications meet the applicable specifications** in order to ensure the best quality scientific assessment

2. **Rules** applicable to, and the **content** required for, the application, prior to its submission. Should not address the design of the studies to be submitted

3. Small and medium sized enterprises **-SMEs-**

Regulation (EC) No 178/2002 as last amended by 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

General Pre-submission Advice - Business Operators

Sarah

Potential applicant may **request** general pre-submission advice at **any time**

Requests for general pre-submission advice

Submit to EFSA

HOW?

Link requests to the individual or joint pre-application ID

Fill in the general pre-submission advice form available on the EFSA's website

Submit questions

Up to 2 G-PSA per pre-app ID

General Pre-submission Advice - EFSA

Receipt of the general pre-submission advice form

Step 1
Administrative Check

EFSA verifies that the related questions **fall within the scope**

Within **15 working days** from the receipt, EFSA informs the requester as to whether the request is **accepted or rejected**.

Step 2
Written or meeting

Where possible, EFSA shall answer the questions in **writing**

A meeting might be organised by EFSA

Step 3
Provide the Advice

The written advice shall be provided within **15 working days** as of the date of the acceptance of the request;

The meeting shall be organised within **20 working days** as of the date of the acceptance of the request

Step 4
Summary of the PSA

EFSA draws up a **summary** providing an overview of the advice and sends it to the requester for information

Notification of Studies (NoS)
Art. 32b

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Notification of studies

Transparency Regulation[1] Article **32b**

1 The Authority shall establish and manage **a database** of **studies commissioned or carried out** by business operators to support an application …

2 For the purposes of paragraph 1, **business operators shall**, without delay, **notify the Authority** …

3 For the purposes of paragraph 1, **laboratories and other testing facilities** located in the Union **shall also**, without delay, **notify the Authority** …

1) Regulation (EC) No 178/2002 as last amended by 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 (aka General Food Law)

Non-EU Laboratories

The Transparency Regulation only applies to EU-based laboratories, but are UK-based, non-EU CROs under the oversight of the Transparency Regulation (and thus require co-notification)?

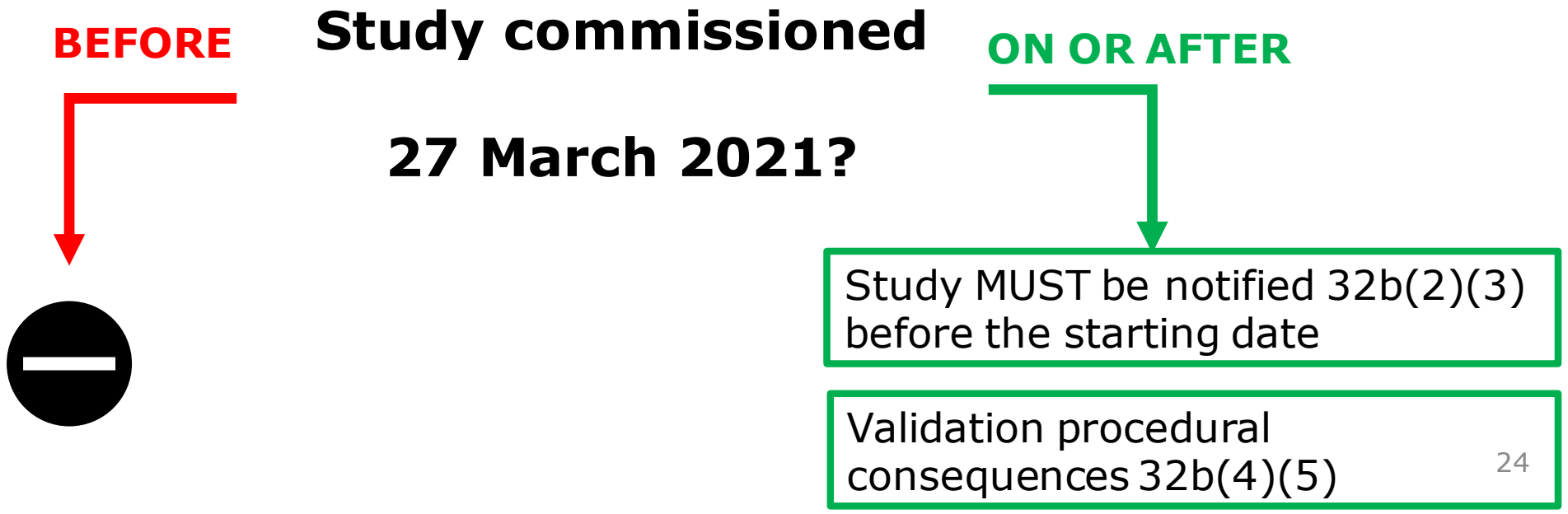
Q&A #35 on the EFSA Practical Arrangements (here)

*[…] This co-notification **is necessary only** when the relevant external laboratory or external testing facility **is located in the EU or in a third country with an agreement or arrangement** within the meaning of Article 32b(3), second paragraph, of the GFL18. With regard specifically to the impact of the withdrawal of the United Kingdom from the European Union, at present, the Protocol on Ireland/Northern Ireland to the EU-UK Withdrawal Agreement makes the **GFL applicable also to and in the United Kingdom in respect of Northern Ireland**. As a consequence, laboratories or external testing facilities located in Northern Ireland are subject to the co-notification obligations of Article 32b(3) of the GFL whereas laboratories and external testing facilities located in Great Britain are not subject to those obligations […]*

Does Art.32b apply?

Q&A #33 on the EFSA Practical Arrangements (here)

[…] In the context of applications submitted on or after 27 March 2021, **studies completed or ongoing on this date are not subject to the Article 32b notification obligations**. In order to be considered **an ongoing study** on 27 March 2021, a study carried out by a potential applicant using its own test facilities must already have been started before this date. In the event that the relevant study is commissioned to an external laboratory or testing facility, the study must have been commissioned before 27 March 2021 to be considered an ongoing study on this date.



List of Intended Studies for Renewal and Renewal Pre-Submission Advice

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List of intended studies for renewal

Transparency Regulation Article **32c(1)**

1. Where the relevant Union law provides that an approval or an authorisation may be renewed, the potential applicant shall **notify the Authority of the studies it intends to perform** for that purpose, including information on how the various studies are to be carried out.

2. Following such notification of studies, the **Authority shall launch a consultation of stakeholders** and the public on the intended studies for renewal, including on the proposed design of studies.

3. Taking into account the received comments which are relevant for the risk assessment of the intended renewal, **the Authority shall provide advice on the content** of the intended renewal application or notification, as well as on the **design of the studies**

Public consultation on intended studies for renewal

Receipt of the list of intended studies for renewal

Step 1
Administrative Check

EFSA launches the consultation of third parties on the **intended studies** for renewal

Including on the proposed **design** of the studies

Within 10 working days from the completion of the administrative check

Step 2
Public consultation

The consultation of third parties shall remain open for a period of **three weeks**

Step 3
Comments

All **comments received** by stakeholders and the public shall be made public by EFSA

Step 4
Summary of R-PSA

The **results** of the consultation of third parties shall be reported in the summary of the renewal pre-submission advice

Renewal Pre-Submission Advice

Comments received

Step 1
Written or meeting

Where possible, EFSA shall provide RPSA in **writing**

A meeting might be organised by EFSA

Step 2
Provide the Advice

The written advice shall be provided within **30 working days** as of the closure of the PC;

The meeting shall be organised within **30 working days** as of the date of the closure of the PC

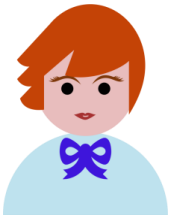
Step 3
Summary

EFSA draws up a **summary** proving an overview of the advice which includes how the **comments** were taken into account and sends it to the requester for information

Non-committal nature of R-PSA and G-PSA

Any subsequent **assessment of applications** by EFSA and the Member States

The **assessment of the** qualification of the specific regulated product under a given **regulated product area**



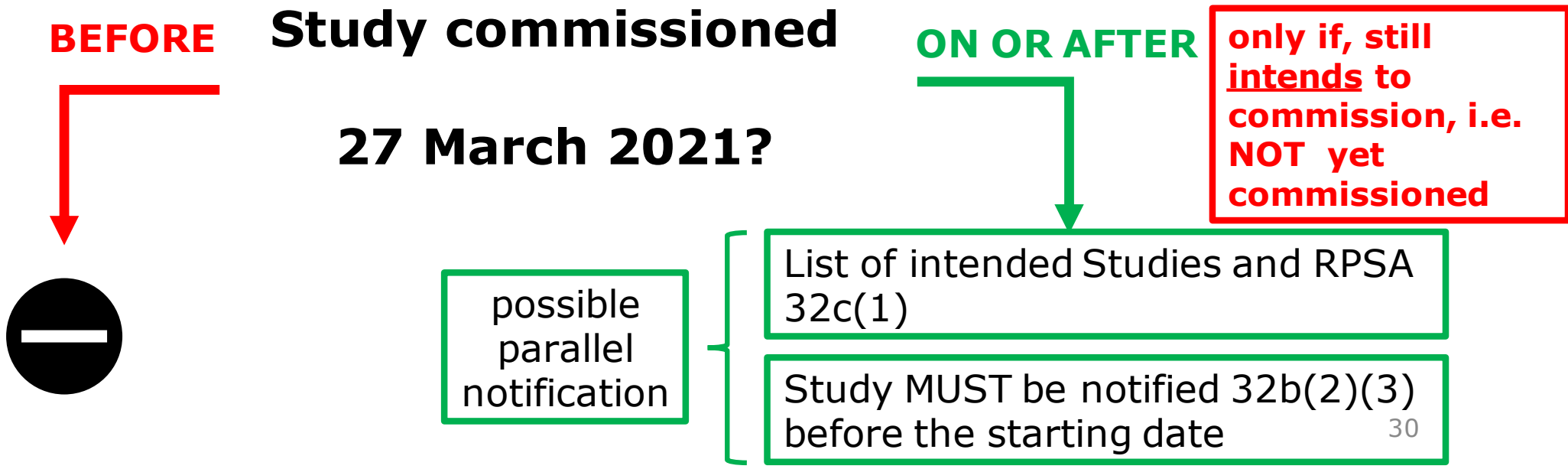
Sarah

The **potential applicant** shall not be bound by any renewal pre-submission advice

Does 32c(1) apply?

Q&A #22 on the EFSA Practical Arrangements (here)

[…] A potential applicant seeking the renewal of an authorisation or approval will be subject to those provisions **only if, on or after 27 March 2021, still intends to commission** or carry out a new study in support of a future renewal. If a study has been **commissioned or started before 27 March 2021**, there is no obligation to notify it as an intended study, even if on 27 March 2021 is still ongoing. If no new studies are planned to support the renewal application, Article 32c(1) of the GFL does not apply.



"Parallel notification"

Q&A #32 on the EFSA Practical Arrangements (here)

[…] Due to this tight timeline, the potential applicant is recommended, ***in parallel/or soon after the notification of the intended study under Article 32c(1) of the GFL, to proceed with the commissioning of the same studies,*** *notifying them in the EFSA database pursuant to Article 32b of the GFL, without waiting for the renewal pre-submission advice. In essence,* ***the two provisions would apply simultaneously****, even pending the renewal pre-submission advice by EFSA, which is anyway a service for the applicant and non-committal neither for EFSA nor for the potential applicant.*

[…] the obligation to notify studies pursuant to Article 32b of the GFL is associated to specific procedural consequences in case of non-compliance (see question 42). To avoid such procedural consequences, the potential applicant has to comply with the notification requirements where applicable, regardless the date in which the submission of the renewal application is due. In light of the above, in brief, and for a certain period of time, a potential applicant that intends to perform new studies as of 27 March 2021 would need to proceed with an (almost) simultaneous notification of Articles 32c(1) and 32b of the GFL.

Webinar Notification of studies and Pre-submission Advice 25/03/2021

Presentation:

Notification of Studies and Pre-submission Advice

Tutorial Videos:

3rd Party working on behalf of Business Operator

Laboratory notifies a study – Business Operator co-notifies adds notifications

Parallel notification article 32c(1) and article 32b

Pre-submission advice: meeting organisation

Can SF applicants simultaneously submit a list of intended studies (32c1) and notify these studies under Article 32b to ensure promptness in study commissioning?

Further material

- EFSA Practical Arrangements (here)
- Questions and Answers on EFSA Practical Arrangements (here)
- Administrative guidance for the preparation of applications on smoke flavouring primary products (here)
- Transparency Regulation Implementation Training Programme (here)
  - 2 webinars on NoS and PSA, 16/02 and 25/03
- Applications Toolkit (here)
- Webinar: Application procedure for food enzymes, flavourings and additives (here) → Calendar here

Updated material coming soon!

Questions and answers

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Questions submitted by industry before the meeting

- **Charles River** → *see separate presentation*
- **European Flavour Association Smoke Flavouring Primary Product Task Force** (EFFA SFPP TF)→ *see separate presentation*
- **Leveret GmbH**
- **Covance by Labcorp**

Leveret GmbH

- Are there any measures in consideration regarding the extension of the legal deadline, and if yes, to what extent?

- In the function of the resulting situation what is EFSA's recommendation for the applicants regarding the study to be conducted?

- If the legal deadline will not be extended, how EFSA will deal with the delayed submission of the study reports in terms of the validity of the applications?

Covance by Labcorp

- Given it is generally accepted that the global capacity for reproductive toxicity studies is currently 'stretched', how flexible will EFSA be in respect of the timelines for the requested studies for smoke flavouring products?

- Could EFSA share the ethical justification for the use of animals in validating the additional endpoints in the OECD 408 study design that is not destined to be the preferred study moving forward.

- EFSA's view on a proposed WoE approach for the integration of immunotoxicity endpoints in OECD 408 study in relation to recently published 2021 EFSA guidance on SFPP

EFSA answer to submission and validation questions

1. **EFFA SFPP TF's question:** Could EFSA accept an application as complete, even when intended studies cannot be finished, due to the legal deadline for renewal applications (June 22) and the resulting timeline constraints? From a practical perspective, missing information could presumably be uploaded to the e-submission system as soon the remaining / intended studies are finished, and reports are finalised. What's important is the legal certainty in the market.

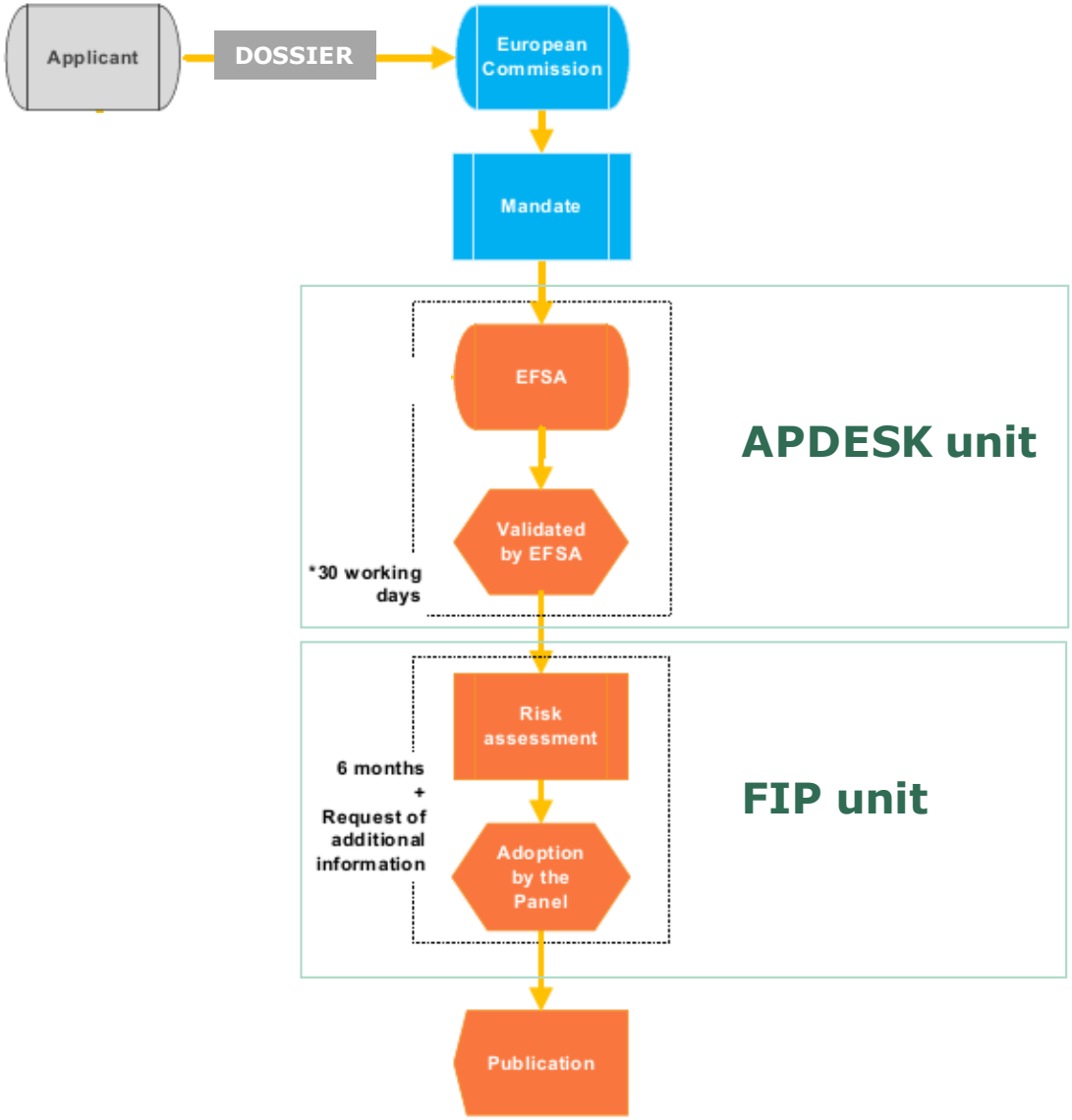
2. **EFFA SFPP TF's question:** f the applicant submits as much data as time allows, and notifies the additional studies under the Transparency Regulation requirements including co-notification by the laboratories, will the submission be considered valid?

3. **Leveret GmbH's question:** If the legal deadline will not be extended, how EFSA will deal with the delayed submission of the study reports in terms of the validity of the applications?

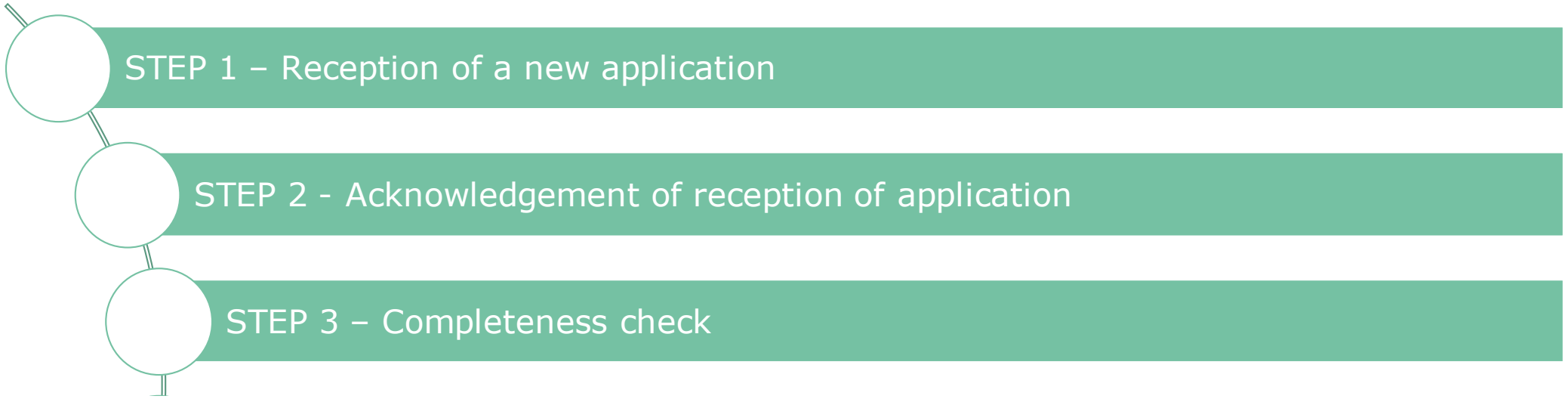
⇒ **Administrative guidance for the preparation of applications on smoke flavouring primary products** (here)

The legal deadlines for submitting a renewal dossier take precedence

SF applications workflow



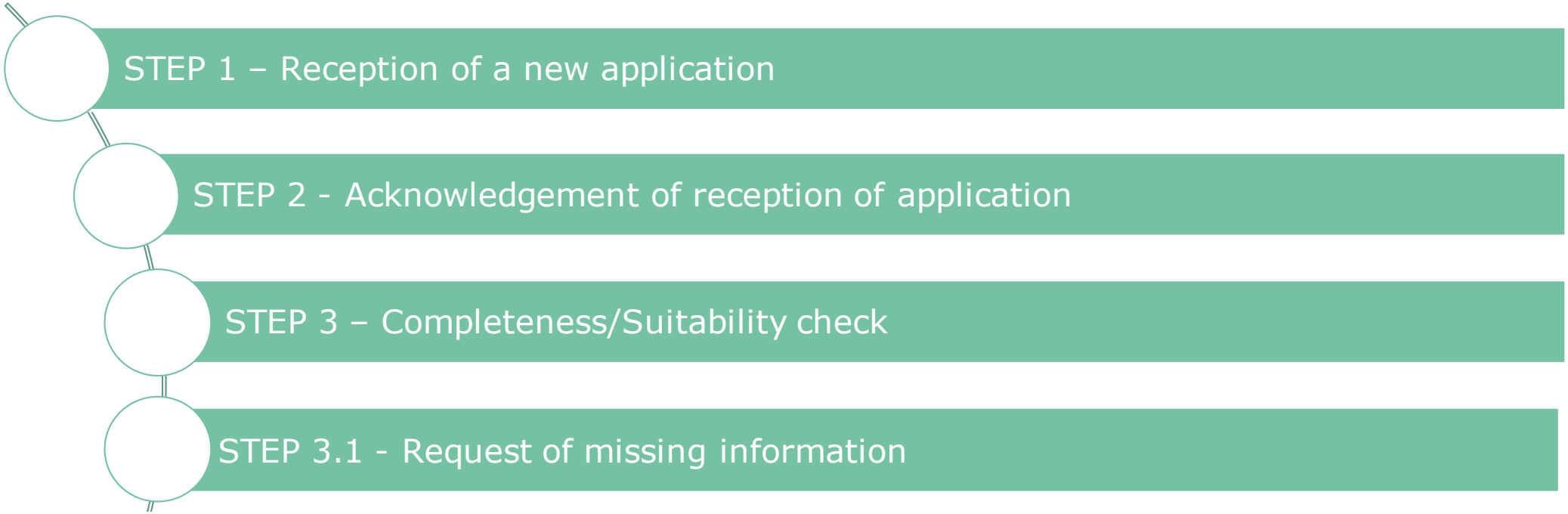
Submission and receipt by EFSA



- Revision of the content of the data in the application in accordance with specific requirements
- Ensure compliance with specific regulations of the applications before starting the risk assessment:
    - Sectorial Regulation
    - EFSA Scientific and Administrative Guidance Documents

EFSA has **30 working days**

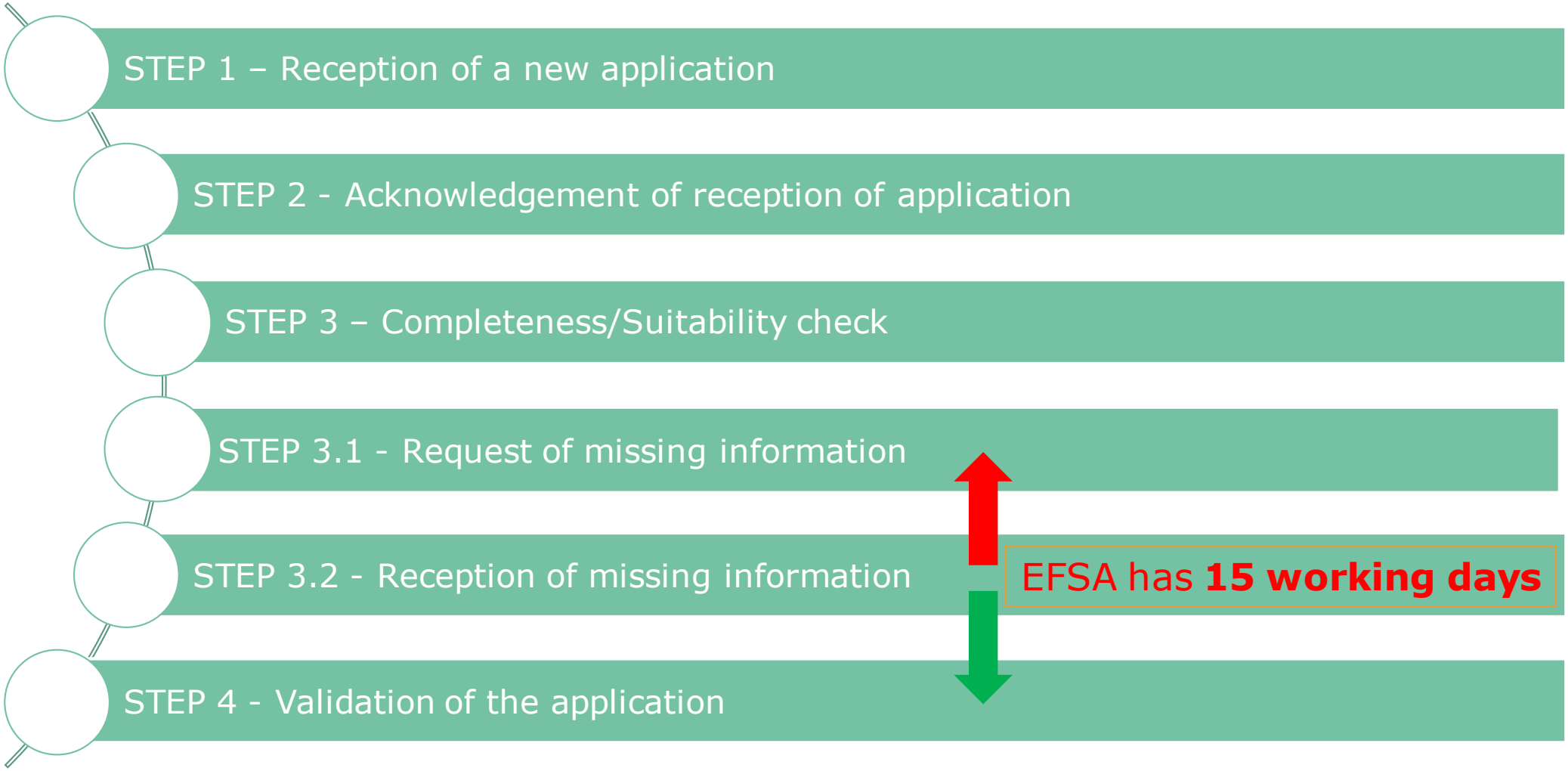
Request for information



Applicant should reply **within 30 days**

When this is not possible, the applicant should **indicate to EFSA the date by which the response is expected**, including an appropriate justification

Request for information or validation



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