Administrative and Procedural topics

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Retrospective analysis

Ad hoc meeting with industry representatives
23 - 24 October 2019, Parma

Trusted science for safe food

efsa
European Food Safety Authority

TOC

I. Ahead of us

- Harmonized strategy for the risk assessment of 'novel' proteins as regards their potential to cause celiac disease

  - Kick off meeting on 5 April 2019
  - Take home messages
    - On the right track
    - Call for flexibility pending commonly agreed approach
    - Commitment to continue the discussion

I. Ahead of us

- Explanatory note on the selection of forage material suitable for the RA of GM feed of plant origin
  - Transition period of 2 years after publication (29 JAN 2018)
  - Submission of data on forage in GM maize, soybean and sugar beet applications
  - Expected data:
    - a complete list of the parts of the plant included in the forage samples analysed;
    - an indication of the growth stage at which the crop selected for the analyses was harvested;
    - a report on how samples have been collected;
    - a description of all the steps from harvest to analyses (e.g. date of harvesting, storage conditions, date of analyses).

II. Fresh on our plate - Updates

- Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual PMEM reports on GMOs authorised in the EU market
  - Update to 2017 version
  - @ ad hoc meeting in June 2019

- EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products
  - Update published online on 1st August 2019
  - No impact on the current way of working
    - Ad hoc meetings with industry
    - Clarifications teleconferences during the RA
    - Clarifications teleconferences after adoption
  - Next update to reflect the new rules on transparency and sustainability of risk assessment

II. Fresh on our plate - Updates

- Administrative guidance for the processing of applications for regulated products

  - Update published online in July 2019

  - Including indicative timelines for submission of add info
  - Implementation of the Ombudsman recommendation for more transparency regarding "*the communications with the applicants' companies on the requests for additional data, information and clarification*"
    - Scope:
      - Correspondence between EFSA – Applicants from validity/acceptance until adoption
      - All applications (new and RX) submitted to EFSA
      - All mandates under Art. 29 and 31 when related to applications (e.g. new publication, supplementing inconclusive opinion, linked to post-market monitoring)

II. Fresh on our plate - Novelties

- EFSA statement on human dietary exposure assessment to NEPs in GM foods
  - Published online in July 2019
  - EFSA letter dated 11 July 2019
  - @ ad hoc meetings in October 2018 and 2019

II. Fresh on our plate - Novelties

- Administrative guidance on the submission of applications for renewal of authorization of GM food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003

  - Published on 24 June 2019
  - Main changes
    - Structure of dossier & Data presentation
    - New/updated guidelines taken on board (e.g. 2018 sequencing note, 2017 allergenicity GD)
    - Novel info 'requirements':
      - 'particulars' referred to in Articles 6(5) and 18(5) of Reg 1829/2003,
      - Info package to JRC-EURL to support their 'suitability' check of the validated detection methods (as provided in the original dossiers) at the time of renewal (Appendices C, D and E)
  - Transition period for submitting RX APs in the former format: 8 weeks as of the publication date (EFSA letter to EuropaBio dated 11 July 2019)

II. Fresh on our plate - Novelties

- Procedures
  - Post-adoption of a SO
    - 'Overall opinion' discontinued
    - For new and RX APs
    - '1829/2003 particulars' attached to SO and published in RoQ
    - Annexes to SO
      - Labelling proposal and Cartagena protocol,
      - PMEM plan,
      - Validation report(s) from JRC-EURL of detection method(s)
        - Monthly update on GMO adoption forecast
      - Certified Reference Material(s) (CRM)
        - New compliance check by JRC-EURL

III. Reporting

- Development/update of technical and administrative guidelines
- Generic mandates: finalized
  - EC mandate to assess the additional information related to application EFSA-GMO-UK-2006-34 for authorisation of maize 3272
  - EC mandate to address comments from an NGO on EFSA SO on maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 (EFSA-GMO-BE-2013-118)
  - EC mandate seeking for scientific assistance on new scientific information (Santos-Vigil et al., 2018) in relation to the risk assessment of GM crops
  - EC mandates to address the public comments on applications submitted under Regulation (EC) No 1829/2003 on GM Food and Feed and adopted by the GMO Panel

    AP103, 112, 113, 131, 133, 135, RX-009, RX-010
- A total of 9 applications adopted
  - New 6
  - Renewal 3

IV. Recurrent questions

1) Your data assessed by external contractors
2) Requests for Public Access to Documents

1) Your data assessed by contractors

Background

- At our ad hoc meeting in 2016
- Systematic release of contractors' reports pertaining to a given application to the respective applicant

- When
  - After publication of the adopted scientific opinion
  - In case the respective final deliverable(s) of the contractor(s)have not been approved yet by EFSA at the time of publication of the said scientific opinion, the contractor(s) report(s) will be released as soon as EFSA approval of the final deliverables has been obtained

1) Your data assessed by contractors

Contractor out

Preparatory support on bioinformatics for the evaluation of the risk assessment of GMO dossiers (till end 2017)

Contractors in

- Preparatory work on the toxicological studies and animal feeding studies (till 2020)
- Statistical evaluation of the comparative assessment of GM plant field trials (till 2020)
- Evaluation of literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market (till 2023)

→ No change to the approach
Contractors reports will be provided when available

2) PAD

- Applicant consultation based on the latest Public Access version of your dossier
- Reminder from procedure set up by EC
  - PA version at validity
  - PA version after adoption

V. Wrap up

Towards a smooth, reliable and robust Risk Assessment …

- **Common understanding**
  - **Overall outline set by the guidelines and by law**
    - **Guidelines implementation**
    - **Implementation of legal requirements**
    - **Data requirements**
  - **Day-to-day operational RA**

V. Wrap up

Towards a smooth, reliable and robust Risk Assessment …

- **Common understanding**
  - **Overall outline set by guidelines**
    - Engagement in development of guidelines
    - Sharing respective expertise (EFSA/Applicants) in developing RA strategies
    - Timely communication on applicability of new/updated guidelines
  - **Guidelines implementation**
    - Not retroactively applied
    - Transition period(s)
      - EFSA commitment to make them more explicit

V. Wrap up

- **Common understanding**

  - **Implementation of legal requirements**

    Examples:

    - Review of unpublished studies performed by the applicant prior and after submission

      → Calling for pragmatism (2018)

    - Scope of high stack of segregating crop, including all sub-combinations not previously assessed

      → Panel strategy adopted in May 2017

      → Translated into request for compiling data on single events, high stack and sub-combinations already assessed

    - 90-day rodent feeding studies

      → Asynchronous streams of incoming info and outgoing (same) questions on a given study

      → Proposal to provide access letters to 90-day studies (positively) assessed by the GMO Panel (July 2019)

V. Wrap up : 90-day studies

- Procedure
  - Single event present in a 'stack' and for which a 90-day study was already (positively) assessed by the GMO Panel
    - **How**

      By submitting an access letter to the full information package related to the 90-day study (previously submitted in a single or stack application)
    - **When**

      For new applications and for ongoing applications (e.g. in response to pending questions)
    - **Who**

      The applicant of the stack application
    - **Why**

      To optimize our respective workforces without undermining the completeness and robustness of the RA

EFSA letter to EuropaBio dated 11 July 2019

V. Wrap up

- **Common understanding**

  - **Overall outline set by guidelines**
  - **Guidelines implementation**
  - **Implementation of legal requirements**
  - **Data requirements**: focus on
    - Completeness of info package
      - Common interest to resolve possible data gap(s) → Inconclusive RA
      - Inconclusive opinions: cons
        - Be detrimental to public trust to RA system,
        - Trigger further delay in RA process and progress
    - Reliable info package
    - Quality of data
      - Compliance with quality standards

V. Wrap up

- **Common understanding**
  - **Overall outline set by guidelines**
  - **Guidelines implementation**
  - **Implementation of legal requirements**
  - **Data requirements**
  - **Day-to-day operational RA**

EFSA

- *In depth completeness check*
- Principle of 'single first'
- No reiteration of questions
- Rationale supporting the questions
- Attempt to cluster questions
- A sequential flow of questions: more insights on EFSA process(es)
  - Screening of dossiers at early stage of RA
  - Discussion at WGs meetings
    - Assessment of specific datasets by contractors go in parallel
  - Possible questions sent out
  - Add data brought to attention of WG experts (when needed, joint meetings)
  - Updated dataset requested (if needed) towards the end of the RA

V. Wrap up

- **Common understanding**
  - **Overall outline set by guidelines**
  - **Guidelines implementation**
  - **Implementation of legal requirements**
  - **Data requirements**
  - **Day-to-day operational RA**

EFSA

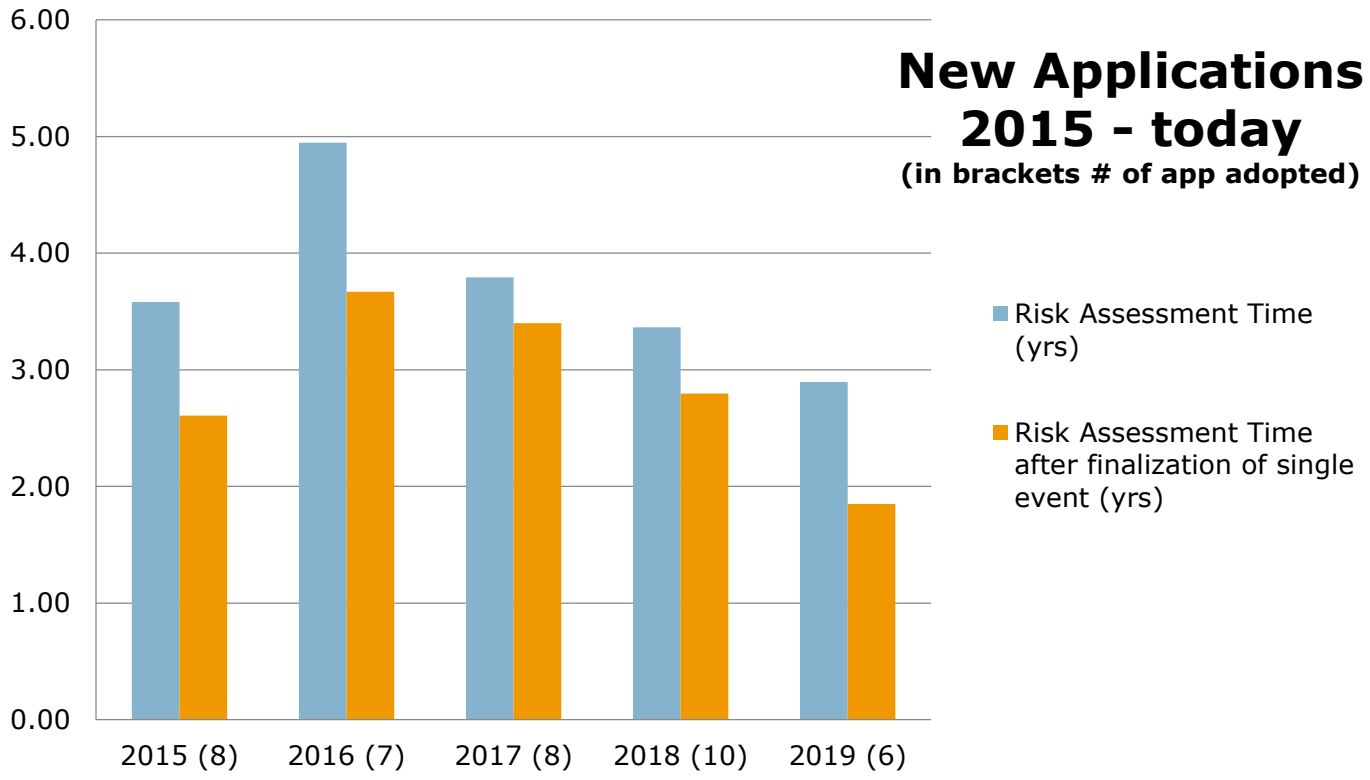
(…)

Applicants

- Catalogue of services to companies during the lifetime of their applications
  - 11 clarifications teleconferences
- Actions expected by specific deadlines
  - Do you plan to provide the info requested? If yes, by when?
  - If deadline is postponed, why?
  - Equally interesting for EFSA to know if you plan to submit the info before the deadline!
- Information received
  - Clear reference to (1) partial vs impartial info package, and/or (2) spontaneous info

V. Wrap up : figures

Overall timeline of RA post-Regulation 503/2013



VI. Way forward

Room for improvement

- Our partners in the RA process: Member States
  - MS consultation per each application
  - Annual Network meetings
    - Guidelines: under development, new, etc
    - Engaging a dialogue on MS consultation and its remit
      - Comments relevant to RA (missing data, non adherence to guidelines)
      - Additional comments (e.g. on single in context of stack dossiers, related to risk management

- To continue and further improve the cooperation
  - Focus on consolidating what is in place
  - Discussion items
  - Ad hoc meetings in 2020

THANK YOU !!!!

To your agenda's…. Registration to the GMO Panel meeting on 27 & 28 November is open