Updates from SANTE

- **Evaluation/review of EURL designations**

- **Revision of Regulation (EU) 2015/1375**

Kris De Smet

Unit G5, DG SANTE

EURL NRL Workshop, 16-17 November 2023

Legal base for review of EURL designations

- Articles 92(3) and 93(2)(b) of Regulation 2017/625 (OCR)

“The Commission shall review regularly the mandate and operation of the European Union reference laboratories.

The designations shall be limited in time and with a minimum period of five years or reviewed regularly.”

DG SANTE review procedure

- DG SANTE has established procedure regarding review of designations

- Objective of procedure:
  - to review the designation, mandate and operation of EURL which are designated in accordance with OCR provisions

- If DG SANTE intends to change the scope of EURLs or intends to replace or add new institutions to consortium, a full designation process by launching a public selection process will be completed

- In any case an evaluation of the existing EURL parasites every 7 years

European Commission

Evaluation committee

- Review to be performed by a SANTE Review Committee for the respective EURL
- Review Committee to consist of at least three Commission officials:
  - DG SANTE technical desk officer responsible for managing the respective EURL,
  - two other colleagues (with relevant technical expertise within DG SANTE and/or other Commission DGs, as appropriate).

The SANTE co-ordination Unit (G4) will participate to ensure a consistent approach across the board

Process of conducting review

- Standing Committee for Plants, Animals, Food and Feed (PAFF) meeting:
  - inform MS about the intention to start the review process,
  - invite MS to provide views on performance, including complains, as regards specific EURL (within 1 month), **involvement of NRLs expected**
  - announce if structured service satisfaction survey involving MS authorities will be conducted

- The EURL to be informed in advance that the review will take place, and may be consulted in the review process where it is necessary to obtain additional specific information

Process of conducting review

Evaluation of following requirements:

- performance of the EURL based on the responsibilities and associated tasks laid down in Art. 94 of OCR, and the outputs of EURL (e.g. implementation of annual(multi-annual) work programme)

- compliance with designation criteria that are established in OCR (Art.93)

- compliance with the requirements set out in the terms of reference of the call for tender for the designation of the EURL and the commitments given in the application(optional)

- where available, the results of Commission controls (Article 99(3) of OCR) to be taken into account

Process of conducting review

Review Committee members to complete their report based on the check-list with their findings, conclusions and recommendations

The report of the review committee to conclude that either:

- existing EURL should continue to remain designated; or

- existing EURL should continue to be designated, but the Commission services should request certain remedial action from EURL; or

- a new EURL should be selected by public selection process

Process of conducting review

• If Review Committee concludes that a new EURL should be designated:

- letter is sent to the EURL concerned to provide comments to the findings,

- the EURL reply is assessed and included in the final checklist/report and recommendation of the Review Committee

• In all cases respective EURL to be informed by the letter about the outcome of the review process

Process of conducting review

- Policy Units must inform MS at a PAFF meeting about the final outcome of the review process

- Following the public selection process to designate new EURL the Policy Units should make changes in legislative acts

No timing yet for the evaluation of EURLs!

European Commission

Revision of Commission Regulation (EU) 2015/1375 (*Trichinella*)

- Commission Implementing Regulation (EU) 2023/2154 of 17 October 2023
- Available at EUR-Lex - 32023R2156 - EN - EUR-Lex (europa.eu)
- Purpose: part of a much broader initiative to reduce the administrative burden for competent authorities
- Reporting requirements for *Trichinella* in domestic swine:

1. To EFSA (all monitoring) within the frame of the zoonosis monitoring Directive 2003/99/EEC (Chapter II to Annex IV)
2. To the Commission when derogating from *Trichinella* testing where animals come from a holding or a compartment officially recognized as applying controlled housing conditions (Article 3(4), BE, DK, FI, IT, UK(NI), CH)

Revision of Regulation (EU) 2015/1375 (*Trichinella*)

- Replacement of Article 3(4) by:

« 4. *Where a Member State implements the derogation provided for in paragraph 3 of this Article, the Member State concerned shall inform the Commission and the other Member States at the Standing Committee on Plants, Animals, Food and Feed. The Commission shall publish the list of Member States implementing that derogation on its website.*

Where a Member State fails to submit, in accordance with Article 9(1), second subparagraph of Directive 2003/99/EC, the data on the Trichinella examination referred to in Chapter II of Annex IV to this Regulation, the derogation, provided for in paragraph 3 of this Article, shall cease to apply to that Member State”

Thank you