18th Annual Meeting of the TSE EURL Torino, Italy 12th-13th September 2019

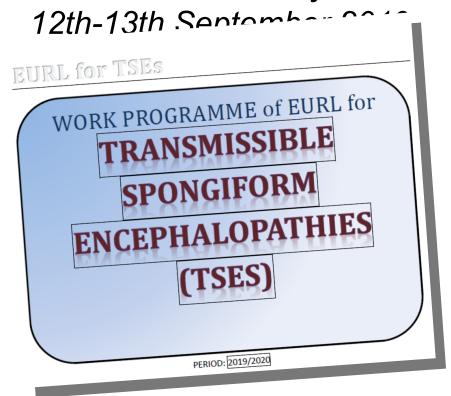
EURL for TSEs Work programme 2019-2020

Giuseppe Ru



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18th Annual Meeting of the TSE EURL Torino, Italy





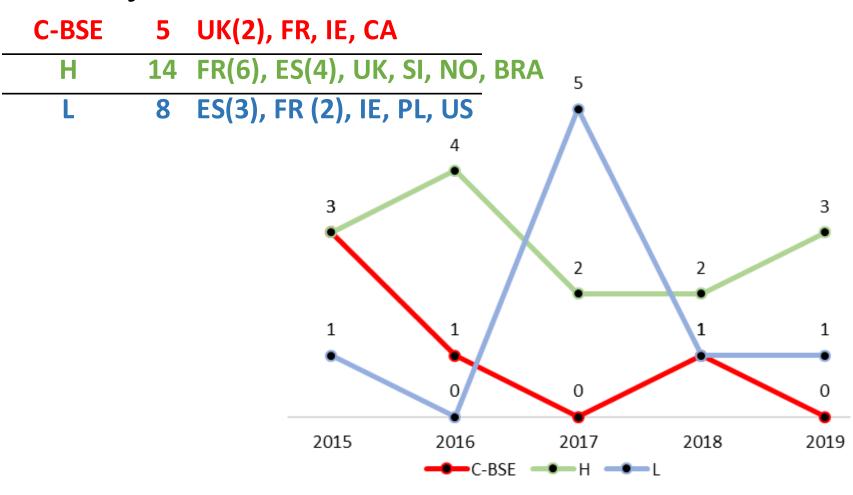
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Where we are and what we have to do



 BSE(s): 27 cases worldwide over the last five years



vCJD: 1995-2019 in total

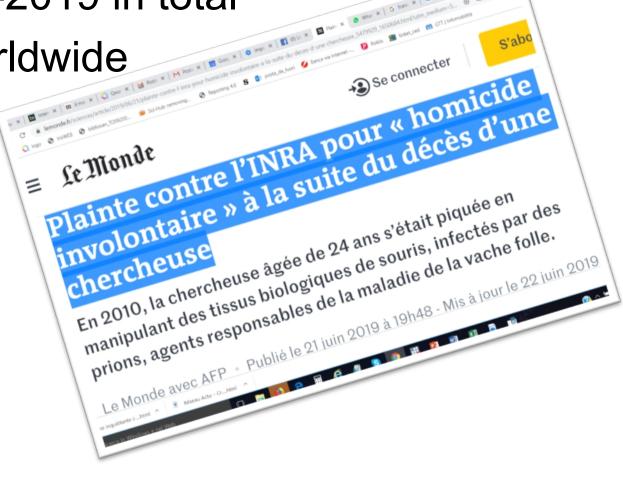
232 cases worldwide

UK	178
France	28
Spain	5
Ireland	4
USA	4
Italy	3
Netherlands	3
Canada	2
Portugal	2
Saudi Arabia	1
Japan	1
Taiwan	1

vCJD: 1995-2019 in total

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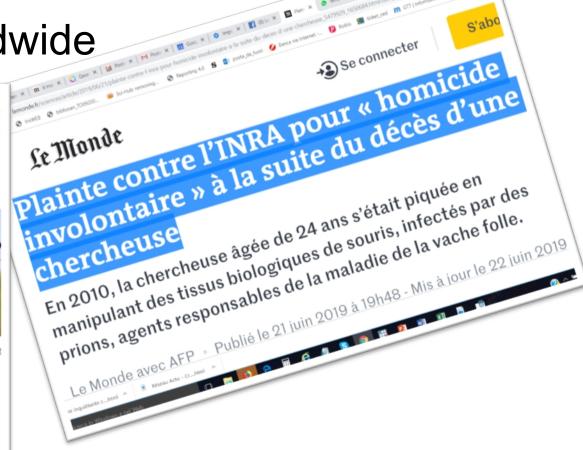
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vCJD: 1995-2019 in total

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Un cas probable de variant de la maladie de Creutzfeldt Jakob a été diagnostiqué en 2019. Cette personne a été possiblement exposée dans son enfance par voie alimentaire à l'instar de la population générale, et a également été possiblement exposée à des protéines prions d'origine humaine dans un contexte professionnel (laboratoire de recherche). https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-infectieuses-d-origine-alimentaire/maladie-de-creutzfeldt-jakob/donnees/#tabs

vCJD: 1995-2019 in total

232 cases worldwide





In 2019, a likely case of variant Creutzfeldt Jakob disease was diagnosed. This person may have been exposed in childhood through food, as in the general population, and may also have been exposed to prion proteins of human origin in a professional context (research laboratory).

https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-infectieuses-d-origine-alimentaire/maladie-de-creutzfeldt-jakob/donnees/#tabs

vCJD: 1995-2019 in total 232 cases

worldwide		It is very likely that all patients have
UK	178	become infected in Italy through food.
France	28	However, the patient who died in 2017
Spain	5	worked in a prion research laboratory
Ireland	4	where he came into contact with huma brain tissue infected with variant CJD
USA	4	and with bovine brain tissue infected
Italy	3	with typical and atypical BSE. It cannot
Netherlands	3	therefore be excluded that the patient has
Canada	2	become infected during laboratory
Portugal	2	activities, even if the epidemiological
Saudi Arabia	1	investigations have not established any
Japan	1	laboratory accident.
Taiwan	1	http://old.iss.it/binary/rncj/cont/Tavola31Luglio2019_it.pd

worldwide

Scrapie in EU in 2017 (EFSA report):

- Cases in sheep
 - -839 CS (145 index) in 8 MSs
 - -94 AS (89 index cases) in 13 MSs.
- Cases in goats
 - -558 CS (42 index) in 7 MSs
 - -9 AS (7 index) in 5 MSs.

Cervids CWD: 27 cases since 2016,
 3 countries (Norway +++, Finland,
 Sweden), 3 species

 Camels CPD in Northern Africa...an update will be provided during this meeting

...and what we have to do

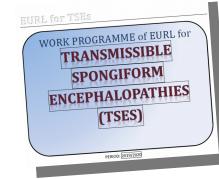


A two-year programme

- It is based on the EURL's responsibilities and tasks as listed within Art. 94 of Regulation (EU) 625/2017
- It accounts also for the functions and duties of the EURL for TSEs as listed in Regulation (EC) 999/2001 (Annex X, Chapter B)

Translate tasks into activities

- All the EURLs are requested to translate their tasks into sub-groups of activities
- These sub-groups form the five chapters of the biannual programme.





The activities

- to ensure availability and use of high quality methods and to ensure high quality performance by NRLs
- 2. to provide scientific and technical assistance to NRLs
- 3. to provide scientific and technical assistance to the European commission and other organisations
- 4. reagents and reference collections
- 5. requirements related to other legislation

The activities

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 work programme of EURL for TSES

 WORK PROGRAMME OF EURL FOR TRANSMISSIBLE
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SPONGIFORM ENCEPHALOPATHIES

(TSES)

- 1. to ensure availability and use of high quality methods and to ensure high quality performance by NRLs: sub-activities:
- 1.1 Revision and development of guidelines on the methods of laboratory analysis, testing or diagnosis
- 1.2 Development of methods of analysis, testing or diagnosis and EURL expertise maintenance
- 1.3 Interlaboratory comparative testing / proficiency testing, EQA
- 1.4 Transition activities



- 1. to ensure availability and use of high quality methods and to ensure high quality performance by NRLs: sub-activities:
- 1.1 Revision and development of guidelines on the methods of laboratory analysis, testing or diagnosis
- For the purpose the existing guidelines have been reviewed, updated and made available
- A survey of the methods in use within the NRL has been carried out



- 1. to ensure availability and use of high quality methods and to ensure high quality performance by NRLs: sub-activities:
- 1.2 Development of methods of analysis, testing or diagnosis and EURL expertise maintenance
- The focus is in establishing at the EURL discriminatory western blot methods for bovine and small ruminants and validating a characterization method for cervid TSEs



- 1. to ensure availability and use of high quality methods and to ensure high quality performance by NRLs: sub-activities:
- 1.3 Interlaboratory comparative testing / proficiency testing, EQA
- One of our main task! The ongoing activities of organization of the annual rounds of EQAs will be described in the following presentations today

1. to ensure availability and use of high quality methods and to ensure high quality performance by NRLs: sub-activities:

1.4 Transition activities

- We do not start from scratch but...
 - first of all we need to set up a collection of reference material: for the purpose a number of NRLs have been contacted, in particular to source H- & L- BSE
 - A new EURL website will be develop and maintained: in the meanwhile a freely accessible electronic repository for documentation (e.g. revised guidelines or batch testing outputs) has been made available to NRL representatives

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ENCEPHALOPATHIES

(TSES)

2. to provide scientific and technical assistance to NRLs

- 2.1 Scientific and technical assistance to NRLs
- 2.1 TSE Workshop and meetings
- 2.3 Conducting training courses for staff from NRLs, official laboratories or experts from third countries
- 2.4 Providing information on relevant national Union or international research activities to national reference laboratories



2. to provide scientific and technical assistance to NRLs

- 2.1 Scientific and technical assistance to NRLs
- Since last January our experts are available in case assistance is needed: technical problems in lab, clinical or epidemiological advices, neuropathological differential diagnoses.
- 2.2 TSE Workshop and meetings
- Today's annual meeting!



2. to provide scientific and technical assistance to NRLs

- 2.3 Conducting training courses for staff from NRLs, official laboratories or experts from third countries
- Training on request at the EURL
- 2.4 Providing information on relevant national Union or international research activities to national reference laboratories
- Networking, in particular through the website when available



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ENCEPHALOPATHIES

- 3.1 Providing scientific and technical assistance to the Commission
- 3.2 Collaborating with laboratories in third countries and with the EFSA, EMA, ECDC
- 3.3 Assisting actively in the diagnosis of outbreaks
- 3.4 Strain typing expert group (STEG)

- 3.1 Providing scientific and technical assistance to the Commission (or national CAs)
- Assistance or investigations in case discriminatory testing or genotyping for referral cases needed
- 3.2 Collaborating with laboratories in third countries and with the EFSA, EMA, ECDC
- Availability of our experts for full collaboration

- 3.3 Assisting actively in the diagnosis of outbreaks
- On demand:
 - Confirmation/characterization of TSE cases referred by NRLs.
 - Assistance to the EURL_STEG for the final assessment of suspected BSE cases (BSE/non-BSE, further strain identification).
 - Reference data and bioassay strategy for BSE identification.

train characterization of CWD isolates referred by NRLs.

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- 3.4 Strain typing expert group (STEG)
- Organization of one STEG meeting to discuss validation/interpretation of the increasing range of Tg bioassay methodologies, and how to interpret complex data
- A potential activity will deal with the validation of any new potential discriminatory method needing further assessment.



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SPONGIFORM ENCEPHALOPATHIES

(TSES)

4. reagents and reference collections

- 4.1 Verification of reagents/lots quality (BT) and approval of minor testing kit changes.
- 4.2 Collection and maintaining a biobank of reference material depending upon availability from DEFRA
- 4.3 Production of reference panels for EQA/Batch testing



4. reagents and reference collections

- 4.1 Verification of reagents/lots quality (BT) and approval of minor testing kit changes.
- Currently an intensive activity is ongoing with manufacturers interacting with our experts for both batch testing and approval of kit changes
- The documentation associated to these activities has been made available

4. reagents and reference collections

- 4.2 Collection and maintaining a biobank of reference material depending upon availability from DEFRA
- Material has been made available by APHA and now is stored. The collection will be further expanded thanks to NRLs kindly sharing further materials. Both TSE infected tissues, blood for genotyping and reference strains will be stored.
- 4.3 Production of reference panels for EQA/Batch testing: now ongoing

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SPONGIFORM ENCEPHALOPATHIES

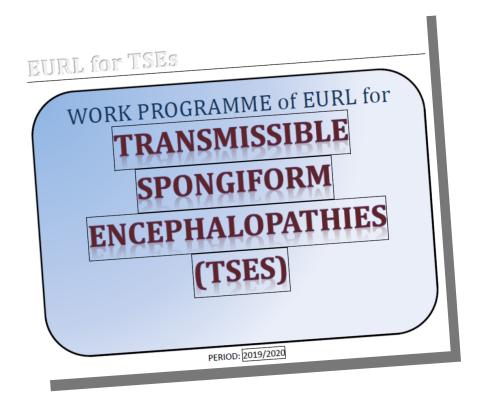
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5. requirements related to other legislation

- 5.1 Production of thematic best practices through dialogue with NRLs (outside the scope of R999/2001)
- The idea is to develop agreed documentation on specific relevant issues: e.g. laboratory decommissioning, effective risk management of biological risks
- To be discussed in the dedicated session tomorrow: volunteering for working groups membership?



Thanks and enjoye our meeting!





Thanks to our outstanding EURL staff!!

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