

V23/7/23

Call for support for preparation of an EFSA dossier on Cat1 Animal By-Product ashes

Context:

Ashes from combustion of Category 1 Animal By-Products represent a quantitatively significant potential secondary resource for phosphorus (P) recovery, contain relatively high concentrations of P and low levels of contaminants, and have significant calorific value. The EU Fertilising Products Regulation 2019/2009 authorises use of a range of ashes and ash-derivates as inputs to CE-mark products (CMC13), but excludes Cat1 ashes. The European Commission (DG SANTE) has agreed to request from EFSA (European Food Safety Agency) an Opinion on the safety of possible use of Cat1 ashes and derivates in fertilisers.

Questions and status of knowledge

It can be assumed that EFSA will consider the most sensitive risk in Cat1 ash to be prions, in particular BSE prions. EFSA are susceptible to consider that the Brown et al. studies (2000, 2004, see <u>ESPP</u> <u>eNews n°73</u>) suggest possible prion infectivity after combustion at 850°C, even in the absence of organic carbon or protein. ESPP organised an online meeting of companies and experts on Cat1 ash safety (22 May 2023), including two co-authors of these studies. This meeting concluded that there are today no practical* methods to reliably test ash samples to show absence of prion infectivity and no experimental evidence of elimination of infectivity by combustion under EU Industrial Emission Directive conditions. [* practical = excluding in vivo animal studies with prion infected material].

The meeting therefore proposed to develop a dossier of evidence to input to EFSA based on input material risk and on epidemiological data:

- Near-zero BSE in cattle today
- Near-zero vCJD in human populations
- Case studies of widespread Cat1 ash use as fertiliser in UK, USA and Canada and elsewhere
- Mass open-air burning of foot-and-mouth cattle in the UK and elsewhere

Services needed and organisation

ESPP proposes to contract a service provider to collect data and write a dossier to submit to EFSA, and also to support ESPP in coordinating with concerned companies.

ESPP will collect co-funding for this service from concerned companies (operators of Cat1 incinerators) and public bodies (interested to take Cat1 for co-combustion to improve phosphorus and heat recovery).

The service provider should also ensure synergy where possible with EFPRA (European Fat Processors and Renderers Association) who are expected to make their own input to EFSA.

Objective is to complete a first outline draft by end 2023.

Competence needed

Proven experience in preparing EU regulatory product safety dossiers, e.g. for REACH, pharmaceuticals, medicines, food additives ... In particular, experience of dossiers for EFSA.

Knowledge of EU Animal By-Product regulations.

Understanding of health safety studies, in particular prions and TSEs.

Experience of coordinating company consortia for regulatory submissions or similar.

Documents

See at <u>www.phosphorusplatform.eu/regulatory</u>: summary of 22 June 2023 meeting, Cat1 ash literature summary by Gonzalez & McDonnell for ESPP 2022, legal Opinion by Love for ESPP 2022.

To express interest, please contact ESPP info@phosphorusplatform.eu before 15th September 2023.