

Summary of ESPP webinar on Category1 Animal By-Product Ash safety and prions

Monday 22nd May 2023 – 12h00 – 13h45 CEST (Paris Summer Time) – online

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Participants

Aichinger, Markus - Borealis	Leahy James - Limerick Uni
Alm, Martin - EFPRA	Léchevin, Samuel - SARIA
Almeida, André - ETSA	Lemieux, Paul - US EPA
Åström, Therese - easyMining (Ragn-Sells)	Manoli, Chiara - Huber
Banuoko, Denis - Netherlands Nutrient Platform	Marullo, Elena - Huber
Blandin, Anne-Françoise - Roullier	McDonnell, Kevin - Uni College Dublin
Burri, René - Centravo Switzerland	Mezino, Valerie - SARIA
Catrycke, Florence - UNIFA France	Murtagh, Colin- Ireland Dept Agriculture
Chiari, Donata - European Biochar Industry Consortium	Oliva, Joao - ETSA
Collignon, Hélène - European Biostimulants Industry Council	O'Regan, Finbarr - Ireland Dept Agriculture
de Leeuw, Gerd Jan - BMC Moerdijk	Philipot, Eric - Phosphea
Doherty, Etain - Irish Nutrient Platform	Pohl, Lukas - ISWA Stuttgart & Flapshphos
El Chami, Daniel - Timac Roullier	Rau, Edward - Sustainable Bioresources LLC
Fock, Leon - Culterra & Eurofema	Santagata, Raffaella - Timac Roullier
Føreid, Bente - NIBIO	Santoro, Veronica - ESPP
Guerra, Nagore - UVIC	Schipper, Willem - industry consultant
Halleux, Hubert - Prayon	Seto, Emily - HoneybeeRobotics
Harpillard, Francois-Victor - Timac Roullier	Socionovo Gioacchini, Elisa - Ancillarycomponents UK
Herbst, Allen - USGS	Stiernström, Sara - Ragn-Sells
Hermann, Ludwig - Proman & ESPP Board	Thornton, Chris - ESPP
Hirsch, Aspen - Georgia Inst Tech	Tuomola, Mika - Honkajoki
Huber, Florian – Vienna City	Umubyeyi, Mihigo Helene - Uni Stuttgart
Hušek, Matěj - Uni UCT Prague	Van Keer, Koen - Yara
Knickel, Tabea - German Phosphorus Platform DPP	van Spingelen, Robert - ESPP President
Koolen, Josje - BMC Moerdijk	Walsh, Daniel - USGS
Langeveld, Kees - ICL	Westwood, Mark – Fibrophos

List of participants with emails and speakers' slides have been circulated to participants.



Acronyms:

ABP = Animal By-Product

BSE = Bovine Spongiform Encephalopathy (a prion disease in cattle)

Cat1 = Category 1 Animal By-Product as defined by art. 8 of the EU Animal By-Product Regulation 1069/2009

COM = European Commission

CWD = Chronic Wasting Disease (a prion disease in deer and other cervids)

EFSA = European Food Safety Agency <https://www.efsa.europa.eu/en/about/about-efsa> - official European Union agency established in 2002 to “provide the scientific basis for laws and regulations to protect European consumers from food-related risks – from farm to fork”

FPR = EU Fertilising Products Regulation 2019/1009

IED = EU Industrial Emissions Directive 2010/75/EU (replaces the IPPC and Waste Incineration Directives)

PrP = **prion protein**. Prion diseases are caused by a misfolded normal body PrP (proteinaceous infectious particle), where the misfolding results in a different 3D structure (and functionalities) and where the misfolding is transmitted to other normal prion protein in the body.

Scrapie = a prion disease affecting mainly sheep and goats.

SRM = Specified Risk Materials (more or less the North America equivalent of Cat1)

TSE = Transmissible Spongiform Encephalopathy = generic term covering all prion diseases (scrapie, BSE, CWD, CJD and vCJD ...)

vCJD = variant Creutzfeldt-Jakob Disease. CJD is a prion disease in humans. The variant vCJD is considered to be caused by the BSE prion.

Opening and context:

Chris Thornton, ESPP: Category 1 Animal By-Products, and all materials derived from them (including ashes) are currently excluded from use in CE-Mark fertilisers under the EU Fertilising Products Regulation (FPR).

ESPP considers this regrettable because:

- Cat1 ash contains significant quantities of phosphorus:
ESPP has made a first estimate of 60 000 tP/y for Europe (i.e. approx. 5% of mineral P-fertiliser consumption) - see calculation in slides. **Comments on this calculation are welcome.**
- Cat1 material has low contaminants, relatively high calorific value, and its ash has relatively high P content (c. 10%P)
- Cat1 ash has been used as fertiliser in some countries (tens of thousands of tonnes per year) with no safety concerns (UK. **Other countries ?**)

On request of ESPP and of others, the European Commission has indicated that it will re-consider the exclusion of Cat1 derived materials in the FPR, and that the first action will be a Commission mandate to EFSA (European Food Safety Agency) to assess the safety.

It is ESPP's expectation that EFSA will mainly address prion risks (as the most resistant pathogen) and will take into consideration the Brown et al. [2000](#) and [2004](#) studies (see presentations below by Ed Rau and Paul Lemieux, two of the co-authors of these studies). These studies indicate Scrapie transmissibility in ash @ 600 °C but not at 1000°C (under the specific conditions of these studies). EFSA may follow the “precautionary principle” and conclude that these studies suggest a risk from ash from Cat1 material incinerated under EU Industrial Emissions Directive (IED) / ABP Regulations conditions (850°C).

ESPP suggests that we need to prepare input to EFSA to try to avoid this negative conclusion.



Available data and ongoing work on prion deactivation

Kevin McDonnell, University College Dublin, summarised the analysis of available data prepared for ESPP ([here](#)).

Published literature show effective elimination of prions under EU IED incineration conditions. However, this is based on protein removal (not on animal infectivity as in Brown studies).

Co-combustion of Cat1 material with other materials (e.g. sewage sludge) would require verification that incineration temperature/time conditions are ensured for all material treated.

There is a lack of defined protocol for assessing prion deactivation in combustion ashes.

Edward Rau, Sustainable Bioresources LLC (co-author of the Brown et al. 2000 and 2004 studies), outlined the challenges of determining the infectivity of prions in incinerator ash and emissions, and factors for assessment of potential BSE transmission risks associated with soil applications of fertilizers made with Cat1 ash. He underlined the primary importance of source reduction in risk reduction and other evidence of minimal risks: near-zero BSE cases in cattle in the UK since 2018, a low number of human cases (< 240 cases of vCJD worldwide), despite widespread population exposure from consumption of contaminated meat products during the BSE crisis. Tens of thousands of tonnes of Cat1 ash has been used on farms annually over the last decade ([ESPP / ELCL 2022](#)) while the number of reported cases of BSE and vCJD has continued to be at near zero levels. He noted that if incineration is considered not to ensure safety of ash, the risks of other disposal methods should be considered, and also that incineration capacity for Cat1 material must be maintained should future outbreaks of animal TSE diseases occur. Responses to these outbreaks would probably require ready access to incineration facilities that could provide safe and effective inactivation and disposal of large amounts of contaminated carcasses.

Paul Lemieux, US Environmental Protection Agency EPA, (co-author of the Brown et al. 2004 study), summarised the studies by Brown et al. These were lab studies using a tube furnace under N₂ or air, at 600°C and 1000°C for 15 minutes. Brain tissue from scrapie-infected hamsters was treated, then ground in water and injected into brains of healthy hamsters. The scrapie strain used was a strain considered to have resistance comparable to BSE. Control hamsters (injection of combusted brain tissue from healthy hamsters) did not develop scrapie. In the 2000 study, 5/35 hamsters were infected with the 600°C ash, none at 1000°C (in both cases under air). The 2004 study was carried out to verify that contamination was not in offgas, which was collected in 2004. In the 2004 study, 2/21 hamsters were infected with 600°C ash under air, and none at 1000°C under air, none at 600°C or 1000°C under N₂.

The infection, despite near-zero residual carbon and despite the fact that proteins normally are denatured at such temperatures, led the authors to propose the hypothesis that the misfolded (scrapie) prions left a fossil-like imprint in the inorganic ash, capable of causing normal prion protein to misfold and so transmit infection.

Daniel Walsh, US Geological Survey (USGS), presented his on-going work to develop and test a method for detecting prions in ash from mobile incinerators, and evaluate the use of these incinerators for disposal of wild deer carcasses. Wildlife management agencies are exploring the use of mobile incinerators to limit risks from chronic wasting disease (CWD) because landfill operators in some areas are no longer accepting deer carcasses out of fear of potential prion contamination of their facilities. His research team is using a prion amplification assay known as real-time quaking induced conversion (RT-QuIC) to test for the presence of prions and is developing extraction protocols to make the assay compatible with ash samples. The assay uses recombinant prion protein substrate that is combined with a fluorescing dye and the sample to be tested. This mixture is then put into a plate reader that monitors the amount fluorescence produced with fluorescence increasing through time if



there are prions present in the test sample. If successful, this assay would allow a sample to be taken on-site and sent to a laboratory for testing for CWD prion presence. Test turnaround would be a few days. Currently the method is in validation phase.

Aspen Hirsch, Georgia Institute of Technology, presented work underway with NASA, aiming to enable testing of materials brought back from space missions to ensure absence of TSE risk. Testing is using a yeast protein surrogate for prions, which is not human infectious. An objective is to test for prions on the material surface. Results show complete inactivation at 350°C for around 12 minutes. Situations were encountered in which the yeast prion protein was not detectable by usual means (colorimetric dye, Western blotting) but was still able to seed amyloid formation.

Industry position

Martin Alm, EFPRA (European Fat Processors and Renderers Association): in 2021 4.2 million tonnes of Cat1 animal by-products were processed into 1 million tonnes Cat1 MBM which was incinerated, but this includes significant tonnages of Cat2 material which is treated with Cat1 for logistic reasons (resulting in the whole batch being classified Cat1). There are currently around 65 Cat1 rendering plants in the EU (80 in Europe), but with a very wide range of size.

Cat 2 Meat and Bone Meal (MBM) can be used directly as a fertiliser, but this is not possible for regulatory and safety reasons for Cat 1 MBM, which must be “disposed of” under ABP Regulations / IED conditions. EFPRA favours incineration in order to enable recycling of the phosphorus content, or co-incineration with other P-containing wastes. Cat1 MBM has a high calorific value, so that co-incineration can bring energy benefits to plants incinerating other wastes.

Moving towards incineration with P-valorisation, rather than thermal “disposal” routes, could push industry investment in upgraded incineration capacity, corresponding also to the industry’s need to replace co-combustion in coal-burning electricity generation which is expected to disappear. On the other hand, Cat2 MBM use as fertiliser enables recycling of both P and N, so industry is tending to move to avoid mixing with Cat1. Quantities of Cat1 material could also be reduced with possible future falling meat production.

Questions and discussion

Questions were raised as to **what combustion conditions are specified for Cat1 material in current EU regulations**.

ESPP note: art. 12 of the ABP Regulation 1069/2009 specifies that Cat1 material shall undergo incineration or co-incineration. The conditions for this are specified in the daughter ABP Regulation 142/2011 Annex III ch.1 section 2: “*the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of 850 °C for at least 2 seconds or to a temperature of 1100 °C for 0.2 seconds ...*”. It is also specified (with exceptions) that total organic carbon in the ash must be <3%. The same conditions are specified in art.50 of the Industrial Emissions Directive 2010/75 (IED) for waste incineration plants (850°C – 2 seconds – for the gas, <3% organic carbon, but in this IED Directive the 0.2 seconds – 1100°C option is not cited).

A key conclusion is that today **there are not today reliable methods available to test ash samples to show absence of prion infectivity**, other than in vivo tests with animals which are not feasible. Existing methods can give false negatives. The Brown studies suggest that absence of organic carbon, absence of protein, absence of amino acids are not sufficient to prove non-infectivity. It should be underlined that infectivity risk by routes possible via fertiliser (oral, respiratory, skin) is considerably lower than by intra-cranial inoculation. The USGS RT-QuIC looks promising but will not be tested and proven for some time, and in any case may not be considered by EFSA as sufficient to override a

“precautionary” interpretation of the Brown studies unless a correlation trial was done (comparing in vivo hamster results with RT-QulC results on the same samples – not feasible).

It was however suggested that the most reliable currently available method is amino acid analysis and it could be informative to carry out such tests on legacy BSE-risk samples from the 1990s (if available).

Further **challenges to infectivity testing proposals** are the difficulty to obtain BSE contaminated samples, few if any laboratories are equipped to handle such potentially infectious material and authorisations would be necessary.

A more promising approach could be to **develop a structured, data-backed argument based on input material risk and on epidemiological data:**

- Near-zero BSE in cattle today - but what about other TSEs (scrapie, CWD ...)?
- Near-zero vCJD in human populations
- Case studies of Cat1 ash use as fertiliser in UK, USA and Canada (Specified Risk Materials), other countries (**to be identified: input welcome please**) – collect data on tonnages, dates, combustion conditions – no BSE outbreak
- Mass open-air burning of foot-and-mouth cattle in the UK (and elsewhere?) – no BSE outbreak from resulting ash or partially burnt particles in smoke

Other points raised by participants

- If Cat1 ash is considered “not safe” for use as a fertiliser, what are the implications for other “disposal” routes for this ash?
- Higher incineration temperatures (> 850°C) tend to result in glassy ash, in which the phosphorus is not plant available or is more slowly plant available, and may be more difficult to extract in recovery processes

Proposed contributions from participants

At and after the webinar

EFPPA: will coordinate with its members a dossier to input to EFSA, either separate from or jointly with ESPP

Wien Energie: have a full-scale fluidised bed sewage sludge incinerator, willing to run co-incineration tests with MBM

ETSA Portugal: have today no data on prions in Cat1 ash but willing to share Cat1 ash samples for testing and participate in studies

EasyMining: interested to join project to investigate safety of Cat1 and sewage sludge ashes depending on temperature/time conditions. Currently working on related risk assessments.

ESPP: will continue to provide coordination and information circulation as best we can

Other proposals are very welcome

How to move forward

NOTE: this section is 'vaguely based' on the meeting discussions but is also largely ESPP proposals – so do not hesitate to disagree or comment.

The European Commission (COM, DG SANTE) may (!) transmit a mandate to EFSA on Cat1 ash during 2023. **It is therefore relatively urgent to prepare input.** This could be in two stages :


- Joint letter to COM requesting that this dossier progress, indicating willingness to provide input and suggesting content of EFSA mandate (see below)
- Data input and arguments (industry context explanation)

What should the EFSA mandate address:

- **Mixing and co-combustion:** implications for incineration conditions (prion deactivation) of mixing with other materials (dilution of risk or “plug flow”). Meeting general agreement that this should be included in the EFSA mandate, including mixing with sewage sludge, Cat2 and Cat3 materials, ...
- **Include consideration of impact of rendering on risk reduction:** rendering is a pre-treatment before incineration of Cat1
- **Possible limitations on input materials or processing conditions:** additional limitations (beyond existing ABP Regulation requirements), such as organic carbon to a limit below 3%, could reduce risk (and so increase likelihood of a non-negative EFSA Opinion)? Any criteria “beyond” current ABP/IED Regulation specifications would generate significant problems for industry because existing installations are generally designed for these specifications (and would not be supported by EFRA). Are there any proposals for such restrictions which would be industrially feasible and useful to limit risk ?
- **Testing of ash for prions / proteins / amino acids ...** This is more likely to be included into the FPR (CMC13) not in the EFSA/ABP Regulations process. In this case, preparation of proposals are less urgent (wait until USGS RT-QuIC method is proven?)
- **Cat1 ash (“as is”) or also ash derivates** (as defined in FPR CMC13, such as phosphoric acid chemically extracted from ash). Meeting proposed to target only ash for fertiliser use. If ash is “prion safe”, then so will be any derivate, and asking for analysis of derivates could cause confusion in EFSA and result in inappropriate analysis.
- **Use for fertilisers only or also for other uses** (industrial uses, food, animal feed). There are other regulatory obstacles to some of these uses, and also strong political and public image issues. However, it could be appropriate to try to ask EFSA to already assess at the same time as fertiliser use. In this case, the other uses would be for derivates (not “ash as is”), which somewhat contradicts the point above.

Proposed next steps:

- **All meeting participants:**
 - confirm or not agreement to share your email with the other meeting participants (only)
 - corrections, comments, additions to this Meeting Summary
 - comments on the estimate of P in Cat1 materials in Europe (see Thornton ESPP slides)
- **ESPP to circulate this meeting summary to other interested stakeholders for information** (after input of comments, without participant emails)
- **ESPP to prepare joint letter** to COM (DGs SANTE & GROW) requesting that the dossier progress, proposing content for EFSA mandate and circulate for comments and 'signature'
- **ESPP to organise a second online meeting of companies and organisations willing to engage actively in preparation of a dossier for EFSA:** by providing samples, process information, data.
- **This meeting should decide whether it is needed to contract support to develop this dossier.** ESPP can coordinate but does not have the resources to prepare the dossier.



European Sustainable Phosphorus Platform

ESPP webinar on Category 1 Animal By-Product Ash safety and prions
Monday 22nd May 2023

Agenda

12h00 **Opening and round table of participants**

12h10 **Context and objectives**, *Chris Thornton, ESPP*

12h15 **Available data on prion safety in ashes**, *Kevin McDonnell [available here](#)*

12h20 **Bench-scale experiments on prion destruction, status of recent work, prion risk**
Paul Lemieux, Ed Rau, co-authors of the Brown et al. studies 2000, 2004, [summary here](#)
Questions

12h45 **Work currently ongoing on prion safety and prion deactivation**
Daniel Walsh, USGS [see here](#)
Aspen Hirsch, Georgia Institute of Technology & Emily Seto, Honeybee Robotics [see here](#)
Questions

13h10 **Position of EFPPA ([European Fat Processors and Renderers Association](#))**, *Martin Alm*
Next steps – discussion

13h45 **Close**



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Context

Category 1 Animal By-Products (Cat1 ABPs) in Europe

How much phosphorus in Cat1 ABPs in Europe?

ESPP **estimate** (for EU)

- 1 million t/y Cat1 MBM (meat and bone meal) with c. 6% P ([SCOPE 122](#)) = c. 60 ktP/y
that is c. 5% of EU mineral P fertiliser consumption
- co-incineration of Cat2 ABPs, so real number currently higher
- Cat1 material has good calorific value
- after incineration: high P-content ash (c. 10 % P), low contaminants
- interest for co-incineration with sewage sludge to increase ash P content, **facilitate P-recovery**



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Regulatory status

in EU Fertilising Products Regulation 2019/1009 (FPR)

[FPR consolidated version here](#)


Cat1 ABPs currently excluded from use as inputs for ash-derived materials (CMC13)

European Commission (COM) has agreed to reconsider this exclusion

- COM will mandate an Opinion from EFSA (European Food Safety Agency)

EFSA will take into account Brown et al. 2000, 2004

→ **Need to prepare input to EFSA**



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Regulatory status in EU Fertilising Products Regulation 2019/1009 (FPR)

[FPR consolidated version here](#)

If (!) EFSA Opinion is not negative ...

- European Commission may (!) then propose regulatory measures to allow Cat1 ABP ash in EU-fertilisers (CMC13)
- COM "Delegated Act" to establish ABP End-Point and/or modification of ABP Regulations (Parliament + Council)
- COM "Delegated Act" to modify FPR CMC13

ESPP has commissioned a Legal Opinion (Love 2022) [here](#)
- concludes modification of ABP Regulations is not necessary



Next steps

What other possible sources of information are we missing ?

Does industry have data (on prions in ash) from existing incinerators ?
How to collect or develop such data ?

Whom else to contact?

How to collect, collate information ?
How to prepare input to the EFSA assessment ?

Who can take the lead and how to organise next steps ?

