

[REDACTED]

From: [REDACTED]
Sent: 08 November 2021 12:58
To: [REDACTED]
Subject: FW: TFA follow-up.

Dear [REDACTED]

Here's an update on the TFA testing.

Seems that it is imminent.

Yours,

[REDACTED]

[REDACTED]
Senior Scientific Officer / Restriction Process Coordinator
Risk Management I / D3
European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki, Finland
Tel. [REDACTED]

<http://echa.europa.eu/>



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From: [REDACTED] <[REDACTED]>
Sent: 08 November 2021 12:56
To: [REDACTED] <[REDACTED]>
Subject: RE: TFA follow-up.

Hi [REDACTED]

The case was handed over to the enforcement authorities and the latest note on the file is from May 2021 where the contact point from the enforcement authority reports "*The OECD 443 study was launched but the laboratory encountered technical problems. The technical difficulties have now been resolved, the study is ongoing and the final report should be available around October 2021. The company will therefore proceed with the complete update of their dossier in November 2021.*"

It seems that we need to wait a few weeks longer for the study results.

Best regards,

[REDACTED]

From: [REDACTED] <[REDACTED]>
Sent: 02 November 2021 16:52
To: [REDACTED] <[REDACTED]>
Subject: FW: TFA follow-up.

Hi [REDACTED]

Hope that you're well. I'm following-up on an enquiry from DK about an EOGRTS study for TFA that we are waiting for (see below)? Do we have any news?

I suspect not given that the deadline has only just expired, but fingers crossed.

Risk Management D3
8578

From: [REDACTED] <[REDACTED]>

Sent: 02 November 2021 14:41

To: [REDACTED] <[REDACTED]>

Cc: [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]>

Subject: SV: TFA follow-up.

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Dear [REDACTED]

In the registration for TFA <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/5203/7/9/1> it says that the EOGRTS study in rats should be ready by now (anticipated). Can you see if it has been submitted to you in ECHA?

▼ Toxicity to reproduction
- Endpoint summary
- Toxicity to reproduction
- Developmental toxicity / teratogenicity
- Toxicity to reproduction: other studies
► Specific investigations
► Exposure related observations in humans
- Toxic effects on livestock and pets
- Additional toxicological data

Key value for chemical safety assessment

Effects on fertility

Description of key information

An extended one-generation study with sodium trifluoroacetate is currently ongoing a end of October 2021.

Link to relevant study records

Reference

+ Reference 1

The study in rabbits, mentioned below, is now available in the TFA registration and has been evaluated by BfR (data included in the draft Annex XV dossier)

Kind regards

Fra: [REDACTED] <[REDACTED]>

Sendt: 22. april 2021 11:28

Til: [REDACTED] <[REDACTED]>
Cc: [REDACTED] <[REDACTED]> ' <[REDACTED]>
Emne: RE: TFA follow-up.

Hi [REDACTED]

We have added a note to the file. If I hear anything about a subsequent update I'll let you know.

[REDACTED]

[REDACTED]

Senior Scientific Officer / Restriction Process Coordinator
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European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki, Finland
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[REDACTED]

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From: [REDACTED] <[REDACTED]>
Sent: 22 April 2021 00:14
To: [REDACTED] <[REDACTED]>
Cc: [REDACTED] <[REDACTED]> ' <[REDACTED]>
Subject: SV: TFA follow-up.

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Hi [REDACTED]

Thank you for coming back to me on this. I think we already have draft results of the developmental toxicity study in rabbits and draft results of the EOGRTS study. According to the letter we received from Bayer the report for the developmental toxicity study in rabbits should be finalized by now. It will be a big help if [REDACTED] can put a note on the file, as TFA is important for the universal PFAS restriction and I guess also for the restriction on firefighting foams

Kind regards

[REDACTED]

Fra: [REDACTED] <[REDACTED]>
Sendt: 21. april 2021 14:48
Til: [REDACTED] <[REDACTED]>
Emne: TFA follow-up.

Hi [REDACTED]

Some follow-up from my colleague [REDACTED] to your enquiry about TFA.

There should be some data available for you to review in an updated registration.

Yours,

[REDACTED]

[REDACTED]

Senior Scientific Officer / Restriction Process Coordinator
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From: [REDACTED] <[REDACTED]>
Sent: 21 April 2021 15:07
To: [REDACTED] <[REDACTED]>
Subject: RE: ECHA one-pager on cooperation on AFFF restriction proposal

Hi [REDACTED]

The information Bayer refers to was requested by ECHA from the lead registrant in a compliance check decision: <https://echa.europa.eu/documents/10162/cdcab64b-d276-1b9b-ca1a-3b7378ac98d1>

The study results will be included in a registration dossier update and then evaluated by our follow-up team.

I checked REACH-IT and the lead registrant last updated their dossier on 15/01/2021, with submission number YG801338-30. This update includes draft results of the developmental toxicity study in rabbits and draft results of the EOGRTS study. Final results have not yet been submitted.

The Danish MSCA can find the dossier in REACH-IT with the submission number or in IUCLID at this link: https://iuclid6-main.echa.europa.eu/iuclid6-web/dossier/1f98e19d-95fc-4129-ac09-b02d19df1f23?content_uri=iuclid6:%2F1f98e19d-95fc-4129-ac09-b02d19df1f23%2FSUBSTANCE%2FIUC5-a452ff71-2bfb-4c72-910b-9c5fff76f744%2FENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity%2F33c6dd4b-faba-406e-be4f-96dc34c095f9&node=33c6dd4b-faba-406e-be4f-96dc34c095f9&treeId=R_ABOVE_1000

Should our follow-up team be made aware of the relevance of this data to the Fire fighting foams restriction? I can put a note on the file.

Best regards,

[REDACTED]

From: [REDACTED] <[REDACTED]>
Sent: 20 April 2021 18:05
To: [REDACTED] <[REDACTED]>
Subject: FW: ECHA one-pager on cooperation on AFFF restriction proposal

Hi [REDACTED]

I'm not sure if you're the right person to ask, but I've been asked about an updated registration dossier for TFA by a Danish colleague working on the Universal PFAS restriction (see below and attached).

Any idea how I can check if this registration update has happened?

Thanks,

[REDACTED]

[REDACTED]

Senior Scientific Officer / Restriction Process Coordinator
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European Chemicals Agency
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From: [REDACTED] <[REDACTED]>

Sent: 17 April 2021 08:32

To: [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]>
[REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]>

Subject: SV: ECHA one-pager on cooperation on AFFF restriction proposal

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Dear [REDACTED] all

Thank you, I think it is a good idea to start the discussion on HH hazard assessment cooperation at the meeting Monday. If we need to go into more depth with the discussion I can invite you to the WP3 HH Sub-group meeting on Wednesday 21. April at 11.00 – 13.00 (CET).

I have a question regarding TFA. Perhaps you are able to answer or refer me to one of your colleagues? In the attached letter from Bayer to the Danish EPA, Bayer states that their developmental toxicity study in rabbits is finalized and that the final report of the study is anticipated to be finalized by the end of March 2021. Have you received this report or an updated REACH registration with this data?

Best regards

[REDACTED]
Danish EPA | Chemical unit
[REDACTED] | [REDACTED]

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