Written communication from EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA)

Communication from FEFANA sent to TransparencyRegulationImplementation@efsa.europa.eu on 30/09/2020 - follow-up to the feedback mechanism in relation to the revised implementing regulation concerning applications for authorisation, scientific evaluation and authorisation of feed additives (amendment of Regulation (EC) No 429/2008)

From: < @fefana.org>
Sent: Wednesday 30 September 2020 12:43
To: < @efsa.europa.eu>
Cc: < @efsa.europa.eu>; < @efsa.europa.eu>; < @fefana.org>; < @fefana.org>
Subject: Implementation of the transparency regulation - specific concern of the specialty feed ingredients industry regarding renewals of authorisation

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Dear Mr. ,

FEFANA had a couple of Email exchanges with the EC DG SANTE about the on-going implementation of the transparency regulation. We have raised particular concerns on behalf of our membership regarding the upcoming new procedure for renewal of authorisations of feed additives.

I am copying you below the latest of these exchanges in full.

We would be very interested in receiving your viewpoint and reconfirmation from the perspective of EFSA, who is in charge of setting-up of the Practical Arrangements, that our initial concerns regarding potential procedural complications that could lead to a loss of authorization for some feed additives are the result of our misinterpretation of the legal text (also in view of the lack of knowledge as to how EFSA will implement certain aspects).

Looking forward to your response, with best regards

[redacted] Secretary General |

FEFANA

FEFANA asbl - EU Association of Specialty Feed Ingredients and their Mixtures Rue de Trèves 45, 1040 Brussels

EU Transparency register 20132976103-18

[redacted]

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Connect with us on:

From: < @ec.europa.eu>
Sent: Monday, 28 September 2020 11:23
To: < @fefana.org>
Cc: < @fefana.org>; < @fefana.org>; @ec.europa.eu; @ec.europa.eu; @ec.europa.eu
Subject: RE: Implementation of the transparency regulation - specific concern of the specialty feed ingredients industry regarding renewals of authorisation

Dear ,

The Commission acknowledges again the concerns raised by FEFANA concerning the implementation of Regulation (EC) No1831/2003 of the European Parliament and of the Council (The Transparency Regulation) in the area of feed additives.

In reply to the questions posed in your email of 23/09:

- The new Art 32c(1) of the GFL, as amended by the TR, will only kick in if the applicant on 27 March 2021 **still intends** to carry out studies. If all the studies it intends to carry out have already been carried out or are already underway, Art. 32c(1) would not apply given the explicit wording *"shall notify the Authority of the studies* ***it intends to perform for that purpose".***
- If however, a renewal application is to be submitted by December 2021 and in March 2021 the Applicant **still needs** to carry out additional studies (i.e. have not yet been commissioned), then it will have to notify under Art. 32c(1) of the GFL these additional studies, while in parallel/or soon after proceed with the commissioning of the same studies (Art. 32b) – so the 2 provisions would apply simultaneously, even pending the pre-submission advice of Art. 32c(1) by EFSA.
- The advice of Art. 32c(1) is a service to the applicant but it is also non committal neither for EFSA, nor he applicant.
- Therefore any delay in the provision of the advice under Art. 32c(1) cannot and shall not affect in any way the timing of the application as far as 32c(1) is concerned. That can be demonstrated with the following example.
    - If an applicant decides for a new study on March 28 (in addition to other ones that are either in the process of being carried out or have already been completed) to support a renewal application that needs to be submitted e.g. 1 August, it will have to notify that study under 32c(1). However, given the deadline of 1 August, it cannot wait for the advice of EFSA, so it would soon afterwards/if not simultaneously need to notify under Article 32b when commissioned [even when the public consultation/EFSA advice under Article 32c(1) is pending]. If the study is completed by May/June, then the applicant can submit on time on 1 August, even if the advice from EFSA may not be timely. So in that respect, it is true the applicant will not be in a position to take the advice into account but the advice is anyway non committal. And precisely because it is not committal (as said both for EFSA and for the applicant), it cannot delay the process of submission, i.e (submission must be submitted by 1 August and no legal extension is required).

- However we need to distinguish the case above with the case of potential non compliance with the new Art. 32b of the GFL. If the applicant does not comply **post 27 March**, with the notification requirement of any study commissioned after that day and there is no valid justification for this, the applicant may lose may lose its window of submitting a renewal application on time; in this case, non compliance on the part of the applicant would be a reason within its control and no extension can be granted.

- So, in brief, and for a certain period of time, a potential applicant that intends to perform new studies after 27 March 2021 would need to proceed to a dual (and potentially simultaneous) notification of Articles 32c(1) and 32b. In any event, as the EFSA advice under 32c(1) is non committal, any timing issues do not affect the submission of the application.

We remain at your disposal for any further clarifications,

Kind regards,

[redacted]

European Commission
DG Health and Food Safety (SANTE)
Directorate E
Unit E5 – Animal Nutrition, veterinary medicines

From: < @fefana.org>
Sent: Wednesday, September 23, 2020 10:19 AM
To: (SANTE) < @ec.europa.eu>; <@ec.europa.eu>; (SANTE); <@ec.europa.eu>; (SANTE) < @ec.europa.eu>
Cc: < @fefana.org>; < @fefana.org>
Subject: Implementation of the transparency regulation - specific concern of the specialty feed ingredients industry regarding renewals of authorisation

Importance: High

Dear colleagues of the European Commission,
I would like to thank you very much for your reply. While we do appreciate that the Commission acknowledges the concerns of our industry we are wondering if these concerns, some of which are

indeed very specific related to our sectorial legislation on feed additives, have indeed been fully understood and will be addressed as part of the on-going interaction between the Commission and EFSA as the implementation of the transparency regulation is progressing.

Please find below an illustrative example of what quite many of our member companies are concerned about:

Applicant X works on renewal dossier for feed additive Y. Expiry date of authorization is 1 August 2022; last possible submission date of renewal dossier according to art. 14(1) of Regulation 1831/2003 is 31 July 2021.
The applicant will submit after 27 March 2021 and hence has to comply with new transparency requirements, including the EFSA public consultation.
They already noted that an additional tolerance test needs to be executed according to the latest guidance.
The Public consultation (of planned studies) instrument is officially launched by EFSA on (say ?) 15 April 2021.
The outcome of the consultation follows 2 months later (say ?) on 15 June 2021.
Next to the further comments on the execution of the intended tolerance test, EFSA's advice also includes suggestions (e.g. from a stakeholder reacting to the public consultation) for an additional study that the applicant had not considered at first.
The applicant then immediately takes action and plans and executes the requested studies according to the transparency rules. However, the studies can only be ready and reported in November 2021, which is many case for most research institutes a very realistic timeline.
Due to this delay, the dossier could then only be submitted in December 2021, so after the deadline as foreseen in art. 14(1) of Reg. (EC) No 1831/2003 and a continued authorization during the evaluation period according to art. 14(4) can normally not be granted.

When considering those feed additives that have an expiry date of its authorization between 27 March 2022 and 27 March 2023 (likely the most affected group), we count a total of 52 authorizations, including technological additives (preservatives and silage additives), sensory additives (colourants and flavouring compounds), nutritional additives (trace elements and urea), and zootechnical additives (digestibility enhancers, gut flora stabilisers and other zootechnical additives). When considering extensive data generation requiring more than a year of execution after having received the official advice after public consultation, also feed additives expiring after March 2023 could be impacted. Between 27 March 2023 and 27 March 2024 there are 75 feed additive authorizations expiring, coming from virtually each functional group.
Hence, from our perspective there could be a very considerable negative impact on the entire feed chain if our concern would not be addressed.

FEFANA questions:

- Would the Commission support our viewpoint that this is an undesirable side effect of the requirements of the transparency regulation for renewal dossiers of feed additives which must be addressed with the implementation the transparency regulation?
- If the Commission would not see possibilities to organize transitional measures through revision of Reg. (EC) No 429/2008, how else could it secure that existing authorizations would not expire due to aforementioned procedural complications, which are due to the new transparency rules, within its mandate as risk manager? For instance, is the phrase **'beyond the control of the applicant' in art. 14(4) of Reg. (EC) No 1831/2003 applicable to the situation described above?**

We should be extremely grateful for receiving your timely response to our specific concern including the questions raised above.

Kind regards

[redacted]

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[redacted]

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