NOTAT

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DEPAs evaluation of formation of TFA, trifluoracetic acid based on results from the TriFluPest research project and additional information, including information from EU-assessments

1) Background

In 2020, the Danish Environmental Protection Agency (DEPA) conducted a large screening for pesticides in Danish groundwater, which included analysis of the substance trifluoracetic acid (TFA)[1]. Extensive presence of TFA was found, as TFA was detected in 89% of the 247 intakes examined, and 86% exceeded the limit value for pesticides in groundwater of 0.1 µg/L. The extensive findings of TFA led to a major investigation and source tracing, which showed that EU assessments of the pesticides Flurtamone and Flufenacet identified TFA as a degradation product. Pesticide products with Flurtamone or Flufenacet have not been authorised in Denmark.

Based on the fact that a number of other pesticides also contain a trifluormethyl group (C-CF3) in their chemical structure, it was assessed that these substances could potentially also degrade to TFA, but that there was no documentation supporting this, that could be used in a regulatory context.
The same applied to a number of biocidal active substances. When approving the active substances in question, it was not investigated whether TFA is formed during degradation. Therefore, no risk assessment of TFA was carried out with regard to soil and groundwater. The likely explanation for this was primarily that TFA had not been detected by use of carbon labelling at the sites in the molecule that would enable detection of TFA in the degradation tests, nor had a targeted analysis been used to identify TFA.

The source tracing showed that TFA can originate from a number of other sources (e.g. degradation of a number of fluorinated gases in the atmosphere, which originate from e.g. refrigerants and flame retardants), which contribute to a globally widespread content of TFA in precipitation. In addition, TFA is the smallest possible PFAS compound and can be formed by the degradation of larger PFAS compounds[2]. The discovery of TFA in groundwater may in principle be due to the degradation of certain pesticides, but due to the very large geographical distribution of TFA, it was assessed that other sources probably make a much larger contribution. It was therefore decided that TFA should not be regulated as a pesticide in the National Drinking Water Order, but instead as an industrial chemical with a health-based limit value of 9 µg/L.

This led to funding of the research project, TriFluPest, which is described in more detail below. The purpose of this document is to provide an overview of the current knowledge about formation of TFA from pesticides, including results from the TriFluPest research project, but also information from other sources.

[1] https://www.ft.dk/samling/20201/almdel/mof/bilag/470/2368152.pdf
[2] https://data.geus.dk/pure-pdf/GEUS-R_2024-4_web.pdf

2) TFA

TFA is an abbreviation for trifluoracetic acid (CAS No. 76-05-1). As the substance is a very strong acid (PkA of 0.5) TFA most often occurs as the anion (trifluoracetate) in the environment. In addition, TFA is highly polar and therefore is attracted to the aqueous phase binds very weakly to organic matter[3].

The weak binding to organic matter, and to soil particles in general, has been demonstrated in sorption experiments conducted as part of EU assessments of the pesticide active substances Flufenacet, Flurtamone and Fluopyram. In these tests, no binding (sorption) was found to soil samples taken from the plough layer of various agricultural soils, and a Kfoc value of 0 ml/g was used in the further risk assessment in the EU.

In addition to the absence of binding to soil particles, TFA is considered to be chemically stable and probably also biologically non-degradable[3]. EU assessments of the above-mentioned pesticide active substances support this, as degradation tests showed very limited degradation of TFA, if any. In addition, degradation tests have been carried out as part of the assessment of the active substance flonicamid, which also showed no significant degradation of TFA. The EU assessments therefore use a standard half-life of 1000 days. **TFA is thus extremely persistent in soil** and does not meet the Danish national persistency criteria, which requires active substances and degradation products to have a half-life of less than 180 days.

3) The research project TriFluPest

The research project, TriFluPest, was funded under DEPAs Pesticide Research Programme, carried out by GEUS (project manager Anders Johnsen), and ran from September 2022 to August 2024. It is published on DEPAs website[4]. The purpose of the project was to conduct simple degradation tests in the laboratory to confirm or refute whether TFA is formed from seven pesticide active substances previously and/or currently available for use in Denmark.

The research project uses a targeted analysis to identify and quantify TFA. As the purpose was not to determine actual kinetic parameters such as half-life (DT50) in soil, but simply to identify any formation of TFA, the degradation tests were not carried out in accordance with the current OECD guideline for degradation tests in soil[5], but followed a simpler and adapted test setup. The test included soil samples from three different organic farmlands, where 3 grams of soil were placed in a small open tube, together with added pesticide. One active substance was added to each tube, which remained open throughout the test, at a temperature of 20 °C and with humidity control throughout. The experiments ran for one year, with TFA formation measured at the start of the experiment and after 4, 10, 24, 38 and 52 weeks. The chemical analysis of TFA was performed by mass spectrometry after chromatographic separation (LC-MS/MS). To rule out false-positive results, parallel experiments were conducted with negative control incubations.

In addition to the laboratory tests, simple and rough estimates (subject to a number of significant uncertainties) have been made in the project with the aim of illustrating the magnitude of any contribution by TFA to groundwater caused by the use in Denmark of the studied pesticides.

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[3] https://data.geus.dk/pure-pdf/GEUS-R_2024-4_web.pdf

[4] https://mst.dk/nyheder/2024/december/ny-rapport-visse-pesticider-kan-danne-trifluoreddikesyre-tfa-i-landbrugsjord

[5] OECD Test guideline No. 307: Aerobic and Anaerobic Transformation in Soil

Results – Degradation studies

The degradation tests show the formation of TFA from all seven pesticide active substances studied (Fluazifop-P-butyl, Fluopyram, Diflufenican, Trifluralin, Fluazinam, Tau-fluvalinate and Mefentrifluconazole). However, the formation varies between the active substances and between the three soils included in the test. The formation percentages of TFA, as stated in the published report, are shown in Table 1 below. The calculations are based on the potential for TFA formation from each active substance (GEUS uses the term 'TFA equivalents'), compared with how much TFA was actually formed during the trial period, which results in a formation percentage. GEUS has included explanatory calculation examples in the appendix to the report.

Table 1: Formation of C-CF_3 pesticides to TFA as a percentage of the parent compound's potential TFA equivalents (maximum possible formation of TFA) in three organic agricultural soils (Sv1, Sv2 and Sv6) determined after 52 weeks of incubation. For each substance, the formation is shown as mean ± standard deviation (n = 3) for each soil, as well as the geometric mean of the three soils. Since Fluopyram and Fluazinam have two C-CF_3 groups, the formation is calculated as moles TFA per mole parent substance (mole percentage), and the formation is therefore twice as large as shown in the table. The table and table text have been copied from the report.

	TFA-formation (% of applied active substance)			
	Sv1	Sv3	Sv6	Geometric mean
Fluopyram	7.9 ±0.3	3.3 ±0.2	10.7 ±0.5	6.5
Fluazinam	6.5 ±0.2	5.3 ±0.2	6.0 ±0.4	6.0
Diflufenican	2.9 ±0.8	2.4 ±0.1	5.2 ±1.1	3.3
Fluazifop-P-butyl	3.0 ±0.0	3.1 ±0.0	5.3 ±0.0	3.7
Trifluralin	1.7 ±0.0	1.1 ±0.1	2.2 ±0.1	1.6
Mefentrifluconazole	2.6 ±0.2	0.8 ±0.0	3.3 ±0.1	1.9
Tau-fluvalinate	1.0 ±0.1	0.4 ±0.1	1.0 ±0.1	0.7

The project also investigated the proportion of the added parent substance that had not degraded at the end of the experiment, with the aim of illustrating the potential for further formation of TFA. The analytical methods used succeeded in quantifying the content of five of the seven pesticides studied, as illustrated in Table 2, which shows the average proportion of remaining parent substance. It is seen that there is a highly variable content of parent substance remaining, reflecting the different degradability of the pesticides. Fluazinam and Fluazifop-p-butyl were almost completely degraded in the experiment, whereas Fluopyram and Mefentrifluconazole were far from fully degraded. The formation percentage for TFA from the former pesticides is therefore more representative of the actual formation of TFA than for the substances where degradation in the experiment was low. This means that potentially more TFA can be formed from Fluopyram and Mefentrifluconazole if they degrade further.

In Table 2, DEPA has calculated TFA formation as a percentage of degraded parent substance. As mentioned, Fluazinam and Fluazifop were almost completely degraded in the experiment, which is why their formation percentages are largely unchanged in this calculation, whereas Fluopyram and Mefentrifluconazole are far from degraded, which is reflected in higher TFA formation percentages compared to the values in Table 1.

Table 2: Average proportion of remaining parent substance (%) at the end of the experiment, after 52 weeks of incubation, and TFA formation as % of degraded parent substance. The analytical method for tau-fluvalinate and trifluralin was unable to quantify the content of these two substances in soil, so they are not included in the calculations. Calculations were performed by the Danish Environmental Protection Agency.

	% remaining parent substance	% TFA formed from degraded parent			
		Sv1	Sv3	Sv6	Gns.
Fluopyram	68.7	20.3	13.2	35.8	23.1
Fluazinam	3.7	6.6	5.6	6.2	6.1
Diflufenican	30.7	3.9	3.9	7.2	5.0
Fluazifop*	0.3	3.0	3.1	5.3	3.8
Mefentrifluconazole	82.7	13.9	6.4	16.7	12.3
Tau-fluvalinate	-	-	-	-	-
Trifluralin	-	-	-	-	-

*Including Fluazifop-p-butyl.

However, it is not only the remaining parent substance that may lead to further TFA formation, as many pesticides will be converted into other degradation products (intermediate degradation products) before the degradation chain reaches its end and free TFA is formed. As analysis of the content of such intermediate degradation products was not included in the project, the significance of this has not been clarified. However, the availability of the parent substance for degradation may be affected by bonds to soil particles that are so strong that they are considered irreversible, and over time the parent substance may be considered more or less permanently incorporated into the soil particles (ageing).

Table 1 shows the formation of TFA from the seven active substances studied, which contain a trifluormethyl group, but the project report also mentions a theoretical possibility that another degradation pathway that may occur, which does not result in the formation of TFA, but rather in free fluoride. This degradation pathway has been demonstrated for two other chemical substances (Benzotrifluoride and Fluoxetine) that are not pesticides. However, the research project does not investigate if this other degradation pathway can occur during the degradation of the studied pesticides.

Results – Simple and rough estimations of leaching
The project contains rough calculated estimates for the content of TFA in water (annual average) leaving the plough layer after the use of selected pesticide products containing the seven active substances studied. The calculations are based on the formation percentages of TFA (Table 1), as well as product-specific information (dosage and amount of active substance reaching the soil surface when used on a given crop at a given time), and an assumption of an annual net precipitation of 300 mm.

The calculations for Mefentrifluconazole[6] and Tau-fluvalinate resulted in TFA concentrations **below** the limit value for pesticides in groundwater of 0.1 µg/L. The calculations for the remaining five pesticides resulted in concentrations **above** 0.1 µg/L for the majority of applications.

The calculations were not performed in accordance with the requirements for modelling for a product authorisation dossier, but they provide supporting documentation. The results indicate that the Danish use of trifluormethyl pesticides can lead to leaching of TFA to groundwater at levels above 0.1 µg/L.

[6] Potentialet for udvaskning af TFA ved anvendelse af mefentrifluconazol er potentielt underestimeret pga. den begrænsede nedbrydning af stoffet i nedbrydningsforsøget.

In order to document whether specific applications will meet the authorisation conditions with regard to leaching to groundwater, the authorisation holder will have to perform model calculations in accordance with EU guidelines and Danish requirements based on well-documented or worst-case formation fractions (ff=1) for TFA. In view of the above considerations, it is not possible to determine a reliable formation fraction based on the tests carried out in the TriFluPest project, as further formation from active substances and intermediate metabolites is expected over time. The measured formation percentages cannot therefore be used as formation fractions in model calculations.

Conclusion
The degradation studies document that TFA is formed from all seven pesticides. Simple estimates indicate that the use of pesticide products containing several of the active substances studied may lead to leaching of TFA to Danish groundwater at levels above 0.1 µg/L.

4) Experiences and information from EU active substance evaluations

DEPA has reviewed relevant information from a number of completed and ongoing EU assessments to find information on possible formation of TFA. This is not a complete review of all active substances containing a trifluormethyl group, but rather selected active substances where DEPA is aware of knowledge about TFA, or active substances that are relevant to Denmark.

Identification of degradation products and radioactive labelling of carbon atoms
In connection with the identification of degradation products to be included in further risk assessment, radioactive labelling of selected carbon atoms in the chemical structure of the active substance is used. The location of this labelling is decisive for which degradation products are identified in experiments involving degradation of the active substance, as well as the measurable formation percentage of these. If a given degradation product does not contain a labelled carbon atom, it will not be identified unless a targeted analysis is performed for this particular substance. This is the main problem with identifying TFA as a degradation product of trifluormethyl pesticides, as the carbon labelling is often located somewhere in the active substance that does not uniquely enable the identification of TFA as a degradation product. Furthermore, it is problematic that there is a lack of targeted analyses for TFA in experiments where the carbon labelling is located somewhere other than at the trifluormethyl group.

The trifluormethyl group, which is crucial for the possible formation of TFA, is often linked to a ring structure in the active substance, as is the case with the five active substances presented in Table 4. The carbon labelling is shown with a symbol, such as an asterisk ('*') or a square ('#'). It can be seen that the carbon labelling is located at the carbon in the ring adjacent to the trifluormethyl group in two of the active substances, Flufenacet and Flonicamid, whereby any TFA formed will be labelled and thus identifiable (assuming that the ring breaks down during degradation and that this particular carbon ends up forming the carboxylic acid group in TFA).

For the active substances Flurtamone, Fluopyram and Tritosulfuron, the carbon labelling is located in the middle of a 6-ring structure, which is known as a 'uniform labelling'. This means that the labelling is located on at least one random carbon atom in the ring, and it is not known exactly which one(s). Thus, the uniform labelling will be represented by a mixture of six different labels, where the radioactivity will theoretically be distributed among the six different carbon atoms in the ring structure. When assessing the results of such degradation tests, it is therefore likely that not enough carbon-labelled TFA has been formed for it to be identified as a degradation product that warrants further risk assessment. Degradation tests that have used this type of uniform labelling and have not identified TFA as a degradation product cannot therefore be used as documentation that TFA is not

formed during the degradation of the active substance in question – these are therefore potentially false-negative results. This understanding of the challenges of uniform labelling of ring structures, and the general guidance for conducting degradation studies in soil (OECD 307), is supported by the German and Austrian environmental agencies, UBA and AGES.

As mentioned, the degradation of Flurtamone has been investigated using uniform labelling, but as described in the section below, TFA was nevertheless identified as a degradation product. This is presumed to be due to the high degradability of Flurtamone and the intermediate degradation products.

Formation of carbon-labelled CO2 – Theoretical indication of possible formation of TFA
As mentioned, degradation tests performed with uniform labelling of a ring structure cannot be used to unequivocally reject the formation of TFA during degradation of the active substance. Theoretically, the formation of carbon-labelled CO2 can be used as a supporting indication that the ring structure has been broken, making it likely that TFA has been formed.

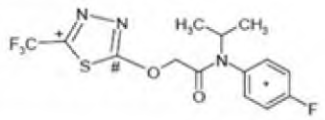
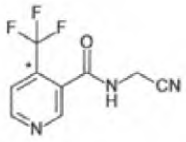
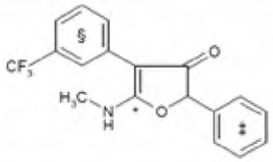
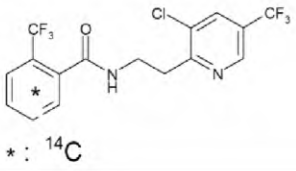
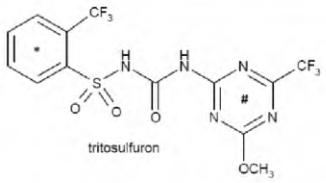
Degradation tests conducted in connection with EU assessments of Flurtamone (where the trifluoromethyl group is attached to a ring structure containing only carbon, a benzene ring) showed formation percentages of carbon-labelled CO2 from four soils of 51.5%, 55.1%, 51.1% and 52.0% after 87 days. In this test, rapid degradation of the parent substance, Flurtamone, was observed. In similar experiments with Fluopyram, which contains two trifluoromethyl groups attached to their respective ring structures, formation percentages for carbon-labelled CO2 of between 1.6 and 24.0% were observed after approximately 120 days. As mentioned, both substances have been tested for TFA formation and have been shown to form TFA.

Active substances investigated for TFA formation
DEPA is currently aware of five active substances that, in EU assessments, have been shown to form TFA in soil degradation studies. The chemical structure of these substances is shown in Table 4, where the location of carbon labelling is indicated. Identified degradation products are also listed with associated parameters describing degradability (DT50) and mobility (Kfoc), as well as the percentage of TFA formation, if known.

When reviewing degradation tests for the five active substances, it was found that TFA was identified as a carbon-labelled fraction in the degradation of Flufenacet and Flonicamid, in contrast to the tests performed for Tritosulfuron and Fluopyram, where TFA was identified using a targeted analysis. Despite the uniform carbon labelling used in degradation tests performed for Flurtamone, sufficient formation of carbon-labelled TFA was demonstrated for TFA to be identified in the test. For this to be possible within the usual timeframe for such studies (typically 120 days), the active substance and any intermediate degradation products must degrade at a certain rate.

There are several examples of active substances where uniform carbon labelling of ring structures has been used in metabolism tests and where TFA has not been identified in the degradation tests performed, for example Fluazinam, Mefentrifluconazole, Diflufenican and Tau-fluvalinate. For these substances, the TriFluPest project has demonstrated the formation of TFA. The same is true for Tritosulfuron and Fluopyram, where the formation of TFA was demonstrated using a targeted analysis. The results from the TriFluPest project confirm that the formation of TFA has not been adequately addressed in the existing EU assessments for Fluazinam, Mefentrifluconazole, Diflufenican and Tau-fluvalinate.

Table 4: Active substances currently known to the Danish Environmental Protection Agency to form TFA in degradation tests carried out as part of the EU assessment.

	TFA formation-percentage	**Applied DT50 (days)**	**Applied Kfoc (ml/g)**	**Active substance chemical structure, with carbon labeling (+, *, ‡, §, #)**
Flufenacet	-	17.89	221.25	
FOE-thiadon	-	15.90	42.10	
TFA	81.5	1000	0	
Flonicamid‡	-	0.59	5.4*	
TFNG-AM	-	0.15	8.7*	
TFNG	-	0.13	1.02*	
TFNA	-	0.71	1.4*	
TFNA-OH	-	2.14	2.7*	
TFNA-AM	-	2.82	5.6*	
TFA	22.5	1000	0	
Flurtamone	-	10.7	257.3	
TFMBA	-	8.3	15.5 / 49.5**	
TFA	5.5	1000	0	
Fluopyram‡		219.0***	232.1***	
Fluopyram-7-hydroxy		17.53***	100.2***	* : ^{14}C
TFA	7.4	1000	0	
Tritosulfuron	-	18.1	8.9	
M635H001	-	155.1	74.3	tritosulfuron
M635H002	-	76.1	33.3	
M635H003	-	193.2	28.6	
M635H004	-	29.7	16.7	
TFA	22	-	-	

*Kdoc, **pH dependence, *** information from current EFSA conclusion for Flufenacet, Flurtamone and Tritisulfuron. For Fluopyram draft RAR List of Endpoints, 12 February 2025, and for Flonicamid RAR List of Endpoints, 4 April 2024. ‡The active substances Flonicamid and Fluopyram are currently under renewal, which is why the information is not finalised. The assessment of Flonicamid has been submitted for comment to the Member States and EFSA, with the next step being the publication of an EFSA conclusion. The assessment of Fluopyram has not progressed that far; a draft prepared by the reporting Member State has been sent to EFSA.

Formation of TFA in other types of studies - Haloxyfop in lysimeter studies

The active substance Haloxyfop-p was assessed in the EU back in 2004, where the degradation studies carried out in laboratory tests did not include a radiolabel that allowed identification of TFA. However, three lysimeter studies were carried out to investigate the mobility of carbon-labelled Haloxyfop-p on

sandy soils. Sugar beet was grown in two of the three lysimeters and rapeseed in the third lysimeter. Haloxyfop-p was sprayed on all lysimeters, with the two containing sugar beet being sprayed in early and late spring, respectively, and the lysimeter containing rapeseed being sprayed in the autumn.

A polar fraction was detected in water samples from two of the lysimeters, sprayed in early spring and in autumn, which turned out to consist mainly of TFA. However, the annual average for TFA leaching did not exceed 0.1 µg/L (0.085 and 0.079 µg/L), which is why an expert meeting held in connection with the EU assessment concluded that TFA should not be included in further risk assessments. Therefore, no further degradation studies with targeted carbon labelling or analysis were carried out.

Degradability of active substances and formation of TFA
As mentioned, it is likely that the extent of TFA formation is linked to the degradability and bioavailability of the active substance and any intermediate degradation products. If the substances degrade sufficiently slowly, it is likely that TFA will not be formed to a measurable extent within the typical test period of 120 days. However, it is considered highly likely that TFA will be formed over time, as it is a terminal degradation product that is not considered to degrade further. The TriFluPest report mentions that there may be another, competing degradation pathway that does not result in the formation of TFA, but rather in free fluoride. However, this degradation pathway is not investigated in the project.

The degradability of the five active substances (which have been shown to form TFA in EU assessments) and their intermediate degradation products is presented in Table 4. The degradability of four of the five active substances is high, as illustrated by the half-life of the substances in soil (data from the latest material published in connection with completed or ongoing EU assessments of the active substances). Fluopyram has a long half-life, but despite this, the formation of 7.4 % TFA after 120 days has been demonstrated, which is in good agreement with the results from the TriFluPest project, where an average TFA formation of 6.5 % was demonstrated.

The available information on the formation of TFA over time therefore indicates that if there is rapid degradation of the active substance and intermediate degradation products, and if TFA has been analysed using targeted analysis and/or appropriate carbon labelling, there is an indication that this is not a false negative. However, DEPA is not aware of any documented cases of this kind.

Estimated leaching of TFA into groundwater
DEPA is aware that in EU assessments model calculations have been carried out for the leaching of TFA into groundwater for four active substances: Flufenacet, Flurtamone, Flonicamid and Fluopyram.

Table 5 below shows a summary of the modelling results. Concentrations of up to 96.7 µg/L are observed. The highest concentrations, 3.6 - 96.7 µg/L, are observed for the active substances Flufenacet and Flurtamone, which have never been authorised for use in Denmark. The modelled concentrations for Flonicamid and Fluopyram, both of which have been authorised for use in Denmark, are between 0.7 - 7.0 and 1.1 - 8.2 µg/L, respectively. These are results from EU modelling that have been carried out for comparable uses and are therefore reasonably representative of Danish uses (but do not fulfil National more restrictive modelling requirements).

For all active substances, the FOCUS modelling in the EU assessment shows leaching to groundwater in concentrations above 0.1 µg/L in all scenarios and for all uses. It is therefore likely that the use of active substances that form TFA will pose an unacceptable risk of leaching to groundwater.

Table 5: Summary overview of model calculations for assessing transport to groundwater, carried out in connection with EU assessments of the four trifluormethyl pesticides Flufenacet, Flurtamone, Flonicamid and Fluopyram. The results (PECgw) are given as an annual average.

	Dose (g/ha)	Season of application	Before or after germination	Number of scenarios that exceed 0.1 µg/L	PECgw – Annual average (µg/L)
Flufenacet	240	Autumn	After	9/9	16.1 – 96.6
	160	Autumn	After	9/9	10.7 – 64.4
	120	Autumn	Before	9/9	8.2 – 49.0
	160	Spring	After	9/9	11.7 – 65.3
	120	Spring	Before	7/9	8.8 – 49.0
Flurtamone	125	Autumn	At germination	9/9	3.6 – 22.1
	125	Spring	At germination	9/9	3.8 – 9.8
Flonicamid	2*70	Spring	After – winter cereal	9/9	2.3 – 6.7
	2*70	Spring	After – spring cereal	6/6	2.2 – 5.1
	2*70	Spring	After – apples	9/9	0.7 – 7.0
	2*70	Summer	After – apples (PHI 21 d)	9/9	1.2 – 8.2
Fluopyram	39	Spring	After - spring cereal	6/6	1.1 – 2.7
	78	Spring	After - spring cereal	6/6	2.3 – 5.5
	39	Spring	After - winter cereal	9/9	1.5 – 4.1
	78	Spring	After - winter cereal	9/9	3.1 – 8.2

5) CLP classification proposal

In 2024, the German authorities submitted a proposal for harmonised classification for TFA under the CLP Regulation[7], proposing that the acute toxicity of TFA be changed from hazardous by inhalation to toxic by inhalation, and that TFA be classified as harmful to the unborn child and suspected of damaging reproductive ability. The classification proposal has not yet been considered by the Committee for Risk Assessment (RAC), which is expected in 2025, and therefore no updated harmonised classification for TFA has been adopted.

In addition, under the pesticide regulation, the Commission has requested the European Food Safety Authority (EFSA) to update the toxicological reference values (including the acceptable daily intake) for TFA based on new data and data underlying the classification proposal from the German authorities. In preparing the updated reference values, EFSA will include existing knowledge about the substance, including its endocrine-disrupting, carcinogenic and reproductive toxic properties. The updated reference values are expected to be prepared by the end of 2025.

DEPA assesses that the above initiatives contain data indicating that TFA will not be able to comply with the requirements set out in Annex 16 to the national Framework for the Assessment of Plant Protection Products[8].

[7] https://eur-lex.europa.eu/legal-content/da/TXT/PDF/?uri=CELEX:02008R1272-20231201

[8] https://mst.dk/media/3w0gjrbk/framework_assessment_pesticides_version_1-7_november_2019-1.pdf

6) Summary and regulatory considerations

It is known that there are several sources of TFA, including an atmospheric contribution, which results in TFA content in precipitation. This causes a 'background level' of TFA in groundwater that is not due to surface applications, such as the use of trifluormethyl pesticides and other industrial emissions. However, geographic analyses of TFA concentrations in groundwater show an increased content of TFA in groundwater in areas dominated by agricultural activities, compared to areas dominated by other land uses, including forest and natural areas. This indicates that agricultural activities, including the use of pesticides, contribute to increased levels of TFA in groundwater.

The TriFluPest project has demonstrated the formation of TFA during the degradation of seven pesticides in soil. In addition, there are five active substances from EU assessments: Flonicamid, Fluopyram, Flufenacet, Flurtamone and Tritosulfuron (and partly from Haloxyfop-p in lysimeter experiments), with a total of 12 trifluormethyl pesticides documented to form TFA (see Table 6 below, Fluopyram is included in both groups). Despite the fact that the research project did not use a traditional experimental design, DEPA assesses that the project has documented the formation of TFA from all seven active substances studied.

There are a total of 12 active substances in currently authorised pesticide products in Denmark that contain a trifluormethyl group, which makes them suspected of forming TFA from degradation in soil. There are six active substances included in currently authorised products where it has now been documented that TFA is formed during degradation, but where this information was not available and therefore not considered for the existing authorisations for products containing the active substances (see Table 6 below). These are the active substances: Flonicamid, Fluopyram, Diflufenican, Fluazinam, Mefentrifluconazole and Tau-fluvalinate.

All well-studied trifluormethyl pesticides have been shown to form TFA, and DEPA is not aware of any examples to the contrary.

Table 6: Overview of the 12 active substances for which it has been documented that TFA is formed during degradation in soil.

	EU-assessment	TriFluPest	Approved for use in Denmark	Previously approved For use in Denmark
Flufenacet	X			
Flurtamone	X			
Haloxyfop-p	X			
Tritosulfuron	X			
Flonicamid	X		X	
Fluopyram	X	X	X	
Diflufenican		X	X	
Fluazinam		X	X	
Mefentrifluconazole		X	X	
Tau-fluvalinate		X	X	
Fluazifop-p-butyl		X		X
Trifluralin		X		X

EU modelling carried out for Flufenacet, Flurtamone, Fluopyram and Flonicamid shows that for all the uses in question, TFA will leach to groundwater in concentrations above the limit value for pesticides and metabolites in groundwater of 0.1 µg/L. It is therefore likely that the use of active substances that form TFA will pose an unacceptable risk of leaching to groundwater.

In order to document whether specific uses will meet the authorisation conditions with regard to leaching to groundwater, the authorisation holders will have to perform model calculations in accordance with EU guidelines and Danish requirements based on well-documented or worst-case formation fractions (ff=1) for TFA. In view of the above considerations, the formation percentages measured from the tests carried out in the TriFluPest project cannot be used as formation fractions in model calculations.

In addition, **TFA is extremely persistent in soil, where EU assessments use a standard half-life (DT50) in soil of 1,000 days**. This means that TFA will not meet the Danish national persistence criteria, which requires active substances and degradation products to have a half-life of less than 180 days. An exception to this requirement can only be made if it can be documented that TFA does not pose a risk of leaching into groundwater and if it is not problematic in terms of health, cf. the requirements in Annex 16 to the Danish national Framework for the Assessment of Plant Protection Products. However, DEPA assesses that it is unlikely that TFA will be able to meet these toxicological requirements based on data included in the proposal for harmonised classification.

7) Conclusions

The GEUS report documents the formation of TFA through the degradation of all seven active substances tested in the study. The formation of TFA was not sufficiently addressed in the majority of the available EU assessments. TFA is persistent (DT50 >> 180 days) and does not comply with the Danish national persistence criteria, and TFA binds very weakly to soil. For all well-studied active substances, the FOCUS modelling in the EU assessment shows leaching to groundwater in concentrations above 0.1 µg/L in all scenarios for all uses.

On this basis, DEPA concludes that there is documentation of the formation of TFA, there is documentation that TFA is persistent, and that it is likely that the use of products containing an active substance with a trifluormethyl group (C-CF3) poses a risk of leaching of TFA to groundwater in concentrations above 0.1 µg/L. Therefore, DEPA assesses that there is no evidence that the authorisation conditions are met with regard to the persistence of TFA (see the assessment principles section: Persistence in soil) and the risk of leaching of TFA to groundwater in concentrations above 0.1 µg/L (cf. the assessment principles section: Groundwater/mobility and the Uniform Principles section A 2.5.1.2) for the authorised uses of Diflufenican, Flonicamid, Fluazinam, Fluopyram, Mefentrifluconazole and Tau-fluvalinate in Denmark.

8) Specific assessment of the 6 active substances[9]

The substance specific assessments described below is a combination of information gathered by DEPA prior to the stakeholder consultation according to Art. 44, and information submitted by authorization holders as part of the consultation.

Diflufenican

The TriFluPest report documents the formation of TFA from degradation of Diflufenican. The experiment showed 2.4 - 5.2 % TFA formation during the test period (Table 1). However, as a percentage of degraded parent substance, there are higher proportions of degraded substance that are converted to TFA, 3.9 - 7.2 % within 12 months (Table 2). A final formation fraction cannot be determined based on the experiments performed, as further formation from the active substance and intermediate metabolites is expected over time.

[9] Further details are available in the specific assessment in Bilag 1 of the individual active substances available in notifications in ESFC.

DEPA considers that the formation of TFA has not been adequately addressed in the available EU-assessment due to inappropriate analytical methodology and labelling, while the TriFluPest report demonstrates formation of TFA in the laboratory study. Groundwater modelling submitted by the authorisation holder as a response to the stakeholder consultation, uses a formation fraction that is based on a theoretical maximum occurrence in soil which is lower compared to what is observed in the TriFluPest study, and cannot be accepted by DEPA. Hence, the submitted modelling report suggest that the currently authorised uses of diflufenican pose a risk of leaching of TFA to groundwater above the limit value of 0.1 µg/L. Furthermore, TFA is highly persistent and thereby does not fulfill the Danish persistence criteria.

DEPA concludes that TFA is formed in soil from diflufenican, it is highly persistent and constitutes an unacceptable risk of leaching to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

Flonicamid

The TriFluPest project does not include investigation of formation of TFA from degradation of Flonicamid. However, the formation of TFA from Flonicamid is demonstrated in the dossier submitted for the ongoing renewal of Flonicamid in the EU. Here, formation reaches 22.5 % (Table 4) after approx. 120 days.

TFA binds very weakly to soil. The FOCUS modelling for the Hamburg scenario in the EU assessment for Flonicamid shows leaching to groundwater in concentrations of 4.2, 4.0 and 2.2 – 3.2 µg/L, respectively, for winter cereals, spring cereals and apples at dosages of 2*70 g as/ha or 1*70 g as/ha, which corresponds to the authorized dose rates in Denmark. The modelling therefore shows that the authorized uses of Flonicamid in Denmark pose an unacceptable risk of leaching of TFA to groundwater. Modelling submitted by the authorisation holder during the stakeholder consultation also demonstrate that the currently authorised uses in Denmark pose an unacceptable risk of leaching of TFA to groundwater in concentrations > 0.1 µg/L. Furthermore, TFA is highly persistent and thereby does not fulfill the Danish persistence criteria.

DEPA concludes that the available studies show that TFA is formed from Flonicamid, it is highly persistent and the available modelling demonstrates that the currently authorized uses pose an unacceptable risk of leaching of TFA to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

Fluazinam

The TriFluPest report documents the formation of TFA from degradation of Fluazinam. The experiment showed 5.3 – 6.5 % TFA formation during the test period (Table 1). However, as a percentage of degraded parent substance, there are higher proportions of degraded substance that are converted to TFA, 5.6 – 6.6 % within 12 months (Table 2). A final formation fraction cannot be determined based on the experiments performed, as further formation from the active substance and intermediate metabolites is expected over time. The formation of TFA from Fluazinam is confirmed by preliminary experimental data submitted by the authorization holder as part of the stakeholder consultation. Preliminary results from two ongoing soil degradation studies show formation of TFA at levels comparable to those reported in the TriFluPest project. TFA is formed in amounts identifying it

as a major metabolite, as it is found in two of each other following time points in more than 5 % of applied active substance.
An indicative formation fraction based on the preliminary degradation studies was used in a modelling study submitted by the authorization holder. The modelling intended to show safe use, however, the provided estimates are based on a modified GAP in terms of dose rates, number of applications, growth stage (BBCH), and use of bi/triennial applications, which results in soil loadings far below the authorized uses. This shows that the authorised uses of Fluazinam in Denmark pose an unacceptable risk of leaching of TFA to groundwater in concentrations > 0.1 µg/L.

DEPA concludes that TFA is formed in soil from Fluazinam, it is highly persistent and constitutes an unacceptable risk of leaching to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

Fluopyram
The TriFluPest report documents the formation of TFA during the degradation of Fluopyram. The experiment showed 3.3 - 10.7 % TFA formation during the trial period (Table 1). However, as a percentage of degraded parent substance, there are significantly higher proportions of degraded substance that are converted to TFA, 13.2 – 35 % within 12 months (Table 2). A final formation fraction cannot be determined based on the trials conducted, as further formation from the active substance and intermediate metabolites is expected over time. The formation of TFA from Fluopyram is confirmed in the dossier submitted for the ongoing renewal of Fluopyram in the EU, where the applicant has also demonstrated the formation of TFA. Here, formation reaches 7.4 % (Table 4) after approx. 120 days.

TFA binds very weakly to soil. The FOCUS modelling for the Hamburg scenario in the EU assessment for Fluopyram shows leaching to groundwater in concentrations of 5.9 and 4.9 µg/L for winter crops and spring crops at a dosage of 78 g as/ha, which is lower than the authorised dose rate in cereals in Denmark of 125 g/ha. The modelling is therefore not fully comprehensive, and leaching is expected to be higher for Danish applications. Modelling submitted be the authorisation holder as part of the stakeholder consultation intended to show safe use of Fluopyram, however, the provided estimates are based on a modified GAP in terms of dose rates, and use of bi/triennial applications, which results in soil loadings far below the authorised uses. This confirms that the authorised uses of fluopyram in Denmark pose an unacceptable risk of leaching of TFA to groundwater in concentrations > 0.1 µg/L.

DEPA concludes that TFA is formed in soil from Fluopyram, it is highly persistent and constitutes an unacceptable risk of leaching to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

Mefentrifluconazole
The TriFluPest report documents the formation of TFA from degradation of Mefentrifluconazol. The experiment showed 0.8 – 3.3 % TFA formation during the test period (Table 1). However, as a percentage of degraded parent substance, there are higher proportions of degraded substance that are converted to TFA, 6.4 – 16.7 % within 12 months (Table 2). A final formation fraction cannot be determined based on the experiments performed, as further formation from the active substance and intermediate metabolites is expected over time.

DEPA considers that the formation of TFA has not been adequately addressed in the available EU-assessment due to inappropriate analytical methodology and labelling, and in the submitted

studies as a response to the stakeholder consultation, while the TriFluPest report demonstrates formation of TFA in the laboratory study. No groundwater modelling with acceptable worst case input values have been submitted by the authorisation holder. Hence, a risk of leaching of TFA to groundwater above the limit value of 0.1 µg/L cannot be excluded. Furthermore, TFA is highly persistent and thereby does not fulfill the Danish persistence criteria.

DEPA concludes that TFA is formed in soil from Mefentrifluconazole, it is highly persistent and the authorisation holder has not demonstrated that the authorised uses do not constitute an unacceptable risk of leaching to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

Tau-fluvalinate

The TriFluPest report documents the formation of TFA from degradation of Tau-fluvalinate. The experiment showed 0.4 - 1.0 % TFA formation during the test period (Table 1). A percentage of degraded parent substance could not be calculated as the analytical method for Tau-fluvalinate could not quantify the content. A final formation fraction cannot be determined based on the experiments performed, as further formation from the active substance and intermediate metabolites is expected over time.

DEPA considers that the formation of TFA has not been adequately addressed in the available EU-assessment due to inappropriate analytical methodology and labelling, while the TriFluPest report demonstrates formation of TFA in the laboratory study. No groundwater modelling with acceptable worst case input values have been submitted by the authorisation holder. Hence a risk of leaching of TFA to groundwater above the limit value of 0.1 µg/L cannot be excluded. Furthermore, TFA is highly persistent and thereby does not fulfill the Danish persistence criteria.

DEPA concludes that TFA is formed in soil from Tau-fluvalinate, it is highly persistent and the authorisation holder has not demonstrated that the authorised uses do not constitute an unacceptable risk of leaching to groundwater. DEPA considers TFA to be a relevant metabolite and it has not been documented that TFA is of no toxicological concern in accordance with the requirements in Annex 16 of the Danish assessment framework.

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Bilag 1 - Rev Diflufenican Miljøstyrelsens faglige vurdering, July 2025

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Bilag 1 - Rev Mefentrifluconazol Miljøstyrelsens faglige vurdering, July 2025

Bilag 1 - Rev Tau-fluvalinat Miljøstyrelsens faglige vurdering, October 2025