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Legal opinion on the amendment of the authorisation of TFA-releasing plant protection products according to EU Regulation No. 1107/2009 and new ECJ case law

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1. Facts and Question

The **question** was raised whether, based on **new scientific findings** on the toxicity and spread of the pesticide metabolite trifluoroacetic acid (TFA), the authorisation of **plant protection products that release TFA <u>can</u>** or **<u>must</u>** be withdrawn to comply with the EU Pesticide Regulation No. 1107/2009.

TFA belongs to the group of over 10,000 chemicals known as PFAS (perfluorinated and polyfluorinated alkyl substances). Numerous and significant effects on human health and the environment have been proven with regard to PFAS. For this reason, around 10,000 PFAS used in everyday products are to be largely restricted or banned through a "group ban" as part of the EU chemicals regulation REACH. This follows a proposal for an EU-wide ban on PFAS that was submitted to the European Chemicals Agency (ECHA) by Germany, the Netherlands, Denmark, Sweden and Norway at the beginning of 2023[1].

However, the PFAS group ban under the REACH chemicals regulation would **not cover** active substances from pharmaceuticals, biocides and pesticides (plant protection products), as these are subject to a legal authorisation process regulated in the corresponding regulations.
Pesticide active substances that belong to the PFAS group of chemicals (hereinafter referred to as **PFAS pesticides**), release large quantities of TFA into the environment.

The **German Federal Environment Agency (UBA) has qualified TFA** as a **"substance of concern for the environment"** [2] with the increased risk resulting from the **extreme persistence** of this substance. TFA is **one of the most stable organic compounds** of all. To date, there are no known environmental conditions under which TFA degrades, which means that

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1 BfR (2023): Updated BfR Communication No 008/2023 of 7 February 2023 https://www.bfr.bund.de/cm/343/per-und-polyfluorierte-alkylsubstanzen-pfas-veroeffentlichung-des-vorschlags-zur-braeschraenkung-nach-der-reach-verordnung-bei-der-europaeischen-chemikalienbehoerde.pdf

2 UBA 2021: Reducing the discharge of chemicals into water bodies - Trifluoroacetate (TFA) as a persistent and mobile substance with many sources. https://www.umweltbundesamt.de/sites/default/files/medien/11850/publikationen/2021_hg_chemiekalieneintrag_bf_v2.pdf

TFA increasingly accumulates in the environment[3]. Subsequent removal from the environment, especially in drinking water production, is not feasible.

Environmental protection organisations therefore argue that limiting the environmental and health risks of PFAS and protecting water requires a ban on all PFAS that release large quantities of TFA into the environment. A ban on PFAS without taking into account the most important precursors of TFA - which would undoubtedly include PFAS pesticides - ignores a dangerous contaminant for which there is now substantial evidence of a health risk, which is also increasing cumulatively over the years. In the past, the chemical industry and the responsible authorities had presented TFA as ecotoxicologically and human-toxicologically safe **against the backdrop of inadequate data**.[4] However, new scientific findings on its toxicity and spread in the environment now argue against this assumption of safety.

This would emerge from a series of new publications from authorities and from academic science, all of which have been published within the last four years. These would provide sufficient evidence that PFAS pesticides are a significant source of TFA contamination of groundwater and drinking water and that this contamination has increased steadily and significantly across Europe over the last three decades (and will continue to increase unless the input sources are eliminated).

There would also be sufficient evidence that TFA is a substance with reprotoxic properties that should be classified as "toxic for reproduction cat. 1B" and thus fulfils a hazard-based exclusion criterion for the approval of active substances.

Against this background, the Austrian environmental protection organisation *GLOBAL 2000 - Friends of the Earth Austria* commissioned the present legal opinion.

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[3] Ibid.

[4] GLOBAL 2000 (May 2024): TFA in water - Dirty PFAS legacy under the radar (p. 12 ff.) https://www.global2000.at/sites/global/files/240527_report_tfa-im-wasser_g2k_pan.pdf

This expert opinion is intended to clarify the extent to which the new scientific findings on TFA enable Austria or, if necessary, oblige Austria to amend or withdraw existing authorisations of plant protection products that release TFA.

1.1 Scientific and technical knowledge of TFA

The information presented in the following section on the current state of scientific and technical knowledge on trifluoroacetate (TFA) was provided by the client of the expert opinion. The legal considerations and conclusions of this report are based on the assumption that this information is correct. A detailed review of the information and the sources cited was not the task of this report.

1.1.1 New findings on sources and distribution in the environment

Analyses of water samples in Austria[5] as well as in other EU countries, which were carried out by authorities, researchers and environmental organisations, consistently show that TFA is by far the dominant PFAS in surface water and groundwater, both in terms of its ubiquitous distribution in the aquatic environment and in terms of the quantities found.[6] This also applies to drinking water[7] [8] where the TFA contamination found was one to two orders of magnitude higher than the total contamination by all other PFAS.

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5 Federal Environment Agency Vienna 2023: Per- and polyfluorinated alkyl substances - Comparison of methods for the determination of PFAS in water samples (p. 27 ff). https://www.umweltbundesamt.at/fileadmin/site/publikationen/rep0859.pdf

6 GLOBAL 2000 (May 2024) TFA in water - Dirty PFAS legacy under the radar (p. 12 ff.) https://www.global2000.at/sites/global/files/240527_report_tfa-im-wasser_g2k_pan.pdf

7 Neuwald et al. Ultra-Short-Chain PFASs in the Sources of German Drinking Water: Prevalent, Overlooked, Difficult to Remove. Environ. Sci. Technol. 2022, 56, 6380-6390. https://pubs.acs.org/doi/10.1021/acs.est.1c07949

8 GLOBAL 2000 (July 2024): TFA - The eternal chemical in the water we drink: https://www.global2000.at/sites/global/files/TFAinTrinkwasser_Report_Final_DE.pdf

The steady and maintainable increase in TFA levels in the environment, particularly in water, was already predicted in the 1990s.[9] [10] [11] However, in the absence of systematic monitoring under the Water Framework Directive, its actual occurrence remained largely undocumented by the state. However, scientific publications have (retrospectively) shown that the measured TFA values in rainwater in Germany have quadrupled within two decades.[12] Similar and even greater increases in TFA over time were found in studies of surface waters in the USA[13] and China[14] and from ice cores in the remote northern regions of Canada[15] have been reported.

In November 2021, the UBA published its first report[16] on the sources and pathways of TFA and the resulting environmental concentrations in German waters. For the first time, plant protection products (PFAS pesticides) were named alongside refrigerant gases as the most important pathway for TFA contamination. In November 2023, in its report
"*Trifluoroacetic acid (TFA): Laying the foundations for effective minimisation - Spatial analysis*

9 Likens GE, Tartowski SL, Berger TW, Richey DG, Driscoll CT, Frank HG, Klein A. Transport and fate of trifluoroacetate in upland forest and wetland ecosystems. Proc Natl Acad Sci U S A. 1997 Apr 29;94(9):4499-503. doi: 10.1073/pnas.94.9.4499. PMID: 9114018; PMCID: PMC20751. https://pubmed.ncbi.nlm.nih.gov/9114018/

10 Ball JC, Wallington TJ. Formation of trifluoroacetate from atmospheric degradation of hydrofluorocarbon 134a: a human health concern? Air Waste. 1993 Sep;43(9):1260-2. doi: 10.1080/1073161x.1993.10467204. PMID: 8217109. https://pubmed.ncbi.nlm.nih.gov/8217109/

11 Klein, A. (1997) Halogenated acetic acids in the environment. Dissertation for the doctoral degree of the Faculty of Biology, Chemistry and Geosciences of the University of Bayreuth, unpublished

12 Freeling, F.; Behringer, D.; Heydel, F.; Scheurer, M.; Ternes, T. A.; Nödler, K. Trifluoroacetate in Precipitation: Derivation of a Benchmark Dataset. Environ. Sci. Technol. 2020, 54 (18), 11210-11219. https://pubmed.ncbi.nlm.nih.gov/32806887/

13 Thomas M. Cahill. Increase in trifluoroacetate concentrations in surface waters over two decades. Environmental Science & Technology 2022 56 (13), 9428-9434 https://pubs.acs.org/doi/epdf/10.1021/acs.est.2c01826

14 Zhai, Z. H.; Wu, J.; Hu, X.; Li, L.; Guo, J. Y.; Zhang, B. Y.; Hu, J. X.; Zhang, J. B. A 17-fold increase of trifluoroacetic acid in landscape waters of Beijing, China during the last decade. Chemosphere 2015, 129, 110- 117 https://pubmed.ncbi.nlm.nih.gov/25262947/

15 Pickard, H. M.; Criscitiello, A. S.; Persaud, D.; Spencer, C.; Muir, D. C. G.; Lehnherr, I.; Sharp, M. J.; De Silva, A. O.; Young, C. J. Ice Core Record of Persistent Short-Chain Fluorinated Alkyl Acids: Evidence of the Impact From Global Environmental Regulations. Geophys. Res. Lett. 2020, 47 (10) https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2020GL087535

16 UBA (2021): Reducing chemical inputs into water bodies - Trifluoroacetate (TFA) as a persistent and mobile substance with many sources: https://www.umweltbundesamt.de/sites/default/files/medien/11850/publikationen/2021_hg_chemiekalieneintrag_bf_v2.pdf

of the entry paths into the water cycle "[17]. UBA identified pesticide-active substances containing a perfluorinated methyl group as the main entry pathway for TFA pollution of water bodies, especially groundwater. The authority estimated their potential to release TFA in Germany at 434 tonnes per year. Precipitation (photo-oxidation of F-gases) followed in second place with a potential TFA release of 96 tonnes and wastewater treatment and liquid manure with around 20 tonnes per year each. According to the same report by UBA, the average TFA values in regions with a high proportion of arable land are significantly higher (1.66 µg/L [micrograms per litre]) than in areas where no agricultural inputs are to be expected, but where precipitation is the dominant input pathway (0.67 µg/L). However, the highest average pollutant values (2.3 µg/L) were measured in areas where industrial emissions dominate (which, according to the UBA, is only the case in a few districts). Away from agricultural areas, the influence of sewage treatment plants (1.06 µg/L) was also identified as the main input pathway in individual cases.[18]

In Austria, TFA measurements were carried out at 80 groundwater monitoring sites in 2019 as part of the GZÜV special monitoring programme "Trace substances in groundwater 2018-2020" on behalf of the Ministry of Agriculture.[19] The test results paint a picture that appears to be consistent with the findings and data from Germany, both in terms of the range of concentrations found and the indications of possible entry paths: TFA was detectable at all 80 groundwater measuring points. The average contamination was 0.71 µg/L TFA. The authors found that "both the influence of wastewater and agricultural land use can cause increased TFA concentrations". [20]

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17 UBA (2023): Trifluoroacetate (TFA): Laying the foundations for effective minimisation - Spatial analysis of entry pathways into the water cycle: https://www.umweltbundesamt.de/sites/default/files/medien/11850/publikationen/102_2023_texte_tfa_v2.pdf

18 Ibid, p. 55

19 BMLFUW 2022: Water Quality in Austria Annual Report 2018-2020 (p. 161) https://info.bml.gv.at/dam/jcr:13a4f19c-dc00-4033-8ab8-136f352e6746/Wasserg%C3%BCte-Jahresbericht_2018-2020_20230220.pdf

20 Ibid.

Based on the information provided by GLOBAL 2000, it can therefore be concluded that, although the pathways for the release of TFA into the environment and in particular for groundwater contamination can be very diverse and have not yet been fully clarified in all detail, it seems to be beyond dispute that PFAS pesticides contribute **significantly to the contamination of water bodies**, especially **groundwater**, for which they have even been identified as the dominant cause by the German UBA.[21] Likewise, there seems to be no scientific doubt that the concentration of TFA in water bodies has increased in recent decades and that the average concentrations detectable today are many times higher than the standards and maximum levels applicable to pesticide active substances and relevant metabolites in groundwater and drinking water, which have been set at 0.1 µg/L (see section 3).

1.1.2 New findings on a potential risk to health

According to GLOBAL 2000, since the market launch of F-gases and PFAS pesticides, the most important precursors of TFA, the chemical has been repeatedly presented - especially in scientific publications funded by the chemical industry - as a chemical that is largely harmless to human health and the environment. However, no studies proving the absence of carcinogenic, reproductive or endocrine-disrupting properties were communicated to regulators.[22] According to GLOBAL 2000, authorities shared this assumption of harmlessness for a long time. This explains why TFA has been considered a pesticide metabolite of no toxicological relevance and was not subject to the legal threshold of the EU Pesticides Regulation, the EU Water Framework Directive or the EU Drinking Water Directive.[23] In recent years, however, the risk of TFA to human

21 Cf. S. Sturm et al, Trifluoroacetate (TFA): Laying the foundations for effective minimisation - Spatial analysis of entry pathways into the water cycle - Final report, UBA 2022; https://www.umweltbundesamt.de/sites/default/files/medien/11850/publikationen/102_2023_texte_tfa_v2.pdf

22 GLOBAL 2000 (May 2024): TFA in water - Dirty PFAS legacy under the radar (p. 12 ff.) https://www.global2000.at/sites/global/files/240527_report_tfa-im-wasser_g2k_pan.pdf

23 GLOBAL 2000 (July 2024): TFA - The eternal chemical in the water we drink: https://www.global2000.at/sites/global/files/TFAinTrinkwasser_Report_Final_DE.pdf

health is being viewed increasingly critically by the authorities. In 2014, the European Food Safety Authority (EFSA) set a provisional "tolerable daily intake" (TDI) of TFA for humans at **0.05 mg/kg/d**[24] (milligrams per kilogramme of body weight per day). In 2020, based on a new manufacturer study, the German UBA derived a significantly lower TDI of **0.0125 mg/kg/d**[25] derived. In 2023, the Dutch authority RIVM finally proposed a further significantly lower TDI of only **0.0003 mg/kg/d**[26] was proposed.

The decisive evidence for a **particular hazard potential of TFA** was provided by a study by the pesticide manufacturer Bayer, which also has PFAS active ingredients in its portfolio: On 7 January 2021, Bayer informed the EU Commission and the EU Member States of potentially harmful or unacceptable effects of TFA in accordance with Art. 56 of the Pesticides Regulation 1107/2009. In a teratogenicity study with rabbits commissioned by Bayer for regulatory purposes, severe malformations had occurred in the foetuses of dams to which TFA had been administered.[27] In their conclusions on this study, the manufacturer and the authority had agreed that these were severe skeletal and visceral malformations, with the latter occurring at all three doses administered. According to GLOBAL 2000, the manufacturer and the authority also agreed that this was a key regulatory study, the reliability of which they had classified with the highest rating of 1 ("reliable without restriction"), which is why TFA should clearly be classified as toxic for reproduction category 1B based on this study.

In fact, in the spring of 2024, Germany applied to ECHA to classify TFA as toxic for reproduction (category 1b) based on the REACH registration dossier.[28]

24 EFSA (2014): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3585 (P. 9)

25 UBA (2020): Derivation of a health guideline value for trifluoroacetate (TFA): https://www.umweltbundesamt.de/sites/default/files/medien/421/dokumente/ableitung_eines_gesundheitlichen_leitwertes_fuer_trifluoressigsaeure_fuer_uba-homepage.pdf

26 RIVM (Netherlands Institute for Public Health and the Environment) 2023: https://www.rivm.nl/sites/default/files/2023-03/DMG-2023-0011%20Bijlage%20Advies%2014434A02_Drinkwaterrichtwaarde%20TFA_07122022.pdf

27 ECHA 2024: Registration dossier of trifluoroacetate. Developmental toxicity / teratogenicity: https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/5203/7/9/3/?documentUUID=bbe1c0df-91db-4cef-a965-89ded98a88c8

28 ECHA 2024: Registry of CLH intentions until outcome - Trifluoroacetic acid: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/

However, it could be several years before a formal classification becomes effective due to the institutional timeframes involved.[29]

1.2 Question

In accordance with these conditions, the **question** was raised as to whether the Pesticides Regulation 1107/2009 provides a suitable basis for Member States **to ban** plant protection products that emit TFA into the environment and, in particular, into groundwater and drinking water**,** or whether it **is necessary** to withdraw the relevant authorisations in the light of new findings, in particular on i) the persistent and significant increase in TFA contamination in the environment, especially in groundwater and drinking water; and on ii) the (presumed) necessary classification of TFA as "toxic for reproduction category 1B".

0b0236e188e6e587#msdynttrid=XuTijdX8JNqFEGuNBOlPVRtfmPgEkJy-wokd-_Garfo

29 Natural Refrigerants (2024): German Chemicals Office Submits Proposal to EU Linking TFA to Reproductive Toxicity. https://naturalrefrigerants.com/german-chemicals-office-submits-proposal-to-eu-linking-tfa-to- reproductive-toxicity/

2. Basic questions

From a legal point of view, this raises the question of whether, in the present case, the **authorisation can or must be withdrawn** based on Pesticide Regulation 1107/2009 for authorised plant protection products, i.e. for products that met the requirements at the time of authorisation under the state of knowledge and understanding at that time; whether new findings call into question the safety of the product and suggest that the authorisation requirements are no longer met.

In particular, it must be taken into account that the accumulation of TFA in the aquatic environment is almost irreversible due to its exceptional longevity (persistence) and can therefore no longer be reversed, while the long-term effects of TFA, including the detailed effects on human health, have not been fully clarified. The **interpretation of the precautionary principle** in EU law will therefore also play an important role. There is a very extensive literature on this principle. Particularly recently, ECJ case law has emerged that is especially relevant in the context of the assessment of plant protection products. It will have to be examined separately and will probably shed a decisive light on the assessment of the TFA problem.

3. The central provisions

Art. 29 of Regulation 1107/2009 regulates the requirements for the authorisation to place plant protection products on the market. **Central to** this are the **provisions in Art. 4** of this Regulation on the "Approval criteria for active substances" contained in these plant protection products.

For the present issue, reference should be made in particular to **paragraph 3(b)** of this Article 4, according to which the following applies to plant protection products containing active substances that fulfil the approval criteria for active substances in accordance with Article 4:

> *"* [A plant protection product] *shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater."*

Furthermore, the following applies to plant protection products according to **paragraph 3(e)**:

> *"* [A plant protection product] *shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:*
>
> > *(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;"*

Almost identical requirements for the approval of active substances also apply to residues (including metabolites and degradation products) resulting from the intended use of plant protection products containing the active substances concerned in accordance with Article 4(2):

> *"(a) they* [the residues] *shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;*

b) they shall not have any unacceptable effect on the environment."

For the purposes of the Regulation, 'residues' means residues as defined in Article 3(1):

> "*one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction product*".

The approval criteria under Article 4 include, in particular, a set of strict hazard-based exclusion criteria based on the precautionary principle[30] for the approval of active substances at the EU level. The Pesticide Regulation's " intention is to eliminate the most toxic substances from the market"[31]. According to Annex II, point 3.6.4. applies in particular to substances with reprotoxic properties:

> *" An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008 [...]".*

Exceptions to this are only possible if the exposure for humans is "negligible", which is obviously not the case for the pesticide metabolite TFA.

30 According to Article 4(1) of the Pesticides Regulation 1107/2009, with reference to Annex II point 3, an active substance is only authorised if it is not classified or is not to be classified as carcinogenic, mutagenic, toxic for reproduction category 1A or 1B, persistent and bioaccumulative, hazardous to the environment or endocrine disruptor for humans and non-target organisms.

31 European Parliament (2018). Report on the implementation of Regulation (EC) No 1107/2009 on plant protection products (p. 5): https://www.europarl.europa.eu/doceo/document/A-8-2018-0268_DE.pdf

With regard to the fate and behaviour in relation to groundwater, the following applies in accordance with point 3.10. of Annex II:

> *" An active substance shall only be approved where it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6)."*

Regulation (EU) No 546/2011 on uniform principles for evaluation and authorisation of plant protection products provides in point 2.5.1.2. of the Annex that no authorisation shall be granted if "*the expected concentration of the active substance or its metabolites, degradation or reaction products in groundwater after use of the plant protection product under the proposed conditions exceeds the maximum concentration permitted under Directive 2006/118/EC*. This maximum permissible concentration is defined there by the "groundwater quality standards" in Annex I and is 0.1 µg/l (micrograms per litre) for pesticide-active substances and their relevant metabolites.

Similarly, the EU Drinking Water Directive 2020/2184 stipulates 0.1 µg/l in its Annex I for "pesticides and their relevant metabolites" as *"minimum requirements for parametric values for the assessment of the quality of water intended for human consumption"*.

Pesticide Regulation 1107/2009 defines a "metabolite" in accordance with Article 3(32):

> *"any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment."*

The following also applies:

" A metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable."

and:

*"Such a [*relevant*] metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures"*

The "Guideline for assessing the relevance of metabolites in groundwater" specifies this as follows:

*"If such a [*relevant*] metabolite exceeds the maximum permitted concentration (0.1 µg/l) for groundwater, a decision on non-inclusion of the active substance would be taken at Community level or a decision on non-authorisation for certain uses of products containing this substance would be taken at national level"* [32]

and:

" The guiding principle of the assessment is that a metabolite or degradation product is considered relevant, if there is reason to assume that it has comparable intrinsic properties as the active substance in terms of its biological target activity, or that it has certain toxicological properties that are considered severe (i.e. genotoxic, toxic to reproduction, carcinogenic, toxic or very toxic), unless demonstrated to the contrary.

[32] COM (2003): Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr.pdf (p. 5f)

toxic to reproduction, carcinogenic, toxic or very toxic), unless proven otherwise "[33]

The interim conclusion can therefore be summarised as follows:

The **object of protection** is both the **health** of humans and animals and the **groundwater** itself - whereby delayed harmful effects must also be excluded - as well as the **environment**, with particular attention being paid to the contamination of water bodies. Plant protection products with a particular potential risk to health, e.g. due to **their reprotoxic properties**, or with a particular potential risk to the environment, e.g. due to **limit values being exceeded in groundwater**, are excluded from authorisation. The use of plant protection products and the residues resulting from this use in food, drinking water and the environment must be compatible with achieving the protection goals of the Pesticides Regulation. This also applies in particular to the **metabolites and degradation products** of the active pesticide substances contained in these plant protection products. Metabolites that are suspected of being toxic to reproduction are relevant metabolites. The same limit values apply to them as for pesticide-active substances.

With regard to the authorisation requirement that plant protection products pursuant to Article 4(3)(e) and their residues, including metabolites, pursuant to Article 4(2)(b) must have "**no unacceptable effects on the environment"**, it should be noted that non-compliance with the environmental objectives set out in Article 4 of the Water Framework Directive, which results significantly from the (intended) use of a plant protection product, constitutes such an unacceptable effect on the environment (further explanations follow in section 4.1)

33 In the Standing Committee on Plants, Animals, Food and Feed of July 2024, the EU Commission confirmed that, in accordance with the existing guidance, metabolites that would be classified as toxic for reproduction are to be considered relevant: https://food.ec.europa.eu/document/download/658b61d5-8fc8-49fb-ae05-1b23b9ff7f4d_en? filename=sc_phyto_20240710_ppl_sum.pdf (p. 8)

For all pollutants - including those which, like TFA, are not listed as "priority substances" under the Water Framework Directive - the following applies with regard to the environmental objectives set out in Article 4 of the Water Framework Directive in accordance with paragraph 1(b) in relation to groundwater:

> *"(iii) Member States shall implement the measures necessary to reverse any significant and sustained upward trend in the concentration of any pollutant resulting from the impact of human activity in order progressively to reduce pollution of groundwater*."

The totality of the available data, which consists of official investigations and scientific publications, unanimously indicates that the pollution of water bodies and especially groundwater with TFA in Europe has increased significantly since the 1990s and that the use of plant protection products that emit TFA has played a decisive role in the increase in groundwater pollution.

The following applies with regard to the possibility or necessity of amending an authorisation:

If there are indications that a requirement in accordance with Article 29 [of Regulation 1107/2009] is no longer fulfilled, the Member States (MS) may **review** an authorisation in accordance with Art. 44 (1) at any time, even if an authorisation has already been granted.[34]

According to paragraph 3 of this article, Member States are **obliged** to **amend** or **withdraw** an authorisation if:

> *"(a) the requirements referred to in Article 29 are not or are no longer satisfied"*

[34] The word "check" at this point corresponds to the correct translation of the English expression "review" in the wording "Member States may review an authorisation at any time ..." in the English version of the Pesticides Regulation, which was adopted by the European Parliament and the Council on 21 October 2009. There is probably an error in the German translation, as "to review" is translated as "to change". See also, for example, "riesaminare" in the Italian version and "riesaminare" in the French version. "réexaminer"

Furthermore, Article 56 requires holders of authorisation to notify the competent authorities immediately of any new findings of potentially harmful or unacceptable effects of authorised plant protection products:

> (1) *" The holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.*
> *In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its* <u>*metabolites*</u>*, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.*

Paragraph 2 of Article 56 specifies as follows:

> *"The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively."*

In summary, it can be said that the EU Pesticides Regulation contains provisions that oblige authorisation holders to immediately notify the Member States of new findings on potentially harmful effects and properties of the plant protection product. Member States have the possibility and, under certain conditions, the obligation to review existing authorisations at any time. If the **requirements according to Art. 29** have not been met, taking into account the latest scientific and technical findings, **Article 44 <u>requires</u> Member States to <u>amend or withdraw</u> the relevant authorisations**

The Pesticides Regulation is therefore **not** to be understood as **static** in the sense that it would only allow an evaluation or re-evaluation of the approval criteria for active substances or authorisation requirements for plant protection products in the course of the legally required authorisation or re-authorisation procedures, but dynamically[35]. Under certain conditions, Member States are even obliged to amend or withdraw existing authorisations of plant protection products, whereby **the focus is not on the interests of the users or manufacturers of plant protection products,** but **on** the protection of the environment and human and animal life as well as the safety of groundwater (and thus in turn - also - the protection of human and animal health).

This principle is also expressed very clearly in recital 24 of Regulation 1107/2009:

> *" The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production [...]."*

Regulation 1107/2009 is the expression of many difficult compromises. This Regulation leaves no doubt as to the **priority of protecting the environment and human and animal health as well as groundwater**; nor can the need to take the latest scientific findings into account on an ongoing basis be called into question. Based on these considerations alone, there is much to suggest that the authorisation of plant protection products that release TFA, and thus a pollutant that is highly stable and mobile in the environment and whose subsequent removal is not possible, especially in the case of drinking water production, is to be seriously questioned on the basis of the precautionary principle enshrined in Regulation 1107/2009 alone.

[35] This also results from the fact that pesticide active substances are generally only authorised for a maximum of 10 years or 15 years in the case of repeated authorisation. Three years before the authorisation expires, the manufacturer must apply for a renewal of the authorisation, which is then reviewed by the EFSA and the MS. Similarly, plant protection products are only authorised for a certain period of time

Above all, it must be examined whether the new findings described in point 1 regarding the **toxicity** (reproductive toxicity of TFA) and its **spread in the aquatic environment** (continuous and significant increase in groundwater contamination as a result of the use of PFAS pesticides) do not inherently require the withdraw of the authorisation for plant protection products that can release TFA, or (if possible) the modification of the conditions for approval in such a way that any further emission of TFA into the environment and onto food (including drinking water) due to the use of these plant protection products are excluded."

The fact that the full extent of the TFA risk was not recognised in earlier approval procedures for PFAS active substances or in the approval procedures for PFAS pesticides does not rule out the possibility that subsequent evidence of such a risk may call into question an approval that has already been granted, as the "immediate or delayed harmful effects" on human and animal health and groundwater and the unacceptable effects on the environment are decisive. Incidentally, the priority of health protection over increasing production has only recently been unequivocally confirmed by the ECJ .[36]

However, as this is uncharted territory in many respects, we will look in particular for approaches in recent ECJ case law that could provide further clarity in this regard.
Although the question to be dealt with here has not yet been directly adjudicated, there is case law and practice on closely related issues.

[36] Judgment of 19 January 2023, Pesticide Action Network Europe (C-162/21, EU:C:2023:30, para. 48 and the case law cited therein.

4. Relevant practice and Case law

4.1 Water protection in the Netherlands

Concerning developments regarding the **quality of surface water in the Netherlands** - specifically, repeated exceedances of limit values by certain pesticide active substances that are classified as "priority substances" under the Water Framework Directive - have led to a **dialogue between Dutch authorities and the European Commission** in 2023 on the question of the extent to which the approval of plant protection products containing the active substances in question can be questioned on this basis. As will be shown, the results of this dialogue are also useful for the present discussion.

Unlike TFA, which is a pesticide metabolite that has not (yet) been classified as relevant and for which no limit values (environmental quality standards) have been set under the Water Framework Directive, the Dutch question concerns specific pesticide active substances that are classified as priority substances under the Water Framework Directive and for which specific limit values, the so-called environmental quality standards (EQS) of Directive 2008/105/EC, apply. As these EQS are regularly exceeded in Dutch surface waters, the question arose as to whether this should lead to a ban on plant protection products containing the active substances in question.

These situations are comparable in that in both contamination situations, the Pesticide Regulation 1107/2009 does not appear to directly provide for the withdrawal of the authorisation of plant protection products. On closer inspection, however, a different conclusion must be reached, which has also been confirmed in this form by the European Commission.

The Dutch Ministry of Agriculture, Nature and Food Quality (LNV) has asked the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) for information on the extent to which exceeding the standards of the Water Framework Directive has an impact on existing authorisations of plant protection products.

The Ctgb recognises that the Pesticides Regulation 1107/2009 refers to the Water Framework Directive in its Articles 21 and 44. However, it only requires that the approval of an active substance or the authorisation of a plant protection product be reviewed if it is determined that the objectives of the Water Framework Directive cannot be achieved. However, compliance with the Water Framework Directive standard is not a condition for authorisation and, as an intervention in the authorisation is only possible if the authorisation conditions are not met. A breach of the Water Framework Directive standard cannot be grounds for amending or withdrawing the authorisation.

The European Commission rightly comes to a partially different conclusion in its subsequent investigation into the same issue.

Even if Art. 44 of the Pesticides Regulation refers to Art. 29 of the same Regulation for the withdrawal of authorisation and refers to the authorisation procedure, in the context of which compliance with the Water Framework Directive is not directly required, **Art. 29 also contains a reference to Art. 4 para. 3** of Regulation 1107/2007, which - as shown - **fundamentally** requires in (e) that a plant protection product has **no unacceptable effects on the environment**. This aspect is decisive for the Commission. In its letter to the Dutch authority, it clarifies that "*non-compliance with the Water Framework Directive resulting exclusively or essentially from the proper use of authorised uses of plant protection products* would constitute *such an unacceptable impact*". This means that non-compliance with the objectives of Article 4 of the Water Framework Directive would result in a violation of the Pesticides Regulation with the obligation to withdraw the authorisation.

This reasoning can also be applied to the central TFA issue here. Article 44(1) of the EU Pesticides Regulation only requires a review of the authorisation of a plant protection product in cases where a Member State concludes that the achievement of the environmental objectives under Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC could be jeopardised, which corresponds to exceedances of the limit values set out in the Water Framework Directive and the Drinking Water Directive by pollutants that are already regulated.

However, the environmental objectives set out in Article 4 of the Water Framework Directive do not only relate to protection against contamination by priority substances. In particular, the protection of groundwater requires Member States - as already shown - to take measures to contain or reverse contamination in the event of a significant and steady increase in the pollution of groundwater with a pollutant due to the effects of human activities.

The fact that TFA is a pollutant within the meaning of the Water Framework Directive is already evident from the fact that the "*Non-exhaustive list of the most important pollutants*" of the Water Framework Directive (Annex XIII) lists in particular "organohalogen compounds", which also include all PFAS, as an important pollutant group.

The fact that, in the absence of official groundwater monitoring for TFA, the steady increase in TFA contamination in groundwater and the causal relationship between this increase and the use of PFAS pesticides in agriculture has **not** yet been **recognised** by Austrian approval authorities and therefore **not taken into account** in approval practice, does not rule out the possibility that plausible evidence of such a relationship - such as that provided by the German Federal Environment Agency, among others - may subsequently call into question approvals that have already been granted. The plausible evidence of such a link - as provided by the work of the German Federal Environment Agency, among others - may subsequently **call into question** authorisations that have already been granted.

It should be noted that the repeated reference to the state of “current scientific and technical knowledge" in the Pesticides Regulation gives this regulation an additional dynamic, present-orientated perspective.

It should also be mentioned that the European Commission emphasises in its opinion that a causal link must be established between the intended use of the plant protection product and non-compliance with the Water Framework Directive. According to the Commission, this means that *“in the event of non-compliance with the environmental quality standards of the Water Framework Directive, the plant protection product authorisation and the resulting uses must be reviewed and that an authorisation under the Plant Protection Products Regulation must be withdrawn or amended if it can be established that the use of the plant protection product in accordance with the authorisation is responsible for or significantly contributes to this non-compliance”.*

In particular, the Commission emphasises that contamination situations can be multi-causal, i.e. they do not necessarily have to be solely attributable to the use of plant protection products - which also applies in particular to the degradation product TFA. A **case-by-case examination** should therefore always be carried out. How detailed this proof must be remains open, although the Commission appears to demand comprehensive testing. The role and interpretation of the precautionary principle, on which Regulation 1107/2009 is based, will be of particular relevance for a comprehensive clarification of this question.

4.2 The ECJ rulings in C-616/17 of 1 October 2019 and in Case C-308/22 as well as in Joined Cases C-309/22 and 310/22 of 1 October 2019. C-309/22 and 310/22 v. 25 April 2024 and the precautionary principle.

Art. **1 para. 4 of the Pesticides Regulation 1107/2009** emphasises the **importance of the precautionary principle** and its central importance for this regulation as a whole:

" The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

In the **judgement of 1 October 2019** in **Case C-616/17, Blaise et al.**, the ECJ had the opportunity to further specify the scope of the precautionary principle, especially in the authorisation and use of plant protection products:

"This principle means that where there is uncertainty about the existence or extent of risks to human health, protective measures can be taken without waiting for the existence and severity of these risks to be fully established. If it proves impossible to determine with certainty the existence or extent of the alleged risk because the results of the studies carried out are inconclusive, but the likelihood of actual harm to public health persists if the risk were to materialise, the precautionary principle justifies the adoption of restrictive measures (see, to that effect, judgments of 22 December 2010, Gowan Comércio Internacional e Serviços, C-77/09, EU:C:2010:803, paragraphs 73 and 76, of 17 December 2015, Neptune Distribution, C-157/14, EU:C:2015:823, paragraphs 81 and 82, and of 22 December 2015, Neptune Distribution, C-157/14, EU:C:2015:823, paragraphs 81 and 82. (EU:C:2018:938, para. 38, Swedish Match, C-151/17, EU:C:2018:938)."

In para. 99 of this judgement, the ECJ clearly states that **new scientific knowledge** can lead not only to the review of active substance approvals but also to the **amendment or withdrawal of such approvals** if there are indications that the approved substance no longer meets the approval criteria in accordance with Art. 4 of Regulation 1107/2009:

Fourthly, Article 21(1) and (3) of Regulation No 1107/2009 states that the Commission may review the approval of an active substance at any time, inter alia if new scientific and technical knowledge indicates that the substance no longer fulfils the approval criteria under Article 4 of this Regulation. Furthermore, Article 44(1) and (3) of the Regulation states that the approval of a plant protection product may be reviewed and then amended or cancelled if, in the light of the latest scientific and technical knowledge, it appears that the product does not comply or no longer complies with the requirements for authorisation for placing on the market under Article 29 of the Regulation, in particular the absence of immediate or delayed adverse effects on human health."

Five years later, in the **judgments of 25 April 2024 (Case C-308/22 and Joined Cases C-309/22 and 310/22)**, the ECJ had the opportunity to once again explore the dimension of the precautionary principle and, in particular, to address the potential **conflict with the principle of legal certainty:**

"106 According to settled case-law, in accordance with the principle of legal certainty, legislation must be clear, precise and foreseeable in its effects so that the persons concerned can orient themselves with regard to facts and legal relationships covered by Union law (judgment of 6 May 2021, Bayer CropScience and Bayer v Commission, C-499/18 P, EU:C:2021:367, para.101).

107 However, in the specific area of authorisation to place plant protection products on the market, this principle must be weighed against the precautionary principle on which the regulation is based.

The Commission's position is based on Regulation No 1107/2009, the objective of which, as stated in paragraphs 68 and 102 of the present judgment, is to ensure a high level of protection of human and animal health and the environment. Thus, where aspects come to light which demonstrate that an active substance or a plant protection product has harmful effects on human or animal health or unacceptable effects on the environment, the Commission and/or the Member States may be obliged to withdraw the approval of that active substance or the authorisation to place that plant protection product on the market and, where appropriate, to take emergency measures.

108 It follows that, in the context of this Regulation, any applicant wishing to place a plant protection product on the market may assume that the state of scientific or technical knowledge will change during the authorisation procedure or during the period for which an active substance is approved or a plant protection product is authorised. It also follows from Articles 46 and 69 to 71 of Regulation No. 1107/2009 that the cancellation of an authorisation or the adoption of an emergency measure can have immediate effect and that the placing on the market and consumption of existing stocks of the product concerned is then no longer permitted.

109 Thus, the consideration of relevant and reliable scientific or technical knowledge that was not yet available at the time of the application for authorisation to place a plant protection product on the market cannot be regarded as a violation of the principle of legal certainty."[37]

The ECJ thus confirms the **absolute priority of protecting human and animal health** as well as the **environment**, whereby **new scientific findings** require **a continuous reassessment of the authorisation** of plant protection products.

In its case law, the ECJ has traditionally attached great importance to the principle of legal certainty. However, the protection of human and animal health as well as the environment has

[37] Cf. paragraphs 106-109 of the judgment of 25 April 2024 in Case C-308/22 and the identical paragraphs 96-99 of the judgment of 25 April 2024 in Verb. C-309/22 and C-310/22.

not only take precedence over the legal certainty of pesticide producers, but this **legal certainty is not even violated by a subsequent cancellation of an authorisation** because every pesticide producer must already know during the authorisation procedure that the **state of scientific or technical knowledge may change.** These possible developments must therefore be part of the corresponding economic calculations. The risk of a negative development in the state of scientific and technical knowledge for the producers must be borne by the producers themselves.

5. Conclusions

5.1 Fundamentals

It is not the purpose of this report to provide a scientific analysis of the hazard potential of TFA. As a legal analysis, this analysis must be based on the available scientific studies. The following questions had to be answered on the basis of the information provided by the client (see Section 2):

1) Does the Pesticides Regulation 1107/2009 give Member States the power to withdraw the authorisation from the market of PFAS pesticides, i.e. plant protection products, that emit TFA into the environment and in particular into groundwater and drinking water?

2) In light of the new findings described in Section 2 on a continued and significant increase in TFA concentrations in the environment, particularly in groundwater and drinking water, caused by PFAS pesticides, is it necessary to withdraw their authorisation?

3) Is it necessary to withdraw such authorisations in the light of new findings on the (presumably) necessary classification of TFA as "toxic for reproduction category 1B"?

The following section attempts to answer these questions:

1: Withdrawal of pesticide authorisations based on the Pesticides Regulation 1107/2009

As shown, an initial analysis of Regulation 1107/2009 can lead to an unclear result. TFA is not regulated under the EU Water Framework Directive, the Drinking Water Directive or the EU Pesticides Regulation, which is why there are currently no limit values and no monitoring obligation for TFA contamination of water bodies or drinking water.

In a strict, formal interpretation, the view has been taken that new potential hazards cannot affect the authorisation granted in the past, as these new hazards would not relate to the authorisation criteria.

This formal position cannot be upheld for several reasons.

Reference should be made to the practice of the key players, to the above-mentioned opinions of the Commission and the EU Parliament and the - largely very recent - case law of the ECJ.

Regulation 1107/2009 focuses on the protection of humans, animals and the environment, whereby **compliance with formal authorisation criteria at the time the authorisation is granted does not** provide **a permanent guarantee for the right to market** plant protection products once they have been authorised. Rather, once an authorisation has been granted, **it can be continuously reviewed** and also withdrawn. New scientific and technical knowledge must be continuously incorporated.

Health protection and its dominant role in Regulation 1107/2009 characterise the structure of this entire regulatory approach in the context of interpretation.[38] The precautionary principle was given central content and consistency via the relevant ECJ case law.

The **fundamental importance of the precautionary principle** in the authorisation of plant protection products is very clearly expressed in Article 1(4) of Regulation 1107/2009 itself. This **regulation is "based" on the precautionary principle**. The scope of this stipulation could be limited again if the precautionary principle itself were to remain unclear or obscure.

However, the content of the precautionary principle has been gradually concretised. There is a very broad literature on this.

However, the ECJ has already taken a clear position on this issue in the more distant past:

"If the existence and extent of risks to human health is uncertain, the institutions may take protective measures without having to wait for the existence and extent of these risks to be clearly established."[39]

In the literature, the precautionary principle was declared to be applicable in particular "if the scientific evidence is insufficient, does not allow clear conclusions to be drawn or is unclear, but there is reason for abstract concern based on a preliminary and objective scientific risk assessment ".[40] The decisive factor in European law is therefore "the replacement of the concrete, sufficient probability by the mere possibility, the abstract concern of the occurrence of damage."[41]

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38 On the relevance of structural principles in EU law as a standard of interpretation in the respective overall context, see J. Bast/A. v. Bogdandy, Grundlagenteil und Verfassungskern der EU-Verträge, in: JZ 4/2024, pp. 115-125 (124).

39 Cf. Case C-15796, Judgment of 5 May 1998, National Farmers' Union, para. 62 et seq.

40 See Ch. Calliess, Art. 191 TFEU, in: Calliess/Ruffert, EUV/AEUV, 6th ed. 2022, para. 34.

41 Ibid.

Literature and case law interpret the concept of risk broadly[42]It is about the "risk of potentially dangerous effects".[43]

The **current and recent ECJ case law on Regulation 1107/2009 has further reinforced this line**. It is likely to become generally influential in the interpretation of the precautionary principle.

If the present analysis therefore focuses on the **question of whether the available indications of a potential risk posed by TFA** in accordance with the Pesticides Regulation 1107/2009 provide a **legal basis** for withdrawing the authorisation of plant protection products whose degradation product is TFA, **then this question must be answered in the clear affirmative for the reasons given**.

The possibility of withdrawing an authorisation due to hazards that were not directly examined as part of the authorisation procedure illustrates the importance of health protection as a central, overall task of Regulation 1107/2009. New scientific and technical findings must be taken into account on an ongoing basis. The extraordinary persistence and mobility of TFA combined with increasing evidence of hazards is undoubtedly of great importance in risk assessment, which always implies a proportionality test.

2: Withdrawal of plant protection product authorisations based on the requirements of the Water Framework Directive in conjunction with Regulation 1107/2009

As shown, it is already clear from the text of Pesticides Regulation 1107/2009, particularly in the light of its application practice and the interpretation by the ECJ with reference to the precautionary principle, that Member States have the option of withdrawing the authorisation of plant protection products that release TFA.

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42 See S. Heselhaus, Art. 191 TFEU, in: Frankfurter Kommentar EUV - GRC - AEUV, 2023, para. 66.

43 Ibid.

In addition, however, the **<u>need</u>** to withdraw or amend such authorisations can be derived from the Water Framework Directive (again in conjunction with the Pesticides Regulation 1107/2009). This results from Art. 4 (1) b. (iii), according to which the MS shall take the necessary measures "*to reverse any significant and sustained upward trend in the concentration of any pollutant resulting from the impact of human activity in order progressively to reduce pollution of groundwater*."

This obligation to act covers not only "priority" pollutants, but all pollutants.

In addition, reference should also be made here to Art. 4 para. 2. (b) of Regulation 1107/2009, according to which the residues of plant protection products must not have an unacceptable impact on the environment. As the European Commission has confirmed to the Dutch authorisation authority Ctbg, this authorisation requirement also demands compliance with the protection goals of the Water Framework Directive.

<u>3</u>: Necessity of banning PFAS pesticides due to the toxicity for degradation of their degradation product

Of particular concern is the wide distribution of TFA in the aquatic environment in conjunction with its persistence and the new findings on its toxicity, in particular its toxicity for reproduction. According to the above statements, however, the latter should **<u>in itself</u> make it necessary** to amend or **withdraw** existing authorisations for plant protection products that release TFA.

Regulation 1107/2009 is structured in such a way that "particularly hazardous substances" and their residues are not accepted even in the smallest quantities (see Art. 4 para. 1). So-called "exclusion" or "cut-off" criteria apply to these. In particular, these are the health-related criteria listed in Annex II No. 3.6.2 to 3.6.4 and in No. 3.7: If an active substance or its residues fulfil one of these exclusion criteria (the requirement of a

Classification as toxic for reproduction Cat. 1 B is such an exclusion criterion), then any further risk assessment is omitted, this is virtually anticipated in the sense of an unacceptable result. Active substances that leave residues with this property in the environment, food or drinking water therefore do not fulfil the approval criteria.

In accordance with the prevailing doctrine and the case law of the ECJ and on the basis of the technical information provided for this report, it can therefore be assumed that a review of the authorisation of those plant protection products that are proven or suspected to release TFA must be initiated immediately. **If the risk situation described is confirmed, the precautionary principle in conjunction with Regulation 1107/2009 dictates that the authorisations of the plant protection products in question must be amended or withdrawn.**

5.2 Summary

The three research questions can therefore be summarised as follows:

1. **Question 1**: Yes. The Pesticides Regulation 1107/2009 **allows the Member States** to withdraw the authorisation of plant protection products that release TFA, in particular in the light of the relevant case law of the ECJ and recent opinions of the EU Commission on the precautionary principle, simply because of the long-known potential of TFA to irreversibly contaminate water bodies.

2. **Question 2**: Yes. If new findings show that TFA pollution in the environment, in particular in groundwater, has persistently and significantly increased and continues to increase and that the release of TFA from PFAS pesticides is a major contributory factor, **Member States** are **obliged** under Pesticide Regulation 1107/2009 to amend the authorisation for PFAS pesticides in such a way that emissions to groundwater are prevented or to withdraw the authorisation.

3. **Question 3**: Yes. If new scientific findings show that TFA is to be classified as toxic for reproduction (cat. 1B), plant protection products that leave residues of TFA in drinking water or on plant or animal products when used as intended no longer fulfil the hazard-based approval criteria according to Annex II (3) of the Pesticides Regulation 1107/2009. In such a case**, the Member States are obliged to withdraw the authorisation of these plant protection products**.

It should be particularly emphasised that, according to the Commission guidance on the assessment of the relevance of metabolites in groundwater**, the reason to assume reproductive toxicity is already** sufficient for TFA to be considered a relevant metabolite, which makes **compliance with a limit value of 0.1 µg/l** in groundwater a requirement for authorisation. As this limit value is exceeded in almost all groundwater monitoring sites according to official test reports, the authorisation of plant protection products that emit TFA must also be amended or withdrawn for this reason in accordance with Article 44(3)(a).