TEXTE
41/2023

Review on the environmental assessment of fertiliser additives

Initial situation, database, methodology, and risk regulation

by:
Ursula Karges, Dr Christine Kübeck, Dr Tim aus der Beek
IWW Rhenish-Westphalian Institute for Water Research gGmbH, Mülheim an der Ruhr

Theresa Seith, Dr Richard Beisecker
IfÖL GmbH Consulting Engineers for Ecology and Agriculture, Kassel

publisher:
German Environment Agency

TEXTE 41/2023

Ressortforschungsplan of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection

Project No. (FKZ) 3720 64 413 0

Report No. (UBA-FB) FB000985/ENG

Review on the environmental assessment of fertiliser additives

Initial situation, database, methodology, and risk regulation

by

Ursula Karges, Dr Christine Kübeck, Dr Tim aus der Beek
IWW Rhenish-Westphalian Institute for Water Research gGmbH, Mülheim an der Ruhr

Theresa Seith, Dr Richard Beisecker
IfÖL GmbH Consulting Engineers for Ecology and Agriculture, Kassel

On behalf of the German Environment Agency

Imprint

Publisher
Umweltbundesamt
Wörlitzer Platz 1
06844 Dessau-Roßlau
Tel: +49 340-2103-0
Fax: +49 340-2103-2285
buergerservice@uba.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt

Report performed by:
IWW Rhenish-Westphalian Institute for Water Research gGmbH
Moritzstraße 26
45476 Mülheim an der Ruhr

IfÖL GmbH Consulting Engineers for Ecology and Agriculture,
Windhäuser Weg 8
34123 Kassel

Germany

Report completed in:
October 2022

Edited by:
Section IV 1.3 Plant protection products
Gesa Amelung and Lisa Noll PhD

Publication as pdf:
http://www.umweltbundesamt.de/publikationen

ISSN 1862-4804

Dessau-Roßlau, March 2023

Abstract: Environmental assessment of fertiliser additives

Recent changes in fertiliser legislation and an increasing number of environmental findings put fertiliser additives (FAs) in the spotlight of users, manufacturers, and regulatory agencies. Nitrification and urease inhibitors (NI and UI) are intended to reduce nitrogen emissions to adjacent environmental compartments and to promote increased nitrogen use efficiency in crops. To improve nutrient uptake, stress tolerance and product quality, biostimulants are designed to enhance or activate plant metabolic processes. However, due to very different modes of action and inconsistent objectives in studies, as well as study designs that are not yet standardized for Central European conditions, experimental results are often not comparable. Hence, available data in literature on mode of action, efficiency and also environmental effects are rather disparate for many inhibitors and biostimulants, so that results often lack comparability. Due to partly lacking information on substance properties and application data, there are still unknown risks for many NIs, UIs, and biostimulants when applied directly into the environment. Competing interests arise in particular where adverse environmental effects potentially counter intend benefits. With regard to NI, for example, the intended reduction in nitrate leaching to groundwater is opposed by increasing concerns on discharges of these very substances (and their degradation products) to water bodies, given their proven occurrence in surface waters. The general lack of a notification requirement impedes the evaluation of the quantities and properties of the products that are actually applied in Germany and thus may enter the environment. Therefore, precise assignment of the active ingredient findings in the environment to individual entry pathways is not possible. In addition, the tonnage-based tiered requirements for the assessment of environmental fate and risk, as laid down in Regulation (EC) No. 1907/2006 (REACH Regulation), on which the authorisation procedures for these substances are based, remain mostly deficient in terms of precautionary environmental protection. This is particularly true in the field of terrestrial ecotoxicology. Extended data requirements for ecotoxicological tests need to address the large-scale application to the environment as well as potential consequences for non-target soil microorganisms. Research is still needed on a suitable ecotoxicologically adapted test battery.

Kurzbeschreibung: Umweltbewertung von Düngemittelzusatzstoffen

Änderungen im Düngerecht und eine zunehmende Anzahl an Umweltfunden rückten Düngemittelzusatzstoffe (DMZ) zuletzt verstärkt in den Fokus von Anwendern, Herstellern und Kontrollinstanzen. Nitrifikations- und Ureaseinhibitoren (NI und UI) sollen Stickstoffemissionen in angrenzende Umweltkompartimente verringern und zu einer erhöhten Stickstoff-nutzungseffizienz der Kulturen beitragen. Biostimulanzien sollen unterstützend und aktivierend auf Stoffwechselvorgänge in den Pflanzen wirken und dadurch Nährstoffaufnahme, Stresstoleranz und Produktqualität verbessern. Die teils sehr unterschiedlichen Wirkungsweisen sowie uneinheitliche Zielsetzungen in Studien und noch nicht für mitteleuropäische Verhältnisse standardisierte Studiendesigns erschweren eine Einordnung von Prüfungsergebnissen. Die Datenlage in der Literatur zu Wirkungsweise, Effizienz und auch den Umweltauswirkungen ist daher bisher für viele der Inhibitoren und Biostimulanzien sehr uneinheitlich und in den Ergebnissen oft nicht vergleichbar. Aufgrund der teilweise unbekannten Stoffeigenschaften und Anwendungsdaten sind die mit der unmittelbaren Ausbringung in die Umwelt verbundenen Risiken für viele der NI, UI und Biostimulanzien oftmals noch unbekannt. Zielkonflikte ergeben sich insbesondere dort, wo den intendierten Wirkungen negative Umweltauswirkungen entgegenstehen können. So steht, beispielsweise im Falle der NI, die beabsichtigte Wirkung verringerter Nitratauswaschungen ins Grundwasser der durch Nachweise in Oberflächengewässern verstärkten Besorgnis über Gewässereinträge der Substanzen (und Abbauprodukten) selbst gegenüber. Eine generell fehlende Anzeigepflicht erschwert dabei die Abschätzung, welche Produkte in welchen Mengen und mit welchen

Eigenschaften tatsächlich in Deutschland ausgebracht werden und in die Umwelt gelangen können. Dadurch ist eine eindeutige Zuordnung der Wirkstofffunde zu den unterschiedlichen Eintragspfaden nicht möglich. Zudem sind die gemäß der Verordnung (EG) Nr. 1907/2006 (REACH-Verordnung) tonnageabhängig gestaffelten Mindestanforderungen zur Abschätzung von Umweltverhalten und -risiko, auf denen die Zulassungsverfahren für diese Stoffe aufbauen, aus Sicht des vorsorgenden Umweltschutzes, gerade im Bereich der terrestrischen Ökotoxikologie, oft ungenügend. Erweiterte Datenanforderungen für ökotoxikologische Tests sollten der großflächigen Ausbringung in die Umwelt und den möglichen Auswirkungen auf die Nichtziel-Bodenmikroorganismen Rechnung tragen, wobei noch Forschungsbedarf bezüglich der Auswahl einer ökotoxikologisch sinnvoll angepassten Testbatterie besteht. Hier besteht noch ein erhebliches Defizit, was die Bewertung der Umweltrisiken erschwert.

Table of content

List of figures

List of tables

List of abbreviations

BLE	Federal Agency for Agriculture and Food (Bundesanstalt für Landwirtschaft und Ernährung)
BMEL	Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft)
BMUV	Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (Bundesministerium für Umwelt, Naturschutz, nukleare Sicherheit und Verbraucherschutz)
CAN	Calcium ammonium nitrate
CE	Conformité Européenne
CEN	European Committee for Standardization
CMC	Component material category
DCD	Dicyandiamide
DMPP	3,4-Dimethylpyrazole phosphate
DMPSA	2-(3,4-Dimethyl-1H-pyrazol-1-yl)succinic acid
DVGW	German Association for gas and water applications (Deutscher Verein des Gas- und Wasserfaches)
EC	European Community
ECHA	European Chemicals Agency
EU	European Union
FA	Fertiliser Act (Düngegesetz)
Fas	Fertiliser additives
FngO	Fertilising Ordinance (Düngeverordnung)
FACO	Fertilisation Advisory Council Ordinance (Düngungsbeiratsverordnung)
FO	Fertiliser Ordinance (Düngemittelverordnung)
FTC	Fertiliser traffic control
GHG	Greenhouse gas
HOV	Health orientation value
IfÖL	Consulting Engineers for Ecology and Agriculture (Ingenieurbüro für Ökologie und Landwirtschaft)
IVA	Agricultural Industry Association (Industrieverband Agrar)

IWW	Rhenish-Westphalian Institute for Water Research gGmbH (Rheinisch-Westfälisches Institut für Wasserforschung gGmbH)
MEC	Measured Environmental Concentration
3-MP	3-Methylpyrazole
MPA	N-((3(5)-Methyl-1H-pyrazol-1-yl)methyl)acetamide
N_2O	Nitrous oxide - laughing gas
NBPT	N-butyl-thiophosphorus triamide
NEC	National Emission reduction Commitments Directive
NH_3	Ammonia
NH_4^+	Ammonium ion
NI	Nitrification inhibitor
2-NPT	N-(2-Nitrophenyl)phosphoric acid triamide
NUI	Nitrification/urease inhibitors (in combination)
PEC	Predicted Environmental Concentration
PFC	Product Function Category
PNEC	Predicted No Effect Concentration
PPA	Plant Protection Act
PPP	Plant Protection Products
T	Tons
TC	Technical Committee
UBA	German Federal Environment Agency (Umweltbundesamt)
UI	Urease inhibitor

Summary

Nitrification and urease inhibitors are increasingly added to fertilisers in agriculture. They are considered to have beneficial effects in terms of reduced nitrogen emissions to adjacent environments. For example, urease inhibitors may decrease ammonia emissions; nitrification inhibitors may reduce both nitrate leaching and nitrous oxide emissions. However, reviews of related literature indicate a wide range of the beneficial effects mentioned, depending on application site, type and form of fertiliser, period of experimentation, or crop type. Results on the reduction of nitrate leaching, for example, vary widely regarding application of nitrification inhibitors. Biostimulants can have a supporting and activating effect on metabolic processes in plants. They are therefore used in agriculture to improve plant nutrient uptake and use efficiency, stress tolerance and product quality, as well as to increase yields. However, there is still a considerable need for research into both the mechanisms as well as proven effects in the application of this very heterogeneous group of substances.

Recent increases in environmental detections of individual active ingredients of inhibitors along with rising application rates due to changes in the German Fertilising Ordinance (FngO, 2020) emphasise the need for an improved assessment of environmental behaviour and the related environmental risk in the application of FAs.

By abandoning the established type system and introducing product function categories, the new EU Fertiliser Products Regulation (EU) No. 2019/1009, which has been in full force since 16 July 2022, marks a new stage in European fertiliser legislation. It is intended to open up the European internal market for fertiliser products currently not covered by harmonisation rules, such as inhibitors and plant biostimulants. Such products will henceforth be recognisable as harmonised for the EU market by a CE label. In parallel, fertiliser products lawfully manufactured and authorised in one member state may continue to be marketed in another member state on the basis of mutual recognition.

Substances approved under the German Fertiliser Ordinance (FO, 2019), such as inhibitors, must not endanger soil fertility, the health of humans, animals, and crops, or the ecosystem as a whole when used according to good agricultural practice. Specific requirements are laid down in the subordinate regulations or within the framework of the authorisation. Given the informality of the national authorisation procedure for fertilisers, which is based on case-by-case decisions and lacks transparency due to the very limited information publicly available on detailed test requirements, it is difficult to derive any reliable conclusions on substance behaviour and the resulting assessment in detail. In the national authorisation process, the environmental assessment of active substances is primarily based on information compiled in the course of chemical registration under Regulation (EC) No. 1907/2006 (REACH Regulation). In this context, however, the information requirements are tiered according to tonnage. Hence, the scope and depth of the basic information available for national authorisation may vary considerably for different active substances and products. In addition, according to REACH, data on terrestrial tests and metabolites are usually only required for high tonnages. This information is, however, of particular relevance for substances that are applied directly onto soil.

There are currently ten inhibitors approved under the German FO, of which seven are nitrification inhibitors and three are urease inhibitors. With regard to the nitrification inhibitors, the active substances dicyandiamide (DCD) and 1,2,4-triazole in particular were repeatedly detected in German surface waters and occasionally in groundwaters. For other substances such as MPA (N-((3(5)-methyl-1H-pyrazol-1-yl)methyl)acetamide), suitable analytical methods have yet to be developed in order to allow reliable judgements on the extent of a potential environmental distribution.

For biostimulants, difficulties arise in national authorisation on account of the ambiguity of their assignment to the different legal regimes of fertiliser law and plant protection law. A highly heterogeneous product group of partly chemical and partly biological substances is concealed with the term biostimulants. It is therefore almost impossible to formulate generally applicable standards for assessing their environmental behaviour and environmental impacts for the entire group. However, standards for "chemical" biostimulants are comparable to those for other substances used in fertiliser applications, such as inhibitors. With microorganism products, ecotoxicological risks such as phytoparasitism, toxin formation in plants or an alteration of the soil microbiome are conceivable. Furthermore, besides their immediate environmental impact, e. g. on the soil biocoenosis, questions also arise with regard to possible metabolites and how to assess them, all of which need to be addressed in view of the increasing application rates.

The new EU fertilising products Regulation introduces biostimulants as a separate product function category defined by their effect. In accordance with the EU Fertiliser Products Regulation, specific standards for testing must be met with regard to the requirements that apply to the CE labelling of fertiliser products and compliance assessment procedures. Uniform efficacy criteria and test standards as well as basic requirements to ensure human, animal or plant health, safety, and environmental sustainability are required. These are developed by technical committees (e. g. CEN/TC 455), whereby special consideration needs to address the diversity within this product function category.

Differing authorisation requirements and assessment procedures among the EU Member States, as well as a general lack of notification requirements, impede the evaluation as to which products, in what quantities and with what properties, are actually applied in Germany and may enter the environment. Although domestic sales of fertilisers are recorded in Germany as part of agricultural statistics (AgrStatG, §89), fertiliser products with additives, such as inhibitors and biostimulants, are not individually recorded. Thus, an estimate of the quantities actually applied in Germany and an assessment of the resulting risk for the environment and the natural balance are infeasible on this basis. Nor is it possible to unambiguously assign the active substance detections to the individual entry pathways.

Besides the need for transparent registration of the actual application quantities and identification of the entry pathways, an intensified monitoring of the active substances and their degradation products in the various environmental media is indispensable in order to achieve a realistic risk assessment. A decisive request in terms of precautionary environmental protection is to expand and adapt the data requirements in the authorisation process. Transparent disclosure of which product has been authorised and based on which criteria is also required. Taking into account the intended large-scale application into the environment, testing requirements must no longer to be tiered according to tonnage. In particular, increased requirements for terrestrial ecotoxicological tests should apply due to the immediate application into this compartment.

This paper provides an overview of the current state of knowledge on environmental assessment, the legal framework and the modes of action of NI, UI, and biostimulants. As such, it constitutes a starting point for the development and adaptation of forthcoming measures and studies. It identifies knowledge gaps and shortcomings, e. g. in environmental risk assessment, and provides indications for further research demand as well as for adjusted authorisation requirements in terms of a precautionary environmental assessment.

Zusammenfassung

In der Landwirtschaft werden den Düngemitteln zunehmend Nitrifikations- und Ureaseinhibitoren zugesetzt. Ihnen werden positive Wirkungen hinsichtlich verringerter Stickstoffemissionen in angrenzende Umweltkompartimente zugeschrieben. So können Ureaseinhibitoren die Ammoniakemissionen vermindern; Nitrifikationsinhibitoren können sowohl den Nitrataustrag mit dem Sickerwasser als auch die Lachgasemissionen reduzieren. Dennoch zeigt die Auswertung der einschlägigen Literatur, dass es für die genannten positiven Wirkungen große Spannbreiten in Abhängigkeit von Standort, Düngerart und -form, der Versuchsdauer oder Kulturart gibt. Für den Einsatz von Nitrifikationsinhibitoren beispielsweise liegen sehr unterschiedliche Ergebnisse zur Verringerung der Nitratauswaschung vor. Biostimulanzien wirken unterstützend und aktivierend auf Stoffwechselvorgänge in den Pflanzen. Daher werden sie in der Landwirtschaft eingesetzt, um die Nährstoffaufnahme und Nährstoffausnutzung, die Stresstoleranz und die Produktqualität zu verbessern sowie die Erträge zu steigern. Allerdings besteht noch großer Forschungsbedarf sowohl hinsichtlich der Mechanismen als auch der nachweislichen Wirkungen beim Einsatz dieser sehr heterogenen Stoffgruppe.

Die zuletzt zunehmende Anzahl an Umweltfunden einzelner Wirkstoffe von Inhibitoren in Verbindung mit den durch Änderungen der Düngeverordnung (DüV, 2020) steigenden Anwendungszahlen zeigen die Notwendigkeit einer verbesserten Bewertung des Umweltverhaltens und des davon ausgehenden Umweltrisikos beim Einsatz von DMZ.

Die seit dem 16. Juli 2022 vollständig in Kraft getretene neue EU-Düngeprodukteverordnung (EU) Nr. 2019/1009 markiert mit der Abkehr vom hergebrachten Typensystem und der Einführung von Produktfunktionskategorien, eine Zäsur im europäischen Düngerecht. Sie soll den europäischen Binnenmarkt für Düngeprodukte öffnen, die derzeit nicht unter Harmonisierungsregeln fallen, wie bspw. Inhibitoren und pflanzliche Biostimulanzien. Diese werden künftig an einer CE-Kennzeichnung als für den EU-Markt harmonisierte Produkte zu erkennen sein. Zugleich dürfen auf Basis der gegenseitigen Anerkennung weiterhin nach nationalem Recht hergestellte und zugelassene Düngeprodukte in einem anderen Mitgliedstaat auf den Markt gebracht werden.

Die Düngemittelverordnung (DüMV, 2019) fordert von zugelassenen Stoffen wie den Inhibitoren, dass von der fachgerechten Anwendung keine Gefahr für die Fruchtbarkeit des Bodens, die Gesundheit von Menschen, Tieren und Nutzpflanzen und für den Naturhaushalt als solchen ausgeht. Die Ausformulierung konkreter Anforderungen liegt dann bei den nachgeschalteten Regelwerken oder ist im Rahmen der Zulassung zu treffen. Da das nationale Zulassungsverfahren im Bereich der Düngemittel ein informelles ist, auf Einzelfallentscheidungen beruht und aufgrund der nur sehr limitiert öffentlich zugänglichen Information zu detaillierten Prüfanforderungen eher intransparent ist, lassen sich hieraus nur wenig fundierte Aussagen zum Stoffverhalten und der resultierenden Bewertung im Einzelnen ableiten. Basis der Umweltbewertung für Wirkstoffe im nationalen Zulassungsprozess sind die im Rahmen der Registrierung nach Verordnung (EG) Nr. 1907/2006 (REACH-Verordnung) zusammengetragenen Informationen. Hier sind die Anforderungen jedoch tonnageabhängig gestaffelt. Umfang und Tiefe der für die nationale Zulassung erhältlichen Basisinformationen können zwischen unterschiedlichen Wirkstoffen und Produkten also erheblich schwanken. Zudem sind nach REACH-VO Informationen zu terrestrischen Prüfungen und zu Metaboliten i. d. R. erst bei hohen Tonnagen zu erbringen. Diese sind jedoch gerade für auf oder in den Boden ausgebrachte Substanzen von Relevanz.

Aktuell sind nach deutscher DüMV zehn Inhibitoren zugelassen, davon sieben Nitrifikationsinhibitoren und drei Ureaseinhibitoren. Von den Nitrifikationsinhibitoren, für die es inzwischen in der Forschung auch verlässliche und ausreichend empfindliche Analysemethoden gibt, wurden insbesondere die Wirkstoffe Dicyandiamid (DCD) und 1,2,4-Triazol öfter in deutschen Oberflächengewässern und vereinzelt in Grundwässern nachgewiesen. Für andere Stoffe wie MPA (N-((3(5)-Methyl-1H-pyrazol-1-yl)methyl)acetamid) steht die Entwicklung geeigneter Untersuchungsmethoden noch aus, bevor sicher über das Ausmaß einer möglichen Umweltverbreitung geurteilt werden kann.

Für Biostimulanzien ergeben sich in der nationalen Zulassung Schwierigkeiten durch die Uneindeutigkeit der Zuordnung zu den unterschiedlichen Rechtsregimen des Düngerechts und des Pflanzenschutzrechts. Hinter dem Begriff Biostimulanzien verbirgt sich eine sehr heterogene Produktgruppe teils chemischer, teils biologischer Stoffzugehörigkeit. Allgemeingültige Standards zur Abschätzung ihres Umweltverhaltens und der Umweltwirkungen sind deshalb für die gesamte Gruppe kaum zu formulieren. Die Anforderungen für die „chemischen“ Biostimulanzien sind dabei tendenziell vergleichbar mit anderen Stoffen aus dem Bereich Düngeanwendungen, etwa den Inhibitoren. Prinzipiell sind von Mikroorganismenpräparaten ökotoxikologische Risiken, wie bspw. Phytoparasitismus, Toxinbildung in der Pflanze oder eine Veränderung des Bodenmikrobioms denkbar. Zudem ergeben sich bei den Mikroorganismen zusätzlich zu der Bewertung ihrer unmittelbaren Umweltauswirkungen, etwa auf die Bodenbiozönose, auch Fragen hinsichtlich möglicher Stoffwechselprodukte und deren Bewertung, die es mit Blick auf die steigenden Anwendungszahlen zu adressieren gilt. In der neuen europäischen Düngeprodukteverordnung werden Biostimulanzien erstmals einheitlich als eigenständige Produktfunktionskategorie genannt und nach ihrer Wirkung definiert und behandelt. Seit dem Inkrafttreten der EU-Düngeprodukteverordnung mit Stichtag 16. Juli 2022 sind auf EU-Ebene konkrete Prüfstandards für die Anforderungen, die für die CE-Kennzeichnung von Düngeprodukten und die Konformitätsbewertungsverfahren gelten, zu erfüllen. Dies setzt einheitliche Wirksamkeitskriterien und Prüfstandards sowie Minimalanforderungen zur Sicherstellung der Gesundheit von Mensch, Tier oder Pflanze und der Sicherheit und Umweltverträglichkeit voraus, welche, so noch nicht vorhanden, von Expertenkomitees (im Falle der Biostimulanzien bspw. das neu berufene CEN/TC 455) erarbeitet wurden bzw. werden, wobei der Diversität innerhalb der Produktfunktionsgruppe Rechnung zu tragen ist.

Unterschiedliche Zulassungsanforderungen und Bewertungsverfahren der Mitgliedstaaten sowie eine generell fehlende Anzeigepflicht erschweren die Abschätzung, welche Produkte mit welchen Eigenschaften und in welchen Mengen tatsächlich in Deutschland ausgebracht werden und in die Umwelt gelangen können. Zwar wird in Deutschland im Rahmen der Agrarstatistik der Inlandsabsatz von Düngemitteln erhoben (AgrStatG, §89), allerdings werden Düngeprodukte mit Zusatzstoffen, wie Hemmstoffe und Biostimulanzien nicht einzeln erfasst. Eine Abschätzung der in Deutschland tatsächlich ausgebrachten Mengen und eine Bewertung des sich daraus ergebenden Risikos für Umwelt und Naturhaushalt sind somit auf dieser Basis bisher nicht möglich, ebenso wenig, wie die eindeutige Zuordnung der Wirkstofffunde zu den einzelnen Eintragspfaden.

Neben der transparenten Erfassung der tatsächlichen Ausbringungsmengen und der Aufklärung der Eintragspfade ist für eine realitätsnahe Risikobeurteilung ein intensiviertes Monitoring der Wirkstoffe und deren Abbauprodukte in den verschiedenen Umweltmedien unerlässlich. Ein entscheidender Aspekt aus Sicht des vorsorgenden Umweltschutzes ist zudem die Erweiterung und Anpassung der Datenanforderungen im Zulassungsprozess und die transparente Offenlegung, welches Produkt wie geprüft und anhand welcher Kriterien zugelassen wurde. Der großflächigen intendierten Ausbringung in die Umwelt sollte Rechnung getragen werden, die tonnageabhängige Staffelung der Prüfanforderungen aufgegeben und aufgrund der unmittelbaren Ausbringung in dieses Kompartiment: insbesondere erhöhte Anforderungen an bodenökotoxikologische Prüfungen gestellt werden.

Das hier vorliegende Papier gibt einen Überblick über den aktuellen Kenntnisstand zur Umweltbewertung, zum rechtlichen Rahmen und den Wirkungsweisen von NI, UI und Biostimulanzien. Es stellt somit eine Ausgangsgrundlage für die Entwicklung und Anpassung zukünftiger Maßnahmen und Untersuchungen dar. Kenntnislücken und Defizite, etwa in der Umweltrisikobewertung, werden aufgezeigt und Hinweise für weiteren Forschungsbedarf sowie angepassten Zulassungsanforderungen unter dem Gesichtspunkt einer vorsorgeorientierten Umweltbewertung gegeben.

1 Introduction

Fertiliser additives (FAs) have gained importance in recent years and must be used mandatorily in agriculture under certain conditions to reduce nitrogen discharges into the environment (water, soil, air) in order to achieve the agreed reduction targets in the Climate Change Act, the NEC (National Emission reductions Commitments) Directive and the Nitrates Directive.

As a result, FAs and their metabolites can enter the terrestrial and aquatic environment, where they can pose a toxicological risk to the environment and humans – especially via the exposure pathway of drinking water. Due to the large number of substances used as FAs and their partly unknown substance properties and application data, the risks associated with direct application to the environment are often unknown.

In view of these facts, the incomplete assessment of FAs and their impact on the environment and the natural balance remains unsatisfactory. For example, the nitrification inhibitor (NI) " 3-Methylpyrazole" has been classified by ECHA (European Chemicals Agency) as a possible endocrine disruptor. However, no regulatory measures have been taken and are not planned within the framework of the new Fertiliser Regulation (EU) No. 2019/1009, which has been in force since July 2022.

The need to obtain in-depth knowledge about the environmental impacts of FAs and to make it transparent has been recognised by the authorities, but also by the water supply sector. It is addressed, for example, by the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) in the project presented here. Regarding water supply, the increasing concern due to environmental findings of individual FAs in water bodies (Schaffer and Schmid, 2019; Scheurer et al., 2014, 2016), and anticipated increases in the use of FAs led the DVGW (German Association for gas and water applications) to investigate the opportunities and risks of the use of these substances in its own research projects focusing on drinking water abstraction (DVGW, 2020).

In order to discuss the current status of the initial situation, the data basis, the methodology, and the risk regulation, the Federal Environment Agency held a symposium on FAs in September 2021, bringing together 90 stakeholders. Due to the large number of FAs substance groups, two substance groups which are of great relevance for the environment were prioritised. On the one hand, the focus was on nitrification and urease inhibitors (NI, UI or, in combination, NUI) and, on the other hand, on the relatively new and increasingly important group of biostimulants in fertiliser legislation. For both groups of substances, basic principles for environmental assessment, their legal classification and regulatory options were discussed. In this paper, the results are summarised and scientifically classified. The respective methods and detailed results can be found in the final report on the FAs symposium (Karges et al., 2022).

Due to the increasing importance of the topic, the relevance for the environment and drinking water resources, as well as regulations already in force or in preparation in the environmental field, for example on the prohibition of deterioration of the Water Framework Directive (2000) and the EU Action Plan "Pollutant-free Air, Water and Soil" (EU, 2021), this paper represents a starting point for the development and adaptation of future measures and investigations. This includes advice on the need for further research, knowledge gaps, the need for legal optimisation, and improved regulations of FAs.

2 Legal background

The legal background regulating the multitude of substances and products that can be grouped under the term FAs is complex. It includes both national legal bases and European regulations and directives and regulates in particular questions of authorisation, use, and appropriate controls.

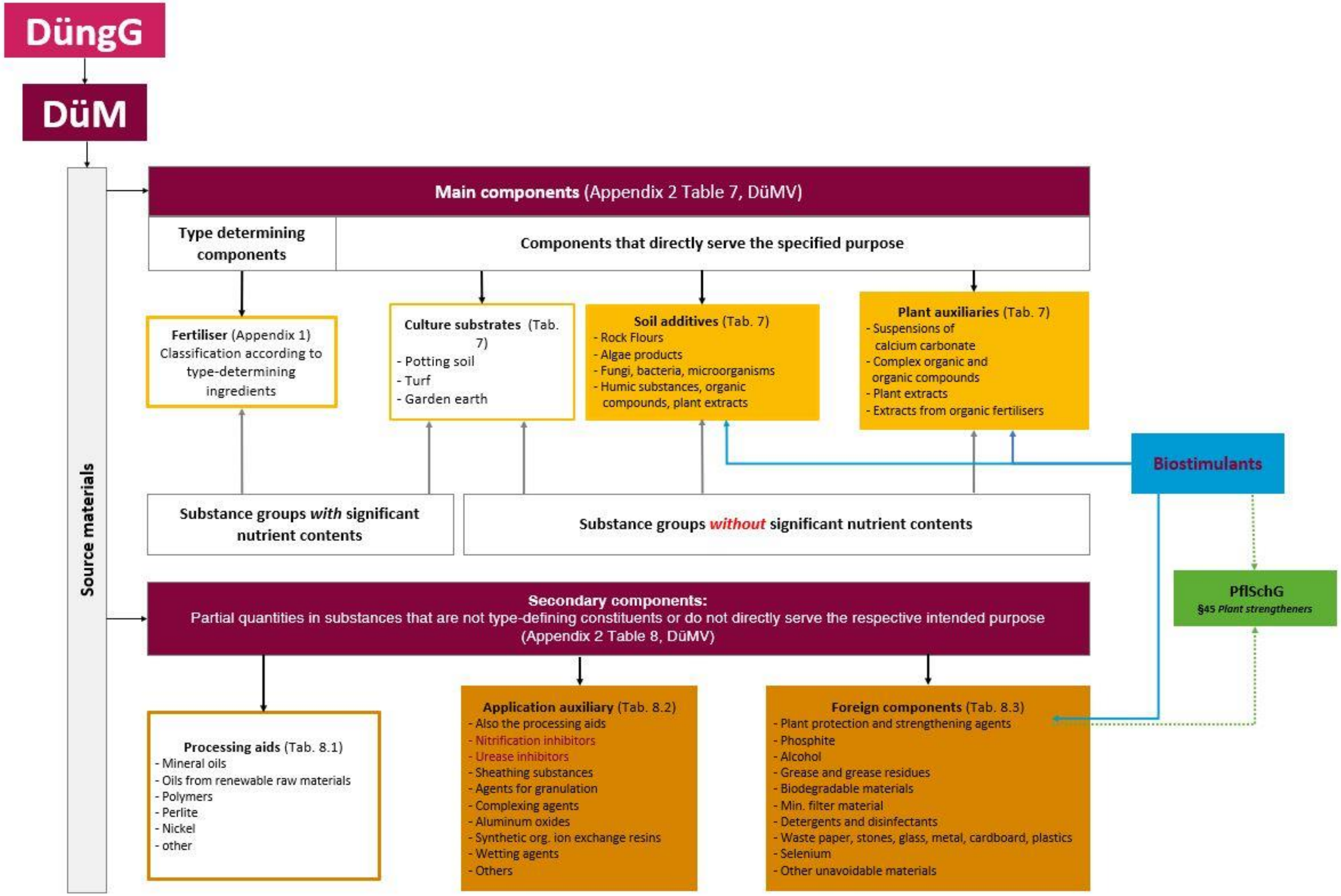
2.1 Legal background of the application

In the legal context of the application of FAs, the Fertiliser Act (FA, 2021), the FngO (2021), and the FO (2019) are relevant for Germany. In general, a distinction is made between the four product categories fertilisers, growing media, soil additives, and plant aids, which are defined depending on the type-determining or purpose-determining main constituents. Many different substances can be added to these product categories as secondary components, which support production or use in terms of application technology as processing and application aids. The FO distinguishes between substance groups with and without significant nutrient content. For better classification, Figure 1 schematically shows the classification of the different product categories fertilisers, growing media, soil additives, and plant aids according to the FO. The substance groups without significant nutrient content include soil additives and plant aids.

The secondary components are listed in the FO in Annex 2 Table 8 and are further subdivided into the processing aids, the application aids and the foreign components. Thus NI, UI, complexing agents or wetting agents are classified as application aids. Phosphites as well as plant protection and plant strengthening agents are among the foreign components. Algae products as well as fungi, bacteria and microorganisms belong to the group of soil additives.

Problematic in national law are overlaps in the group of biostimulants (cf. chap. 3.2), which result from the different classification as soil additives or plant additives or as plant strengthening agent (cf. Figure 1). Depending on the intended use, a product can be placed on the market either as a "plant strengthening agent" according to § 45 of the Plant Protection Act or as a "soil additive" or "plant auxiliary" according to the FO. The difficulty arises from the lack of unambiguity in assigning the individual biostimulants to the three groups and thus in delimiting the areas of application of the two legal regimes. In particular, the distinction between plant adjuvants and plant strengthening agents can be a matter of interpretation in the authorisation procedure and offers scope for interpretation, both for the applicant and for authorities and users. In order to avoid circumvention of the comprehensive data requirements of the Plant Protection Act, the substance specific effect of the product is relevant for the authorisation in addition to the intended use. If, for example, a product consists of two chemical active substances, one of which acts as a plant protection product and the other as a plant fertiliser, the product requires both a plant protection authorisation and conformity with the requirements of the Fertiliser Act. If a product consists of a chemical active ingredient that acts both as a plant protection product and as a fertiliser, the predominant purpose and the exact material composition are decisive for the authorisation.

Figure 1 **Scheme for the legal classification of the substance groups of fertiliser additives; highlighted in red are the substance groups that will be the main focus of the symposium, the orange and yellow boxes contain substance groups of fertiliser additives.**



Source: IfÖL GmbH.

2.1.1 Legal background of the authorisation

In order for a fertiliser product to be authorised on the European market under the Fertiliser Products Regulation (EU) No.2019/1009, which has been in force since July 2022, and to receive a CE marking when it is made available, it must comply with the following requirements:

- Annex I specifications for the relevant product functional category (PFC)
- Specifications according to Annex II for the relevant component material category (CMC)
- Labelling requirements according to Annex III

The definitions include requirements and effects of the products. The NI and UI considered here are defined as *inhibitors* in PFC 5:

"A nitrification inhibitor must inhibit the biological oxidation of ammonium nitrogen (NH_4 -N) to nitrite nitrogen (NO_2^-) and thus slow down the formation of nitrate nitrogen (NO_3^-)". The requirement is that NI reduces the oxidation of ammonium nitrogen by 20 % over a period of 14 days.

"A urease inhibitor inhibits the hydrolytic activity of urea ($CH_4 N_2 O$) by the urease enzyme predominantly aimed at reducing ammonia volatilisation". The requirement is that the rate of hydrolysis of urea is reduced by 20 % by the addition of UI.

Biostimulants are defined in PFC 6 as *"EU fertiliser product designed to stimulate plant nutritional processes, irrespective of the nutrient content of the product, aimed exclusively at improving one or more of the following characteristics of the plant or the rhizosphere of the plant:*

a) Efficiency of nutrient utilisation

b) Tolerance to abiotic stress

c) Quality features

d) Availability of nutrients contained in the soil or rhizosphere".

In the case of biostimulants, limits are also set for certain contaminants such as cadmium, lead or inorganic arsenic and the essential plant nutrients copper and zinc as well as certain pathogens are specified for microbial plant biostimulants. In addition, a plant biostimulant with CE marking must necessarily have the effects indicated on the label for the plants named therein.

Even after the European Fertiliser Products Regulation (EU) No. 2019/1009 came into force, it is still possible for fertilisers to be placed on the market under national law (BLE, 2021). Subsequently, there are two possibilities for the approval of fertilisers:

- as an EU fertiliser product with a CE marking in accordance with the Fertiliser Products Regulation (EU) No. 2019/1009
- as a fertiliser manufactured and authorised under national law (of Germany, as well as all other Member States of the internal market) (in this case, the rules under Regulation No 2019/515 for the mutual recognition of goods apply and the product does not receive a CE marking).

This makes the overview and transparency with regard to approval requirements considerably more difficult. Products that are covered by the FO are generally marketable in Germany without requiring individual approval by the authorities. On the other hand, a product which, despite proper use, leads to an environmental or health hazard may not be marketed in Germany because it does not comply with the FA.

2.1.2 Scientific Advisory Board for Fertilisation Issues

In Germany, the BMEL is advised by the Scientific Advisory Board on Fertilisation on issues related to fertilisation. The establishment of the Scientific Advisory Board on Fertilisation and its tasks are regulated by law in the Fertilisation Advisory Council Ordinance (FACO, 2015). According to this, *"it (the Scientific Advisory Board on Fertilisation) advises the Federal Ministry on fertilisation issues by issuing expert opinions and is independent in its activities"* (FACO, 2015; §1 paragraph 2). The Advisory Council is composed of ten scientists, three of whom work in the field of plant nutrition and two in the field of plant cultivation or soil science. In addition, one member comes from each of the specialist areas of organic farming, fertiliser analysis, toxicology, ecotoxicology, and environmental and animal hygiene. The members are appointed by the BMEL and work on an honorary and independent basis.

The tasks of the Scientific Advisory Board on Fertilisation are not defined in the FACO, but are listed on the BMEL website (2022). According to this, they include in particular the development

- "of opinions on fertiliser law regulatory projects at national and European level,
- recommendations for the authorisation of new fertilisers, soil additives, growing media or plant aids, taking particular account of agronomic efficacy, environmental compatibility, and consumer protection,
- of viewpoints on specific issues of fertilisation,
- of proposals for appropriate measures and instruments for efficient and environmentally sound fertilisation."

The Scientific Advisory Board on Fertilisation assesses the hygienic, toxicological, and ecotoxicological safety of the substances based on the basic information from the chemical safety data sheets in accordance with the European Chemicals Regulation, the so-called REACH Regulation. If, in the opinion of the Scientific Advisory Board on Fertilisation, this information does not cover the criteria relevant for authorisation, the applicant must submit further information (Severin, 2021, Hartmann, 2021). Since there is no formal authorisation procedure for FAs in Germany, each individual authorisation process corresponds to a case-by-case assessment and is not subject to any uniform and transparent assessment criteria, unlike, for example, in the authorisation of plant protection products. More detailed information on the evaluation criteria on the basis of which the recommendations for individual products and active substances are made are not published in this procedure and are neither transparent for users, nor for research or official experts. Usually, the BMEL follows the recommendations of the Scientific Advisory Board on Fertilisation as an expert committee, even if these are not formally binding. The Scientific Advisory Board on Fertilisation therefore plays a decisive role in national authorisation. In the event of a positive assessment of a new fertiliser product by the Scientific Advisory Board on Fertilisation, an amendment to the FO can be made, subject to the approval of the Federal Council (Bundesrat).

2.1.3 Conformity assessment

The conformity assessment of fertiliser products is regulated in the European Fertiliser Products Regulation (EU) No.2019/1009, Chapter IV. Conformity assessment is understood to be the procedure to prove that the requirements of the regulation for an EU fertiliser product have been met. For this purpose, so-called conformity assessment bodies are established, which carry out the conformity assessment (tests, certifications, and inspections). In Germany, the Federal Agency for Agriculture and Food (Bundesanstalt für Landwirtschaft und Ernährung, BLE) has taken over the tasks of assessing and notifying conformity assessment bodies and monitoring the notified bodies, including their subsidiaries.

3 Environmental assessment, environmental exposure

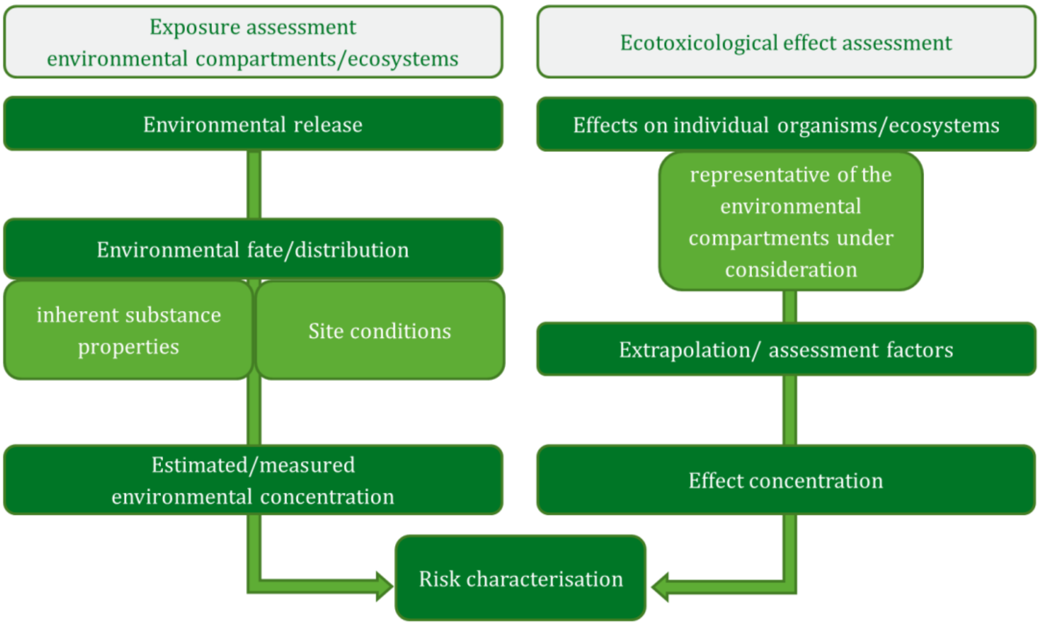
Increasing knowledge about the behaviour and fate of environmental chemicals and their metabolites in the various environmental compartments increasingly calls for a transparent assessment of these substances and the environmental risk they pose. This holds true for NI and UI applied directly to the soil with fertilisation and, analogously, for all those substances that are applied directly or indirectly to the environment, as is the case with the heterogeneous group of biostimulants.

Exposure and risk assessment are the key components of a comprehensive environmental risk assessment. In the exposure assessment, the expected (PEC - Predicted Environmental Concentration) or measured environmental concentrations (MEC - Measured Environmental Concentration) must be determined for the various compartments, taking into account realistic input quantities. The ecotoxicological effect assessment includes data on the toxic effects on non-target organisms as well as safety factors to address the remaining uncertainties. The concentration at which no toxic effect occurs is described by the PNEC (Predicted No Effect Concentration). In the subsequent risk assessment, the PEC and PNEC (including a safety factor) are compared in order to derive the risk posed by a substance to the non-target organisms of a compartment in a specific application (Fent, 2013). The basic concept is illustrated in Figure 2.

The protection goals of such exposure assessments for NI and UI result from their application to or in the upper soil layers. Relevant input pathways into surrounding environmental media are run-off after heavy rain events, input via drainage into surface waters, seepage, dust drift and possibly volatilisation. The protection targets for the exposure assessment of NI and UI therefore include surface waters (including sediment), groundwater – with a view to a possible indirect exposure of humans via drinking water – and possibly the air, as well as terrestrial ecosystems in particular due to the direct application. The inherent substance properties and their descriptive parameters required for an exposure assessment, which can provide information on the fate and distribution of a substance in the environmental compartments, include for example (but are not limited to): Distribution coefficients, stability to degradation and hydrolysis, vapour pressure and, depending on the issue, other parameters.

Since several thousand tonnes of fertiliser are applied to agricultural land every year, it should be ensured that NI, UI, and biostimulants do not themselves lead to negative effects on the environment due to their physical/chemical as well as (eco-)toxicological properties, thereby overriding the intended positive effect.

Figure 2 Simplified approach for the environmental risk assessment of chemicals.



Source: IWW; adapted from Fent, 2013

Unlike NI and UI, biostimulants are not only chemical substances or mixtures of substances – microorganisms, algae preparations, plant extracts or extracts of animal products can also be biostimulants, depending on their effect (Bickert et al., 2018). Since these are also intended to be released directly into the environment, harmful effects on humans and the environment must also be addressed and excluded in the authorisation process. Open questions arise, especially in the area of microorganism preparations, for example, as to how precisely possible toxic metabolic products are tested.

3.1 Nitrification and urease inhibitors

The application of NI and UI may be associated with potential risks to associated ecosystems via inputs to the various environmental compartments (Kösler et al., 2019; Salis et al., 2019). Individual studies provide indications of the distribution of some of the active substances in German water systems, even if the positive findings cannot yet be clearly attributed to use in fertiliser applications. For example, data monitoring on the occurrence of 1,2,4-triazole and DCD in German flowing waters showed peak concentrations for both active substances in the range of several µg/L (~2 µg/L DCD, > 5 µg/L 1,2,4-triazole) in the Rhine. The frequency of detections and measured concentrations for both substances changed over the course of the river, albeit with an opposite trend (Scheurer et al., 2014). An overview screening carried out in Lower Saxony in the surface water system for contamination with 2-NPT, NBPT, DCD, 3-MP, 1,2,4-triazole and DMPP, which focused primarily on smaller water bodies with a pronounced agricultural influence, also showed comparable concentration levels for DCD and 1,2,4-triazole. For the other NI and UI, no contamination could be detected with the applied methodology, whereby the high analytical determination limits for DMPP and 3-M of 0.25 µg/L and 0.1 µg/L, respectively, must be taken into account (Schaffer & Schmid, 2019).

In addition to possible effects on aquatic ecosystems, fundamental questions therefore arise from an environmental assessment perspective regarding the estimation of the environmental behaviour of the active substances, such as their migration capacity and degradation behaviour.

According to European and German fertiliser legislation, humans, animals, plants, and the natural environment must be protected from harmful effects and hazards caused by fertilisation or fertiliser products and the substances they contain. This requires a comprehensive understanding of possible hazards and risks that the application of these substances may entail. Therefore, due to their direct application into the environment, a tonnage-independent environmental risk assessment and evaluation should be carried out for NI and UI.

The NI and UI considered in more detail here, which are contained in a nationally authorised fertiliser in Germany or in an EU fertiliser and are also applied directly to the environment with an intended effect, are primarily registered in accordance with the REACH Regulation. Fertiliser-regulatory, national and European authorisation procedures are based on the information collected in this procedure. In the course of registration, all relevant information must be collected and submitted in a dossier by the registrant. This dossier contains both the standard information on intrinsic substance properties required in Annexes VI, VII, and VIII of the REACH Regulation (see Tab. 1) and, from a tonnage of 10 t a^{-1}, a chemical safety report summarising the results of a chemical safety assessment. The requirements for the substance information depend on the tonnage and are graded according to the annual production or import quantity per registrant. Justified deviations from the minimum requirements are possible, so that not all requested data are necessarily actually available in all dossiers and can be included in further assessments. The assessment of whether the respective substances may have harmful effects on human health and the environment is primarily the responsibility of the registrants themselves. They also have the obligation to collect and report data and information available to them that go beyond the standard requirements. The downstream environmental risk assessments of active substances based on this information in the context of the authorisation for use are thus often poorly comparable.

Although the steps and information requirements necessary for an environmental risk assessment are in principle also anchored in the REACH Regulation, the ultimate purpose of the chemical safety report is to assess hazards and identify exposure scenarios. However, the exposure assessment and the risk characterisation are not required for every substance per se. In principle, they must only be carried out for substances in tonnage bands ≥10 t a^{-1}. However, this only applies if the respective substance is to be classified as hazardous in the first step of the hazard assessment according to the hazard classes mentioned in Article 14(4), which include the identification of adverse effects on human health and the environment, or if it meets the criteria PBT (persistent, bioaccumulative, toxic) or vPvB (very persistent, very bioaccumulative). The substances listed here as environmental hazards are those that are hazardous to water and those that deplete the ozone layer. The requirements do not include a separate hazard class that represents a hazard to soil ecosystems and thus the compartment that is most directly affected by an application of NI and UI. In addition, the "determination of adverse effects on the environment" to be included in the chemical safety assessment is based on the information contained in the technical dossier. The standard requirements for this in turn follow the tonnage-dependent graduation according to the annual production quantities. Only from a tonnage of ≥ 100 t a^{-1} simple ecotoxicological tests on the effect on terrestrial organisms are provided. More meaningful tests for soil ecosystems, such as testing the long-term toxicity of the substances for invertebrates and for plants, are even only obligatory from a tonnage of ≥ 1000 t a^{-1}. Without this information, however, it is hardly possible to make a well-founded statement about the risk to terrestrial ecosystems from the application of NI and UI (cf. Figs. 2, 3; Tab. 1).

An improved approach to environmental risk assessment should be based on the requirements for other substances with agricultural application. For example, although the intended effect and toxicity of many plant protection products are significantly more problematic than those of NI and UI, the intended agricultural use and the prohibition of negative environmental impacts through their use (Regulation (EC) No.1107/2009) are comparable. Plant protection product active substances are applied to the environment with a targeted intention to act, for example, against certain organisms. A comprehensive environmental risk assessment is a mandatory part of their authorisation procedure laid down in Regulation (EC) No.1107/2009 and in the downstream regulations (for requirements see Table A of the Annex). A chemical active substance that is authorised as a plant protection product under this procedure is also considered to be registered under the REACH Regulation.

Table 1 shows the standard data requirements (exceptions excluded) in the successive tonnage bands and the allocation of the NI and UI to the tonnage bands. It is clear that there are different data requirements for the various NI and UI due to the differing quantities. The seven NI and three UI currently approved in Germany are allocated to the annexes according to their tonnage bands by way of example.

Table 1 **Simplified overview of standard data requirements for substances in the REACH registration (Regulation (EC) No.1907/2006) in comparison with requirements under plant protection law according to the data requirements of Regulations (EU) No.283/2013 and (EU) No.284/2013**

Allocation of NI and UI to the tonnage bands; due to the large number of possible exceptions, these are not listed in the overview.

	Data requirements according to REACH				Data requirements for plant protection products
	Annex VII *Non-phase-in substances & phase-in substances 1-10 t/a meeting Annex III criteria and & All substances: ≥ 10 t/a*	**Annex VIII** *Substances ≥ 10 t/a*	**Annex IX** *Substances ≥ 100 t/a*	**Annex X** *Substances ≥ 1000 t/a*	
Nitrification inhibitors	Nitrapyrin, 1,2,4-triazole		3-MP; DMPP; DMPSA, MPA	DCD	
Uresa inhibitors		2-NPT; NPPT	NBPT		
7. information on the physico-chemical properties of the substance					
7. Physico-chemical data	State of aggregation; Melting/freezing point; Boiling point/boiling range; Relative density; Vapour pressure; Surface tension; Water solubility; Partition coefficient; Flash point; Inflammability; Explosive capacity; Auto-ignition temperature; Fire-promoting properties; Granulometry		Stability in organic solvents and identity of decay products; dissociation constant; viscosity		Requirements comparable with Annex VII In addition: parameters of identification, among others: - Spectra (UV/VIS, IR, NMR, MS) & Absorbance
9. information on ecotoxicity					
9.1 Aquatic toxicity	Short-term toxicity (or long-term toxicity) in invertebrates -preferably daphnia; Inhibition of aquatic plant growth (preferably algae)	Short-term toxicity (or long-term toxicity) to fish; inhibition of respiration of activated sludge, alternatively: nitrification inhibition - if the available data indicate that the	Long-term toxicity to daphnia and to fish; toxicity to fish in early developmental stage (fish-early-life-stage) and to fish embryos		a.o.: - Acute, long-term and chronic toxicity to fish (toxicity to fish in the early developmental stage (fish-early-life-stage + life cycle). - Acute and chronic toxicity in *Daphnia magna* - Inhibition of algae growth

	Data requirements according to REACH				Data requirements for plant protection products
		substance inhibits the growth or function of microbes, especially nitrifying bacteria. data indicate that the substance inhibits the growth or function of microbes, especially nitrifying bacteria.	and juveniles with yolk sac, growth test on juveniles.		
9.2 Degradability	Biotic; Degradability	Abiotic (further tests possible); hydrolysis depending on pH value	Simulation tests to test biodegradability: final degradation in surface water - degradation in soil - degradability in sediment; **identification of degradation products.**	If necessary, more detailed/extended testing for biodegradability, depending on the chemical safety assessment according to Annex I.	a.o.: Aerobic, anaerobic and photolytic degradation of the active substance, metabolites, degradation and reaction products in the soil Degradation pathway and rate - Hydrolytic, photochemical and biological degradation of the active substance, metabolites, degradation and reaction products in aquatic systems as well as in the water-sediment system Degradation path and rate - Degradation path and speed in the air - For persistent active substances metabolites, degradation and reaction products, field tests on dissipation and accumulation in soil shall be submitted. - Residue definitions for risk assessment and monitoring, if applicable
9.3 Environmental fate and behaviour		Adsorption/desorption screening	Bioaccumulation in aquatic organisms, preferably in fish in fish; adsorption/desorption: more information than given in Annex VII.	If necessary, further tests, depending on the chemical safety assessment according to Annex I.	a.o.: - Fate and behaviour of the active substance, metabolites, degradation and reaction products in soil, air, water and sediment. - Adsorption and desorption of the active substance, metabolites, degradation and reaction products - for mobile active substances, metabolites, degradation and reaction products, column tests for infiltration, lysimeter tests or field infiltration studies must be submitted, if applicable. - Atmospheric transport - Local and global impacts
9.4 Effect on terrestrial organisms			Short-term toxicity to invertebrates and plants; effect on microorganisms in the soil	Long-term toxicity to invertebrates and to plants - not required if no direct or indirect exposure of the soil is expected.	a.o.: - Effects (including acute, chronic, contact toxicity) on non-target soil meso- and macrofauna. + Arthropods + bees - Effects on nitrogen transformation in the soil

	Data requirements according to REACH				Data requirements for plant protection products
					- Effects on non-target plants
9.5 Long-term toxicity to sediment-dwelling organisms				Testing for long-term toxicity to sediment-dwelling organisms, if applicable.	If applicable, chronic risk for *Chironomus riparius* or *Lumbriculus* spp. (other test species if necessary)
9.6 Long-term toxicity to birds				Only under careful consideration of necessity: Testing for long-term toxicity to birds.	- Acute oral toxicity - Reproductive toxicity
					Toxicity to mammals * - Acute oral toxicity - Reproductive toxicity

Numbering of column 1: According to Annex VII-X of the REACH Regulation.

*Toxicity to mammals: Standard data requirement in the PPP authorisation.

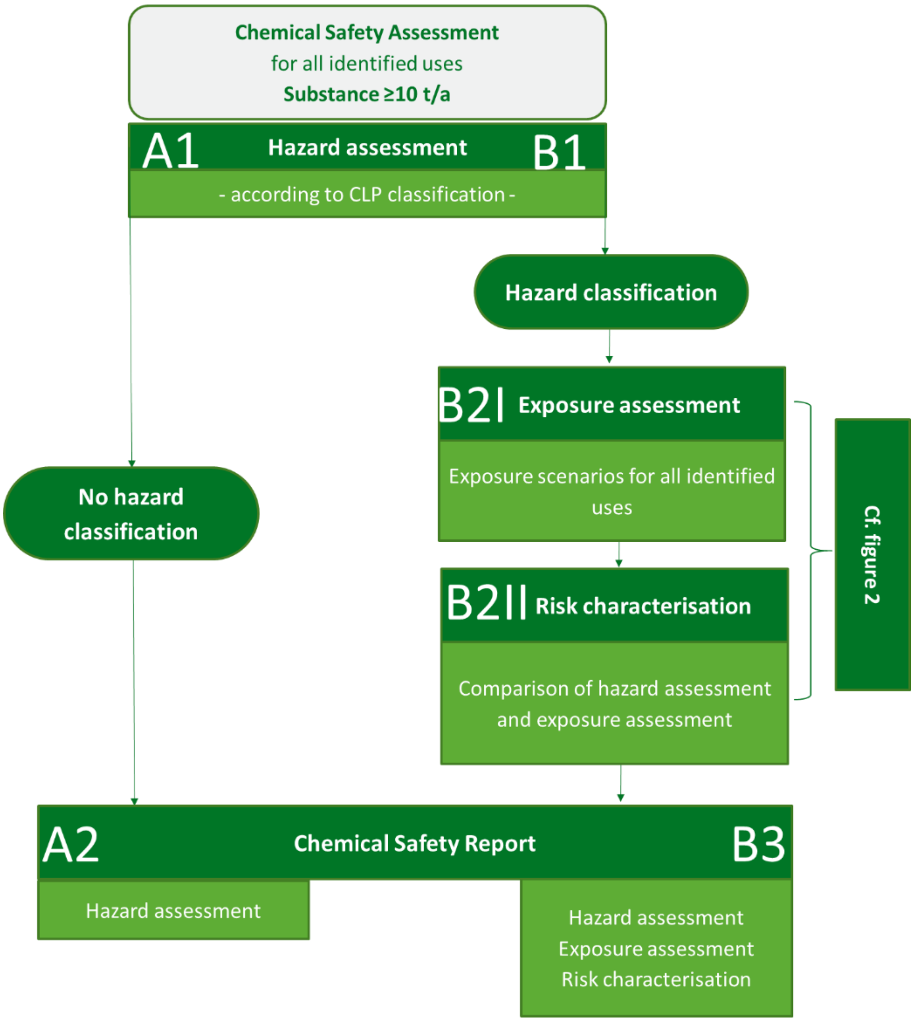
Some of the information on the substance properties of NI and UI that is relevant for an initial assessment of the environmental behaviour is already required at the lowest tonnages, such as partition coefficients within the scope of the physico-chemical data and the basic information on degradability and environmental behaviour required under Annex VII (≥10 t a^{-1}) (cf. Tab. 1). The distribution coefficients are essential for estimating the leaching behaviour of a substance in soil. Thus, low K_{ow} values (and K_{oc}) that can be derived from them indicate a high mobility in the aqueous soil phase and thus, in principle, an increased risk of leaching; the persistence of a substance, on the other hand, can be represented, for example, by DT_{50} values (time after which half of the amount of a substance is degraded).

However, this information is insufficient for a comprehensive exposure assessment, as would be required for an evaluation of possible impacts on the natural balance. This requires further data on adsorption/desorption as well as simulation tests on degradation in soil, which are only required under REACH from a tonnage band > 100 t a^{-1}onwards.

Figure 3 Pathways to the Chemical Safety Report according to Regulation (EC) No.1907/2006 (REACH)

Simplified approach for the environmental risk assessment of chemicals

The risk assessment and evaluation include, on the one hand, the exposure assessment for environmental compartments/ecosystems (input, fate/distribution, estimated measured environmental concentration) and, on the other hand, the ecotoxicological effect assessment (effect on individual organisms/ecosystems, extrapolation/safety factors and effect concentration) of the chemicals.



Dark green: main steps of implementation, light green: explanatory.
Pathway A maps the pathway to the safety report for substances ≥ 10t/a if no hazard classification according to Article 14(4) of Regulation (EC) No.1907/2006 is available. Pathway B applies if a hazard classification has been determined on the basis of the available information.
Source: IWW

The tonnage dependency of the testing and information requirements also affects the general chemical safety assessment. The staggered data requirements in the hazard assessment of the chemical safety assessment alone do not necessarily result in a "hazard" according to Regulation (EC) No.1272/2008 (CLP[1]) for substances in low tonnages, so that no exposure assessment would then be required. This gives rise to general concerns about the estimation of the input quantity and the effects of these substances through fertiliser applications and the exposure of environmental compartments and associated ecosystems in the context of authorisation.

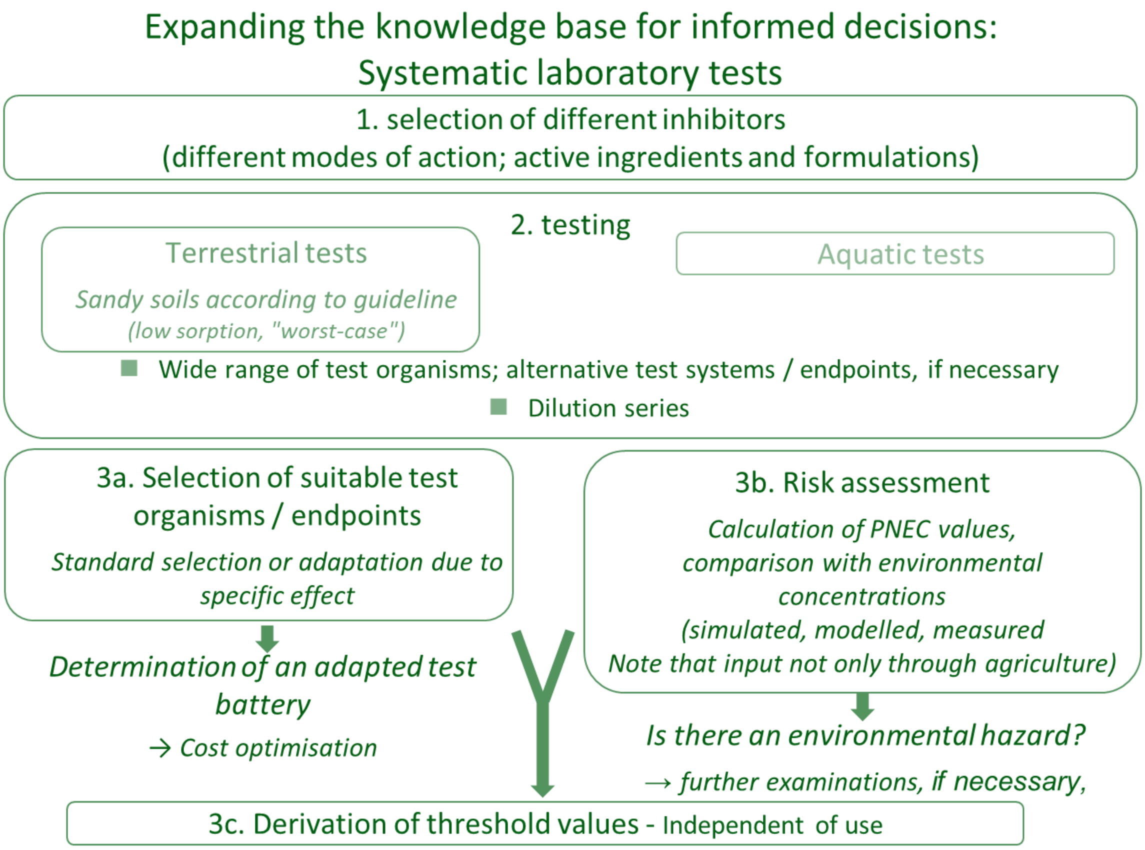
The information, which is limited in different ways due to the staggering of data requirements, and the partial lack of adapted ecotoxicological effect tests show the deficits of an environmental assessment for chemicals such as NI and UI on the basis of REACH information alone. The intended effect as well as the immediate and large-scale environmental application should be reflected in the information requirements of the registration, or at the latest in the authorisation processes. Ideally, therefore, the data requirements for agrochemicals such as NI and UI, in contrast to other REACH-regulated industrial chemicals, should be extended to take account of the intended use. In accordance with the precautionary principle, it is recommended that the tonnage-dependent information requirements for such chemicals be abandoned in favour of a catalogue of requirements adapted to the assessment of possible impacts on the natural balance, or that the data requirements be combined across the various tonnage bands (cf. Table 1). The aim should be to make a reliable statement on the basis of these data as to the extent to which the associated ecosystems and environmental compartments are burdened by the application of the fertiliser products.

Based on the PPP authorisation, this includes information and studies on degradation pathways, degradation mechanisms and degradation rates in soil, water and air, as well as in-depth ecotoxicological studies of terrestrial and aquatic ecosystems.

The Scientific Advisory Board on Fertilisation therefore proposed to adapt the data requirements for ecotoxicological tests of NI and UI accordingly. For this purpose, suitable study designs and test systems with adapted test organisms should be selected, on the basis of which the environmental risk from the application of NI and UI can be estimated as realistically as possible (Figure 4). Particularly with regard to non-target soil microorganisms there is still a need for research on the selection of an ecotoxicologically appropriate test battery (Hund-Rinke, 2021).

[1] CLP Regulation: Classification, Labelling and Packaging - European legal basis for the hazard classifications of chemicals

Figure 4 **Proposal of an adapted, systematic testing strategy for assessing the environmental risk posed by nitrification and urease inhibitors.**



Source: K. Hund-Rinke, Fraunhofer IME; in "Nitrification and urease inhibitors (focus: ecotoxicology)"; lecture at the UBA Symposium on Fertiliser Additives, 2021

3.2 Biostimulants

The term biostimulants includes a wide range of compounds or active substances for which no conclusive, scientifically recognised list has yet been found (Garcia-Garcia et al., 2020; du Jardin, 2015). For the first time, they are uniformly regulated as an independent product function category (PFC) under the European Fertiliser Products Regulation (EU) No. 2019/1009, but were previously regulated in part via the Plant Protection Products Regulation (EC) No. 1107/2009. Pursuant to Article 47 of (EU) No. 2019/1009, this regulation has been amended in such a way that plant biostimulants, which previously may have been covered, are now explicitly excluded from the scope of the regulation, which severely limits the possibilities of an environmental risk assessment for these substances. The definition used in the European Fertiliser Products Regulation (EU) No.2019/1009 is now requirement-based. Biostimulants are thus defined by their effect and not by their ingredients as fertiliser products that stimulate plant nutritional processes and can thus improve nutrient uptake or utilisation (Ricci et al., 2019).

As such, biostimulants can belong to a wide variety of parent products. A uniform approach or concept for environmental assessment that covers all biostimulants is already difficult due to this diversity, as is the investigation of the effects of a single component due to the often complex composition of biostimulant products (Bulgari et al., 2019).

The new Fertiliser Products Regulation (EU) No. 2019/1009 makes a basic distinction between microbial plant biostimulants such as fungi and bacteria and non-microbial plant biostimulants. These can in turn be further subdivided according to their main origins into, for example, algae and plant extracts, fulvic and humic acids, amino acids and proteins, inorganic substances and plant extracts (Ebert, 2020). The limit values for heavy metal content specified in the requirements of the Ordinance under Annex 1, PFC 6 may not be exceeded by either microbial or non-microbial biostimulants. In addition, for all substances falling under Annex 2, component material category (CMC) 1, a chemical safety report for use as a fertiliser product must be prepared in accordance with Annex IV of the REACH Regulation (2006). However, this means that a large proportion of biostimulants, such as those of microbial origin, are not subject to this requirement. Requirements for testing their environmental effects have not yet been regulated in more detail (EU Commission, 2021a). Working groups and committees of the European standardisation organisations, such as CEN/TC 455 or CEN/TC 223, as well as the expert group for fertilisers of the EU Commission are currently working on the creation of standardised specifications and definitions, for example for specifications and test bases (Ebert, 2020 EU-Kommission, 2021b; Hartmann, 2021).

Taking into account environmental concerns and hygiene requirements, the European Fertiliser Products Regulation (EU) No. 2019/1009 defines a "positive list" for the group of microbial biostimulants (PFC 6) under CMC 7 with microorganism taxa that may be contained in them. It currently includes *Azotobacter* spp., mycorrhizal fungi, *Rhizobium* spp. and *Azospirillum* spp. Ecotoxicological risks that can arise from such microorganism preparations are, for example, phytoparasitism, toxin formation in the plant or a change in the soil microbiome (Baum et al., 2021). According to the assessment of experts, these risks in agricultural use for the biostimulants on the positive list have so far been rated as rather low (Baum et al., 2021; Karges et al., 2022). However, examples from biological crop protection indicate that a residual risk cannot be ruled out even with established microorganisms (Pfordt et al., 2020). Monitoring the long-term effects of microbial biostimulants in agricultural cultivation, especially when using living microorganisms, is therefore also recommended from a precautionary point of view.

4 Efficacy

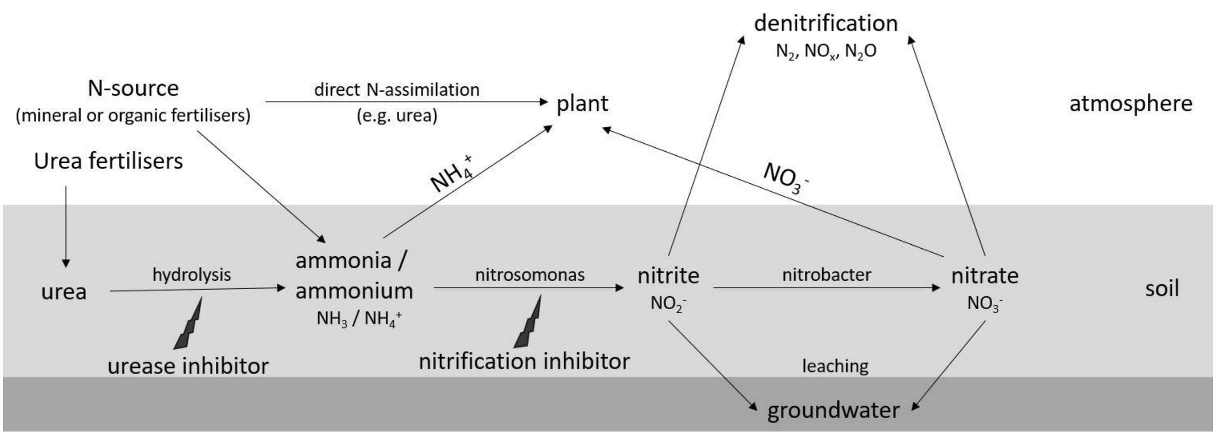
Key research results on the efficacy of NIs and UIs, as well as on biostimulants, are summarised below.

4.1 Efficacy of NI and UI

NI, UI, and NUI are used in agriculture to reduce nitrogen losses by better adapting microbial nitrogen transformation in the soil to the nitrogen demand and uptake by crops. NI and UI differ in their mode of action and effects, and thus in their use. NI can be used with all ammonium-containing fertilisers, including manure and fermentation residues, to delay the nitrification of ammonium to nitrate. Since ammonium is less mobile in the soil than nitrate, the fertiliser nitrogen is less prone to leaching. However, depending on soil conditions (pH value, moisture), higher gaseous N losses due to ammonia (high pH values) can occur.

In the amended FngO, the use of UI in the application of urea fertilisers is regulated by law for the first time as an overriding measure of efficient fertiliser use to reduce ammonia emissions during application. The application of UI in urea fertilisers is obligatory in Germany according to FngO, unless they are incorporated immediately, but within four hours after application at the latest. The obligation to use UI in urea fertilisers results primarily from the sometimes considerable ammonia emissions that occur during the application of urea fertilisers. According to Bundesratdrucksache 148/17, this is justified by the fact that "in order to reduce nitrogen inputs into non-agricultural ecosystems via the air pathway, measures are required that lead to a significant reduction in emitted ammonia emissions". This obligation is thus also one of the measures within the national clean air programme (BMU, 2019).

Figure 5: Mode of action of nitrification and urease inhibitors



Source: Scheurer et al (2014), adapted for the DVGW project "INHIBIT".

Figure 5 shows the mode of action of microbial inhibition of nitrification by NI and UI, but also that NI and UI have different points of attack within the nitrogen cycle in the soil. The European Fertiliser Products Regulation (EU) No. 2019/1009 takes up this situation by defining NI and UI as inhibitors in the PFC 5 via their mode of action (cf. 2.1.1).

In Germany, more NI and UI are currently approved than are mentioned in the European Fertiliser Regulation (EC) No. 2003/2003, which is still in force. An overview of the NI and UI approved according to the regulations at EU level and the national FO is given in the final report on this project (Karges et al., 2022). An overview according to FO can also be found in Table A1 of the Annex.

The use of NI and UI is intended to reduce nitrogen losses in the agricultural application of fertilisers. In addition to reducing nitrogen leaching in form of nitrate, the use of these substances is primarily aimed at reducing gaseous nitrogen losses through ammonia and nitrous oxide emissions.

The following subchapters summarise the most important results of the literature research on the use of NI and UI to reduce nitrate leaching, ammonia emissions, and nitrous oxide emissions. In general, it must first be stated that the positive effects for climate and water protection are strongly dependent on the site, environmental and management influences and thus the relationship between the precautionary principle with regard to climate and water protection and the actual, measurable effect must be viewed critically.

4.1.1 Reduction of nitrate leaching

Nitrogen fertilization that is appropriate to the demand and timing ensures that the crops efficiently take up the available nitrogen from the soil. If at the beginning of winter leachate formation there are still considerable amounts of nitrate in the soil that were not taken up by the crop plants during the vegetation period, the easily mobile nitrate can be washed out with the leachate into deeper soil layers and subsequently into the groundwater, or it thus reaches surface waters and can lead to eutrophication there. Nitrate is undesirable in groundwater and drinking water because it can be converted into nitrite in the human body, which poses a health risk. For this reason, a limit of 50 mg/L nitrate is prescribed in the Drinking Water Ordinance. Also, according to the European Nitrates Directive (EU-RL 91/676/EEC) as well as the Groundwater Ordinance (GrwV, 2017) and the Surface Water Ordinance (OGewV, 2020), agricultural nitrate inputs must be reduced and a threshold value of 50 g/L nitrate in groundwater and surface waters must be observed.

NI delay the conversion of the less mobile ammonium ion into nitrate, which can reduce the risk of nitrogen leaching (Di und Cameron, 2002; Barth et al., 2019; Zerulla et al., 2001; Gaßner, 2014). However, there are also studies in which the use of NI does not always reduce nitrate leaching into the saturated zone (Corré und Zwart, 1995; Gioacchini et al., 2002; Misselbrook et al., 2014). This is due to several influencing factors such as soil parameters (e. g. Barth et al., 2001 or Barth et al., 2019), fertiliser application form (e.g. Barth et al., 2008), climate and current weather or management practices (e.g. Di and Cameron, 2002), which affect microbial turnover in the soil. The duration of effect of the NI also plays a major role, which is a maximum of eight weeks under field conditions (DVGW, 2022; Barth et al., 2008). Overall, clear and generally valid statements on the effectiveness of reducing nitrate leaching through the use of NI are not possible due to the different study results.

4.1.2 Reduction of ammonia emissions

Ammonia is a precursor for particulate matter, contributes to acidification and eutrophication of ecosystems via dry and wet deposition, and indirectly to nitrous oxide emissions (Geupel et al., 2021). Ammonia emissions originate to 95 % from agriculture, half of which originates from the application of organic fertilisers, mineral fertilisers, and digestate (BMU, 2019). Emissions were on the rise between 2005 and 2016, in part due to an increase in the proportion of urea fertiliser used in mineral fertilisation (BMU, 2019). Therefore, the national clean air programme (BMU, 2019) sets the goal of significantly reducing ammonia emissions as indirect climate-relevant trace gases in agriculture. One possible measure to achieve this goal is the use of UI (Hu and Schmidhalter, 2021) and also the combined use of NI and UI (NUI) (Ni et al., 2017) in nitrogen fertilisation in agriculture.

With the amendment of the FngO (2017), UI are prescribed for the application of urea fertilisers if the urea fertiliser is not incorporated within four hours after application. UI enzymatically inhibit the catalytic urea hydrolysis (Figure 5). The fact that UI significantly reduce ammonia emissions has been shown by many studies and meta-analyses (San Francisco et al., 2011; Gaßner, 2014; Misselbrook et al., 2014; Ni et al., 2014; Schraml et al., 2016; Castellano-Hinojosa et al., 2020, Hu et al., 2020; Pan et al., 2016; Silva et al., 2017; Lam et al., 2017). However, the results of the studies are only comparable to a limited extent, which is due to the different site conditions and climatic conditions as well as the different study approaches and study designs, resulting in a wide range with regard to the concrete reduction potential.

The addition of NI to ammonium-containing mineral or organic fertilisers delays nitrification, causing ammonium to remain in the soil longer. Site and weather conditions such as soil temperature and pH can shift the ammonium-ammonia dissociation equilibrium in the soil solution towards ammonia, favouring increased ammonia losses/emissions. This may be particularly the case for sandy soils, soils with low cation exchange capacity and soils with organic layers (Lam et al., 2017; Gioacchini et al., 2002; San Francisco et al., 2011; Cantarella et al., 2018; Castellano-Hinojosa et al., 2020; Kim et al., 2012). As a result, the positive effects of reducing nitrous oxide emissions can be offset by partially increased ammonia emissions.

For combination products containing both NI and UI (NUI), the same issue as described above can occur. There may be an increase in the ammonium phase in the soil due to the NI, which increases the risk of ammonia emissions (Kim et al., 2012; Castellano-Hinojosa et al., 2020). However, there are also opposite results: For example, the incubation studies by Ni et al. (2017) show no difference in ammonia emissions with the addition of NUI compared to the addition without NI.

Overall, it is also evident for the reduction of ammonia emissions that the individual studies are only partially comparable and therefore general and universally valid statements should be regarded with caution.

4.1.3 Reduction of nitrous oxide emissions

A not insignificant source of direct nitrous oxide emissions is nitrogen fertilisation. Nitrous oxide is one of the most important greenhouse gases and about 300 times more harmful to the climate than carbon dioxide. Through the NEC Directive (EU) 2016/2284, Germany commits to reduce national emissions of NH_3 by 5 % from 2020 and 29 % from 2030 compared to 2005. This also includes measures to reduce nitrous oxide emissions from agriculture, such as optimising N efficiency.

In this context, the intended effect of NI in the application of ammonium-containing fertilisers to contribute to a reduction of nitrous oxide emissions by delaying nitrification has been widely documented (Akiyama et al., 2010; Ruser und Schulz, 2015; Recio et al., 2019; Flessa et al., 2014; Pfab et al., 2012; Lam et al., 2017; Hu et al., 2020; Cowan et al., 2020, ten Huf und Olfs, 2020; Linzmeier et al., 2001). In particular, the application method, the weather, and the stock of organically bound nitrogen in the soil play a major role. However, soil type (Friedl et al., 2020) or soil moisture (Wu et al., 2017) also have an influence on nitrous oxide emissions. For this impact pathway, there are many site and management influences that affect the impact of NI, which is why the study results are difficult to compare.

The evaluation of the effect of NI on the reduction of nitrous oxide emissions shows that the potential increase in ammonia emissions must be included as a side effect in the evaluation of the effectiveness for climate protection. It is thus an indirect effect, which in turn increases nitrogen inputs into atmospheric ecosystems. In this context, the increased ammonia emissions can partly override the positive climate effect of NI by reducing nitrous oxide emissions (Lam et al., 2017) so that overall the desired benefit for climate protection is no longer given.

4.2 Efficacy of biostimulants

In agriculture, biostimulants are used to improve nutrient uptake and -utilisation, stress tolerance, product quality, and yield performance of crops (Van Oosten et al., 2017). According to current expert opinion, this happens less through nutrient mobilisation and much more through the promotion of root growth, which opens up more soil space and thus makes more nutrients accessible (Nkebiwe et al., 2016). Biostimulants also have a supporting and activating effect on metabolic processes in the plants. Thus, in the case of biostimulants, the effects on metabolic processes in the crop plants from the synergistic interaction with the soil and the plant are particularly significant (Paul und Lade, 2014; Neumann, 2017; Hestrin et al., 2019; Raupp, 2020). However, for a large number of biostimulants, the mechanisms behind the effect have not been clarified, so that there is still a considerable need for research (Van Oosten et al., 2017).

Some studies show positive effects on yield and plant growth by adding biostimulants such as algal extracts, mycorrhizal fungi, rhizobacteria or amino acids and peptide mixtures of protein hydrolysates (Neumann, 2017; Olivares et al., 2017; Rouphael und Colla, 2020). However, these are results from laboratory and vessel trials and from use in closed systems in horticulture and greenhouses. When used at field level under field conditions, the results have a higher variability (Wiesler and Armbruster, 2021) and show wider ranges, from no effect (Hege et al., 2005 and Wendland et al., 2006) to yield increases of up to 20 % (Neumann, 2017). In contrast, the addition of phosphite to rapeseed and winter wheat as field crops in field trials showed scientifically proven improved plant growth as well as significant yield increases (Verreet et al., 2020; Verreet et al., 2019).

In a Europe-wide collaborative project on biostimulants, the greatest effects were demonstrated in the combination of various biostimulants such as mycorrhiza-forming fungi, rhizobacteria, algae extracts or plant extracts with fertilisers – especially with ammonium-emphasised fertilisation or with an additional fertilisation of trace nutrients (Neumann, 2017). Overall, it should be noted that there is a great influence of environmental and site characteristics as well as cultivation measures on the effects of biostimulants, which makes it difficult to prove clear correlations of effects.

The agricultural use of biostimulants has increased significantly in recent years (IVA, 2020, 2021). Therefore, on the one hand, it is imperative to show the efficacy and mechanisms at both the molecular and field level by standardised methods under field conditions and, on the other hand, to establish uniform standards in the regulation and authorisation of the very heterogeneous product groups (Barros-Rodríguez et al., 2020; Ricci et al., 2019). At the current state of knowledge, there is not yet sufficient information on the environmental risks that may be posed by biostimulants. Also, no information on monitoring programmes related to biostimulants was found.

5 Conclusion and outlook

FAs have become increasingly important in recent years and comprise different groups of substances with different properties. The FO distinguishes between the four product categories fertilisers, growing media, soil additives, and plant aids, which are defined depending on the type-determining or purpose-determining main components. In the present document, emphasis was placed on NI and urease inhibitors (UI) as well as on biostimulants. These two groups of substances are increasingly applied in agricultural practice and are of particular interest due to their inclusion in the amended EU fertiliser legislation and their increased quantities sold.

NI and UI are used in agriculture because they are considered to have positive effects in terms of reduced nitrogen emissions into adjacent environmental compartments. However, findings of individual NI in water bodies are a cause for concern with regard to negative environmental effects. In the case of NI and UI, the main focus is on the conflicting goals of climate protection (reduction of greenhouse gas emissions through the use of inhibitors) and environmental and water protection (input and occurrence of individual inhibitors as potentially persistent, mobile substances). Here, the unclear data situation with regard to the actual sales volumes proves to be a particular obstacle to a concrete assessment of the risks for the environment and (drinking) water resources. Registration under the REACH Regulation does often not provide sufficient information on persistence, mobility and toxicity for the terrestrial and aquatic environment. The data requirements designed for industrial chemicals without an intended environmental release are usually insufficient for substances such as NI and UI for which there is an intention for direct release and effect in the environment. Due to the linkage of data requirements to broad tonnage bands in the REACH Regulation, few ecotoxicological studies exist for some NI and UI, especially for terrestrial ecosystems. However, meaningful ecotoxicological tests adapted to the actual exposure situation are indispensable for environmental assessment and within the framework of an authorisation procedure oriented towards the precautionary principle. There is still a need for improvement here. The authorisation of active substances according to the precautionary principle requires a transparent procedure with clear legal responsibilities. Tonnage-independent information obligations, adapted to agricultural use and application directly in the environment, and with regard to risk assessment, regulatory access to the approval-relevant studies on environmental behaviour and ecotoxicity should be guaranteed.

Legally, NI and UI are assigned to the application aids according to the list of secondary ingredients under FO, while biostimulants, depending on the intended use, are either assigned to the plant aids or soil additives under FO or are subject to authorisation as plant strengthening agents under the Plant Protection Act. The lack of clarity in the classification of biostimulants leads to overlaps and ambiguities with regard to the requirements for the authorisation and placing on the market of this group of substances as well as the delimitation of the respective legal areas. Although the EU Fertiliser Products Regulation (EU) No. 2019/1009, , marks a departure from the traditional type system and the introduction of product function categories, it does not ultimately lead to more transparency and clarity with regard to authorisation requirements. In particular, since fertiliser products manufactured and approved under the national law of one Member State may continue to be placed on the market of another Member State on the basis of mutual recognition in the EU.

Although domestic sales of fertilisers are recorded in Germany according to the AgrStatG, no data on additives in fertilisers and biostimulants have been collected so far. Therefore, the amount of NI and UI and biostimulants actually applied to the environment is not known, so that the entry paths of the environmental findings of these active substances are not or only insufficiently known. Knowledge of the specific sales volumes of the commercial products with information on the active ingredient concentrations is necessary to assess the risk of exposure to various environmental compartments and to be able to take specific measures to clarify findings in the environment.

So far, only a few monitoring studies have been carried out in Germany for NI and UI. Since it is known that some of the approved NI are not only used as FAs but can also arise as degradation products from other products used in construction, industry and agriculture, environmental findings should be linked to the investigation and clarification of the causal input pathways. In the clarification of findings in groundwater, the input pathway soil-groundwater should be investigated scientifically in depth in order to achieve a better understanding of the input process. For example, permanent soil monitoring plots within the framework of multi-year monitoring programmes would be a suitable means for this.

For the very heterogeneous product group of biostimulants, only few study results on environmental assessment, applied quantities, and efficacy are available so far. As the agricultural use of biostimulants has increased considerably in recent years, greater importance should be attached to the investigation of possible harmful effects of the application of biostimulants, especially on associated ecosystems. Precise knowledge of the effects of the various biostimulants, especially on the soil (micro)biome, is often still insufficient, and long-term monitoring is rare or difficult to transfer to other study areas. Since many biostimulants do not have to be registered under the REACH Regulation, there are often no ecological assessments and quantity data for them, so that there still is a considerable need for research in this area.

In addition to the necessary adjustments to the requirements relevant to authorisation, Germany-wide monitoring programmes for NI, UI and biostimulants in soils, surface waters, and groundwater would contribute to an improved assessment of any potential risk to the environment – and also to humans via the drinking water pathway – enabling regulatory countermeasures to be taken if necessary.

6 List of references

Akiyama, H., Yan, X., Yagi, K. (2010): Evaluation of effectiveness of enhanced-efficiency fertilizers as mitigation options for N2O and NO emissions from agricultural soils: meta-analysis. Global Change Biology, 16(6), 1837-1846.

Barros-Rodríguez, A., Rangseekaew, P., Lasudee, K., Pathom-aree, W., Manzanera, M. (2020): Regulatory risks associated with bacteria as biostimulants and biofertilizers in the frame of the European Regulation (EU) 2019/1009. Science of The Total Environment, 740, 140239.

BLE Federal Agency for Agriculture and Food (2021): FAQs - Frequently asked questions to the notifying authority on Regulation (EU) 2019/1009 laying down rules for making EU fertiliser products available on the market. https://www.ble.de/SharedDocs/Downloads/DE/Landwirtschaft/EU-Duengeprodukte/BLE_FAQs_zur_Verordnung_2019_1009.pdf?__blob=publicationFile&v=7 (Status: 06.04.2021)

Barth, G., von Tucher, S., Schmidhalter, U. (2001): Influence of soil parameters on the effect of 3,4-dimethylpyrazole-phosphate as a nitrification inhibitor. In: Biology and Fertility of Soils 34, pp. 98-102.

Barth, G., von Tucher, S., Schmidhalter, U. (2008): Effectiveness of 3,4-Dimethylpyrazole Phosphate (DMPP) as Nitrification Inhibitor in Soil as Influenced by Inhibitor Concentration, Application Form, and Soil Matric Potential. In: Pedosphere 18 (3), pp. 378-385.

Barth, G., von Tucher, S., Schmidhalter, U., Otto, R., Motavalli, P., Ferraz-Almeida, R., Meinl Schmiedt Sattolo, T., Cantarella, H., Vitti, G. C. (2019): Performance of nitrification inhibitors with different nitrogen fertilizers and soil textures. Journal of Plant Nutrition and Soil Science, 182(5), 694-700.

Baum, C., Vitow, N., Schulz, S., Schloter, M. (2021): Microorganism preparations and soil microbiology - use, benefits and possible risks. Conference contribution UBA Fachtagung zur Umweltbewertung von Düngemittelzusatzstoffen.

Bickert, C., Rutt, K., Erdle, K. (2018): Biostimulants - hope in fertilisation and crop protection? DLG e.V., Frankfurt am Main, p.

Bulgari, R., Franzoni, G., Ferrante, A. (2019): Biostimulants Application in Horticultural Crops under Abiotic Stress Conditions. Agronomy. 9(6):306. https://doi.org/10.3390/agronomy9060306

Federal Ministry of Food and Agriculture (BMEL) (ed.) 2022: https://www.bmel.de/DE/ministerium/organisation/beiraete/dueng-organisation.html (25.05.2022)

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (ed.) (2019): National Clean Air Programme of the Federal Republic of Germany. pursuant to Article 6 and Article 10 of Directive (EU) 2016/2284 on the reduction of national emissions of certain atmospheric pollutants and pursuant to Sections 4 and 16 of the Ordinance on national obligations to reduce certain atmospheric pollutants (43rd BImSchV).

Cantarella, H., Otto, R., Soares, J. R., Silva, A. G. d. B. (2018): Agronomic efficiency of NBPT as a urease inhibitor: A review. Journal of Advanced Research, 2018(13), 19-27.

Castellano-Hinojosa, A., González-López, J., Vallejo, A., Bedmar, E. J. (2020): Effect of urease and nitrification inhibitors on ammonia volatilization and abundance of N-cycling genes in an agricultural soil Journal of plant nutrition and soil science, 2020(1), 99-109.

Corré, W. J., Zwart, K. (1995): Effects of DCD addition to slurry on nitrate leaching in sandy soils. Netherlands Journal of Agricultural Science, 43(2), 195-204.

Cowan, N., Carnell, E., Skiba, U. Dragosits, U., Drewer, J., Levy, P. (2020): Nitrous oxide emission factors of mineral fertilisers in the UK and Ireland: A Bayesian analysis of 20 years of experimental data. Environment International, 135, 105366.

Di, H. Cameron, K. (2002): The use of a nitrification inhibitor, dicyandiamide (DCD), to decrease nitrate leaching and nitrous oxide emissions in a simulated grazed and irrigated grassland. Soil use and management, 18(4), 395-403.

DVGW (2022): INHIBIT - Abschlussbericht W 201917- Chancen und Risiken von Nitrifikations- und Ureaseinhibitoren für den Gewässerschutz. https://www.dvgw.de/themen/forschung-und-innovation/forschungsprojekte/dvgw-forschungsprojekt-inhibit (Stand 03.06.2022).

Ebert, G. (2020): Biostimulants - Innovative products for crop production. Conference contribution Virtual Symposium Biostimulants. Frankfurt am Main.

EU (2021): Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Towards a healthy planet for all EU Action Plan: "Pollutant-free air, water and soil". Brüssel, 12.05.2021.

EU Commission (2021a): Answer given by Mr Breton on behalf of the European Commission to Written Question E-002636/2021. Brussels, 7.7.2021. https://www.europarl.europa.eu/doceo/document/E-9-2021-002636-ASW_EN.pdf (as of 03.03.2022).

EU Commission (2021b): Commission Expert Group on Fertilisers (E01320). https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=1320. (as of 16.03.2022)

Fent, K. (2013): Ecotoxicology: Environmental Chemistry-Toxicology-Ecology. Georg Thieme Verlag, ISBN/ISSN 3131693045, pp.

Flessa, H., Greef, J. M., Hofmeier, M., Dittert, K., Ruser, R., Poddey, E., Osterburg, B., Wulf, S., Pacholski, A. (2014): Mitigation of nitrogen emissions from agriculture: recommendations for practice and current questions for science. In: Research, (ed.), Senate of the Federal Research Institutes of the Federal Ministry of Food and Agriculture, Berlin, ISBN/ISSN 2363-6823978-3-95547-015-9.

Friedl, J., Scheer, C., Rowlings, D. W., Deltedesco, E., Gorfer, M., Rosa, D. (2020): Effect of the nitrification inhibitor 3,4-dimethylpyrazole phosphate (DMPP) on N-turnover, the N2O reductase gene nosZ and N2O:N2 partitioning from agricultural soils. In: Scientific reports 10 (1), p. 2399.

Gaßner, M. (2014): Ammonia and nitrous oxide emissions after application of calcium ammonium nitrate and urea in combination with urease and nitrification inhibitors in wheat Dissertation at the Technical University of Munich (Supervisor: Schmidhalter, U). Munich, 167 p.

García-García, A.L., Garcia Machado, F., Borges, A. A., Morales-Sierra, S., Boto, A., Jimenez-Arias, D. (2020): Pure Organic Active Compounds Against Abiotic Stress: A Biostimulant Overview. Frontiers in Plant Science. 11. 10.3389/fpls.2020.575829.

Geupel, M., Richter, S., Schlesinger, L. (2021). Nitrogen - element with effect. Federal Environment Agency

Gioacchini, P., Nastri, A., Marzadori, C., Giovannini, C., Vittori Antisari, L., Gessa, C. (2002): Influence of urease and nitrification inhibitors on N losses from soils fertilized with urea. Biology and Fertility of Soils, 36(2), 129-135. DOI: 10.1016/j.atmosenv.2017.12.002.

Hartmann, S. (2021): Approval and use of FAS from an industry perspective. Conference contribution UBA-Fachtagung zur Umweltbewertung von Düngemittelzusatzstoffen.

Hege, U., Schmidt, K., Offenberger, K. (2005): Versuchsergebnisse aus Bayern Ernte 2003 bis 2005 Wirkung von Bodenhilfsstoffen und Pflanzenhilfsmitteln. Bavarian State Research Centre for Agriculture. Institute for Agroecology - Fertilisation, Freising, S.

Hestrin, R., Hammer, E. C., Mueller, C. W., Lehmann, J. (2019): Synergies between mycorrhizal fungi and soil microbial communities increase plant nitrogen acquisition. Communications biology, 2(1), 1-9.

Hu, Y., Gaßner, M. P., Weber, A., Schraml, M., Schmidhalter, U. (2020): Direct and Indirect Effects of Urease and Nitrification Inhibitors on N2O-N Losses from Urea Fertilization to Winter Wheat in Southern Germany. Atmosphere, 11(8).

Hu, Y. Schmidhalter, U. (2021): Urease inhibitors: opportunities for meeting EU national obligations to reduce ammonia emission ceilings by 2030 in EU countries. In: Environ. Res. Lett. 16 (8), p. 84047.

Hund-Rinke, K. (2021): Nitrification and urease inhibitors (focus: ecotoxicology). Conference contribution UBA Fachtagung zur Umweltbewertung von Düngemittelzusatzstoffen.

IVA (2020): Press release - The fertiliser market 2018/19. https://www.iva.de/sites/default/files/pdfs/der_duengemittelmarkt_2018-19_jpk_050520.pdf (15.12.2021)

IVA (2021): Biostimulants - Building blocks for modern and sustainable agriculture. https://www.iva.de/sites/default/files/benutzer/%25uid/publikationen/flyer_biostimulanzen_layout_final_210304.pdf (15.12.2021).

Du Jardin, P. (2015). Plant biostimulants: definition, concept, main categories and regulation. Scientia horticulturae, 196, 3-14. doi: 10.1016/j.scienta.2015.09.021

Kim, D. G. Saggar, S., Roudier, P. (2012): The effect of nitrification inhibitors on soil ammonia emissions in nitrogen managed soils: a meta-analysis. Nutrient Cycling in Agroecosystems, 93(1), 51-64.

Kösler, J. E., Calvo, O. C., Franzaring, J., Fangmeier, A. (2019): Evaluating the ecotoxicity of nitrification inhibitors using terrestrial and aquatic test organisms. Environmental Sciences Europe, 31(1), 1-11.

Lam, S. K., Suter, H., Mosier, A. R., Chen, D. (2017): Using nitrification inhibitors to mitigate agricultural N^2 O emission: a double-edged sword? Global Change Biology, 23(2), 485-489.

Linzmeier, W., Gutser, R., Schmidhalter, U. (2001): Nitrous oxide emission from soil and from a nitrogen-15-labelled fertilizer with the new nitrification inhibitor 3,4-dimethylpyrazole phosphate (DMPP). In: Biology and Fertility of Soils 34 (2), pp. 103-108. DOI: 10.1007/s003740100383.

Misselbrook, T. H., Cardenas, L. M., Camp, V., Thorman, R. E., Williams, J. R., Rollett, A. J., Chambers, B. J. (2014): An assessment of nitrification inhibitors to reduce nitrous oxide emissions from UK agriculture. Environmental Research Letters, 9(11), 115006.

Neumann, G. (2017): BIOFECTOR - Project Final Report (Resource Preservation by Application of BIOefFECTORs in European Crop Production).

Ni, Kang, Pacholski, A., Kage, H. (2014): Ammonia volatilization after application of urea to winter wheat over 3 years affected by novel urease and nitrification inhibitors. In: Agriculture, Ecosystems & Environment 197, pp. 184-194. DOI: 10.1016/j.agee.2014.08.007.

Ni, K., Kage, H., Pacholski, A. (2017): Effects of novel nitrification and urease inhibitors (DCD/TZ and 2-NPT) on N2O emissions from surface applied urea: An incubation study. In: Atmospheric Environment 175, pp. 75-82.

Nkebiwe, P. M., Weinmann, M., Müller, T. (2016): Improving fertilizer-depot exploitation and maize growth by inoculation with plant growth-promoting bacteria: from lab to field. In: Chem. Biol. Technol. Agric. 3 (1). DOI: 10.1186/s40538-016-0065-5.

Olivares, F. L., Busato, J. G. de Paula, A. M., da Silva, Lima L, Aguiar, N. O., Canellas, L. P. (2017): Plant growth promoting bacteria and humic substances: crop promotion and mechanisms of action. Chemical and Biological Technologies in Agriculture, 4(1), 30.

Pan, B., Lam, S. K., Mosier, A., Luo, Y., Chen, D. (2016): Ammonia volatilization from synthetic fertilizers and its mitigation strategies: A global synthesis. Agriculture, Ecosystems & Environment, (232), 283-289.

Paul, D., Lade, H. (2014): Plant-growth-promoting rhizobacteria to improve crop growth in saline soils: a review. Agronomy for sustainable development, 34(4), 737-752.

Pfab, H., Palmer, I., Buegger, F., Fiedler, S., Müller, T., Ruser, R. (2012): Influence of a nitrification inhibitor and of placed N-fertilization on N2O fluxes from a vegetable cropped loamy soil. Agriculture, Ecosystems & Environment, 150, 91-101.

Pfordt, A., Schiwek, S., Karlovsky, P., & von Tiedemann, A. (2020). Trichoderma afroharzianum ear rot-a new disease on maize in Europe. Frontiers in Agronomy, 11.

Raupp, M. G. (2020): The Use of Bio-Effectors for Crop Nutrition. madora gmbh, Lörrach, 113 p.

Recio, J., Alvarez, J. M., Rodriguez-Quijano, M., Vallejo, A. (2019): Nitrification inhibitor DMPSA mitigated N2O emission and promoted NO sink in rainfed wheat. Environmental Pollution, 245, 199-207.

Ricci M., Tilbury L., Daridon B., Sukalac K (2019) General Principles to Justify Plant Biostimulant Claims. Front. Plant Sci. 10:494. doi: 10.3389/fpls.2019.00494

Rouphael, Y., Colla, G. (2020): Editorial: Biostimulants in Agriculture. Frontiers in plant science, 11, 40-40.

Ruser, R., Schulz, R. (2015): The effect of nitrification inhibitors on the nitrous oxide (N2O) release from agricultural soils-a review. Journal of Plant Nutrition and Soil Science, 178(2), 171-188.

Salis, R. K., Bruder, A., Piggott, J.J., Summerfield, T. C., Matthaei, C. D.: Multiple-stressor effects of dicyandiamide (DCD) and agricultural stressors on trait-based responses of stream benthic algal communities. DOI: 10.1016/j.scitotenv.2019.07.111

San Francisco, S., Urrutia, O. Martin, V., Peristeropoulos, A., Garcia-Mina, J. M. (2011): Efficiency of urease and nitrification inhibitors in reducing ammonia volatilization from diverse nitrogen fertilizers applied to different soil types and wheat straw mulching. Journal of the Science of Food and Agriculture, 91(9), 1569-1575.

Schraml, M., Gutser,R., Maier, H., Schmidhalter, U. (2016): Ammonia loss from urea in grassland and its mitigation by the new urease inhibitor 2-NPT. The Journal of Agricultural Science, 154(8), 1453-1462.

Severin, K. (2021): Zulassungsverfahren von Düngemittelzusatzstoffen - Konfliktpotentiale im Regulierungsprozess, conference contribution UBA-Fachtagung zur Umweltbewertung von Düngemittelzusatzstoffen.

Silva, A. G., Sequeira, C. H., Sermarini, R. A., Otto, R. (2017): Urease inhibitor NBPT on ammonia volatilization and crop productivity: A meta-analysis. Agronomy Journal, 109(1), 1-13.

Huf ten, M., Olfs, H. -W. (2020): Effect of the nitrification inhibitor DMPP on nitrous oxide emissions and the stabilization of ammonium following the injection of dairy slurry and digestate in a soil-column experiment. In: Z. Pflanzenernähr. Bodenk. 183 (2), pp. 129-135. DOI: 10.1002/jpln.201900025.

Van Oosten, M. J., Pepe, O., De Pascale, S., Silletti, S., Maggio, A. (2017): The role of biostimulants and bioeffectors as alleviators of abiotic stress in crop plants. Chemical and Biological Technologies in Agriculture, 4(1), 1-12.

Verreet, J. -A., Birr, T., Prahl, K., Loof, S., Cai, D., Zhou, Z. (2020): Alternative means of production or hocus-pocus? Use of biostimulants in agriculture. S.

Verreet J. -A., Klink, H., Birr, T., Prahl, K. (2019): Phosphite. White paper prepared for BBSRC LINK grant partners. Kiel University (CAU), last checked 13.01.2020, Kiel, p.

Wendland, M., Salzeder, G., Offenberger, K. (2006): Wirkung von Effektiven Mikroorganismen im ökologischen Landbau - Versuchsergebnisse aus Bayern 2004 bis 2006. Freising, S.

Wiesler, F., Armbruster, M. (2021): Biostimulants - a building block for integrated cultivation? A new group of substances in the EU Fertiliser Products Regulation. Agricultural Weekly

Wu, D., Cárdenas, L. M., Calvet, S., Brüggemann, N., Loick, N., Liu, S., Bol, R. (2017): The effect of nitrification inhibitor on N 2 O, NO and N 2 emissions under different soil moisture levels in a permanent grassland soil. In: Soil Biology and Biochemistry 113, pp. 153-160.

Zerulla, W, Barth, T., Dressel, J., Erhardt, K., Horchler von Locquenghien, K., Pasda, G., Rädle, M., Wissemeier, A. (2001): 3,4-Dimethylpyrazole phosphate (DMPP) - a new nitrification inhibitor for agriculture and horticulture. Biology and Fertility of Soils, 34(2), 79-84.

7 List of legal bases

Germany:

Bundesratsdrucksache 148/17: Verordnung zur Neuordnung der guten fachlichen Praxis beim Düngen; Ordinance on the reorganisation of good agricultural practice in fertilising.

FO (2019): Düngemittelverordnung; Fertiliser Ordinance of 5 December 2012 (BGBl. I p. 2482), as last amended by Article 1 of the Ordinance of 2 October 2019 (BGBl. I p. 1414).

FA (2021): Düngegesetz; Fertiliser Act of 9 January 2009 (BGBl. I p. 54, 136), last amended by Article 96 of the Act of 10 August 2021 (BGBl. I p. 3436).

FACO (2015): Düngungsbeiratsverordnung; Fertilisation Advisory Council Ordinance of28/ August 2003 (BGBI. I p. 1789), last amended by Article 369 of the Act of 31 August 2015 (BGBI. I p. 1474).

FngO (2021): Düngeverordnung; Fertilising Ordinance of 26 May 2017 (BGBl. I p. 1305), last amended by Article 97 of the Act of 10 August 2021 (BGBl. I p. 3436).

GrwV 2017: Grundwasserverordnung; Groundwater Ordinance of 9 November 2010 (BGBl. 1 p. 1513), as last amended by Article 1 of the Ordinance of 4 May 2017 (BGBl. 1 p. 1044).

OGewV 2020: Oberflächengewässerverordnung; Surface Water Ordinance of 20 June 2016 (BBl. 1 p. 1373), as last amended by Article 2(4) of the Act of 9 December 2020 (BGBl. 1 p. 2873).

PflSchG (2020): Pflanzenschutzgesetz; Plant Protection Act of 6 February 2012 (Federal Law Gazette I p. 148, 1281), last amended by Article 278 of the Ordinance of 19 June 2020 (Federal Law Gazette I p. 1328).

EU:

EU Directive 2016/2284: Directive (EU) 2016/2284/EU of the European Parliament and of the Council of 14 October 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC. Official Journal of the European Union, L 244, 1 - 31.

Fertilisers Regulation (2003): Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (Text with EEA relevance).

Fertiliser Products Regulation (2019): Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules concerning the making available on the market of EU fertilizer products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003.

Nitrates Directive (1991): Council Directive of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (91/676/EEC).

REACH Regulation (2006): Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93, Commission Regulation (EC) No 1488/94, Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Directive 2016/2284 (2016): Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC.

Regulation 2019/515 (2019): Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008

A Appendix

A.1 Nitrification and urease inhibitors approved in Germany according to FO (2019)

Active substance	Abbreviation	Sum formula	Approval according to FO (2019)
Dicyandiamide	DCD	$C_2 H_4 N_4$	before 2003
3-Methylpyrazole	3-MP	$C_4 H_6 N_2$	before 2003
1H-1,2,4-triazole	Triazole	$C_2 H_3 N_3$	2003
3,4-dimethyl-1H-pyrazole 3,4-dimethylpyrazole phosphate	DMPP	$C_5 H_8 N_2$ $C_5 H_{11} N_2 PO_4$	2003
N-((3(5)-Methyl-1H-pyrazol-1-yl)methyl)acetamide	MPA	$C_7 H_{11} N_3 O$	2015
Nitrapyrin [2-chloro-6-(trichloromethyl)pyridine]	Nitrapyrin	$C_6 H_3 Cl_4 N$	2015
Isomeric mixture of 2-(4,5-dimethyl-1H-pyrazol-1-yl)succinic acid and 2-(3,4-dimethyl-1H-pyrazol-1-yl)succinic acid	DMPSA	$C_9 H_{12} N_2 O_4$	2019
N-(2-Nitrophenyl)phosphoric acid triamide	2-NPT	$C_6 H_9 N_4 O_3 P$	2008
N-butyl-thiophosphorus triamide	NBPT	$C_4 H_{14} N_3 PS$	2015
N-propylthiophosphorus triamide	NPPT	$C_3 H_{12} N_3 PS$	2015

Urease inhibitors marked in italics