Organic contaminants in fertilising products and components materials

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Abstract
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The new European Fertilising Products Regulation (EU) 2019/1009 (FPR) enters into force in 2022. With a few exceptions, organic contaminants are not restricted in CE fertilisers. For food/feed intended as component materials, labelling requirements are set with a view to inform the end user to decide whether it can be safely used. Labelling is only required when threshold values are exceeded and not for other component materials. The Dutch Fertiliser Act (DFA) sets more concentration limits to various, but not all, fertilisers. The implementation of the FPR in 2022 provides options to uphold the DFA for national products, and to set provisions to the use of CE products. All combinations of options offer different benefits for producers, end users, administration and environment, and are variably flexible to respond to future developments. Recommendations are made to streamline the control of organic contaminants for the purpose of reducing waste and valorising nutrients while protecting human health and the environment.

Keywords: FPR, fertilisers, organic contaminants, environment, risk

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De nieuwe Europese Bemestingsproducten Verordening (EU) 2019/1009 (FPR) treedt in 2022 in werking. Op enkele uitzonderingen na zijn organische verontreinigingen in EU-bemestingsproducten niet beperkt. Voor levensmiddelen/diervoeders die bedoeld zijn als ingangsmaterialen, worden etiketteringseisen gesteld, om de eindgebruiker te informeren en te laten bepalen of een product veilig gebruikt kan worden. Etikettering is enkel vereist als concentratiegrenzen overschreden worden en dit is niet vereist voor andere ingangsmaterialen. De Nederlandse Meststoffenwet (MW) stelt meer concentratiegrenzen aan verschillende, maar niet alle, meststoffen. De implementatie van de FPR in 2022 biedt opties om de MW voor nationale producten te handhaven en om bepalingen te stellen aan het gebruik van CE-producten. Alle combinaties van opties bieden verschillende voordelen voor producenten, eindgebruikers, overheid, en milieu, en zijn verschillend flexibel in het inspelen op toekomstige ontwikkelingen. Het rapport doet aanbevelingen om de beheersing van organische verontreinigingen te stroomlijnen om verspilling van grondstoffen te voorkomen en nutriënten te benutten, terwijl gelijktijdig de publieke gezondheid en het milieu worden beschermd.

Trefwoorden: FPR, meststoffen, bemestingsproducten, organische verontreinigingen, milieu, risico

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Preface

The European Commission is working towards a more circular economy. By its action plan, reuse is promoted. One of the actions is to replace the current European fertiliser regulation EC/2003/2003 for mineral fertilisers and liming materials through a new European regulation EC/2019/1009 on making EU fertilising products available on the market. Unlike EC/2003/2003 the new European regulation on fertilising products also regulate fertilising products from vegetable and/or animal origin. Due to the publication of the new regulation, implementation in the Dutch Fertiliser Act necessary. The Scientific Committee on the Nutrient Management of the Dutch Fertiliser Act (CDM, in Dutch 'Commissie Deskundigen Meststoffenwet') has made on request of the Ministry of Agriculture, Nature and Food Safety an assessment of the impact of implementation of the new European regulation on fertilising products for standards for free trade of national categories of fertilising products. The assessment consisted of four studies on scenarios for implementation, plant biostimulants as a new category fertilising product and two studies on the impact assessment of new European standards for contaminants. Each study is reported as a technical report. This technical report is one of the reports. The report is an impact assessment on the standards for organic micropollutants.

Contents

Preface **5**

Executive summary **9**

Samenvatting **11**

1 Organic contaminants in fertilising products and component materials **13**

1.1 Introduction 13

2 How the Dutch Fertiliser Act regulates organic contaminants **15**

3 How the FPR regulates organic contaminants **19**

3.1 Criteria for PFCs (Annex I) 19
3.2 Criteria for CMCs (Annex II) 21
3.3 Labelling Requirements (Annex III) 21
3.4 Conformity Assessment (Annex IV) 25

4 Comparison of the FPR and DFA **27**

5 Policy options for managing environmental risks for organic contaminants **31**

References **35**

Justification **37**

Executive summary

The new European fertilising products regulation (EU) 2019/1009 (FPR), after entry into force in 2022, regulates all fertilisation products. The Dutch Fertiliser Act (DFA) currently regulates the trade in and use of fertilisers in the Netherlands. This research investigates the way organic contaminants are assessed in both frameworks and formulates options for national implementation.

FPR
The FPR sets restrictions to the presence of eleven organic contaminants (eight prohibited, three limited) in fertilising products. The FPR additionally sets a concentration limit to PAH_{16} in two organic component material categories. The presence of other organic contaminants is not restricted. The FPR does require that the presence of a large number of substances, for which a maximum residue limit (MRL) or maximum level (ML) is set, is assessed *in component materials if that component material were otherwise to be placed on the market as food or feed*. If the presence of these substances is above the MRL/ML, the maximum concentration *in the fertilising product* should be recorded on the label, followed by a warning directed to end users. This labelling is not mandatory in case component materials would not qualify as food/feed. Compliance to aforementioned can either be analytically verified, or, *without testing*, be based on the nature of the manufacturing process - at the responsibility of the manufacturer.

DFA
The DFA sets limits for a long list of organic contaminants (including PAH_{10}, mineral oil, PCBs and organochlorine insecticides) for all products in four out of nine fertilising product categories. Organic contaminants in animal manure, (fertilisers for) growth medium, compost and WWTP sludge are not regulated, while the list does not apply to current EC fertilisers. The list with organic contaminants does apply to waste and by-products intended as (component material of) a fertiliser, and to fertilisers or materials for co-digestion. By expert judgement, the latter two are case-by-case assessed for other organic contaminants. This is a risk-based assessment for soil and groundwater.

Two policy options that concern organic contaminants can be considered:
1. Either the FPR legislation is implemented for all fertilising products, or a combination of both CE marked fertilising products (based on the FPR) and fertilising products for the Dutch market only (based on the DFA) is regulated. The latter option enables the trade of Dutch products, within the Netherlands, that are not CE marked.
2. Uphold, or not, the current level of protection for the environment, also for CE products. This could be done through adopting provisions concerning *the use* of EU fertilising products, subject to what is legally possible in terms of, amongst others, additional requirements on analysis of potential organic contaminants.

All combinations of options offer different benefits for producers, end users, administration, environment, and are variably flexible in responding to future developments. Recommendations are made to streamline the control of organic contaminants for the purpose of reducing waste and valorising nutrients while protecting human health and the environment.

Samenvatting

De nieuwe Europese meststoffen Verordening (EU) 2019/1009 (Fertilising Products Regulation, FPR), regelt, na inwerkingtreding in 2022, alle bemestingsproducten in het Europese handelsverkeer. De Nederlandse Meststoffenwet (MW) regelt momenteel de handel in en het gebruik van meststoffen in Nederland. Dit rapport onderzoekt de manier waarop organische verontreinigingen in beide kaders wordt beoordeeld en formuleert opties voor nationale implementatie van de FPR.

FPR
De FPR stelt eisen aan de aanwezigheid van elf organische verontreinigingen (acht verboden, drie gelimiteerd) in bemestingsproducten. De FPR stelt ook een concentratiegrens aan PAK_{16}: in twee organische '*component material categories'* (compost en digestaat). De aanwezigheid van andere organische verontreinigingen is niet beperkt. Wel vereist de FPR dat de aanwezigheid van een groot aantal stoffen, waarvoor een Maximale Residu Limiet (MRL) en/of Maximum Level (ML) is vastgesteld, wordt beoordeeld in component materials - als dat component material anders als levensmiddel of diervoeder op de markt zou worden gebracht. Indien de aanwezigheid van deze stoffen boven deze MRL ligt, dient de maximale concentratie in het bemestingsproduct op het etiket te worden vermeld, gevolgd door een waarschuwing gericht aan eindgebruikers. Deze etikettering is niet verplicht als het gaat om component materials die niet als voedsel of diervoeder zouden worden gekwalificeerd. De naleving van de criteria kan worden geverifieerd met analytische testen of, *zonder test*, door de fabrikant worden gebaseerd op de aard van het productie- en verwerkingsproces.

MW
De MW stelt grenswaarden aan een lange lijst van organische verontreinigingen (waaronder PAK_{10}, minerale olie, PCB's en organochloor-insecticiden) voor alle producten in 4 van de 9 categorieën van bemestingsproducten. Organische verontreinigingen in dierlijke mest, (meststoffen voor) groeimedium, compost en rwzi-slib zijn niet gereguleerd en de eisen zijn niet toepasbaar op de huidige EG-meststoffen. De lijst met organische verontreinigingen geldt ook voor afvalstoffen en bijproducten die bedoeld zijn als (bestanddeel van) een meststof, en voor meststoffen of materialen voor co-vergisting. Laatstgenoemden worden casusspecifiek beoordeeld op andere organische verontreinigingen, op basis van een deskundigenoordeel. Dit is een risico-gebaseerde beoordeling voor bodem en grondwater.

Twee beleidsopties die betrekking hebben op organische verontreinigingen kunnen worden overwogen:
1. Ofwel uitsluitend de FPR-wetgeving voor alle bemestingsproducten implementeren, ofwel een combinatie van implementatie van de FPR voor CE-gemarkeerde producten en het voortzetten van de MW voor bemestingsproducten bestemd voor de Nederlandse markt. De laatste optie maakt het mogelijk om Nederlandse producten te verhandelen, binnen Nederland, die niet CE-gemarkeerd zijn.
2. Nastreven, of niet, van het huidige beschermingsniveau voor het milieu, ook voor CE-producten. Dit kan door voorwaarden te verbinden aan het gebruik van EU-bemestingsproducten, onder voorbehoud van wat wettelijk mogelijk is in termen van onder meer aanvullende eisen voor de analyse van potentiële organische verontreinigingen.

Alle combinaties van opties bieden verschillende voordelen voor producenten, eindgebruikers, administratie, en het milieu, en zijn verschillend flexibel in het inspelen op toekomstige ontwikkelingen. Het rapport doet aanbevelingen om de beheersing van organische verontreinigingen te stroomlijnen om verspilling van grondstoffen te voorkomen en nutriënten te benutten, terwijl gelijktijdig de publieke gezondheid en het milieu worden beschermd.

1 Organic contaminants in fertilising products and component materials

1.1 Introduction

The Dutch Fertiliser Act (DFA, in Dutch Meststoffenwet) regulates the trade in and use of fertilisers in the Netherlands, and sets criteria to the presence of organic contaminants based on environmental risks. The new European fertilising products regulation (EU) 2019/1009 (FPR), after entry into force in 2022, regulates all fertilising products and also sets criteria to organic contaminants. The assessment of environmental risks in the FPR differs from that applied in the MW. This research investigates the way organic contaminants are assessed in both frameworks and formulates options for national implementation.

Both the FPR and DFA require that normal use of fertilising products does not pose a risk to, or affect, the environment. How the risks posed by organic contaminants is regulated clearly differs. This research describes what is arranged for environmental protection, in particular with regards to organic contaminants, in both in the DFA (Chapter 2) and the FPR (Chapter 3). The next chapter then explores the impact of the implementation of the FPR on the potential risks of the use of fertilising products for the environment (Chapter 4).

Chapter 5 explores viable policy options for regulating organic contaminants at a national level, given potential impacts on environment, regulatory preparedness for future developments, and impacts on practicability for industry and end users, as well as for regulators and enforcement. Recommendations are made to streamline the control of organic contaminants for the purpose of preventing waste and valorising nutrients, while protecting human health and the environment.

2 How the Dutch Fertiliser Act regulates organic contaminants

The Dutch Fertiliser Act (DFA, in Dutch *Meststoffenwet*) regulates the trade in and use of fertilisers in the Netherlands. The DFA distinguishes four categories which are considered fertilisers: 1) fertilisers of animal origin, 2) products to improve soil or growing media, 3) products to be used as growing media, and 4) other fertilisers for plants or parts of plants. The Fertiliser Decree (FD, in Dutch *Uitvoeringsbesluit Meststoffenwet*) subdivides the category 'other fertilisers' in terms of whether or not they are governed by EC Regulation 2003/2003 (only other inorganic fertiliser and lime fertilisers), and in terms of their composition. To distinguish an organic fertiliser from animal manure, sewage sludge and compost, the DFA distinguishes 'other organic fertiliser'. See Table 2.1 for an overview of the different fertilising products.

The FD regulates that the trade and use of fertilisers is prohibited, unless specific conditions are met. The trade ban applies for all fertilisers. To enable free trade, no quality criteria are implemented for manure or growing media. For the other fertilising products, specific requirements apply, including criteria for organic contaminants; see Table 2.1 and 2.2. For sewage sludge and compost, there are no requirements for organic contaminants.

The fertilising product might also contain contaminants that are not listed in the FD but nevertheless are not desirable. Article 6.3 of the FD states that a fertiliser should not have harmful effects on human, animal or plant health, or the environment under normal use conditions. The production process and the composition and origin of raw and/or auxiliary materials are instrumental in deciding which of these potential organic contaminants should be assessed.

Table 2.1 *Types of fertilisers and requirements according to the Fertiliser Decree (FD) that have to be met in order to be allowed to be traded as fertiliser. Note that the trading regulations of the FD do not apply to the first three categories and no requirements have to be met for these fertilisers.*

Types of fertiliser	General requirements	Specific requirement for organic contaminants
1. Animal manure	Art 6.3 Fertiliser Decree: the fertilising product has under normal conditions of use no harmful effect on human, animal or plant health or on the environment.	None
2. Growing media		
3. Inorganic EC fertilisers (EC 2003/2003) & lime fertilisers (EC/463/2013)	Art 14.c EC Regulation 2003/2003: under normal conditions of use it does not adversely affect human, animal, or plant health, or the environment.	Not applicable
4. Other inorganic fertilisers	Art 6.3 Fertiliser Decree: the fertilising product has under normal conditions of use no harmful effect on human, animal or plant health or on the environment.	See Table 2.2
5. Lime fertilisers, other than EC fertilisers		See Table 2.2
6. Sewage sludge		None
7. Compost		None
8. Recovered phosphates		See Table 2.2
9. Other organic fertilisers		See Table 2.2

A relevant provision in Article 5.1 of the FD is that fertilisers (with the exception of sewage sludge, compost and recovered phosphates) may not consist of waste materials (nor be mixed with them). The term waste in Article 1.1 of the Dutch Environmental Management Act (in Dutch: 'Wet Milieubeheer') is defined as 'all substances, mixtures or objects which the holder discards, intends to discard or must discard'. In the FD, a distinction is therefore made in the origin of the constituents that a fertiliser could consist of; waste materials or virgin materials. However, a statutory provision has been adopted that permits the use of approved and designated wastes as fertilisers or as secondary raw materials for fertiliser or biogas (digestate) production. Before wastes may be designated, these are reviewed to assess their agronomic fertilisation (nutritional)

value and any environmental risks associated with the uses. The wastes can be divided into three function categories: 1) lime fertilisers and 2) other inorganic fertilisers containing organic matter of animal or plant origin, and 3) other organic fertilisers. Waste can also be used as a secondary raw material for fertiliser production, and as a secondary raw material for biogas production via co-digestion with manure in a digestion plant. The assessment criteria and evaluation procedures are described in detail in a protocol[1] (Scientific Committee on the Nutrient Management Policy, 2016).

An Expert Committee (named in Dutch '*Werkgroep Toetsing Stoffen'*) of the Scientific Committee on the Nutrient Management of the DFA (CDM, in Dutch '*Commissie Deskundigen Meststoffenwet*'), assesses whether it is plausible that the organic micropollutants presented in Table 2.2, and other non-specified micropollutants, are present in the fertiliser and would pose an environmental risk if the fertilisers were applied. If the first cannot be ruled out, the Expert Committee can require analytical verification to determine presence and concentration levels. For example:

- For raw materials and/or auxiliary materials from primary agriculture, the Expert Committee considers whether (residues of) plant protection products can be a problem for the quality of the material when used as fertiliser.
- Raw materials and/or auxiliary materials from the animal feed industry are assessed by the Expert Committee on levels of coccidiostats and other feed additives authorised for these products.
- Raw materials and additives from the food industry must be assessed for contents of stock protection products (germination inhibitors, fungicides), disinfectants and preservatives.

For contaminants of which the environmental risks cannot be excluded, the concentrations in the environment, as a result of the application as fertiliser, are calculated. The environmental quality standards, which these contaminants should not exceed, are:

- the target value for the soil. The Maximum Permissible Concentration[2] (MPC) level must not be breached by the maximum concentration as a result of repeated yearly application. Also, the negligible risk level (NR), (equal to the MPC / 100) has to be reached within one year after the maximum concentration is reached.
- the target value for groundwater (dissolved). If no target value has been set, the predicted groundwater concentration, as a result of the yearly application, at 1 m depth is tested against a concentration of 0.1 µg per litre.

[1] Protocol for assessing the value and risks of waste used as fertiliser
[2] In Dutch: '*Maximaal toelaatbaar risiconiveau*' MTR

Table 2.2 *Maximum level of organic contaminants in fertilisers (other inorganic fertiliser and other organic fertiliser according to the FD). The values are given in mg contaminant/kg of component which adds nutritional value to the fertiliser. The maximum value that applies depends on the component that reaches a threshold value (amount) first during the application. These are: 80 kg of phosphate (P_2O_5), 100 kg of nitrogen, 150 kg of potassium (K_2O), 400 kg of neutralising value or 3000 kg of organic matter.*

	Phosphate P_2O_5	**Nitrogen N**	**Potassium K_2O**	**Neutralising value**	**Organic matter**
Σ PCDD/PCDF	0.019	0.015	0.010	0.0038	0.00051
α-HCH	310	248	165	62	8.3
β-HCH	12	9.6	6.4	2.4	0.32
γ-HCH (lindane)	1.2	0.96	0.64	0.24	0.032
HCB	31	31.2	20.8	7.8	1.0
Aldrin	7	5.6	3.7	1.4	0.2
Dieldrin	7	5.6	3.7	1.4	0.2
Σ aldrin/dieldrin	7	5.6	3.7	1.4	0.2
Endrin	7	5.6	3.7	1.4	0.2
Isodrin	7	5.6	3.7	1.4	0.2
Σ endrin/isodrin	7	5.6	3.7	1.4	0.2
Σ DDT + DDD + DDE	23	18.4	12.3	4.6	0.6
PCB-28	18.5	14.8	9.9	3.7	0.48
PCB-52	18.5	14.8	9.9	3.7	0.48
PCB-101	75	60	40	15	2
PCB-118	75	60	40	15	2
PCB-138	75	60	40	15	2
PCB-153	75	60	40	15	2
PCB-180	75	60	40	15	2
Σ 6-PCB (excl. PCB-118)	375	300	200	75	10
Naphthalene	600	480	320	120	16
Phenanthrene	750	600	400	150	20
Anthracene	600	480	320	120	16
Fluoranthene	185	148	98	37	4.9
Benzo(a)anthracene	230	184	123	46	6.1
Chrysene	230	184	123	46	6.1
Benzo(k)fluoranthene	270	216	144	54	7.2
Benzo(a)pyrene	290	232	155	58	7.7
Benzo(g,h,i)perylene	210	168	112	42	5.6
Indeno(1,2,3-c,d)pyrene	235	188	125	47	6.3
Σ 10-PAH	11500	9200	6133	2300	307
Mineral oil	935000	748000	498668	187000	24933

3 How the FPR regulates organic contaminants

The analysis in this chapter is based on the text of the EU Regulation 2019/1009, amended by a proposed delegated act[3] (further: the FPR).

All CE marked fertilising products belong to a Product Function Category (PFC). Each fertilising product needs to be composed of at least one component material category (CMC). The fertilising products are divided into different PFCs, and the component materials have to meet the criteria of one of the listed CMCs. A fertilising product can contain different component materials. A fertilising product (a blend) can be composed from different PFCs. The FPR lays down requirements for fertilising products in Annex I for the relevant PFCs and in Annex II for CMCs.

For organic contaminants, the FPR hence lays down criteria for fertilising products in all PFCs, as well as criteria for some CMCs. In addition, some requirements for the labelling of the fertilising products with regard to organic contaminants are described in the FPR Annex III. These are discussed below.

Article 4.2 of the FPR states: 'For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment'.

A relevant provision in Article 19 is that the FPR in principle permits the use of approved and designated wastes and by-products.[4] Article 42 for example then stipulates that such products cannot be included in CMCs 1 and 11.[5] Article 42 also stipulates that the Commission shall take relevant scientific opinions into account when adopting delegated acts which introduce new contaminant limit values in Annex I.

3.1 Criteria for PFCs (Annex I)

Criteria that apply to all PFCs are laid down in Annex I of the FPR Regulation. The regulation, as amended, sets strict criteria regarding organic contaminants in point 5 of Part 2 to Annex I, which apply to all CE fertilising products (all PFCs):

> 'Residues of a pharmacologically active substance within the meaning of Regulation (EC) No 470/2009 of the European Parliament and of the Council may be present in an EU fertilising product only if that substance:
> - is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, or
> - has had a reference point for action established in accordance with Commission Regulation (EU) 2019/1871, and the substance or its residues are present in the EU fertilising product at a level below that reference point.'

[3] Draft delegated regulation - Ares(2021)898281. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12135-Technical-amendments-to-the-annexes-to-the-Fertilising-Products-Regulation

[4] Art 19 FPR: 'This Regulation lays down criteria in accordance with which material that constitutes waste, as defined in Directive 2008/98/EC, can cease to be waste, if it is contained in a compliant EU fertilising product. In such cases, the recovery operation under this Regulation shall be performed before the material ceases to be waste, and the material shall be considered to comply with the conditions laid down in Article 6 of that Directive and therefore to have ceased to be waste from the moment that the EU declaration of conformity was drawn up.'

[5] Art 42: '….. Where the Commission adopts delegated acts in order to add or review component material categories so as to include materials that can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, those delegated acts shall explicitly exclude such materials from component material categories 1 and 11 of Annex II to this Regulation. …'

Maximum residue levels (MRLs) or maximum levels (MLs)

What are MRLs and MLs?
Maximum residue levels (MRLs) or maximum levels (MLs) are the maximum allowed concentrations of residues or contaminants in food and feed products obtained from animals or crops. The MRLs are established for residues that can be expected after the proper use of authorised products, such as veterinary medicines, feed additives, pesticides and biocides. MLs are set for unintentional environmental contaminants. MRLs are never higher than is considered safe on the basis of human diets and toxicological limits, and always as low as reasonably achievable. MRLs do not take into account that residues may end up in the environment, for example via fertilising products, and consequently in new crops and livestock and subsequently in food/feed products. MRLs and MLs are specific for contaminant/product combinations. These residue limits are intended to regulate the placing of food and feed on the market. Consequently, this is not allowed if the residue limits are exceeded. Also, it should be noted that such limit values do not apply to non-food/feed materials.

The role MRLs and MLs play in the FPR
In the FPR, as amended, MRLs are mentioned in Annexes I and III and MLs in Annex III, but not for the purpose of regulating the placing on the market of food and feed. Instead, they are used to identify contaminants in fertilising products that need (no) further attention.

- Annex I identifies all contaminants mentioned in one Regulation (EC No 470/2009), that are allowed to be present in EU fertilising products, regardless of the concentration. The presence of these contaminants, which are all pharmacologically active substances, is allowed based on the fact that an MRL is already established in this regulation or was deemed not necessary. The regulation also identifies eight contaminants that are not allowed to be present at all (MRL cannot be established), and three contaminants that are allowed up to a certain level (reference point of action – RPA).
- Annex III specifies that in case materials that could have been placed on the market as food/feed are used as component materials, these component materials must be analysed for all contaminants for which a (default) MRL and/or ML is derived in one or more of five different EU regulations. And if contaminants indeed are present above the MRL/ML in that food/feed product, then the resulting PFCs must be analysed for only those contaminants. The PFCs must be labelled with the measured concentrations and with a warning sentence.

What seems to be intended in terms of safeguarding in food or feed
The Annex III warning sentence reads '… the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.' The FPR does not demand that the end user demonstrate this before applying the fertilising product. Here, the end user is tasked to make sure that concentrations in crops or in livestock as a result of using the fertilising product will not exceed the MRL for that contaminant/food-/feedstuff combination. The end user automatically commits to this by marketing the crops and/or food-/feedstuff. The FPR, however, does not address how the end user can assess how and when using the fertilising product will (not) risk leading to the exceedance of the MRL in food or feed. Information on contaminant levels is relevant but is only available when food/feed is used as component material and for those contaminants that exceeded their MRL. However, such information is not available to the end user about non-food/feed component materials, or about component materials made of medicated feed, or feed fortified with feed additives, that may contain the same (and potentially higher levels of) contaminants. Note that the report on the FPR and inorganic contaminants in fertilising products in the Netherlands (Ehlert et al., 2022) further explores the challenges using MRL values for protection of human health and the environment.

What is covered by this provision? Regulation (EC) No 470/2009 lays down community procedures for the establishment of maximum residue limits (MRLs) of pharmacologically active substances in foodstuffs of animal origin. The substances for which MRLs apply are listed in the EC/37/2010. Table 1 in Annex I to Regulation 37/2010 lists the allowed substances with MRLs (or for which no MRL is required) for specific animal species and target tissues. For these substances, no residue limit values apply to fertilising products. Some labelling requirements may apply (see Section 1.3.3). Table 2 lists the prohibited substances for which an MRL cannot be established. Regulation EC/2019/1871 details how reference points for action (RPAs) for substances for which no MRL can be established can be derived and provides such RPAs for three substances. This means the following for any PFC, whether it contains animal food product components or not:

- the FPR sets limits to the following residues in any fertilising product:
  - chloramphenicol (0.15 µg/kg)
  - malachite green (0.5 µg/kg)
  - nitrofurans and their metabolites (0.5 µg/kg)

- The FPR does not allow any presence of the following residues in any fertilising product (Table 2 in the Annex to Regulation 37/2010):
  - *Aristolochia* spp. and preparations thereof[6], chloroform, chlorpromazine, colchicine, dapsone, dimetridazole, metronidazole, ronidazole.
- The FPR allows the presence of a pharmacologically active substance, regardless of its concentration, when listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.

The Annex I to the FPR does not specify that the criteria intend to manage the risk to the environment. The Annex I to the FPR also sets no criteria to the presence of any other organic contaminant in any of the PFCs. We recall Article 4 of the FPR: 'For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment'. It can be understood that any other contaminants, outside those listed by Regulation 470/2009, are to be considered as an aspect not covered by Annex I. In that case, they are regulated by the FPR, but the FPR provides no criteria for (un)acceptable risk.

It is also noted that the FPR Annex I Part 2 point 5a reads: 'An EU fertilising product shall not contain an active substance within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 giving the product a plant protection function within the meaning of Article 2(1) of that Regulation'. Basically, this stipulates that a product that would be within the scope of the plant protection product regulation cannot be a fertilising product.

3.2 Criteria for CMCs (Annex II)

The criteria for component material categories (CMCs) are laid down in Annex II of the FPR regulation. For compost (CMC 3) and digestate other than fresh crop digestate (CMC 5), neither the compost, nor the input material, nor the solid nor liquid part of the digestate shall contain more than 6 mg/kg dry matter of PAH_{16}[7].

3.3 Labelling Requirements (Annex III)

The labelling requirements of EU fertilising products are laid down in Annex III of the FPR. Part 1, point 3 stipulates:

> 'Where the EU fertilising product contains a component material which, if placed on the market as food or feed, would have been subject to maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council, maximum residue levels set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council, or maximum levels established pursuant to Council Regulation (EEC) 315/93 or Directive 2002/32/EC of the European Parliament and of the Council, and which contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.'

Annex III of the FPR, Part 1, point 3 sets no limits to the concentrations of the residues in the fertilising products. The Annex does not specify that the criteria intend to manage the risk to the environment. It deals with risks for food or feed. For this purpose, it stipulates a labelling requirement, for which information is needed on potential contaminants and on the potential that the component material could have been a food product. The substance/product combinations in scope follow from five legal acts for substances in food or feed for which MRLs or MLs have been established. An overview of the different regulations and directives is

[6] Note this is a plant species, which sets stringent limits for products that could contain such plant material.

[7] PAH_{16}: Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

given in Table 3.1. To assess the implications of these legislations on the labelling of fertilising products containing these 'food or feed' component materials, it is important to have knowledge of the content of the legislations. Therefore, these are discussed below the table.

Regulation (EC) No 470/2009

Regulation (EC) No 470/2009 lays down community procedures for the establishment of residue limits (MRLs) of **pharmacologically active substances in foodstuffs of animal origin**. This regulation was discussed earlier, as Annex I of the FPR specifies that PFCs must comply with this regulation, meaning that the presence of substances for which MRLs are derived (or MRLs were deemed not needed) is acceptable, while some substances are not allowed in fertilising products. Regarding labelling the following is of importance:

- For many pharmacologically active substances, no MRL is required, and hence no action nor labelling is required.
- For several substances, an MRL is set, hence labelling of the fertilising product is required if limits in the corresponding component material (foodstuff of animal origin) are exceeded. This has to be assessed. It should be noted that the presence in the component material should be assessed and not in the fertilising product and that a fertilising product can consist of multiple component materials. Component materials containing concentrations of substances above the MRL are allowed to be used in fertilising products.

Table 3.1 *Different types of legislation can lead to the communication of residue limits of substances in fertilising products. If a component material contains substances higher than MRLs established in legislation which would apply on the component material by placing it on the market as food or feed, then the maximum concentration in the fertilising product has to be communicated in combination with a warning that 'the product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed'.*

Legislation	Type of food or feed to which MRLs or MLs apply	Substances addressed	Are Specific substances indicated for which no MRL apply?	Are default MRLs or MLs applicable for substance/ product combinations not specifically addressed?	Other regulations that have an effect on deriving MRLs or MLs
Regulation (EC) No 470/2009	Foodstuffs (of animal origin)	Pharmacologically active substances	Yes, • For some No MRL needed • For some no MRL derived (and they are prohibited)[a]	No	
Regulation (EC) 396/2005	Food and feed (of plant and animal origin)	Pesticides	Yes, for some no MRL needed[b]	Yes, default MRL at LOD (0.01 mg/kg)	
Council Regulation (EEC) No 315/93	Food (of plant and animal origin)	Broad number of contaminants (e.g. nitrate, metals and dioxins)	No	No	Regulation applies to contaminants not subject to other legislation
Directive 2002/32/EC	Animal feed (of plant and animal origin)	Broad number of contaminants (e.g. dioxins, mycotoxins and inorganic contaminants)	No	No	
Regulation (EC) No 1831/2003	Foodstuffs (of animal origin)	Additives	Yes, for some no MRL needed[c]	No	MRLs from other regulations apply when already established

A: Table 2 to Regulation 37/2010. A reference point for action (RPA) can be established for a substance, in that case the substance is allowed in concentrations below the RPA.

B: Annex IV of Regulation (EC) 396/2005.

C: The MRL values for feed additives are published in substance-specific Commission Implementing Regulations.

- Table 2 for Regulation 37/2010 lists prohibited substances for which an MRL cannot be established. Annex I of the FPR already does not allow any presence of these residues in any fertilising product, except for substances for which a 'reference point for action' (RPA) is set. In that case, the concentration of that substance in the EU fertilising product cannot be higher than the RPA. Nevertheless, it follows from Annex III point 3 that in case a concentration *in the component material* is above this RPA, the concentration of that substance *in the fertilising product* must be mentioned on the label (even if it is below the RPA in the fertilising product), together with the warning to the person responsible for using the fertilising product. Annex I already detailed that *a fertilising product* with a concentration of that substance above its RPA cannot be placed on the market.

Regulation (EC) No 396/2005

Regulation (EC) 396/2005 applies to 315 fresh products and to the same products after processing, adjusted to take account of dilution or concentration during the process. The products to which MRLs apply are laid down in the Commission Regulation (EU) 2018/62. Legislation covers **pesticides currently or formerly used in agriculture** in or outside the EU (around 1100 substances). A general default MRL of 0.01 mg/kg applies for food or feed products where a pesticide is not specifically mentioned. The general default does not apply to the substances listed in Annex IV of Regulation 396/2005, since for these active substances no MRLs are required.

Council Regulation (EEC) No 315/93

Council Regulation (EEC) 315/93 establishes community procedures **for contaminants in food**. The regulation applies to contaminants which are not subject to other specific legislation, such as pesticides or the pharmacologically active substances mentioned above. For certain contaminants, maximum levels (MLs) are set in certain foodstuffs. The consolidated version[8] of Commission Regulation (EC) 1881/2006 contains in the annexes the MLs in the EU for: nitrate, mycotoxins, metals, 3-MCPD and 3-MCPD fatty acid esters and glycidyl fatty acid esters, dioxins and (dioxin-like) PCBs, polycyclic aromatic hydrocarbons, melamine and its structural analogues, inherent plant toxins and perchlorate. The MLs apply to the food products of plant and animal origin mentioned in the regulation.

- For several substances an ML is set, hence labelling of the fertilising product is required, if limits in the component material exceed the MLs set for this food product. This must be assessed.

Directive 2002/32/EC

Directive 2002/32/EC lays down maximum levels (MLs) of **undesirable substances in animal feed**. The consolidated version[9] of the regulation divides the undesirable substances in different sections, including inorganic contaminant and nitrogenous compounds, mycotoxins, inherent plant toxins, organochlorine compounds (except dioxins and PCBs), dioxins and PCBs, harmful botanical impurities and lastly authorised feed additives in non-target feed following unavoidable carry-over. MLs are listed for individual substances and different types of feed materials. Directive 2002/32/EC also prohibits the dilution of contaminated feed materials.

- For several substances, an ML is set; hence labelling of the fertilising product is required, if limits in the component material are exceeded. This has to be assessed.

A number of Commission recommendations also have implications on the contaminants in animal feed. These are particularly related to mycotoxins:

- Commission Recommendation 2006/583/EC on the prevention and reduction of Fusarium toxins in cereals and cereal products.
  - Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding as amended by 2013/637/EU of 4 November 2014 as regards T-2 and HT-2 toxin in compound feed for cats.
- Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of the T-2 and HT-2 toxin in cereals and cereal products. This applies for animals when the cereals and cereal products are intended for animal feed.

[8] Latest date 14/10/2020 at time of visit.
[9] Latest date 28/11/2019 at time of visit.

Regulation (EC) No 1831/2003

The purpose of Regulation (EC) No 1831/2003 is authorising the placing on the market and use of **feed additives** and to lay down rules for the supervision and labelling of feed additives and premixtures. One aspect of the regulation lays out the procedures to establish maximum residue limits (MRLs) in foodstuffs of animal origin, i.e., the animal food products obtained from the animals fed with feed containing the additives. When a feed additive is authorised, an MRL is established for relevant foodstuffs of animal origin, unless the authority's opinion concludes that the establishment of MRLs is not necessary for consumer protection. The Commission has established the European Union Register of Feed Additives, which is regularly updated. Annex I of the register holds all the additives authorised. The MRL values for feed additives are published in substance-specific Commission Implementing Regulations. For example the MRL for salinomycin is published here.[10] The Commission Implementing Regulations for the different feed additives can be accessed via the European Union Register of Feed Additives[11], which is regularly updated.

In summary:

- For those substances where no MRL is required, no action nor labelling is required.
- Labelling of the fertilising product is required, if the component material is a foodstuff (of animal origin) and (one of) the established MRLs for this foodstuff are exceeded. This has to be assessed.
- In case fortified animal feed would be intended as component material, it should be noted that the MRLs referred to here do not apply to the substances added to this feed. The Commission Implementing Regulations concerning the authorisation of feed additives also set minimum and maximum concentrations of the additive in the complete feedingstuff (mg of active substance/kg of complete feedingstuff with a moisture content of 12%). The MRL to which the FPR refers is thus not set for the animal feed fortified with the additive but for the foodstuffs obtained from animals fed with the feed containing these additives. The same situation holds for expired or obsolete *medicated* feed (with components of animal origin) (Regulation 2019/4), if directed towards the FPR as a component material. The MRL for veterinary medicines in food or feed (set by Regulation 470/2009) is not set for the medicines added to the medicated feed. As a consequence, if obsolete animal feed with feed additives or medication is intended as a component material, those additives and medicines do not have to be assessed.
- It also follows that animal feed that contains foodstuff not of animal origin (for example when it is only plant material), is not subjected to the MRLs of 470/2009 nor 1831/2003 (since these MRLs are for animal products), even if it would contain such contaminants.

Implications

There are several lists of combinations of substances and food/feed products for which MRLs and MLs have been established. There are also substances identified for which an MRL or ML is not established (in that case the substance is not allowed at any concentration), or not required (in that case the substance is allowed regardless of the concentration). These lists contain several hundreds of combination of substances and products and are not static, but are regularly revised. It follows that the consolidated versions at the time of the marketing of the fertilising product are to be observed.

The General Labelling Requirements require that the producer supply instructions for intended use, including application rates, timing and frequency, and target plants or mushrooms. The producer must also supply any relevant information on measures recommended to manage risks to human, animal or plant health, or to the environment. It follows from the information presented above that regarding contaminants, the labelling information and the general warning sentence suffice to fulfil these obligations and that further instructions are not needed to manage the risks.

The labelling requirement places the responsibility:

- For demonstrating that any component material would have been subject to the MRLs or maximum levels (MLs) in the listed legislation, or not, at the producer
- For demonstrating the presence of all of the substances for which MRLs or MLs were set, in the component materials for which the MRLs or MLs apply, at the producer
- For demonstrating the maximum concentration in the fertilising product, of any substance that exceeds the MRL or ML in the component material, at the producer

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1914&rid=7

[11] Last accessed release date: 21-01-2021

- For indicating the maximum concentration of the respective substance(s) in the fertilising product, and issuing a warning, on the label, at the producer
- For the safe use of the fertilising product, i.e., that the use does not lead to the exceedance of that limit in food or feed, at the end user of the fertilising product (**There is no guidance on how the end user must comply with this requirement.**)

We emphasise that these requirements for labelling do not apply for any other organic component materials that could by definition not be placed on the market as food or feed (e.g. plant stems, some animal by-products), although they may contain the same contaminants as food (e.g. tomatoes, meat).

3.4 Conformity Assessment (Annex IV)

The FPR Annex IV, part II, gives the description of conformity assessment procedures. Here, it is stated that the manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The documentation shall contain (amongst others) 'results of calculations made, examinations carried out, etc.' The conformity assessment procedure does not specify which calculations or examinations must be performed or how. However, to assess the conformity to the relevant requirements, information has to be available on contaminants that have to be assessed with regard to Annex I, II and III.

From this follows that in the conformity assessment procedure, the presence (and level) or absence of several contaminants has to be assessed. Some requirements apply to all fertilising products (Annex I), only one requirement to two specific CMCs (Annex II), and some specifically to a very narrow selection of 'food or feed' component materials (Annex III). We note, however, what is arranged in Annex I, part II, under point 4: 'Where compliance with a given requirement follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer.' In principle, the manufacturer can take the responsibility not to perform testing when claiming compliance.

4 Comparison of the FPR and DFA

In summary, the FPR and DFA can be summarised and compared with regards to organic contaminants as follows.

FPR
The FPR sets restrictions to the presence of certain specific organic contaminants in fertilising products:

- Restrictions for eleven organic contaminants in any fertilising product: chloramphenicol (0.15 µg/kg), malachite green (0.5 µg/kg), and nitrofurans and their metabolites (0.5 µg/kg)). The FPR does (currently) not allow any presence in any fertilising product of *Aristolochia spp.* and preparations thereof[12], chloroform, chlorpromazine, colchicine, dapsone, dimetridazole, metronidazole, and ronidazole. Since it concerns veterinary medicines that are banned in livestock, it is unclear from what component material such residues could arise. We note that the criteria in Annex I on organic contaminants can be modified by the Commission.
- There are concentration limits to PAH_{16}: 6 mg/kg dry matter in compost (CMC 3) or in input material, or solid or the liquid part, of the digestate other than fresh crop digestate (CMC 5). Therefore, compost must be checked on PAH_{16} (in contrast to PAH_{10} in the DFA).

The presence of other organic contaminants is not restricted in Annex I or II.

The FPR does require that the presence or absence of a large number of substances is assessed *in component materials* for which an MRL is established, *if* that component material were otherwise to be placed on the market as food or feed. If the presence of these substances is above this MRL, the maximum concentration *in the fertilising product* should be put on the label, followed by a warning. Which MRL values are in scope for what 'food or feed' material, is specific per substance and component material.

The presence of all contaminants that would be in scope, either in the fertilising product (Annex I), in the CMC (Annex II), or in the component material (Annex III), can either be verified with analytical testing, or the compliance can be based, without testing, on the nature of the manufacturing process - at the responsibility of the manufacturer.

The Annexes I, II and III do not specify that the criteria intend to manage the risk to the environment, even though Annex III lists labelling requirements, which includes the communication of 'any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment'. The criteria in Annex III aim at the safety of food and feed produced using the fertiliser products.

DFA
The DFA has a long list of limits for organic contaminants (including PAH10, mineral oil, PCBs and organochlorine insecticides) for all products in 4 out of 9 fertilising product categories:

- Other inorganic fertilisers
- Lime fertilisers
- Recovered phosphates
- Other organic fertilisers

Organic contaminants in animal manure, growth medium, compost and WWTP sludge are not regulated in the DFA. EC fertilisers are also not further assessed.

The list with organic contaminants also applies to:

- Waste and by-products intended as component material of a fertiliser
- Fertiliser or material for co-digestion

[12] Note this is a plant species, which sets stringent limits for component materials that could be composed of such plant material.

Additionally, the last two are case-by-case assessed for other, non-specified, organic contaminants, based on expert judgement. This is a risk-based assessment for soil and groundwater.

The DFA does not specify that the criteria intend to manage the safety of food and feed produced using the fertiliser products. The criteria aim at protecting the quality of soil and groundwater.

Table 4.1 *Quality standards to which products regulated by the Dutch Manure and Fertilisers Act and the EU Fertilising Product Regulation have to comply. Note that a PFC can contain any CMC in principle, but in this table only CMCs are presented that contain requirements for organic contaminants.*

Dutch Manure and Fertilisers Act – product categories	**Quality standards**	**EU Fertilising Product Regulation – product categories (PFCs)**	**Quality standards**
Animal manure	-	PFC 1. Fertiliser (organic, organo-mineral or inorganic)	Organic contaminants (when consisting of CMC 3 and/or CMC 5 [b] or of foodstuffs of animal origin [c])
Growing media	-	PFC 2. Liming material	
EC fertilisers & liming fertilisers	-	PFC 3. Soil improver (organic or inorganic)	
Other inorganic fertilisers	Organic contaminants (when fertiliser is from animal or plant origin) (FD) [a]	PFC 4. Growing Medium	
Lime fertilisers excluding EC-liming fertilisers	Organic contaminants (when fertiliser is from animal or plant origin) (FD)	PFC 5. Inhibitor (nitrification, denitrification or urease)	
Sewage sludge	-	PFC 6. Plant biostimulant (microbial or non-microbial)	
Compost	-	PFC 7. Fertilising product blend	
Recovered phosphates	Organic contaminants (FD)		
Other organic fertilisers	Organic contaminants (FD)		
Designated waste (when not harmful for the environment)	Organic contaminants (FD) Other expected organic contaminants		

A: Organic contaminants listed in the Fertiliser Decree (‘*Uitvoeringsbesluit Meststoffenwet*’) and implementation regulation of the Fertiliser Act (‘*Uitvoeringsregeling Meststoffenwet*’).

B: Organic contaminants listed in EU fertilising Product Regulation. CMC 3: Compost, CMC 5: Digestate other than fresh crop digestate.

C: List of pharmacologically active substances prohibited by Annex I (Table 2) to regulation 37/2010 or with an RPA (Reference Point for Action) as threshold.

Analysis

The labelling requirements in the FPR Annex III place a huge burden on the manufacturer where component materials are involved that could have been marketed as food or feed, regardless of the fraction of this component material in the fertilising product.

The manufacturer has to analyse these component materials for over a thousand contaminants, and, if one or more are present above the limits, he has to indicate what the level would be in the fertilising products for those contaminants.

This may be done by analysis or by calculations. This then results in a warning on the label, with additional information on residue levels. This administrative burden can be avoided if the manufacturer argues (and takes the responsibility) that compliance follows from the manufacturing process, and that testing is not needed, and no levels or warnings need to be given.

For other non-food and non-feed component materials, with similar or higher residues (animal by-product, non-food plant materials, waste streams from food industry), or for other contaminants (e.g. SVHCs in auxiliary products like detergents or flocculants), no requirements are set.

Under the DFA, based on expert judgement, most likely those component materials – assuming they would be assessed as waste to be used as a fertiliser, fertiliser component, or material for co-digestion - would be subjected to data requirements and an environmental risk assessment. However, in the Netherlands it is possible to direct component materials to compost, if they would not meet the DFA standards for use in organic fertilisers, or organic soil improver or growth medium. Via this route, it is possible that the protection offered by the DFA by not authorising certain component materials for use in fertiliser products, has no effect; the component material is then turned into compost. Under the FPR the data requirements are linked to the component material, and hence the destination (compost or other) makes no difference. However, as mentioned, the FPR currently sets few specific restrictions on organic contaminants.

5 Policy options for managing environmental risks for organic contaminants

Both the Fertilising Products Regulation (FPR) and the Dutch Fertiliser Act (DFA) require that the normal use of fertilising products does not pose a risk to the environment. This has been the basis for the current provisions and protocol in the DFA and the subordinate regulations on the environmental risks of organic contaminants, as reviewed in this chapter. The FPR currently does not set limits to contaminants (except for PAH_{16}) that are plausibly present in major component materials, in contrast to the DFA and the approach for materials dealt with in the CDM protocol.

Two policy decisions involving organic contaminants should be made:

1. Either solely the FPR legislation should be implemented or a combination of implementing the FPR for CE-marked products and continuing the DFA for fertilising products on the Dutch market only. The latter option enables the trade of Dutch products, within the Netherlands, that are not CE marked.
2. Uphold, or not, the current level of protection for the environment where it concerns organic contaminants, also for CE products. If so, this could be done by adopting provisions concerning the use of EU fertilising products. The FPR states in Article 3.3: '*This Regulation shall not prevent Member States from maintaining or adopting provisions for the purpose of protecting human health and the environment which are in compliance with the Treaties, concerning the use of EU fertilising products, provided that those provisions do not require modification of EU fertilising products which are in compliance with this Regulation and do not influence the conditions for making them available on the market.*' The burden of proof is in that event on the Member State. It requires further investigation how CE products can be assessed to underpin such provisions (e.g. a maximum loading rate), given a lack of information on the presence of potential contaminants. At least with products that do report concentration levels, this information can be used to determine potential environmental risks, e.g., according to the Dutch protocol, and relevant provision for the use. For other potential contaminants, there is no information available, and it is recommended to investigate what is legally possible in terms of additional provisions or requirements (dosage regulations, measurements, other measures).

Depending on what can actually be arranged for organic contaminants in these policy options for national products and for the use of EU products, there are different implications. Assuming that organic contaminants will be regulated on environmental risk for (Dutch) NL products (if opted) and via the use of (CE-marked) EU products (if opted), the tables below illustrate possible effects of the policy options on:

- administration and inspection
- trade
- environmental quality
- users
- future developments

Table 1.1 *The impact of policy options for regulating fertilising products on administration and inspection for the government.*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Conformity check on 11 organic contaminants in any product. PAH_{16} in products containing CMC3 and/or CMC5. If fertiliser contains a 'food' or 'feed' component material, check on >1000 organic contaminants. Check argumentation on compliance.	CE products: Conformity check on 11 organic contaminants in any product. PAH_{16} in products containing CMC3 and/or CMC5. If the fertiliser contains a 'food' or 'feed' component material: check on >1000 organic contaminants. Check argumentation on compliance. NL products: Administrative burden for NL products as it currently is.
Adopt provisions for the use of EU products	Additionally to the conformity check, assess fertilisers on organic contaminants and issue provisions on use for EU products.	CE products: In addition, assess fertilisers on organic contaminants and issue provisions on use for EU products. NL products: Administrative burden for NL products as it is currently.

Table 5.2 *The impact of policy options for regulating fertilising products on trade (for producers).*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Level playing field within NL.	The manufacturer can choose which option has least barriers (e.g. administrative costs and meeting quality criteria).
Adopt provisions for the use of EU products	Certain products may be marketed only abroad and end up in countries with less strict standards.	

Table 5.3 *The impact of policy options for regulating fertilising products and impact on environmental quality.*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Organic contaminants are not assessed, except PAH-16, for 'compost products' and 11 pharmacologically active substances. For certain contaminants, the concentrations might be placed on the label.	CE products: organic contaminants are not assessed except PAH-16 for 'compost products' and 11 pharmacologically active substances. NL products: All relevant organic contaminants would be evaluated. Compost is, however, not assessed.
Adopt provisions for the use of EU products	Impact on environmental quality can be assessed for the known contaminants. The unknown contaminants might not be assessed, as demanding new measurements might intervene with free trade.	

Table 5.4 *Policy options for regulating fertilising products and impact on end users (from an environmental perspective)*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Impact on soil and produce is unclear, end user is not guided how to determine the potential impacts.	Impact on soil and produce is clear for the end user for NL products only.
Adopt provisions for the use of EU products	The quality of the production soil can be protected; quality of crops and animal products (MRL) can be guided and therefore protected.	

Table 5.5 *Policy options for regulating fertilising products and impact on end users (from a use perspective)*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Level playing field within NL.	The end user can choose between EU and NL products based on their own preferences, e.g., safety information, application guidance, price.
Adopt provisions for the use of EU products	Can create a level playing field for both CE and NL products.	

Table 5.6 *The impact of policy options for regulating fertilising products and preparedness for future developments.*

	Only CE products	**Both CE and NL products**
No provisions for the use of EU products	Not flexible. The FPR allows the Commission to amend the annexes, but this can take a lot of time.	Flexible. NL products can facilitate (new) products for which CE labelling is not (yet) an option.
Adopt provisions for the use of EU products	Potentially flexible, depending on access to information on composition.	Most flexible.

From the perspective of safeguarding environmental quality, we make the following recommendations:

1. It is recommended to clarify what is now arranged in the FPR, satisfies Article 4.2 of the FPR: 'For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment'. The analysis made in this report assumes that all *relevant* aspects are indeed covered by Annex I or II. Should it be understood that risks arising from residues of organic contaminants not covered by the current provisions, for example for contaminants for which no MRLs are established, or for component materials that are not food/feed, still need consideration, then further implications should be explored.
2. It is recommended to investigate what is legally possible in terms of additional provisions or data requirements (dosage regulations, measurements, other measures) concerning the use of EU fertilising products, for the purpose of protecting human health and the environment which are in compliance with the Treaties.
3. It is recommended to set environmental protection goals within a flexible legal framework, anticipating (new) contaminants like Substances of Very High Concern, PFAS, pharmaceuticals, and plant protection products, but also new types of fertiliser products (e.g. struvite, biochar), and future policy developments e.g. in the context of Circular Economy.
4. It is recommended to update the default list of organic contaminants of the DFA when the list will still be used as a standard to determine the safe use of fertilisers. The original list with organic contaminants in the DFA was based on a study performed in 1994 (Olde Venterink and Linders, 1994). Afterward, a number of very persistent active substances were banned in a European context, and the use substances have been phased out. The list should include other organic micropollutants in line with designated treatment processes from which the waste and residues are released.
5. It is recommended to assess all fertiliser types, including compost and sludge, against the same standards (tailored where needed).
6. It is recommended to develop a (long) list of known and expected contaminants in fertilisers, which can be tailored (shortlisted) for each fertiliser based on the origin of the material, the production process and the life cycle.
7. It is considered that incorporating MRLs in crops grown after applying the fertiliser product, as criteria in both the methodology of the DFA and to formulate NL-provisions for use for EU products, does not provide the same level of protection to the environment as explicit environmental criteria do. It may lead to less protection or it may lead to more stringent standards, depending on the crop, product and contaminant. It may even lead to (contaminated) fertiliser products being marketed specifically for *non-food* crops (bioethanol, flax, oilseeds, flower bulbs, flowers, ornamentals), for which no MRLs apply, which would defy the rationale.
8. It is recommended to bring the issue, that exposure of soil is always possible though the reuse of organic materials in fertiliser products, to the attention of the respective agencies (EFSA plant protection

products, feed additives; ECHA biocides, REACH; EMA veterinary medicines). Under the European circular economy action plan as well as the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM/2020/667 final), the risk assessment for product authorisation should include a life cycle stage of valorising nutrients, and data requirements and methodology should be harmonised (one substance, one assessment).

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