PROPOSAL STANDARDS FRAMEWORK PFAS

Karl Vrancken
PFAS Commissioner
for the Government of Flanders

9 November 2022

ADJUSTMENT OF THE PFAS STANDARDS FRAMEWORK

Assessment values of soil remediation and free use

Assignment

Managing PFAS contamination in soil and groundwater requires a standards framework that provides clarity about the maximum allowed concentrations in function of the use of soil and groundwater. Exposure to PFAS needs to be restricted to the absolute minimum. In order to do this as correctly as possible, it is imperative to carry out a scientific assessment of the risks.

In his second report,[1] the PFAS Commissioner introduced a temporary action framework with an indicative 'environmental policy' perspective. This framework took into account developments in the field of Flemish and European standards, the application and optimization of BAT frameworks and the tools within the permit policy. Linked to a preventive health-related approach, this temporary framework tightened the existing values.

In the meantime several stakeholders (companies, citizens, etc.) have indicated the need for legal anchoring of these standards in order to obtain more legal certainty. In addition, new insights were gained about the measurements of background values in food. These developments have urged the need of a revision, as announced in March 2022,

This discussion paper describes the update of the PFAS standards framework that takes into account the EFSA 2020 health-based guidance value (HBVG). It seems impossible to convert the EFSA HBVG for the sum of 4 PFAS into a standard for those 4 compounds. Additional assumptions are followed to achieve individual reference values for PFOS and PFOA, which will be based on the full EFSA dose. Furthermore, the limit value for free use of soil was updated and supplemented with a test criterion for architectural land use, applying the European drinking water standard as a reference value.

VITO carried out the update of the standards framework, which was subsequently subjected to a peer review by the Remediation and Earthmoving Committee, consisting of academic experts and experts in the field, applying these standards. A detailed description of the method for deriving the standards framework can be found in the scientific background document ('Binding standards framework for PFOS and PFOA', VITO, 5 October 2022, hereinafter referred to as 'the VITO report'). The main points of discussion and how they are included in the consensus proposal are set out in the opinion of the Remediation and Earthmoving Committee, dated 6 October 2022. Based on the VITO report, a discussion paper was presented to Flemish stakeholders. The latter are sector and umbrella organisations of industries and enterprises concerned. Several of these organisations indicated that the response time was too short for surveying their members properly. Despite the limited time frame, the input from the stakeholders is included in the proposal

[1] https://www.vlaanderen.be/pfas-vervuiling/summary-of-second-interim-report-on-the-pfas-contamination

presented below. After legal translation, this document will serve as the basis for a proposal to be submitted to the Government of Flanders.

Policy principles and preconditions

PFAS are persistent, bio-accumulating and mobile. This combination ensures that these substances break down poorly in the environment. They accumulate in humans, in soil, in groundwater and surface water and they can be transported over large distances. Therefore, the spread must be limited even when it concerns low doses. Policies need to consider the specificity of these substances when approaching them in the same way as other pollutants that cause health risks. The action framework must fit within the existing legislation.

Creating a framework of standards for soil pollutants involves explicit policy choices. Since zero risk cannot be achieved, VITO calculated the risks of certain choices in the report, starting from the existing regulatory policy frameworks and the associated methodologies to derive standards, consistent with the standardisation approach for other pollutants, such as PAHs or heavy metals.[2]

The present proposal provides an additional substantiation and adjustment of the temporary action framework of March 2022. The new framework will also be more embedded in law. Because of the rapid scientific evolutions around PFAS, they will be consider as 'non- standardized parameters' for the time being. As long as the proposed standards framework for PFOS and PFOA is not included in VLAREBO, they are considered non-parameters and defined as 'reference values'.

The scope of this discussion paper is to develop an assessment framework, without focusing on the practical application and implementation of the earthmoving regulations, the VLAREBO or the applicable codes of good practice. Where necessary, these aspects will be further developed at a later stage.

A new change to the standards framework may be introduced in the future:

- when new data are available on the health risk of PFAS other than PFOS or PFOA;
- when new insights are gained about the transfer factors between soil and crop (nutrition);
- on the basis of new data allowing comparison of different PFAS in terms of their toxicity;
- with scientific clarity about background concentrations and leaching behaviour of PFAS.

In the medium term, the expert Commission recommends to asses pollution problems in a more integrated way, taking an ecosystem services and biodiversity perspective, according to progress in relevant scientific knowledge.

Soil experts should not only be given a standards framework, they also need to know how to apply the standards in soil research. Therefore, the soil policy also provides the necessary tools and instruments to facilitate site-specific risk assessments. Risk assessments can, for example, consider the use of groundwater,

[2] The methodology used to draw up a framework of standards is described in the 'Basic information for risk assessment: Working method for drawing up soil remediation standards and assessment values, guide values and target values' (OVAM, 2016).a). Deriving the values for the free use of soil materials in the context of earthmoving (WVG) is described in the document 'Derivation and substantiation of the common framework of standards for raw materials and excavated soil in Flanders' (OVAM, 2015).

the presence of vegetable gardens, the risk of spreading dust, etc. for a particular site. VITO and the Remediation and Earthmoving Committee have made concrete proposals for this.

Proposal for assessment values for fixed parts of the soil

The adjusted assessment values for soil remediation for different types of land use are presented in the table below.

Destination type	I/II	III	IV	V
PFOS (µg/kg)	3,8*	4,9	110	268
PFOA (µg/kg)	2,5*	7,9	632	303

*adjusted standard based on the value of free use (see below)

An assessment value always applies to a certain destination type. Destination type I/II is agriculture/nature, destination type III is housing, IV is recreation and V is industry. When drawing up the assessment values, risks to humans as well as risks to the environment are considered. The more stringent value of the two provides the assessment value. The distinction between standards in the different destination types is due to variance in human exposure during normal activities in the area concerned. The ecological thresholds for destination type IV are lower than the human toxicological ones and are therefore adopted as the proposed assessment value.

In order to derive the assessment value, a health-related limit value must be selected. The tolerable weekly intake (TWI) for 4 PFAS (PFOS, PFOA, PFHxS and PFNA), as determined by EFSA in 2020, is the most recent and appropriate value for this and amounts to 0.63 ng/kg body weight per day. Calculating this value as a sum is not feasible due to insufficient data on the health effects of PFHxS and PFNA. As a result, no assessment values can be determined for these two components. EFSA has set a standard for intake but does not indicate how this should be converted into a soil standard. Splitting the dose up evenly over the 4 components also gives rise to assessment values, which are lower than the current average soil quality in Flanders (the target value). The Remediation and Earthmoving Committee agreed to an approach whereby the full EFSA dose is allocated to PFOS and to PFOA separately for technical reasons in the absence of soil transfer figures. And so this is an approach in which more than the EFSA dose may be allowed in highly contaminated areas. The Commission therefore asked for this risk to be clearly calculated. This calculation and further motivation of the calculation rules are described in detail in the VITO report. The risk calculations for the soil remediation test values indicate that in worst case conditions, i.e. simultaneous contamination with PFOS and PFOA and at maximum exposure, the EFSA dose could be exceeded by a factor of 10-12.

PFAS levels measured in blood serum of young people in Flanders (general population) exceed the EFSA-based reference value in about 10% of the population. 90% of young people therefore have lower levels. 95% of the population has less than twice the health assessment value (sum 4 PFAS). This gives indications that the model calculations used to derive the reference values may be very conservative.

The derivation of the norm considers the background exposure from food, which is the dose that the average Belgian receives through his daily food intake. EFSA set that dose for all EU countries in 2012 and

in 2020. These results show that the dose is decreasing. Measurements by the Federal Agency for the Safety of the Food Chain (FASFC) in March 2022 show that the PFAS values in Flemish food products are in line with the values published by EFSA in 2020. These EFSA 2020 background values were therefore used in the new calculations. Additionally, the exposure of adults was used in the calculations.[3] This choice was made from a technical point of view and is not entirely in line with the EFSA approach. However, by limiting exposure to mothers, their children will also be protected.

Application of the destination type II method described above leads to calculated assessment values below the target value. Therefore, the value was calculated on the basis of the free use value (see below).

Groundwater assessment value

The assessment value for the soil remediation standard for groundwater is the European limit for drinking water (EU Directive 2020/2184).[4] This is 0.1 µg/l or 100 ng/l for the sum of 20 PFAS and 0.5 µg/l or 500 ng/l for the sum of all PFAS. For the time being, no groundwater soil remediation standards for individual PFAS are applied. This assessment value was already applicable in the temporary action framework of March 2022.

A process for deriving groundwater standards is ongoing at European level. These evolutions are actively monitored for the purpose of transposing them into Flemish legislation.

Value for free use of soil

The value free use (VFU) is the concentration at which soil, which is already present in the environment, can be reused while retaining all functions. This value also protects the recipient of a batch of (purchased) soil against possible contamination problems. The value free use indicates which soil is considered clean. On the one hand determining the value free use of soil takes into account leaching (risk-based limit values) as much as possible. On the other hand, there must be a sufficiently large difference in policy terms between the target value (average uncontaminated soil quality), the value free use and the soil remediation standard for destination type II. The value free use is at least twice the target value. The reference value for type I/II is at least 80% above the value free use. This is the standard method in Flemish policy to determine the value free use, not only for PFAS, but also for other substances. [5,6] In this way both, the value free use and the minimum assessment value for soil remediation standard type I/II, are calculated from the target value.

The table below shows the limit of quantification (LOQ), target values (TV) and the adjusted assessment value soil remediation standards for type I/II:

---

[3] see 'From Knowledge to Action', 2[of] report PFAS assignment holder, https://www.vlaanderen.be/pfas-vervuiling/tweede-rapport-opdrachthouder

[4] https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:32020L2184&from=EN

[5] https://ovam.vlaanderen.be/documents/177281/0/Principes+bij+het+afleiden+van+de+waarde+vrij+gebruik+en+de+waarde+voor+bouwkundig+bodemgebruik.pdf/0c9b85b3-6100-40ca-2920-0ba34a4fef79?t=1647343885222&download=true

[6] https://ovam.vlaanderen.be/documents/177281/0/Afleiding+en+onderbouwing+gemeenschappelijk+normenkader+voor+grondstoffen+en+uitgegraven+bodem+in+Vlaanderen.pdf/c0eb30b4-6111-1bee-37e1-3b934d1da5f4?t=1654775685419&download=true

Parameter	LOQ	TV	VFU	AV I/II
PFOS (µg/kg)	0,2	1,5	3,0	3,8
PFOA (µg/kg)	0,2	1,0	2,0	2,5

If soils comply with the value free use (3 µg/kg DS PFOS, 2 µg/kg DS PFOA, 8 µg/kg DS sum PFAS), unlimited reuse is permitted both as soil and in architectural applications. Materials that comply with the values of free use and are intended to be applied under water or in drinking water abstraction areas must be subjected to a quality test before they can be used. In this way possible contamination of surface water and drinking water is prevented.

Data	PFOS	PFOA	sum PFAS
Free use value (µg/kg DS)	3	2	8

Data requested from the soil management organisations (Grondbank, Grondwijzer) indicates that in 14% of the soil analyses (out of a total of 4947 analyses) this 3-2-8 criterion is exceeded. This means that 86% of the soil samples tested meet the free use criterion.

Risk assessment for adjusted value free use

If the derivation of the reference values were to be made solely on the basis of human risk for destination types I and II, then we end up with reference values of respectively 0,2 µg/kg PFOS and 0,6 µg/kg PFOA. These values are lower than the average concentration in uncontaminated soil (the target value) and are at or just above the limit of determination. Consequently, they are not enforceable and a switch to the calculation rules explained above to determine the attribution value has to be made.

In this respect, the standard setting implies that we accept a certain risk. The Remediation and Earthmoving Committee unanimously agrees with this approach, but wants to clarify the risk. The VITO report estimates these risks based on worst-case assumptions. For an average soil, it appears that the value free use can lead to groundwater concentrations, that exceed the drinking water quality by a factor of 5-13. On the other hand, recent research by VMM shows that the groundwater in Flanders meets the drinking water standard.

The value calculated in this way implies a confirmation of the applicable value free use for PFOS of 3 µg/kg ds. For PFOA, the applicable value is adjusted from 3 µg/kg ds to 2 µg/kg ds. This is to maintain full consistency with PFOS and other parameters. In addition to the specific value free use for PFAS and PFOA, a sum parameter of 8 µg/kg ds is applied for the sum of all PFAS. There is no proposal for changing this value.

Working with the assessment values of solid soil

As long as the proposed PFAS assessment values are not included as a soil remediation standard in Annex IV of VLAREBO, PFAS will be considered as non-standardized parameters.

This means that the proposed assessment values for soil remediation standard, in the context of soil investigations, are mainly used to assess the presence of serious soil contamination in the preliminary/exploratory soil investigation (PSI/ESI). This investigation, conducted by an expert, entails an analysis of the 'clear indication of serious soil contamination (CISSC), a scoring system laid down by OVAM,

If OVAM's CISSC methodology (as part of the standard ESI procedure) clearly indicates a serious soil contamination, a descriptive soil investigation (DSI) is required. In that DSI, the proposed soil remediation standards and guide values/values free reuse are solely applied for the purpose of mapping the extent of the pollution.

On the basis of a site-specific risk assessment, with a separate assessment of the human risk, the ecotoxicological risk and the risk of spreading, it will be decided whether control measures are necessary or if a soil remediation project needs to be developed.

The scientific report further discusses the implications of the standards framework on the CISSC and more specifically the aspects of leaching into groundwater, living with a vegetable garden, the presence of a chicken coop and the presence of other PFAS. In this way, the soil remediation expert is provided with additional tools to apply the assessment values site-specific within the contours of the current soil policy.

Derivation value architectural land use

Soils with a higher concentration than the value free use may be used for specific architectural applications. As there are for example, embankments, sub-bases for roadworks,.. where the contaminated soil used, is not in direct contact with the environment. In such earthworks, a top layer is always provided, a solid layer on top of the used and slightly contaminated soil. Infiltration of water, and consequently leaching of the contamination, is therefore limited.

The VITO report studies a two-pronged approach: standardisation of the total concentration or of the leaching value. The risk assessment of the value free use shows that already at that quality (VFU, 3-2-8 criterion) there is a potential risk of exceeding the groundwater reference value. In order to maximise the protection of the groundwater quality, it is therefore decided to let the leaching criterion prevail for architectural application. In general, the total concentration for architectural land use should never exceed the highest soil remediation threshold value (to date always SRTV V). In addition, a generic leaching criterion for architectural land use is introduced, whereby the leaching must comply with a threshold value of 0.1 μg/l sum 20 PFAS and 0.5 μg/l for sum PFAS total, in accordance with the reference value for groundwater.

The use of soil in architectural applications can only happen after going through a decision procedure, elaborated below.

Working with the values free use and an approach to architectural applications

For handling soil and earthmoving, the general principles of VLAREBO continue to apply like for example in connection with soil reuse and architectural applications. This proposal for a standards framework does not change that.

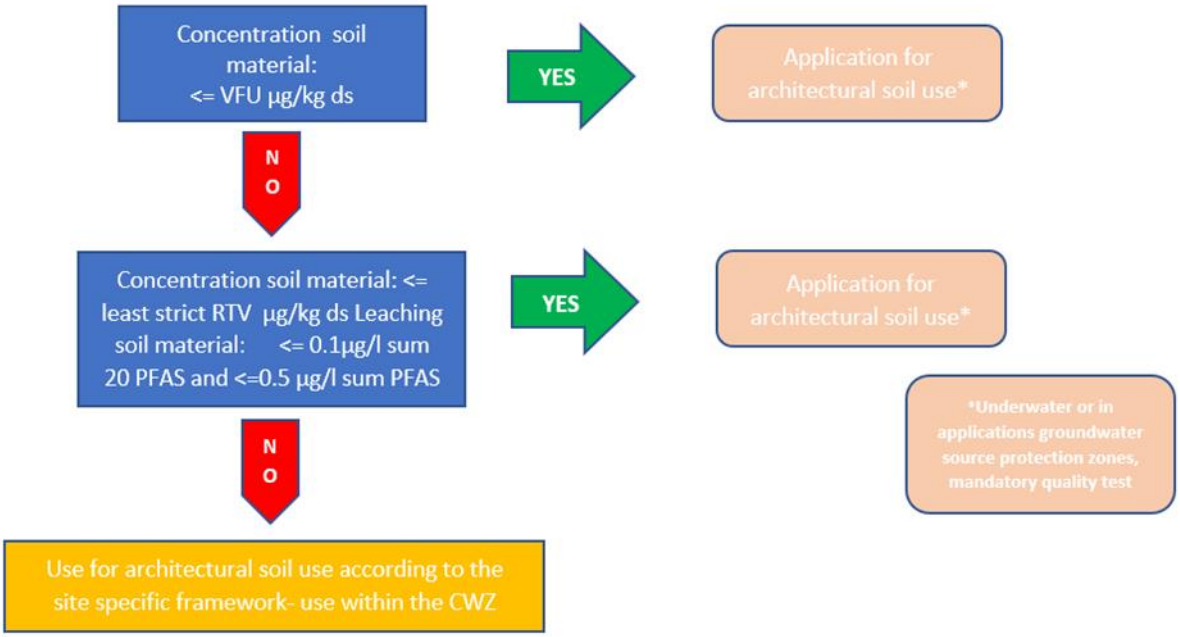
A decision tree was created for dealing with values of free use and architectural land use. 2 parts can be distinguished here: a generic part and a location-specific evaluation.

Generic part

For underwater applications and applications groundwater source protection zones (SPZs), a quality test is mandatory, both for application as soil and for application in architectural land use and as a dimensionally stable product. In these areas application is only possible if a quality test shows that there is no additional risk to the quality of the surface water or water intended for drinking water. This quality test is conducted by a certified soil remediation expert.

If soils comply with the value free use (3 µg/kg DS PFOS, 2 µg/kg DS PFOA, 8 µg/kg DS sum PFAS), free reuse is permitted both as soil and in architectural applications.

If the leaching measured in a shake test meets the drinking water criterion for groundwater of 0.1 µg/l for the sum of 20 PFAS and 0.5 µg/l for sum PFAS, the structural applications are permitted both inside and outside the cadastral work zone (CWZ). If the measured leaching of an application meets this criterion, the application cannot give rise to exceeding this criterion in the groundwater. This is the last step in the generic part of the methodology.

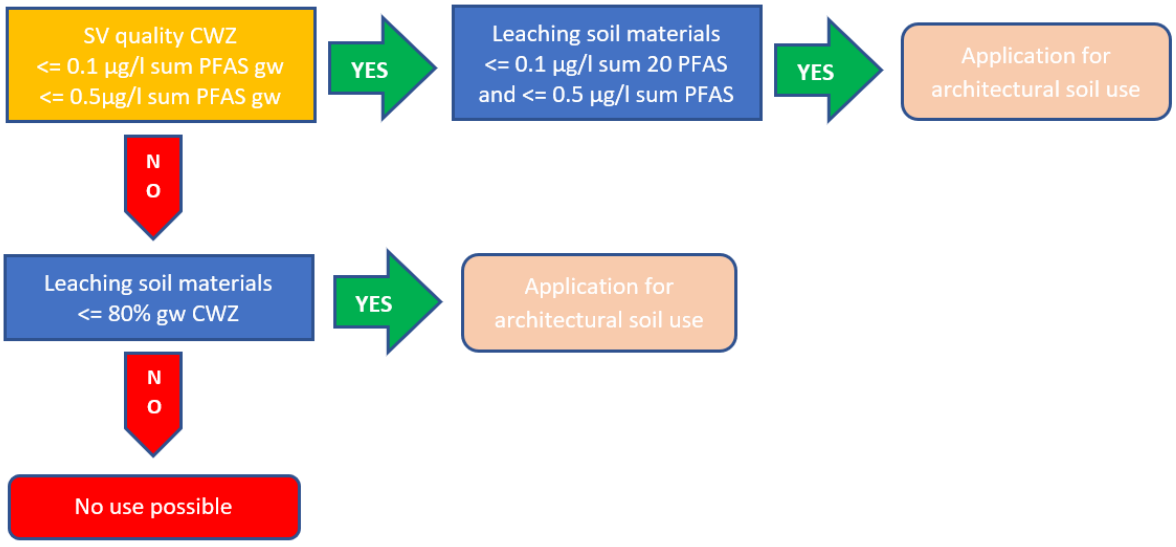


Site specific evaluation – use within CWZ

Soil materials that do not fulfil the above criteria can be used within the cadastral work zone (CWZ), provided that they comply with a site-specific evaluation of the standstill. This *standstill* evaluation shall demonstrate that the use of the soil materials does not cause additional contamination of the groundwater. This means that the concentration of PFAS in the receiving groundwater will not increase. In order to do so, the following assessment route is proposed:

If the quality of the groundwater in the cadastral work zone meets the groundwater criterion (0.1 µg/l for sum 20 PFAS and 0.5 µg/l for sum PFAS), the leaching of the soil material should be evaluated. If the leaching meets the groundwater criterion, use for architectural land use in the cadastral work zone is permitted.

If the quality of the groundwater in the cadastral work zone does not meet the groundwater criterion (0.1 µg/l for sum 20 PFAS and 0.5 µg/l for sum PFAS), the leaching of the soil material must be evaluated. If the leaching measured in a leaching test is less than 80% of the average PFAS concentration on site, the material can be used for use as architectural soil use in the CWZ. It can then be assumed that the PFAS concentration in the groundwater on site will not increase due to the use of the materials.



In order to carry out the site-specific evaluation of the preservation of standstill, the necessary tools are available, but still a number of aspects need to be further elaborated:

- Protocol for performing the leaching test with due consideration for elements specific to PFAS such as the use of PFAS-free materials
- Guidelines for determining the average concentration in groundwater on site: number of measurements, distribution, scale of the zone
- Guidelines for carrying out the quality test for free use in a water abstraction area

- Defining the preconditions for applying the site-specific evaluation, this can be limited to the cadastral work zone

These protocols and guidelines will be elaborated through an adaptation of the Codes of Good Practice for soil remediation experts, the standard procedure for the Technical Report and the compendium for environmental analyses (CEA).

Conclusion

This proposed revision of the PFOS and PFOA standards framework is based on the risk assessment and takes into account the main route of dietary exposure. The new standards framework is based on (i) the background exposure in food, which has been reduced compared to 2012 (ii) new insights and advice on health-related threshold values of EFSA 2020 and (iii) protection of the unborn child by limiting exposure of adults.

The value free reuse of soil as soil or in architectural applications is also adjusted in this new framework of standards. For the application in architectural applications, a leaching criterion is introduced. The leaching of the soil in a shake test must comply with the groundwater reference value of 0.1 µg/l sum 20 PFAS and 0.5 µg/l sum PFAS total.

It is not possible to derive soil remediation standards that are fully in line with the EFSA framework. There is no scientific data for this and the standard values would be lower than the average soil quality or even the limit of quantifications. Consequently, a certain risk of health effects from PFAS exposure must be accepted. Public support is required for a social discussion in order to determine which risk can be accepted. At the request of the Commission and as a basis for such a debate, the risks for the different assessment values were calculated.

The risk calculations for the free use and soil remediation assessment values indicate that in worst case conditions, i.e. simultaneous contamination with PFOS and PFOA and at maximum exposure or high mobility in the soil, the EFSA dose for the drinking water standard may be exceeded by a factor of 10. At the same time, we note that only a limited part of the Flemish population has elevated PFAS levels in their blood and that the groundwater quality meets the drinking water standard.

The EFSA health-based guidance values (HBGV) can be seen as target in the longer term for total exposure via different compartments (food, drinking water, dust ingestion,…). Therefore the policy should address exposure through each of those compartments simultaneously, through a systemic approach. In this respect soil remediation threshold values are only one of the possible means. At the same time, efforts must be made to phase out PFAS production and products containing PFAS and to limit emissions and spread.

This new proposal was developed after feedback from various stakeholders. This note will be used as a starting point for legal anchoring of the standards framework for PFAS in soil.

Prof. Dr. Karl Vrancken
PFAS Commissioner for the Government of Flanders
9 November 2022