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## Defining the scope and the term “(zeer) Zorgwekkende Stoffen” within the Flemish policy framework

### Summary

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The responsibility for the content of this summary lies with the authors.

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## SUMMARY

### CONTEXT OF THE STUDY

The use of chemicals is essential both in industry and everyday life, but exposure to some chemicals poses a risk to human health and the environment. In Flanders, this was strongly demonstrated during the PFAS crisis in 2021. PFAS are considered substances of concern<sup>1</sup> ('Zorgwekkende Stoffen' (ZS)) for which the Flemish government developed the concept note 'Vision ZZS' in 2024. The goal is to keep these substances out of our living environment, so that by 2050 air, water and soil pollution will be reduced to acceptable levels for both people and the environment. This policy is in line with the European zero pollution ambition and the Flemish sustainability objectives.

ZS are substances that pose a potentially serious risk to human health and the environment because they e.g. affect reproduction, are carcinogenic or accumulate in the food chain and the human body (bioaccumulation). European regulations, such as the REACH Regulation, provide criteria for identifying substances for example as 'Substances of Very High Concern' (SVHC). A crucial step in the Flemish ZS policy is to identify which substances are considered of concern in Flanders, based on this European legislation.

Existing international treaties and legal frameworks on chemical substances focus on the minimisation of ZS in the living environment. Each of these frameworks have a specific purpose and focus on certain hazard properties and/or environmental compartments. Therefore, they often deal with a relatively limited range of concerns. Flanders, by analogy with the Netherlands, intends to create an overarching policy framework for 'Zorgwekkende Stoffen', integrating environmental compartments (soil, groundwater, water, air) and health care.

Commissioned by the Department of Environment, and in close collaboration with OVAM, VMM, Department of Care, FPS Economy and FPS Health, a study was therefore carried out to determine which chemical substances are considered as 'Zorgwekkende Stoffen' within the Flemish policy framework.

The assignment consisted of defining the concept of '(potentiële-) Zorgwekkende Stoffen' and to develop a first proposal for prioritisation of ZS for the Flemish ZS policy. Furthermore, guidelines were drawn up for managing and updating the ZS lists, as well as for establishing a structured stakeholder collaboration to further develop a supported Flemish ZS policy.

### APPROACH TO THE STUDY

The study built on approaches applied in other European countries and took recent developments into account. The various research steps were conducted in close consultation with the relevant

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<sup>1</sup> Substances of concern as defined in Flanders (called 'zorgwekkende stoffen') are not necessarily the same substances as the substances of concern defined within European regulations/legislations/frameworks such as BPR, ESPR, SSbD,

Flemish and federal administrations. Additionally, relevant stakeholders from policy, science, industry and society were involved to ensure a clear and widely supported policy framework. The study resulted in 17 policy recommendations and future perspectives for the Flemish ZS policy.

## INSIGHTS FROM THE STUDY

### Criteria for 'Zorgwekkende Stoffen'

Based on a thorough literature study and in collaboration with stakeholders of the Flemish and federal administrations, a system was developed for the identification of ZS in Flanders. This system can be used to develop a list of ZS and an associated (policy) framework to be further expanded in the coming decades.

In Flanders, a substance is considered a substance of concern if it exhibits one or more of the following hazard properties:

- Carcinogenic, mutagenic or reprotoxic (CMR), Category 1a or 1b
- Endocrine Disruption in humans (ED HH), Category 1
- Endocrine Disruption in the environment (ED ENV), Category 1
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)
- Persistent, mobile and toxic (PMT) or very persistent, very mobile (vPvM)
- Individual substances of equivalent concern to CMR or PBT/vPvB substances (in accordance with REACH, Article 57f)

The above criteria for Flemish ZS are based on Article 57 of the REACH Regulation, with explicit inclusion of the new CLP hazard classes (ED category 1, PBT/vPvB and PMT/zPzM, see section 6.6).

### Source lists for identification of ZS

Specific sources are used to compile a ZS-list based on the criteria mentioned above. This system aligns with the policy in the Netherlands and enables anticipation of recent European developments regarding CLP classification.

An overview of the specific sources used for identification of ZS is shown in the table below.

Table 1: Overview of sources used to identify ZS

'Zorgwekkende Stoffen'
CLP Regulation Annex VI, Harmonized Classification (CLH) for: <ul style="list-style-type: none"> <li>• CMR Cat 1A or 1B</li> <li>• PBT/vPvB</li> <li>• ED ENV/HH Cat 1</li> <li>• PMT/vPvM</li> </ul>
ECHA SVHC Candidate List for Authorisation
ECHA Restriction List (Annex XVII)
POP Regulation, substances listed in Annexes I, II, III
OSPAR Convention, Substances for priority action



numerous lists of priority ZS will emerge side by side, which may hinder an integrated approach. A general discussion on the opportunities and challenges of prioritisation within the ZS-list is included, as well as an overview of potentially relevant criteria for prioritisation and development of a prioritisation system for Flanders.

## Data management

A structural and data-driven operation is necessary for the development and maintenance of a Flemish ZS-list. A high-performance ZS operation needs linkable and exchangeable data across policy domains. In the study, a first step towards this goal was taken with the development of a data management structure.

The Environment Policy Domain (BOMG) aims to become a data-driven domain, where linkable environmental data support every step of the policy cycle. The joint Master Data Management (MDM) operation at policy level ensures a common understanding and language so that the data is easily findable, available, linkable and (re)usable across the entire policy domain. BOMG's data approach is layered with master data and reference data forming the basis.

The starting point for the development of a ZS operation was therefore the MDM operation within the BOMG which is based on Open Standards for Linking Organisations (OSLO). To make this data policy concrete, practical data management and responsibility are assigned to data-related working groups, which are accountable to the appointed Steering Committees.

In the meantime, a Working Group data ZS has been established to work on operationalizing the ZS list and the broader ZS policy, including the development of a process for managing and updating the ZS list according to the principles of the MDM operation. The existing 'Core Team ZS' is appointed as a steering committee in the ZS operation.

The further development of a data management system for the future ZS framework will be a dynamic process in which input from various stakeholders will remain crucial.

## Legal analysis

Regarding the use of the term 'Zorgwekkende Stof' or 'Zeer Zorgwekkende Stof' in Flanders for substances that meet the criteria as formulated in this study, the legal analysis advises to use the term 'Zorgwekkende Stoffen'. The REACH regulation uses the term 'Substances of Very High Concern' (SVHC) and provides specific criteria for identification of substances as SVHC. The literal Dutch translation of SVHC is 'Zeer Zorgwekkende Stoffen' (ZZS), meaning that the use of this term for substances other than SVHC identified under REACH could cause confusion.

In addition, it is recommended that the definition and criteria for ZS be anchored in Flemish legislation (e.g. VLAREM). This is, among other reasons, required to enable enforcement. The detailed legal advice can be found as a legal note in the appendix of the full study report.

## Stakeholder engagement

When developing a policy framework for ZS in Flanders numerous concerns arise. It is essential to properly map out and understand the different needs and perspectives of stakeholders to propose and implement a widely supported approach. A structural stakeholder collaboration within the 'HUB ZS' provides an environment in which:

- Different perspectives are exchanged and valued.

- This approach makes it possible to approach challenges from various angles and develop a shared understanding that extends beyond individual perspectives. Various parties have already indicated their intention to actively contribute to this collaboration.

Based on the study work carried out and the accompanying dialogue several policy recommendations and future perspectives have been formulated.

- An ambitious ZS policy
- A supported ZS approach
- A high-performance ZS operation

In addition, an ambitious ZS policy looks at substances that are not yet on the ZS-list but are (potentially) of concern because of their intrinsic properties. This can be done, for example, by providing a framework for individual assessment of chemicals that are flagged to be of potential concern. In addition, more extensive non-target screening and the development of an early warning system for identifying and assessing emerging substances could ensure that action is taken more quickly.

To be able to implement the ZS approach, there is a need for a **high performing ZS operation**. The most important first step is to operationalise the ZS-list with a clear management structure as proposed in the study. Central management plays an important role in maintaining an overview and can also provide support to parties responsible for implementation of the ZS policy.

For an efficient and impactful implementation of the ZS framework in Flanders, it is important to consciously focus on all three objectives: an ambitious policy, supported by a high performing operation and backed by a broad group of stakeholders.