

PFASs in the action plan for a toxic-free everyday environment

Selected parts of report 6/17

REPORT 7/18

KEMI

Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Preface

In December 2010, the Swedish Government assigned the Swedish Chemicals Agency to prepare and implement an action plan for a toxic-free everyday environment: *Action plan for a toxic-free everyday environment 2011 – 2014 – protect the children better* (the Action Plan). The Action Plan has been prolonged to 2020. Work is ongoing in several areas, both in Sweden, within the EU and globally and often in co-operation with other authorities.

Reducing chemical risks in the everyday environment is one step towards attaining the Swedish Parliament's environmental quality objective: A Non-Toxic Environment, which is the objective that the Swedish Chemicals Agency is responsible for. Within the framework of the Action Plan, the Agency compiles knowledge in its report and PM series, which are prepared by experienced colleagues, researchers or consultants. By this means, the Agency presents new and essential knowledge in publications, which can be downloaded from the website www.kemikalieinspektionen.se.

One focal area for the action plan is highly fluorinated substances (PFASs). The Swedish Chemicals Agency has been assigned to develop a national programme of measures for PFASs – a task that involves various projects and activities. This report presents results from the Swedish Chemicals Agency's work on PFASs relating to the Action Plan and describes further efforts that are needed. Originally this was part of the Agency's report 6/17 which presented results, initiatives, and impacts from all of the Agency's work relating to the Action Plan during that period.

The work on the national programme for PFASs was carried out by the Department of Development of Legislation and Other Instruments. The head of unit responsible for this assignment was Ing-Marie Olsson Rensner and the project group comprised of Karin Abrahamsson, Alicja Andersson, Daniel Borg, Inger Cederberg, Stellan Fischer, Johan Forsberg, Jenny Ivarsson (project leader), Bert-Ove Lund and Gregory Moore.

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Summary

In 2010, the government assigned the Swedish Chemicals Agency to develop and execute an Action Plan for a toxic-free everyday environment. The assignment was prolonged in 2015. In its report 6/17, the Swedish Chemicals Agency presents the results, actions and effects of its work with the Action Plan 2011-2017. Highly fluorinated substances (per- and polyfluoroalkyl substances (PFASs)) are one of the focal areas of the Action Plan. The present report reproduces the parts of report 6/17 that specifically concern PFASs. It summarises the PFAS-related activities that have been completed and the measures that need to be further adopted or implemented.

Glossary

Article	An object, which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition.
Chemical products	Substances and mixtures.
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
Mixture	A mixture or solution composed of two or more substances.
PBT	Persistent, bioaccumulative and toxic
PFASs	Per- and polyfluoroalkyl substances
PFDA	Perfluorodecanoic acid
PFHxS	Perfluorohexane sulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
vPvB	Very persistent and very bioaccumulative

1 Activities and Results

1.1 Proposal for national restrictions

In January 2016, the Swedish Chemicals Agency submitted a proposal¹ of conditions for the use of highly fluorinated substances in fire extinguisher foam to the government. This is included as a part of the strategy for highly fluorinated substances². Based on currently available information, the Agency concluded that the most problematic end-use is fire-fighting foam, as this involves the direct release of PFASs into the environment. In several parts of Sweden, the ground and drinking water have been polluted as a result of PFASs release from the use of fire-fighting foam. This is why the Agency has proposed criteria on how fire-fighting foam containing PFASs can be used in Sweden. The proposal consists of a legal requirement, backed by the Swedish Environmental Code, according to which film-forming foam/extinguishing water from fluorine-based fire-fighting foam must be collected and destroyed. The proposal encompasses all PFASs, as all PFASs are poorly biodegraded in the environment. As to forms of use that are exempted from the proposed regulation, work will continue with informational activities and education, to ensure that fire-fighting foam is used in an environmentally safe way. In addition, the Agency has proposed that the government review the regulations a few years after they have entered into effect to further reduce the number of exemptions.

The Agency has concluded that there is a need for national legislation regulating the use of fire-fighting foam that contains highly fluorinated substances. However, it noted that exemptions are necessary in certain situations and for substances that are or will be regulated at an international or EU level³.

In addition to the conditions on how fire-fighting foam containing PFASs can be used, the Swedish Chemicals Agency has also proposed to develop, together with the Swedish Civil Contingencies Agency a proposal for an obligation for users to report the use of fire-fighting foam. The Swedish Chemicals Agency is waiting to introduce such a proposal until it is clearer how the proposed restrictions for use of fire-fighting foam containing highly fluorinated substances will be developed as a national regulation.

At this time, the Agency does not see areas other than fire-fighting foam that could be regulated for the use of PFASs at national level. The Agency has nonetheless initiated a collaboration with the Swedish National Food Agency to conduct a dialogue with the manufacturers and importers of food contact materials with the aim of encouraging a voluntary replacement of PFASs.

1.2 Strategy for highly fluorinated substances (PFASs)

The Swedish Chemicals Agency considers that the use of PFASs, which can cause environmental contamination, should be minimised and discontinued in the long-term. Thus, it has developed a strategy for working with PFASs. The Agency views this strategy as a

¹ The Swedish Chemicals Agency, 2016. Report 1/16. Proposal for national regulations of highly fluorinated substances in fire-fighting foam. Report of a government assignment.

² The Swedish Chemicals Agency, 2016. Report 1/16. Proposal for national regulations of highly fluorinated substances in fire-fighting foam. Report of a government assignment.

³ PFOS and substances that can degrade to PFOS are strictly forbidden for use, according to the EU POPs regulation. EU regulations are directly applicable to all Member States, and therefore, shall not be executed via national legislation. PFOA and substances that can degrade to PFOA will be restricted in the EU. The legislation will enter into force on 4 July 2020.

process that must be done in several stages and in several arenas (in Sweden, the Nordic countries, the EU and globally). Collaboration between different agencies and other actors is an important part of the strategy⁴.

1.2.1 PFASs are a concern for many national agencies and actors

In the spring of 2015, the Swedish Chemicals Agency conducted a survey on the occurrence and use of PFASs and the alternatives to PFASs⁵. The report has been translated into English⁶ and has received international attention. It has been used as reference material in publications in countries within and outside of the EU.

The results of the survey showed that more than 3,000 PFASs are used, for commercial purposes, on the global market. The largest group consists of polymers. However, the survey does not provide a complete picture as there is a lack of available information on the substances. One reason for the lack of information is that thresholds for registration under the REACH Regulation⁷ are too high for this group of substances. Most PFASs are highly potent and used in low concentrations. Under the REACH Regulation, manufacturers and importers do not have to report any information for the manufacture and import of chemical products under 100 tonnes per year. As of 1 June 2018, the limit for registering will be lowered to 1 tonne per year, which means there will be some improvement in the availability of information on chemical products, but not on their occurrence in articles.

The survey also showed that the existing Swedish registration requirement for chemical products is insufficient for finding all PFASs. Companies whose products contain PFASs concentrations below five per cent are not, generally, required to report them to the Swedish Products Register. As PFASs are often used at concentrations below five per cent, there is a need to make the current requirements more stringent. The Swedish Chemicals Agency proposed to introduce a new additional reporting requirement according to which not only all substances in concentrations above five per cent would be reported but also all substances that are classified as hazardous, regardless of concentration. The Swedish Chemicals Agency has concluded that these more stringent requirements could be put into effect at the earliest at the turn of 2018/2019, which would mean that the first occasion for reporting would occur in February 2020.

As a result of the Swedish Chemicals Agency's conclusion that the most problematic use of PFASs is in fire-fighting foam, the agency has proposed several measures directed at this use. In addition to the proposal on the conditions for using PFASs in fire-fighting foam described in part 1.1, the Agency has, in collaboration with the Swedish Civil Contingencies Agency (MSB) and the Swedish Environmental Agency, developed an informational booklet, with recommendations for reducing the use of fire-fighting foam. The booklet⁸ has been handed out at seminars and training sessions that primarily target emergency and rescue services.

⁴ The Swedish Chemicals Agency, 2016. Report 9/16. Strategy for reducing the use of highly fluorinated substances, PFASs, Interim report as part of a Government assignment.

⁵ The Swedish Chemicals Agency, 2015. Report 6/15. Occurrence and use of highly fluorinated substances and alternatives. Report of a government assignment.

⁶ The Swedish Chemicals Agency, 2015. Report 7/15. Occurrence and use of highly fluorinated substances and alternatives.

⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

⁸ The Swedish Chemicals Agency, the Swedish Environmental Agency and the Swedish Civil Contingencies Agency, 2016. Brochure. Recommendations for reducing the use of fire-fighting foam.

The problems with PFASs, and primarily that of contamination of ground, surface and drinking water, are so complex that there has been a need to strengthen the collaboration between civil society actors. Thus, in collaboration with the Swedish National Food Agency, the Swedish Chemicals Agency has initiated a network for government agencies, researchers, county administrative boards, municipalities and water suppliers. The Swedish Chemicals Agency also maintains a network between the most relevant Swedish government agencies.

The Swedish Chemicals Agency has taken the initiative to propose that all relevant Swedish government agencies shall publicly associate themselves with a declaration of intent to increase collaboration on developing knowledge and reducing PFASs use. The collaboration will occur on the basis of the respective government agencies' assignment and operation. So far, the Swedish Chemicals Agency along with 36 other government agencies and research organisations⁹, has signed the declaration of intent. Government agencies that currently belong to the government agency network include: the National Food Agency, the Swedish Environmental Agency, the Swedish Agency for Marine and Water Management, the Geological Survey of Sweden, the Swedish Geotechnical Institute, the Swedish Civil Contingencies Agency, the Surgeon General, the County Administrative Boards, the Water Management Authorities, and Sweden's Municipalities and County Councils. These government agencies have developed a guide¹⁰ for PFASs, which has been available on the Swedish Chemicals Agency's website since summer 2016. The guide indicates the responsibilities of the different government agencies and is to be used as a tool for finding information on, for example, drinking water suppliers, municipal supervisory authorities, private persons as well as manufacturers of fire-fighting foam and other products containing PFASs.

The Swedish Chemicals Agency is also involved in a network, run by ECHA at the EU level, and actively participates in several PFAS-related research programmes and networks in Sweden and the EU. Moreover, the Swedish Chemicals Agency maintains close contact with researchers, which is necessary in order to monitor the latest information in this area.

1.2.2 Nordic cooperation

The Swedish Chemicals Agency is part of the Nordic Risk Assessment Project (NORAP), a project group under the Nordic Chemical Group (NKG), which is a part of the Nordic Council of Ministers for the Environment. Within NORAP, the Nordic countries exchange information and knowledge on hazard and risk assessments, as well as risk management of chemicals, including PFASs. In addition, the Agency has initiated a special cooperation with its counterpart government agency in Denmark (The Danish Environmental Protection Agency). The Danish Environmental Protection Agency was part of project group for the Nordic PFAS workshop that the Swedish Chemicals Agency arranged in spring 2017 (see below). Together with the Danish Environmental Protection Agency, the Swedish Chemicals Agency plans to increase awareness of the PFAS problem among the general public and

⁹ The Public Health Agency of Sweden; FORMAS (The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning); the Swedish Fortifications Agency; the FRAM Centre for Future Chemical Risk Assessment and Management Strategies, the University of Gothenburg; the Surgeon General; the Swedish Agency for Marine and Water Management; Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University; the Karolinska Institutet; the National Food Agency, Sweden; the County Administrative Boards (21 associated agencies); the Swedish Civil Contingencies Agency (MSB); the Swedish Environmental Agency; the Swedish Geotechnical Institute (SGI); the Geological Survey of Sweden; the Swedish University of Agricultural Sciences (SLU) and Örebro University.

¹⁰ The Swedish Chemicals Agency. Guide for PFASs (highly fluorinated substances). Accessed on 2017-05-11 from <http://www.kemi.se/pfasguide> (in Swedish)

decision-makers. This could, for example, be done via a Nordic project on the costs of not taking any action (cost of inaction) to reduce the spread of PFASs¹¹.

1.2.3 The Swedish Chemicals Agency is pushing for the regulation of PFASs under the REACH and CLP regulations

In 2013-2016, the Swedish Chemicals Agency submitted a proposal for a harmonised classification and identification of perfluorononanoic acid (PFNA) and perfluorodecanoic acid (PFDA) as substances of very high concern. Both substances now have a harmonised classification and have been added to the Candidate List¹². The Agency also submitted a proposal for perfluorohexane sulfonic acid (PFHxS) to be classified as a substance of very high concern¹³. In June 2017, PFHxS was added to the Candidate List. In collaboration with Germany, the Agency has developed a proposal for an EU restriction of a group of PFASs compounds that is estimated to include a couple of hundred different PFASs. Thus, the continued and future use of these substances that have been identified as either persistent, bioaccumulative and toxic (PBT) or as very persistent and very bioaccumulative (vPvB) will be prevented.

Together with other Member States, the Swedish Chemicals Agency has begun work on investigating how very persistent and environmentally mobile PFASs (which, based on the current level of knowledge, do not fulfil the criteria for bioaccumulation and toxicity) should be managed in a better way by the REACH regulation.

1.2.4 The Swedish Chemicals Agency is pushing for an EU action plan for PFASs

In accordance with the assignment for a toxic-free everyday environment, the Swedish Chemicals Agency has begun work on a joint EU action plan for PFASs. As a step in the process, the Swedish Chemicals Agency organised and executed a workshop, with funding from the Nordic Chemical Group (NKG). The object of the workshop was to discuss and work towards the development of a common EU action plan with political and regulatory strategies for PFASs. Participants represented authorities and agencies from the Nordic countries as well as Belgium, Germany and Austria, ECHA, the EU Commission, EFSA and the European Environment Agency (EEA).

At the workshop, a number of areas were identified that need to be developed in order to improve the possibilities for managing PFASs problems. Some of the requirements that were highlighted include increasing the scope of PBT criteria¹⁴, unifying terminology for PFASs, a more flexible interpretation of the REACH regulation for polymers and an internationally accepted list of individual PFASs, with unambiguous names, to allow for easier identification. The need to assess and manage PFASs as a group, in order to prevent substitution to other PFASs within the same group and establish a method with a low detection limit for measuring the Total Organic Fluorine (TOF), was the second area to be discussed, as was an awareness-raising campaign at both the national and EU levels. During the workshop, the participants also emphasised the importance of closing knowledge gaps and promoting the innovation of non-toxic alternatives to PFASs, of avoiding their spread through reuse or recycling, only allowing their use for critical purposes where no suitable replacement exists. The need to

¹¹ Ing-Marie Olsson et al. 2014. TemaNord 2014:557. The Cost of Inaction. A socioeconomic analysis of costs linked to the effect of endocrine disrupting substances on male reproductive health.

¹² See Article 59 of the REACH Regulation.

¹³ The criteria are provided in Annex XIII of the REACH Regulation.

¹⁴ The criteria are listed in Annex XIII of the REACH Regulation.

develop environmental PFASs monitoring as well as the need for the identification and decontamination of affected areas were also emphasised. Finally, the participants agreed that REACH and CLP regulations¹⁵, as well as product safety legislation, such as the cosmetic products regulation and food legislation, are the primary tools for regulating the use of PFASs in the EU. However, in the end, global measures are needed. The final conclusions have been published on the Nordic Council of Ministers for the Environment's website¹⁶.

Based on the results of the Nordic workshop, the Swedish Chemicals Agency has submitted proposals for an underlying strategy for persistent substances, which could be included in the EU strategy for a non-toxic environment. The Swedish Chemicals Agency is also continuing its involvement in ECHA's working group on PFASs, whose goal is to coordinate the work on PFASs done by the Member States, primarily within the framework of the REACH and CLP regulations.

1.2.5 The spreading of PFASs is a global problem

PFASs are transported over international borders via air, water and articles. That is why a global prohibition is needed if the spread of these substances is to be prevented. The global arena is, thus, vital to the Swedish Chemicals Agency's work with PFASs. We work, for example, with several highly fluorinated substances under the Stockholm Convention.

The Stockholm Convention is a global convention that aims at protecting human health and the environment from persistent organic pollutants (POPs)¹⁷. The global prohibitions enshrined in this convention prevent these toxic substances from spreading globally, thereby protecting Swedish citizens as well. At the moment, the Convention covers 28 substances. EU Member States cannot propose on their own a new substance for listing under the Convention: only the EU Commission can do so. Therefore, the Swedish Chemical Agency has provided support to the EU Commission in its work to propose new substances for listing under the Convention and has helped with the coordination for the proposals.

In the recent years, both perfluorooctanoic acid (PFOA) and perfluorohexane sulfonic acid (PFHxS) have been proposed for listing under the Convention by the EU and Norway respectively. The proposals for both substances are currently being examined by the Persistent Organic Pollutants Review Committee (POPRC)¹⁸, which is the expert committee under the Stockholm Convention. The Swedish Chemicals Agency has supported this work by participating in the POPRC. A Swedish expert from the Swedish Chemicals Agency has been a member of POPRC since May 2014. Before that, the Swedish Chemicals Agency was present as an observer. The Swedish Chemicals Agency has contributed to the POPRC's work with comments on the various drafts of risk profiles and risk management plans for all substances that have been listed under the Convention between 2011 and 2017, including PFOA and PFHxS. The Swedish Chemicals Agency has also shared its experience with the committee regarding the alternatives to PFOS. During the meetings of the POPRC in 2016 and 2017, the Swedish Chemicals Agency contributed further by sending an expert to work on PFOA and PFHxS.

¹⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

¹⁶ Borg, D, Ivarsson J, Andersson A, Moore G, 2017. Nordic Workshop on PFASs, Outcomes. Nordic Working Papers, ISSN 2311-0562.

¹⁷ Persistent organic pollutants, POPs

¹⁸ Persistent Organic Pollutants Review Committee.

2 Further measures are needed

The Swedish Chemicals Agency intends to

- Press for further measures to be taken against PFASs in ground, surface and drinking water in collaboration with other concerned national agencies
- Based on the national strategy and the agreements that were reached at the workshop in April 2017, continue the EU collaboration to reduce exposure to PFASs through strategically chosen efforts alone or in collaboration with other Member States
- Within the framework of the EU strategy for a non-toxic environment, work towards the development of an action plan for extremely persistent substances, such as PFASs, at the EU level.

The problem with PFASs is far from being solved. The common points between all PFASs is that they are persistent and many are easily mobile in the environment. The Agency's mapping from 2015 shows that the number of PFAS substances is extensive, that the development of new substances is increasing and new areas of use are being developed. Therefore, the Swedish Chemicals Agency considers it vital that the national collaboration on highly fluorinated substances continues to ensure that the issue is not inadequately addressed because of ambiguities as to the distribution of responsibilities between the concerned government agencies. Awareness of the presence of PFASs must be increased. One way to achieve this is to increase reporting to the Swedish Products Register. From a circular economy perspective, the presence of PFASs in different articles, such as textiles, is problematic as they increase difficulties in recycling a large group of products. As many PFASs are spread via water, the EU Water Framework Directive¹⁹ is an important piece of legislation. As many highly fluorinated substances are water soluble and mobile in soil, more than a few drinking water sources are at risk of contamination. Contamination of lakes and waterways can also cause high levels of PFASs in fish for human consumption. Since 2015, the parts of the directive that concern groundwater have been strengthened, which has caused increased activity in the different working groups. The Swedish Chemicals Agency intends to press the issue for further measures against PFASs in ground, surface and drinking water, in collaboration with other concerned government agencies. The PFASs problem requires measures at the EU level. Even if further numbers of PFASs are regulated or in the process of being regulated within the EU, the fact is that the alternatives used to replace regulated substances are other PFASs with shorter carbon chain lengths. In general, finding alternatives that can match the desired characteristics of PFASs is considered difficult. Even if there are developments, such as in textiles for example, it will be challenging to continue working towards having the PFASs currently in use be reduced or banned in the future. An EU action plan is an important part of the Swedish Chemicals Agency's strategy to reduce the exposure of people and the environment to highly fluorinated substances.

The workshop²⁰ that the Swedish Chemicals Agency held in April 2017, with funding from the Nordic Chemical Group (NKG), pointed out a number of vital areas for continued development on the path to an EU action plan with political and regulatory strategies for PFASs. Therefore, when it is strategically appropriate, the Swedish Chemicals Agency will continue to develop the current EU *Acquis Communautaire*, through collaboration with other

¹⁹ Directive 2000/60/EC of the European Parliament on establishing a framework for Community action in the field of water policy.

²⁰ Borg, D, Ivarsson J, Andersson A, Moore G, 2017. Nordic Workshop on PFASs, Outcomes. Nordic Working Papers, ISSN 2311-0562.

Member States, in order to develop a clearer and more comprehensive definition of PFASs. It will also investigate how the REACH regulation's definition of polymers should be used in relation to PFASs. It will actively participate in ECHA's informal PFAS working group by developing a basis for identifying/describing very persistent and mobile substances for inclusion in Article 57(f) of the REACH regulation (substances giving rise to an equivalent level of concern to CMR, PBT and vPvB) and thus enable them to be included in the Candidate List. The Swedish Chemicals Agency will also work to close the existing knowledge gaps for PFASs by pointing out the need for research, developing tools for identifying PFASs, working to further develop environmental monitoring and by spreading knowledge that patent information can be used to predict future uses. The Swedish Chemicals Agency also needs to increase awareness among the general public, companies and decision-makers in order to avoid any further spreading of PFASs. The new Centre for Substitution²¹ should be able to play a vital role in the work to reduce PFASs use.

²¹ Substitution i Centrum – stärkt konkurrenskraft med kemikaliersmarta lösningar, SOU 2017:32.

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