National Institute for Public Health and the Environment
*Ministry of Health, Welfare and Sport*

# Risk Management Option Analysis Conclusion Document

**Substance Name:** ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (FRD-902)

**EC Number:** 700-242-3

**CAS Number:** 62037-80-3

**Authority:** The Netherlands/RIVM

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

## 1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

FRD-902 is not yet regulated and is self-classified under the CLP Regulation (*Regulation (EC) 1272/2008*) by the registrant and 30 additional notifiers. Under REACH, A substance evaluation is ongoing. FRD-902 has been listed on the CoRAP because of suspected PBT/vPvB properties, exposure of the environment and suspected carcinogenicity[2]. A Draft Decision has been prepared by the evaluating Member States DE and NL. This Draft Decision was sent out to the Registrant on 9th of April 2018 and focusses on two specific aspects of concern:

- The half-life of FRD-902 in humans. The Draft Decision motivates that this should be further elucidated, in analogy with the bioaccumulative properties of other perfluorinated substances such as perfluorooctanoic acid (PFOA) and perfluorohexane sulfonic acid (PFHxS).
- Carcinogenicity. The Draft Decision motivates that a carcinogenicity study in mice is needed to determine if FRD-902 is presumed to have a carcinogenic potential for humans. The Draft Decision argues that current data suggest that classification as a Category 2 carcinogen may be applicable, but the data are not sufficient to differentiate between a carcinogenicity classification in CLP Category 1B or Category 2. The information request as proposed in the Draft Decision will be essential to conclude what further regulatory action on the basis of this endpoint is required.

At the time of drafting of the RMOA, the SEv Decision has not yet been concluded.

Other processes ongoing do not yet specifically address FRD-902 but refer to the larger group of long-chain and short-chain PFCAs and PFSAs. Some of the long-chain PFSAs and PFCAs are already regulated, i.e. perfluoro-octanoic acid to perfluoro-tetradecanoic acid and perfluoro-hexane sulfonic acid and perfluoro-octane sulfonic acid. For short-chain PFCAs and PFSAs, the SC-PFAS discussion paper evaluates common concerns, an overarching grouping approach these substances, and possible regulatory measures. This paper has been discussed at RiME+2 2018 and at CARACAL. FRD-902 can be considered as one of the substances to which this discussion paper may apply. Several of the short-chain PFCAs and PFSAs are now considered for further regulatory action (Perfluoro hexanoic acid, perfluorbutanoic acid and perfluorobutane sulfonic acid).

Under CLP, 4 joint submissions each self-classify FRD-902 as:

- Acute Tox. 4 H302: Harmful if swallowed
- Eye Dam. 1 H318: Causes serious eye damage
- STOT RE 2 H373: May cause damage to organs through prolonged or repeated exposure:
    - for blood = 1 aggregated submission with 27 notifiers,
    - for blood and liver = 2 aggregated submission and 3 notifiers and
    - for blood (Oral and Inhalation) = 1 aggregated submission with 1 notifier)

Of which 1 notifier (1 joint submission) additionally self-classifies FRD-902 as:

- Acute Tox. 4 H312: Harmful in contact with skin
- Acute Tox. 4 H332: Harmful if inhaled

## 2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant

[2] https://echa.europa.eu/documents/10162/b2a648a7-e2f9-ca6e-fba4-d5f5bcdcff9c

information taking into account the SVHC Roadmap to 2020, where appropriate.

| **Conclusions** | **Tick box** |
|---|---|
| Need for follow-up regulatory action at EU level: | |
| *Harmonised classification and labelling* | |
| *Identification as SVHC (authorisation)* | X |
| *Restriction under REACH* | |
| *Other EU-wide regulatory measures* | |
| Need for action other than EU regulatory action | |
| No action needed at this time | |

FRD-902 belongs to the group of perfluorinated substances (PFAS), and is a member of its subgroup of PFECAs (per- and polyfluoroether carboxylic acids). In several of its properties, FRD-902 resembles the properties of short chain perfluorinated carboxylic acids (PFCAs) and perfluorinated sulfonic acids (PFSAs).

Under environmental conditions, FRD-902 quickly dissolves to form its anion HFPO-DA. The human and environmental health properties and environmental behaviour and fate characteristics of FRD-902 are attributed to the properties of this anion. To date, there are two other substances known that also form HFPO-DA under environmental conditions and that hence are expected to show similar environment and health properties. These are FRD-903 (EC 236-236-8; CAS 13252-13-6), from which FRD-902 is produced, and the potassium salt of HFPO-DA (Potassium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionate; EC 266-578-3; CAS 67118-55-2), which is currently pre-registered under REACH.

To prevent undesirable substitution and to increase transparency and predictability, SVHC identification should preferably involve HFPO-DA and its salts, including also FRD-903 and its potassium salt for which there is a pre-registration.

## 3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

### Need for (further) risk management

FRD-902 can be considered a short-chain PFAS. Toxicity data show that FRD-902 may have adverse effects on liver and red blood cells and suggest that the substance is carcinogenic. The available information on (bio)degradation obtained from experimental and modelling data indicate that this substance is likely to be extremely persistent (eP). Furthermore, information available from the study by Pan et al. (2017) shows that its anion HFPO-DA is present in environmental organisms and humans. HFPO-DA is highly soluble in water and does not adsorb to soil or sediment. The high solubility and inability to adsorb to soil and sediment make the substance potentially very mobile in the environment. The potential very high mobility of the substance is supported by the available monitoring data summarized in section 3.2.2. The data show that HFPO-DA is found amongst others at locations without an apparent local emission source to explain this environmental presence, and indicate that HFPO-DA can be transported via water over a long range with the potential to contaminate remote areas. The fact that FRD-902 has been imported in Europe since 2012 suggests that this long range transport takes place in a very short time. HFPO-DA is also found in drinking water, in fish and in home grown vegetables, and is modelled in air pointing at indirect exposure of the general population via the environment.

Recent work by the Dutch enforcement agencies also points at significant emissions of

an unpredictable and uncontrollable nature as a result of HFPO-DA containing waste transport and waste treatment (*study in press*). They signal that HFPO-DA concentrations in waste are often unknown but may be as low as <0.1 w/w %. Still it is signalled that even these low concentrations may results environmental concentrations of high concern. Upon personal communication, they note that the Waste Framework Directive is insufficiently specific and insufficiently stringent to facilitate the necessary communication on HFPO-DA containing waste to allow for appropriate emission reducing measures at the waste phase. They also flag that under the Industrial Emissions Directive, it depends on the industry type whether or not an emission permit is mandatory. Emission permits for FRD-902 or HFPO-DA may therefore not be required for all industries that may work with the substance.

The available information demonstrates that remediation techniques commonly in use are not effective to remove HFPO-DA from the environment and from drinking water[3]. Given the apparent toxicity, extreme persistence, very high mobility and exposure to humans and the environment, as well as the uncertain, wide spread and uncontrollable emission at the waste phase, the NL-CA is of the opinion that HFPO-DA and its salts, among which FRD-902, can be considered as a substance of very high concern to human health and the environment.

**Table 1: SVHC Roadmap 2020 criteria.**

| | Yes | No |
|---|---|---|
| a) Art 57 criteria fulfilled? | art. 57(f) by being eP, very Mobile and showing adverse effects | |
| b) Registrations in accordance with Article 10? | X | |
| c) Registrations include uses within scope of authorisation? | X | |
| d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution? | X | |

## Identification and assessment of risk management options

### Substance Evaluation

There are various uncertainties related to the toxicity, kinetics, emission and exposure profiles of FRD-902 and further insight in these issues would be helpful for assigning the most appropriate regulatory measures to reduce the concern at hand. The proposed request for additional information laid down in the ongoing Substance Evaluation for FRD-902 is expected to result in further insight in the potential for bioaccumulation in humans and the carcinogenic properties of the substance. When the requests for further

[3] Upon personal communication, the registrant informed the NL-CA that they are working on possible remediation techniques to remove HFPO-DA from the water phase. The registrant noted that results are promising. No study results have been shared in the context of this RMOA to date to verify this information, nor did the registrant provide information on the wide applicability of possible techniques by drinking water companies, possibilities for implementation and associated costs. Via a press release, the registrant did indicated that industrial emissions from their industrial site will be reduced by 99% in 2020, and information was shared that the emissions permits for 2020 have been revisited accordingly.

information will be approved, this information is expected to become available at the earliest in 2021-2022. The outcome of the information requested will impact any further regulatory measures for FRD-902, e.g. harmonized classification as Carcinogen Cat 1B, or identification of the substance as PBT/vPvB through Candidate listing by providing the information to conclude “B” in line with the REACH Guidance for PBT Assessment. Also, it may be possible that the information requested will turn out not in support of a Cat 1B carcinogen under CLP or show bioaccumulation that is not substantive enough to warrant the “B” criterion for PBT.

It is noted that where PBT assessment will mainly result in risk management for the environment, identifying carcinogenicity and bioaccumulation in humans will provide further information and ground for risk management options for human health.

Because of the expected time to results and the already very high concern for FRD-902 based on the information described in this RMOA, of which an important factor is its current widespread environmental appearance in the Netherlands and elsewhere in Europe that developed over a period of only 5 – 6 years (2012 – 2018), it is concluded not to await any information coming from the ongoing SEv but to initiate regulatory measures as soon as possible.

Exposure characteristics are not a topic under the ongoing SEv and have not been evaluated in the Draft Decision. Better insight into production and use profiles of the substance, including its distribution, use and waste treatment locations in Europe may contribute to a better understanding of the widespread appearance of the substance. Upon personal communication, the registrant informed the NL-CA that they are the only registrant of FRD-902 in the EU. They further state that the only intended use is as polymerization aid to produce fluoropolymers and that the only site of use is at a single plant in the Netherlands. However, under the CLP Regulation 30 additional notifiers, organized in 4 joint notifications, have notified the use of FRD-902, which may point a more wide spread use of FRD-902 or a more wide spread further processing of HFPO-DA containing mixtures. In addition, a study conducted by the Dutch enforcement agency leads to conclude that at least part of the HFPO-DA containing wastewater is being regenerated outside the Netherlands elsewhere in Europe.

## Classification and Labelling

FRD-902 does not have a harmonized classification. As summarized in section 3.2.1, the toxicity data available for FRD-902 may warrant classification for STOT RE 2 based on observed effects on the liver and for Carc. Cat. 2.

*Carcinogenicity*

The NL-CA is of the opinion that the effects observed for carcinogenicity are sufficient to warrant a Carc. Cat 2 classification (see section 3.2). In time, the ongoing Substance Evaluation may provide information with which to resolve any possible need for classification as carcinogen Cat 1B.

Harmonized classification for Carc. Cat 1B will directly impact occupational exposures through the Carcinogens and Mutagens Directive (CMD). In case there would be any use in consumer products, it would also impact its use there. It will also make FRD-902 a candidate for SVHC according to art. 57(a), be of influence for granting industrial emission permits under the Industrial Emissions Directive (IED) and will fulfil the T criterion for PBT identification according to art. 57(d) of REACH. A classification as Carc. Cat 1B also results in FRD-902 fulfilling the ZZS criteria (criteria for being a ‘Zeer zorgwekkende stof’, i.e. the Dutch national equivalent of a substance of very high concern), which will directly lead to minimization requirements of industrial emissions of HFPO-DA within the Netherlands. Classification as Carc. Cat 1A/1B will impact the waste treatment for waste containing more than 0.1 w/w% of the substance (Waste Framework Directive).

Harmonized classification for Carc. Cat 2 will not trigger any regulatory risk management measures for workers nor any emission reduction under IED. It will not be sufficient to meet the criteria for SVHC under art. 57(a) and will not be sufficient to meet the T-criterion for any possible PBT identification according to art 57(d). It will however facilitate transparent communicate that the substance is a suspected human carcinogen and may thereby strengthen motivating that the adverse effects observed for HFPO-DA are severe, supporting the motivation that HFPO-DA and its salts, among which FRD-902, may be of Equivalent level of concern (ELoC) according to art. 57(f) (see also further discussion in section 5.2.3). Also, classification as Carc. Cat 2 will impact the waste treatment for waste containing more than 1 w/w% of the substance (Waste Framework Directive).

*STOT RE*

Like Carc. Cat 2, Harmonized Classification for STOT RE 2 does also not impact any measures to be taken to reduce occupational exposures as strongly as Carc. Cat 1B would, nor will it directly impact the Industrial Emissions Directive. It would however strengthen the motivation that the adverse effects observed for HFPO-DA are severe, supporting the motivation that HFPO-DA and its salts, among which FRD-902, may be of Equivalent level of concern (ELoC) according to art. 57(f) (see also further discussion in section 5.2.3). Also, classification as STOT RE 2 will impact the waste treatment for waste containing more than 10 w/w% of the substance.

The registrant and all other 30 notifiers have self-classified FRD-902 as STOT RE 2. The NL-CA notes that the assessment factors used by the registrant to arrive at this self-classification may have been incorrectly applied and should in its opinion not lead to STOT RE 2. The NL-CA considers the STOT RE effects observed borderline for classification as a category 2 (see section 3.2 for a more detailed discussion) Information on the bioaccumulation in humans, which may be provided by the SEv, may turn out relevant in this discussion. Namely, when the results from the biomonitoring study in humans (currently requested in the SEv) would show that HFPO-DA accumulation in humans is higher than what is extrapolated based on the accumulation observed in rodents, this may imply that adverse effects occurring at higher external FRD-902 dose levels in test animals (above the threshold for classification) may still be relevant for classification.

*In summary*

Recent discussions in RAC support the general understanding that where relevant, harmonized classification is the preferred step before proposing a substance as SVHC. However, RAC nor MSC have yet evaluated a substance of potentially very high concern on the basis of extreme persistency and very high mobility. It is therefore difficult to say to what extend harmonized classification will be seen as a prerequisite rather than a supporting asset. The NL-CA concludes that proposing harmonized classification as Carc. Cat 2 will support further risk management measures for HFPO-DA and its salts, among which FRD-902. The NL-CA also concludes that classification for STOT RE 2 is borderline and a proposal for harmonized classification needs further consideration.

Given the high concern for HFPO-DA and its salt FRD-902, in the Netherlands, the NL-CA is of the opinion that further information on carcinogenicity and bioaccumulation on FRD-902 should not be awaited before harmonized classification is initiated. To strengthen the concern for human health, and to facilitate some first communication on the presence of HFPO-DA in waste the NL-CA therefore suggests to prepare an Annex VI proposal to harmonize the classification for Carc. Cat 2. When this Annex VI proposal is prepared, one could consider adding the proposal for STOT RE 2. In that case, update of any Annex VI proposal should be considered once new information on toxicity and bioaccumulation will become available. At RiME+3 2018, several Member States, the Commission and ECHA voiced that harmonised classification for Carc. Cat 2 (or STOT RE

2) would in their opinion not be a prerequisite for motivating an equivalent level of concern according to art 57(f). One Member State strongly suggested to postpone harmonised classification until the information requested under SEv process has been received in order to make best use of the available resources.

## SVHC identification followed by Authorization

Main concerns identified for the substance in Europe stem from industrial emissions of HFPO-DA (water, air, soil, waste) due to industrial use of FRD-902 and due to polymers containing HFPO-DA as an impurity. Emissions from use by consumers is not of immediate current concern, though the NL-CA does not exclude that residual amounts of HFPO-DA may remain present in articles and may from these articles emit to the environment or lead to direct exposure. Another concern is that FRD-902 may be considered part of a larger group of fluorochemicals. The substance is structurally similar to PFASs among which PFOA. Many, if not all of these substances are very persistent and their environmental abundances may give rise to aggregated exposure for which the sum of exposures may have a higher impact on human and environmental health than what would have been expected from their individual presence.

According to the currently available information, FRD-902 does not yet meet the requirements under art 57a-e for SVHC identification. The SEv may change this. The current information does already suggest that FRD-902 is extremely persistent (no degradation at environmentally relevant concentrations). Monitoring data within the Netherlands and several locations in Europe, among which Norway and Germany (see section 3.2.2) show HFPO-DA being present in concentrations about 1 ng/L in marine waters, and higher concentrations in Dutch freshwater depending on the exact location with peak concentrations up to 108 - 812 ng/L in streams and up to 7500 ng/L in other water bodies. Such concentrations were also observed in China and the USA in water systems in the vicinity of the fluorochemical production plants. Concentrations of 100 ng/L up to several thousand ng/L (2000 – 4000 ng/L) were found. Further away from the production plant, concentrations were found to be lower again and of a similar order as was found in Europe. Recent monitoring data furthermore indicate the environmental abundances in Sweden and the United Kingdom and point at unpredictable, wide spread and uncontrollable emissions at the waste phase (*study by the Dutch Enforcement Agency, 2018 in press)*. The fact that HFPO-DA is found at more remote locations in the North Sea and is found in several drinking water locations gives rise for concern that this substance is very mobile and is able to reach parts of the environment that should not be affected directly by humans. HFPO-DA found in the North Sea and the Baltic sea may originate from the Dutch rivers Rhine and Meuse, as is the same for the low concentrations of HFPO-DA found before the coast of Norway. There are also findings of HFPO-DA at locations where there is no apparent link between an emission source and the concentrations measured in water. The fact that FRD-902 was only introduced in Europe in 2012 adds to the very high concern for the mobility observed.

Its very mobile character is highlighted as a very high concern also from the side of the drinking water companies. They signal that HFPO-DA is found in drinking water at some locations at levels on the order of 5 ng/l. They also signal that with current techniques it is not possible to remove the substance (see also Pan et al. 2017; Sun et al. 2016). Upon recent communication, the registrant indicates that remediation techniques are under investigation and may be available. At the time of this RMOA, it was not possible to evaluate this information, nor assess the possibility for a wide applicability of these techniques. Earlier communication with the registrant suggested that such techniques might be applicable at the level of reducing industrial emissions but would not be acceptable as a standard technique required to prepare drinking water. A recent press communication informed that industrial emissions will be reduced by 99% by 2020. This however will not likely hold similarly true for the emissions resulting from waste

transport and treatment processes and may not impact emissions from other industries that process material that is relatively rich in HFPO-DA.

As a consequence of its extreme persistence, water solubility and the absence of adsorption to soil, HFPO-DA is expected to migrate practically without any borders and may be expected to turn up eventually in remote and pristine areas that should be protected against such human influences. Its extreme persistency furthermore makes that HFPO-DA will not degrade and will therefore spread to form a “constant” background pollution and consequently, exposure. As long as FRD-902 will be brought on to the market, the NL-CA is concerned that this background exposure levels of HFPO-DA will steadily rise. Taking that the substance was only brought at the EU market in 2012, its observed spread in the environment adds to the very high concern of the NL.

In combination with its toxicity (see section 3.2.1), the extreme persistency and very high mobility may furthermore lead to a very high concern for human health and wildlife. As is discussed in section 5.2.2, the available information on FRD-902and HFPO-DA may warrant classification as Carc. Cat 2 and is borderline for STOT RE 2. The NL-CA is of the opinion that the information available suggests that the substance will adversely impact human health and wildlife when (background) environmental concentrations rise. Information that may become available from the SEv may further add to this concern. The extreme persistency and mobility feed the concern that this impact then will be irreversible.

- SVHC identification followed by Authorization of HFPO-DA and FRD-902will prevent undesirable substitution of PFAS. Several years ago, when PFOA became identified as SVHC and regulated under restriction, FRD-902 was imported in Europe as an alternative for the production of fluoropolymers. At present, work is ongoing to regulate also other PFAS and several proposals have recently been submitted or are in a progressed phase of development. There may therefore be a chance that FRD-902 may in the near future find an even broader use in the production of fluoropolymers. It is therefore of importance to evaluate to what extent FRD-902 may be a desirable alternative. With regard to persistence, FRD-902 should not be considered a desirable alternative. Data on bioaccumulation are as of yet inconclusive but the NL-CA is concerned that bioaccumulation may be higher than can be deduced from currently available *in vivo* studies. Biomonitoring data in workers in the Netherlands and residents in China does not exclude that HFPO-DA remains in the human body for some time. The NL-CA is of the opinion that the available information on persistency, mobility, toxicity and exposure to humans and the environment rises sufficient concern to suggest that identifying HFPO-DA and FRD-902, as SVHC is desirable to counteract possible undesirable substitution of other perfluoro substances.

- To improve transparency, predictability and equal treatment of substances, and to further counteract possible undesirable substitution of other perfluoro substances, the NL-CA is of the opinion that not only HFPO-DA and FRD-902, but also the pre-registered potassium salt and FRD-903 should be identified as SVHC according to art. 57(f).

- Identification of HFPO-DA and its salts, among which FRD-902, as SVHC under 57(f) for being of equivalent level of concern may support further regulation of emissions of this substance throughout Europe via the Industrial Emissions Directive. Annex II of this directive stipulates the polluting substances for which industrial emissions should be regulated. Important for FRD-902 is that organohalogens are identified as polluting chemicals for emission to water and that fluorine and compounds are identified as pollutants for emissions to air. Furthermore is identified that “Persistent hydrocarbons and persistent and bioaccumulable organic toxic substances” are considered polluting substances for water. Candidate listing of HFPO-DA and its salts, among which FRD-902 and identifying these substances as SVHC for their persistent, mobile and toxic properties may strengthen any action under the IED

that is already in place because the substance is an organohalogen, and might lead to more stringent emission permits. However, the additional impact of this measure is uncertain and may be limited, for one because under the IED only specific types of industries need to request for an emission permit.

- SVHC identification followed by inclusion in Annex XIV will allow industrial users to apply for authorization for those uses in which the substance can be used safely or for which there is no acceptable alternative and the impact on society of no longer using the substance would be disproportionately high. SVHC identification followed by Authorization would thereby keep the possibility open to identify FRD-902 as a substance to use over other perfluoro substances for a possibly limited number of dedicated uses. It would also keep the possibility open for uses for which industrial emissions could be sufficiently reduced.

- In Europe, one registrant is known to import FRD-902, which is located in the Netherlands. Regulating FRD-902 through Candidate Listing will identify this substance as ZZS in the Netherlands (*Zeer zorgwekkende stof*, ZZS: Dutch equivalent of a substance of very high concern) and will be an effective means to support this registrant to minimize its industrial emissions to the absolute minimum. FRD-902 is furthermore notified under CLP by 30 other companies and candidate listing will provide the municipalities where the substance is used with the tools to set minimum emissions through emission permits and gives enforcement agencies the tools to enforce the allowed emissions. In a recent communication, the registrant informed the NL-CA about ongoing initiatives to reduce industrial emissions to water and air. No data are communicated yet to validate this information. From previous communication with the registrant has been concluded that regulatory incentives are needed to support minimization of emissions beyond current industry ambitions. In a recent press release, the registrant announced the further reduction of emissions by 99% in 2020. Nothing is known about any emission management on site of the other 30 notifiers. Since the available data point at a very important emission source of HFPO-DA located in the Netherlands, identifying FRD-902 as SVHC and hence facilitating the possibility to take further regulatory measures under the ZZS-policy program is considered very effective to address the concern for HFPO-DA.

- SVHC identification will support the identification of possible emission sources as a result of the obligation of article producers or manufacturers to notify the agency about the use of FRD-902 and communicate its presence in articles above 0.1 w/w% (art.7 and 33). The impact of this information on further regulating possible emissions is expected to be limited because article manufacturers will most likely only work with the polymerized substance. SVHC identification and the associated need to communicate the presence of FRD-902 will contribute to the overall profiling of distribution and use.

- The unpredictable, wide spread and uncontrollable emissions observed due to waste transport and waste treatment activities suggests that emissions of HFPO-DA at the waste phase are no longer manageable in an efficient way. SVHC identification of HFPO-DA and its salts, among which FRD-902, followed by Authorisation is one way of addressing the very high concern for HFPO-DA at its source (it will not impact measures under the Waste Framework Directive).

- HFPO-DA is extremely persistent and may be a so called *arrow-head* substance (a substance into which a group of substances breaks down). At present, a small group of HFPO-DA and its salts can be formed. To the best of our knowledge, no other substances are known to form HFPO-DA as (one of their) metabolite or degradation product.

- SVHC identification of HFPO-DA and its salts may be used to facilitate further regulation of similar substances of the group of PFECAs.

Authorization will not affect the emission due to the use of fluoropolymers containing HFPO-DA as an impurity at concentrations below 0.1%. In addition, Authorization will also not affect the import of articles produced with FRD-902 that may contain residual amounts of HFPO-DA as an impurity. Also, because production and use outside Europe will remain possible and import of articles is unrestricted, production of fluoropolymers made by means of the GenX process may move to countries outside the EU and emissions of HFPO-DA may continue or potentially increase. The fact that monitoring data from China and the USA show abundances in water that are higher than has been observed for the Netherlands, does raise concern. Therefore, an increase in production and use in these countries may be undesirable, unless emission reducing measures are implemented to a higher degree. This finding supports that in parallel to any measures under REACH, worldwide regulatory measures should also be considered. In the US, first steps have already been taken to initiate local and federal risk management measures. US EPA has announced that it will publish a toxicity value in 2018 for the GenX technology in which FRD-902 is used[4].

Given the relatively low number of potential users of the substance that notified their use under CLP (31 notifiers in total), SVHC identification followed by inclusion in Annex XIV is expected to result in a relatively low number of applications for authorization. The authorization process will serve to maintain overview of the uses and their users, which will support enforcement of emission reducing measures and stimulate research and development for substitution.

## Restriction

A restriction requires demonstration that action on a community wide basis is necessary beyond any measures already in place (REACH article 69.4). When restriction is being considered, current information suggests that any emission may be considered irreversible (because of the very high mobility of the substance and its extreme persistence) and increasing exposures in the form of increasing environmental abundances are expected to lead to adverse effects on human and environmental health.

- Restriction allows for targeted risk management. The concern for FRD-902 and its anion HFPO-DA focusses on emissions from industrial use first, and only to a much lesser extend on emissions from residual HFPO-DA still present in fluoropolymers as impurity. Restricting industrial emissions by setting emission limits and restricting maximum allowed residual concentrations in polymers may be a possible approach to address the concerns at hand.

- Restriction allows to address concerns for combined exposure of multiple substances. FRD-902 can be considered part of the group of short-chain PFAS and is similar to PFOA in terms of chemical structure and technical applications. It further is a member of the sub-group of per- and polyfluoroether carboxylic acids (PFECAs). Due to the very high persistence of these substances, combined exposure can be expected. Their structural similarities result in similar hazard profiles (that may only differ in potency). Consequently, combined exposure will lead to combined toxicity and regulating one substance should preferable take into account the possible presence of the others too.

- Restriction addresses an EU-wide risk. The available monitoring data sketch abundances in water with the centre of gravity of highest concentrations located in the Netherlands. It should be noted that this picture could be influenced by the Dutch activities to generate monitoring data. The limited number of monitoring data

[4] https://www.epa.gov/pfas/epa-actions-address-pfas ; Speech van EPA Administrator Scott Pruitt, 22 mei 2018.

for other European countries namely do show HFPO-DA at some places but do not show the possible ubiquitous presence as observed in the Netherlands. Also, for a significant part of the monitoring data, the emission source is related back to emissions from the Dutch rivers Rhine and Meuse. This risk pattern may point towards national measures as most appropriate risk management measure. However, the fact that there is information on an EU wide distribution of HFPO-DA (through e.g. wastewater regeneration activities) and there are more notifiers active than only the one Registrant located in the Netherlands, together with the high mobility of the substance (the current environmental spread has taken place within a period of 2012 – 2017) and the possible concern for risk as a consequence of combined exposure to other fluoro substances leads the NL-CA to conclude that exposure to HFPO-DA is of EU-wide concern. However, as monitoring data are only available for some Member States, it is difficult to be more conclusive on the need to act on a European scale through the process of restriction.

- Restriction allows to address concerns for exposure occurring from the degradation of longer fluoro polymers. For the group of PFAS and for PFOA, available information shows that the substances of concern are (also) formed from the degradation of other fluoropolymers or perfluoro substances. For HFPO-DA, there is no information available to the NL-CA suggesting a concern for formation of this chemical from degradation of larger fluoropolymers or larger perfluoro substances. Hence, there is yet no ground to enlarge the scope of concern and add such larger substances to any restriction to be possibly developed for HFPO-DA. It is however possible that alternative salts, like the potassium salt, or the acid (FRD-903) may contribute to HFPO-DA concentrations in the environment and could therefore be considered in a possible restriction.

- Restriction can be an effective regulatory route for substances that are produced and used in high tonnages with many registrants and downstream users and for which many Applications for Authorization would be expected. As described in section 5.2.3, the limited number of notifiers (31 in total), the single registered use and the registered tonnage band of 10 -100 tpa suggest to conclude that this is not the case for FRD-902.

- The scope of a Restriction also applies to imported articles. Restricting the use of FRD-902 may therefore also be used to prevent import of articles containing residual HFPO-DA. In the case of HFPO-DA, residual concentrations in the fluorpolymers used in articles is expected to be very low (see confidential Annex, Annex I) and hence, any emissions from that source are expected to be limited. However, restricting the content of HFPO-DA in imported articles may also be used as a tool to discourage the production and use of this substance elsewhere outside Europe. At least as far as this production and use concerns production of articles for the European market.

- SVHC identification of substances for which CLP does not provide for Harmonized Classification of the hazard is considered a preferred first step towards Restriction (e.g. PBT identification through SVHC identification as a first step before Restriction is initiated).

Industrial emissions in the Netherlands may be well controllable through the ZZS-policy and in addition to SVHC identification Restriction may not be needed to address that part of the concern. However, the ZZS-policy does not affect the waste transport and waste treatment activities that are regulated under the Waste Framework Directive, nor does the SVHC status directly impact on waste management measures. SVHC identification and Authorisation also do not address the concern for combined exposure. Evaluating the possible need to restrict the use of the PFAS sub-group PFECA, of which HFPO-DA and its salt, including FRD-902, are members, is therefore proposed as a follow-up step of SVHC identification that is concluded in this RMOA.

### Stockholm Convention

FRD-902 and its anion HFPO-DA may meet the criteria for being a persistent organic pollutant (POP) in the context of the Stockholm Convention. There may however be insufficient information available to meet the specific criteria to identify the substance as undergoing long range transport in the context of the Stockholm Convention. Given the mobility that is observed, NL-CA expects to see long range transport for HFPO-DA with time. Obtaining this type of information will however require targeted monitoring programs and may only become visible within some years. In addition to long range transport, there is currently also insufficient information to conclude on the bioaccumulation potential (see section 5.2.1).

In the opinion of the NL-CA, based on the available data the concern may signal a possible need for a worldwide restriction of use of HFPO-DA forming substances including FRD-902, but also at least the substances FRD-903 and the potassium salt: because of the persistency, mobility and possible toxicity of HFPO-DA. A worldwide restriction of use of HFPO-DA and its salts could be well facilitated through the Stockholm Convention. It is anticipated that this process, and the generation of data required to initiate the drafting of a proposal for POP identification has a very long time span which is not appropriate in the light of the immediate concern at hand. It is however concluded that the possibilities for regulatory action under the Stockholm Convention should be explored in parallel to the development of further regulatory measures under CLP and REACH.

## Conclusions on the most appropriate (combination of) risk management options

In view of the present concern for the substance which relates to its wide spread abundance in the environment, its abundance in drinking water, its extreme persistency, its very high mobility in water, the concern for any possible accumulation in the human body being higher than can be extrapolated from animal data, its possible toxicity and the present difficulty to remove HFPO-DA from drinking water and the environment, it is judged that regulatory measures should be taken as soon as possible in order to reduce emissions. It is also concluded that regulatory measures should preferably be aimed at the production and use phase and should prevent a situation in which HFPO-DA containing waste cannot be traced and treated responsibly. Awaiting the data that are currently being requested within the SEv process and that may at the earliest arrive after 2022 is therefore concluded undesirable. The NL-CA is of the opinion that HFPO-DA and FRD-902 may be of Equivalent level of Concern according to article 57(f) of REACH and should be proposed for SVHC identification as soon as possible. To prevent undesirable substitution and to increase transparency and predictability, this SVHC identification should preferably involve HFPO-DA and its salts, including also FRD-903 and its potassium salt for which there is a pre-registration. This regulatory action will ensure that additional emission reducing measures can be requested and enforced within the Netherlands through the ZZS policy where the current concerns for emissions are highest within Europe. Identifying FRD-902 and HFPO-DA as SVHC will also help obtaining a more coherent picture of possible uses in Europe and is considered a preferred first step when proposing for a Restriction.

SVHC identification will, however, not directly impact on any waste treatment activities. Possibly, waste treatment could be considered as part of any future application for Authorisation. How this will play out remains to be seen. Harmonized classification under CLP on the other hand will build a trigger to communicate on HFPO-DA in waste, but will leave low concentration waste unaffected.

The NL-CA is of the opinion that in addition to SVHC identification the need for restriction should be further evaluated in the light of ongoing work on the group of short chain perfluoro substances and restrictions considered in that context. In considering further

Restriction, it is advised to include further elaboration on a possible concern for combined exposure and toxicity and to explore possibilities for further regulation of waste handling. In addition to these, the NL-CA is of the opinion that Restriction should be further elaborated in the light of imported articles[5] and discouraging production and use for the European market elsewhere. This further evaluation may however be only effective when more information on a European wide concern of emissions becomes more clear.

NL-CA concludes the following approach in which actions will be initiated in parallel as much as possible:

- Annex XV proposal for SVHC identification. In view of the two not registered substances FRD-903 and the potassium salt EC 266-578-3 that both form HFPO-DA under environmental conditions and may eventually be used as alternative to FRD-902, it should be considered to formulate the Annex XV proposal such that it includes all substances that form HFPO-DA under environmental conditions: HFPO-DA and its salts.
- CLH for Carc. Cat 2

A possible need for an Annex XV proposal for Restriction should be considered as part of the broader evaluation of risk management option for the group of short-chain PFAS and in particular of the PFECAs. Possibly, a restriction could be inspired by an increasing insight on use and emissions in Europe, for example as a result of Applications for Authorization.

Once the SEv data become available, NL-CA concludes that these should be reviewed and the conclusions of this RMOA should be revisited to the extent that CLH for Carc. Cat 1B should be evaluated, the need for SVHC identification according to art. 56(a), (d) and (e) should be discussed and a further extension of any proposed Restriction should be considered.
Many comments and suggestions for additional information were received on the draft RMOA that was put up for commenting by the MSCAs, ECHA and the Commission, and that was discussed at RiME+3 2018. The NL-CA has assessed all comments and has taken these on board where this was deemed appropriate. Most comments were concluded to further strengthen the proposal for SVHC identification. In view of time and capacity available, the NL-CA therefore decided to only include a brief reference in this RMOA and to include further elaboration and more detailed analysis of the information provided only in the Annex XV dossier for SVHC identification.

## 4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

| Follow-up action | Date for intention | Actor |
|---|---|---|
| Annex XV dossier for Authorization | 2019 | NL-CA |
| Evaluation of a possible need for further | 2019 | NL-CA |

[5] It is noted that ECHA will assess the need for restricting use in articles when HFPO-DA and its salts are put in Annex XIV

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|---|---|---|
| regulatory measures on the group of PFECAs similar to FRD-902 | | |