Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion related to the request by the Executive Director of ECHA under Art. 77(3)(c) of REACH to review a derogation request for the restriction of PFOA, its salts and PFOA-related substances (entry 68 of Annex XVII to REACH)

ECHA/RAC/RES-C-0000001412-86-221/F
ECHA/SEAC/RES-C-0000001412-86-222/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 14 September 2018) and SEAC's opinion (adopted 13 September 2018)

14 September 2018

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13 September 2018

ECHA/SEAC/RES-C-0000001412-86-222/F

OPINION

Pursuant to Article 77(3)(c) of 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 (the REACH Regulation), the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions on the request to review a derogation request for the restriction of PFOA, its salts and PFOA-related substances (entry 68 of Annex XVII to REACH).

I. PROCESS FOR ADOPTION OF THE OPINION

On 23 May 2018[1], the Executive Director of ECHA requested RAC and SEAC to review by 1 December 2018 the derogation request for the restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (entry 68 of Annex XVII to REACH).

Rapporteur, appointed by RAC: **Bert-Ove LUND**

Rapporteur, appointed by SEAC: **Johanna KIISKI**

In accordance with the mandate from the Executive Director of ECHA, the rapporteurs developed the opinions, summarising the justifications for including a derogation.

The RAC opinion was adopted **by consensus** on **13 September 2018**.

The SEAC opinion was adopted **by consensus** on **14 September 2018**.

[1] https://www.echa.europa.eu/documents/10162/13580/rac_seac_mandate_pfoa_derogation_request_en.pdf/d13a1e42-143a-799b-e08e-52ece2399112

II. OPINION OF RAC AND SEAC

The current restriction is:

'68. Perfluorooctanoic acid (PFOA) CAS No 335-67-1 EC No 206-397-9 and its salts. Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements. Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements. The following substances are excluded from this designation: — C_8F_{17}-X, where X = F, Cl, Br. — C_8F_{17}-C(=O)OH, C_8F_{17}-C(=O)O-X′ or C_8F_{17}-CF_2-X′ (where X′ = any group, including salts).	1. Shall not be manufactured, or placed on the market as substances on their own from 4 July 2020. 2. Shall not, from 4 July 2020, be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above 25 ppb of PFOA including its salts or 1 000 ppb of one or a combination of PFOA-related substances. 3. Points 1 and 2 shall apply from: (a) 4 July 2022 to: (i) equipment used to manufacture semi-conductors; (ii) latex printing inks. (b) 4 July 2023 to: (i) textiles for the protection of workers from risks to their health and safety; (ii) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (iii) plasma nano-coatings. (c) 4 July 2032 to medical devices other than implantable medical devices

	within the scope of Directive 93/42/EEC. 4. Points 1 and 2 shall not apply to any of the following: (a) perfluorooctane sulfonic acid and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004; (b) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms; (c) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met; (d) a substance, constituent of another substance or mixture that is to be used, or is used: (i) in the production of implantable medical devices within the scope of Directive 93/42/EEC; (ii) in photographic coatings applied to films, papers or printing plates; (iii) in photo-lithography processes for semiconductors or in etching processes for compound semiconductors; (e) concentrated fire-fighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other fire-fighting foam mixtures.

	5. Point 2(b) shall not apply to fire-fighting foam mixtures which were: (a) placed on the market before 4 July 2020; or (b) produced in accordance with point 4(e), provided that, where they are used for training purposes, emissions to the environment are minimised and effluents collected are safely disposed of. 6. Point 2(c) shall not apply to: (a) articles placed on the market before 4 July 2020; (b) implantable medical devices produced in accordance with point 4(d)(i); (c) articles coated with the photographic coatings referred to in point 4(d)(ii); (d) semiconductors or compound semiconductors referred to in point 4(d)(iii).'

The derogation proposed is:

Substance Identity (or group identity)	Conditions of the restriction
– Substance name, – CAS No xxx, – EC No xxx	Point 2 shall not apply to import[2] and use of perfluorooctane bromide (PFOB) containing perfluorooctane iodide (PFOI) in concentration lower than 250 ppm for the manufacture of pMDI (pressurised metered

[2] The derogation is limited to import and use in order to be as specific as possible in relation to the actual processes at AstraZeneca. If a derogation were to include EU production of PFOB as well as import, RAC would have to consider potential emissions from the EU production, and SEAC related socio-economic aspects. However, there is no production of PFOB in the EU, and as RAC and SEAC cannot assess a potential future EU production, the derogation is focused on import and use as described by AstraZeneca.

	dose inhaler) products for the treatment of respiratory diseases.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed derogation based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the relevant report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the derogation proposed on Perfluorooctanoic acid (PFOA), CAS No 335-67-1, EC No 206-397-9 is the most appropriate Union wide measure to address the issue as demonstrated in the justification supporting this opinion.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed derogation based on an evaluation of the information related to socio-economic impacts documented in the relevant report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the derogation proposed by the Dossier Submitter on Perfluorooctanoic acid (PFOA), CAS No 335-67-1, EC No 206-397-9 is the most appropriate Union wide measure to address the issue taking into account the proportionality of its socio-economic benefits to its socio-economic costs as demonstrated in the justification supporting this opinion.

III. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of the risk(s) addressed by the proposed restriction

The original restriction proposal is based on the Persistent Bioaccumulating and Toxic (PBT) properties of PFOA. No relevant quantitative environmental risk assessment can as such be conducted for PBT substances (REACH Guidance R.11.1 page 10, version 2.0, 2014), so the overall intention is to minimise emissions. Any environmental exposure has the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects via the food chain). Information on environmental emissions (supported by environmental and human monitoring data) for PFOA and PFOA-related substances are therefore used as a proxy for potential risk. PFOI is a PFOA-related substance that is expected to degrade to PFOA in the environment. PFOB is not covered by the PFOA restriction.

AstraZeneca uses perfluorooctyl bromide (PFOB) as a processing aid in the manufacture of porous particles, which are a functional component in pressurised metered-dose inhaler (pMDI) medicines. These porous particles provide a uniform suspension inside a pMDI, which is able to deliver an optimal distribution of drug crystals in the lungs for alleviation of lung diseases such as chronic obstructive pulmonary disease. The technology also enables consistent delivery of multiple active ingredients from a single pMDI. The PFOB is produced outside the EU and typically contains up to 200 ppm PFOI as an impurity, which exceeds the threshold of 1 ppm set for PFOA-related substances in the current restriction on PFOA.

The focus in the evaluation of the risk reduction capacity is in estimating the releases of the substances covered by the restriction. This follows the current practise on the evalution of PBT and vPvB cases under REACH.

The current volumes of use are not reported, but AstraZeneca will invest in an additional “manufacturing suite” in 2018, and it is predicted that 10 tonnes PFOB will be used annually in 2025 in Sweden. The PFOI concentration in PFOB is typically below 200 ppm, but 250 ppm is given as the maximum concentration. This gives a maximum of 2.5 kg of PFOI that could be expected to be present as impurity in PFOB per year. AstraZeneca reports that they have the best available technology to ensure negligible releases to the environment. Based on the maximally used volume of 10 tonnes PFOB and a typical concentration of 200 ppm, AstraZeneca estimates that less than 4 grams of PFOI will be released to the environment per year. The management of the gaseous and liquid waste streams leading to such low emissions is described in the CSR, and additional clarifications have been recieved from AstraZeneca in the Public Consultation (see RCOM document).

The final products available to consumers contain even less PFOI in concentration below 2 ppb.

Occupational exposure at the AstraZeneca plant is also discussed in the chemical safety report, but this exposure has not been assessed by RAC as the PBT assessment focuses on

establishing that environmental emissions have been minimised. Also, as PFOB is imported into the EU, and the derogation concerns 'import and use', potential emissions from the production of PFOB have not been assessed.

Information on hazard(s)

The PBT properties of PFOA, and the PFOA-related substances such as PFOI, are not discussed further in this opinion as there is already an EU agreement on PFOA fulfilling the PBT criteria. That is, PFOA is persistent, bioaccumulative and toxic (see Section B.4.3 of the restriction proposal and the Member State Committee (MSC) opinion for identification of PFOA as an SVHC, June 2013). There is no indication of new data challenging the 2013 opinion from the MSC.

Information on emissions and exposures

The Chemical Safety Report and the derogation request describe that PFOB is used in the preparation of porous particles, which are a functional ingredient in the pMDI products. Additional clarifying information was subsequently received from AstraZenca during the Public Consultation. PFOB typically contains approximately 200 ppm PFOI (maximum 250 ppm) and the PFOB waste stream therefore contains a proportionately low level (200 ppm) of PFOI. The porous particles are spray-dried using a spraydryer. Gaseous emissions are extracted directly from the spray drier and captured through two carbon beds used in series in a stand alone building (99.8% efficiency). Continuous monitoring of PFOB before and after the carbon beds with online infrared gas analyser technology has according to data provided by AstraZeneca never shown concentrations in the discharge above the detection limit of 0.1 ppm PFOB (stated to be equivalent to 0.55 g PFOB/hr at the typical flow rate). However, values slightly above this concentration have also been considered to represent zero emissions, so the detection limit of this continuous online method seems unsure. Based on PFOB data, an efficiency >99.8% has been calculated, and a similar efficiency is assumed for PFOI.

Manual sampling and GC/MS analysis of PFOB in a few samples from the purified process gas seems to verify very low concentrations of PFOB in the discharge. As PFOB concentrations in the incoming gas has not been measured by GC/MS, this more exact method cannot verify the efficiency. However, based on the available data and the general knowledge of C8-PFAS chemistry, RAC is confident that two carbon beds in series will be very efficient and accepts the estimated 99.8% efficiency.

Ten tonnes of PFOB (typically containing 2 kg PFOI) per annum is expected to be used in Sweden in 2025, and with an assumed efficiency of 99.8%, this corresponds to <4 g PFOI released per annum to the atmosphere as gaseous waste. The waste PFOB/PFOI is removed from the carbon beds via liquid in-situ removal to dedicated tanks before proceeding to off-site incineration at high temperature (at least 1100°C) with a 2 seconds residence time for flue gases. RAC accepts that incineration at 1100 °C is expected to fully degrade PFOI. The carbon beds are re-used and eventually incinerated at the end of life. A release of 4 g PFOI per year will increase the local contamination with PFOI/PFOA, but can be viewed as minimised emissions considering the >99% capturing of PFOI in the carbon beds.

Liquid waste from other streams, e.g. dishwashers and laboratories, is currently collected for specialised waste treatment by incineration. This liquid waste represents approximately 2%

of the total PFOB used (<200 kg/year), hence the total quantity of PFOI in this waste stream is <40 g/year, which is incinerated at high temperature (at least 1100°C). There is capacity to incinerate all liquid waste, also at the higher production capacity expected in 2025. The incineration is expected to eliminate emissions of PFOI from the liquid waste stream.

RAC concludes that the present waste handling fulfils the requirements for minimising emissions of PBT-substances, with total emissions of less than 4 g PFOI per year at maximum production capacity in 2025.

At full production capacity, the current way of handling of liquid waste will result in large volumes of aqueous waste to be incinerated. Hence, the CSR discusses the possibility to treat the low concentration waste stream at the on-site AstraZeneca Waste Water Treatment Facility (WWTF) in the future. However, the planning for 'future' treatment of waste water in a WWTF is of concern for RAC. Firstly, the removal in the WWTF is estimated using QSAR models that most likely are not valid for these perflourinated substances. Secondly, if the predicted fate in the WWTP would be correct, it would not be consistent with the concept of minimising environmental emissions. RAC considers that no degradation can be expected in an ordinary WWTF and that PFOI/PFOA will subsequently be released from the WWTF. Based on the current information and knowledge of PFAS, the use of a WWTF is not consistent with the concept of minimisation of emissions, and thus, cannot be supported by RAC. AstraZeneca states in the Public Consultation that the company “accepts that incineration must continue if no better aqueous waste separation is identified” and that the company has capacity to incinerate the increasing volumes of liquid waste that are expected as production increases”.

In summary, the description of the waste handling is rather poor in the CSR, but based on further data and clarifications received from AstraZeneca in the Public Consultation RAC is of the view that both air and water emissions are minimised. **Based on an estimated total local release of 4 g/year, the derogation can be supported provided the current way of waste handling is maintained. Trusting that AstraZeneca will incinerate all liquid waste for the foreseeable future, and not pursue other treatment methods until these are proven to achieve a similar level of removal of PFOI (see RCOM), no specific condition concerning the potential use of a waste water treatment plant is needed.**

Characterisation of risk(s)

The original restriction proposal for PFOA and PFOA-related substances (which includes PFOI) is based on environmental concerns for the PBT properties of PFOA. No relevant environmental risk assessment can as such be conducted for PBT substances, so the overall intention is to minimise emissions.

Based on the assessment of the information provided in the present derogation request, it is concluded that AstraZeneca have minimised current emissions of PFOI.

However, the plans for the future handling of waste water are not sufficiently well justified to be supported by RAC. It is acknowledged that from an EU perspective the overall emissions are small, but they concern one single site and thus are not insignificant from a local point of

view. Furthermore, the emission minimisation requirement for PBTs is also valid for individual emission sites.

Uncertainties in the risk characterisation

The request for a derogation is rather brief when it comes to substantiating the measures taken to reduce the environmental emissions, but additional data has been received in the Public Consultation. With this additional information, the high efficiency of the carbon beds is accepted by RAC. The only potential uncertainty remaining is that the efficiency is calculated based on data for PFOB, and not on PFOI. However, based on similar chemical characteristics for PFOB and PFOI, RAC accepts that the high efficiency for PFOB can be assumed to be valid also for PFOI.
The effectiveness of waste water treatment plants for removal of PFOI is questioned by RAC, but as AstraZeneca has agreed to continue to incinerate the liquid waste, this uncertainty will not affect the derogation request.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

See the previous RAC opinion on PFOA (ECHA, 2015).

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

The current waste handling seems to fulfil the emission minimisation requirements that apply for PBT-substances. However, a potential handling of aqueous waste in the companys waste water treatment facility cannot be supported.

See also the previous RAC opinion on PFOA (ECHA, 2015).

Socio-economic impact

Justification for the opinion of SEAC

The ECHA report analysing the case and making a proposal to add a derogation addresses the impacts of restricting a use instead of the impacts of derogating a use already included in a restriction (albeit the latter is actually what is proposed in the case at hand). SEAC agrees that is appropriate; this way the terms costs and benefits will have the same meaning as usually in opinions on restriction proposals.

Availability of alternatives

AstraZeneca has described their search of alternatives in a separate document annexed to the proposal by ECHA. Four different possible alternatives were identified: 1) PFOB which is further purified to reduce levels of PFOI, 2) PFOB that is manufactured via alternative routes,

3) using perfluorooctyl ethane instead of PFOB, 4) use of structurally different alternatives to PFOB. All these options are reported to be subject to significant difficulties.

Using a structurally different substance would appear the most viable long-time solution (no associated emissions of perfluorinated substances). According to the analysis of alternatives, a large number of substances was evaluated at the time of development of the current process. No suitable substitute has been found at that time or later and it is not possible to foresee when one would be available. This route for substitution is expected to be very expensive because of unpredictable R&D costs before success in finding a suitable alternative and high costs after possibly finding one because new clinical trials would most probably be needed. It is also stated that it would be time-consuming to get the necessary regulatory approvals.SEAC considers that the report on the search for alternatives, while not going into a lot of details, gives a clear overview of a systematic approach. SEAC finds that a more detailed description of the process used in the search of structurally different alternatives (option 4) would have been helpful to describe the efficiency of the search. Also further information on the efforts made to find structurally different alternatives after the initial search would have been helpful to reduce uncertainties. However, SEAC considers that the remaining level of uncertainties is tolerable taking into account the low level of emissions connected to this use.

SEAC agrees that suitable alternatives do not appear to be available and therefore relocation outside the EU appears the most probable option for AstraZeneca in case the use in question will not be allowed in the EU.

Costs

According to the ECHA report, applying the PFOA restriction to the use of PFOB containing traces of PFOI in the manufacture of pMDI (pressurised metered dose inhaler) products for the treatment of respiratory diseases is expected to cause the following economic impacts:

- Loss of sales for AstraZeneca if their manufacturing capability outside the EU does not meet the demand,
- Cancelled investment in a second manufacturing suite[3] in Sweden, and
- High equipment relocation costs and significant investment in a new production plant outside Europe, or significant R&D costs to develop a process with an alternative to PFOB with an interruption in the supply of medicine to patients.

SEAC notes that loss of sales for AstraZeneca can represent either a pure distributional effect (in case EU competitors gain the market) or a social cost to the EU (in case non-EU enterprises take the market). Cancelled investment in Sweden could be interpreted as savings for AstraZeneca, however it would also be associated with loss of future profits from this production.

AstraZeneca claims that in case the use in question will not be allowed in the EU, manufacture could be relocated outside the Union. SEAC agrees that relocation is expected to lead to additional costs (relocation of machinery, start up effects, etc.). As regards increased research

[3] The proposed additional manufacturing suite will be a new production line in the current premises.

and development if a process with an alternative to PFOB would be developed, SEAC agrees that potentially high additional costs would be expected.

In regard to the scale of the costs, while SEAC regards that some expenditure on continuous improvement relating to safety aspects could be expected to be a part of a sustainable business strategy, SEAC also understands that significant expenditure to avoid <4 g of emissions per year, even if of a PBT substance, would not appear proportionate to industry.

Impacts on patient welfare are discussed under "other impacts" below.

Generally, the SEAC approach to the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances expects that the costs of compliance are quantified. However, SEAC considers that:

- the level of emissions is relatively very low here (<4 g per year, this is lower than for some of the derogations already supported by RAC and SEAC in the original opinion on the PFOA restriction proposal[4]), and
- the costs of applying the PFOA restriction to the use in question have been clearly described in a qualitative manner such that considering the level of emissions, the conclusion on proportionality is obvious.

Therefore, quantification of economic impacts in this case is considered unnecessary. Overall SEAC considers that costs have been represented satisfactorily.

Benefits

The benefits of restricting the use relate to reduced emissions of PFOI to the environment. As is discussed in the RAC/SEAC opinion on the PFOA restriction proposal, PFOI is a PFOA-related substance, meaning that it can produce PFOA through degradation. PFOA fulfils the PBT criteria, which means that emissions to the environment must be minimised. PFOA also has potential for environmental long-range transport.

AstraZeneca estimated the emissions to atmosphere at <4 g per year. This level was confirmed by RAC.

There has not been an effort to quantify the damage expected to the environment from the additional emissions (or perhaps more relevant, the raised level of environmental exposure concentrations, i.e. the stock). SEAC agrees that currently there are no suitable tools available for the quantification of the damage caused by emissions of PFOI, or most PBT/vPvB substances more generally. Quantification of the damage from PBT/vPvB substances is not necessary according to the SEAC approach to PBT/vPvB substances (ECHA 2016), and is not needed in the case at hand to be able to conclude on the socioeconomic impacts expected.

SEAC considers that the approach taken is proportionate to the issue at hand (very low level

[4] Combined RAC and SEAC opinion on PFOA, Table 2: <4 kg/year for semiconductors and <200 g/year for photographic materials; footnote 11: medical devices 20 g/year (in implantable devices, of which all perhaps not available for release).

of emissions).

Other impacts

According to the ECHA report and annexes thereof, a ban of the use in the EU/EEA is expected to lead to **loss of employment opportunities** in Sweden, France and the UK. Porous particle manufacture in Sweden now employs approximately 20 FTE, and investment in a second suite would generate additional employment. AstraZeneca claims that cease of manufacture of porous particles in Sweden would reduce manufacturing activity further down the supply chain in France and the UK, however, the magnitude of the related cuts in personnel has not been stated. In any case, it seems clear that at least new employment opportunities would not be created in the EU/EEA.

Also a possible **decrease in the possibilities for patients to manage their symptoms** is reported. The socio-economic analysis provided by AstraZeneca highlights the importance of availability of a choice of medicines. Different products are necessary to enable patients with different conditions to find a well-suited medication that alleviates their symptoms appropriately and increases their possibilities to lead a near normal lifestyle. Inability to find suitable medication could render patients unable to work. The technology used by AstraZeneca provides a stable, homogeneous suspension designed to prevent sedimentation of drug crystals over time and to prevent drug crystals from interacting with one another, thus allowing for consistent dosing of one or more different drugs from a single pMDI. A new product currently in clinical development is expected to be a unique product with three active ingredients. It is also stated in the socio-economic analysis that education of patients in the correct use of devices is sometimes a challenge in respiratory healthcare, and the combination of multiple medicines in the same product increases the probability that a patient receives the correct dose of medicine. SEAC regards that effects on patient welfare are a significant impact to be considered and overall agrees that these impacts appear plausible.

Overall proportionality to the risk

SEAC regards that the fact there will be (significant) costs expected due to the PFOA restriction applying to the use in question has been adequately demonstrated. The level of emissions is relatively very low (<4 g per year) and the emissions have been adequately minimised according to RAC. SEAC therefore considers that it has been demonstrated that the current restriction is not proportionate to the risk for this use.

SEAC therefore finds derogation of import and use of perfluorooctane bromide (PFOB) containing perfluorooctane iodide (PFOI) in concentration lower than 250 ppm for the manufacture of pMDI products for the treatment of respiratory diseases justified.

Based on the information available, SEAC regards that there is no reason to expect a relevant change in costs, releases or availability of alternatives in the coming years. SEAC considers that because of the very low emissions, and also to be consistent with the approach used in assessing derogations during the evaluation of the original PFOA restriction proposal, the derogation proposed here should be not limited in time. Non-time-limited derogations were recommended where adequate minimisation of emissions was demonstrated, and according to RAC, that is the case here.

Uncertainties in the proportionality section

SEAC has not received information on possible alternative methods that could be used to manufacture the products in question by other manufacturers. If such methods existed, allowing the derogation might be not proportionate to the risk. In that case many if not all of the patients would be able to acquire the medication they need elsewhere, and that might be the preferable solution. The analysis of alternatives submitted by AstraZeneca demonstrates that they are not currently aware of any promising alternatives themselves. The public consultation carried out also did not produce information on potential alternatives.

SEAC notes that the uncertainties related to the future emissions after new production suite is operational have been reduced after AstraZeneca committed to continue incineration until other methods to treat the waste are proven as efficient.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

The current waste handling is practical, at least at the present level of production, and according to AstraZeneca also practical as the production will increase.

The alternative approach discussed in the CSR to be used when the production increases (i.e. the use of WWTF), is questioned by RAC. The commitment by AstraZeneca in the Public consultation to continue to incinerate the liquid waste is therefore acknowledged. Any alternative method used in the future must have a similar efficiency as incineration. The efficiency has to be proven with good monitering data, making the method and efficiency enforceable. As gaseous emissions are monitored, enforcement is possible.

Monitorability

Justification for the opinion of RAC and SEAC

PFOB is monitored in the gaseous emissions, and based on these measurements a removal efficiency of >99.8% is assumed also for PFOI. Thus, PFOI is not measured, but RAC supports that the monitoring of PFOB will be a proxy for PFOI when it comes to assessing the removal efficiency.

A limit of quantification of 10 µg PFOB/L is given for the aqeous emissions, but the aqeous emissions are incinerated so currently no monitoring is needed for the aqeous waste.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

There are no significant uncertainties, assuming that liquid waste will be incinerated also in the near future until other methods with proven high efficiency can be used. See above concerning other uncertainties in the RAC assessment.

The uncertainties in the SEAC assessment are discussed above under the title Socio-economic impact.

REFERENCES

ECHA 2015: Compiled RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (ECHA/RAC/RES-O-0000006229-70-02/F, adopted 8 September 2015) (ECHA/SEAC/RES-O-0000006229-70-03/F adopted 4 December 2015)

ECHA 2016: Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC (SEAC/31/2016/05 Rev.1). Available at: https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf