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Socio-economic analysis in practice: Developing best practice and quality standards of socio-economic analysis as part of a restriction proposal under REACH –

Information collection and analysis of possible restriction effects regarding the technical use of PTFE and related fluoropolymers

- Final Report -

by

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Abstract

The objective of the project was to prepare an SEA as part of a restriction proposal under REACH. This included not only the content of the analysis such as the collection and the evaluation of relevant data, but also the practical implementation and the management of the SEA process in an authority. Hence, the aim of the activities was to support UBA in the collection of relevant data and in the analysis of socio-economic impacts of an EU-wide restriction of PFOA. Due to its broad use pattern and the possibility of formation of PFOA from precursor substances the scope of this study was limited to the use of PFOA in the manufacture of Polytetrafluoroethylene (PTFE).

Kurzbeschreibung

Es war Ziel des Vorhabens, eine SEA als Teil eines Beschränkungsvorschlags unter REACH zu erarbeiten. Dabei ging es nicht nur um die inhaltlichen Aspekte der SEA - wie die Recherche und die Bewertung relevanter Daten - sondern auch um die praktische Umsetzung und das Management des SEA-Prozesses in einer Behörde. Dementsprechend sollte das UBA in der Sammlung relevanter Daten und in der Bewertung sozioökonomischer Folgen einer EU-weiten Beschränkung von PFOA unterstützt werden. Wegen des breiten Verwendungsmuster von PFOA sowie dessen potentieller Entstehung aus Vorläufersubstanzen war der Fokus des Vorhabens auf die Verwendung von PFOA in der Herstellung von Polytetrafluorethylen (PTFE) begrenzt.

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List of Abbreviation

APFO	Ammonium Perfluorooctanoate
CBI	Confidential business information
ECF	Electro-Chemical Fluorination
EPSM	European manufacturers of Engineering Polymer Shapes for Machining
DU	Downstream user
I	Importer
M	Manufacturer
PBT	Persistent, bioaccumulative and toxic
PFOA	Perfluorooctanoic acid
PTFE	Polytetrafluoroethylene
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SEA	Socio-economic analysis
TFE	Tetrafluorethylene
UBA	Umweltbundesamt - German Federal Environmental Agency

Summary

The present report documents the work performed was part of a supporting research project for the elaboration of a restriction dossier according to Annex XV of Regulation (EC) No. 1907/2006 for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by the German Federal Environmental Agency (UBA). UBA is completing this task in its function as competent authority (authority for the assessments of risks for substances that are hazardous for the environment) for the environment responsible for restriction proposals according to Article 69 (4). The substance a restriction should be proposed for was Perfluorooctanoic acid (PFOA, CAS No. 335-67-1).

The aim of the activities was the support of UBA in the collection of relevant data and the analysis of socio-economic impacts of an EU-wide restriction for PFOA. Due to its broad use pattern and the possibility of formation of PFOA from precursor substances the scope of this study was limited to the use of PFOA in the manufacture of Polytetrafluoroethylene (PTFE). Besides the specific socio-economic analysis of a restriction of PFOA another aim of the study was the generation of information needed for the derivation of evidence for a description of the risk and the cost efficiency of the regulatory measure.

The methods applied for the collection of information include primarily interviews with sector experts, whereas the focus was not set on the direct downstream users of PFOA in PTFE manufacture but rather on the users of the PTFE because there are indications that a part of emissions of potential residual PFOA occur during downstream processing of PTFE at these actors. Furthermore, existing documents and internet resources were analysed and taken into consideration as well as the results of a questionnaire campaign initiated by UBA.

With regard to the relevance of PTFE uses several interview partners confirmed the potential importance of this pathway. This is less based on existing data of specific PFOA emissions from PTFE processing than on several process descriptions demonstrating in almost all cases a process at elevated temperatures above the boiling point of PFOA but lacking information on the fate of PFOA that very likely is evaporated. This assumption is supported by the fact that in almost all cases in the matrices of the final products the absence of residual PFOA can be detected. Additionally, only single actors described the presence of risk management measures for the environment in PTFE uses with the aim of collecting possible emissions from a process and taking them to a subsequent processing.

Regarding the PTFE manufacturing process a substitution has already been implemented in large parts of industry by replacing PFOA by other substances which also are fluorinated. This substitution is ongoing. Detailed hazard assessment of the alternatives is not performed in this study, but reports on the alternatives indicate that these were less toxic and less persistent compared to PFOA. In overall term the analysis of alternatives show that a sufficient amount of alternatives is available and already established in PTFE manufacture and at least in part commercially available for third parties. Concerning the quality of the PTFE manufactured with alternatives there are no reductions for the application of PTFE and after the implementation only slightly increased raw material costs, compared to the application of PFOA.

Market effects for PTFE manufacturers could be described as insignificant and can be added to the price for the costumers because of the high demand in the market. Besides, other influences on the market price of PTFE seem to have more important effects than the substitution of PFOA.

On the base of the information available the effects on PTFE-users in all likelihood can also be evaluated as irrelevant, as PTFE is used in technically sophisticated applications which justify the use of a rather expensive material (even if there will be a slight raise in the costs) and as a consequence from that the production of certain products is not hampered. Exemptions are few, comparably small applications, where PTFE is used.

The costs of the implementation of an alternative substance in PTFE-manufacture were numbered as < 50 Mio Euro (including all development costs). The cost increases with regard to the raw materials where estimated to10 %. The percentage of the raw material costs in comparison to the overall costs of the product could not be determined (e.g. compared to wages, energy, etc.), so that it is not possible to define, in which extent the overall price is affected. However, because of the special applications of PTFE it is likely that only low amounts of material are used per work piece. For this reason the expected costs were estimated as comparably low.

With regard to the emission reduction potential several scenarios were compared. As “worst case” scenario it was assumed that almost the complete EU-demand for PTFE would contain residual PFOA and would be released with 100 %. Other scenarios contained assumptions on the degree of already implemented substitution and the residual PFOA content. Estimations from these calculations for PFOA release from PTFE processing uses ranged from 83 (worst case) to 2 t/a.

Zusammenfassung

Der vorliegende dokumentiert Arbeiten, die im Kontext eines Unterstützungsvorhabens zur Erstellung eines Beschränkungsdossiers gemäß Anhang XV von Verordnung (EG) Nr. 1907/2006 (REACH) zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe durch das deutsche Umweltbundesamt (UBA), durchgeführt wurden. Das UBA führt die Arbeiten in seiner Funktion als zuständige Behörde (Bewertungsstelle für umweltgefährliche Stoffe) für Beschränkungsverfahren im Sinne von Artikel 69 (4) durch. Der Stoff, für den eine Beschränkung angestrebt wurde, war die Perfluoroctansäure (PFOA, CAS Nr. 335-67-1).

Ziel der Arbeiten war die Unterstützung des UBA bei der Erarbeitung sozioökonomischer Argumente zur Rechtfertigung einer EU-weiten Beschränkung für PFOA. Aufgrund des breiten Anwendungsspektrums und der möglichen Neubildung von PFOA aus Vorläufersubstanzen wurde der Untersuchungsgegenstand auf die Verwendung von PFOA in der Herstellung von Polytetrafluorethylen (PTFE) begrenzt. Neben der konkreten sozioökonomischen Analyse einer Beschränkung von PFOA war ein weiteres Ziel der Arbeiten, Informationen zu ermitteln, die für die Aussagen zur Beschreibung des Risikos und die Effizienz der regulatorischen Maßnahme notwendig sind.

Die für die Informationserhebung eingesetzten Methoden umfassten vornehmlich Interviews mit Branchenexperten, wobei der Schwerpunkt weniger bei den direkten Anwendern des PFOA in der PTFE-Herstellung lag als vielmehr bei den Anwendern des PTFE, da die Vermutung nahelag, dass ein Teil der auftretenden Emissionen von Restgehalten an PFOA erst während der Verarbeitung des PTFE bei diesen Akteuren auftritt. Weiter wurden bestehende Dokumente und Internetinformationen bei der Bearbeitung der Fragestellung ausgewertet und Ergebnisse einer Fragebogenaktion des UBA in die Betrachtungen integriert.

Hinsichtlich der Relevanz der PTFE-Anwendung bekräftigten zahlreiche Interviewpartner die potentielle Wichtigkeit dieses Pfades. Dies geschah weniger auf Basis von verfügbaren Daten zu konkreten PFOA-Emissionen aus der PTFE-Verarbeitung als vielmehr auf Basis der gelieferten

Prozessbeschreibungen, die nahezu in allen Fällen Materialbearbeitungsschritte oberhalb der Siedetemperatur von PFOA beinhalten, jedoch keine Aussagen zu dem Verbleib des PFOA machen können, das aller Wahrscheinlichkeit nach ausgetrieben wird. Diese Vermutung wird gestützt durch die Tatsache, dass in fast allen Fällen die Abwesenheit von PFOA in den Matrices der Erzeugnisse belegt werden kann. Weiter beschrieben nur vereinzelte Anwender die Anwesenheit von Risikomanagementmaßnahmen für die Umwelt in den Verwendungen des PTFE, die zur Aufgabe haben, mögliche Emissionen aus dem Prozess aufzufangen und einer weiteren Behandlung zuzuführen.

Hinsichtlich der Herstellung des PTFE hat in weiten Teilen der Industrie bereits ein Substitutionsprozess des PFOA durch andere, ebenfalls fluorierte Stoffe stattgefunden und befindet sich in einem Prozess der weiteren Umsetzung. Eine detailliertere Bewertung der Stoffeigenschaften der Alternativen wurde in dieser Studie nicht vorgenommen, generell werden diese aber als weniger persistent und toxisch als PFOA charakterisiert. Insgesamt zeigte die Analyse der Alternativen jedoch, dass diese in ausreichender Anzahl verfügbar sind, in der Herstellung von PTFE inzwischen etabliert und dass sie, zumindest teilweise, auch kommerziell für Dritte zur Verfügung stehen. Die Verwendung der Alternativen bei der Herstellung von PTFE führt zu keinerlei Einschränkungen des Materials für das Spektrum der PTFE-Anwendungen und erhöht die Rohmaterialkosten verglichen zum Einsatz von PFOA nach deren Einführung nur in geringem Maße.

Markteffekte für die Hersteller von PTFE sind nach der Einführung der Alternativen ebenfalls überschaubar und können aufgrund der grundsätzlich verstärkten Nachfrage auf dem Markt aller Voraussicht nach an die Kunden weitergegeben werden. Zudem unterliegt der PTFE-Preis auch anderen Einflüssen, die gegenüber der Verteuerung durch die Verwendung eines PFOA-Substituts vorrangig zu bewerten sind.

Auch die Effekte, die sich für die PTFE-Verarbeiter ergeben, können auf Basis der verfügbaren Informationen wahrscheinlich als nachrangig betrachtet werden, da PTFE vornehmlich in technisch anspruchsvollen Einsatzgebieten verwendet wird, welche den Einsatz dieses vergleichsweise teuren Rohstoffs rechtfertigen (auch bei etwas höheren Kosten) und eine Produktion bestimmter Erzeugnisse nicht grundsätzlich verhindert wird. Ausnahmen sind wenige, vergleichsweise kleine Anwendungen, in denen PTFE zum Einsatz kommt.

Die Kosten für die Implementierung einer stofflichen Alternative in der PTFE-Herstellung wurden mit < 50 Mio. beziffert (inkl. aller Entwicklungskosten). Kostensteigerungen hinsichtlich der Rohstoffe für die nachgeschalteten Anwender lagen bei etwa 10 %. Dabei konnte jedoch nicht ermittelt werden, welchen Anteil die Rohstoffkosten an den Gesamtkosten (z.B. im Vergleich zu Lohn, Energie etc.) der Produkte ausmachten, sich also auf den Endpreis auswirkten. Da jedoch angenommen werden kann, dass aufgrund der Spezialanwendungen des PTFE nur geringe Rohstoffmengen je Werkstück anfallen, wurden diese Kosten als vergleichbar gering angesehen.

Hinsichtlich des Emissionsminderungspotentials wurden verschiedenen Szenarien verglichen. Als „Worst Case“-Annahme wurde ein Szenario definiert, bei dem nahezu der gesamte EU-Bedarf an PTFE als PFOA-haltig angesehen wurde und dieses auch zu 100 % freigesetzt wurde. Bei anderen Szenarien wurden Annahmen zum Grad der bereits erfolgten Substitution und des PFOA-Restgehalts im PTFE formuliert. Die Berechnungen ergaben Schätzungen für die Freisetzung von PFOA aus Verarbeitungsprozessen von PTFE von 83 (worst case) bis 2 t/a.

1 About this report

1.1 Context and content

In a previous UFOPLAN project[1] Ökopol & RPA documented the core requirements of a socio-economic analysis (SEA) under REACH including a description of main challenges and possible different approaches to overcome these problems based on the experiences from cases based on substances that have been under discussion for EU-wide regulation before REACH has been entering into force.

The intention of the current UFOPLAN project was the collection of “real life” experiences with SEA work under REACH and by that creating the starting point for the generation of best practise examples.

Due to the setting of the project designed as a process observation combined with support activities it was necessary that the project work closely followed the internal work plan of UBA.

So after UBA has internally decided for which substance (PFOA and its precursors) possibly a restriction proposal should be drafted, the consultant team as a first step provided conceptual support to UBA staff during the basic screening of available information in a first project phase in 2011. The consultants prepared respective information collection schemes which were intended to structure the necessary information to be gathered for an evidence-based argumentation, which justifies that a restriction under REACH of the substance (PFOA) is necessary and supported from a socio-economic perspective.

PFOA (perfluorooctanoic acid) and its salts, mainly the ammonia salt (APFO) have been observed to be present in the environment since several years now. Since no source of natural occurring PFOA is known and levels are consciously increasing it has to be assumed that they are the result of anthropogenic activity.

PFOA has been identified to be persistent, bioaccumulative and toxic (PBT) according to the criteria laid down in Annex XIII of REACH. A dossier according to Annex XV of REACH has been prepared by UBA to identify the substances as substances of very high concern in accordance with Article 57 and 59 of REACH. The PBT status of PFOA justifies further regulatory measures as such substances are considered to pose a risk in any case, which needs to be managed according to the precautionary principle according to Article 1(3) of REACH.

Historically one main direct use of PFOA has been its use as processing aid (emulsifying agent) in the production of fluoropolymers. Substances that were manufactured by the use of PFOA often contained residual impurities which were diverted to other products (mainly articles in REACH terminology). Further direct uses have been the use as surface active agent. Due to its high stability it could be used under very rigid conditions.

A subsequent analysis on the use profile of PFOA and APFO strongly indicated that regulation of the substances under authorisation might not end up in successful regulation as it was apparent that direct uses were only of limited relevance and PFOA was present in imported articles to a large extend.

[1] UFOPLAN project FKZ 3708 65 401 “METHODS FOR THE SOCIO-ECONOMIC ANALYSIS UNDER REACH” (not yet published)

Article import would not be covered by an authorisation under REACH but could only be regulated with a restriction. Therefore the UBA decided to prepare a restriction proposal for PFOA seeking a very broad elimination of the substance in the EU.

As the use and emission pattern of PFOA and precursors is very complex and manifold UBA and the consultants agreed that the further project work should focus on filling data gaps on the use of PFOA in the manufacture of PTFE, the subsequent (technical) uses of these PTFEs and the responding residues of PFOA as well as on the assessment of the facts gathered against possible SEA related aspects.

Against this scoping from March 2012 till April 2013 the consultant team performed the assessment steps 2 to 4 from the initial project plan. The results from this activities are documented in this report.

The report is divided in three parts:

1. A description of the consultants approach and the work steps during the information collection (Information collection)
2. A description of the facts gathered during the information collection on the production and use of PTFE containing PFOA residuals.
3. Conclusions drawn matching the facts gathered with the need of a SEA argumentation

1.2 Rationale for the scoping

The report on the analysis of risk from PFOA prepared by the Dutch consultancy RPS Advises B.V. for the EU-Commission[2] indicates that 95 % of all fluoropolymers used are ending in industrial applications. The report does not give any further information about what is understood by the term “industrial application”. Furthermore some articles are addressed under consumer applications (the remaining 5%).

From the perspective of Ökopol and RPA, it is likely that these articles are manufactured under industrial conditions (e.g. frying pans) as well. So this manufacture is not a consumer use in a REACH meaning but articles sold to the consumer contain PTFE and by that possible PFOA residuals.

Despite this possible correction need, the Commission report does identify the production of fluoropolymers as the most important direct use of PFOA and it does identify the industrial sector as the most important use of fluoropolymers. Furthermore it comes to the conclusion that the most relevant field for further investigation whether a restriction of PFOA in fluoropolymer manufacture is justified or not should focus on the import of manufactured articles and residual PFOA content in finished articles.

No further detailed information on polymer types is given. But it is stated that the applications are often “critical” with regard to the very specific requirements on the technical properties of the material that have to be met, which is seen as a possible barrier for substitution of such polymers.

As indicative examples, the following fields are mentioned in the Commissions report:

- wire isolation for computer networks (heat resistance)

[2] RPS 2010, http://ec.europa.eu/enterprise/sectors/chemicals/files/docs_studies/final_report_pfoa_pfos_en.pdf

- semiconductor manufacturing equipment (non stick properties)
- corrosion prevention in environmentally sensitive chemical plants (non reactive surfaces)
- automotive fuel hoses (non stick properties, non reactive surfaces)
- electronics and telecommunications.

No data have been reported on amounts or types of polymers used in the respective sectors.

Because of the possible overall PFOA mass flow relevance in these applications and because “critical applications” (in case of possibly missing substitution alternatives) will play a central role in any socio-economic assessment of the overall PFOA restriction debate, the technical use of PFOA containing PTFE was regarded as a useful scope for the project work.

2 Information collection

2.1 Target information

In order to support a rational argumentation for the necessity of a restriction and its socio-economic adequacy, the information collection intended to gather data and information regarding the following issues:

1. The current status of PTFE containing PFOA
    - Amounts of PTFE used (in EU)
    - Applications of PTFE (focus on technical uses in industry)
    - PFOA content in the PTFE used
    - Function and/or technical effects of PFOA content
    - PFOA release from use of PTFE
2. Possibilities to substitute PFOA in PTFE
    - Information on PFOA substitution and alternatives to PFOA in PTFE manufacture
    - Technical specifications in the market that determine the quality of the PTFE (possibilities/boundaries for substitution with PFOA-free alternatives)
3. Market effects
    - Price relationship between PTFE containing PFOA and PFOA free PTFE alternatives
    - The cost for polymer manufacturers to substitute PFOA from their PTFE production
    - Possible costs for PTFE users if PFOA free PTFE is used

The collected information forms the baseline scenario of the use of PFOA as surfactant in PTFE manufacture and use (including service and waste life cycle step of articles and mixtures containing the respective compounds). Further it is intended to provide the necessary information to assess the main socio-economic effects, if the use of PFOA for the manufacture of PTFE and the import of PFOA containing PTFE and products made from these polymers (having residual amounts of PFOA) would be restricted.

2.2 General approach

The information collection in principle can be done via two approaches, top-down and bottom-up:

1. Top-Down:

The Top-Down approach follows the flow of substances starting with the manufacturers (M) and importers (I) of PFOA and the users of PFOA for the manufacturing of fluoropolymers (like the PTFE) going down through the supply chain to the final articles, which contain (residual) amounts of PFOA.

2. Bottom-Up

The Bottom-Up approach starts directly with the end uses that apply PTFE (and other fluoropolymers).

In available studies, the top-down approach has been used, but only quite limited information on the final applications of PTFE and residual PFOA contents was found. So in order to gain complementary information, the bottom-up approach was used in this project.

By this approach, the consultants expected to obtain different new and possibly more detailed information regarding the real use of PFOA containing PTFE in the various areas of their “potential” application and, regarding the drivers for their use/respectively, the possible barriers for a substitution.

Considering that only quite limited information is available from documents that can be assessed publicly, the information collection was designed as a direct interview process with market actors.

2.3 Staged interview process

Following the bottom-up concept, the staged interview process includes 4 assessment steps:

Step1: Identification of applications of PTFE into/onto articles.
In this first step, a screening regarding PTFE-applications based on literature and internet research is performed. Based on this knowledge, PTFE applicants and/or final industrial users of those PTFE containing articles are identified.

Step 2: Interviews with PTFE applicants and/or final industrial users of those PTFE containing articles.
The following information is collected from those interviews:

- Technical function of PTFE containing parts and specific requirements (drivers for PTFE use)
- Possible PTFE/PFOA free alternatives
- Contacts to suppliers (downstream user / formulators => step 3)
- Hints for additional PTFE applications used in the same sector (=> recursion to step 1)

Step 3: Interviews with formulators and distributors of PTFE coatings and other PTFE formulations.
Expected results are information on:

- Technical function of PTFE for the article production
- PFOA content in the PTFE used for formulations
- Effects of PFOA substitution for PTFE formulations
- Market effects from substitution of PFOA from PTFE manufacture
- Alternative solutions for the respective technical requirements
- Information regarding the market structure for PTFE formulations
- Direct contacts to PTFE manufacturers (=> step 4)
- Hints for additional PTFE applications used in sector (=> recursion to step 1)

Step 4: Interviews with PTFE manufacturers
The following information should be gained from these interviews:

- Market volume and market share of PFOA containing PTFE

- Other fluoropolymers manufactured with PFOA
- Market share of PFOA free PTFE
- Price relations of PTFE containing PFO and PFOA free alternatives

Additionally, when new facts were made available to the consultants via the interview process, an aimed search for publically available sources has been performed to confirm or refine information.

The following picture shows these staged assessment steps in a graphical overview:

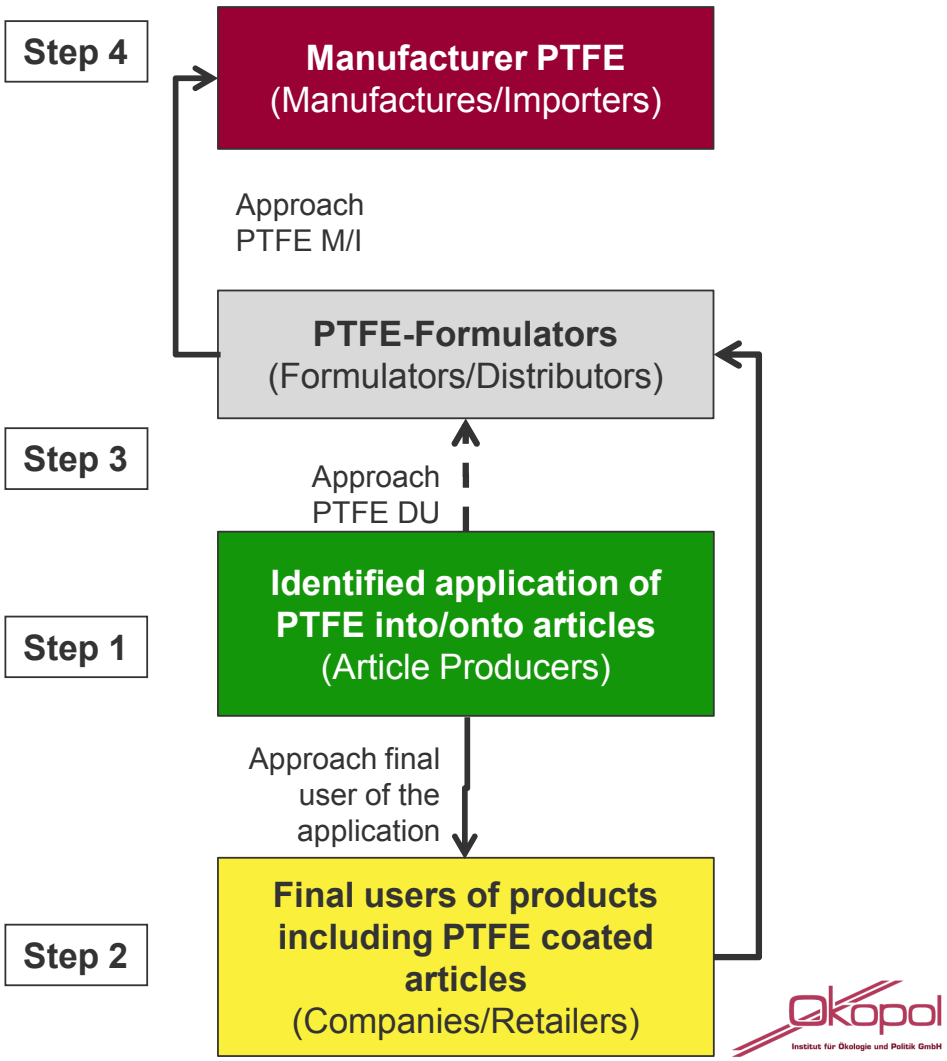

Fig. 1: Staged interview processes for the information collection of PFOA in PTFE applications

2.4 Experience from identification of PTFE applications (step1)

2.4.1 Approach

The identification of (possible) PTFE applications was performed in a staged process.

This process started with the collection of information regarding the technical properties gained by the use of PTFE. As a result, specific properties could be identified in the following areas:

- Surface properties
- Resistance properties
- Electrical properties
- Mechanical properties

Using these properties or respectively the intended application effects, it was possible to conclude in a next step on industry sectors possibly using PTFE coated parts. As a result from these considerations various sectors could be identified like e.g. food industry, paper processing industry and many others.

This “possible applicant sector list” was then used as a start point of a more detailed search for PTFE users on the internet.

The target properties and the “possible applicant sector list” as well served as starting point for a discussion during interviews with companies delivering parts possibly PTFE coated to clients from different sectors.

2.4.2 Gained results

Using the technical properties intended and gained by the use of the substances under question (PTFE) has shown up as a quite fruitful approach. It allowed a focused literature and internet research while not narrowing down the scope of further assessment steps too much. Furthermore, the link to the intended properties already served as a clear indication on the functionalities that need to be provided by any alternative to be discussed later in the process under SEA perspective.

2.5 Experience from interviews with users of PTFE containing parts (step 2)

2.5.1 Approach

Using the possibly PTFE containing parts (from step 1) as an indicator in the second step, producers of complex technical facilities/final products including PTFE containing/coated parts were identified. Market actors were mainly identified via internet searches but also by suggestions from other market actors.

The interview process with these market actors addressed amongst others the following questions:

1. Which PTFE-(coated) parts (articles/materials) are used in the products placed on the market?
2. What is the technical requirement to these parts? What is the specific function of the PTFE?
3. Are there alternative solutions that would ensure the technical functionality to the same extent (alternative substances or technologies)?
4. What are the limits and obstacles to apply the alternatives (economically, technically)?
5. Do companies have information about PFOA residue levels?
6. Do in-company specifications/requirements, sector specific industry standards or other efforts to use only PFOA-free PTFE already exist?
7. If respective specifications/requirements exist, how is PFOA-free defined? (e.g. by limit value, below the detection limit – test xyz, produced without PFOA)?
8. Are further applications of PTFE or other fluoropolymers known?

During these interviews the companies were also asked to provide useful contacts to suppliers to support the generation of information.

2.5.2 Short project description

During the first contacts with market actors, it appeared that a short project description was needed to support the interview partners by internal discussion in their companies/institutions with more information about the background, the basic intentions and the main questions.

A respective project description was drafted and agreed upon with UBA.

2.5.3 Gained results

During the interview process, Ökopol was able to establish a long list of contacts. From these contacts with the market actors it became clear that the issue of residual PFOA in PTFE in many application areas is a rather new debate for the actors. Therefore, information is not readily available and respectively time was needed by the contacts to gather relevant information within the companies.

When on the other hand huge multinational companies like e.g. from the automotive industry were contacted the PFOA issue was quite obviously seen as a political issue which led to the effect that the decision about possible answers to the consultant's questions are forwarded in the hierarchy to the central EU industry association level. This process also took quite a long time and in most

cases did not result in answers during the project period. Furthermore, reference was made by the interview partners to specific sub-sector associations. The consultants contacted these associations but here as well the political dimension of the issue was more in focus than a technical point of view. Still these contacts might serve as useful focal point for the specific sectors in future consultations during the further restriction process.

The results of the assessment are documented as well in chapter 3.1.3

2.6 Interviews with PTFE formulators and manufacturers (step 3 and 4)

2.6.1 Approach

The interview process with the downstream users of PTFE and the producers of complex articles soon indicated that relevant knowledge on residual PFOA content of the various PTFE types and its release during processing is only available at the polymer manufacturers and some independent experts. So the consultants started the direct communication with respective companies and their association already simultaneously with the interview process on the downstream user/article producer level.

The questions asked here like e.g.:

- Is PFOA still used in the manufacturing process of PTFE or are there alternative substances?
- Are there other fluoropolymers or substances containing PFOA? Which are they?
- If so, what is the level of residual PFOA in the final product?
- Are there substitution activities on-going and what is the timeline for a possible substitution of PFOA?
- Are there other applications known in which fluoropolymers are currently used? (In order to complement information from the bottom-up approach)

The project description (see section 2.5.2) has also been used here to give more information on our activities to the contact people for internal discussion.

2.6.2 Gained results

In order to establish contacts to manufacturers, the project team contacted the German plastics association PlasticsEurope Deutschland e. V. as a fluoropolymer working group is existing within this association.

But no data on market actors, amounts of PTFE and/or residual contents of PFOA were provided beyond some information on worker protection during processing of PTFE and except very general statements that materials are in line with legislation and approved for certain applications. The contact with the European section of PlasticsEurope did not deliver more information as well.

2.7 Observations made during the staged interview process

During the staged interviews, several contacts could be established that showed up as not specifically related with PTFE. Nevertheless, these contacts are documented as they might be helpful in other areas of the overall PFOA restriction proposal.

Further background research has been carried out on statements made and hints given by the interview partners.

2.8 Results from additional stakeholder consultation via questionnaires

The work performed in this part of the project is aimed at an exemplification of a “real life” SEA for the use of PFOA in the manufacture of PTFE and the downstream uses of the PTFE and the possible content of unintended residual PFOA as well as its presence in articles and possible risks from import of such. The scope of the related UBA activities is broader. The intention is not only to restrict the use of PFOA contained in PTFE but also the restriction of PFOA in all other uses as well as the restriction of all substances which can end in the formation of PFOA in the environment when emitted, so called precursor substances.

In this broader context, UBA initiated a stakeholder consultation via questionnaires in early 2013. A specific section with questions addressing PTFE related aspects was included. These questions were developed by the consultants based on the experiences and information from the staged interview process in an attempt to close the remaining data gaps.

The questionnaire was send out by UBA to manufacturers, downstream users and sector associations expected to be concerned with the use of PFOA or related substances. Partly, companies and organisations that had been already contacted in the interview process were once more contacted. Ökopol received from UBA those responses that contained information on the questions related to PTFE (21 companies responded[3]).

Some companies or organisations responded by formulating “free text” and did not communicate in the structure of the questionnaire (three companies and two associations). One company forwarded extra information to complement the questionnaire.

The responses can be sorted by the REACH roles of the responding bodies. Associations are sorted by the most likely role of their members.

Tab. 1: Questionnaire responses and REACH role received in the project

Role under REACH	Number of responses
Manufacturer/importer of PTFE	5
Downstream user of PTFE (formulator)	1
Downstream user of PTFE (article producer first level – integration of PTFE in article)	4
Article producer second level – assembly of articles from articles)	7
Associations	2

Ökopol assessed the received responses and extracted information and data. This information is documented in this report only in an anonymised and aggregated level in order to protect the confidential business information of the respective companies.

[3] Results are documented in separate report, not part of this report because of CBI

3 Facts gathered on residuals of PFOA in PTFE

In the following chapter the main facts gathered during the investigation process described in based on interviews and available literature as well as internet resources (see Chapter 2= on the use of Perfluorooctanoic acid (PFOA, CAS- Number 335-67-1) and Ammonium Perfluorooctanoate (APFO, CAS-Number 3825-26-1) in the production of fluoropolymers like Polytetrafluoroethene (PTFE) are presented. Similar to the interview process, the main focus lies on the technical use of those fluoropolymers, namely the PTFE.

This chapter creates the basis for the discussion of socio-economic effects from the planned PFOA and AFPO restriction proposal under REACH (see chapter 5).

The facts are not presented in chronological order of the receipt of the information but along the life cycle of the PFOA and the PFOA containing PTFE. Common information from other publications and the internet on the manufacturing process of PFOA and PTFE has been included to enable a better understanding of the situation for the reader and to provide a clear picture on the current situation in PTFE manufacture and use and related potential relevance for a PFOA restriction and socio-economic arguments.

3.1 Description of the life cycle of PFOA in PTFE

In the following sub-chapters a short description of the life cycle steps of PFOA/APFO will be given as far as it is relevant for its use in the manufacturing and further applications of PTFE.

3.1.1 Manufacture/Import of PFOA

The production of PFOA/APFO is located mainly outside the EU. The only company known to produce PFOA in Europe (Miteni in Italy[4]) reportedly ceased production and commercialisation of PFOA in 2010[5]. In the RPS-study, it was further predicted that the manufacture of PFOA will be phased out by the end of 2012-2013 in Europe. An assessment of the website of the manufacturer confirms that PFOA is not produced any more but indicates that several other perfluorinated substances are[6]. These substances are not do not contain PFOA as structural element and are therefore not regarded as precursors.

The processes used for the production of PF0A are

1. Electro-Chemical Fluorination (ECF)
2. Telomerisation

[4] OECD SIDS on PFOA, http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=FF9EAC38-0716-432E-B30A-C190FDEDDAF7

[5] RPS 2010

[6] http://www.miteni.com/Products/perfluorinatedde.html status 02.2012

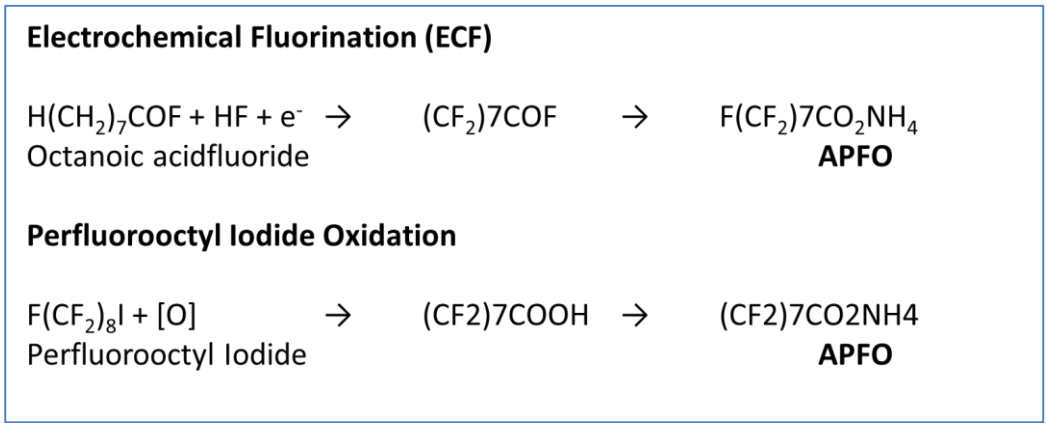

Fig 2: Industrial processes for the synthesis of PFOA (According to the RPS report)

Due to information of the RPS report, only one manufacturer has been using the ECF method but ceased production after 2002. Most of the other manufacturers use the telomerisation process.

No further source of information regarding to the exact numbers on the manufacture and import of PFOA could be identified during the interview process. The best basis in this context still seems to be the RPS report. The report estimates the EU demand for PFOA/AFPO between 20 and 50t/y and predicts a stable demand up to 2015 with a shift to imports from Asia.

The results from the industry survey did not confirm this prognosis as all former manufacturers and importers of PFOA and those who have non-EU-production who participated in the current study have declared that they have terminated the use of PFOA in PTFE manufacture with reference to the year 2013. Although it should be noted that the same companies reported imported amounts for the year 2012. Only one company answered that it still imported the substance in 2013.

Overall, only few companies responded on this issue and the consultation has not been broad enough to give an estimation of the overall import of PFOA to the EU. Only one company provided data on the market price of PFOA. Others did not indicate the price for PFOA as they have been the manufacturers of PFOA and the DU of it as manufacturers of fluoropolymers at the same time and did not make market price calculations on PFOA as they were using it only internally. Some provided relative costs of PFOA in relation to a chemical substitute in PTFE manufacture. Other information on market prices could not be investigated.

In the following chapters cost effects are always discussed with reference to the alternatives and relative price changes to ensure confidentiality.

3.1.2 Use of PFOA in the production of PTFE

Manufacture of PTFE

The use of PFOA in the manufacturing process of other fluoropolymers is not an “intermediate use” in the meaning of REACH. It is not used as a reactant or monomer in the PTFE production. It must be seen as a “direct use” of PFOA as a processing aid in the manufacture process. Its function is to serve as an emulsifying agent. That means it enables reactants from the aqueous phase and reactants of the hydrophobic phase to get in contact in an emulsion and to react to a polymer. PFOA itself is not degraded or incorporated into the molecule. This leads to a situation, where PFOA (AFPO) in principle can be recovered from the process and reused several times in the process of PFC production (like a catalyst).

The manufacturing process of PTFE is a three step reaction process[7]. The final step is the polymerisation of tetrafluorethylene (TFE), which is a highly reactive and unstable explosive gas. It cannot be fed into the process as a precursor directly but has to be synthesised within the process from other substances. In a first step, a partial fluorination is performed in which chloroform and hydrofluoric acid react with each other. This is the relevant step for the application of PFOA. As hydrofluoric acid is present in aqueous solution and chloroform is hydrophobic, a process has to be established that enables the two compounds to react with each other. This can be done via two processes:

1. Emulsification
   In this process the PFOA is needed as emulsifier. Note: Some manufacturers have already substituted PFOA completely by using other chemical substances as emulsifier in this kind of PTFE production, and several others have announced that they will follow soon (details see section on alternatives in chapter 3.1.5).
2. Suspension
   It has been assumed by the consultants and interviewed company experts, that this process is performed without PFOA. Nevertheless, one manufacturer of PTFE reported that historically PFOA was used in his process. He stated that this was unusual in fact and confirmed that this process has been adapted to be PFOA free[8].

In the second step of the reaction cascade the TFE is formed which rapidly polymerises. The reaction is highly exothermic and the heat has to be removed from the reaction vessel (danger of explosion of TFE). This is done via the water in the emulsion/suspension.

Both processes are established in the manufacture of PTFE but the manufactured PTFE differs in its molecular structure and size. Polymers from suspension reactions are larger (so-called reactor beads – size ~2 mm) and have to be processed in several subsequent steps (Grinding to ~ 10 µm followed by agglomeration to particles of ~ 100 – 700 µm) to be ready for use by customers.

As no PFOA is used for the “suspension route” of PTFE manufacture, it will not be affected by a PFOA/APFO restriction nor during PTFE production or as part of any of the downstream uses of this PTFE[9].

PTFE from emulsification has very small primary particles of only 200nm which are arranged in a secondary structure of ~ 400 – 600µm, the so called coagulate. As described above, PFOA can be removed from this product and be recycled for further manufacturing rounds. Still, depending on

[7] Process description based on “Technisches Merkblatt 02:Einführung in die Verarbeitung von PTFE-Kunststoffen“ (in German) Editor: Fachgruppe pro-K Fluoropolymergroup 2010 Edition http://www.pro-kunststoff.de/wp-content/uploads/2013/05/tm-2-finale-fassung.pdf

[8] 2013 manufacturer pers. comm. to the author

[9] Note: Some interview partners explained that due to its properties this kind of PTFE cannot be used in all types of downstream uses. Up to now, the consultants did not find sufficient ration whether this is really a hard technical exclusion for some uses or just a “soft” exclusion because the alternative material fits better to the downstream process conditions.

the efficiency of the recycling process and further subsequent treatment processes of the virgin PTFE, like drying and sintering, residual PFOA remains in the PTFE material[10].

All companies that responded to the questionnaire campaign stated that they are not using PFOA for the manufacturing of PTFE anymore with reference to the year 2013. One company that is still importing PFOA indicated that the use is intended as emulsifiers for the manufacturing of fluoropolymers but clarified in the questionnaire section on PTFE that for this polymer there is an alternative in use (so it is assumed that no PFOA is in use for PTFE manufacture but for some other polymer which is supported by information on residual PFOA in PTFE). The companies that responded all stated that they have replaced PFOA in the last few years (from 2008 to 2012).

Different types of PTFE in the market

PTFE is sold in different preparations depending on respective downstream use. Three[11] basic types of preparations can be distinguished:

- Granulated material (suspension route manufacturing)
- Emulsion route manufacturing raw material (dry[12])
- Emulsion route manufacturing material (dispersed)

Below some facts from interviews with experts are given on the different types.

Granulated material, as already indicated in the description of the manufacturing process, is almost exclusively produced from the “suspension type” of PTFE, so without any use of PFOA[13]. There could also be material on the market manufactured with PFOA. This kind of material is further processed in a sintering process (> 342 °C[14]). The manufacture of this type of PTFE in this kind of manufacturing process was confirmed by one manufacturer, but the process has already been revised and is nowadays performed without PFOA. Estimated residual PFOA content of such material was of the order of around 3 ppm[15]. Other companies did not report the use of PFOA in this manufacturing route.

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[10] pro-K Fluoropolymergroup, 2010 http://www.pro-kunststoff.de/wp-content/uploads/2013/03/tm-02-einfuhrung-in-die-verarbeitung-von-ptfe-kunststoffen-finale-fassung-juli-2010.pdf

[11] Not all types can be used for all polymer processing activities. For example extrusion processes are exclusively with PTFE manufactured via the emulsion route (see also pro-K Fluoropolymergroup 2010, footnote 9)

[12] Boiling Point: 189 - 192 °C, e.g. Gestis database (http://gestis-en.itrust.de/nxt/gateway.dll?f=templates$fn=default.htm$vid=gestiseng:sdbeng) on the basis of safety data sheet by Merck)

[13] Schlipf, pers. comm. 2012

[14] Crystallization temperature, Note: degradation temperature of PFOA in literature > 300 °C, e.g. Gestis database (http://gestis-en.itrust.de/nxt/gateway.dll?f=templates$fn=default.htm$vid=gestiseng:sdbeng) on the basis of the safety data sheet by Merck

[15] Reichel pers. comm. 2012

Contacted experts estimated that emulsified PTFE (dry) contains less than 10 to up to 50 ppm of PFOA. Another expert contacted during our assessments expressed his opinion that the PFOA content in material from European and North-American manufacturers is more likely to be in the area of 10 ppm. The removal of the PFOA is a side effect of the drying process after removal of the material from the manufacturing process. To the knowledge of the experts the off-air from these processes (potentially containing a share of the residual PFOA, which is volatile under these conditions) is collected in an off-gas system. But up to now, it is unclear whether this treatment includes an efficient abatement step (like thermal oxidisation) reducing the PFOA emissions in a relevant manner[16].

Estimates for dispersed PTFE by the contacted experts have been 3 – 4 orders of a magnitude higher than the content of the material described above (in conclusion ~ 1,000 – 50,000 ppm).

Data on residual PFOA in PTFE manufactured via the emulsification process have been provided by several manufacturers and importers of PTFE via the questionnaires. Some provided past information on this issue as the material placed on the market now is manufactured exclusively without PFOA.

The answers ranged from < 5 ppm to < 1,000 ppm for dry PTFE manufactured via the emulsion process and < 20 to 5,000 ppm for dispersed PTFE manufactured via the same process. One company indicated that their dispersed material has been treated subsequent to manufacture with regard to PFOA reduction and therefore has a reduced PFOA content of < 50 ppm after the initial content has been at < 2,000 ppm (comparable to other manufactures content).

All responses from companies manufacturing PTFE (EU-manufacturer and importer) attest that PFOA has been substituted. Alternatives to PFOA are always based on substitution of PFOA by another chemical (names and CAS-numbers are confidential business information). An overall picture of the alternatives showed that most companies developed their own substitutes. It was not stated by any of the companies that the originating PTFE manufactured with the alternatives shows any technical differences to the material manufactured with PFOA.

The overall situation on the PTFE manufacturer market is that there are large “western” country manufacturers that are engaged in a US-EPA stewardship program and try to eliminate all PFOA from PTFE production until 2015. Up to now and to the consultant’s knowledge, only Dyneon/3M has phased out PFOA completely from its production (since 2010). As a consequence, companies are working on chemical substitutes to replace PFOA in the emulsification process at the moment. It was not indicated in the interviews to which degree there could be a shift to the suspension production processes well. Until substitution is realised, the companies have committed themselves to minimise emissions from processes.

The US-EPA stewardship program started in 2006 and all companies already reduced residual contents of PFOA in the PTFE as defined by the commitment[17]. The stewardship program not only covers PTFE but also the manufacture of other fluoropolymers[18]. The participating companies are:

- Arkema

[16] This VOC emissions containing the PFOA might still be a relevant pathway to the environment in the overall PFOA flow

[17] Aim was 95 % of the content compared to a year 2000 baseline

[18] For detailed information on the programme and reports see: http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html

- Asahi
- BASF Corporation (successor to Ciba)
- Clariant
- Daikin
- 3M/Dyneon
- DuPont
- Solvay Solexis

According to contacted experts from downstream users, PTFE with similar low PFOA content as the material produced by the companies engaged in the EPA program can be procured from India[19]. These experts also stated that PTFE from China is produced in similar qualities. Other sources indicated that PTFE from China has higher contents of PFOA as well as material from Russia[20]. Nevertheless experts suspected this, information from the Russian manufacturer website indicate that PTFE complies with standards for food contact material and therefore low PFOA content can also be assumed for PTFE originating from Russia[21].

Market situation of PTFE

The prices of PTFE ranged from 8 €/kg to 20 for material manufactured via the suspension method. Prices for material manufactured via the emulsion method were given as slightly higher, 9 €/kg to 20 with no differences between dry material and material in dispersed form. Few companies submitted higher price ranges (double to 20-fold) than the range given above. It seemed that these high prices correlate with rather low amounts of material procured (below 20 kg per company and year) or highly specialised compounds[22].

As already mentioned, various alternatives to PFOA have already been developed. Most companies with such a solution do not sell the alternative but use it for their own manufacturing processes exclusively (names and CAS-no. CBI). At least one alternative is available to other market actors via licensing. Most companies indicated relative differences in manufacturing costs. Some stated that the costs of the overall process remained the same. Some stated an increase in costs of 10 to 30%. A reason for this might be differences in the way in which costs were calculated. Some companies reported clearly that increases in cost are basically due to the necessary efforts for the adaptation of the processes to the chemicals of the alternative process. Once it is implemented, the overall costs of the PTFE manufacturing process are more or less the same as before.

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[19] Company Gujarat Fluorochemicals Limited (GFL) was investigated by internet search. A manufacturer's name could not directly be mentioned in the interviews by the contacted experts. http://www.gfl.co.in/ptfe_products_pro.htm

[20] Only one producer, HaloPolymer, OJSC, about 9 % market share world wide (company information http://halopolymer.com/)

[21] It is indicated that the material is conform with US-EPA standards for food contact material now, which are the standards and also fulfilled by manufacturers of the stewardship program.

[22] Verified by a call back to the respective actor.

To ensure sufficient supply with alternatives is no problem for all the companies responding.

Producers of articles that are entirely made from PTFE responded that the material costs of the PTFE are 100% of the final product. For other products the cost share of the PTFE varies from ~ 40 to < 1%. Some stated that they do not see relevance for the price of their products due substitution of PFOA in PTFE. It can clearly be observed that the share of the costs of PTFE decreased with the complexity of the final products (use of PTFE particles in a mixture to use of PTFE in only a part of a very complex article).

The PTFE process is nevertheless volatile. An internet blog that is hosted by an Indian PTFE manufacturer reported the price development from 2010 to 2012 as shown in the figure 2.

Several reasons for the increase in prices are discussed in the blog article. These include the lack of sufficient supply of raw materials for PTFE manufacture, especially fluorspar, and a lack of production capacity (which in turn explains the drop in price in 2011 where according to the author new capacities from Russia and China entered the market), and/or the price development of fluorspar, another important raw material for fluoropolymers. Furthermore, from the perspective of the consultants the economic crisis may play a role as the demand was hit in 2008 and 2009 and that this depressed the market reducing the price. Then demand picked up again in 2011, allowing manufacturers to raise prices. This effect can be observed in other plastic sectors as well. It seems important to remember that all these effects are independent from the debate on PFOA or PFOA free PTFE.

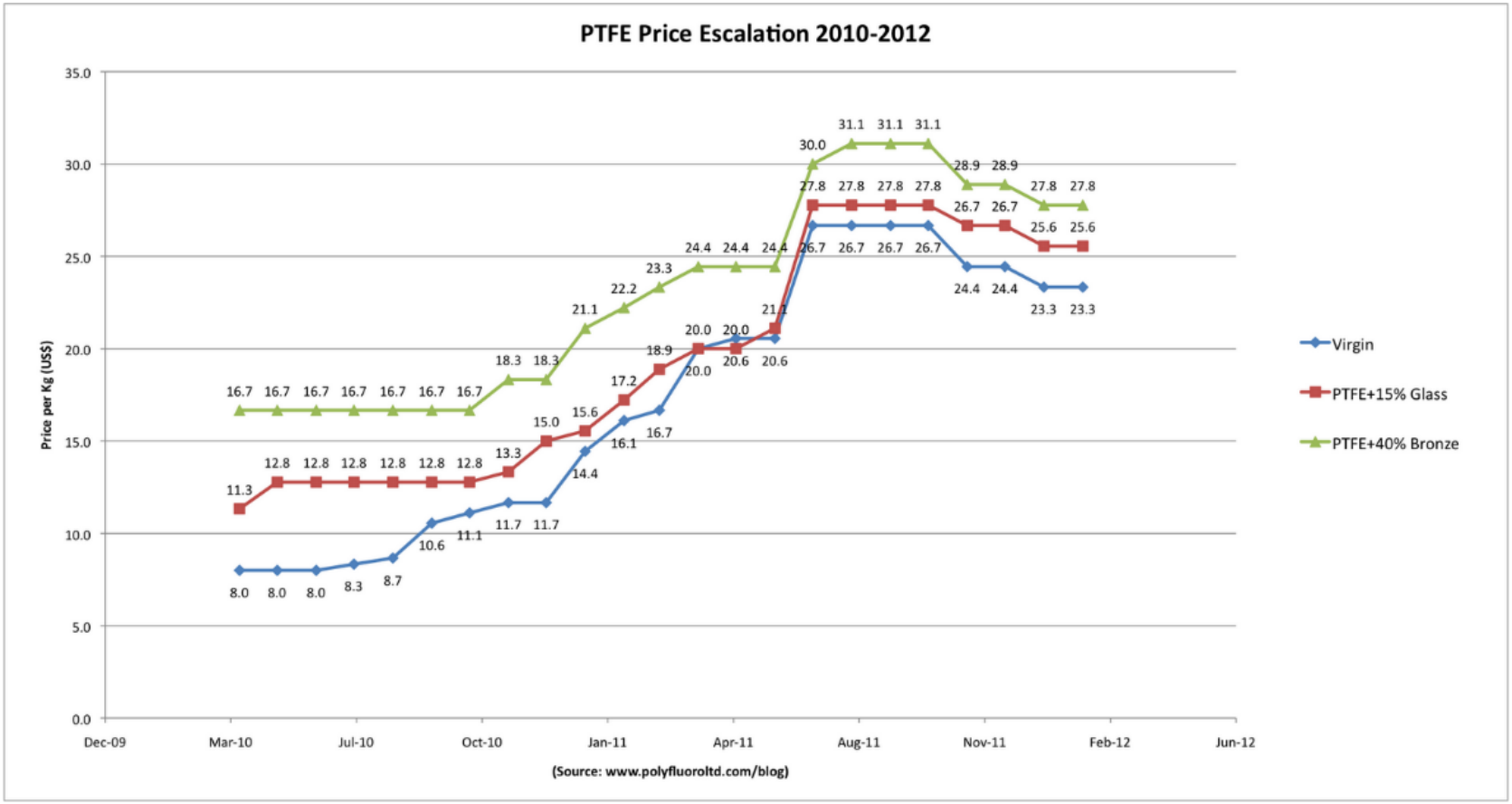

Fig. 3: PTFE price development form 2010 to 2012 (data source Blog Poly Fluoro Ltd. download 2013.04.15, http://polyfluoroltd.blogspot.de/2012_03_01_archive.html)

3.1.3 Uses of PTFE potentially containing residual PFOA

None of the companies contacted stated that shortage in PTFE supply is foreseeable in the near future. Many companies stated that they are already using PTFE manufactured without the use of PFOA.

Regarding to the technical specifications of material manufactured without PFOA most manufacturers and DU of PTFE stated that no differences occur or they do not know whether this is the case. Two DU reported that alternatives are not as good as PTFE from PFOA based production and the stability of products made from the PFOA-free PTFE is lower (USE: non stick coatings, yarns).

As described above, various forms of PTFE are being produced and sold for downstream uses. An overall estimate on the fluoropolymer demand in Europe suggesting 80,000 to 90,000 t/a (PTFE and other Polymers) come from the Plastics Europe website[23]. To gather exact numbers on amounts used by the downstream sectors was not possible during the project period because manufacturers claim confidentiality on this information. Very rough estimates by contacted experts are in the area of 6,000 – 8,000 t/a of emulsified material that is used in the textile industry to a large extent and another 2,000 t/a emulsified material in the building material sector.

Several other use sectors of PTFE could be identified.

As far as valid information is available, direct use of PTFE in mixtures intended to be sold to the consumer is limited to some specific applications:

- Ski wax
- Outdoor paints
- Release agents
- Leather polish
- Lubricants

It could not be determined in detail to which extent a possible restriction would affect such uses. Some formulators of such mixtures use PTFE with registered trademarks like e.g. DuPonts Teflon®. This indicates that in such cases no problems would occur as it can be assumed that DuPont has already substituted PFOA completely. A formulator of ski wax confirmed this assumption. He contacted the supplier and received a respective confirmation that only PTFA manufactured without PFOA was delivered. Other formulators did not indicate what the origin of the PTFE is.

Nevertheless, from a technical perspective the shift from PTFE with residual content of PFOA to total PFOA free PTFE does not make any difference because the PFOA residuals do not have a technical function in the mixture.

Most of the manufactured PTFE is used for the production of articles in the meaning of REACH. A first screening on the internet of PTFE applications delivered hints that the main fields of technical application are:

[23] Retrieved on 13.06.2013: http://www.plasticseurope.org/what-is-plastic/types-of-plastics/fluoropolymers.aspx

1. PTFE coated machine parts, surfaces that are intended to have
    a. Non sticking properties
    b. Dry lubricating properties

or

2. High performance PTFE material that is heat resistant like cable isolation due to high isolation properties combined with resistance against chemicals and extreme temperatures (-200 – 260°C, some producers indicate a peak resistance of PTFE up to 300°C[24])

But also some additional properties of PTFE coatings are interesting from the technical perspective of possible applications. An overview of these technical properties and connected application effects is given below[25]:

Surface properties

- Easy release and washable
- Lowest co-efficient of friction and high lubricity
- Food compliant & hygienic
- Hydrophobic
- Controlled porosity/openings

Resistance properties

- Chemically inert against almost all chemicals
- Thermally stable from –150°C/–238F to 260°C/500F
- Non-flammable/fire resistant
- UV and weather resistant
- Increased wear & void-free versions available

Electrical properties

- Excellent heat transfer
- High dielectric strength
- Low dielectric constant
- Microwave transparent
- Low electrical losses

[24] At higher temperatures thermal decomposition of PTFE occurs which leads to a loss of the intended technical properties, partially. The German BfR defines a limit of 360°C (see Q&A document on PTFE http://www.bfr.bund.de/cm/343/fragen_und_antworten_zu_koch_und_bratgeschirr_mit_antihaftbeschichtung.pdf. Above this development of toxic fumes has to be expected from the degradation process.

[25] Source: Saint-Gobain Performance Plastics, 2011, http://www.chemfab.com/products/non_stick_benefits.aspx status 13.04.2012

- Static dissipative

Mechanical properties

- High tensile and tear strength
- Dimensionally stable
- Puncture resistant
- Flexible and conformable
- Thermally weldable

Using these properties or respectively the intended application effects, it is possible to identify industry sectors possibly using PTFE coated parts. These sectors are listed in the following:

- Food industry
- Paper processing industry
- Petrochemicals/chemicals industry
- Automotive industry, tubes
- Packaging industry
- Textile and printing industry (additionally textiles that are made out of PTFE fibres)
- Paint and coating industry
- Plastic and rubber processing
- Aerospace industry
- Pharmaceutical industry
- Medical products industry (here also PTFE is used as material itself not always as coating)
- Defence related industry

As this list shows, a large spectrum of potential uses could be identified. More uses than expected are located in the consumer related field. Still, there is very little information on these applications compared to the identified industrial uses. So, for example, it is not totally clear to what extent these are of relevance to the EU. Some of the PTFE containing consumer products are only presented on US websites, e.g. contact lenses treated with Teflon or some paints and polish treatment products.

3.1.4 Market potential of PTFE downstream uses

The market potential of the different downstream uses is difficult to assess as no valid data are publicly available. As stated by PlasticsEurope on their website fluoropolymers do represent just 0.1% of all plastics.

The internet research also supported the impression that there are several industrial uses where potentially rather large amounts of PTFE could be applied per installation/machine/plant (e.g. food contact installations).

A search in a database of the Gesamtverband Kunststoffverarbeitende Industrie e.V. (German plastics converters – GKV) delivered only a list of thirteen companies processing PTFE. Still there

might be several other companies that can be seen as first level downstream users, like producers of complex articles that process some of the parts themselves (e.g. surface treatment of parts).

According to EUPC[26] PTFE processing companies much diversified and can be assigned to various sectors. The world market is estimated at 240 billion Euros, of which Europe represents about a third. This market has been growing despite the economic crisis with an average of 7.9% and this trend is expected to be continued with a rate of 7.1% until 2017 EUPC states.

On a next level of the supply chain where producers of articles use parts (other articles) made of PTFE it is hard to say to which extend these sectors are affected by a PTFE related regulation. In most applications the PTFE is only used in very limited extend, though often in a very important part responsible for special technical function, safety of the whole article.

In the sector of medical and pharmaceutical devices such parts have to undergo a qualification process. The efforts for this process varies depending whether or not biocompatibility has to be assessed also. The value of the material incorporated in the devices is rather small compared to the overall price of devices from that sector.

The building sector is also a very important market for the plastic industry (estimated €9,000 billion per year in Western Europe and 11 million employees, source EUPC). Estimates of experts in the interview process have been about 2,000 t PTFE per year end in the building sector, which represents a value of €18 – 40 million per year only on material costs. Having in mind that PTFE is used predominantly in special technical applications, one can expect that the added value in this sector is far higher.

For the electronic sector, a total value in Europe was estimated in 1998 of about €400 billion of which plastics account for 15 -20% of the total value (€60 – 80 billion). Again, PTFE will only make a small share of all plastic used. Taking the number of PlasticsEurope that the share of fluoropolymers is just 0.1% of all plastics it will still account for €60 – 80 Mio[27].

The European manufacturers of Engineering Polymer Shapes for Machining (EPSM) association represents companies that deliver special polymer parts for various machine constructions (e.g. gear wheels, conveyor screws etc.). This sector has an annual turnover of €1.5 billion in Europe and about 15,000 employees (source http://www.plasticsconverters.eu/docs/EPSM.pdf)

In the textile sector according to the estimate of the experts 6,000 – 8,000t PTFE are used representing €54 – 72 or 120 – 160 million pure material value per year. The real added value in the textile sector can hardly be estimated as textiles with PTFE represent more a niche.

It is also very hard to determine in the automotive sector as the final product is made only to a very low extend from PTFE. Some of the added value already is covered by the EPSM data. Still one can conclude that due to the importance of the automotive sector this is a very important market for PTFE application. The German VDA[28] states that the annual turnover in the production of parts used in car in the German market has a turnover of €68,376 million (2012).

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[26] European association: European Plastics Converters http://www.plasticsconverters.eu

[27] Real value could be higher, as again special solutions can be expected to be more expensive then standard solutions like e.g. in wires.

[28] Verband der deutschen Automobilindustrie http://www.vda.de/de/zahlen/jahreszahlen/allgemeines/

3.1.5 Alternatives to the use of PFOA in PTFE manufacture

From the interviews and via the questionnaires, a range of alternatives to PFOA could be identified in the manufacture of fluoropolymers. Some of them are used exclusively by some companies which are often also the manufactures of the alternatives. These alternatives are often seen as CBI and therefore are not included into this report. Other alternatives have already been assessed for application in food contact materials and the manufacturers of these are therefore publically known from respective documents. These alternatives are shown in Tab. 2. It is known and confirmed by 3M that 3H-Perfluoro-3-((3-methoxy-propoxy)propionic acid), ammonia salt is also commercially available for other parties.

Tab. 2: Known alternatives of PFOA in PTFE manufacturing based on publically available information

CAS no.	Chemical	Company[29]	Legislation for approval in food contact materials	Background information
958445-44-8	3H-Perfluoro-3-((3-methoxy-propoxy)propionic acid), ammonia salt	3M/DYNEON GMBH	Regulation EU No. 1282/2011	Scientific Opinion on the safety evaluation of the substance, 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt, CAS No. 958445-44-8, for use in food contact materials http://www.efsa.europa.eu/de/efsajournal/doc/2182.pdf
908020-52-0	Perfluoro((2-ethyloxy-ethoxy)acetic acid), ammonia salt	AGC Chemical Europe Ltd, UK.	Regulation EU No. 1282/2011	Scientific Opinion on the safety evaluation of the substance, Perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt, CAS No. 908020-52-0, for use in food contact materials http://www.efsa.europa.eu/de/efsajournal/doc/2183.pdf
51798-33-5	Perfluoro(2-(poly(n-propoxy))propionic acid	not included in background document	Regulation EU No. 10/2011	24th list of substances for food contact materials Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF), http://www.efsa.europa.eu/fr/efsajournal/doc/1157.pdf
13252-13-6	Perfluoro(2-(n-propoxy)propionic acid)	not included in background document	Regulation EU No. 10/2011	24th list of substances for food contact materials Scientific Opinion of the Panel on food contact materials, enzymes,

[29] Company names assessable from EFSA background documents on food contact material approval.

CAS no.	Chemical	Company[29]	Legislation for approval in food contact materials	Background information
				flavourings and processing aids (CEF), http://www.efsa.europa.eu/fr/efsajournal/doc/1157.pdf
329238-24-6	Perfluoro acetic acid, alpha-substituted with the copolymer of Perfluoro-1,2-propylenglycol and Perfluoro-1,1-ethylenglycol, containing Chloro hexafluoro propyloxy endgroups	not included in background document	Regulation EU No. 10/2011	24th list of substances for food contact materials Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF), http://www.efsa.europa.eu/fr/efsajournal/doc/1157.pdf

All alternatives shown here are linked to the manufacture process of[30] fluoropolymers. For this process only chemical alternatives are known[31]. Since all compounds are also fluorinated molecules, the properties are alike to a certain degree, but with regard to the bioaccumulation potential and the toxic effects on human health they are regarded of less concern[32]. Furthermore, they are no precursor substances of PFOA or other regulated PBT substances (e.g. PFOS).

The assessment of alternatives has been limited to the use of PFOA in the manufacture of PTFE. This includes the assumption that PTFE shall not be restricted and is an accepted use. Alternatives to the uses of PTFE in the respective downstream uses have therefore not been assessed in detail (there are e.g. other non sticking surfaces for cooking devices on the market). With regard to the intended restriction aim (minimisation of PFOA in the environment), the consultants think this is justified as an assessment of alternatives to the use of PTFE would extend the scope of the restriction too much.

[30] In fact this would mean that restrictions for PTFE use in certain applications would also have to be introduced in an Annex XV dossier, as a consequence.

[31] Besides the fact that the suspension manufacture route also works without PFOA but the resulting material is not suited for all downstream uses. So this is not seen as an alternative as not all functionalities of the product are maintained.

[32] This must not be understood as a final statement whether these substances are SVHC under REACH or not. They are only of less concern compared to PFOA.

4 Lessons learned from information collection

4.1 Content and structure of the chapter

In the following chapter the main conclusions and further considerations on effects on an environmental and an economic level will be presented with regard to a planned regulatory measure.

The considerations have been ordered into different thematic fields to give the reader some orientation.

4.2 Overall observations from information collection process

4.2.1 Limited knowledge with the market actors

Many producers of articles (DU of PTFE) who have been contacted during the interview process are not aware that PFOA might be present in the used material (PTFE) or that it could even be a problem. This general observation differs between the applications - the knowledge is better in sectors where consumers might get in direct contact with the PTFE material - but basically there are no quality standards established that address PFOA by producers of the articles themselves. Some producers reported they would only buy material from producers who declared that no PFOA is present in their material. Others have to fulfil rules for food contact materials. In this respect, the German Federal Agency for Consumer Protection sets a migration limit for its recommendation on food contact materials of Perfluorooctanoic acid and its ammonium salt + sodium salt of perfluoro-alkenyl-oxybenzene sulfonic acid in total max. 0.005mg/dm^2 under the conditions of a test laid down in the recommendation document.[33]

The questionnaire consultation showed that some of the responding companies were aware of the PFOA in PTFE issue. These companies claimed to procure PTFE manufactured without PFOA.

None of the companies contacted and/or who responded reported to have own measures implemented to reduce residual PFOA from the material or to handle possible PFOA release or even to measure such releases during processing of PTFE.

4.2.2 No valid information about amounts and vague information on prices accessible from market actors

No data on exact amounts (production and/or use) and prices of PTFE in general and from the different production routes and/or qualities are provided from downstream users and/or manufacturers or importers of PTFE during the interview process. The questionnaire contributed some data but overall they have not been representative (only five manufacturers/importers responded).

A rough estimate on the worldwide demand of fluoropolymers in general (not PTFE exclusively) was 80,000 to 90,000 t/a provided on the internet by PlasticsEurope[34]. The Russian manufacturer HaloPolymer, OJSC estimated its own world market share with 9% reflecting a production of

[33] http://bfr.zadi.de/kse/faces/resources/pdf/510-english.pdf, last revision 01.03.2011

[34] Status 30.04.2013 http://www.plasticseurope.org/what-is-plastic/types-of-plastics/fluoropolymers.aspx

7,000 t/a[35]. Extrapolated to 100%, this would mean that the estimate of PlasticsEurope may be a bit too high as it ends up with ~ 77,800 t/a.

Prices for PTFE submitted by PTFE manufacturers and downstream users were in a similar range - ~ 9-20 €/kg, suspension and emulsion route manufacture virgin material[36]. Therefore, the overall value of the total PTFE amount marketed per anno worldwide can be estimated with ~ €700 million to 1.5 billion.

No information has been available on the situation during the economic crises of 2008. But it is very likely that it could also have been a reason for rather low prices, due to a lack of demand on the market during the crises. Such effects have at least been reported for most other polymers.

No indications were found that the overall demand for PTFE had decreased due to the increase in prices of PTFE. None of the assessed sources addressed the change from PFOA to alternatives or correlated research and implementation activities of alternatives (neither in interviews nor on the internet).

Data on the absolute market price of PFOA was only reported by one PTFE manufacturer (CBI). Other statements from PTFE manufacturers concerning the relative cost effects caused by a substitution of PFOA by an alternative varied from none to about 25% with regard to the manufactured PTFE per unit.

Some DU also reported that no cost effects occurred when their suppliers substituted PFOA. Others said the price for the raw materials increased up to 20%.

4.2.3 Relevant reduction of PFOA content during article production

An additional ”general” observation from several expert interviews is that PFOA is not present anymore in/on the final articles in similar quantities as in the original PTFE material containing residual content of PFOA. Residual PFOA in final articles is only assumed when articles produced with aqueous dispersed PTFE. In such cases relevant removal steps following the descriptions of the experts are missing.

This is because the processing of PTFE is mostly connected with one or several high temperature steps (often a drying step with rather elevated temperatures of 120 to 250°C in extrusion followed by a sintering step at >300°C)[37]. In such steps, the PTFE material constitutes a coherent matrix (cristallisation) and possible residues of PFOA are expected to emit from the matrix to the air.

Based on interview responses, by applying usual quality control measures no PFOA can be detected in the surface PTFE after these processes. Whether these controls are suitable to detect all residual PFOA could not be clarified in the interviews. As the boiling point of PFOA is given to be in the 189 - 192°C range, it must be questioned if all PFOA is completely removed from

[35] Status 30.04.2013 http://halopolymer.com/about/company/

[36] This fits as well to Figure 32, p. 23

[37] ProK Technisches Merkblatt 02: Einführung in die Verarbeitung von PTFE-Kunststoffen, Juli 2010, http://www.pro-kunststoff.de/wp-content/uploads/2013/03/tm-02-einfuhrung-in-die-verarbeitung-von-ptfe-kunststoffen-finale-fassung-juli-2010.pdf

matrices at lower temperatures (150°C was often mentioned as treatment temperature in interviews).

4.2.4 Possibly relevant PFOA emissions from article production sites

Regarding the likely PFOA emissions from the processes of coating with PFOA containing PTFE mixtures, only one of the contacted downstream users had implemented any specific risk management measures[38]. As those PTFE coating processes are normally not connected to any air abatement facilities, it can be assumed that PFOA is released via the ambient air to the environment if the processes are performed at temperatures below 300°C with a high certainty (degradation of PFOA > 300°C). Whether PFOA is released from processes with temperatures above 300°C has not been assessed by any of the contacted companies. But regarding normal temperature gradients in such processes, it seems probable to many of those experts that such emissions might occur during the „heating“ of the surface/material. Since data on the exact degradation temperature are missing it can even e assumed as a worst case scenario that PFOA is completely stable at temperatures that are reached in PTFE processing steps[39].

4.2.5 PFOA-Free is not a dominant market driver for PTFE selection

A third observation from the interviews made with downstream users was that in sectors where no customer requirements had to be fulfilled (e.g. no food contact), the reasons for selecting a specific raw material (with possible higher or lower PFOA residuals) are determined by other drivers like:

Marketing: Well known trade names (Teflon®, Deyneon®) of certain manufacturers are used as a quality argument for own articles (but this quality understanding is not necessarily connected with the question of PFOA from the marketing perspective).

Price: There is PTFE available from some manufacturers (mostly China and Russia were mentioned) with a price up to 60% lower compared to the material of the well-known manufacturers. But there is no evidence available that this price ratio correlates in any way with a possible higher content of PFOA residuals.

Market availability: Many experts state that in the near past the availability of PTFE is compared with the world-wide production of PTFE containing articles may be quite limited, so that price will not be the main driver anymore but the simple question of supply guaranties. It is not documented whether “low quality” in the meaning of PFOA-rich PTFE is placed on the market in higher amounts.

4.2.6 Market experts see limited effects from possible PFOA restriction

Concerning a planned PFOA restriction for the substances, mixtures and final articles, contacted experts said that a restriction with a threshold of 10 ppm or lower might have effects to the EU market:

[38] In that case an off air collection with thermal abatement technology

[39] No indication has been found that relevant degradation already happens e.g. below 400°C. So the faith of PFOA in such processes is highly speculative.

1. Additional purification steps would be needed for some parts of the production plant. This might lead to an increase of PTFE market prices => cost for the raw materials produced in or imported into EU would increase.
2. For EU producers of final articles, besides the possible increase of raw material prices (as said above), no effect would occur because they would only be able to source PFOA free PTFE.
3. For non-EU producers, the situation would remain unchanged as far as they use a high temperature production step (threshold will not be exceeded then) => but in fact, the non-EU producers are then allowed to use raw materials with higher PFOA contents. This might lead to an uneven playing field. For production without high temperature processes, non-EU producers would be in the same position as EU producers (needing to source PFOA free PTFE as well)

From the viewpoint of the consultant team, it is not necessarily the case that PTFE prices will increase due to a PFOA restriction. The price effects depend very much on the shares of PFOA-free to non-PFOA-free PTFE on the world market at that moment and the investment and strategies of the PTFE producers. With respect to the increasing market demand for PTFE, new plants are likely to be built and for new plants a PFOA-free production line is much easier to implement.

But overall, interview-partners expressed their opinion that costs for substitution of PFOA in PTFE manufacturing are assumed to be moderate in comparison to price effects induced by the actual limitations in world-wide PTFE supply.

4.2.7 PFOA alternatives are well known and available

As indicated before, some PTFE producers have already or will substitute PFOA in emulsified PTFE manufacturing and also other fluoropolymer production processes. All of these substitutes have less concerning properties and have been approved for use in food contact materials by the European Food Safety Agency (EFSA). A list of known alternatives has been given in chapter 3.1.5, p. 33.

Experts contacted stated that in principle these alternatives are available to other market actors either via licensing or just buying them from the market. This has been verified for alternatives produced by 3M/Dyneon in a response to the authors (licensing).

Responses from other participants in the consultation indicate that alternatives have not been offered, at least not at the moment as companies were not providing prices on the alternatives but stating those were only used in own manufacturing activities.

4.2.8 PFOA substitution from PTFE production is time- and cost-intensive but not necessarily driven by announcement of PFOA restriction proposal

Based on current knowledge, a transition in production from PFOA to alternative substances needs some adaptations of the PTFE production facilities and processes. This is time- and cost-intensive. Interview-partners confirmed the main costs for substitution of PFOA in PTFE manufacturing are not driven by the cost of the alternative substances but the efforts for readjustment of the process-

conditions. Following the experiences of some interview partners, such a process readjustment needs between three to five years[40].

It should be noted that the transition to other processing aids for the companies of the US-EPA program cannot be seen as additional costs due to a possible EU PFOA restriction. Such a restriction would probably be implemented under REACH and enter into force after 2015. 2015 is as well the deadline to be met under the US-EPA program. Only shorter transition periods would have caused extra efforts in these companies.

4.3 Findings on economic effects

For the manufacture and use of PTFE, a broad restriction of PFOA would have different impacts depending on the current company situation.

4.3.1 Effects for PTFE manufacturers

The general situation in that sector is that many manufacturers of PTFE have already - or they are on a good way to - implemented full substitution of PFOA in their manufacturing process or shift to a total PFOA-free process route. Additionally, several less toxic alternatives have been developed and (at least partially) are commercially available. If a possible PFOA restriction includes a minimum transition period until 2015, an additional burden for manufacturers who already committed themselves to the US-EPA stewardship program will be avoided.

On the other hand, manufacturers who have not begun substitution activities might face some investment costs for development of an own alternative or the introduction of a commercially available one. The process needs to be adapted and with regard to the time indicated (3 – 5 years[41]) there could be a situation where full manufacturing capacity cannot be adapted by 2015. So depending on a sunset date of the potential restriction, this might lead to an interim price increase for DUs.

The investment costs associated with substitution and adaptation (process adaptation, development of alternative) were reported to be < €50 Mio[42].

Concerning the long term cost increases because of the use of alternatives, this seems strongly dependent on the alternative used. The price could vary from remaining stable (9 – 20 €/kg) or increasing by 10 to 25% (9.90 – 22 €/kg to 10.25 – 25 €/kg). Similar prices have been reported for the year 2011 (~26 US$ ≈ 19.70€). As many of the applications of PTFE are located in the field of “specialised” applications where the unique properties of the material are needed, it can be assumed that in most cases customers will accept this increase in price. In fact, most DUs already pay either higher prices (if manufacturers are able to request these) or manufacturers do not

[40] Note: This is not the time frame for the readjustment itself but the period that is needed gains fully stable process conditions, excluding quality problems etc.

[41] Assumed time range indicated by several experts in interviews based on their experiences from own substitution processes.

[42] One Manufacturer reported much higher costs (> €400 Mio) in the UBA questionnaire – here the complete transition from PFOA and precursor substances was analysed and is not representative for only this application.

transfer the price increase to their customers but still seem to be profiting as none has terminated manufacturing but all invested in substitution.

4.3.2 Effects for PTFE users

Concerning the downstream uses, it can be concluded that none is dependent on the presence of the PFOA from a technical point of view. Residual PFOA contents have no technical function in any of the final PTFE containing products. Therefore, a restriction would not limit the range of applications of PTFE in any way.

Availability of PFOA-free PTFE for European downstream users might be limited for some time after the implementation of a restriction as mandatory usage of such material will increase the market demand for those qualities (see above). Though it should be noted that in applications for consumer products PFOA free PTFE is already in use.

Non-EU downstream users might have an advantage for some time as usage of PFOA containing PTFE does not affect the marketability of the final product as long as PFOA is emitted during article production[43] (PFOA-free production and PFOA-containing production cannot be distinguished by the final product). In principal this might lead to a shift of production to non-EU (as indicated by some interview partners).

How and whether this possible effect is based on facts cannot be assessed as long as no data about the total volume and the share of PFOA-free PTFE production is made available by the manufacturing industry. Additionally, substitution activities have been triggered by the US EPA program as well. Furthermore, a restriction in Europe would support these activities in a way that material with PFOA would not be compliant to a part of the world market.

A relevant shift of PTFE coating processes outside the EU does not seem too likely from the consultant's perspective because referring to the costs, in many cases the application of PTFE containing coatings is only a relatively minor process in a long production chain of complex industrial goods, e.g. in the automotive industry or in the medical device industry. It should be noted that for the latter sector extra costs could arise when a qualification process has to be performed due to a changed formulation of the input materials which could be the case due to other regulatory rules that apply to the articles.

This would be especially cost intensive if tests for biocompatibility in case of direct contact with human material have to be performed. Then the procedure would lead into a new approval process. If only technical parts are involved, an assessment by the producer could be sufficient. Similar procedures are known in the aviation sector.

Assessing the costs for downstream users, the importance of the price of PTFE varies a lot depending on the type of product and the position on the market. In the following, some cases are discussed. General assumption for the discussion of price effects for these actors is that increased costs for the manufacture of PFOA-free PTFE can be allocated in the supply chain[44].

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[43] Due to the emissions from coating under higher temperatures

[44] In this case the negative effect on the manufacturer of the PTFE must be seen as compensated and only the investment cost for development and adaptations of the plant remain.

Case 1: First tier downstream user of PTFE (formulator)

A first tier downstream user of PTFE in the understanding of this report is a company, which is processing virgin PTFE to a material with special properties (formulator).

The cost share of the PTFE raw material of the final product has been estimated by such actors with about 10% of the final product. On the basis of the manufacturers estimate of price increase between 10 – 25% for the raw material (see chapter 4.3.1, p. 39), this would lead to an increase of 1 – 2.5% of the costs for the product (e.g. a polymer blend).

Case 2: Producers of articles

Producer of articles also often use virgin PTFE, therefore they are tier one DUs of polymer manufacturer. Here PTFE is processed for its final use during service life.

The effect of costs varies from the level of integration of PTFE in an article:

- simple article, sold to a next level article producer
- (simple) article integrated into a more complex article by the article producer himself

Simple articles often consist entirely of PTFE (100%). In consequence, any increase in price of PTFE will have a direct effect on the final product. Some actors stated that the share of PTFE costs will be 100% of the final product costs. In fact, this is not true as other costs like e.g. wages, electricity and other production costs remain stable.

The elemental question is whether the producer of such an article is able to allocate the increase in price to its clients. If so or in cases where the article is produced for a more complex article where the costs of the PTFE represent a much smaller share of the overall costs (< 10%), the increase of the material costs will have limited effect on the market actors. Many stated that although the material costs are rather low, the material is essential for the operation of the article (cables for special applications, medicine and analytical products). Only for some articles, where certain properties of PTFE might represent “nice to have” rather than really needed for function, the increase in price might be problematic (one example mentioned in the investigation were fishing lines).

Retailers of PTFE parts indicated they do not anticipate price effects nor negative effects on availability due to PFOA substitution. Instead it was indicated that limitations in the availability of other raw materials for the PTFE production might influence the price development to a much larger extend.

4.4 Findings on environmental emissions

Since PFOA is a PBT, direct effects on the environment are difficult to identify. Concerning the fate of PFOA, one can state that it has been described in literature that PFOA can be found ubiquitously in environmental compartments, mainly in aquifers and in organisms due to its rather good solubility properties in water. Via this path, it is spread throughout Europe and beyond. From the information gathering on PFOA application in PTFE manufacture, it is hard to predict to which extend a restriction will reduce the PFOA presence in the environment because it is unclear which amounts were contributed to the current situation. What can be achieved with the data that have been collected in the described process are estimates on the emissions from PTFE manufacture

and subsequent downstream uses. A broad PFOA restriction including the PFOA residuals in PTFEs will clearly reduce the emission of PFOA to the European environment:

There is some clear evidence that PFOA emissions from downstream processing of PTFE (PTFE coating and drying) are current practise as none of the interview partners reported (environmentally related) risk management measures, but all indicate that residual PFOA is not present in the final products anymore if high temperature steps are involved in processing (> 150°C).

These PFOA emissions would be minimised by a broad restriction of PFOA including the PTFE formulations for coating.

Products that contain any PTFE with residual PFOA will be excluded from the EU-market effectively by a restriction. This would mainly address products where PTFE is not processed via a high temperature process (e.g. technical textiles, PFOA containing mixtures).

4.4.1 Estimation of PFOA emissions from PTFE processing (reduction potential of a restriction)

In the following three scenarios are described that are used to estimate the range of PFOA emissions resulting from its further downstream use as residual in PTFE in Europe.

Scenario 1: worst case

Assumption 1:

- PlasticsEurope estimates the world overall fluoropolymers demand with 80,000 – 90,000 t/a.
- Most sources describe the North American market as the largest in the world. There is also some manufacturing and processing of PTFE in Asia. Therefore, an estimation of the EU share of manufactured PTFE is made of 25%.

⇒ The estimated demand of fluoropolymers in EU is 20,000 – 22,500 t/a

Assumption 2:

- No details on the specific fluoropolymers could be gathered.
- Other fluoropolymers are or have also been manufactured with the help of PFOA.
- Most DU of PTFE indicated in the interviews and questionnaires to use all types of PTFE. No preference could be determined.

⇒ The amount estimated for the EU demand of fluoropolymers is treated like equal to PTFE (no other fluoropolymers). The amount is divided into the different types of PTFE as follows:

- 1/3 (6,667 – 8,333 t/a) is seen as PTFE from the suspension route. No PFOA emissions will be assumed from the processing of such material, although one manufacturer reported the use of PFOA in this manufacturing process, as well[45].
- 1/3 is seen as material that is manufactured via the emulsification process and processed afterwards, leading to lower PFOA residues (10 – 50 ppm)
- 1/3 is seen as material that is manufactured via the emulsification process and sold as dispersed material accounting for higher PFOA residual content (1,000 – 50,000 ppm)

Assumption 3:

- The processing of PTFE ends in articles that are more or less free of PFOA (after coating/sintering).

⇒ It is assumed that all PFOA is released and emitted to the environment via untreated off air.

Result:

The overall release from processing PTFE with low PFOA contents is estimated with ~ 66 – 83 kg/a.

[45] The manufacturer clarified that this was a historical use and it was unusual in the market. As future avoided emission shall be estimated, this will not be taken into account.

The overall release from processing PTFE with high PFOA contents is estimated with ~ 6,600 – 83,000 kg/a.

On the whole, **the release of PFOA in Europe can be estimated with 6.6 – 83.0 t/a**.

Discussion/uncertainties:

A basic assumption that might lead to an overestimation of emissions is the fact that the amount of fluoropolymers as provided by PlasticsEurope included all fluoropolymers. Not all of them are PTFE or probably not even manufactured with PFOA as processing agent. Cumulated numbers from consultations indicate that a possible overestimation could be in the range of about 25% (numbers CBI).

The higher end of the estimate is mainly based on the guess of one expert. Results from questionnaires showed that more likely an upper concentration of PFOA for dispersed PTFE material is 2,000 ppm. This would then lead to an estimate of 6.6 to 13.2 t/a.

Further it can be assumed that some of the material in dispersions was also purified before using it in solution as a consequence of the PFOA emission reduction initiatives of the PTFE manufacturers (as indicated by actors in questionnaires from 2,000 ppm down to 50 ppm.

Another point that should be considered and which is more significant is that at the moment, various manufacturers already substituted PFOA from fluoropolmer manufacture. Therefore, no emissions of PFOA result from the use of these PTFE.

Senario 2: reasonable worst case

Assumption 1 (same as in scenario 1):

- PlasticsEurope estimates the world overall fluoropolymer demand with 80,000 – 90,000 t/a.
- Most sources describe the North American market as the largest in the world. There is also some manufacture and processing of PTFE in Asia. Therefore, an estimation of the EU share of manufactured PTFE is made of 25%.

⇒ the estimated demand of fluoropolymers in EU is 20,000 – 22,500 t/a

Assumption 2:

- No details on the specific fluoropolymers could be investigated.
- Other fluoropolymers are or have been manufactured with the help of PFOA as well.
- Most DU of PTFE indicated in the interviews and questionnaires to use all types of PTFE. No preference could be determined.
- Almost all manufacturers contacted have declared that PFOA is already completely substituted.

⇒ The amount estimated for the EU demand of fluoropolymers is treated like equal to PTFE (no other fluoropolymers). It is assumed that PFOA is already substituted in all materials manufactured via the suspension route and 2/3 of all PTFE manufactured via the emulsification route. The amount is divided into the different types of PTFE as follows:

- 1/3 (6,667 – 8,333 t/a) is seen as to-be PTFE from the suspension route. No PFOA emissions will be assumed from the processing of such material, although one manufacturer reported the use of PFOA in this manufacturing process, as well.
- 2/3 are manufactured via the emulsification route (13,334 – 16,666 t/a)
- 2/3 thereof are manufactured without PFOA (8,990 – 11,110 t/a) and thus leading to no emission of PFOA
- One half of the remaining amount (4,445 – 5,555 t/a) is processed dry material with low PFOA residue (10 – 50 ppm) and the other half dispersed material with high residual PFOA content whereas the upper limit is adapted to the more realistic value of 2,000 ppm (1,000 – 2,000 ppm)

Assumption 3:

- The processing of PTFE ends in articles that are more or less free of PFOA (after sintering)
- Whether this accounts to release or decomposition could not be differentiated.

⇒ It is assumed all PFOA is released and emitted to the environment via untreated off air.

Result:

- The overall release from processing PTFE with low PFOA contents is estimated with ~ 22 – 28 kg/a.
- The overall release from processing PTFE with high PFOA contents is estimated with ~ 2.2 – 2.8 t/a.
- The **release of PFOA in Europe** from the use of PTFE can be estimated with a total of **2.2 – 2.8 t/a**.

Discussion/uncertainties:

Concerning the basis for the calculation for PTFE, the same uncertainty remains. It could be that the realistic demand of PTFE potentially manufactured with PFOA (material from suspension route excluded) is somewhat lower than 15,000 – 20,000 t/a.

Scenario 3: refined scenario

Assumption 1:

- Most sources describe the North American market as the largest in the world. There is also some manufacture and processing of PTFE in Asia. Therefore, an estimation of the EU share of manufactured PTFE is made with 25%.
- PlasticsEurope estimates the world overall fluoropolymers demand with 80,000 – 90,000 t/a.
- With regard to consultation findings, an estimate of the demand of PTFE manufactured only via the emulsification route might be somewhat lower than the estimate based on the PlasticsEurope data (exact data CBI).
- Estimate is based on data from a part of the market and relative shares as indicated in Fig. 4.

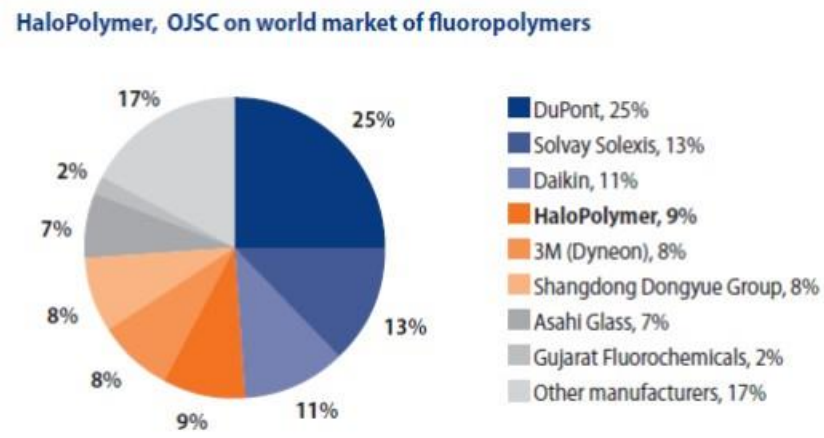

Fig. 4: relative world market shares of fluoropolymer producers, data source http://halopolymer.com/about/company/ (02.05.2013)

⇒ the assumed demand of PTFE in EU is 12,000 – 15,000 t/a

Assumption 2:

- Almost all manufacturers contacted have declared PFOA is already completely substituted.

⇒ The amount estimated for the EU demand of fluoropolymers is treated like equal to PTFE (no other fluoropolymers).
It is assumed, that PFOA is already substituted in all material manufactured via the suspension route (not further considered) and 2/3 of all PTFE manufactured via the emulsification route. The amount is divided into the different types of PTFE as follows:

- 2/3 of the PTFE considered here is manufactured without PFOA (8,000 – 10,000 t/a) and thus leading to no emission of PFOA
- One Half of the remaining amount (4,000 – 5,000 t/a) is processed dry material with low PFOA residue (10 – 50 ppm) and the other half dispersed material with high residual PFOA content whereas the upper limit is adapted to the more realistic value of 2,000 ppm (1,000 – 2,000 ppm)

Assumption 3:

- The processing of PTFE ends in articles that are more or less free of PFOA (after sintering)
- It could not be differentiated whether this accounts for releases on decomposition.

⇒ It is assumed that all PFOA is released and emitted to the environment via untreated off-gases.

Result:

- The overall release from processing PTFE with low PFOA contents is estimated with ~ 20 – 25 kg/a.
- The overall release from processing PTFE with high PFOA contents is estimated with ~ 2.0 – 2.5 t/a.

- The **release of PFOA in Europe** from the use of PTFE can be estimated with a total of **2.0 – 2.5 t/a**.

Discussion of the scenario analysis

In the scenarios 1 and 2, a top down approach was used to calculate the demand for PTFE – worldwide demand broken down to Europe. Scenario 2 was additionally narrowed with some possibly more realistic assumptions based on interviews and questionnaires. Scenario 3 was set up bottom up from some data gathered in the questionnaire process and further refined with assumptions on relative market shares. While scenario 1 is a real worst case and might overestimate the situation (driven mainly by the upper limit content in dispersed material and by not regarding a large share of material already manufactured with substitutes), scenario 2 and 3 end up in results that show only slight differences.

The largest uncertainty is still that it is not known to what extent PFOA has already been substituted in PTFE manufacture worldwide.

Another uncertainty which is inherent in all scenarios is the lack of knowledge to what extent emission reduction measures are currently implemented although nearly all users of PTFE reported to have none.

Both uncertainties are by far the ones that affect the estimates the most (probably more than knowing the exact numbers on PTFE demands).

In consequence, this means that the scenarios might overestimate the current/future situation by far and therefore does not necessarily reflect the reduction potential of a regulatory measure of a restriction of the PFOA content to the determination limit.

5 Conclusions drawn with regard to an argumentation for SEA

In the previous sections of this report (chapter and 4.2), the basic facts on the use of PFOA in the manufacture of PTFE and subsequent article service life stages of technical parts containing PTFE gathered during the information collection phase (described in 2) are documented. These facts describe and define the baseline scenario of the current use of PFOA and residual PFOA content in PTFE applications.

In an SEA, the intended restriction – here the completed restriction of PFOA in all uses and in all products placed on the EU-market – needs to be assessed against this baseline in terms of economic as well as health and environment effects .

Major effects of such a restriction are described above (see chapter 4.3 and 0) based on the understanding of the consultant team. This represents already main parts of the “stage 3 – Identifying and assessing impacts” of a SEA.

The question, whether these findings and arguments on the impacts are complete and robust enough, leads back to the scoping stage[46] of a SEA.

[46] Step two SEA workflow according to the ECHA Guidance on restriction page 31, http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf

As the Restrictions guidance document sets, a SEA can be used to support four potential purposes[47]:

Purpose 1: Justification that community wide action is required;

Purpose 2: Assessing whether the proposed restriction is the most appropriate community wide action compared to other risk management options;

Purpose 3: Refining the scope of the proposed restriction;

Purpose 4: Assessing the proposed restriction in terms of the net benefits to human health and the environment, and the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

In the following, it is discussed whether the available facts, information and knowledge about the possible effects are sufficient to support these purposes for the area of PFOA in the technical use of PTFE.

[47] see section 1.2 of the ECHA guidance for further information

5.1 Purpose 1: Justification that community wide action is required

PFOA has been identified as a PBT substance according to REACH Article 59. For these kinds of substances, a strict precautionary approach applies resulting in measures that facilitate minimization of the substance in the environment.

This justification is seen as sufficient for the proposal of a regulatory proposal for PFOA.

An estimation of emissions showed that emissions in the range of 2.2 – 2.8 t PFOA per year (refined scenario 2) or 2.0 – 2.5 t per year (scenario 3) could be realized by implementing a restriction for PTFE material placed on the market that restricts the residual content of PFOA to the detection limit (<1 ppm).

5.2 Purpose 2: Assessing whether the proposed restriction is the most appropriate community wide action compared to other RMO

In the field of manufacture and the technical applications of PTFE two alternative options to a broad restriction can be considered in principle:

i. Efficient reduction of PFOA emissions from manufacture and technical downstream uses of the (PFOA containing) PTFE, e.g. via regulations on industrial emission etc.

ii. Implementation of a voluntary agreement with the PTFE manufacturers covering almost all (or at least the largest share) of PTFE brought on the market.

Alternative i. would need a whole set of measures to be implemented to gain the intended overall efficiency. All plants that process PFOA containing PTFE would need to install efficient risk management measures (e.g. off air collection with subsequent abatement technology, process water collection with subsequent treatment). The effectiveness of such measures will have to be controlled in a routine.

Products that do not emit possible PFOA residues during production would not be allowed for use under conditions that lead to emissions to the environment (e.g. direct outdoor applications with chance of release of PFOA by water contact)[48]. Further they will have to be collected separately when entering the waste life cycle stage making sure that suited treatment of such wastes is ensured (waste incineration under conditions that ensure complete destruction and also have an effective off gas purification).

The costs that would be caused for the implementation of these set of measures can be assumed to be comparably high, even without having performed a detailed compliance cost assessment (CCA)[49].

[48] For some major product groups like e.g. treated technical textiles for the construction sector such boundaries would clearly not be in line with the intended use of the products.

[49] Such CCA can not be performed due to the lack of all input parameters – amounts of PFOA and contents, number of plants, type of plants, and size of plants (all necessary e.g. for to judge whether these plants are covered by mandatory permitting procedures under IED or not) etc.

A semi quantitative assessment shows that it would be more cost-effective when measures have to be taken by manufacturers than measures that have to be implemented by downstream users of PTFE. This assumption is mainly based on the fact that there is a relatively small number of manufacturers and manufacturing sites compared to the larger number of downstream users which is based on the fact that PTFE is used in various sectors. This results in far more processing sites than if only manufacturing sites were targeted.

If an investment of 25 mio per manufacturer would be assumed and the number of manufacturers was assumed to be about 15, the overall invest would be €375 mio (research & development, adaptation of process and plant, licensing costs) [50].This estimate reflects rather a worst case scenario as not all costs in reality can be attributed to a possible restriction. Research and development activities which can be very cost intensive have been already performed by companies before a restriction was announced. In fact, many companies already substituted PFOA in PTFE manufacture without a restriction in the last years so only a relatively small share of the manufacturers will have to start from the beginning. Still, for this assessment all manufacturers will be treated as all costs were generated by the restriction.

The average one time investment of a downstream is estimated to be about €100,000 each for incineration technology and €8,000 for water treatment via active coal filters (1,200 l capacity)[51] in a relatively unproblematic industrial field. Latter means production sites which are not too large, no special features like e.g. explosive protection.

Further costs will originate on a regular basis for the operation of risk management measures. Since the share off compounds that burn without gas feed in, the off gas is assumed to be rather low, an average cost for the incineration is assumed to be at about €100,000 per year. This costs originate almost exclusively from the gas needed to feed the incinerator. The annual operating cost for the active coal filters (exchange of coal, subsequent waste incineration, new coal) are estimated at €20,000 per year[52]. Based on a 10 year time period and 300 downstream user sites, the investment and operation cost for the downstream users would be at about €392.4 mio. So the point at which costs for the manufacturers (based on the scenario above) and costs for the downstream users are more or less equal will be in the area of 15 manufacturers to 300 downstream users. One aspect that should also be kept in mind is that substitution is a one time investment while the downstream user measures will continue beyond the time frame of 10 years from the scenario.

In comparison, continuous costs caused by the fact that the manufacture becomes more expensive after substitution might vary from €9.0 mio (10% increase of manufacturing costs 10.000 t/a PTFE

[50] The real investment costs caused by a restriction would be much lower as most manufacturers already have substituted and the costs have not been induced due to the restriction, whereas almost no DU has implemented measures for the treatment of PFOA emissions. In reality it seems as if the substitution is only limited to the Asian manufacturers (Japan excludes) estimated five to 10.

[51] Estimate for active coal filter technology taken from: Dr. Andreas Fath/Hansgrohe AG/Technologie (2008): „Minimierung des PFT Eintrags in die Galvanikabwässer“ http://www.umweltschutz-bw.de/PDF_Dateien/Downloadbereich/Downloads_2011/Abschlussbericht_PFOS.pdf

[52] Numbers might be a bit high as taken from a report for a galvanic plant and the elimination of PFOS which is assumed to be present in higher concentrations in that process then PFOA in the processes investigated.

demand) to €37.5 mio (25% increase of manufacturing costs 15.000 t/a PTFE demand). These permanent costs will have to be covered by the market with a good chance for manufacturers to forward at least some of the costs to customers because the technical performance of the material seems to be more important than price development. This will be an average extra cost for the more expensive raw material of €12,300 per year based on the assumption of 300 downstream users of PTFE.

For option ii., it cannot be estimated how far a voluntary agreement on the basis of the US stewardship program could provide a substantial share for the reduction of PFOA in Europe as most basic data are not publicly available. A minimal precondition to be able to compare this voluntary agreement with a regulatory measure would be that market data on amounts, types, residual PFOA content of manufactured PTFE, the market share of the involved parties in Europe and other parts of the world would be presented in a transparent way by the partners of such an agreement.

Some estimates on the reduction potential of the existing measure in the US have been incorporated in the scenarios on emissions (substitution in 2/3 of the material placed on the market). Still the residual emissions have been estimated to be > 2 t/a. For exact calculations more data are needed.

This information needs be presented in a way that an independent third party would be able to check the correctness of the data.

A scenario that includes the necessary transparency described would clearly demonstrate that via the ongoing voluntary activities the largest share of PFOA content is eliminated (e.g. > 95 %) and that might be a basis for an alternative risk management option. To which extend this could be a good option in the context of the overall regulation option (restriction of precursors, other PFC produced via telomerisation) depends on the findings of the parallel information collection and research activities in these areas.

5.3 Purpose 3: Refining the scope of the proposed restriction

In the context of aspired restriction proposal (overall restriction), a refinement may include specific exemptions from the restriction. Uses of PFOA containing PTFE could in our opinion only qualify for such an exemption if no technical alternatives could be identified for a certain use. On the basis of the facts from the information collection performed, there is no application that is technically not possible with PFOA free material. So there is no justified technical reason to grant an exemption. Indicated cost effects (possible higher cost on raw materials) would in our opinion only be seen as temporary and as relatively small.

With regard to the restriction proposal, the following facts should be considered:

A tiered scenario for the restriction might be a good way forward to ease the burden for PTFE manufacturers and downstream users that are not yet involved in substitution of PFOA or have not been regulated by customer or other demands. This could result in a moderate threshold limit for PFOA from 2015 on (e.g. 10 ppm for the raw-material) and a more ambitious of 1 ppm or lower later on (considering a transition time of about 5 years for a shift to alternatives 2018 might be a suitable aim). For the technical PTFE mixtures placed on the market, it seems necessary to include dispersed material giving special focus to the liquid phase the PTFE is dispersed in. Data on PFOA residual content of PTFE dispersions are often referred to the dry matrix not to the liquid matrix

which is dispersed in. PFOA is well soluble in aqueous solutions. So the threshold limit of first 10 ppm and later of 1 ppm should be valid for this as well.

5.4 Purpose 4: Assessing the proposed restriction in terms of the net benefits to human health and the environment, and the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole

To be able to perform an assessment of overall benefits or costs from PFOA release or the restriction of its use respectively fundamental data on current emission levels and their pathways is required. This information is not available from information sources accessible for the consultants.

As far as the interview process has shown, at least no or minor negative overall effects for society could be identified. Only some vague statements on ceasing some product lines (low cost products that could be affected specifically by the price of raw materials) have been reported.

As already stated, all estimated costs for the measure are vague. Although some considerations can be made:

- If permanent extra manufacturing costs of €37,5 mio per year are generated (15,000 t/a, upper price limit, increase of costs 25% = worst case), each manufacturer has to compensate €2.5 mio.
- Permanent costs have a good chance to be (at least partially) allocated to the customers because of the technical need to use PTFE. So costs are distributed across a relative large number of different market actors and sectors.
- One time investment costs for manufacturers have often already been realised due to a general trend to substitute PFOA for polymer manufacture and will therefore only affect some of the manufacturers.
- User of PTFE will not have investment costs in their plants and processes due to PFOA substitution in PTFE.
- PFOA emission from PTFE will be eliminated because imported articles with PTFE do not contain PFOA (anymore) and PTFE processed in Europe does not contain PFOA (neither will articles made from it), leading to an estimated emission reduction of > 2 t/a.

5.5 Conclusion

On the basis of the review of the arguments presented above, a restriction seems appropriate to reach the aim of minimizing emissions of PFOA from the use and manufacture of PTFE. As there is only limited quantitative data the estimations performed by the consultant team for the PFOA in PTFE case include a respective uncertainty. Furthermore to the knowledge of the consultants it will be quite difficult to come up with similar estimations for the other uses and/or source of PFOA.

So with regard to the overall restriction dossier the consultants recommend not to elaborate an in depth SEA but rather base the SEA part on a qualitative argumentation.

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More information used in this report originate from interviews or questionnaires with sector experts and companies (manufacturers, downstream users of PTFE). The contact details and the primary information are known to the UBA and have been made available to the contractor via an internal report, to ensure confidentiality and privacy.