RIVISTA GIURIDICA DELL' AMBIENTE

diretta da FAUSTOCAPELLI e STEFANO NESPOR

2-2018

[Estratto]

Editoriale Scientifica NAPOLI

PROCEDURA DI VALUTAZIONE SCIENTIFICA

- Sono sottoposti alla procedura di valutazione scientifica gli elaborati da pubblicare nella Rivista come articoli o saggi (CONTRIBUTI, OSSERVATORIO INTERNAZIONALE, ESPERIENZE DI AMMINISTRAZIONE E DOCUMENTAZIONE, OSSERVATORIO EUROPEO E FOCUS) e come annotazioni giurisprudenziali (GIURISPRUDENZA – COMMENTI E NOTE), nel rispetto dell'anonimato sia dell'Autore sia dei valutatori. Questi ultimi sono scelti dai Direttori della Rivista tra i membri della Direzione o del Comitato Scientifico.
- 2. Il giudizio dello scritto da parte dei valutatori si fonda sui seguenti criteri:
 - ordine e chiarezza dell'esposizione;
 - coerenza logica e metodologica;
 - idonea documentazione o originalità del contenuto.

L'esito della valutazione potrà essere:

- positivo (pubblicabile);
- positivo subordinato a modifiche e integrazioni indicate dal valutatore (pubblicabile con riserva);
- negativo (non pubblicabile).

osservatorio internazionale

a cura di TULLIO SCOVAZZI

PFAS and the Scary Family The International Outlook

DAVID DESFORGES

The compounds which form the subject matter of this article are persistent and very stable. They do not break down, resist degradation in the environment, are highly persistent, and mobile. They are neither degraded by fire, water, or oil nor by acids. They bioaccumulate and are not assimilated. Their concentration increases in blood and organs over time. Yet, they are not an alien life form brought back to earth by some end-of-life satellite incompletely combusted in the atmosphere. They are man-made and have been used in hundreds of industrial applications, and consumer and household products since the late 1940s early 1950s.

"They" are compounds known as per- and polyfluoroalkyl substances (PFASs). The acronym embraces a whole family of products including particularly perfluorooctanoic acid (PFOA), perfluoro-octane sulfonic acid (PFOS), and perfluoroalkyl acids (PFAAS). While PFOA and PFOS have been phased out of production and use in the United States, other countries still manufacture and use them. Regardless of efforts already made to phase these products out, available evidence suggests a legacy of environmental and health conditions going back decades and promises difficult identification and remediation work for decades ahead.

Some PFAS have been manufactured for over 50 years. They were poorly documented in samples until the early 2000s¹. Abundant scien-

¹ Interstate Technology Regulatory Council (ITRC), History and Use of Per- and Polyfluoroalkyl Substances (PFAS), Nov. 2017, p. 1. Available at: *https://pfas-1.itr-*

tific literature now exists on the issue². As evidence of contamination surfaces here and there and poorly reversible exposure persists, PFAS are likely to receive even more widespread publicity in the coming years. Specialists and decision-makers alike would therefore be well advised to populate their already long list of suspicious chemical compounds with these acronyms as well. PFASs are here to stay.

1. Product(s)

PFAS are man-made chemicals. They are part of a complex family of more than 3,000 fluorinated organic chemicals, a term that captures a wide range of substances which contain at least one atom of fluorine (F). However, their mere scientific designation appears to be challenge itself as no less than 42 families and sub-families of PFASs involving 268 selected individual compounds have been identified and are yet to gather consensus in terms of terminology and classification³.

As far as production methods are concerned, scientific literature on the matter indicates that "PFAS are produced using several different processes. Two major processes have been used to manufacture fluorosurfactants (which includes PFAAs) and side-chain fluorinated polymers: electrochemical fluorination (ECF) and telomerization. ECF was licensed by 3M in the 1940s and used by 3M until 2001. ECF produces a mixture of even- and odd- numbered carbon chain lengths of approximately 70% linear and 30% branched substances. Telomerization was developed in the 1970s, and yields mainly even numbered, straight carbon chain isomers"⁴.

In view of their properties⁵ and water repellency, temperature resistance, friction reduction – to name just of few – PFAS have unsurpris-

cweb.org/wp-content/uploads/2017/11/pfas_fact_sheet_history_and_use__11_13_-17.pdf.

² Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins, Robert C. Buck *et al.*, Integrated Environmental Management and Assessment, 2011, Vol. 7, n°4, pp. 513-541. Available at: *https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.258*

³ Id., p. 513 and p. 515 et seq.

⁵ Https://en.wikipedia.org/wiki/Perfluorooctanoic_acid - cite_note-Lindstrom-6oil.

⁴ ITRC, 3.1 p. 2.

ingly been manufactured in industrial quantities and widely used in industry and consumer products worldwide since the 1950s. Uses include non-stick cookware, water-repellent clothing, "breathable" clothing and the likes, stain resistant fabrics all of which bear trade names well known to the professional and wider publics.

They can also be found in some impregnation agents for textiles, paper, and leather as well as in wax, polishes, paints, varnishes, and cleaning products for general use. They are further present in metal surfaces, some cosmetics, firefighting foams, alcohol-type concentrate foams, and more generally in a variety of products that resist grease, water, and oil. Manufacturers include or have included most if not all international chemical giants. On their end, downstream users are probably innumerable.

2. Issues

Repeated uses and uncontrolled releases have resulted in significant traces of PFASs being identified worldwide, on all continents, even in areas remote from where they were initially manufactured or used⁶.

PFAS are pervasive. They can indeed be found in the soil, water and air. The environment, wildlife and humans are impacted. The first demonstration of such general and global impact was first administered in 2001⁷. However, the blood of a group of fluorochemical industry workers had already been confirmed to contain PFOA in the early 80s.⁸. Exposure scenarios and pathways are numerous.

Typically, individuals and animals can be exposed to PFAS *via* food where contaminated soil and water are used to grow fruits and vegetables and provide PFASs an opportunity to enter the food chain (milk, meat, etc.). Food packaging containing PFAS is another source while equipment using PFAS during food processing may also be yet another

⁶ Id.

⁷ J. P. GIESY – K. KANNAN, *Global distribution of perfluorooctane sulfonate in wildlife*, Environmental Science and Technology, 2001, 35, pp. 1339-1342 *cited in* RC Buck.

⁸ F. A. UBEL – S. D. SORENSON – D.E. ROACH, *Health status of plant workers exposed to fluorochemicals: A preliminary report.* American Industrial Hygiene Association Journal, 1980, 41, pp. 584–589 *cited in* RC Buck.

source of contamination⁹. The biodegradation or disposal of consumer products containing PFAS, but their uses are considered sources of contamination as well¹⁰. In this latter case sources galore again: non-stick cookware, leather and apparel, carpeting are prime suspects.

PFAS also take their toll in the workplace. Certain occupational settings are reputed to be hazardous as PFAS have been determined to be airborne as well.

Drinking water can also be a significant source of contamination. It is often associated with facilities such as PFAS-producing facilities or PFAS-using facilities as well as oil refineries and airfields where PFAS are being heavily used for firefighting drills. Indeed, samples taken at sites where firefighting foams were used or spilled show that airports and air force bases are the prime victims and contributors to such categories of contaminations¹¹.

According to the US Environmental Protection Agency (USEPA), PFOAs and PFOSs, the most studied PFAS cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Both chemical have caused tumors in animals. The most consistent findings are increased cholesterol levels among exposed populations, and more limited findings related to low infant birth weights, weakened immune systems, cancer (for PFOA) and thyroid hormone disruption (for PFOS)¹². It has also been determined that PFAS exposure may pass from mother to child through the placenta and through breast milk.

According to the International Agency for Research on Cancer (IARC), there is limited evidence in humans for the carcinogenicity of PFOA. Still, a positive association was observed for cancers of the testis and kidney. To date therefore, the IARC considers PFOA as a possible

⁹ See An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns. Available at: https://www.atsdr.cdc.gov/pfc/docs/pfas_clinician_fact_sheet_508.pdf.

¹⁰ Id. p. 7.

¹¹ The precautionary principle and chemicals management: The example of perfluoroalkyl acids in groundwater, Ian T. Cousins *et al.*, Environment International 94 (2016), pp. 331-340, see Table 1, p. 332. Available at: *https://www.sciencedirect.com/science/article/pii/S0160412016301775?via%3Dihub*; see also, ITRC, 4.2 p. 6.

¹² Available at: *https://www.epa.gov/pfas/basic-information-pfas#important*; see also *https://www.atsdr.cdc.gov/pfas/bealth-effects.html* and

carcinogen to humans (Group 2B)¹³. PFOSs however are not yet classified by the IARC.

It remains that their impact is widespread already. Statistics show that most people in the United States and in other industrialized countries have measurable amounts of PFAS in their blood.

In 2011-2012, the Centers for Disease Control and Prevention (CDC) conducted a program to assess the health and nutritional status of adults and children in the United States. The concentration of PFAS in the blood of a representative sample of the U.S. population (12 years of age and older) was measured. It is staggering. Average blood levels found were, for PFOA, 2.1 part per billion (ppb) with 95% of the general population at or below 5.7 ppb, and for PFOS, 6.3 ppb, with 95% of the general population at or below 21.7 ppb.

3. Responses

Mounting evidence of the health and environmental impact of PFASs has led regulators to act in a variety of ways.

PFAS qualify as Persistent Organic Pollutants (POPs) under the Stockholm Convention signed under the auspices of the United Nations in 2001 (Convention)¹⁴. The Convention aims at reducing or eliminating the production, use and release of key POPs defined as synthetic, organic compounds that, to varying degrees, resist photolytic, biological, and chemical degradation. PFOS were added to Annex B of the Convention considering its persistence in the environment and the absence of known degradation at any environmental condition. At this time, PFOA and PFHxs are also proposed for listing¹⁵.

In 2006, the USEPA urged eight leading chemical companies to join

¹³ IARC PFOAS Monograph. Available at: *https://monographs.iarc.fr/ENG/Mono-graphs/vol110/mono110-01.pdf*.

¹⁴ See Stockholm Convention on Persistent Organic Pollutants adopted on 22 May 2001. Available at: *http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx.*

¹⁵ *Http://chm.pops.int/TheConvention/ThePOPs/ChemicalsProposedforList-ing/tabid/ 2510/Default.aspx.*

in the so-called PFOA Stewardship Program and agree to eliminate the use of PFOA and PFOA-related chemicals in their products and as emissions from their facilities¹⁶. The plan was:

- to achieve, no later than 2010, a 95% reduction, measured from a year 2000 baseline, in both facility emissions to all media of PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals;

- to working toward the elimination of these chemicals from emissions and products by 2015.

According to the USEPA: "most companies stopped manufacture and import of long-chain PFAS, and then transitioned to alternative chemicals. Other companies exited the PFAS industry altogether. (...) PFOS was not reported as manufactured (including imported) into the U.S. as part of the 2012 Chemical Data Reporting (CDR) effort or the previous collection effort in 2006. CDR requires manufacturers (including importers) to report if they meet certain production volume thresholds, generally 25,000 lbs. at a single site. The last time PFOS manufacture was reported to USEPA as part of this collection effort was 2002. There are some limited ongoing uses of PFOS. The manufacture and import of PFOA has also been phased out in United States as part of the PFOA Stewardship program. Existing stocks of PFOA might still be used and there might be PFOA in some imported articles"¹⁷.

Alongside phasing-out efforts, in a variety of countries rising public concern has led national or provincial authorities to set guideline values for PFAAs in drinking water standards¹⁸. Limited conclusive epidemiological evidence and missing data are illustrated by different levels having been retained¹⁹.

¹⁶ See Fact sheet on the PFOA Stewardship Program. Available at: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program.*

¹⁷ See id. Q7 and Q8.

¹⁸ See IT Cousins, p. 333.

¹⁹ See id. Table 2.

REGULATORY GUIDELINES FOR PFOA AND PFOS (IN NG/LITER) IN DRINKING WATER					
Authority	PFOA OA	PFOS OA	Reference		
German Drinking Water Commission (HPV)	$100^{\mathrm{ac}^{20}}$	100 ^{ac}	German DWC (2011)		
German Drinking Water Commission (GV)	300 ^{ad}	300 ^{ad}	German DWC (2011)		
German Drinking Water Commission (PAV)	500 ^{ae}	500 ^{ae}	German DWC (2011)		
German Drinking Water Commission (PAV)	5000 ^{ac}	5000 ^{af}	German DWC (2011)		
Environmental Protec- tion Agency, Denmark	100 ^b	100 ^b	DEPA (2015)		
National Food Agency, Sweden	90 ^b	90	NFA (2013)		

²⁰ a) Refers to the sum of PFOA and PFOS present in drinking water.

b) Refers to the sum of PFASs including PFOA and PFOS (the sum of 7 PFASs in Sweden and the sum of 12 PFASs in Denmark) present in drinking water.

c) Health-based precautionary value (long-term minimum quality goal) for non-genotoxic substances.

d) Strictly health-based guidance value for safe lifelong exposure for all population groups.

e) Precautionary action value for infants.

f) Precautionary action value for adults.

g) Minimum action to be taken: consult with local health professionals; and monitor levels in drinking water.

h) Minimum action to be taken: as tier 1 plus: put in place measures to reduce concentrations to below 1,000 ng/L (PFOS) or 10,000 ng/L (PFOA) as soon as practicable.

i) Minimum action to be taken: as tier 2 plus: ensure consultation with local health professionals takes place as soon as possible; and take action to reduce exposure from drinking water within 7 days.

j) Provisional short-term value.

Regulatory guidelines for PFOA and PFOS (in ng/liter) in drinking water					
Authority	PFOA OA	PFOS OA	Reference		
UK Drinking Water Inspectorate	300	300 ^g	DWI (2007)		
UK Drinking Water Inspectorate	10,00	10,00 ^h	DWI (2007)		
UK Drinking Water Inspectorate	90,00	90.00 ⁱ	DWI (2007)		
New Jersey Department of Environmental Protection	40	-	NJ DEP (2007)		
Minnesota Department of Health	300	300	MDH (2008)		
Maine Center for Disease Control and Prevention	100	6	NFMCDCP (2014)		
US EPA Office of Water	400	200 ^j	US EPA (2012) (2013)		

Recently, in 2016, the USEPA issued a lifetime Health Advisory (LHA) for PFOA and PFOS. It is set at 70 nanograms per liter (70 parts per trillion) and applies for each PFAA (perfluoroalkyl acids), as well as in combination, in drinking water²¹.

Europe is also taking steps. On December 12, 2006, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on

²¹ Available at: *https://www.epa.gov/ground-water-and-drinking-water/drinking-water/drinking-water-bealth-advisories-pfoa-and-pfos.*

the marketing and use of certain dangerous substances and preparations was amended for the 30th time (!) to include PFOS to the list with the obligation for Member States to adapt their laws and regulations accordingly by December 27, 2007²².

This Directive prohibited the placement on the market or use of PFOS as a substance or constituent of preparations in a concentration equal to or higher than 0,005 % by mass. It also prohibited the same in semi-finished products or articles, or parts thereof, where the concentration of PFOS is equal to or higher than 0,1% by mass calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, where the amount of PFOS is equal to or higher than 1 g/m² of the coated material.

Derogations were nevertheless granted for: photoresists or anti reflective coatings, photolithography processes, photographic coatings applied to films, papers, or printing plates, mist suppressants for non-decorative hard chromium (VI), plating and wetting agents for use in controlled electroplating systems where the amount of PFOS released into the environment is minimized (by fully applying relevant best available techniques), and hydraulic fluids for aviation.

Another specific derogation was also extended to fire-fighting foams placed on the market before December 27, 2006 which use was permitted until June 27, 2011.

Finally, the Directive provided for the Commission to be informed on a regular basis so that the derogations only be continued for essential uses for which safer alternatives did not exist and where the efforts undertaken to find safer alternatives had been reported on.

Subsequently, in 2010 the EU Commission issued a recommendation that PFASs be monitored in food²³. Interestingly also, PFOA was classified as reprotoxic category 1B and carcinogenic category 2 in Regulation (EC) 1272/2008 on the classification, labelling and packaging of sub-

²² *Https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32006-L0122&from=FR.*

²³ Commission Recommendation 2010/161/EU of March 17, 2010. Available at: *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32010H0161&-from=EN.* stances and mixtures (CLP) as a persistent, bio-accumulative and toxic substance (PBT)²⁴.

On the REACH front, note that PFOA is on the candidate list of Substances of Very High Concern since June 20, 2013 while PFHxS are on that same list since July 7, 2017.

Recently also, things moved further as Regulation (EU) 2017/1000 of June 14, 2017 made of PFOA (CAS 335-67-1), its salts and certain related substances a completely new entry 68 to Annex XVII of REACH which lists restrictions of certain hazardous substances, mixtures and articles for their marketing and use on the European market including a variety of derogations²⁵.

Under entry 68, PFOA and its salts:

1. Shall not be manufactured, or placed on the market as substances on their own from July 4, 2020;

2. Shall not, from July 4, 2020, be used in the production of, or placed on the market in:

a) another substance, as a constituent;

b) a mixture;

c) an article, in a concentration equal to or above 25 ppb of PFOA including its salts or 1000 ppb of one or a combination of PFOA-related substances.

3. Points 1 and 2 above shall only apply from:

a) July 4, 2022 to: (*i*) equipment used to manufacture semi-conductors; (*ii*) latex printing inks.

b) July 4, 2023 to: (*i*) textiles for the protection of workers from risks to their health and safety; (*ii*) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (*iii*) plasma nano-coatings.

c) July 4, 2032 to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC.

Finally, on February 1, 2018, the Commission further proposed a mod-

²⁴ *Https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02008-R1272-20180301&qid=1529335402422&from=FR.*

²⁵ Https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017-R1000&from=EN.

ification to the Directive on water intended for human consumption²⁶. It stated that although the World Health Organization recommended adopting parametric values for two individual perfluorinated substances (PFOS with a value of 0.4 μ g./l. and perfluorooctanoic acid (PFOA) with a value of 4 μ g./l.), the Commission's proposal was to regulate the group of PFAS, and to suggest values of 0.1 g./l. for individual PFASs and 0.5 g./l. for PFAS in total, as is done for pesticides for example.

As an implied *caveat* to industrial companies, the Commission interestingly stated that "*as these values are higher than those referred to in Sweden or the United States, it should be feasible to meet them*".

4. Outlooks

On May 1, 2015, 200 scientists from 38 countries issued a declaration in Environmental Health Perspectives calling on the international community to cooperate in limiting the production and use of PFASs and in developing safer nonfluorinated alternatives. They urged scientists, governments, chemical and product manufacturers, purchasing organizations, retailers, and consumers alike to act²⁷. Since then, pressure on the matter has only increased with more alarming being released recently.

At both ends of the spectrum, prevention and remediation will bring about their own set of challenges.

Prevention includes in part the development of replacement technologies. The reformulation of substances from long-chain (8 or more fully fluorinated carbons) to shorter-chain perfluoroalkyl or polyfluorinated substances is one of the approaches. On the one hand, from a practical perspective, it has not been determined yet whether these shortchain substances can achieve the same performances as their longer-chain counterparts. On the other, limited data available yet does not enable to determine whether short-chain substitutes are less hazardous. In addition, treatment processes used to remove these substances from waste streams may not as effective as with long-chain substances²⁸.

²⁶ Http://ec.europa.eu/environment/water/water-drink/pdf/revised_drinking_water_directive.pdf.

²⁷ See Madrid Statement. Available at: https://ehp.niehs.nih.gov/1509934/.

²⁸ See M. SUN – E. AREVALO – M. STRYNAR – A. LINDSTROM – M. RICHARDSON – B.

Remediation is highly problematic as well. As stressed by specialists, despite experience drawn from the recent history of massive releases of persistent chemicals (PCBs, PCDD, Furans and PBDEs to name a few), problems associated with poorly reversible contaminations have not been adequately addressed in regulations yet²⁹. Remediation costs are mindboggling. For PCBs alone, its is estimated that \in 75.3 billion were spent in the EU on cleanup costs between 1971 and 2018³⁰. There is reason to believe that the PFAS/PFOS remediation price tag will be equally significant. In 1999-2000, the clean-up of PFOS-contaminated drinking water for 23 households on the Channel Island of Jersey cost an estimated £ 3.7 and 30 million³¹. Finally, as sources are diverse and responsible parties not easily identifiable, the likelihood is that eventually society at large and hence taxpayers will bear the burden of 50 years of PFAS/PFOS mismanagement at all levels.

The latest news is not reassuring. On May 22, 2018, the Environmental Working Group, a US-based watchdog group reported that up to 110 million Americans could have PFAS-contaminated drinking water, that is more than 1,500 water systems impacted across the continental US (based on 2013-2015 data)³². After some delay³³, the US Agency for Toxic Substances and Disease Registry eventually made a long-awaited report public³⁴. It suggests that exposure to PFOA and PFOS may be harmful at levels 10 times lower than what the 70 parts per trillion which EPA had deemed safe... in 2016³⁵.

KEARNS – A. PICKETT – C. SMITH – D. R. U. KNAPPE, Legacy and Emerging Perfluoroalkyl Substances Are Important Water Contaminants in the Cape Fear River Watershed of North Carolina, 2016, Environmental Science and Technology Letters 3 (12): 415-419, cited in ITRC, 3.5 p. 4.

²⁹ In IT Cousins, p. 336.

³⁰ Ibidem.

³¹ Ibidem.

³² Https://www.ewg.org/research/report-110-million-americans-could-have-pfas-contaminated-drinking-water#.WyvLUaf-g2w.

³³ Https://www.ewg.org/release/hhs-releases-nightmare-pfas-chemical-study-suppressed-scott-pruitt-white-house#.Wy5Ykaf-g2x.

³⁴ Https://www.politico.com/story/2018/06/20/trump-report-toxic-chemicals-656319.

³⁵ In November 2017, New Jersey announced it would enforce a 14 parts per trillion standard in PFOA as Maximum Contaminant Level in public drinking water. Researching the matter reveals the abundance of literature available and raises yet again the question of the delay between the identification of an issue and reasonable action on the part of decision-makers. Scientists contend that the reason may lie in the fact that the traditional riskassessment approach was used to determine whether action was warranted. In absence of sufficient information evidencing the existence of unacceptable high risks related to PFAS/PFOS in the late 1990s' when high levels were identified, it took another ten years to conduct further research and issue drinking water guidelines³⁶. Conversely, they argue that had the poorly reversible exposure criterion been used according to the precautionary principle, PFAS/PFOS would have been regulated earlier and further releases and contamination might have been averted³⁷.

Interestingly, in the field, PFAS and PFOS are seldom investigated on the occasion of site surveys in the course of transactions for example. Therefore, it is advisable that stakeholders wait not for regulatory action where there is none and to apply precautionary measures in keeping with reasonable and state-of-the-art scientific findings.

In the meantime, PFAS continue to be manufactured across the world. The OECD reported in 2015 that the increased production of PFOA and related PFAS in China, India, and Russia had potentially offset the global reduction anticipated as the result of the US' efforts to phase these substances out³⁸. The World Bank further described that China began manufacturing PFAS in the 1980s.³⁹. Also, in what appears to be striking interconnected vessels' move, the Chinese PFOS production started to increase with the long-chain PFAA phaseout in the US.

As far as Europe goes, as late as 2016, PFOS and its derivatives were still being produced in Germany, and Italy⁴⁰.

Meanwhile, in January 2018, Michigan indicated it would continue to adhere to the 70 parts per trillion standard.

³⁶ See IT Cousins, p. 337.

³⁷ ibidem.

³⁸ See http://www.oecd.org/chemicalsafety/risk-management/Working%20Towards%20a%20Global%20Emission%20Inventory%20of%20PFASS.pdf cited in ITR, 3.4 p. 4.

³⁹ See Concawe (Conservation of Clean Air and Water in Europe). 2016. *Environmental Fate and Effects of Poly- and Perfluoroalkyl Substances (PFAS)*. Report No. 8/16. Auderghem, Belgium, *cited in* ITRC, 3.4 p. 4.

⁴⁰ See WHO report with contamination cases detailed in the Veneto region and in

And on June 22, 2018, the European Chemicals Agency launched a 2-month public consultation in view of possibly reviewing entry 68 of Annex XVII of REACH to include yet another... derogation to the benefit perfluorooctane bromide (PFOB) containing perfluorooctane iodide (PFOI) in concentration lower than 250 ppm for the purpose of producing pharmaceutical products⁴¹.

the Ruhr region in Germany. Available at: *http://www.euro.who.int/en/publications/-abstracts/keeping-our-water-clean-the-case-of-water-contamination-in-the-veneto-region,-italy-2017.*

⁴¹ See http://www.worldbank.org/en/news/press-release/2017/04/07/gef-grant-toassist-china-efforts-to-phase-out-pops; see also http://www.worldbank.org/en/news/loans-credits/2017/04/07/china-reduction-and-phase-out-of-pfos-in-priority-sectorsproject cited in ITR, 3.4 p. 4.