





Keeping our water clean: the case of water contamination in the Veneto Region, Italy









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Abstract

Perfluoroalkylated substances (PFAS) are highly resistant persistent compounds used for repelling oil, grease and water and protecting the surfaces of carpets and clothing; they are also found in fire-fighting foams. They have negative consequences for human health, although these are not fully established. In 2013, PFAS contamination was found in the drinking-water in parts of the Veneto Region, Italy. This publication describes the experience of the Veneto Region in responding to this public health emergency. The challenges met were typical of those any public health authority might face in responding to a sudden and acute environmental health threat; thus, the lessons learnt in the Veneto Region in dealing with the incident will undoubtedly be useful to other countries facing similar health threats.

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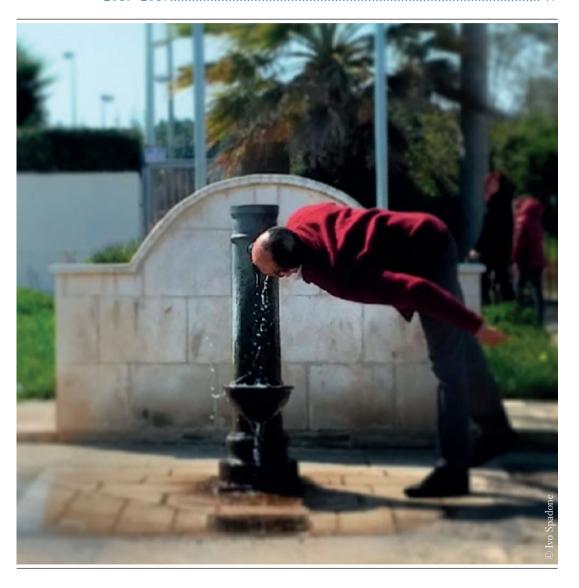
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CONTENTS

Foreword	.v
Foreword	vi
Acknowledgements vi	iii
Executive summary	.X
Aim of the publication	1
Setting the scene	3
The Veneto Region	3
Organization of the health system and environment and health	4
Historical information on the industrialization of north-eastern Italy	5
Taking action	7
PFAS contamination in Veneto: the problem as it arose	7
Description of framework used for managing environmental contamination	0
Key steps	4
Short-term measures	6
Medium-term measures	28
Long-term measures	30
Lessons learnt	8
Enabling factors3	8
The way forward: challenges	39

Key messages	ł2
References 4	14
Annex 1. Key steps in tacking PFAS water contamination, Veneto Region, 2013–2017.	19



Foreword

The Regions for Health Network documents cases of best practice in implementing the Health 2020 policy framework. I am pleased to present this report on the response of the Veneto Region, Italy, to an episode involving the contamination of drinking-water with polyfluoroalkylated substances (PFAS), which has affected over 120 000 citizens. The management of complex cases of environmental contamination has never been easy. The Veneto Region was faced with multiple questions, which called for assessing risk, dealing with numerous stakeholders, managing the media, preventing intense public alarm, developing short- and long-term countermeasures, and mobilizing human, technical and financial resources – all under strong time pressure. The Veneto Region took a bold, no-compromise stance, put the health of citizens first and, applying a precautionary approach, started their response with an extensive clean-up operation, even in the absence of legal standards and established guidelines on dealing with the contaminants in question.

Various factors contributed to making this remarkable response possible, the most essential being the Veneto Region's commitment to intersectoral, whole-of-government work. While its health system is patient-centred, managing the crisis involved all levels of regional government, exemplifying thorough governance for health, a key principle of Health 2020. Communication with the citizens and stakeholders and transparency regarding the situation, were of particular importance, as was the technical and scientific collaboration at the regional, national and international levels.

I believe that this example can be inspirational to many other regions that experience environmental hazards. In wishing the Veneto Region every success in continuing to address this public health emergency, I commend the remarkable strides it has made so far.

Christoph Hamelmann Head of Office WHO European Office for Investment for Health and Development WHO Regional Office for Europe

Foreword

Looking back at all the stages of the PFAS crisis while drafting this foreword, a quotation came to mind from a woman of science and medicine, Nobel laureate Rita Levi Montalcini: "...above all, don't fear difficult moments; the best comes from them".

The discovery of PFAS water contamination in the Veneto Region, which was both complex and severe, was undoubtedly a testing moment for both the institutions and the population of the Veneto Region. The way in which the emergency has been handled from the very beginning shows outstanding scientific, political and communicative professionalism.

The environmental, health and epidemiological factors that came into play were interpreted with a unique sense of responsibility towards our citizens: their health, safety and right to receive sound information were our key priorities.

The response, namely, an investigation into the state of health of the entire population living in the area affected by the contaminated water, was precise and outstandingly implemented, not only as regards scientific accuracy, but also in terms of ethics and conduct. It was coordinated jointly by the Veneto Region, the Regional Health Council, the Prevention Directorate and all offices of the health sector.

I can proudly confirm that throughout the response, we insisted on transparency and professionalism. From the very start, the tools we selected were aimed at the protection of the people living in the affected areas who responded to our efforts in a true spirit of collaboration. We are grateful for their trust, which motivated us immensely.

Someone once wrote, "rules can do a lot, but encouragement is everything". This incident has not been an easy experience for us and the support we received both nationally and internationally proved to be essential. The support of the National Institute of Health was vital. The enormous contribution of the World Health Organization in advising, guiding and supporting us in dealing with, and eventually reporting on, the incident was crucial.

This publication offers a very important testimony of the steps taken so far by the Veneto Region to understand and manage this threat to the health of a large portion of our population in the best way possible.

My hope is that, between the lines, the reader will be able to identify all the ethical, professional, political and human values – rooted in science and medicine – incorporated in our approach to tackling the problem.

The promise we implicitly made to our citizens to devote our entire attention to the PFAS case is one we have kept and are continuing to keep, as referenced in this publication.

I wish everyone a valuable reading experience. The pages of this book are witness to how an initial moment of considerable difficulty was turned into an effective response, thanks to the unique reliability of our institutions.

Domenico Mantoan Secretary General for Health, Veneto Region

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Executive summary

For decades prior to 2013, the people living in 21 municipalities in the southwest of the Veneto Region, Italy, were unaware that the tap water they were drinking contained perfluoroalkylated substances (PFAS). The contamination was affecting the groundwater, the surface water and the drinking-water. PFAS are highly resistant persistent compounds used for repelling oil, grease and water and protecting the surfaces of carpeting and clothing; they are also contained in fire-fighting foam. They have been found to have negative consequences for human health, such as pregnancy complications, thyroid disease, high cholesterol, and cancer, though these are not fully established. This case story describes the experiences of the Veneto Region in managing PFAS contamination in its waters. It provides a snapshot of the situation prior to the discovery of the contamination in 2013 and describes the short, medium- and long-term steps taken to deal with it up to spring 2017.

Despite the lack of legislation on and enforceable threshold values for PFAS, the Veneto Region immediately set up an intersectoral working group and undertook a series of actions, using a precautionary approach. Within three months of the alarm, filters had been installed and most of the PFAS had been removed from the drinking-water in the area. A retrospective health impact assessment (HIA) approach was applied to identify the most appropriate mitigation and remediation measures needed to alleviate the situation, taking future monitoring and evaluation needs into consideration. These needs were substantial given the persistence of PFAS in the area. HIA was based on the results of monitoring the contamination in various components, including drinking-water, groundwater, surface water, soil, air and food, and of measuring serum concentration in the exposed population. This response involved the health, environment and agriculture sectors, the local authorities and civil society.

In responding to this complex threat, the regional health authorities faced multiple challenges. There were several enabling factors, however, including a mandate for intersectoral action, supportive institutional arrangements, the availability of quality, comprehensive data covering the whole population, and already existing mechanisms for screening noncommunicable diseases (NCDs).

The response included the rapid establishment of standards for PFAS in drinking-water for humans, which were quickly extended to cover water for livestock and agriculture.

The management of the incident involved technical and political challenges, such as: preparing delicate risk communications for the public; managing the sensationalism created by the media and several interest groups; and identifying substantial financial resources to meet the high costs of carbon filters and the legal work involved in applying the "polluter pays" principle, which required proving that the main source of the PFAS was a local chemical plant.

Meanwhile, enhanced scientific collaboration came into play at the local, national and international levels to fill knowledge gaps relating to the effects of PFAS on health, design epidemiological and monitoring follow-up studies, analyse data and interpret the results, and ensure that no-one was left behind (for example, highly exposed minorities, such as people using private wells and the most exposed agricultural workers).

Although massive PFAS contamination of drinking-water is uncommon (only a couple of comparable cases are known), the challenges this episode raised were typical of those any public health authority could face because of an acute emerging health threat. Thus, some of the lessons learnt through the response of the Veneto Region, particularly in terms of institutional arrangements, risk management, governance and communication, could be of value to others.

Intersectoral mechanisms offer versatility and value

Building on existing intersectoral mechanisms, the Veneto Region set up ad hoc working groups to deal with the crisis at hand. The combination of a clear mandate and legal measures made it possible to approach non-health sectors for collaboration and expertise.

Transparent management creates a collaborative culture

The routine documentation and reporting of actions taken by all sectors and stakeholders helped build a repository of information that could be shared with the public and used as evidence to support legal action.

Timely action is key

Even if the impact of the chemical contamination is not clearly established, a precautionary approach is critical; it is also expected of a modern, forward-looking health authority. Acting in a timely manner and taking risk-mitigation measures, despite the lack of a legislative instrument and relevant funding, are key to minimizing damage to public health.

Capitalizing on national and international expertise

Both national and international entities can be approached about and engaged in the response. The Veneto Region established collaborative relationships with the National Institute of Health, Rome, and WHO, which facilitated management of the case. This action also demonstrated to the public that everything possible was being done to support and take care of the health of the population.

Effective risk communication strategies are long-term investments in well-being People have the right to know and expect to be informed about potential hazards to their health; they also have the right to be heard. It is important that communications with the public are in a language they understand.

Emergency crises call for short-, medium- and long-term measures

Responding to emergency situations calls for a short-term strategy that includes the elements of uncertainty, risk communication, financial concern and the need for partnerships. Medium- and long-term responses also need to be planned, including the development of norms and standards (technical and legal) and the implementation of containment measures.

Aim of the publication

In 2013, it became known that approximately 127 000 people in the Veneto Region of Italy were exposed to PFAS through their drinking-water (Box 1). The contamination had resulted primarily from the industrial emissions of a chemical plant in the area that produces these substances. It had affected the groundwater, surface water and drinking-water in 21 municipalities. The Regional Health Authority was thus faced, not only with a case of contamination from substances with possible, though not fully proven, adverse health effects, but also with the alarm of the affected population, high media attention, and no enforceable standards for PFAS in water. Reacting immediately, the Veneto Region's priority was to protect the health of the population. Using a precautionary approach, the Region implemented a series of information-, monitoring- and analysis-related activities and developed a comprehensive risk-management programme to deal with the situation.

Box 1. PFAS

Perfluoroalkyls are a family of human-made chemicals that do not occur naturally in the environment. Of the 12 PFAS mostly used, perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) are the most common. These substances repel oil, grease and water and are used to protect the surfaces of carpeting and clothing, packaging materials and cardboard; they are also found in fire-fighting foams. PFAS show high thermal, chemical and biological inertness. They are extremely persistent in the environment and in natural degradation processes and have a strong diffusion capacity. They have been found in air, dust, surface and ground water, soil and sediment, the highest levels occurring near facilities that produce them (1).

The capacity of living organisms to metabolize these substances is very limited and the excretion rate is slow. When introduced into aquatic environments, soil or living organisms (including humans), they are very persistent and accumulate over time.

Drinking-water and food are the primary routes of exposure for people living near facilities manufacturing PFAS. Humans have much slower PFOA and PFOS excretion rates than other animal species. The estimated half-life¹ of PFOA ranges from 2.3 to 3.8 years whereas that of PFOS is 5.4 years, even if intake is stopped (2,3).

¹ A half-life is the time it takes for a given amount of a substance to become reduced by half in the body. The average half-life of PFOS is up to 5.5 years in exposed workers; the average half-life of PFOA is up to 4 years in exposed workers.

The aim of the publication is to share the experiences of the Veneto Region in tackling PFAS contamination with managers and administrators of regional health and environment authorities elsewhere. It provides an overview of the situation prior to the discovery of the contamination and describes the short, medium- and long-term action taken from the time it was discovered in 2013 until spring 2017, as well as facilitating factors, challenges met and lessons learnt.



Setting the scene

THE VENETO REGION

With a surface area of 18 378 km², the Veneto Region is the eighth largest of the 21 regions in Italy. Its borders cover a total of 1104 km. The Veneto plain is known for its size and flatness, which is occasionally broken up by hills. It is also known for its agricultural yield; with plenty of water and a temperate climate, the Region has always been well cultivated and highly populated (4). Since the 1980s, the Veneto Region has seen considerable growth and industrialization. It is one of the richest regions in Italy and has a population of just under five million (Fig. 1).

AUTO
ADICE
TRENTINO
T

Fig.1. Map of Veneto Region

Source: Veneto Region, Venice, Italy.

Life expectancy for both men and women is slightly higher than the national average (83.3 years for females and 80.7 years for males in 2015), while mortality rates are comparable to those at the national level (5). The major

Setting the scene 3

causes of morbidity and mortality are cardiovascular diseases and cancer. In 2014–2015, standardized rates for acute myocardial infarction were 179.3/100 000 for males and 70.48/100 000 for females; those for stroke were 216.9/100 000 for males and 167.1/100 000 for females (6).

The Government of the Veneto Region is responsible for the health system, which is managed through the departments for health and social services with technical support from the General Management Secretariat.

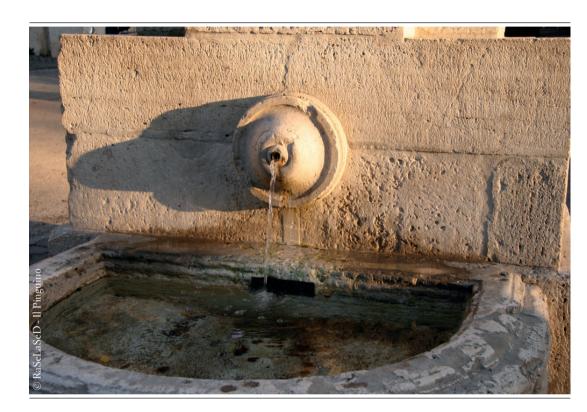
ORGANIZATION OF THE HEALTH SYSTEM AND ENVIRONMENT AND HEALTH

The Veneto Region has a universal, single-payer health care system financed by general tax revenues. Health care is provided by nine health care trusts (Aziende Sanitarie or Unità Locale Socio Sanitaria (ULSS)) and three hospital trusts. These trusts regularly submit data on the utilization of health care and diagnostic services to the Region's administration, which forwards them to the Ministry of Health of Italy in Rome (6). Diagnostic data (coded by the physicians) are collected during clinical consultations, while service data are used in claiming reimbursement from the providers and for budgeting purposes. Anonymization procedures related to record linkage (based on individual identity codes) facilitate the integration and indirect surveillance of the data, and cancel the need for ad hoc data collection. This system also permits the production of descriptive data on the entire population, providing up-to-date data flows on mortality, and prevalence and incidence rates for the most common diseases.

In the Veneto Region, all prevention-related issues, including those pertaining to the areas of health and environment, such as water and sanitation, and chemical safety and environmental pollution, fall within the remit of the Regional Directorate of Prevention, Food Safety and Veterinary Public Health (hereafter, the Regional Prevention Directorate) in the health and social affairs area of the regional administration. At the level of the local health care trusts, the operational units for prevention and public health, and veterinary and food safety, are called "prevention departments"; they encompass different services, including the Food Safety and Nutrition Services, which are actively involved in environment and health issues.

² As a result of reforms in 2017, the then 22 health care trusts were regrouped into nine.

At the political level, in terms of health and environment, the regional authorities consider it essential to ensure that policies and preventive measures are aligned and that there is no conflict between economic development and environmental protection. The health and environment sectors work closely together on the cross-cutting topic of water.



HISTORICAL INFORMATION ON THE INDUSTRIALIZATION OF NORTH-EASTERN ITALY

Veneto is a striking example of the "Italian economic miracle" of the 1950s and 1960s. Until the mid-1950s, Veneto was marked by poverty. After the Second World War, it became one of the leading Italian industrial regions. Today, the Veneto Region is responsible for 14% of the nation's exports. The economy is represented by small and medium-sized enterprises, forming a widespread network of business sectors all over the territory. The production sector, represented by over 70 000 business units, is based mainly on the manufacture of goods, such as: clothing; textile and footwear; and metal-

Setting the scene 5

engineering products, including electromechanics, metalwork, machine-tool manufacturing and installation, precision machining, woodwork and furniture. Agriculture is also important in the Veneto Region, accounting for nearly 10% of the national agricultural production; agricultural companies, almost all them mechanized with high levels of specialization, are very competitive (7,8). The agroindustrial system is responsible for about 38% of the Region's gross domestic product (GDP), winemaking accounting for approximately 20% of Italy's total production.

A special feature of the Veneto model lies in its so-called "industrial clusters", that is, geographically defined areas in which there are concentrations of enterprises specializing in the same type of product: mechanics, agro food, printing and publishing in Verona; textiles in Treviso and Vicenza; food in Rovigo; glass in Belluno and Cadore; gold and jewellery in Vicenza; electrical appliances in Conegliano; and furniture in Bassano del Grappa. According to data of the National Institute of Statistics of Italy, in 2013, there were almost 400 000 companies in the Veneto Region, 12% in industry, 13% in construction and 75% in the service sector (8).

During the period, 2008–2014, the average GDP for the Veneto Region was € 146 226 million; currently, it accounts for approximately 9% of the GDP for the whole of Italy. The Veneto Region's employment rate (63.7%) was higher than the national average (55.7%) although lower than that for Europe (64.8%). The employment rate increased considerably in this period, from 3.4% in 2008 to 7.5% in 2014, though the difference was less than at the national and European levels (respectively, from 6.1% to 12.7% and from 7.2% to 10.2%) (8). Between 2013 and 2014, the employment rate increased by 0.6%.

Taking action

PFAS CONTAMINATION IN VENETO: THE PROBLEM AS IT AROSE

The PFAS contamination of the water in the Veneto Region is linked to industrial production, dating back at least 20 years. A chemical plant has been active in the area since 1968, producing chemicals for crop production (herbicides), pharmaceuticals, and PFAS. In 1977, a series of control measures were taken by the health authorities (provincial doctors) who reported the presence of triflourobenzene derivatives in numerous aqueducts. There was a lack of international scientific literature in this field at the time, making it difficult to define the acute and chronic toxicity of the contaminants and determine the risk to the area, which was full of wells. As a result, a series of emergency interventions were put in place. In the short term, the aqueduct's sources of water supply were replaced and some of the wells closed. Mediumterm interventions comprised a series of studies to define the size, scope and characteristics of the problem. One of these, an unpublished geological and chemical study of groundwater contamination in the municipalities of Altavilla Vicentina, Creazzo, Montecchio Maggiore and Sovizzo, conducted by the Regional Institute for Economic and Social Research and Studies in 1979, summarized the findings. Years later, it has been ascertained that the contamination discovered around the end of 1966/beginning of 1967 originated from the same source as the current case of contamination.

The European Union (EU) Perluorinated Organic Compounds in the European Environment (PERFORCE) project (2004–2006) was the first to raise the environmental problem of contamination from perfluorinated compounds (PFC) in the waters and sediments of major European rivers. Though not a partner in the project, the Ministry of Environment, Land and Sea participated. The project found that the Po River in Italy had the highest concentrations of PFOA of all the European rivers studied.

This discovery was confirmed by subsequent investigations of the Po Basin carried out by research institutions, such as the Joint Research Centre, Ispra, Italy, and the Institute of Water Research of the National Research Centre (IRSA–CNR), Rome, Italy. In 2011, the Ministry for the Environment, Land and Sea commissioned the Institute to conduct a study on the environmental and health risks associated with the PFAS contamination of the Po River

Taking action 7

and other major Italian river basins. The objectives of the study were to understand the distribution of PFAS in these waters, identify their sources, carry out an assessment of consumer risk, and estimate the toxicological and ecological consequences.

This comprehensive study, which lasted two years, was the first on the distribution and sources of PFC and the possible risks associated with their presence. Very high concentrations of PFOA were found in some small rivers of the provinces of Padua, Verona and Vicenza, and in samples of drinking-water from public and private catchment points in the same geographical area, suggesting a common contamination source for surface and groundwater (9). PFOA concentrations in the drinking-water were remarkably higher than the threshold limits recommended by the United States Environmental Protection Agency (US-EPA) and the German Drinking Water Commission, which raised concerns about population health. The results of the study were communicated to the Veneto Region in 2013 (Box 2). Boxes 3 and 4 provide examples of two other cases of PFAS contamination.

Box 2. The effects of PFAS exposure on human health

Epidemiological studies have found an association between exposure to PFOA and PFOS and increased cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia. They have also found associations between serum PFOA and kidney and testicular tumours. There is also concern that PFOA and PFOS exposure results in suppression of the immune system, which is manifested as impaired immune function. Increases in blood cholesterol, similar to those found in adults, have also been found in children exposed to PFOA in drinking-water (1, 10).

The C8 study in high-exposure community settings in West Virginia and Ohio, United States of America, observed six possible and probable health effects linked to PFAS exposure: pregnancy-induced hypertension/pre-eclampsia, ulcerative colitis; thyroid disease; cancer of the testes (threefold risk in exposed workers); kidney cancer; and high cholesterol. An elevated standardized mortality ratio was found for exposed workers, as well as a significant trend of increasing risk with increasing exposure. A modest increase in the risk for cancer of the kidney was also seen in the population of a highly exposed community (11).

The International Agency for Research on Cancer (IARC) carried out an evaluation to investigate the association between PFOA exposure and cancer in humans. The results showed limited evidence of the carcinogenicity of PFOA and a positive association with cancers of the testes and kidney. IARC has classified PFOA as possibly carcinogenic to humans (Group 2B) (12).

Box 3. Germany's management of water contamination

In May 2006, a serious case of contamination with PFC was identified in Arnsberg, Germany. The contamination had been caused by farmers' use of soil conditioners in the upper Ruhr area. These conditioners were produced by recycling companies, using – among other materials – industrial waste containing PFAS. PFAS from the soil in the farming areas was washed into the lakes and streams. This led to contamination of the drinking-water, which is produced from the Rivers Ruhr and Möhne after bank filtration. In parts of the affected area, PFOA concentrations in the drinking-water were >0.5 μ g/L. The health-based guidance value set by the German Drinking Water Commission for safe life-long exposure to PFC in drinking-water, for all population groups, was 0.3 μ g/L for PFOS and PFOA.

The following action was taken to manage this case of contamination:

- systematic monitoring of the environment and quality of drinking-water and action to minimize further contamination;
- installation of additional treatment steps (activated carbon filters) in water works;
- a human biomonitoring study of mother—child pairs and men;
- an analysis of PFC in breast milk;
- development of recommendations to reduce fish consumption (due to high levels of PFOS found in fish from contaminated lakes and rivers).

The study revealed that increased PFOA exposure from the drinking-water had led to a four- to eightfold increase in the levels of PFOA in the plasma of those exposed compared to the levels in the plasma of the non-exposed groups. The levels of PFC found in the analysis of breast milk were low and not considered a risk for lactating infants.

Through recognition of the problem and elimination of the use of the soil conditioner in question, PFOA concentrations in plasma decreased in the following years as did concentrations in surface and drinking-water. By 2010, the internal exposure of children was approximately 60% lower than it had been four years earlier.

The discovery of high concentrations of PFAS in neighbourhoods located near plants manufacturing or handling PFAS, or in areas where PFAS-containing fire-fighting foams, fertilizers, and soil conditioners were distributed, stimulated numerous biomonitoring and epidemiological studies and experimental investigations on the adverse effects of PFOA and PFOS (13).

Taking action

Box 4. PFOA contamination of water in the United States of America

From the 1950s until the early 2000s, the chemical plant, DuPont Washington Works, in southwest Parkersburg, West Virginia, USA, released C8 into the air and the Ohio River. C8 is a surfactant for polymerization of tetrafluoroethylene (TFE) used to produce polytetrafluoroethylene (PTFE), or Teflon. PFOA in these emissions reached drinking-water supplies by entering the groundwater where it was detected in six districts near the DuPont plant in 2002.

Air emissions from the plant have been largely eliminated, as have any significant releases into the Ohio River. Carbon filters are used to remove C8 from nearby water systems.

A class-action lawsuit against Dupont ended in a settlement, which involved:

- carrying out a supplies' clean-up;
- conducting a biomonitoring survey;
- establishing a C8 science panel, including international experts.

A biomonitoring survey, called the C8 health project, was conducted between August 2005 and July 2006. Information was gathered through interviews and questionnaires, and blood samples were collected from about 69 000 people living near the plant.

The C8 health panel found six probable cause–effect links, namely between C8 and pregnancy-induced hypertension/preeclampsia, autoimmune ulcerative colitis, thyroid disease, cancers of the testes and kidney, and increased cholesterol (14).

DESCRIPTION OF FRAMEWORK USED FOR MANAGING ENVIRONMENTAL CONTAMINATION

In the case in question, a traditional risk-assessment approach could be applied to estimate the extent of risk to human health. Risk assessment is often defined through its stages, namely, hazard identification, dose-response modelling, exposure assessment and risk characterization. This type of assessment is normally carried out for each individual chemical involved and for all relevant health endpoints, producing various estimates, such as the life-time risk of people developing a certain type of cancer at a given exposure level (15).

While this approach has been used by the public-health community in assessing the connection between many established factors and chemical

agents in standard settings, it is limited when dealing with agents whose underlying evidence is uncertain. In the case of PFAS, for example, hazard identification cannot be decisive since these substances are classified as "possible carcinogens" and, even more importantly, there are no reliable dose or response models available. Thus, a sound risk assessment is difficult to carry out and requires more research to strengthen the evidence base. If decision-makers opt not to defer remedial action while awaiting the outcome of a rigorous risk assessment, alternative or complementary approaches would be required.

Due to the timing of the discovery of PFAS water contamination in the Veneto Region, a retrospective HIA approach was applied to identify the most appropriate mitigation and remediation measures needed to address the situation. HIA is an intersectoral, multidisciplinary process that complements chemical-risk assessments with the purpose of protecting and promoting public health. Through an evidence-informed participatory process, HIA aims at identifying actions and/or policies to maximize health protection, reduce health inequities and promote open dialogue between interested parties in a transparent decision-making process (Fig. 2) (16).

Quickly establishes "health relevance" of the Screening icy or project. Is HIA required? Policy and programme development Scoping phase for prospective assessments Rapid or in-depth assessment of health impacts using available evidence – who will **Appraisal** be affected, baseline, prediction, significance, Conclusions and recommendations to remove/ Reporting mitigate negative impacts on health or to enhance positive. **Policy** implementation phase Action, where appropriate, to monitor actual **Monitoring** impacts on health to enhance existing evidence base.

Fig. 2. HIA procedure

Source: WHO (16).

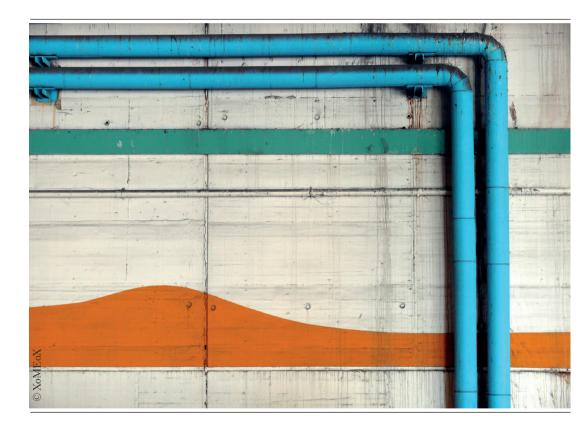
The retrospective HIA approach taken in the Veneto Region also allowed for the collection of basic data for further evaluation and monitoring over time. The Regional Prevention Directorate planned short- (immediate), medium- and long-term action, depending on risk grading. The assessment was based on monitoring the contamination of various components, namely, drinking-water, groundwater, surface water, irrigation water, soil, air, food and the sera of those exposed. The multidisciplinary skills needed for the assessment required the involvement of the Regional Prevention Directorate, the Regional Environment Directorate, the Agriculture Directorate, the Experimental Zooprophylactic Institute of Venice, the health care trusts and the central Government, namely the National Institute of Health and the Ministry of Health.

The HIA process included:

- a preliminary evaluation and the integration of already available information;
- identification of the potential health risks posed by PFAS exposure, based on relevant scientific literature and institutional documents (for example, from US-EPA and the European Food Safety Authority (EFSA));
- identification of the contamination source;
- identification of exposed areas;
- a series of initial technical meetings and consultations with stakeholders (for example, civil society, mayors, health care trusts);
- monitoring of main contamination matrices;
- biomonitoring of the contaminant in a representative sample of the population;
- assessment of the health profiles of people living in the contaminated area through available electronic health archives, and an ecological comparison of the results with the health profile of whole of the Veneto Region or the non-contaminated areas;
- defining and grading the contaminated area, based on biological and environmental monitoring;
- development of regulatory and short-, medium- and long-term measures;

- conducting periodic consultations with stakeholders;
- analysing and reviewing the contamination trend;
- investigating the health status of the exposed population (according to a health-surveillance plan);
- evaluating subgroups of the population (agricultural workers, pregnant women and factory workers).

The methodology of the retrospective HIA was aimed at identifying the direct and indirect effects of PFAS exposure on the health of the population, the most vulnerable groups in particular.



Taking action 13

Key steps

The discovery of PFAS in the drinking-water of the Veneto Region posed several challenges. Firstly, the Region was faced with an environmental disaster involving a range of effects on humans. Despite considerable scientific uncertainty, the Regional Health Authority took immediate action, even in the absence of EU thresholds for PFAS content in drinking-water and national legislation regulating PFAS at the time (17). Since then, the Italian Government has issued statements of the National Institute of Health on legal thresholds for PFAS in various matrices, including superficial water and biota (18), groundwater (19), drinking-water (National Institute of Health statement, protocol no. 0001584/16 January 2014), soil (National Institute of Health statement, protocol no. 0018668/23 June 2015) and sewage (National Institute of Health statement, protocol no. 0009818/6 April 2016).

The response from the Veneto Region was complex in nature and entailed substantial costs, which were met partly by the Region itself and partly



through water taxes. In addition, the work was carried out without the polluter having taken responsibility for the contamination and in the light of the media's dissemination of uncontrolled information to the public, which often generated anxiety.

The Veneto Region took an integrated precautionary approach to addressing the issue by putting short-, medium- and long-term measures in place (Fig. 3). These are described in the following section.

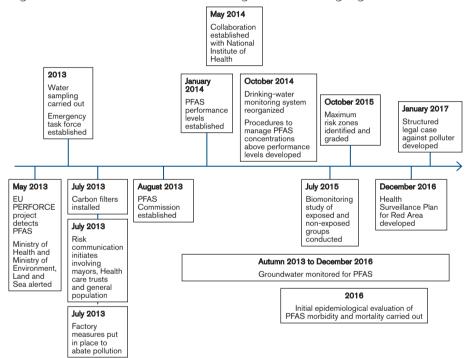


Fig. 3. PFAS contamination in Veneto Region, timeline highlights, 2013–2017

Intersectoral collaboration was set up at the institutional level. The roles of each sector and stakeholder were defined and new intersectoral coordination mechanisms established. The needs and goals of the Veneto Region included: to protect the drinking and irrigation water; to monitor water, soil and air frequently; to inform the exposed population in the right manner; to assess levels of PFAS in the food chain; to conduct epidemiological studies to assess the health consequences of the contamination; and to take institutional action while ensuring that all sectors and stakeholders were kept informed. The sections below describe the process followed in managing the contamination. Annex 1 lists the key steps in chronological order.

Key steps 15

SHORT-TERM MEASURES

These focused on the assessment and management of the immediate risk, namely, the presence of PFAS in the drinking-water.

Identification of PFAS contamination

During the spring of 2013, following the results of a IRSA–CNR study (20), the Regional authorities were alerted about the presence of PFAS in the groundwater, surface water and drinking-water in some parts of the Veneto Region. The area involved spanned more than 200 kms². Studies carried out by the Regional Environmental Protection Agency showed two main pathways for the spread of the contamination: (i) wastewater from the factory responsible for the pollution, which was emitted into a creek and percolated into the ground-water system; and (ii) water from a wastewater-treatment plant connected to the factory; this wastewater was deposited into a canal that drained into a river, the high flow rates of which enabled PFAS to be transported over long distances.

In 2013, there were no reference values in Italy for PFAS in drinking-water. Also, at the time, neither the EU Drinking Water Directive (21) nor the WHO Guidelines for drinking-water quality (22) included health-based guideline values. Upon the discovery of PFAS contamination in the Veneto Region, an official request was made to the Ministry of Health and the National Institute of Health to set these values. The Veneto Region administration also requested guidance on dealing with the situation, including how to set up a biomonitoring study. On 16 January 2014, the National Institute of Health issued statement no. 0001584 on PFAS contamination, which helped the Veneto Region implement the necessary risk-mitigation measures.

Setting up emergency mechanisms of risk assessment, management and communication

A series of communications on the PFAS contamination of ground, surface and drinking-water took place between the Regional Prevention Directorate and the Ministry of Health. Parallelly, communications on the same subject were taking place between the Regional Environmental Protection Agency, the Regional Environment Directorate and the Ministry of Environment, Land and Sea.

An emergency task force was set up comprising representatives of the Regional Prevention Directorate, the Regional Environment Directorate, the Regional Environmental Protection Agency and the regional health care trusts. The aim of the task force was to oversee the situation with a view to protecting population health and to consider how best to collect and share data, coordinate activities, gather institutional information and approach risk communication.

Identification of sectors and stakeholders

It was necessary to involve various sectors and stakeholders (see Table 1). An interinstitutional PFAS commission was set up with the mandate to ensure their overall coordination, assess the situation, and define mitigation measures. The Commission comprised the Regional Health Secretary, the Regional Environment Secretary, the Director of the Regional Prevention Directorate, and representatives of the Regional Environment Directorate and the Regional Environmental Protection Agency. Among the sectors and stakeholders involved in on-the-ground activities were the National Institute of Health, the Regional Environmental Protection Agency, water-supply service providers in the Veneto Region, mayors of the municipalities affected by the contamination and health care trusts in the contaminated areas. It was also necessary to engage water-service companies and the private sector regarding the installation of activated carbon filters at water-treatment plants.

Table 1. Sectors involved in tackling PFAS contamination in the Veneto Region

Entity	Sector(s) involved	Role/responsibility/action taken
Department of Health and Social Affairs of the Veneto Region	Health	Management of public health issues and coordination of the health-sector departments involved in the issue
Regional Prevention Directorate	Environment	Monitoring of contaminants in various environmental and food matrices and provision of technical support to the remedial action

Key steps 17

Table 1 contd

Entity	Sector(s) involved	Role/responsibility/action taken
National Institute of Health	Health	Provision of advice and guidelines on health issues to support the national and regional health authorities
Ministry of Environment, Land and Sea	Environment	Responsible for environmental issues at the national level
Ministry of Health	Health	Responsible for health issues at the national level
PFAS Commission (Regional Health Secretary, Regional Environment Secretary, representatives of Regional Prevention Directorate, Regional Environment Directorate and Regional Environmental Protection Agency)	Health Environment	Coordination of the different sectors and entities involved in the management of the PFAS contamination
Health Directorate	Legal	Regional Prevention Directorate
		Regional Environmental Protection Agency
		Regional Environment Directorate
		Health trusts
Water service providers	Private	Action taken:
		Formation of a corporation and cooperation with public-control institutions
		Analysis of systems for supply, treatment and distribution of water.
		Installation of granular-activated carbon filters.
		Implementation of sampling plans (analysis of PFAS compounds from the PFAS family in approximately 40 000 water samples)
		Creation of a hydraulic model for the supply, treatment and distribution of drinking-water in Lonigo
		Planned action:
		To investigate the availability of granular- activated carbon filters with higher performance
		To utilize powdered activated carbon
		To utilize ion-exchange resins (in collaboration with the University of Padua)

Table 1 contd

Entity	Sector(s) involved	Role/responsibility/action taken
Ad hoc task force groups	Health	Food monitoring design
Foodstuffs group comprising representatives of: Prevention Directorate Environment Directorate Agriculture Directorate Regional Environmental Protection Agency Venetian Experimental Institute for Zooprophylaxis National Institute of Health EFSA	Environment Agriculture Veterinary medicine Food Safety	Recommendation to apply PFAS levels to animal drinking-water and irrigation water Food-sample monitoring and risk assessment
Clinical epidemiological group comprising representatives of the following disciplines: nephrology haematology internal medicine cardiology oncology and of the: Tumour Registry health care trusts in high-exposure areas National Institute of Health	Health	Evaluation of available literature on the effects of PFAS on health. Identification of the haematochemical panel of tests to be included in the plan on surveillance of the exposed population
Agriculture Directorate	Agriculture	Contribution to food contamination assessment Sharing of measures to control water for livestock Monitoring of wells used to supply water for livestock water Study to the reduce PFAS concentrations
		Study to the reduce PFAS concentrations in irrigation water

 $\underline{\text{Key steps}}$ $\underline{\underline{19}}$

Table 1 contd

Entity	Sector(s) involved	Role/responsibility/action taken
Health care trusts	Health	Surveillance and monitoring of PFAS in
Prevention departments (food safety and nutrition) of health care trusts		drinking-water Evaluation of the potability of drinking-water in private wells
		Sampling of animal drinking-water
		Sampling of foodstuff
		Communication with the population
		Initiation of call for surveillance cohorts
Regional Prevention	Health	Provision of information for the press
Directorate	Environment	PFAS-specific press conferences
Regional Environmental		Public meetings with the population
Protection Agency National Institute of Health		Meetings with mayors
		Training for health-care professionals
Local authorities	Civil society	Application of regional indications on water potability
		Ordinance on the evaluation of the PFAS values in private wells used for drinking
		purposes
Maro b : 10tt t	TT 1d	Provision of information for the population
WHO Regional Office for Europe:	Health	Technical assistance in addressing environment and health issues
European Centre for Environment and Health (Bonn, Germany)		
European Centre for Investment for Health and Development (Venice, Italy)		

Risk assessment measures to identify source of pollution

Immediately after the contamination was discovered, the Regional Environmental Protection Agency developed an analytical method of measuring the concentration of PFAS in water. The Agency initiated a series of environmental assessments to demarcate the contaminated area and locate the source of the contamination. Tests carried out on samples of groundwater, surface water, river water and lake water identified it as wastewater from a local chemical plant. A regular monitoring system for detecting PFAS

concentration in aqueducts was also put in place. The exposed areas were rated according to the levels of contamination in the drinking-water, and environmental matrices showing the resulting demarcation were established.

In collaboration with the Regional Environmental Protection Agency and the Regional Environment Directorate, the Regional Prevention Directorate matched the results of the biomonitoring study to those of tests carried out on water from the corresponding aqueducts and reconstructed the aqueduct network to identify the municipalities exposed to the highest levels of drinking-water contamination (known as Red Areas A and B) prior to the installation of active carbon filters.

The highest concentration levels of PFAS (equal to 1214 ng/L) were found in June 2013 in the municipalities of Brendola, Lonigo and Sarego before the installation of water filters in the distribution systems. The biomonitoring study confirmed that citizens residing in these municipalities had the highest levels of PFAS in their sera (see Box 5).

Red Areas A and B included these three municipalities, as well as 18 others supplied by the same aqueduct.

The health impact area was subdivided into:

- the Red Area (maximum exposure area) comprising the 21 municipalities served by the contaminated aqueducts, which was further divided into two sub areas:
 - Red Area A where there was a greater concentration of PFAS in the surface water, drinking-water and groundwater;
 - Red Area B where the contamination of surface water and groundwater was less;
- the Orange Area where there were private wells at risk of contamination, but where aqueducts were connected to clean water supplies;
- the Yellow Area, comprising networks of environmental control systems for surface water and groundwater;
- the Green Area where PFAS were present in environmental matrices and needed to be further monitored and studied.

Key steps 21

Box 5. Biomonitoring study to assess PFAS exposure in people residing in contaminated areas of the Veneto Region, 2015–2016

From July 2015 to April 2016, a biomonitoring study was carried out using samples of the exposed and the unexposed population. The study was coordinated by the National Institute of Health, the Regional Environmental Protection Agency and health care trusts in the areas identified as being most affected (Health Care Trusts 5 and 6 in west Vicenza) and the control areas (Health Care Trusts 6 in Vicenza, 8 in Asolo, 9 in Treviso, 15 in Cittadella and 22 in Bussolengo). The study involved six local health and social-care units and 14 municipalities (seven exposed and seven unexposed).

The aim of the study was to understand how people residing in areas with contaminated water had been affected compared to those living in areas with only background exposure to the pollutants. Serum samples were taken from 507 people aged 20–49 years, using a population target (n=88 438). The participants were also requested to complete a questionnaire on their dietary habits, water-supply sources and consumption of local food. Because of the contribution of other factors to PFAS body burden, the biomonitoring study also included a subgroup of 120 people living and working in agricultural areas, or working with livestock. These people were living in the Red Area in the municipalities of Padua and Verona.

The study's initial results showed that the PFAS blood concentrations of the exposed population were significantly higher than those of the unexposed population. Median PFOA levels were 13.8 ng/g for the exposed group and 1.64 ng/g for the unexposed group (p<0.05). Median PFOS levels were 8.69 ng/g for the exposed group and 5.84 ng/g for the unexposed group (p<0.05). Furthermore, a number of people in the exposed group who were working in the field of agriculture and/or with livestock had higher levels of exposure to PFAS (25).

The dashed zone on the map (runs vertically from top to bottom starting from the orange zone through the red zone) represents the plume of contamination (chemical plant discharge spreading through groundwater) (Fig. 4).

The Regional Environmental Protection Agency expanded the investigation to other settings, such as marine and lagoon waters, sludge and food, and it eventually covered the entire Region through networks monitoring groundwater and surface water. This was done in close coordination with the Veneto Region administration and the National Institute of Health.

Samples of groundwater, surface water, river water and lake water were then tested, using the analytical method developed by the Agency. A regular monitoring system aimed at detecting PFAS concentration in aqueducts and maximum-risk zones was also established and grading carried out. Longer-

term action was initiated, such as the mapping and monitoring of private wells used for drinking purposes, and the monitoring of groundwater for PFAS. Twelve PFAS were found in the regional groundwater.

Consultation of the Consul

Fig. 4. Health impact areas

Source: Veneto Region, Venice, Italy.

Sectoral and stakeholder collaboration

Initial contact with and consideration for the stakeholders resulted in a collaborative agreement between the Regional Prevention Directorate, the Regional Environmental Protection Agency and the National Institute of Health on the provision of technical and scientific support in connection with risk assessment and management. The National Institute of Health carried out a literature review on the health effects of PFAS contamination with the establishment of threshold values for drinking-water in mind. This review formed the basis of the Institute's statement no. 0001584 of 16 January 2014 to the Ministry of Health and the Ministry of Environment, Land and Sea on threshold values for PFAS in drinking-water.

Development of risk-communication strategy

In July 2013, meetings were held with mayors of the involved municipalities

and directors of the health care trusts in the affected areas (Health Care Trusts 5, 6, 17, 20 and 21) to provide them with information that would help them formulate their risk communication to the public. The Environment Directorate and Regional Environmental Protection Agency were represented at all these events. Information received from the stakeholders on their activities related to the contamination was periodically summarized and distributed to policy-makers and the stakeholders. It was also made available to the public on the website of the Veneto Region. As direct contact with the exposed population was the role of the health care trusts, the Regional Prevention Directorate provided them with guidance on how to communicate the risk of PFAS contamination both adequately and consistently. They were also provided with relevant tools, such as a list of frequently asked questions, monthly e-bulletins on the situation, and other web-based materials. People who were unable to access the Internet were reached through their main health-care providers (general practitioners) and meetings held in the Town Hall.

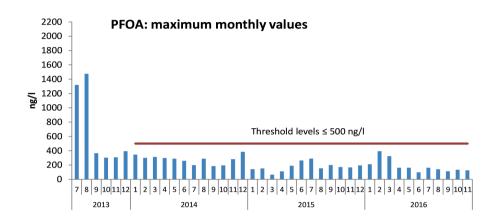
Pollution abated

By August 2013, three months after the alarm was first raised, water-service companies had installed activated carbon filters in the water-treatment plants of the contaminated area to ensure the safety of the drinking-water. Between July 2013 and spring 2014, the chemical plant also took a series of technical measures to abate the contamination, which included the installation of activated carbon filters to clean the wastewater.

While the chemical plant reported that it had stopped producing long-chain perfluoroalkylated compounds (PFOA and PFOS) in 2011, it was still making short-chain perfluorocrystalline compounds (four carbon atoms).

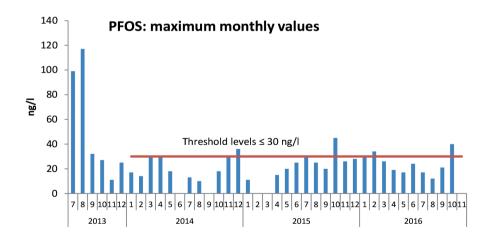
Thanks to the prompt installation of activated carbon filters, within three months of discovering the PFAS contamination, maximum PFOA and PFOS concentrations in drinking-water had dropped, respectively, from approximately 1475 ng/L to 386 ng/L and from approximately 117 ng/L to 36 ng/L (Figs 5, 6 and 7). Median and average PFAS concentrations in drinking-water were reduced to well below the threshold levels established by the National Institute of Health (Fig. 8).

Fig. 5. Maximum PFOA concentrations in drinking-water before and after installation of activated carbon filters, Veneto Region, Italy, 2013–2016



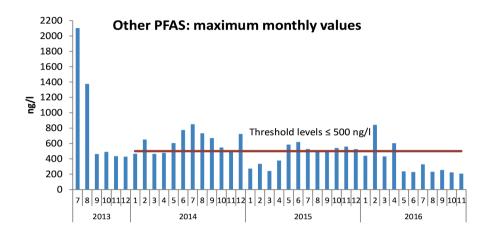
Note: The red line indicates when threshold values were established by the Ministry of Health. Source: Bolletino acqua potabile in Veneto, Febbraio 2017 [Potable water in Veneto bulletin, February 2017] (23).

Fig. 6. Maximum PFOS concentrations in drinking-water before and after installation of activated carbon filters, Veneto Region, Italy, 2013–2016



Note: The red line indicates when threshold values were established by the Ministry of Health. Source: Bolletino acqua potabile in Veneto, Febbraio 2017 [Potable water in Veneto bulletin, February 2017] (23).

Fig. 7. Maximum concentration of PFAS other than PFOA and PFOS in drinking-water before and after installation of carbon filters, Veneto Region, Italy, 2013–2016



Note: The red line indicates when threshold values were established by the Ministry of Health. *Source*: Bolletino acqua potabile in Veneto, Febbraio 2017 [Potable water in Veneto bulletin, February 2017] (23).

In autumn 2013, private wells were mapped according to the regional operational guidelines for municipalities on assessing PFAS in drinking-water from private wells. The mayor, as the local health authority and representative of the community, was legally authorized to adopt contingency measures obliging citizens with private wells to have their water supplies assessed for potability.³

Establishment of PFAS threshold values

Based on the National Institute of Health's statement no. 0001584 of 16 January 2014 to the Ministry of Health and Ministry of Environment, Land and Sea on the PFAS contamination in the Veneto Region, a Ministerial Decree (no. 2565-P-DGPRE) was passed on 29 January 2014 establishing the following threshold values for PFAS in drinking-water:

PFOS: \leq 30 ng/L; PFOA: \leq 500 ng/L; other PFAS: \leq 500 ng/L.

³ Italian law ("Testo unico degli enti locali (TUEL)", article 50, paragraph 5) states that, "in the case of health emergencies or issues of public hygiene in the local area only, the mayor is authorized to adopt contingency and urgent ordinances to protect the health of the population in that municipality".

Fig. 8. Average and median PFAS concentrations in water supplied by water network by trimester, Veneto Region, Italy, July 2013 – November 2016



Source: Bollettino acqua potabile in Veneto, Febbraio 2017 [Potable water in Veneto bulletin, February 2017] (23).

2015-4T

2016-1T

2015-3T

2016-2T

2016-3T

2016-4T

2014-3T

0

2013-4T

2013-3T

2014-1T 2014-2T The Ministry of Health also recommended the installation of appropriate absorption technologies and/or filters to ensure maintenance of the threshold values and the removal of PFAS from water used for drinking and production purposes. This recommendation was incorporated in Regional Decree no. 168 of 20 February 2014 (24).

Involvement of the legal authorities

Just after the discovery of PFAS in the drinking-water, the Veneto Region sent an initial communication to the legal authorities of Padua, Treviso and Vicenza describing the problem. Shortly thereafter, Veneto also provided them with relevant correspondence on the topic, periodic technical reports summarizing action taken by various stakeholders, and the results of epidemiological studies of the exposed general population, including people working at the chemical plant.

MEDIUM-TERM MEASURES

A second set of measures focused on assessing risks to human health and the environment.

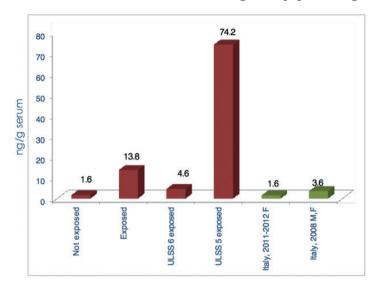
Human biomonitoring study

From July 2015 to April 2016, a biomonitoring study examined groups of the exposed population, the population working in the agricultural sector, and the unexposed population (control group) (Box 5). The group working in the agricultural sector deserved special attention due to its possible exposure to PFAS not only through the drinking-water, but also through the consumption of contaminated locally produced foods (from, for example, crops irrigated with livestock given contaminated water).

Fig. 9 shows median values of serum PFOA concentrations in exposed and unexposed subjects of the biomonitoring study (red bars). The exposed subjects are further stratified according to their health care trust: those residing in the territory of Health Care Trust 5, where the surface water, the groundwater and the aqueduct network were contaminated, had higher serum PFOA

concentrations compared with those residing in the territory of Health Care Trust 6, where only the surface and groundwater were affected by pollution. For the sake of comparison, serum PFOA concentrations measured in two previous surveys of the general Italian population are also shown (green bars).

Fig. 9. Median PFOA serum concentrations in exposed and unexposed subjects recruited in a human biomonitoring study in the Veneto Region, 2015–2016 (red bars), and in subjects of other Italian studies of the general population (green bars).



Note. ULSS = health care trust.

Source: The human biomonitoring study (25).

Environmental monitoring

The Regional Environmental Protection Agency took the lead in carrying out a series of environmental monitoring actions in 2014–2016. In August 2014, a preliminary evaluation of local food products revealed contamination in some categories, such as eggs from locally bred hens and fish from contaminated rivers, that could affect the health of the consumers. The Region's drinking-water monitoring system was reorganized and procedures to manage PFAS concentrations above the threshold value were established. The monitoring system included not only drinking-water but also other environmental matrices, such as surface water, groundwater, soil and air; thus, a comprehensive PFAS data warehouse was created for all water sources. Moreover, an environmental early-warning system was set up to identify key water-sampling points that should

be regularly monitored. The selection of water-sampling points was systemized and the drinking-water network re-evaluated according to the water-safety plan approach promoted by WHO (26).

A hydrogeological study was carried out to investigate the distribution of groundwater and the extension and flow velocity of the contamination plume. These data eventually allowed for estimations of the duration of contamination, which dated back more than 20 years. Soil monitoring showed a widespread presence of PFAS, not only in areas where human activity or erosion could have produced contamination, but also in those assumed to be free of it. Of 14 soil samples taken in the summer of 2016, half were found to have PFOA values higher than the threshold. Levels of PFAS in water from other industrial sources than the chemical plant were also measured but found to be considerably lower than those in water from the plant.

Application of water-safety standards to livestock and food production

Threshold values for PFAS in water were quickly established for other settings, such as livestock farming and food production.

Foodstuff monitoring plan

Since September 2016, samples of products from an assortment of crops⁴ and livestock,⁵ including milk and eggs, from Red Areas A and B have been monitored. The resulting data are being used to estimate food contamination in the areas in question.

Long-term measures

The focus of the long-term measures introduced is on the continuous monitoring of different environmental settings, further investigation of the

⁴ Apples, pears, other fruit, wine grapes, potatoes, chicory, lettuce, spinach, endive, chard, tomatoes, asparagus, onions, string beans, zucchini, peppers, squash, peas, cabbage, beans, corn.

⁵ Pork (muscle, liver), milk, fresh-water fish, beef (muscle, liver).

effects of PFAS on human health and finding the most appropriate ways of protecting it.

Setting up a health surveillance plan within the context of NCD control

In December 2016, the Government of the Veneto Region approved the Health Surveillance Plan, the general objective of which is to prevent chronic degenerative diseases resulting from PFAS exposure and inappropriate lifestyle. The Plan covers all residents in the Red Area (maximum exposure area) and is based on the assumption that people exposed to PFAS may be at increased risk for some chronic diseases. The reason for this is that health outcomes linked to PFAS share the same pathways as NCDs, for which the main risk factors are smoking, alcohol, physical inactivity and overweight (Box 6).

The Plan aims to characterize PFAS exposure in people residing in the contaminated areas, evaluate the effects of PFAS on the health of those exposed to it, and identify risk behaviours for chronic degenerative diseases.

By means of a questionnaire, relevant data are collected from a cohort of people who have been exposed to contamination. Those completing the questionnaire receive health-promotion information. Because of their exposure to PFAS, this cohort constitutes a more protected part of the population in that they are targeted through NCD prevention and screening measures.

Understanding the long-term consequences of PFAS contamination

A series of studies was carried out to understand the long-term consequences of PFAS contamination on human health. One of these was an ecological study of women who had given birth in the Veneto Region between 2003 and 2015, using place of residence as a proxy for exposure. Pregnancy outcomes from among 15 582 live births in the Red Area were compared to those in an unexposed area or the whole of the Veneto Region (Box 7).

Box 6. Health surveillance plan

Implementation of the Health Surveillance Plan started in December 2016. The aim of the Plan is to identify areas of expected/possible health impact, using data on PFAS contamination of the water supply before the installation of filters. The Red Area covers 21 municipalities in the Provinces of Padua, Verona and Vicenza; it is subdivided into Red Areas A and B, depending on the contamination parameters of the surface and ground waters.

The Plan covers five local health units and involves almost 85 000 people between the ages of 14 and 65 years. Biennial screening of the exposed population for cancer was introduced, starting with 14-year-olds in December 2016. The reason for choosing youth to begin with was that unhealthy lifestyles are not associated with this age group; thus, if high PFAS concentrations and/or significant metabolic changes were found, they could provide an insight into the correlation between exposure to PFAS and health outcomes.

People with unhealthy lifestyles are informed of the risks to their health and provided with support in modifying their behaviour. Those with PFAS serum concentrations higher than the median for the Italian population, and/or showing biochemical or blood-pressure changes, are taken over by their family doctors and placed on a second-level care path for the timely diagnosis of diseases related to PFAS exposure. The Veneto Region has a regional PFAS screening information system, which manages the entire survey process, from the mailing of invitation letters to the delivery of the results and the development of the most representative health indicators. The programme is completely free of charge for the target population. An ad hoc surveillance plan is scheduled for pregnant women and those working in the manufacture of these substances (27).

Another retrospective study examined morbidity and mortality among workers of the chemical plant (Box 8). Currently another biomonitoring study of factory workers is being conducted.

An ecological study was also carried out to compare NCD morbidity and mortality in the 21 affected municipalities and in the whole of the Veneto Region in 2007–2014 (Box 9).

Two retrospective ecological studies on cancer incidence carried out in 2016 examined the rate of testicular and kidney cancer (Box 10).

Box 7. Ecological study of pregnancy and birth outcomes

The study examined fertility data, the health status of women during pregnancy, and the health of the newborns. During the period of the study (2003–2013), there were 556 314 deliveries in the Veneto Region, 15 365 of which occurred in the Red Area (the most contaminated area).

Exposure to PFAS seemed not to affect fertility. On the other hand, compared with women residing in areas not contaminated by PFAS, a higher risk was observed among those residing in the Red Area for preeclampsia (4.46% vs 3.5% in unexposed areas) and gestational diabetes (5.35% vs 3.06% in unexposed areas). Furthermore, a gradual reduction in gestational diabetes was observed the further away from the Red Area the women resided. More infants were born small for their gestational age in the Red Area (3.5%) than in unexposed areas of the Veneto Region (2.7%) and the region as a whole (3.0%) (28). In 2014–2015, low birth weight in the Red Area peaked at 5.4% compared with 3.1% for the whole of the Veneto Region.

A multivariate logistic regression analysis, adjusted for confounders, such as maternal age, ethnicity, parity, gender and birth year of newborns, also showed a significantly increased risk for gestational diabetes (odds rate (OR) 1.69, 95% confidence interval (CI) 1.51–1.90), preeclampsia (OR 1.49, 95% CI 1.32–1.69), small size for gestational age (OR 1.30, 95% CI 1.19–1.43) in the Red Area compared to the unexposed area (29). A biomonitoring study and individual exposure data would be needed to confirm direct cause and effect.

Box 8. Occupational retrospective cohort study of employees at the chemical plant

Currently, out of a total of approximately 600 employees at the chemical plant, 130 work in the production department, the pilot plant, the laboratory and the waste-processing area. The probable long-term effects of PFOA exposure on the health of 415 male employees, including former employees, were examined through a retrospective cohort mortality study (1975–2016). The study looked at all-cause mortality and mortality from diseases of the circulatory system, malignant neoplasms, cirrhosis and diabetes.

The sera of a group of employees have been measured for PFOA contamination since 2000; in 2004–2012, the levels of those working in the PFAS production departments were steady. Mortality rates were higher for those exposed to PFOA and excess rates of liver, bladder and kidney cancer and cirrhosis were also observed for this group. Excess rates of cirrhosis, diabetes and hypertension were observed among all employees though they were higher among those exposed to PFOA (30).

Box 9. Retrospective ecological study of the exposed population

This study compared routine morbidity and mortality data collected in the 21 affected municipalities in 2007–2014 with data for the general population of the Veneto Region for the same period.

In the exposed communities, moderate but significant excess mortality rates were found for: ischaemic heart disease (+21% in males, +11% in females); cerebrovascular disease (+19% in males); diabetes mellitus (+25% in females) and Alzheimer's disease and dementia (+14% in females). There was also a moderate but significant excess in the prevalence of: hypertension (+22% in males, +20% in females); diabetes mellitus (+15% in males, +17% in females); and ischaemic heart disease (+6% in males, +8% in females). Some municipalities demonstrated a statistically significant excess of hypothyroidism in both males and females (31).

Box 10. Retrospective ecological studies on cancer incidence

In 2016, a retrospective ecological study of hospital admissions for the surgical removal of testes because of cancer (orchiectomy) was carried out by the Regional Epidemiological System, looking at data collected between 1997 and 2000 from men aged 15 to 54 years. In the 21 municipalities of the Red Area, a total of 70 cases were observed and no excess risk of orchiectomy was found when compared to the whole of the Veneto Region (standardized incidence ratio 1.02; 95% CI 0.81–1.29). In the Lonigo municipality, however, a statistically significant excess of orchiectomy was observed (standardized incidence ratio 1.84; 95% CI 1.05–2.98).

A further retrospective ecological study on cancer incidence was conducted the same year, using data from the Regional Cancer Registry for the period, 2010–2013. While the 21 exposed areas were included in the Registry from 2013 only, data on kidney and testicular cancers dating back to 2010 were retrieved to enable the analysis to be carried out.

In 2013, 727 cases of cancer (all types) were diagnosed in the Red Area. The standardized incidence rates were similar to those for all of Veneto (447/100 000 for males in the Red Area vs 497/100 000 in the whole of Veneto, and 339/100 000 for females in the Red Area vs 366/100 000 in the whole of Veneto).

In 2010–2013, 86 cases of kidney cancer were diagnosed in the Red Area. The standardized incidence rates were similar to or lower than those for the whole of Veneto (14.8/100 000 vs 18.7/100 000 for males and 8.0/100 000 vs 7.7/100 000 for females).

In the same period, 19 cases of testicular cancer were diagnosed. The standardized incidence rates were similar to those for the entire region (7.0/100 000 vs 7.1/100 000) (32,33).

Both a retrospective and a prospective cohort study on the incidence, prevalence and mortality from PFAS-related risks are planned.

Expanding PFAS monitoring

In 2016, the Regional Environmental Protection Agency monitored the transitional, marine and coastal waters of Veneto for the presence of PFAS. They also developed a method of monitoring sediment, as well as animal and plant life. At the same time, the Regional Prevention Directorate developed guidance on water for livestock and for companies producing foods.

In the first quarter of 2016, on the request of the Veneto Region, the National Institute of Health and the Regional Prevention Directorate, in collaboration with the Venetian Experimental Institute for Zooprophylaxis, developed a plan on monitoring foodstuff for PFAS contamination in some areas of Veneto. The aim was to estimate the level of PFAS contamination in the major agro-livestock farms in the risk areas of the Veneto Region. The resulting data can then be linked to data on food consumption from the same areas to estimate PFAS exposure from food, including food from water sources. The data can also be compared with those obtained in studies conducted in other geographical areas and described in the literature; this will provide an indication of the level of contamination in the study area compared to other areas.

Addressing the costs of PFAS contamination

A first and partial evaluation of spending by the Veneto Region and the agencies involved was estimated as follows:

- € 2 000 000 towards the installation of activated carbon filters by the water-service providers;
- € 4 300 000 for activities involving the exposed population during the first two years of implementation of the Health Surveillance Plan;

The above figures reflect only a portion of the total amount already spent and of what will be needed in the future. Academic experts will be commissioned to carry out a study to determine the total costs of the response to the PFAS contamination, keeping in mind the entirety of the impact.

Setting norms for PFAS at the national and international levels

In 2006, the EU adopted Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (the Groundwater Directive). The Directive established standards for groundwater quality and introduced measures of preventing the direct or indirect introduction of high-priority pollutants into groundwater, and limiting the introduction of other pollutants to avoid contamination with these substances (34).

Italian legislation sets minimum safety requirements, covering a relatively limited number of priority substances. According to Decree no. 31/2001 on the implementation of EU Directive 98/83/EC (the Drinking Water Directive (21)), water intended for human consumption "...must not contain microorganisms and parasites and must be free from any substances that could pose a potential risk to human health". Threshold values for PFAS are not given in the Drinking Water Directive (21), nor in the WHO Guidelines for drinking-water quality (2011) (22). The case of PFAS contamination in Veneto provided the impetus at both the national and the international levels to establish legal norms for the presence of these substances.

The EU has taken steps to regulate the production and use of PFAS to diminish their release into the environment. In 2013, in the context of the Registration Evaluation, Authorization and Restriction of Chemicals (REACH) project (35), PFOA was added to the candidate list of persistent bioaccumulative and toxic compounds, indicating that it is harmful to reproduction. In July 2016, IARC produced the monograph, *Some chemicals used as solvents and in polymer manufacture*, which classifies PFOA as a Group 2B carcinogen, "that is possibly carcinogenic to humans" (12).

The legal trial against the polluter

The Veneto Region submitted the first report on the contamination to the legal authorities of Padua, Venice, Verona and Vicenza through the Regional Environmental Protection Agency on 11 July 2013 and affirmed its status of injured party.

To date, over 18 legal measures have been taken in the Veneto Region to safeguard the population from exposure to PFAS and ensure the safety of the

water for human and animal consumption and irrigation purposes (Table 2).

Table 2. Regional decrees to protect the population from PFAS contamination, Veneto Region, Italy

Regional decree no.	Date	Торіс
1490	12 August 2013	Establishment of an interinstitutional PFAS Commission
2014	4 November 2013	Identification of a regional reference structure for the control of drinking-water
168	20 February 2014	Activities to address PFAS in drinking-water as per the ministerial note of 29 January 2014 and technical document of the National Institute of Health of 16 January 2014
618	29 April 2014	First guidelines on the use of water from private wells
619	29 April 2014	Updating of the composition of the PFAS Commission
1847	2014	Regional guidelines on detecting and monitoring PFAS in water supplies intended for human consumption
764	2014	Collaborative agreement between the Veneto Region and the National Institute of Health on technical and scientific support in analysing the risks related to PFAS contamination and on conducting a human biomonitoring study
565	2015	Human biomonitoring study for detection of PFAS in some parts of the Veneto Region
248	2015	Establishment of the Regional Biomonitoring Group
1517	2015	Adoption of reference levels for PFAS other than PFOA or PFOS in water destined for human consumption
318	2015	Partial modification of the biomonitoring study
19	2016	Establishment of a working group on surveillance of PFAS in foodstuffs
243	2016	Delegation of plan on monitoring PFAS contamination of foodstuffs to National Institute of Health
248	2016	Updating of the composition of the PFAS Commission

Key steps 3'

Lessons learnt

Enabling factors

Development of a model of good management

From the start, the Veneto Region made the case of PFAS contamination a political and public health priority, mobilizing sectors and stakeholders to contribute to remediating the situation as quickly as possible. In the face of adversity and complexity, the Regional Health Authority took an environmental threat and converted it into an opportunity to promote the health of the population.

A clear mandate for intersectoral action

Faced with one of the largest cases of PFAS contamination in humans, the Regional Health Authority could rely on sound institutional arrangements and intersectoral cooperation. It had a clear mandate to approach other sectors for support in prioritizing public health. A combination of legal measures and the willingness to work together helped the Regional Health Authority to capitalize on the expertise available and ensure coherence at the different levels of governance (local, regional and national). This was exemplified in the collaborative agreement drawn up between the Veneto Region and the National Institute of Health and the establishment of working groups to address specific components of the PFAS contamination.

Taking timely action with a precautionary approach

In the absence of legislation on and national or international thresholds for PFAS in drinking-water and freshwater bodies, and despite the uncertainty of the underlying evidence, the Veneto Region took decisive action to adopt a precautionary approach. Within three months, the Region had reduced the contamination by installing activated carbon filters, putting measures in place to stop factory discharge, and taking several risk-mitigation measures to deal with the contamination.

Willingness to take more than minimal action

The application of threshold values for PFAS contamination in water used for purposes other than human consumption, for example, livestock and irrigation, showed the willingness of the Veneto Region to go a step further in protecting the health of the population and the environment. This was especially important in preventing exposure to PFAS through pathways other than drinking-water. Today, water given to livestock in the Veneto Region must comply with the standards for drinking-water.

Building on existing mechanisms

Cost-efficiency in monitoring population health is important. By including PFAS as a risk factor in NCD screening, the Veneto Region ensured that the population would be monitored in a comprehensive, cost-efficient way and that it would be offered the appropriate care to prevent morbidity and mortality from these diseases. Incorporating PFAS in existing NCD prevention programmes allowed for the collection of data on modifiable behavioural risk factors (alcohol, tobacco, sedentary lifestyles and nutrition) thus controlling these confounders to understand the impact of PFAS on health

A solid database and quality data

The existence of an integrated health-information system enabled Veneto to secure a picture of the health situation in the entire area. In addition, they used information from biomonitoring studies to assess the exposure of the population and improve target-specific interventions.

Shared equity values

In addition to health data, the information collected through implementation of the Health Surveillance Plan includes socioeconomic indicators developed to ensure the inclusiveness of interventions. The biomonitoring data collected from a subgroup of agricultural workers who had been contaminated through both the drinking-water and locally produced foods will contribute to addressing inequitable exposure.

The way forward: Challenges

PFAS contamination has been removed from the drinking-water of the Veneto Region and the health impact it has had is being assessed. Despite this successful response, the Veneto Region still faces several challenges.

Communicating risk without raising fear

Communicating with the public about such an incident and providing the

Lessons learnt 39

advice and knowledge necessary to help them feel empowered to deal with the situation prevents unjustified alarm. For example, young people with high levels of PFAS in their blood, and their families, need to be able to understand what the contamination means for their future health. Despite the technical measures taken, people will continue to ask questions about the safety of the drinking-water for consumption.

Media sensationalism

The media and several interest groups have in the past, through sensationalism, caused panic in the population about the contamination. The media should be regarded as a partner in communicating information about such events and the related risk-management measures taking place.

Cost issues

Applying the "polluter pays" principle, that is, making the party responsible for producing the pollution pay for the damage done, is a challenge that remains. The Veneto Region and the taxpayers paid for all the interventions implemented to protect public health and safeguard the environment (for example, the installation of activated carbon filters). Cost recovery will be a persistent issue; for example, the maintenance of the carbon filters will also require funding.

Legal responsibility

To date, the polluting party has not taken responsibility for the contamination of the drinking-water. The Veneto Region has affirmed its status as the "injured party" and a legal case is under development.

Organizational concerns

Staff time has been shifted from other areas to this priority issue. The challenge remains of finding a balance between carrying out "business as usual" and dealing with a longer-term emergency. Keeping the momentum high and securing political support will need to be at the forefront to protect the public from environmental health risks.

Interpretation and use of data

The interpretation of data resulting from food sampling and how they affect food-safety issues and the local agricultural economy need to be considered. Sensitive data on two important subgroups, pregnant women and factory

workers, need to be safeguarded; at the same time, they must be used if these groups are to receive the most appropriate advice, care and compensation. Lastly, the estimated risk profile of the exposed population, based on biomonitoring and lifestyle data, will be a key piece of information to guide the future steps of the Veneto Region in protecting public health.

Gaps in scientific evidence

Scientific evidence on various PFAS is evolving. There are still gaps, however, and it is important to continue to produce, compile and evaluate information in this area to strengthen the knowledge base.



Lessons learnt 41

Key messages

The key messages from the PFAS contamination case in the Veneto Region relate to mechanisms, management, governance and communication.

Intersectoral mechanisms offer versatility and value

The Veneto Region built on existing institutional arrangements and set up ad hoc collaboration to deal with the crisis at hand. The combination of a clear mandate and legal measures facilitated their approaching other sectors for collaboration and expertise.

Transparent management creates a culture of collaboration

The routine documentation and reporting of action taken by all sectors and stakeholders helped build a repository of information that could be shared with the public and used as evidence to support legal action.

The right approach is key

In the face of widespread chemical contamination, a precautionary approach is a must to minimize damage to public health. Acting in a timely manner and taking risk-mitigation measures despite uncertain evidence and without the necessary legislation are key to this end.

The importance of capitalizing on national and international expertise Both national and international entities should be involved in the response. The Veneto Region established collaboration with the National Institute of Health, EFSA, IARC, WHO and international experts, which facilitated the management of this case. The scientific evidence on PFAS contamination and measures taken to deal with it in the Veneto Region were discussed at an international workshop on PFAS. This action showed the public that everything possible was being done to protect their health.

Ensure coherence at different levels of governance

When working on such a complex issue, with different parties operating at different levels in the country (local, regional and national), finding a balance is necessary. This involves acknowledging the role and contributions of each party.

Effective risk-communication strategies are long-term investments in well-being People have the right to be fully informed about potential hazards to their health. Therefore, they should be made aware of the various risk-assessment and risk-management measures taking place and, most importantly, in a language they understand. The root causes of and the structural changes needed to reduce health risks should be explained to them and advice on personal risk-reduction behaviour should be offered.

Emergency crises call for short-, medium and long-term measures

Responding to emergency situations calls for a short-term strategy to deal with issues relating to uncertainty, risk communication, financial concerns and partnerships. Medium- and long-term responses, including the development of norms and standards (technical and legal) and containment measures should be planned. Planning and investing in a proactive long-term strategy, involving prospective studies, biomonitoring and measures to prevent future damage to human health, will reveal the extent to which the short- and medium-term strategies for tackling the contamination have reaped benefits for future generations.

Key messages 43

References

- Public Health Statement. Perfluoroalkyls. Washington, DC: U.S. Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry; 2015 (https://www.atsdr.cdc.gov/toxprofiles/ tp200-c1-b.pdf, accessed 24 May 2017).
- 2. Bartell SM, Calafat AM, Lyu C, Kato K, Ryan PB, Steenland K. Rate of decline in serum PFOA concentrations after granular activated carbon filtration at two public water systems in Ohio and West Virginia. Environ Health Perspect, 2010;118(2):222 (https://www.ncbi.nlm.nih.gov/pubmed/20123620, accessed 15 May 2017).
- 3. Olsen GW, Burris JM, Ehresman DJ, Froehlich JW, Seacat AM, Butenhoff JL, Zobel LR. Half-life of serum elimination of perfluorooctanesulfonate, perfluorohexanesulfonate and perfluorooctanoate in retired fluorochemical production workers. Environ health perspect. 2007;115(9)1298–305 (https://www.ncbi.nlm.nih.gov/pubmed/17805419, accessed 15 May 2017).
- 4. Physical profile. In: Consiglio regionale del Veneto [Veneto Regional Council] [website]. Venice: Veneto Region; 2017 (http://www.consiglioveneto.it/crvportal/pageContainer.jsp?n=87&p=92&c=6&e=122&t=0&, accessed 15 May 2017).
- 5. ISTAT [website]. Rome: National Institute of Statistics; 2017 (http://www.istat.it/en/, accessed 15 May 2017).
- 6. Corti MC, Fedeli U, Avossa F, Schievano E, Ferroni E. The Epidemiological Regional Service: monitoring mortality, prevalence and incidence of chronic diseases. Presentation by Maria Chiara Corti, Chief, Veneto Region Epidemiological Unit, at the International conference on designing an epidemiological study on the population exposed to PFAS in the Veneto Region, Venice, 22–23 February 2017. Venice: Veneto Region Directorate of Prevention, Food Safety and Veterinary Public Health; 2017 (https://www.regione.veneto.it/web/guest/comunicati-stampa/dettaglio-comunicati?_spp_detailId=3094314, accessed 23 May 2017).
- 7. Bardin F, Fabbris L, Rota G. Occupazione e professionalità nel settore chimico veneto [Occupation and professionalism in the Veneto chemical industry]. Padua: University of Padua; 2005.
- 8. Veneto. In: Growth Internal market, Entrepreneurship and SMEs [website], Brussels: European Commission; 2017 (https://ec.europa.eu/growth/tools-databases/regional-innovation-monitor/base-profile/veneto, accessed 15 May 2017).

- 9. Rischio associato alla presenza di sostanze perfluoroalchiliche (PFAS) nelle acque potabili e nei corpi idrici recettori di aree industriali nella Provincia di Vicenza e aree limitrofe [Risk associated with the presence of perfluoroalkylated substances (PFAS) in drinking-water and other recipient water bodies in industrial areas in the province of Vicenza and surrounding areas]. Venice: Institute of Water Research–National Research Centre (IRSA–CNR); 2013 (http://www.ulss5.it/binary/ulss5/carta_servizi_guide_depliant/1_studio_CNR.1428908998. pdf, accessed 15 May 2017).
- DeWitt JC, editors. Toxicological effects of perfluoroalkyl and polyfluoroalkyl substances. Cham: Springer International Publishing; 2015 (http://http://www.springer.com/gp/book/9783319155173, accessed 15 May 2017).
- 11. Fletcher T. The C8 Study: PFOA exposure, aims, methods and findings. Presentation at International conference on designing an epidemiological study on population exposed to PFAS in Veneto Region, Venice, Italy, 22–23 February 2017. Venice: Veneto Region Directorate of Prevention, Food Safety and Veterinary Public Health; 2017 (https://www.regione.veneto.it/web/guest/comunicati-stampa/dettaglio-comunicati?_spp_detailId=3094314, accessed 23 May 2017).
- 12. International Agency for Research on Cancer, WHO. Some chemicals used as solvents and in polymer manufacture. Volume 110. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Lyon: International Agency for Research on Cancer; 2016 (http://http://monographs.iarc.fr/ENG/Monographs/vol110/mono110-01.pdf, accessed 15 May 2017.)
- 13. Wilhelm M, Kraft M, Rauchfuss K, Hölzer J. Assessment and management of the first German case of a contamination with perfluorinated compounds (PFC) in the Region Sauerland, North Rhine-Westphalia. J Toxicol Environ Health A. 2008;71(11–12):725–33.
- 14. Poisoned legacy: the C8 Science Panel. In: Know your environment: protect your health [website]. Washington DC: Environmental Working Group; 2017 (http://www.ewg.org/research/poisoned-legacy/c8-science-panel, accessed 23 May 2017).
- 15. Hertz-Picciotto I. Epidemiology and quantitative risk assessment: a bridge from science to policy. Am J Public Health. 1995 Apr;85(4):484–91 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1615131/, accessed 15 May 2017).
- 16. Tools and methods. How to undertake an HIA. In: Health Impact Assessment (HIA) [website]. Geneva: WHO; 2017. (http://www.who.int/hia/tools/en/, accessed 19 May 2017).
- 17. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as

References 45

- regards priority substances in the field of water policy. Brussels: European Commission; 2013 (http:// http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32013L0039, accessed 15 May 2017).
- 18. Decreto Legislativo del 13 ottobre 2015, n. 172. Attuazione della direttiva 2013/39/UE, che modifica le direttive 2000/60/CE per quanto riguarda le sostanze prioritarie nel settore della politica delle acque. (15G00186) (GU Serie Generale n.250 del 27-10-2015 [Legislative Decree of 13 October 2015, no. 172. Implementation of Directive 2013/39 / EU amending Directive 2000/60/ EC as regards priority substances in the field of water policy. (15G00186) (GU General Series No.250 of 27-10-2015)]. Rome: Ministry of Economy and Finance; 2015 (http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2015-10-27&atto.codiceRedazionale=15G00186&elenco30giorni=false, accessed 15 May 2017).
- 19. Decreto 6 luglio 2016. Recepimento della direttiva 2014/80/UE della Commissione del 20 giugno 2014 che modifica l'allegato II della direttiva 2006/118/CE del Parlamento europeo e del Consiglio sulla protezione delle acque sotterranee dall'inquinamento e dal deterioramento. (16A05182) (GU Serie Generale n.165 del 16-7-2016) [Decree 6 July 2016. Transposition of Commission Directive 2014/80/EU of 20 June 2014 amending Annex II to Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration. (16A05182) (OJ General Series No.165 of 16-7-2016). Rome: Ministry of the Environment, Land and Sea; 2014 (http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario;jsessionid=RJISWOtUdlBCdmvvdfkI8Q__. ntc-as 2-guri 2b?atto.dataPubblicazioneGazzetta=2016-07-16&atto.codiceRedazionale=16A05182&elenco30giorni=true, accessed 15 May 2017)
- 20. Relazione in tema di sostanze perfluoroalchiliche prodotte dalla ditta Miteni Spa di Trissino (VI) [Report on perfluoroalkyl compounds produced by the company Miteni Spa of Trissino (VI)]. Venice: Veneto Region; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinate-al-consumo-umano, accessed 15 May 2017).
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Official Journal of the European Communities. 1998;330:32–54 (http://eur-lex.europa.eu/legal-content/EN/ TXT/?uri=CELEX:31998L0083, accessed 23 May 2017).
- 22. Guidelines for drinking-water quality. Fourth edition. Geneva: WHO; 2011 (http://apps.who.int/iris/bitstream/10665/44584/1/9789241548151_eng.pdf, accessed 20 May, 2017).

- 23. Bolletino acqua potabile in Veneto, n. 2, Febbraio 2017 [Potable water in Veneto bulletin, no. 2, February 2017]. Venice: Veneto Region; 2017
- 24. Deliberazione della Giunta Regionale n. 168 del 20 febbraio 2014: pianificazione delle attività a tutela della salute dei soggetti esposti alla presenza di sostanze perfluoroalchiliche (PFAS) nelle acque potabili [Regional Council Resolution no. 168, 20 February 2014: planning of activities to protect subjects exposed to perfluoroalkylated substances (PFAS) in drinking-water]. Bollettino Ufficiale della Regione del Veneto [Official Bulletin of the Veneto Region]. 30;2014 (http://bur.regione.veneto.it/BurvServices/pubblica/DettaglioDgr. aspx?id=269219, accessed 19 May 2017).
- 25. The human biomonitoring study. Presentation by Elena De Felip; National Institute of Health, Rome, Italy, at the International conference on designing an epidemiological study on population exposed to PFAS in Veneto Region, Venice, Italy, 22–23 February 2017. Venice: Veneto Region Directorate of Prevention, Food Safety and Veterinary Public Health; 2017
- 26. Water safety plan: a field guide to improving drinking-water safety in small communities. Copenhagen: WHO Regional Office for Europe, 2014, http://www.euro.who.int/__data/assets/pdf_file/0004/243787/Water-safety-plan-Eng. pdf?ua=1, accessed 20 May 2017).
- 27. Deliberazione della Giunta Regionale n. 2133 del 23 dicembre 2016. Allegato A [Resolution of the Regional Council no. 2133 of 23 December 2016. Annex A]. Bollettino Ufficiale della Regione del Veneto [Official Bulletin of the Veneto Region]. 2017;5 (http://bur.regione.veneto.it/BurvServices/pubblica/DettaglioDgr.aspx?id=336455, accessed 23 May 2017).
- 28. Relazione in tema di sostanze perfluoroalchiliche prodotte dalla ditta Miteni S.p.a. di Trissino (VI) [Report on perfluoroalkyl substances produced by the Miteni chemical plant of Trissino (VI)]. Venice: PFAS Technical Commission; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acquedestinate-al-consumo-umano, accessed 24 May 2017).
- 29. Studio sugli esiti materni e neonatali in relazione alla contaminazione da sostanze perfluoroalchiliche (Pfas) [Study on maternal and neonatal outcomes in relation to contamination by perfluoroalkylated substances (PFAS)]. Padua: Rare Diseases Centre; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinate-al-consumo-umano, accessed 24 May 2017).
- 30. Girardi P, Merler E. Valutazione degli effetti a lungo termine sulla salute dei dipendenti di un'azienda chimica che ha prodotto intermedi per l'indusstria agro-alimentare, l'industria farmaceutica e derivati perfluorurati (PFOA, PFOS) (20 Marzo 2017) [Evaluation of the long-term health effects of employees in a chemical company that produced intermediates for agro-food industry,

References 47

- pharmaceutical industry and perfluorinated derivatives (PFOA, PFOS) (20 March 2017)]. Padua: Regional Registry of Mesotheliomas; 2017 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinate-al-consumo-umano, accessed 09.05.2017).
- 31. Ricognizione epidemiologica iniziale nell'area interessata dalla contaminazione idropotabile da PFAS. Padova, 23/06/2016 [Initial epidemiological diagnosis in the area affected by PFAS contamination. Padua, 23/06/2016]. Padua: Regional Epidemiological System; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinate-al-consumo-umano, accessed 23 May 2017).
- Analisi esplorativa di livello comunale sulle orchiectomie per tumore del testicolo. Padova, 30/08/2016 [Municipal level investigation of orchiectomy for testicular cancer. Padua, 30/08/2016]. Padua: Regional Epidemiological System; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinateal-consumo-umano, accessed 23 May 2017).
- 33. Registrazione dei tumori maligni diagnosticati nella popolazione residente nei 21 Comuni del Veneto di cui alla nota regionale 203887 del 24 maggio 2016 [Record of malignant tumors diagnosed in the population resident in 21 municipalities of Veneto as per Regional Note 203887 of 24 May 2016]. Padua: Veneto Tumour Registry; 2016 (https://www.regione.veneto.it/web/sanita/tutela-acque-destinate-al-consumo-umano, accessed 23 May.2017).
- 34. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. Official Journal of the European Union. 2006;372:19–31 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006;372:0019:0031:EN:PDF, accessed 15 May 2017).
- 35. REACH. In: ECHA [website]. Helsinki: European Chemicals Agency; 2017 (https://echa.europa.eu/regulations/reach, accessed 20 May 2017)

Annex 1. Key steps in tacking PFAS water contamination, Veneto Region, 2013–2017

Date	Steps	Taken by
Early 2013	Triggered by the results of the PERFORCE project (2006), IRSA–CNR conducted study, the results of which show PFAS in water.	IRSA-CNR for the Ministry of Health
May 2013	Ministry of Health informed Regional Prevention Directorate about detection of PFAS contamination in surface water, drinking- water and wells	Ministry of Health Ministry of Environment, Land and Sea
	Ministry of Environment, Land and Sea of Italy informs Regional Environmental Protection Agency and Environment Directorate about detection of PFAS contamination in surface water, drinking-water and wells	
June 2013	Regional Environmental Protection Agency informed Regional Environment Directorate about Ministry of Environment, Land and Sea communication on PFAS contamination in surface water, drinking-water and wells	Regional Environmental Protection Agency
June 2013	Development of analytical method of measuring the PFAS concentration in water	Regional Environmental Protection Agency
June 2013 – ongoing	Water sampling of groundwater, surface water, river water, lake water between August 2013 to December 2016:	Regional Environmental Protection Agency
	• 145 water sites samples (river and lake)	
July 2013	Regional health and environment sectors jointly approached Ministry of Health and	Regional Prevention Directorate
requesting guidance on dealing with contamination. Agreement reached to be taken. In coordination with the Regional Environment Directorate, the Regional Prevention Directorate sent a specific communication the Ministry of Heat Ministry of Environment, Land and requesting information and institution coordination to address the issue of contamination. Regional Prevention Directorate information and insection of the contamination.	Ministry of Environment, Land and Sea requesting guidance on dealing with PFAS contamination. Agreement reached on action to be taken.	Regional Environment Directorate
	Environment Directorate, the Regional Prevention Directorate sent a specific communication the Ministry of Health and Ministry of Environment, Land and Sea requesting information and institutional coordination to address the issue of PFAS	
	Regional Prevention Directorate informed legal authorities in Padua, Vicenza and Verona of PFAS contamination.	

Date	Steps	Taken by
July 2013	Technical meeting of representatives of Regional Prevention Directorate, Regional Environment Directorate, Regional Environmental Protection Agency and regional health care trusts involved. Aim: to ensure optimal action for the protection of population health and to discuss data collection and	Regional Prevention Directorate
		Regional Environment Directorate
		Regional Environmental Protection Agency
	sharing, coordination of activities, institutional information and risk communication	Health care trusts
July 2013	Meeting with water-service companies on the installation of activated carbon filters at water-	Regional Prevention Directorate
	treatment plants	Regional Environment Directorate
		Regional Environmental Protection Agency
		Water-service companies
July 2013	Meetings with mayors of involved municipalities on risk communication	Regional Prevention Directorate
		Health care trusts
		Mayors of municipalities involved
July 2013	Preparation of briefing notes for the general population on PFAS contamination	Health care trusts
		Regional Environmental Protection Agency
July 2013	Identification of the source of contamination	Regional Environmental Protection Agency
July 2013– April 2015	Implementation of technical measures at chemical plant to reduce PFAS contamination:	Regional Environment Directorate
	 hydraulic barrier upgraded 	Regional Environmental
	 additional wells constructed 	Protection Agency Chemical firm identified as the source of contamination
	 number of pumps in wells increased 	
	 water extraction from new wells activated and water purification system upgraded 	
	• carbon filters installed	
July–August 2013	Installation of activated carbon filters at water- treatment plants in the contaminated area to ensure safety of drinking-water	Water-service companies

Date	Steps	Taken by
July—August 2013	Implementation of regular monitoring of PFAS concentration in aqueducts	Regional Prevention Directorate
		Regional Environment Directorate
		Regional Environmental Protection Agency
		Health care trusts
July – September	Reduction of PFAS concentration in drinking- water from aqueducts	Regional Prevention Directorate
2013		Regional Region, Environment Directorate
		Regional Environmental Protection Agency
		Health care trusts
July 2013 – January 2014	National Institute of Health began background work for development of statement on PFAS contamination establishing threshold values in drinking-water	National Institute of Health
August 2013	Establishment of interinstitutional PFAS commission, comprising Regional Health Secretary, Regional Environment Secretary, and representatives of Regional Prevention Directorate, Regional Environment Directorate and Regional Environmental Protection Agency	Regional Health Secretary
		Regional Environment Secretary
		Regional Prevention Directorate
		Regional Environment Directorate
		Regional Environmental Protection Agency
September 2013	Reminder sent to health care trusts to initiate or finalize mapping of wells used for drinking purposes	Regional Prevention Directorate
		Health care trusts
	Recommendation to prohibit drinking-water from wells found to have high PFAS values	
September 2013 – ongoing	Mapping and monitoring of private wells used for drinking purposes and monitoring of groundwater for PFAS.	Regional Prevention Directorate
		Regional Environmental Protection Agency
		Health care trusts

Date	Steps	Taken by
Fall 2013 -December 2016	Monitoring of groundwater for PFAS (7 phases) Establishment of threshold values following EU Directive 2014/80/EC modifying EC Directive 2006/118/EC	Regional Environmental Protection Agency
	Inclusion of 12 PFAS in regional groundwater monitoring system	
January 2014	Establishment of threshold values for PFAS in drinking-water (in the absence of existing norms at the national and EU levels)	Ministry of Health (based on the technical opinion of the National Institute of Health)
	Ministry of Health requested National Institute of Health to issue statement calling for an adequate water-treatment system to abate the contamination and for the safety of the drinking-water supply chain in the affected area.	
	Ministerial decree (based on the National Institute of Health's statement) established threshold values for PFAS in drinking-water as:	
	PFOS: ≤ 0.03 ng/L; PFOA: ≤ 0.5 ng/L; other PFAS: ≤ 0.5 ng/L	
	Ministry of Health recommended installation of appropriate absorption technologies and/ or filters to ensure maintenance of the threshold values and removal of PFAS from drinking-water and water used in production. This recommendation was incorporated in a regional decree.	
April 2014	Veneto Region approved guidance concerning the use of private wells as a source of drinking- water	Regional Prevention Directorate
May 2014	Collaboration agreement set up with National Institute of Health for technical and scientific support in risk assessment and management	Regional Prevention Directorate
		National Institute of Health
		Regional Environmental Protection Agency

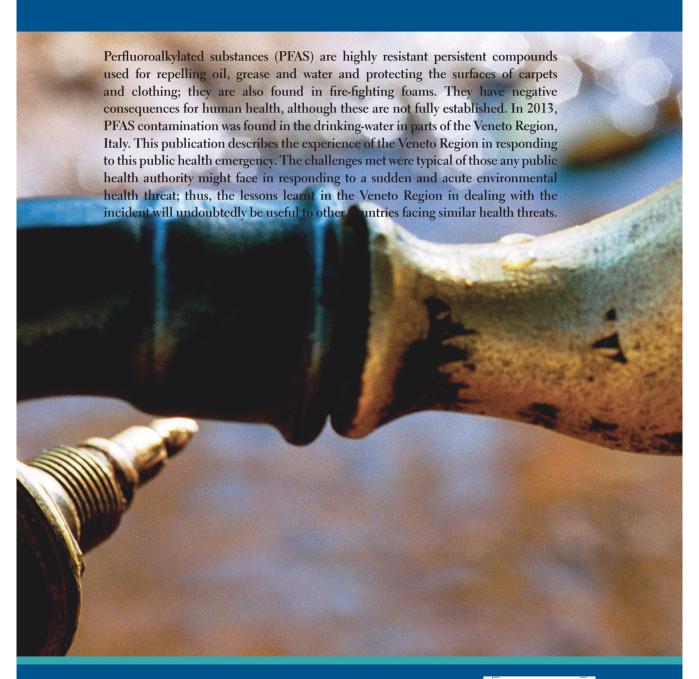
Date	Steps	Taken by
August 2014 – June 2015	Preliminary evaluation of PFAS contamination of local food products	Regional Prevention Directorate
		National Institute of Health
		Istituto Zooprofilattico Sperimentale delle Venezia (IZSVe)
		Regional Environmental Protection Agency
		Health care trusts
October 2014	Reorganization of the drinking-water monitoring system and establishment of	Regional Prevention Directorate
	procedures to manage PFAS concentrations above the threshold values	Regional Environment Directorate
		Regional Environmental Protection Agency
		Health care trusts
July 2015 – April 2016	Biomonitoring study on representative samples from the exposed population and control groups of the unexposed population	Regional Prevention Directorate
		Health care trusts
		National Institute of Health
July 2015 – January 2017	Biomonitoring of a subgroup of the population working in the agricultural sector	Regional Prevention Directorate
		Health care trusts
		National Institute of Health
October 2015	Identification of maximum risk zones and risk grading	Regional Prevention Directorate
		Regional Environment Directorate
		Regional Environmental Protection Agency
May 2016	Monitoring of sludge from sewage-treatment plants	Regional Environmental Protection Agency
June 2016	Monitoring of soil in areas with contaminated surface water	Regional Environmental Protection Agency
August 2016	Estimation of spreading time of groundwater contamination plume	Regional Environmental Protection Agency

Date	Steps	Taken by
September 2016 – June 2017	Monitoring of agricultural and livestock farming products to assess the degree of PFAS contamination in at-risk agricultural settings (crops assessment ^a by the Regional Environmental Protection Agency) and livestock-farming settings (animal-food assessment ^b by the National Institute of Health) and to provide an estimate of contamination from foods in the population living in these areas in both large-scale (industrial) and small-scale (family-owned) farms. Sampling of Red Zone A and Red Zone B (maximum health exposure area) ^a Crops: apples, pears, other fruit, wine grapes, potatoes, chicory, lettuce, spinach, endives, chard, tomatoes, asparagus, onions, string beans, zucchini, peppers, squash, peas, cabbage, beans, corn ^b Livestock: pork (muscle, liver), milk, fresh-water fish, beef (muscle, liver), eggs, poultry	Regional Prevention Directorate Health care trusts Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe) Regional Environmental Protection Agency National Institute of Health EFSA
December 2016	Launch of biomonitoring and clinical surveillance plan of all residents (14–65 years) in the maximum exposure area (Red Area)	Regional Prevention Directorate Health care trusts
2016	Development of guidance on drinking-water for animals and companies producing foods	Regional Prevention Directorate
2016	Initial epidemiological evaluations of morbidity and mortality from PFAS-related risks (ecological studies on cancer, NCDs and pregnancy complications and birth outcomes	Regional Prevention Directorate Regional Cancer Register Regional Epidemiological System Regional Birth and Congenital Malformations Register
January 2017	Development of structured legal case against the polluter	Veneto Region
March 2017	Retrospective cohort study on morbidity and mortality among workers of the chemical plant identified as source of contamination	Mesothelioma Register, Veneto Region
Ongoing	Monitoring of transitional marine coastal waters Development of methodology to monitor sediment and animal and plant life in the waters	Regional Environmental Protection Agency

Date	Steps	Taken by
Ongoing	Biomonitoring of industry workers	Regional Prevention Directorate
		Health care trusts
Ongoing	Planning of retrospective and prospective cohort studies of the general population to evaluate health effects of PFAS exposure	Regional Prevention Directorate
		National Institute of Health
Ongoing	Planning of prospective cohort study of pregnant women and newborns to assess the effect of PFAS exposure on pregnancy, perinatal and long-term health outcomes	Regional Prevention Directorate
		Birth and Congenital Malformations Register, Veneto Region







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