Scientific Committee on Health, Environmental and Emerging Risks
SCHEER

OPINION ON
the public health impacts and risks resulting from onshore oil and gas exploration and exploitation in the EU

The SCHEER adopted this Opinion by written procedure on 30 November 2018

ABSTRACT

The SCHEER was requested to assess public health risks resulting from onshore oil and gas exploration and extraction activities on a commercial scale in the EU, and to identify knowledge gaps.

Onshore oil and gas exploration and exploitation can induce increased human exposure to biocides, scale and corrosion inhibitors, oxygen scavengers, surfactants, and various hydrocarbons such as Volatile Organic Compounds (VOCs), polycyclic aromatic hydrocarbons (PAH), as well as particulate matter and noise in surrounding populations. Another consequence of onshore oil and gas exploration and exploitation relates to seismic activity: the level of evidence linking this phenomenon to onshore oil and gas exploration and extraction is moderate to strong.

Some of these environmental factors are recognised carcinogens or contribute to the risk of other chronic diseases such as cardiovascular or neurological illnesses.

Epidemiological studies have tried to characterise the possible impact of emissions from onshore oil and gas exploration and exploitation on human health; the vast majority of these studies are from outside the EU, generally the USA. They have relied on relatively imprecise exposure estimates, which is likely to lead to attenuation of dose-response functions. These studies indicate that the risk of haematological cancers and of preterm delivery may be higher in populations living around onshore oil and gas exploration and exploitation sites in comparison to populations living further away. The corresponding level of evidence is weak to moderate. A complete quantified risk assessment cannot be undertaken given the existing limited knowledge base but existing risk assessment studies show some coherence with the associations found in epidemiological studies.

The SCHEER is surprised at the very limited scientific assessment and monitoring of both the environment and people's health near long-established onshore oil and gas exploration and exploitation sites in the EU, given the numerous studies conducted on similar American oil and gas exploration and exploitation activities and the amount of scientific evidence pointing towards possible adverse effects of these activities.

The review undertaken by the SCHEER suggests a number of knowledge gaps that could be addressed through the following actions: (i) development of a centralised and harmonised inventory of all oil and gas exploration and exploitation sites in the EU; (ii) conduct of analytical and modelling studies that identify, quantify and characterise exposure mixtures and their levels in the vicinity of these sites; (iii) initiation of targeted biomonitoring and exposure assessment studies of populations potentially at risk; (iv) implementation of large-scale epidemiological studies with accurate exposure assessment and (v) carrying out of quantitative risk assessment studies.

Keywords: public health impacts, public health risks, onshore oil and gas exploration and production, SCHEER

Opinion to be cited as:
SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Opinion on the public health impacts and risks resulting from onshore hydrocarbon exploration and production in the EU, 30 November 2018

ACKNOWLEDGMENTS

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All Declarations of Working Group members are available at the following webpage:
http://ec.europa.eu/health/scientific_committees/experts/declarations/scheer_wg_en

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Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

These committees are the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The Scientific Committees review and evaluate relevant scientific data and assess potential risks. Each Committee has top independent scientists from all over the world who are committed to working in the public interest.

In addition, the Commission relies upon the work of other Union bodies, such as the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHEER

This Committee, on request of Commission services, provides Opinions on questions concerning health, environmental and emerging risks. The Committee addresses questions on:

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- complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health, for example antimicrobial resistance, nanotechnologies, medical devices and physical hazards such as noise and electromagnetic fields.

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ISSN 2467-4559 ISBN 978-92-76-00230-7
doi:10.2875/37937 EW-CA-19-002-EN-N

European Commission. The Opinions are published by the European Commission in their original language only.

http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

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MANDATE FROM THE EU COMMISSION SERVICES

1.1 Background

Hydrocarbons have been explored for more than 150 years in many areas of the world, including in the EU, where crude oil and natural gas are produced. This activity results in planned and unplanned releases of crude oil and gas components as well as other substances to air, groundwater, surface water and soil. The population living in oil and gas extraction areas is exposed to these agents. Releases of the following substances are considered to be among the most problematic during crude oil and natural gas production: benzene, SO_2, NOx, formaldehyde, PAHs and hydrofluoric acid.

In the EU, there seems to be limited information available on possible public health impacts and risks resulting from decades of hydrocarbon exploration and production, including in populated areas. A significant increase in the incidence of lymphoma, myeloma and leukaemia in certain age and gender groups has been identified in several municipalities in Lower Saxony, Germany, that are located close to hydrocarbon extraction sites. The possible causes are being investigated.

In North America, a number of scientific papers and studies have been recently published, drawing attention to possible public health impacts and risks resulting from the fast development of onshore unconventional hydrocarbon exploration and production (e.g. shale gas), requiring the use of well stimulation[1] techniques, such as high-volume hydraulic fracturing. This is a process by which fracturing fluids, typically a mixture of water, a proppant (such as sand) and chemicals, are injected under high pressure in the underground so as to break the rock and access hydrocarbons. Some US studies reported preterm birth, high-risk pregnancy, possibly low birth weight, asthma exacerbation, nasal and sinus problems, migraine headache and severe fatigue symptoms near unconventional gas developments[1,2]. These studies do not distinguish to what extent the possible health impacts and risks identified are specific to activities involving the use of high-volume hydraulic fracturing (e.g. shale gas) or could be caused by exposure to agents that occur in oil and gas extraction in general.

While some papers argue that exposure to pollutants is expected to remain below the thresholds set by the World Health Organisation or other such bodies, or that public health effects resulting from such activities are not significant provided that adequate measures are in place, other reports tend to stress the lack of biomonitoring and epidemiological research, making it difficult to have clear evidence of public health impacts and risks. Recommendations for increased transparency have been made, in particular as regards the use of chemicals and air emissions[3]. General EU legislation on environmental protection and

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[1] Well stimulation is a general term describing a variety of operations performed on an oil and gas well to improve productivity. It is generally divided into matrix treatments and hydraulic fracturing. (Amec 2016) High-volume hydraulic fracturing was defined in the Commission Recommendation 2014/70/EU as "1 000 m^3 or more of water per fracturing stage or 10 000 m^3 or more of water during the entire fracturing process into a well".

[2] Presentation from Johns Hopkins School of Public Health made at the European Commission workshop on public health impacts and risks from hydrocarbons exploration and production, 8 November 2016 http://ec.europa.eu/environment/integration/energy/unconventional_en.htm

[3] Minutes of a European Commission workshop on public health impacts and risks from hydrocarbons exploration and production, 8 November 2016 http://ec.europa.eu/environment/integration/energy/pdf/health_impacts_and_risks-from-oil_and_gas_extraction.pdf

workers' health applies to hydrocarbon exploration and production. In addition, the non-binding Commission Recommendation 2014/70/EU on minimum principles for the exploration and production of hydrocarbons using high-volume hydraulic fracturing (such as shale gas) aims *inter alia* at ensuring that public health is safeguarded.
As part of our mission to protect human health, we would like to have a better understanding of exposure to agents resulting from onshore oil and gas exploration and exploitation and of the overall risks to and impacts on public health associated with this activity in the EU.

1.2 Terms of Reference

The SCHEER is asked to provide an answer to the following questions:

1. Can you assess public health risks resulting from onshore oil and gas exploration and extraction practices at commercial scale in the EU?

2. What are the main knowledge gaps identified and what should be done to address such gaps?

In this work the SCHEER should build upon the available scientific literature, focusing on information relevant to practices in oil and gas exploration and extraction at commercial scale in the EU (from construction until the post decommissioning). In the absence of relevant data in the EU, experience from outside the EU can be examined, provided that it is deemed comparable to EU practices, in view of standards applied by the industry. Please note that this Opinion is not expected to duplicate recent literature reviews *(see non exhaustive list of studies/papers below).*

1.3 Additional information

DG ENV provided the SCHEER with a non-exhaustive list of recent studies/papers including the following:

North America:

– Toward an Understanding of the Environmental and Public Health Impacts of Unconventional Natural Gas Development: A Categorical Assessment of the Peer-Reviewed Scientific Literature, 2009-2015, 2016: http://dx.doi.org/10.1371/journal.pone.0154164;

- Environmental health impacts of unconventional natural gas development: A review of the current strength of evidence, 2015: http://dx.doi.org/10.1016/j.scitotenv.2014.10.084
- Environmental and health impacts of 'fracking': why epidemiological studies are necessary, 2016: http://jech.bmj.com/content/70/3/221
- Potential Public Health Hazards, Exposures and Health Effects from Unconventional Natural Gas Development, 2014: http://pubs.acs.org/doi/abs/10.1021/es404621d
- Human health risk assessment of air emissions from development of unconventional

natural gas resources, 2012: http://dx.doi.org/10.1016/j.scitotenv.2012.02.018

EU:

- Health impact assessment of Unconventional oil and gas in Scotland, 2016: http://www.hps.scot.nhs.uk/resourcedocument.aspx?resourceid=3102
- Unconventional Gas Exploration and Extraction (UGEE) Joint Research Programme, Ireland, 2016: http://www.epa.ie/pubs/reports/research/ugeejointresearchprogramme/EPA%20-%20UGEE%20Integrated%20Synthesis_web.pdf
- Bekannte oder vermutete Risikofaktoren für das Multiple Myelom, Institute of public health of Lower Saxony, 2009
- Review of the Potential Public Health Impacts of Exposures to Chemical and Radioactive Pollutants as a Result of the Shale Gas Extraction Process, Public Health England, 2014 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332837/P HE-CRCE-009_3-7-14.pdf
- AMEC study on the assessment and management of environmental impacts and risks resulting from the exploration and production of hydrocarbons, 2016: http://ec.europa.eu/environment/integration/energy/pdf/Study_on_the_management_of_ environmental_impacts_and_risks_of_conventional_oil_and_gas%20.pdf
- AMEC technical support for the risk management of unconventional hydrocarbon extraction, 2016: http://bookshop.europa.eu/en/technical-support-for-the-risk-management-of-unconventional-hydrocarbon-extraction-pbKH0116390/
- AMEC technical support for assessing the need for a risk management framework for unconventional gas extraction, 2014:
- http://ec.europa.eu/environment/integration/energy/pdf/risk_mgmt_fwk.pdf

Other:

- Green Energy Choices: the Benefits, Risks and Trade-Offs of Low-Carbon Technologies for Electricity Production (2015)
- http://www.unep.org/resourcepanel/KnowledgeResources/AssessmentAreasReports/EnvironmentalImpacts/tabid/133331/Default.aspx

1. OPINION or CONCLUSIONS

This section provides the SCHEER's responses to the questions posed by the Commission services in the Terms of Reference (ToR).

Q1. Can you assess public health risks resulting from onshore oil and gas exploration and extraction practices at commercial scale in the EU?

The oil and gas exploration and extraction lifecycle includes a number of stages from identification and exploration of the site, construction of wells, site operation and extraction to closure and abandonment. Human exposure to hazardous substances can occur at any of these stages.

It has been estimated that more than 1300 different chemicals may be emitted in the environment as a consequence of oil and gas exploration and exploitation, in addition to physical factors, such as noise and related seismic activity. Emitted chemicals include biocides, scale and corrosion inhibitors, oxygen scavengers, surfactants and, particulate matter. In terms of hazard, the possibly emitted compounds include chemicals with a known high toxicological profile such as Volatile Organic Compounds (VOCs) and specific Polycyclic Aromatic Hydrocarbons (PAHs) that have been linked to adverse effects on human health. VOCs may include proven carcinogens (e.g., benzene), neuro- or reproductive toxicants, and other chemicals for which the hazard is not well characterised. In general, during standard operations, the probability of occurrence of emissions of hazardous chemicals in water and in the atmosphere is relatively low when appropriate management measures are in place. However, the amount of accidental spillages can be up to about 5% of the operational yield per well per year.

The inferred relationship between natural gas exploration and exploitation and earthquakes has been investigated and is also a public health concern.

Studies on human exposure to emissions from oil and gas exploration and exploitation in the EU are scarce. The majority of available information comes from onshore oil and gas exploration and exploitation activities in North America. Major routes of human exposure to oil- and gas-related chemicals are direct exposure through air, in particular for residents living in close proximity to well pads. Levels of VOC such as benzene, toluene, ethylbenzene and xylene (BTEX), ozone, H_2S and formaldehyde amongst other compounds have been detected and can exceed acceptable exposure levels given in current guidelines. Other exposure pathways include contamination of food and drinking water. Insufficient quantitative information is available on these pathways. Exposure to noise and to naturally occurring radioactive materials constitute additional health hazards and have been shown to exceed guidelines near some well pads.

The SCHEER concludes that insufficient quantitative information is available on exposure pathways and levels and that therefore more data needs to be generated from environmental modelling and monitoring, including human biomonitoring in order to characterise the population exposure to oil and gas exploration and exploitation related-chemicals, and other environmental factors such as noise, naturally-occurring radioactive materials (NORM) and particulate matter around the production sites.

With the existing information on exposure and hazard, it is currently not possible to perform a thorough risk characterisation of human health risk associated with oil and gas exploration and exploitation. The few human health impact assessments that have been conducted focus on a small proportion of the possibly emitted chemicals; based on this limited evidence, an increased risk of cancers related to VOCs such as benzene could be expected in populations living nearby oil and gas sites.

The existing epidemiological studies provide weak to moderate evidence that onshore oil and gas exploration and exploitation entails health risks for the general population and point to specific endpoints, such as adverse birth outcomes, asthma exacerbation and possibly increased occurrence of haematological cancers in the vicinity of oil and gas exploration and exploitation sites.

Conclusion Q1

In conclusion, based on a few exposure and epidemiological studies, the risk of some cancers and of adverse birth outcomes may be increased in populations living around onshore oil and gas exploration and exploitation sites. The corresponding level of evidence is considered to be weak to moderate.

Q2. What are the main knowledge gaps identified and what should be done to address such gaps?

Although the SCHEER was requested to evaluate the existing scientific evidence related to potential human health risks in Europe, most of the studies reported have been conducted in North America. Furthermore, most studies focus on enhanced oil and gas exploration and exploitation, in which well stimulation is being used, whereas studies on oil and gas exploration and exploitation using the primary and secondary methods are underrepresented despite the large scale of this type of exploration and exploitation.

In relation to spill frequency, although in the US, 2-16% of wells report yearly spills with 75-94% of spills occurring in the first three years of well life, this type of information is not available for European countries. As it is predictable that these spill emissions may impact human health, this type of information should be also compiled at European level.

Data concerning the specific geographical locations and the nature of gas and oil exploration and exploitation within Europe is required to be able to make better assessments of the risks and exposures from conventional/unconventional hydrocarbon extraction to the population. There are challenges in the harmonisation of the information provided, meaning that, while it may be possible to identify these locations in some countries, the categorisations of the wells or types of chemical emissions is not always available, nor does a centralised inventory exist at the EU scale. Quantitative data on exposure levels to chemicals from oil and gas exploration and exploitation activities, either from environmental exposure assessment, biomonitoring, or food basket studies are also lacking. Likewise, measurements of noise levels, particulate matter or naturally-occurring radioactive materials (NORM) exposure are scarce. Development of a public database for unconventional oil and gas sites at EU level is under construction, and needs to be completed. This should be extended to include conventional oil and gas sites.

Considering hazard assessment, in many locations the chemicals used or emitted are not adequately identified. Moreover, human health hazard will result from exposure to chemical mixtures. At this point in time, the scientific knowledge on the effect of complex mixtures is limited.

Exposure assessment is a major gap and cannot be based only on proxy measures, as is the case in a number of existing epidemiological studies resulting in possible misclassification of exposure.

The SCHEER is surprised at the very limited scientific assessment and monitoring of both the environment and people's health near long-established onshore oil and gas exploration and exploitation sites in the EU, given the numerous studies conducted on similar American oil and gas exploration and exploitation activities and the amount of scientific evidence pointing towards possible adverse effects of these activities.

Recommendations

While development of a public database for unconventional oil and gas sites at EU level is under construction, and needs to be completed, this should be extended to include conventional oil and gas sites.

A central, harmonised data system would allow easy identification of the oil and gas well exploration and exploitation activities, which could then be linked to population density data, as a first building stone for adequate health surveillance at European level.

The SCHEER advises that this information ought to be compiled (location specific) for all chemicals used in oil and gas exploration and exploitation activities and made available in a harmonised EU-wide open access database.

Environmental monitoring, and/or human biomonitoring to chemicals, particulate matter, noise, NORM and seismic activity is recommended.

For chemicals not yet registered in REACH and/or whenever detailed toxicological information is not available, the hazardous properties of individual chemicals should be characterised.

More attempts should be made to improve the common knowledge on health risks for the European situation, in particular of complex mixtures emitted by oil and gas exploration and extraction, on spill frequencies and volumes and on seismic activity. The extension of cancer and other disease registers should be encouraged, in particular in areas where changes in industrial activities are expected.

Future high-quality studies, with improved (personal or semi-individual) exposure assessment and large population size, would be required to confirm or invalidate the limited evidence brought by the evaluated epidemiological studies.

Conclusion Q2:

The SCHEER identifies large knowledge gaps with regard to exposure and health impacts of contaminants emitted by onshore hydrocarbon exploration and exploitation activities. There is a need for more precise data on individual chemicals and mixture compositions and levels to which populations living near onshore hydrocarbon exploration and exploitation activities may be exposed and for epidemiological data relevant for Europe (epidemiological data gap).

The SCHEER suggests that these gaps be solved by undertaking (i) a centralised and harmonised inventory of all oil and gas sites in the EU, (ii) systematic collection of information on spill frequencies and volumes for the European situation (iii) analytical and modelling studies that identify, quantify and characterise exposure to chemicals and mixtures; (iv) human biomonitoring studies of populations potentially at risk, and (v) large-scale epidemiological studies with accurate exposure assessment.

2. MINORITY OPINIONS

None expressed.

3. DATA AND METHODOLOGIES

Information was obtained through a number of sources, mainly literature searches, an open call for information and the information provided in the TOR. Whilst all information was reviewed, the conclusions are primarily based on peer-reviewed scientific papers.

A call for information was launched by the European Commission on 'Public health impacts and risks resulting from onshore oil and gas exploration and exploitation in the European Union' and was open on the website of the non-food Scientific Committees from 17 May to 18 June 2017.

Five organisations and two individuals (providing in total 21 papers and several links to information) responded to the call by providing comments and additional information sources.

A literature search was conducted to retrieve scientific literature available on ‘public health impacts and risks resulting from onshore oil and gas exploration and exploitation in the European Union’. Publications were selected based on the search terms using Find-eR (a tool for searching multiple library resources in one interface which includes the European Commission Library collections, plus millions of online full-text journal articles and eBooks). The initial search covered a 20-year period (1997-2017). The search terms used in the searches were:

(Oil OR gas Or Hydrocarbons OR petroleum OR fossil fuel) extraction, development
Update with:

- Biomarkers
- Environmental impact
- Environmental risk
- Risk assessment
- Europe

Information was also provided in the mandate from the EU Commission Services, as indicated under ‘1.3 Additional information’.

Relevant publications identified during the evaluation of the literature (snowballing) and received during public consultation were also reviewed and considered.
In total, 207 unique publications and documents were identified. Since only a few publications specifically reported on EU hydrocarbon exploration and production and most reported on stimulated wells, it was decided to include information from outside of the EU and to consider all types of well stimulation. Before writing the Opinion 31 of these documents were considered highly relevant, although during writing and detailed reviewing 7 of the documents scored as highly relevant were discarded. Studies focusing on exposures of workers were *a priori* not considered relevant because of our focus on risk in the general population.

According to the Weight of Evidence (SCHEER 2018) principles, potential conflicts of interest among the authors of a study as well as the funding sources need to be identified for each source of data. Several of the peer-reviewed studies the SCHEER has evaluated for this Opinion have been commissioned by the oil and gas industry, a fact that may influence the weight given to such studies. Where deemed relevant, the SCHEER critically reviewed the paper's original data and drew independent conclusions.

4. ASSESSMENT

4.1 Introduction

4.1.1 Overview of most common oil and gas exploration and exploitation activities

Oil and gas exploration and exploitation activities are usually classified as conventional and unconventional fossil fuels. However, a universally recognised distinction between both types is not available. In the Opinion, no distinction between conventional and unconventional operations has been made.

In general, oil and gas exploitation activities consist of three main phases whose extensions depend on the geological factors of the reservoir:

- **Primary production**: It relies on the reservoir's internal pressure to extract the oil and/or gas. It usually accounts for approximately 5 - 15% of the total potential recovery depending on the physical characteristics of the reservoir (e.g. viscosity, porosity, wettability, amount of water, etc.).
- **Secondary production**: Water or natural gas is used to enhance the oil extraction. Water flooding is a mature technology which consists of the pumping of water into several sites of the reservoir to force the oil into the production well. This production phase accounts for approximately 20 to 40% of the production. Secondary production is only used in oil wells (i.e. water flooding is not used in gas wells due to its low viscosity).
- **Tertiary production**: It involves a number of different techniques for the enhanced recovery of oil and gas by altering the properties of the reservoir. It can lead to an additional 20% total recovery.

The type of the enhanced recovery technology used depends on the characteristics of the reservoir, formations and hydrocarbons and as such. They can greatly vary in nature and approach. Broadly speaking, the enhanced recovery technologies can be grouped as follows:

i. Chemical injection: It consists of the introduction of a mixture of water and chemicals including polymers, surfactants and alkalis to alter the physical properties of the water and, thus, increase the effectiveness of the water floods.
ii. Thermal injection: It consists of altering the physical properties of the oil and gas (mainly viscosity) by introducing heat through steam/hot injection or *in-situ* combustion.
iii. Gas injection (only applicable to gas fields): It consists of the introduction of gases such as natural gas, nitrogen or carbon dioxide to raise the well pressure as well as lower the viscosity of the oil.
iv. Well stimulation: It consists of the improvement of the oil and gas permeability by cleaning the available flow channels and/or creating new ones in the rock formation (e.g. hydraulic fracturing).

Hydraulic fracturing uses pressurised fracturing liquids which consist of water, proppants and different additives, to fracture formations and release hydrocarbons. A distinction can be made between conventional low-volume hydraulic fracturing used as an enhanced recovery technology in single wells (normally vertical wells) and high-volume hydraulic fracturing used in the completion of tight gas and shale gas wells.

Low-volume hydraulic fracturing has been practiced since the 1950-60s and it is generally considered to be a well-stablished technology. It requires lower pressures than high-volume hydraulic fracturing due to the smaller volumes of fluid and proppant used.

In addition, there are a number of alternative enhanced recovery technologies already available on the market or currently being developed, including advanced polymers and foams, acid gas injection, microbial and hybrid technologies.

Further details of each of these technologies as well as the scale of them on the global and European market can be found elsewhere, including in the 2016 AMEC report (AMEC, 2016). As forecasted in this report, while the extent of the tertiary technologies used in oil and gas wells in Europe is unclear, their use is expected to be more widely applied in years to come.

4.1.2 Lifecycle stages in oil and gas exploration and exploitation

The lifecycle of oil and gas exploitation activities can be divided into different stages as shown in Figure 1. It spans from the site identification and preparation (Stage 1) to the project closure and abandonment of the well (Stage 5).

Each of these stages involves different timescales (depending on the projects) and activities aligned to the nature of the reservoir. In incidental cases, there can be emissions for decades after project closure (Schout *et al.,* 2017). A tailored risk evaluation and the identification of impacts on human health are normally carried out according to the existing legislation and regulatory requirements for each of the stages.

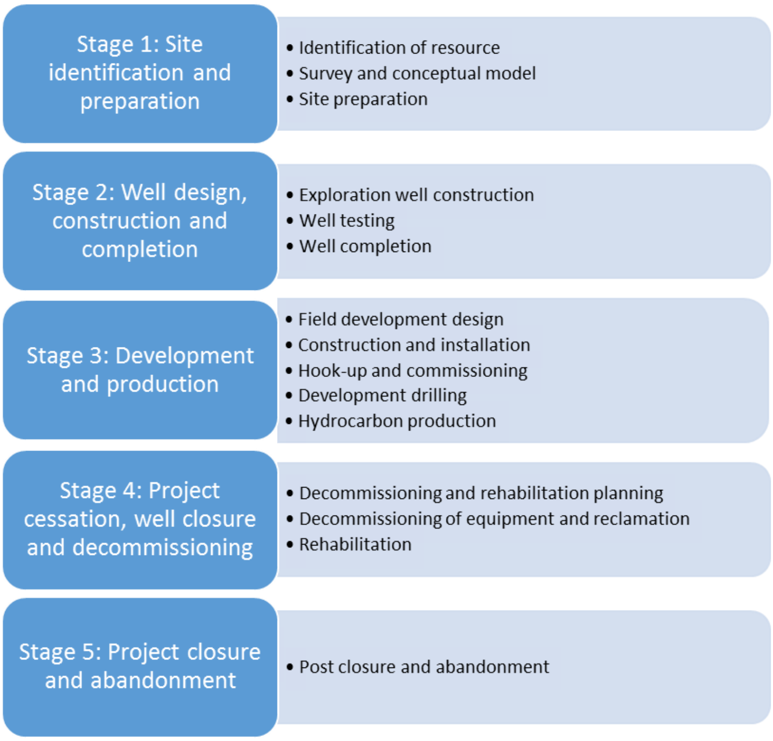

Figure 1: Lifecycle stages in oil and gas exploration and exploitation activities.

4.1.3 Gas and oil exploration and exploitation in Europe

Data concerning the locations and nature of gas and oil exploration and exploitation within Europe is required to be able to make better assessments. As a first step, this data should be compiled to allow quantification of the general population's risks and exposure from oil and gas exploration and exploitation activities.

Currently there is no central, harmonised database of onshore hydrocarbon exploration and exploitation sites (e.g. number of well pads, volumes of chemicals used and emitted, environmental monitoring) that would allow the required risk quantification at European level[4].

Industrial manufacturers and operators involved in exploring, extracting and exploiting oil and gas have to comply with rules set by REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and must register the chemicals under this overarching system[5].

All industrial chemicals with a production volume greater than 1 ton/year need to be registered under REACH and a set of data requirements addressing physicochemical, and (eco) toxicological properties, need to be fulfilled and submitted to ECHA[6].

[4] The JRC is developing (launched 2017) a public platform "European Unconventional Hydrocarbon Portal" (Open Echo, https://ec.europa.eu/jrc/en/openecho) covering sites for shale gas, tight gas, coal bed methane wells, which should compile environmental information available for each site, provided the operator releases such information. At the time when this report was written, the site contained information for Austria, Denmark, France, Germany, Hungary, Lithuania, Poland, Romania, Spain, Sweden, The Netherlands and UK; for other Member States the site is still under construction.

The portal incorporates three tools: 1) the European Atlas of Unconventional Hydrocarbons Resources, 2) a prototype of the European Database of Unconventional Hydrocarbons Wells, and 3) the energy market Impact Analysis Tool. Presently, the database prototype is migrated to an interactive database that allows its users to search, retrieve or add information about existing or new unconventional hydrocarbons wells and provide at once for one or more wells detailed information about environmental parameters (e.g. baseline studies, monitoring studies). In the future the database is going to be compatible with other Commission's database systems (e.g. IPCHEM) by using CAS unique numerical identifiers and it will be made publicly available during 2018. The tool focusses mainly on unconventional hydrocarbon exploitation; as discussed above the distinction between conventional and unconventional is not always well defined.

In 2013, JRC published a report "Projected population density map overlain with allocated shale gas well pads, in Poland and Germany"
(http://ec.europa.eu/environment/integration/energy/pdf/land_water_shale_gas.pdf).
This database is due for completion by 2020 and although it is an important information source, it does not plan to include conventional oil and gas wells.

[5] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

[6] The composition of the data package is triggered by the volume of the chemicals, as placed on the European market by the manufacturers. REACH places responsibility on industry to manage the risks that chemicals may pose to public health and to the environment, by supplying data on the properties of their chemicals. Industry is obliged to develop chemical safety assessments and implement risk management measures. In this sense, as any other operator, REACH requires oil and gas operators to notify the European regulatory authorities about the use of hazardous substances and mixtures. In addition, if fulfilling certain hazard criteria (e.g. CMR, vPvB and PBT), chemicals used in oil and gas activities may be subjected to authorisation procedures before they are allowed to be used, at European level, which requires submission of a dossier demonstrating safety and identified risk mitigation measures.

4.2. Scope of the Opinion and limitations

The potential health effects linked to the exploration and exploitation of oil and gas have been recently reviewed by a number of authors. In 2016, several significant reviews appeared: Balise *et al.,* provided a systematic review on oil and natural gas extraction processes and human reproduction; Hays reviewed the literature between 2009 and 2015 concerning the human health impact of unconventional gas development and O'Callaghan *et al.* discussed the health effects of non-occupational oil extraction and made suggestions on how to add significant data to the scarce database. In 2015, Werner *et al.,* evaluated the strength of evidence concerning the health impacts of unconventional natural gas development.

In this Opinion, the public health impact of oil and gas exploration and exploitation has been reviewed with a focus on the European onshore explorations and on the potential causative factors (use of chemicals, nature of the activities, etc.).

Only studies in which an association is made between the nearby exploration of wells and the health of the general population have been considered by the SCHEER; consequently, health effects on workers at these explorations are disregarded. Furthermore, the focus is only on exploration and extraction – considering the whole life-cycle described above – without the related activities in which crude oil and gas are prepared for sale (refinement, desulfurisation etc.).

Herein, the main focus is on the 'chemical' environment of the exploration and exploitation activities, although factors such as traffic, air pollution, noise and seismic activity have been considered. However, aspects such as economic welfare associated with exploration and exploitation activities, emissions from greenhouse gasses or aerosols have not been considered despite their potential influence on public health, e.g. through psychosocial impacts (Tollefson J., 2013).

The assessment was conducted as follows:

First, the possible environmental emissions and pathways to human exposure resulting from oil and gas exploration and exploitation were evaluated.

Second, a human risk assessment was considered based on the available exposure and hazard data of known chemical and physical entities released and/or used during oil and gas exploration and exploitation.

Third, the most relevant epidemiological studies in the general population living around hydrocarbon exploration and exploitation sites were discussed and assessed.

A review of the health impact assessment (HIA) studies was then provided.
Finally, the collected data was evaluated in order to draw conclusions on the potential link between public health and oil and gas exploration and exploitation.

4.3. Environmental impacts and environmental risks related to onshore hydrocarbon exploration and exploitation

4.3.1. Emissions of contaminants in the environment

The assessment and management of environmental impacts and risks resulting from the exploration and exploitation of hydrocarbons associated with different activities involved in each stage of the lifecycle of the oil and gas exploitations were reviewed by AMEC in 2016.

Identification and preparation of onshore hydrocarbon exploitation sites (Stage 1) resulted in relatively low environmental impacts although it is important to highlight the direct consequences of land take, including vegetation clearing and possible community displacement (Amec Foster Wheeler, 2016).

The activities related to well design, construction and completion (Stage 2) present high environmental risks even in the presence of management measurements in place. Main emissions are related to the drilling of vertical or deviated wells, including a very high risk of accidents with major spillages (e.g. chemicals, drilling fluids, drill cuttings, etc.) to ground and surface water depending on the depth it takes to reach groundwater and the permeability of the intervening material, in most cases because the wells have not been completely sealed (UNEP/O&G, 1997 and Appea, 2015). In addition, drilling and well development often yield large quantities of what is called "produced water", originally held in the same formations as the hydrocarbons. This produced water may contain a number of chemicals such as organic acids, alkalis, diesel oil, crankcase oils, and acidic stimulation fluids (Tribal Energy, 2015). This produced water is normally reinjected into the original formation with potential risks containment of contaminants (IFC, 2007) or treated through conventional waste water systems and finally discharged in rivers. Well design, construction and completion activities also present a high risk of air emissions, mainly associated to drilling and the spillage of trapped gases mainly natural gas (Larsen *et al.,* 2015) and VOCs with local and global impacts.

The development and production activities (Stage 3) present high risks of minor and major spillages to the atmosphere and also to ground and surface water during normal site operations. Emissions highly depend on failure probabilities associated with the permeability of the reservoir, geological environment, technology used and management as well as inadequate design or poor construction of wells (UNEP/O&G, 1997).

Insufficient cementing is the main reason for the occurrence of failures, followed by oil-based fluids released due to leaking connectivity. Blowouts are the least frequent failures, however the associated spill volumes are very high and effects to surrounding groundwater can last for decades after the incident (Schout *et al.,* 2017). The main fluids of concern are wastewater, crude oil, fracturing fluid and drill waste. 2-16% of wells report yearly spills and 75-94% of spills occur in the first three years of well life.

Surface and groundwater contamination might occur at the surface via accidental spills, or in the subsoil via leaks (Gordalla *et al.,* 2013) due to structure integrity problems or human error. Surface spills can affect surface waters and shallow aquifers via infiltration or direct leaching. Underground leaks can affect aquifers via migration through artificial and/or natural faults and fractures. While accidental surface spills may not always impact groundwater systems, they do however impact surface waters (Harkness *et al.,* 2017). During wastewater production, most of the injected fracturing fluid (92-96%) remains in the subsurface formation (Kondash *et al.,* 2017). Most of this water resides in the shale matrix and only a small portion goes into surrounding fractures (O'Malley *et al.,* 2015).

Emissions consist of naturally occurring substances such as heavy metals, natural gas, etc. or operating compounds such as fracturing fluids, chemicals used to maintain the wells, etc. Another important emission route is the well blowouts due to well failure which can release large amounts of oil, chemicals, drilling fluids, etc. creating plumes of groundwater and surface water pollution (Golder 2014). The operation of sites also presents a high risk of releases to air. The high risk of minor and major accidental spillages should be specially highlighted, including flaring of gas, fugitive hydrocarbons and a range of volatile chemicals (Macey *et al.,* 2015).

Generally, under "normal" operation, the probability of water and air releases are relatively low with mitigating measurements in place. However, the risk of accidental spillages is usually large and must be taken into account. These spill and leak probabilities, depending on the contamination pathway, can be up to about 5% of the operational yield per well per year (Faber *et al.* 2017). The resulting emissions can be estimated for surface or near-surface spills and leaks by considering publicly available data on spill occurrences and released volumes from the US. Failures and consequently leak volumes occurring deep underground could be underreported in these databases due to the lack of monitoring at these depths, even though monitoring of pressure decreases might be ensured. There is little information available on spill frequencies and volumes for the European situation, meaning that related studies must rely on US databases (Faber *et al.,* 2017; Maloney *et al.,* 2017, Patterson *et al.,* 2017).

Environmental risks are lower during the project cessation, well closure and decommissioning (Stage 4); however, it is important to mention that improper controls, accidents, infiltrations and spillages can also result in soil, air and water contamination (UNEP/OG, 1997; Macey *et al.,* 2015; Maloney *et al.,* 2017, Patterson *et al.,* 2017).

The AMEC 2016 technical report also includes other environmental impacts and risks such as the effect of land take, noise, visual impact, seismic and traffic as well as an estimation of the decrease of these risks by the deployment of expected management measures. The seismic risk is specifically detailed below.

4.3.2. Seismic activity

An inferred relationship between natural gas extraction and earthquakes was investigated by Foulger *et al.*, (2017) as part of a global review of studies addressing human-induced earthquakes. In this analysis, the authors built a database on earthquakes postulated to be induced by human activity (Human-induced Earthquake Database (HiQuake)) containing more than 700 events (over the period 1868–2016) related to human activity. Human activities related to earthquakes included impounding water reservoirs, erecting tall buildings, coastal engineering, quarrying, extracting groundwater, coal, minerals, gas, oil and geothermal fluids, excavating tunnels, engaging in enhanced oil recovery, hydrofracturing, storing gas, sequestrating carbon and adding material to the subsurface.

The term 'induced' was defined by the authors as "earthquakes related to human activities". The authors also use the term "nuisance earthquakes", defined as those earthquakes causing societal inconvenience, which may be social, economic, physical and/or psychological. This includes damage or distress related to ground shaking and noise or environmental effects such as hydrological changes.

Haak *et al.*, (1993), Segall *et al.*, (1994) and Vlek *et al.,* (2018), among others, have shown that there is a relation between natural gas extraction and earthquakes due to soil subsidence, where at least some of the physical mechanisms are understood. It is also understood that the amount of stress released in an induced earthquake is not necessarily the same as the anthropogenic stress added because pre-existing tectonic stress may also be released.

In the HiQuake database, 36 cases of seismic activity are linked to extraction of natural gas, and 8 to oil extraction. It is notable that in many fields, multiple processes are used simultaneously, including waste-water disposal, water injection to aid oil recovery and hydrofracturing and thermal fracturing (Weingarten *et al.*, 2015).
Out of the 36 cases linked to gas extraction, 28 were reported in Europe: 18 in the Netherlands, 7 in Germany, 2 in France and one in Italy.
According to Foulger *et al.*, (2017), human-induced earthquakes rarely cause problems, but in some cases the resulting problems may be significant.
The hydrocarbon-producing areas of Oklahoma (USA), for example, cause some disturbances to the adjacent population. In Europe, the gas extraction from the Groningen gas field in the northern Netherlands has recently led to negative societal impacts including: damage to property, declining house prices, concerns about the chance of dykes breaking, feelings of anxiety and insecurity, health issues, and anger (Vlek *et al.,* 2018).

The study of Foulger *et al.*, (2017) concludes that:

- Seismicity due to oil and gas extraction is severely under-reported, especially the smaller events. The authors bring up the case of the hydrocarbon fields around Britain. Comparing the UK earthquake database (British Geological Survey) with maps of hydrocarbon fields in the North Sea, the authors note a correlation between fields and earthquake locations, e.g. an epicentre cluster near the Beatrice Oilfield (Moray Firth), the Britannia Gas Field, the Southern North Sea Gas Province and the Leman Gas Field.
- As the size of projects and density of populations increase, the potential nuisance of induced earthquakes also tends to increase.

4.3. Human exposure assessment

4.3.1. Sources, emissions and pathways

Potential emissions from conventional and unconventional oil and gas operations may be composed by a considerable number of different organic and inorganic chemicals. It has been estimated that more than 1300 different chemicals may be emitted in the environment as a consequence of oil and gas exploration and exploitation (Faber *et al.,* 2017). Some of them are components of the oil and gas mixtures and their reservoirs, but many are used for extraction procedures, particularly as fracturing additives used for unconventional operations may be classified in several functional categories (Colborn *et al.,* 2011).

The physical-chemical properties and the environmental behaviour of these chemicals are widely different. Most of these chemicals, including the hydrocarbon mixtures, are volatile and can become airborne. Many others are water soluble and can become water pollutants (Colborn *et al.,* 2011). Therefore, in the literature, much attention is paid to air and water contamination.

4.3.2. Pollutants released in the atmosphere

Emissions from onshore oil and gas exploration and exploitation activities to and through the atmosphere occur as a result of leaks, off-gassing, from e.g. flow-back ponds / reservoirs, emissions from engines, including traffic, and venting (of tanks) (Paulik 2016). In addition, from conventional oil and gas wells experience, it is known that even after closure of a well, the abandonment process is not always successful or can deteriorate with time and that stray gas leakage can occur (Hooper *et al.,* 2014). Air emissions from the wells, production tanks, compressors and pipelines and maintenance operations include volatile organic compounds (VOCs), methane, other hydrocarbons (USEPA, 2011), greenhouse gases, photochemical air pollutants such as ozone, and air toxins (TAMEST, 2017). Emissions from combustion associated with truck traffic, generators used to power drilling rigs, hydraulic fracturing, and flaring include particulate matter, polycyclic aromatic hydrocarbons and other hydrocarbons, VOCs, sulphur oxides, and nitrogen oxides (Witter *et al.,* 2013) Source apportionment results indicate a significant contribution to regional VOCs from gas production sources, particularly from lower-molecular-weight alkanes (<C6) (Zielinska 2014). Exposure levels are likely to be higher during the well development period with lesser potential impact throughout the production period (typical 20-30y; Witter *et al.*, 2013). In contrast, Maskrey *et al.* (2016) did not find elevated VOC levels during drilling.

Brown *et al.,* (2015) described a hypothetical case study designed to demonstrate the direct effect of weather on exposure patterns of $PM_{2.5}$ and VOC from onshore oil and gas exploration and exploitation activities. The model and findings provide a possible explanation for the episodic nature of health complaints and symptoms in gas drilling and processing areas. The findings show that peak PM 2.5 and VOC exposures occurred 83 times over the course of 14 months of well development.

Source term estimates need to be developed and then applied to a pollution dispersion model. Profiles such as this will assist in understanding the frequency and intensity of the human exposures in individuals living near onshore oil and gas exploration and exploitation activities.

Air concentrations of potentially dangerous compounds and chemical mixtures have been reported to be higher around some oil and gas exploration and exploitation sites. Of special concern are benzene, hydrogen sulphide, and formaldehyde, as well as chemical mixtures linked to operations. Carrierri *et al.* (2010) and Andreoli *et al.* (2015) studied benzene, while Tsangari *et al.* (2017) studied BTEX (benzene, toluene, ethylbenzene and xylenes) and succeeded to correlate low environmental exposure and biomonitoring data.

An EPA study (2011) found that methane, hazardous air pollutants and VOC were emitted at about 20 times the level in fracked gas wells when compared to unfracked wells.

Oil and gas operations also produce noises at levels that may increase health risks (Hays *et al.,* 2017). This holds true especially during the exploitation and drilling phase. Witter *et al.,* (2013) examined noise monitoring data and concluded that noise levels were likely to increase during the well development period.

4.3.3. Pollutants released in soil and water systems

Human error in various stages of the life cycle of onshore hydrocarbon exploration and exploitation plays an important role in the exposure scenarios to groundwater and surface water (Faber *et al.,* 2017). Most evidence suggests that contamination of groundwater, if it occurs, is most likely to be caused by leakage through the vertical borehole (PHE, 2016). Surface spills and well casing leaks near the surface are the most likely pathways for oil and gas activities to lead to contamination of drinking water sources and environmental damage (TAMEST 2017). Contamination of drinking water aquifers from the underground hydraulic fracturing process itself (i.e. from targeted injection zones) is unlikely. However, failures such as surface spills of hydraulic fracturing fluids or wastewater may affect groundwater, even a long time after the incident occurred (Schout *et al.,* 2017). Problems are typically a result of operational failure, which occurs both under a poor regulatory environment but also with a good regulation framework in place (Maloney *et al.,* 2017, Patterson *et al.,* 2017, Faber *et al.,* 2017). For example, elevated levels of methane in drinking water were associated with poor well construction (Jackson *et al.,* 2013). Surface and groundwater contamination might occur at the surface via accidental spills, or in the subsoil via leaks (Gordalla *et al.,* 2013) due to structure integrity problems or human errors.

In their review, the National Health Services Scotland (2016) concluded that unconventional onshore hydrocarbon exploration and exploitation activities are likely to negatively impact the quality of aquifer-based groundwater drinking sources.

Another environmental route that can lead to human exposure related to wastewaters is flow back or produced waters and their transport to and release after treatment facilities (Butkowskyi *et al.,* 2017). Not all techniques that are currently applied in these treatment facilities are very efficient at removing the chemicals in question. UGD operators in the US initially discharged the production wastewater to public treatment systems that ultimately discharged into rivers. Consequently, this was associated with increasing concentrations of bromine and other contaminants in drinking water pulled from the rivers (Stacy *et al.,* 2015). The presence of brominated compounds could increase disinfection by products (DBP) formation in chlorinated drinking water supplies (States *et al.,* 2013; Voltz 2011 cited in PHE 2014). Effluents from wastewater treatment plants were found to have a unique DBP signature including brominated compounds disinfection by products when compared with effluents from plants not accepting wastewater from oil and gas exploration and exploitation (Hladik *et al.,* STE 2014). In line with these earlier studies Elliott *et al.,* (2018) recently reported that the residential proximity to unconventional oil and gas developments and oil is associated with the detection and concentrations of health-relevant drinking water contaminants (particularly bromoform and dibromochloromethane) in Belmont County, Ohio, USA.

The fracking process intentionally generates cracks in the rocks that typically extend to 100–200 m; however statistical analysis suggests that they can extend by up to 300 m and, in extreme circumstances, by up to 500 m (Hooper *et al.,* IrEPA 2014). If the separation between the fracking activity and the base of the aquifer is less than these distances, then there will be a risk of pollutant and gas migration to the aquifer. In fracking, a chemical deep underground will be subjected to high temperatures (up to 200°C), high pressure (above 10MPa), and high salinity (TDS: 100-300 g/L), which might alter the chemical behaviour (Kahrilas *et al.,* 2016).

4.3.4. Naturally occurring radioactive materials (NORMs)

As for any mining activity, oil and gas extraction may produce emissions of naturally occurring radioactive materials (NORMs). These materials are ubiquitous, in variable amounts, in the subsoil and may be brought to the surface by extraction operations (Doyi *et al.,* 2016). They may originate from various radioactive elements, such as uranium, thorium and radium. However, uranium and thorium, being relatively insoluble, remain in the oil products, while radium radionuclides, particularly ^{226}Ra and ^{228}Ra, are more soluble and may contaminate water.

Data on the activity of ^{226}Ra and ^{228}Ra in formation and produced waters, as well as in scale and sludge, are available for several sites all over the world (Doyi *et al.,* 2016; Annevelink *et al.,* 2016).

The International Commission on Radiological Protection recommended a maximum permissible limit of 1 mSv/year for non-nuclear work environments and the general public (ICRP 2007). From the available literature, this limit may be exceeded at the extraction sites, producing a health risk for workers (Doyi *et al.,* 2016; Hamlat *et al.,* 2001; El Afifi and Awwad, 2005; Jonkers *et al.,* 1997).

In the general environment, the potential risk is substantially reduced due to dilution effect. However, according to AMEC Foster Wheeler (AMEC, 2016) and the UK Department of Energy and Climatic Change (DECC, 2014) there is the possibility of environmental impact. In the classification proposed by AMEC Foster Wheeler (AMEC, 2016), the consequences (i.e. the potential effects) determined by NORM in surface water may be classified as "Moderate" on a five-level scale (Slight, Minor, Moderate, Major, Catastrophic). However, considering the likelihood of emissions, the overall risk for surface waters and biodiversity is classified between "Low" and "Moderate" in a four-level scale (Low, Moderate, High, Very High) (AMEC, 2016). The assessment of AMEC is based on theoretical estimates. Although the approach used by AMEC is correct, there are insufficient experimental data to validate the assessment in different environmental conditions.

4.3.5. Transfer in the food chain and through food consumption

Many compounds resulting from oil and gas exploration and exploitation operations may have bioaccumulation and biomagnification properties and some of them may fulfil the characteristics of PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) chemicals. Crude oils contain numerous compounds (e.g. long-chain alkanes), which because of their likely persistence and extremely high bioaccumulation potential could be potential PBT or vPvB substance candidates, with logKow values higher than 5 (Vrabie *et al.,* 2012). However, the so-called PMOCs (persistent and mobile organic compounds) are emitted during onshore hydrocarbon exploration and exploitation activities. The PMOC are especially relevant for aqueous environmental matrices and are difficult to remove from (drinking) water by treatment technologies (Reemtsma *et al.,* 2016).

Another chemical group constantly present at U/COG sites is PAH. Although many variants of PAH may be metabolised in vertebrates, some of them (e.g. phenanthrene, fluoranthene) may be classified as 'bioaccumulative' in vertebrates and 'very bioaccumulative' in invertebrates.

Several chlorinated compounds, which are not typical components of oil and natural gas or their combustion products and are not reported in products used in drilling or hydraulic fracturing, are frequently found at onshore hydrocarbon exploration and exploitation sites (Allen, 2014; Rich *et al.,* 2013). In a one-year study on a natural gas operation site, methylene chloride, not reported in products used in drilling or hydraulic fracturing, was detected in 73% of the samples at very high concentrations; in a ranking of measured concentrations it was second only to methane (Colborn *et al.,* 2014). Other chlorinated organics frequently detected close to onshore hydrocarbon exploration and exploitation sites are chloromethane, 1,1,2-Trichloro-1,2,2-trifluoroethane, carbon tetrachloride, trichlorofluoromethane and many others (Brown *et al.,* 2015), and, indirectly – as discussed above – DBP from treatment of production wastewaters. In some sites, the presence of PCBs is also reported (Butkowskyi *et al.,* 2017). According to Allen (2014), the understanding of toxic pollutants associated with natural gas production is limited; a recent study (Webb *et al.* 2016) found increased concentrations of mercury in the urine of Indigenous people in the Peruvian and Ecuadorian Amazon near oil production sites.

4.3.6. Conclusions on exposure

Studies on human exposure to emissions from conventional oil and gas exploitation are scarce in the EU and the majority of information available comes from onshore hydrocarbon exploration and exploitation sites in North America. Major routes of human exposure to oil and gas related chemicals are probably direct exposure through air, in particular for residents living in close proximity to exploration and exploitation sites. Levels of VOC, ozone, BTEX, H_2S and formaldehyde amongst other compounds have been detected and can exceed current guidelines. Indirect exposure pathways include contamination of food and drinking water. The SCHEER concludes that limited quantitative information is available on both direct (air and water) and indirect (diet) pathways. Exposure to noise and to naturally occurring radioactive materials (NORM) poses an additional health risk and emissions have been shown to exceed guidelines near well pads. The SCHEER concludes that more monitoring and recording of data are necessary.

4.3.7. Knowledge gaps/Limitations

Quantitative data on exposure levels to chemicals from OG activities from environmental exposure assessment, biomonitoring and food basket studies are lacking. Noise levels during well development and well exploitation should be collected in a systematic way, and monitoring of NORM is recommended.

4.4. Human hazard assessment related to onshore hydrocarbon exploration and exploitation

In this particular industrial sector as in many others, a large number of chemicals are involved; while for many of them, human health hazard information is available, for many others there is limited or even no information (Faber *et al.,* 2017, Yost *et al.,* 2016).

For instance, fracturing fluids screened for carcinogenicity potential based on IARC methodology showed that some chemicals are classified as known human carcinogens (Group 1) and probable or possible human carcinogens (Group 2A/2B), but the majority of chemicals are not classifiable due to lack of supporting data (Elliot *et al.,* 2017).

In unconventional oil and gas exploration and exploitation wastewater (West Virginia, USA) and unconventional oil and gas exploration and exploitation-impacted environmental water extracts (Colorado, USA), elevated endocrine activity was associated with natural gas drilling operations (Kassotis, 2014 & 2018).

As reported in the literature, about half of the chemicals reported in the literature that is used in global onshore hydrocarbon exploration and exploitation activities are regulated in the EU (Faber *et al.* 2017). In these cases the basic toxicity information is available in the dossiers provided to the regulator. The broad variety of more than 1300 chemicals include reproductive/developmental toxicants (Kahrilas *et al.,* 2015) and carcinogenic agents (*et al.,* 2012; Elliott *et al.,* 2017). A more in-depth hazard assessment can be carried out for a specific endpoint exploiting *in vivo* and *in vitro* toxicity data submitted in regulatory chemical dossiers (e.g. ECHA, EFSA), scientific literature or databases (e.g. ITER, Toxcast). In addition, toxicity alerts can be estimated by using QSAR or read-across techniques (OECD Toolbox).

Hazard assessment is predominantly based on individual substances, but in real situations, humans are exposed to a wide variety of substances in mixtures comprising the potential adverse effects of the interactions between those substances when present simultaneously in a mixture (SCHER 2011).

Chronic noise is known as a strong risk factor for many chronic diseases such as metabolic diseases (including diabetes) fatigue, impaired cognition, mood changes, diminished school performance, hypertension, and cardiovascular effects (Basner *et al.,* 2014; Witter *et al.,* 2013) but no detailed quantitative analysis has been performed so far for this stressor either.

Conclusions

There are a large number of chemicals involved in onshore hydrocarbon exploration and exploitation, for many of which human health hazard information is available, but for others and mostly for mixtures there is limited or even no information. In addition, there are clearly deficiencies in the exposure assessment, which make it impossible to determine what levels/doses of onshore oil and gas exploration and exploitation emissions the general population is exposed to.

Therefore, it is currently impossible to perform a robust characterisation of the human health hazards associated with oil and gas exploration and exploitation activities in the EU.

Recommendations

- Considering the hazard assessment, in many cases a full toxicological assessment based on *in vivo* data is not available for all chemicals involved in the exploration and exploitation of onshore oil and gas activities. However, *in vitro* data, QSAR and/or read-across techniques can be applied to better describe the inherent hazardous properties of the chemicals involved.
- Human health hazards will result from exposure to the mixture of which the composition varies over time and from site to site. At this point in time, the common knowledge on health hazards of complex mixtures is limited. The SCHEER recommends giving particular attention to this topic and thereby developing an adequate hazard assessment methodology, taking into consideration the main contributors to the hazard of the chemical mixtures generated from oil and gas exploration and exploitation sites.
- The SCHEER advises that for all chemicals used in oil and gas exploration and exploitation activities, this information is compiled in open access databases as a basis for further (location specific) hazard assessment, including the mixture toxicity.

4.5. Epidemiological studies and health effects identified in the populations living around onshore hydrocarbon production sites

4.5.1 Introduction

The epidemiological studies that considered the possible health effects of living in the vicinity of oil and gas sites have been mostly conducted in North America: to SCHEER's knowledge three of these studies have been conducted in Europe, out of which only one has been published in the peer-reviewed literature. These studies focus on health events occurring between 1980 and 2015, and consider various health outcomes with some *a priori* plausibility for an influence of oil and gas exploration and exploitation sites, such as adverse birth outcomes, haematologic cancers (which have been associated to benzene and particulate matter exposure) and respiratory health (which has been associated to volatile organic compounds and particulate matter). The impact on hospitalisation rates was also assessed.

The exposure conditions and the characteristics of the populations involved in the studies carried out in North America might be different from those in Europe, and the situation in Europe is itself expected to be heterogeneous. However, on the basis of the overall data regarding oil and gas on shore exploration and exploitation sites in Europe, the SCHEER assumed that the exposures and hazards are similar in both continents and the available studies allow for some initial assessment of the potential health risks in the EU.

Most published studies relied on a proxy measure of exposure, such as residence within a given buffer around an oil and gas exploration and exploitation site (yes/no); in some cases, this proxy was improved by using, for instance, an inverse-distance weighted score taking into account the number of wells in a given distance, and sometimes their activities. These exposure metrics are likely to induce exposure misclassification, as they ignore, among other factors, wind direction, any chemical reaction in the atmosphere and differences in exposure levels between the outdoor and indoor environments, where people spend most of their time. Although the impact of this likely misclassification is hard to predict with any precision, the use of such proxy metrics is expected to lead to loss of statistical power and possibly attenuation (i.e., underestimation) of any dose-response function. Confounding by sociodemographic factors is another methodological issue, and may be hard to control efficiently although several studies did directly or indirectly (as is e.g. the time series studies) correct for such potential confounders.

4.5.2 Cancer and mortality

To the SCHEER's knowledge, only one published study and two (unpublished) epidemiological studies have been conducted in the EU around oil and gas exploration and exploitation sites.

The published study was conducted in Croatia in the Koprivnica-Krizevci county in the 1971-2000 period (Gazdek 2007). It relied on the data from Croatian Cancer Registry of the Croatian National Institute of Public Health (operating since 1959). The study follows a "before-after" design in which cancer incidence rates for lymphohematopoietic malignancies have been compared between the 1971-1980 period (before the start of major hydrocarbon production) and the 1981-2000 period (after its start) in the Koprivnica-Krizevci county, divided into 3 areas: 2 with production wells (Djurdjevac and Korpivnica) and one without a well (Krizevci). Spatial comparisons (the area without a well being taken as a reference) were also undertaken for the production period (1981-2000). Analyses were conducted for 7 cancer sites, for all leukaemias together and all lymphohematopoietic malignancies together, both for men and women together and separately.

Regarding the temporal comparisons, elevated rate ratios between the periods during production (1981-2000) and before production (1971-1980) were observed in the areas with wells for several types of cancer; however, for a large proportion of these cancer types, an increase of a similar magnitude was also observed in the area without a well. For chronic myeloid leukaemia, the temporal increase in the area with wells (rate ratio, 2.7, 95% CI, 1.4 to 5.1) seemed higher than in the area without wells (rate ratio, 1.3, 95% CI, 0.3 to 6.2)

Regarding the spatial comparison in the production period (1981-2000), elevated rate ratios between the two areas with wells, compared to the area without a well, were observed for multiple myelomas (rate ratio, 1.6, 95% CI, 1.01 to 2.63) and for chronic myeloid leukaemia (rate ratio, 3.4, 95% CI, 1.7 to 6.9), while no such increases were reported for the (shorter) period before production.

A limitation of this study is the lack of correction for multiple testing and the purely temporal and spatial nature of comparisons, without direct exposure assessment.

Another (currently unpublished study) was conducted in the area of Bothel (Landkreis Rotenburg, in the Lower-Saxony, region of Germany[7]) where oil and gas exploration and exploitation has been conducted. The study design corresponds to a cluster investigation, with haematological cancers being the health outcome in focus. The incidence of cancer in the Bothel area for the period 2003-2012, based on the data collected by the cancer register of Lower-Saxony, shows that 41 incident cases of leukaemia and lymphoma were observed in men, for an expected number of 21.3 (standardised incidence rate, SIR, 1.93, 95% confidence interval 1.38-2.61); for women, the number of observed cases was 15, for an expected number of 16.8. After using a Bonferroni-Holm correction for multiple testing, the increased incidence observed in men for leukaemia and lymphoma was considered to be statistically significant. There was no strong evidence of any major increased incidence rate for any of the other cancer types considered nor for leukaemia and lymphoma incidence in women. A more detailed analysis of the subtypes of leukaemia and lymphoma cases in men shows that an increased incidence was in particular noticeable for multiple myeloma and non-Hodgkin lymphomas. Based on currently available information, no assessment of exposures has been published nor has any etiological epidemiological study relating the incidence of cancer cases to some proxy of exposure, but such studies are planned. The design of this study stands in contrast to the American studies that investigate the health status of citizens living around oil and gas exploration and exploitation sites, whereas the starting point of these other studies is the presence of the industrial site, whose potential health effects are investigated. In the Bothel study, the event initiating the study was the suspicion of a cancer cluster (i.e., spatiotemporal aggregation of cases), leading to further investigations of its potential causes. Generally, cluster investigation in relation to environmental risks is a challenging task, with strong limitations, in particular in terms of the ability to control for false positive findings (Goodman *et al.,* 2012). For these reasons,

[7] https://www.nlga.niedersachsen.de/startseite/umweltmedizin/umweltepidemiologie/krebsclusteruntersuchungen/krebsclusteruntersuchung_samtgemeinde_bothel/krebsclusteruntersuchung-in-der-samtgemeinde-bothel-157055.html

the evidence presented in this study regarding the possible link with oil and gas exploration and exploitation activities is much weaker than that presented in the other studies discussed in this section.

A third study was conducted in Europe and appeared so far in the form of a report (Bianchi F – coordinator)[8]. It was conducted around the cities of Viggiano and Grumento Nova, in the Val d'Agri area (Basilicata region in Southern Italy), where an oil refinery and several extraction wells are located, making it one of the largest oil fields in Europe. In addition to studies of air pollution emission and dispersion, the study compared the mortality rates in the 2000-2013 period, between the two towns of Viggiano and Grumento Nova and either the rest of Basilicata region or other 20 towns of the Val d'Agri area. Compared to both control populations, the standardized death rates for diseases of the circulatory system were increased in the cities of Viggiano and Grumento Nova, particularly among women. In a further analysis for the period 2000-2014, the population of the two towns was classified according to the level of exposure to nitrogen dioxide, used as an indicator of the overall exposure to emissions, previously assessed through an historical analysis and a dispersion model. The risk of death and hospitalizations for cardiovascular and respiratory diseases were associated with emissions of nitrogen oxides from the oil refinery. Both these excess risks were more frequent among women. Two additional investigations were carried out in the same populations, assessing the respiratory function and symptoms as well as the perception of risk. A higher frequency of cough, allergies and eye symptoms was observed in the population that was most exposed. The survey on risk perception also revealed a high level of concern and anxiety among people living in the area. In the small population of the two towns, the difference observed did not reach the level of statistical significance. Few details are provided in the report that was made available to the SCHEER to closely scrutinize and assess the quality of these studies in Val d'Agri.

In the following paragraphs, a description of the studies conducted outside the EU on the potential impact on cancer incidence is provided.

In an ecological study, Fryzek *et al.* (2013) described the incidence rates of childhood (until the age of 20 years) cancers in Pennsylvania counties in the 1990-2009 period.

The design compared standardised incidence rates (SIR) of cancer (grouped as all cancers, leukaemia and Central Nervous Systems (CNS) tumours) between areas with hydraulic fracturing sites and areas without any; comparisons were done both before and after the start of drilling activities.. Before the start of drilling activities, the incidence rate of all cancers in counties where an oil or gas exploration or exploitation site was eventually set up was lower than in the other counties in the state (SIR, 0.94, 95% CI, 0.90 to 0.99). After the start of drilling activities, the SIR in counties where an oil or gas exploration or exploitation site had been set up was 1.02 (95% CI, 0.98 to 1.07). When considering childhood leukaemia only, the corresponding SIRs were 0.97 before drilling (95% CI, 0.88 to 1.06) and 1.01 after drilling (95% CI, 0.92 to 1.11), while for CNS tumors, SIRs were 0.89 before drilling (95% CI, 0.79 to 0.99) and 1.13 after drilling (95% CI, 1.02 to 1.25).

It would have been relevant for the authors to make within-county comparison of incidence rates between the before and after the start of hydrocarbon exploration and extraction activities studies, rather than distinct spatial comparisons before and after the start of drilling activity; indeed, the most relevant comparisons with the data at hand correspond to

[8] www.comune.grumentonova.pz.it/docvar/Sintesi_VIS_VdA_092017.pdf

the changes between, before and after the start of drilling activities in given locations. The corresponding SIRs (after the start of drilling vs. before the start) correspond to approximately 1.09 for all cancers, 1.13 for leukaemia and 1.27 for CNS tumours. We believe that this does not warrant the authors' conclusion that "The study offers comfort concerning health effects of [hydraulic fracturing] on childhood cancers".

In a case-control study in Colorado, McKenzie *et al.* (2017) investigated the association between leukaemia risk until age 24 and proximity to an oil or gas well. The study relied on 87 acute lymphocytic leukaemia cases, 50 non-Hodgkin lymphoma cases and 528 controls. Exposure to oil and gas well was assessed as the inverse distance weighted number of wells in a 16.1 km radius around the home of each case, taking into account a latency period of up to 10 years. Oil and gas wells are likely to emit several compounds known to be toxicants of the hematologic cell line, such as benzene and other hydrocarbons. The study was restricted to rural areas and towns with less than 50,000 inhabitants. Controls were randomly selected from the same cancer registry from which cases had been identified, but with a non-hematologic cancer. In the 0-4 years age group, there was no clear evidence of a monotonic increase with the inverse distance-weighted number of wells around the home; in the 5-24 years age group, the risk of acute lymphocytic leukaemia increased with the exposure metric, with a monotonic trend, with an adjusted odds-ratio of leukaemia of 4.3 (95% confidence interval, 1.1-16) in the highest exposure quartile, compared to the group of children with no oil or gas well within 16.1 km from home.

Finally regarding cancer, a study in Ecuadorian Amazon considered cancer incidence in 4 provinces in the 1985-98 period (Hurtig and San Sebastian, 2002). In these areas, the incidence rate of cancer in 4 counties where oil exploitation had been conducted for 20 years or more was compared with that in 11 counties without oil exploitation. Although the area lacked a cancer registry, authors indicate that cancer cases occurring in these areas have been referred to Quito, where a cancer registration exists. Increased risks were observed in the areas with oil exploitation compared to without oil exploitation for the following cancers: stomach, rectum, skin melanoma, kidney, soft tissue (in men); cervix and lymph nodes (women); hematopoietic cancers (children below 10 years of age).

The strength of the overall epidemiological evidence regarding an increased incidence for haematological cancers in the vicinity of oil and gas exploration and exploitation sites may be classified as "weak to moderate", following the classification proposed by the SCHEER (2018)[9].

4.5.3 Birth outcomes

Casey *et al.,* (2016) conducted a retrospective cohort study including 9,384 mothers linked to 10,946 neonates born in 2019-2013). Exposure to air pollutants, polluted water and psychosocial stress can be generated by unconventional gas development. As a proxy of all these different potential pathways, an index taking into account characteristics of the well, length of operations, type of operation, distance from the mothers' residences and other variables was developed to characterise directly or indirectly the potential risk. Values of the index were classified in quartiles and quartile 1 was used as reference.

[9] In the SCHEER proposal, the overall Weight of Evidence is classified in five classes: Strong, Moderate, Weak, Uncertain, Not possible.

Analyses were adjusted for a number of covariates including personal characteristics, including socio economic status. The outcomes were birth weight, gestational age, Apgar score preterm birth and Small for Gestational Age (SGA) risks. There was an association between a high exposure index value and preterm birth, with evidence of a trend with increasing exposure. An association was also observed for the occurrence of "high-risk" pregnancy. The association was more evident in the most recent years, when the gas operations became more extensive and widespread. No statistically significant association was observed with birth weight or Apgar score.

This is a well-designed study which classifies exposure to onshore hydrocarbon exploration and exploitation activities in a very detailed way through an index dependent on the presence and activities of hydrocarbon. Adjustment for socio economic factors (one of the powerful predictors of preterm birth in the USA) is done through a measure of socio-economic status.

McKenzie *et al.,* (2014) conducted a retrospective cohort study of 124,842 births that occurred in rural Colorado between 1996 and 2009. The associations of exposure to air pollutants, including particulate matter (PM), but also volatile organic compounds (VOC) such as benzene, with several adverse pregnancy outcomes have been characterised. Exposure was calculated by an inverse distance weighted (IDW) approach: a score summing up the number of (gas or oil) wells and the distance within a 10-mile radius of the residence of each mother was calculated. Mothers without any well within the 10 miles were chosen as reference. Exposure was classified in tertiles compared to the reference group. A number of sociodemographic variables (age, education, etc.) were used to correct for potential confounding. The health outcomes considered were three large birth defects groups (congenital heart defects, neural tube defects and clefts), low birth weight, gestational age, and average weight. Subjects in the highest exposure tertile were at increased risk of CHD and, less clearly, neural tube defects. No association of the exposure proxy was highlighted with clefts occurrence and low birth weight risk. Exposure to benzene and PM was considered as a plausible explanation for the association with congenital heart defects.

This is a well-designed large study which classifies exposure essential by distance from the wells and their number. Although the authors adjusted their estimates for traditional measures of socio-economic status and pregnancy-related risks (age, parity), this adjustment could not fully take into account other potential issues which could lead to misclassification such as pregnancy termination due to early diagnosis or spontaneous abortion. Birth defects were grouped in large categories, which may dilute any association with a specific disorder (see table 4 in the paper, which seems to suggest this). The lack of association with LBW, described in other studies, might be explained by limited statistical power and/or exposure misclassification. The study suggests a possible association of significant public health importance. Future studies should improve exposure assessment and better assess confounding. The small incidence of birth defects and their heterogeneity may make any replication particularly challenging.

Stacy *et al.*, (2015) conducted a retrospective birth cohort analysis, based on the birth certificate data from three Pennsylvania counties. The population included about 15,000 deliveries that took place between 2007 and 2010. Exposure was assessed from the inverse- distance weighted number of wells within a 16.1 km radius from the home address, like in McKenzie *et al.* (2014). There was no association between distance to gas wells and preterm delivery risk, while the risk of small for gestational age births increased between the first and fourth exposure quartiles.

An adverse association was also observed between the inverse-distance weighted sum of active wells around the home and the risk of preterm birth in a retrospective birth cohort among about 159,000 births in North Texas (Barnet Shale) (Whitworth *et al.* 2017); similarly to the study by Casey *et al.* (2016), no association with birth weight was observed.

In addition, Whitworth *et al.* (2018) conducted a case-control study on preterm birth risk in Texas, apparently based on the same population as the study by Whitworth *et al.* (2017). The study included about 167,000 newborns from the Barnett Shale area that occurred in 2010-2012. After adjustment for maternal education, smoking, ethnicity, parity, age, timing and frequency of prenatal care, the risk of preterm delivery tended to increase with an inverse squared distance weighted count of wells. Given the fact that both studies (Whitworth *et al.,* 2017; 2018) seem to rely on the same population with a different design and protocol, these two studies should not be considered to bring independent information and should be interpreted with caution.

Balise (2016) conducted a systematic review that identified 45 original published research articles related to oil and gas extraction activities and human reproductive endpoints.

Overall, the results of these studies point towards moderate evidence for an increased risk of preterm birth and a weak evidence for birth defects. The evidence is low and/or inadequate for stillbirths and low birth weight incidence.

4.5.4 Respiratory health and other outcomes

Respiratory health

In a case-controls study, Rasmussen *et al.* (2016) tested the hypothesis of an increased risk of asthma exacerbation in association with living close to unconventional gas development. The population consisted of all subjects with asthma, aged 5 to 90 years and treated at a single clinic from Pennsylvania between 2005 and 2012. The health outcome considered was asthma exacerbation (mild, n=20,749; moderate, n=1870, and severe, n=4782), controls corresponding to asthmatic subjects without exacerbation. Exposure was assessed as an activity metric taking into account the activity of the well (pad preparation, drilling, stimulation [hydraulic fracturing, or "fracking"], and production) at the time of occurrence of asthma exacerbation, distance between the home and the closest well, and the duration of the phase of activity of the well. Out of the 12 associations tested (4 types of well activity times three levels of asthma exacerbation), 11 corresponded to deleterious associations. For half of the associations tested, the exacerbation odds-ratios increased across exposure tertiles.

In a cross-sectional study in Washington county (Southwestern Pennsylvania), Rabinowitz *et al.* (2015) recruited 492 people following a random geographical sampling. The health status was assessed by questionnaire, and covered several types of diseases, including skin and respiratory diseases. The exposure metric corresponded to the presence of a well of active natural gas drilling within 1 km from the home. The number of health symptoms reported was higher for subjects living less than 1 km from a well. Specifically, the probability of declaring a skin condition or upper respiratory airway troubles was increased in association with living less than 1 km from a well. This study is limited by its cross-sectional design, the lack of specific hypothesis related to a given medical condition with strong *a priori* (which is why the authors considered this study a hypothesis-generating one) and, most importantly, the potential for declaration bias. Authors attempted to correct for the latter bias by statistically adjusting for awareness for environmental risk. This study is clearly based on a design less robust to bias than that of most of the other epidemiological studies considered here.

The strength of the overall evidence regarding an increased risk of asthma exacerbation in association with living close to unconventional gas development, may be classified as "weak", following the classification proposed by the SCHEER (2018).

Exposure to noise

Two studies (Boyle MD, 2017; Hays J, 2016) reviewed the potential impact of noise produced by oil and gas exploration and exploitation sites on health. In particular Boyle *et al.* conducted a pilot study to assess exposure levels in 11 locations in West Virginia while Hays reviewed the published literature on the issue. Both studies indicate that living in the proximity of UOD sites can result in high levels of noise exposure.

Chronic noise exposure causes various health effects. Besides consequences on hearing capacity and increase of deafness risk, proven impacts include sleep deprivation (which is itself a strong risk factor for many chronic diseases such as metabolic diseases, including diabetes) and cardiovascular effects (Basner *et al.,* 2014).

Hospitalization rates

The relationship between total inpatient prevalence rates and number of admissions for 25 medical subcategories with well numbers (per zip code) and density (wells per km^2) was examined in three Pennsylvania counties during 2007–2011 (Jemielita *et al.,* 2015). There had been a large increase in oil and gas exploration and exploitation development in two of the counties during this period, while the third county was deprived of wells. A Poisson time series analysis was performed, correcting for multiple comparisons and taking into account the date of the start of operation of each well. The total population was 157,311, and almost 93,000 inpatient records were identified. Cardiology inpatient prevalence rates were significantly associated with well numbers and density, while neurology inpatient prevalence rates were significantly associated with wells density only. While this study involved a large resident population, there are limitations, most of which are recognised by the authors. While population demographics were similar by county, there was no control for smoking, a key confounder for cardiology inpatient prevalence. Most wells appear to have been established in the last year of the study that covered a relatively short period, and there was considerable variation in the number of wells by zip code adding to the potential for exposure misclassification that affects all studies with no direct measure of exposure.

Werner *et al.*, (2017) examined hospitalisation rates as a function of gas extraction activities in Queensland, Australia, during the period 1995–2011. Admissions data were examined by gas well numbers, which served as a proxy for development activity. Time series models were used to assess changes in hospitalisation rates for periods of "low", "medium", "high", and "intense" activity, compared to a period of "very low" activity, adjusting for covariates. "All-cause" hospitalisation rates increased monotonically with increasing gas well development activity in females (324.0 to 390.3 per 1000 persons) and males (294.2 to 335.4 per 1000 persons). Hospitalisation rates for "blood/immune" conditions generally increased for both sexes but not for "circulatory" conditions that actually decreased with increasing gas extraction activity. Hospitalisation rates were generally low for reproductive and birth outcomes and no clear associations were observed with these outcomes. This time-series study showed that some outcomes were statistically associated with increasing gas development activity. However, the data about the population and outcomes were aggregated by broad geographic area, which may have diluted associations as in any time-series study.

Peng *et al.* (2018) modelled the yearly hospital admissions for specific causes at the county level in Pennsylvania (Marcellus shale) between 2001 and 2013, relying on a difference-in-difference approach corrected for county-specific temporal trends that may exist independently of oil and gas extraction activities and for county characteristics including population size. Information on well presence in each county at each year of the study period was retrieved. Hospitalization rates for acute myocardial infarctus, asthma, chronic obstructive pulmonary diseases, upper respiratory infections and pneumonia above 5 years of age were modelled separately. There was evidence that admissions for pneumonia increased with the presence of a well in the county. When examined by age group, the association was obvious only for the age group above 65 years, where the number of cases was much larger than in the younger age groups.

The strength of the overall evidence regarding an increased risk of hospitalizations for certain diseases in association with living close to unconventional gas development, may be classified as "uncertain", following the classification proposed by the SCHEER (2018).

Community impacts

The evidence reviewed on the wider implications of onshore oil and gas exploration and exploitation activities on health was primarily qualitative. This identified ambivalent views in the studied communities regarding the perceived positive and negative impacts of onshore oil and gas exploration and exploitation development. It focused on self-reported concerns, anxieties and stress reported as being associated with onshore oil and gas exploration and exploitation activity including: traffic-related impacts (noise, accidents, air pollution, community severance, and access to services); housing availability; environmental degradation; loss of community identity, control and social capital; increased demands on local services; and inequalities in the distribution of impacts, especially on those with existing poor health. Beneficial impacts cited by communities included: economic benefits; increased training and employment opportunities; prospects for higher quality jobs and higher incomes; investment and improvements in local infrastructure and service provision. Although these topics are relevant as wider determinants of health, the published evidence lacks quantified estimates of actual direct or indirect health impacts associated with onshore oil and gas exploration and exploitation activities.

4.5.5 Overall assessment of the epidemiological evidence

The strength of the overall epidemiological evidence regarding an increased risk for hematological cancers, preterm birth, asthma exacerbation in the vicinity of oil and gas exploration and exploitation sites, may be classified as "weak to moderate", following the classification proposed by the SCHEER (2018)[10].

Monitoring the health of the general population living in the vicinity of hydrocarbon exploration and exploitation sites would be easier if disease registries existed, but they are not available for most diseases in many of the EU countries; an important exception is found in the Scandinavian countries, where cancers and many other chronic diseases are monitored through registers at the national level. However, these countries represent a small proportion of the EU population, and in most remaining countries, registries exist only for cancer, and sometimes congenital malformations, and often exclusively in specific regions of each country, where a systematic data collection and follow-up is carried out. However, monitoring of disease occurrence is not enough to allow for causal inferences since epidemiological studies, also require accurate data on environmental exposures, which are numerous in the case of gas and oil exploration and exploitation sites. This means that, unless strong support is given to research and monitoring institutions (implying the setting up of cohorts, the development of biomonitoring surveys and biobanks, the collection and harmonization of healthcare data), there will not be a scientifically valid follow-up of the population living around gas and oil exploration and exploitation sites to assess the presence of adverse outcomes associated to these sites.

As underlined above, exposure assessment is a major issue and cannot be based only on proxy measures. Any new studies to assess the association between oil and gas on shore development and health effects in the populations, should use more specific methods to quantify, qualify and characterise exposure and assess possible confounding factors. Biomonitoring initiatives at the EU level might have some relevance for documenting exposures and performing health impact assessment studies. An example of such a large biomonitoring study that is ongoing at the time of this report is the EU Human biomonitoring Initiative (HBM4EU); it is, however, unclear if individuals living in the vicinity of oil and gas exploration sites will be sampled and if relevant compounds will be assessed. Moreover, one has to keep in mind that, for a number of compounds possibly emitted by oil and gas emission sites such as VOC, measurements in the air would probably be one of the most efficient approaches given the very short half-life of most VOC in the human body.

Biomonitoring studies need to be conducted in Europe, starting before the site openings, as well as high quality studies on the environmental levels of the compounds and factors known to be emitted by gas and oil exploration sites, with a good spatial and temporal resolution. These would make it possible to conduct health impact assessment studies. Cohorts with semi-individual or personal exposure assessments would also be relevant given the large number of adverse health effects possibly induced by these aggregated exposures.

4.5.6 Conclusions and recommendations

Overall, the existing epidemiological studies provide weak to moderate evidence that onshore oil and gas exploration and exploitation entails a health risk for the general population, and point to specific endpoints, such as preterm births,

[10] In the SCHEER proposal, the overall Weight of Evidence is classified in five classes: Strong, Moderate, Weak, Uncertain, Not possible.

hematological cancers and asthma exacerbations in populations living in the vicinity of oil and gas exploration and exploitation sites.

Proficiently designed epidemiological-quality studies, with improved (personal or semi-individual) exposure assessment and a large enough population size, would be required to confirm or infirm the limited evidence brought by the existing published research.

4.6. Health impact assessment studies

Health impact assessment studies typically rely on an assessment of exposure (or of the increased exposure to specific compounds incurred by the industrial site) in a population near a site of interest, combined with knowledge from existing literature on dose-response functions for specific health outcomes, making it possible to estimate the expected number of disease cases attributable to the environmental exposures considered, assuming that the dose-response function is applicable to the study area. This makes it possible to directly assess health data and conduct follow-ups with the population involved, but the validity of the result relies on that of the dose-response function, and this approach cannot be used to generate new hypotheses regarding health outcomes which have not yet been considered in relation to the exposures of interest.

Several health impact assessment studies have been conducted in the USA. McKenzie *et al.,* (2012) addressing chronic and sub chronic health risks among residents living in the vicinity of an unconventional natural gas development project in Garfield County, a rural area in Colorado (USA). They relied on the US EPA methodology to estimate non-cancer hazard indices and excess lifetime cancer risks for exposure to hydrocarbons (other exposures have not been considered). Authors used air quality monitoring data collected in 2008-2010 and dose-response functions from the US-EPA IRIS (Integrated Risk Information System) or CalEPA for carcinogens. For non-carcinogenic substances, a hazard index was calculated for each health effect considered (neurological, respiratory, haematological and developmental)) defined as the sum of hazard quotients (ratio between an estimated exposure concentration and a reference concentration, also generally obtained from EPA IRIS). Measurement sites were categorised according to their distance from well-pads (below or above half a mile) and according to whether the closest well-pad was an unconventional natural gas development site or a well-completion site. Population exposure was estimated assuming a 20-month phase of well completion (based on the well-completion sites measurements) followed by 340 months of well exploitation (based on the natural gas development area samples), using the 95% upper confidence limit of the mean concentration among all measurement sites in the same category.

Regarding non-cancer risks, the highest risk was estimated for neurological effects, with a hazard index of 0.3 for residents living more than ½ mile from a well and of 0.9 for residents living less than ½ mile from a well. Quoting from the study, “for residents living less than ½ mile from a well, trimethylbenzenes (45%), aliphatic hydrocarbons (32%), and xylenes (17%) are primary contributors to the chronic non-cancer HI, and tri-methylbenzenes (46%), aliphatic hydrocarbons (21%) and xylenes (15%) also are primary contributors to the subchronic Hazard Index.” The greatest hazard index corresponded to the well completion period.

For cancer, the cumulative (over 30 years) cancer risk was 6 in a million for residents further than ½ mile from wells, and 10 in a million for residents less than ½ mile from a well.

Overall, the strengths of this study include the reliance on measurements both close and further away from natural gas sites, both during the development and exploitation phases, and the use of a hazard index approach that allows combining risks for a given type of effects from different compounds. It is limited by the lack of consideration of routes of exposure other than inhalation, which is likely to have led to an underestimation of risk, and by the fact that there was no estimation of air concentrations at the home address of the citizens, leading to a rather simple (binary) categorisation of areas as being close or farther away from natural gas development wells.

Bunch *et al.,* (2014) studied the potential impact of shale gas exploration and production (E&P) in the area of the Barnett Shale, in north-central Texas (USA), in the context of a study supported by the Barnett Shale Energy Education Council and performed by private contractors. This area is one of the largest, most active onshore gas fields in North America, at least as of 2011. They used data on the concentration of air contaminants deriving from an extensive air monitoring network in the region developed by the Texas Commission on Environmental Quality. The study aimed to evaluate the community-wide exposures to six volatile organic compounds (VOCs) in the Barnett Shale region and their potential impact on health. About 4.6 million data points from seven monitors at six locations were analysed, mostly for the period 2010-2011: for a couple of monitoring stations the records dated back to 2000. Time trends showed a downward concentration of benzene concentrations over time in the 1997-2011 period. Measured air concentrations were compared to federal and state health-based air comparison values (HBACVs) to assess potential acute and chronic health effects. Contrary to the study by McKenzie *et al.,* (2012), the main approach (deterministic risk assessment) relied on a compound-by-compound consideration of the substances. In an additional approach (probabilistic risk assessment), a hazard index integrating the exposures of the six VOCs was built. None of the measured VOC concentrations exceeded applicable acute HBACVs. Only one chemical (1.2-dibromoethane) exceeded its applicable chronic HBACV, but this chemical is not known to be associated with shale gas production activities. Annual average concentrations were also evaluated in deterministic and probabilistic risk assessments; risk estimates were in the $1.2x10^{-6}$ to $1.3x10^{-4}$ range for the estimate based on "reasonable maximum exposure", showing heterogeneity between areas (with a ratio between areas of up to 72). Authors indicate that the highest risk values were driven by a high proportion of non-detected values for 1,2-dibromomethane, and a relatively high detection limit for this compound. The authors concluded that the shale gas production activities have not resulted in community-wide exposures to those VOCs at levels that would pose a health concern.

This is a large exposure assessment study without any measure of the actual health outcomes potentially associated with emissions from oil and gas onshore operations. The probability of occurrence of health impacts were evaluated using reference values applied by national agencies. This approach was meant to evaluate both the impact of complex mixtures and the occurrence of health effects at low concentrations. Only six substances belonging to a specific group of substances (VOCs) were considered and no other relevant contaminants was mentioned or analysed. Specifically, only some of the substances identified as being of highest concern in the McKenzie (2012) health impact assessment were not considered here (trimethylbenzenes, aliphatic hydrocarbons and xylenes, with xylenes being the only one considered by Bunch *et al.*) The methodology consisting of comparing concentrations of compounds to reference values individually assumes a lack of effect of the compounds below the reference value; this approach further assumes that mixtures have no effects beyond those predicted from the individual compounds they are made of, even if they affect the same pathway. In this regard, this approach is much more conservative than the hazard index approach used e.g. by McKenzie *et al.,* (2012). The quantitative risk assessment estimates should be interpreted with caution given the issues related to the high limit of detection for 1.2-dibromomethane; although authors interpret it as showing that most of the risk estimates were in a range considered acceptable by guidelines from the US-EPA (1 in 1 million to 1 in 10,000), one can note that it shows ratios of risks of up to 72 between the 7 considered areas under one of the risk scenarios.

Another recent health impact assessment study by McKenzie *et al.* (2018) relied on the assessment of the atmospheric concentrations of non-methane hydrocarbons in Colorado (USA). The atmospheric concentrations of benzene and other volatile organic compounds tended to decrease with distance from oil and gas exploration or exploitation sites. As a result, cancer risk tended to increase with increasing vicinity from such sites, as well as the risk for neurologic, blood system and developmental effects, in particular for subjects living within about 150 m from oil and gas exploration and exploitation facilities. In this assessment, among the compounds assessed, benzene was the one most strongly contributing to the increased risk.

In addition, Public Health England (2016) has published a comprehensive assessment of the scientific evidence. The Committee in charge of this assessment took into account non-epidemiological evidence, epidemiological studies and qualitative evaluations looking at the social and personal impacts as well as the perceptions of populations living in the areas close to oil and gas exploration and exploitation activities.

The evidence was assessed using a standardised approach and categorized as being '**sufficient**', '**limited**' or '**inadequate**', as a basis to establish associations between hydrocarbon exploration and exploitation sites-sourced risks and potential health impacts[11].

The overall conclusion of this HIA was that there was insufficient evidence to determine whether the development of shale oil and gas or coal bed methane, if permitted in Scotland, would pose a risk to public health. Specific conclusions were drawn on particular types of hydrocarbon exploration and exploitation-related hazard and specific types of health outcomes, which are summarised in table 1 below.

[11] **'Sufficient'** evidence defined where published evidence showed that the role of unconventional oil and gas exploration and exploitation as the source of a hazard or health risk could be established unequivocally and where there was no doubt that an effect had occurred, or it could be confirmed that exposure at hazardous levels could occur.

'Limited' evidence defined where confounding factors or random, systematic or logical errors were not adequately accounted for to allow demonstration of a health risk.

'Inadequate' evidence defined where the published evidence was judged not to be of adequate quality, consistency or statistical power to demonstrate a health risk.

'Adequate' evidence of no health risk defined where published evidence demonstrated convincingly that no effect was associated with exposure to a onshore oil and gas exploration and exploitation.

Table 1: Level of evidence regarding specific health outcomes resulting from oil and gas extraction (Public Health Scotland, 2016)

	Level of evidence		
Health outcome	**Inadequate**	**Limited**	**Sufficient**
Overall evidence on risks for health	X		
Exposure to airborne and waterborne hazards			X
Seismicity and risk to physical health	X		
Workers' exposure to crystalline silica			X
Risk to health associated to VOC, ozone, waterborne dissolved solids and metal ions		X	
Other chemical hazards, noise, odour-associated risks to physical health	X		
Effects on reproductive and developmental health, childhood cancer, adverse neurological, cardiovascular and dermatological outcomes	X		

Conclusions

A few rigorous quantitative health impact assessment studies have been conducted around oil and gas exploration and exploitation sites. One study observed increased exposures for specific chemicals for the population living closest to the oil and gas exploration and exploitation site and reported an increased risk of adverse health effect, while another one in which no increased exposure was identified reported no increased health effect, without considering many of the *a priori* relevant chemicals. A broad national review carried out through a vast analysis of the existing literature confirms the presence of potential health impacts and wider health implications, although the evidence is lacking in quantity, quality and consistency.

Overall, the existing health impact assessment studies provide weak to moderate weight of evidence regarding a possible increase of hematological cancers in relation to vicinity to onshore oil and gas exploration and exploitation activities, which is coherent with the evidence presented in epidemiological studies. For other cancers, the evidence is inadequate.

Future quantitative health impact assessment studies would need to rely on measurement and/or modelling of a variety of chemicals (justifying their strategy regarding the selection of chemicals and any sampling of measurement sites in time and space) at various phases of sites development (including the exploration phase), and to consider their cumulative health effects.

5. CONSIDERATION OF THE RESPONSES RECEIVED DURING THE CONSULTATION PROCESS

A public consultation on this opinion was opened on the website of the non-food scientific committees from 22 March to 6 May 2018. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

A total of twenty-eight submissions from 5 contributors (providing more than 80 comments and 20 documents) provided input to different chapters and subchapters of the opinion. The vast majority of comments came from industry.

Each submission was carefully considered by the SCHEER and the scientific opinion has been revised to take account of relevant comments. The literature has been accordingly updated with relevant publications.

The SCHEER expresses its thanks to all contributors for their comments and for the literature references provided during the public consultation.

The text of the comments received and the response provided by the SCHEER is available at:

https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_07_en

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7. LIST OF ABBREVIATIONS

BTEX	Benzene, toluene, ethylbenzene and xylenes
CLP	Classification, Labelling and Packaging of chemical substances and mixtures regulation
CMR	Carcinogenic, mutagenic and reprotoxic substances
CNS	Central Nervous Systems
DBP	Disinfection by products
HBACV	Health-based air comparison value
HIA	Health impact assessment
IDW	Inverse distance weighted
JRC	Joint Research Centre (EU)
NORMs	Naturally occurring radioactive materials
PAH	Polycyclic aromatic hydrocarbons
PBT	Persistent, bioaccumulative and toxic
PCB	Polychlorinated Biphenyls
PM	Particulate matter
QSAR	Quantitative structure–activity relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EU Directive)
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SGA	Small for Gestational Age
SIR	Standardized incidence rates
UnGD	Unconventional natural gas development
VOCs	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative
WWTP	Wastewater Treatment Plant