Biodiversity Series

An Overview of the Environmental Impact of Non-Wind Renewable Energy Systems in the Marine Environment

OSPAR Commission
2006

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.

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Executive Summary/Récapitulatif

Considerable effort has been invested in the engineering aspects of the development of coastal and offshore energy generation devices with minimal investment to consider the potential environmental impact of installing such devices. This document presents an initial overview on marine renewable energy sources other than wind-farms and their potential environmental impacts.

Des efforts considérables ont été investis dans les aspects techniques du développement de dispositifs côtiers et offshore producteurs d'énergie, mais les efforts investis dans l'étude de l'impact environnemental potentiel de l'installation de tels dispositifs sont minimes. Le présent document comporte une synthèse préliminaire des sources marines d'énergie renouvelable, autres que les parcs d'éoliennes, et de leur impact potentiel sur l'environnement.

The overview draws on outputs from workshops and literature and includes short descriptions of the various devices for wave and tidal energy generation. It is not an exhaustive review of all devices but it provides details for most of the prototype technologies currently under development.

La synthèse se fonde sur les résultats d'ateliers et la bibliographie et comporte de brèves descriptions des diverses centrales houlomotrices et marémotrices. Il ne s'agit pas de présenter une étude exhaustive de tous les dispositifs mais de fournir des détails sur la plupart des technologies prototype en cours de développement.

Developers of tidal and wave devices need to provide robust baseline data detailing site specific information in relation to deployment of their devices. They should also consider what environmental monitoring should be carried out in advance as part of the consents process and included in the project costs. At present it is apparent that most monitoring and planning considers only the mechanics of wave and tidal devices and not their potential impact on the marine environment.

Les promoteurs de centrales marémotrices et houlomotrices doivent fournir des données de base solides sur les caractéristiques de l'emplacement en ce qui concerne l'utilisation de leurs dispositifs. Ils étudieront également la surveillance environnementale à effectuer à l'avance dans le cadre du processus d'obtention d'autorisations et en tiendront compte dans les devis. Il est évident, actuellement, que la plupart de la surveillance et de la planification ne porte que sur l'aspect technique des dispositifs et pas sur leur impact potentiel sur le milieu marin.

It is further recognised that there is a need for guidelines on what should be monitored, together with advice on how monitoring should be undertaken, in advance of any commercial deployments of wave and tidal devices. In the UK guidance on the regulatory process is available for a number of analogous industries including offshore wind, dredging and aggregate extraction, all of which are highly regulated and subject to Environmental Impact Assessment. This document is of an informative nature and does not aim at setting guidance to be followed.

In the longer term, regulation of the industry should be governed by the best available scientific knowledge. At present, there are some clear knowledge gaps, which need to be filled to allow good methodologies to be developed, and to inform the regulatory process. The overview identifies generic research which will be required in order to investigate any larger scale environmental impacts, as well as areas requiring further work.

On reconnaît de plus qu'il est nécessaire d'avoir des lignes directrices sur ce qui est à surveiller, ainsi que des conseils sur la manière d'entreprendre cette surveillance, avant de démarrer l'exploitation de centrales houlomotrices ou marémotrices. Le Royaume-Uni dispose d'orientations sur le processus de réglementation pour un certain nombre d'industries analogues, notamment les parcs d'éoliennes, le dragage et l'extraction d'agrégat. Elles sont toutes extrêmement réglementées et assujetties à une évaluation de l'impact environnemental. Le présent document est informatif et n'a pas pour objectif de présenter des orientations à suivre.

Des efforts considérables ont été investis dans les aspects techniques du développement de dispositifs côtiers et offshore producteurs d'énergie, mais les efforts investis dans l'étude de l'impact environnemental potentiel de l'installation de tels dispositifs sont minimes. Le présent

document comporte une synthèse préliminaire des sources marines d'énergie renouvelable, autres que les parcs d'éoliennes, et de leur impact potentiel sur l'environnement.

Dans le long terme, la réglementation de l'industrie sera gouvernée par la meilleure connaissance scientifique disponible. A l'heure actuelle des lacunes évidentes des connaissances doivent être comblées afin de permettre le développement de bonnes méthodologies et d'informer le processus de réglementation. La synthèse détermine les recherches génériques qui devront être effectuées afin d'étudier les impacts environnementaux potentiels à une plus grande échelle ainsi que les domaines qui nécessitent de nouveaux travaux.

1. Introduction

It is widely acknowledged that if non-wind marine energy generation devices (wave and tidal devices) can be successfully developed that they have the potential to make a significant contribution to the Kyoto Protocol renewable energy targets. It is clear that considerable effort has been invested in the engineering aspects of the development of coastal and offshore energy generation devices with minimal investment to consider the potential environmental impact of installing such devices. This manifests itself in the current position in the UK whereby a test centre, the EMEC facility on Orkney, has been consented through based on the findings of an Environmental Impact Assessment. The site consists of and is consented for the necessary infrastructure to test and evaluate prototype wave and tidal energy devices but does have consent for individual prototype devices that may be installed. Individual consents for each prototype device must be sought for the duration of installation. It is apparent that to satisfy this requirement for individual consents it will be necessary to both conduct generic research and derive knowledge from other sectors (principally the offshore wind and oil and gas industry) to fill current knowledge gaps. A second test centre in the south-west of England has also been proposed.

To address a number of these issues it is likely that generic research will be required. It will obviously be necessary to allow the installation of some prototype devices prior to and parallel with generic research in order to investigate any larger scale environmental impacts.

Areas requiring further work are:

- Create a direct link between physical modelling of devices and biological models or data sets.
- The impact on sea-mammals, birds and fish, in particular their interactions with devices.
- Pre, operational and post deployment environmental monitoring programmes with determined boundaries of acceptability, suitable parameters for monitoring, guidelines to be adopted by individual developers and appropriate funding streams for the instigation of such programmes during the testing phase of prototype devices. Monitoring should also make use of best available technology.

This report draws on the outputs from two workshops run by the DTI in the UK on 14 January 2005 and 16 March 2005; a workshop hosted by EMEC/UKERC entitled “Environmental Impacts and Monitoring of Marine Energy Conversion Devices” held on 14th September 2005 and the booklet Wave and Tidal Energy Devices, BWEA 2005 ISBN: 1 87 00065 41 0.

Non-Wind Renewable Energy Devices

Most wave and tidal devices are currently at the prototype development stage although a small number are now approaching sufficient levels of development where more advanced demonstrator projects can be deployed and tested. This section of the report provides a brief overview of some of the prototype technologies under development. It is not an exhaustive review of all devices but provides details for most of the technologies under development.

2. Wave Devices

2.1 AquaBuoy

http://aquaenergygroup.com/

Can be moored as a single device or clusters of several buoys offshore. Power generated can be from hundreds of kilowatts for a small number of devices to hundreds of megawatts for clusters. The device comprises a slack-moored float and a submerged vertical tube, which is open to sea at both its top and bottom. Incident waves cause the device to heave up and down, and sea water to be drawn in and out of the tube. Halfway along the tube is a piston attached to two hose pumps, which contract and expand to provide a pumping effect. The hose pumps and the separate water masses contained within them react against the heaving motion and convert the oscillatory motion into a high-pressure water flow to drive a turbine and generator.

2.2 Archimedes Wave Swing (AWS)

http://www.waveswing.com/

The floating device consists of a submerged telescopic cylinder filled with air, the lower part of the cylinder is attached to the sea bed whilst the upper part oscillates up and down in response to the changing water pressures caused by passing waves. A linear generator converts this relative movement directly to electricity. Commercial scale units are expected to be 12m diameter and 35m height and operate in 65 m water depths. A single device is capable of a continuous output of 1.7 MW in a rough sea and a load factor of 30%.

2.3 Wave Rotor

http://www.ecofys.nl/nl/expertisegebieden/product_systeemontwikkeling/waverotor.htm

Transfers energy from tidal currents and waves directly into rotational motion relying on the principles of hydrodynamic lift. The orbital velocities of waves exert lift forces on vertical (Darrieus) and horizontal (Wells) blades that move around in a common axis. Structures are fixed to the sea bed by monopile foundations.

2.4 SPERBOY

http://www.sperboy.com/

A floating point absorber works from air displaced by the oscillating water column passing through rectifying turbine generators. A 3 megawatt unit is likely to have a diameter of 25m. Can be deployed as a single unit or in arrays of hundreds.

2.5 PS Frog Mk 5

http://www.engineering.lancs.ac.uk/REGROUPS/LUREG/Research%20Home.htm

A point absorber wave energy converter made up of a larger floating paddle and an integral ballasted handle. Oscillations from waves acting on the paddle generates the electricity.

2.6 The GRAMPUS

http://owel.co.uk/grant.htm

Is designed for deployment in offshore sites to take advantage of energetic wave conditions before their energy is attenuated by friction from the sea bed. It needs to be large (approximately 150m in length and 30,000 tonnes in weight) to capture energy from the long lengths of the wave crest and optimized to absorb a large proportion of the energy from small waves. It has a horizontal duct floating such that the freeboard is approximately equal to the amplitude of the ambient waves. Air is trapped by the incoming waves and forced into reservoir via a compression manifold. Air from the pressure reservoir can be used to drive a turbine and generate electricity. Average output anticipated to be 5 megawatts.

2.7 Pelamis

http://www.oceanpd.com/

The Pelamis is an attenuator wave energy converter intended for waters of 50-60m depth. It consists of several cylindrical sections linked by hinged joints, rotation of which is restrained by hydraulic rams. As the converter sections heave and sway, hydraulic oil is pumped at high pressure via smoothing accumulators to hydraulic motors that drive electrical generators. Features of the joint configuration are the ability to increase power capture in small seas and at other times restrict motions and loads for survivability. Other features include a mooring system that allows the converter to maintain its position but also swing head-on into oncoming waves.

2.8 The PowerBuoy

http://www.oceanpowertechnologies.com/technology/

Consists of a large floating buoy anchored to the sea bed.

2.9 Wave Rider

http://www.dhi.dk/FieldAndLab/EquipmentRental/WaveriderGlossary.htm

Consists of a point absorber buoy system designed for water depths in excess of 50m. The freely floating symmetrical buoy is built from steel and concrete with a service life of 20 years and requiring minimal maintenance.

2.10 Wave Dragon

http://www.wavedragon.net/

Two curved 'arms' focus oncoming waves onto a central ramp that the waves travel up and 'overtop' the moored device into a reservoir. At the bottom of the reservoir is a set of low-head hydro turbines, through which the collected water flows back out to sea. The reservoir has a smoothing effect on the water flow, and the turbines are coupled directly to variable speed generators. Since the head of water in the reservoir accounts for the energy, the concept is similar to a hydroelectric power plant.

2.11 Seawave Slot Generator (SSG)

http://www.waveenergy.no/OffshoreInstallation.htm

The concept is based on storing the potential energy of the incoming waves in several reservoirs placed one above the other. The incoming wave will run uphill of the sloping surface and on its return down hill will flow into the reservoirs. After capture in the reservoirs the water runs through the multistage turbine to generate electricity.

2.12 Limpet

http://www.wavegen.co.uk/what_we_offer_limpet.htm

Built into coastlines this device has an inclined oscillating water column that couples with the surge-dominated wave field adjacent to the shore. The water depth at the entrance to the OWC is typically seven metres. The design of the air chamber is important to maximise the capture of wave energy and conversion to pneumatic power. The turbines are carefully matched to the air chamber to maximise power output. The performance has been optimised for annual average wave intensities of between 15 and 25kW/m. The water column feeds a pair of counter-rotating turbines, each of which drives a 250kW generator, giving a nameplate rating of 500kW. Devices are operational on Islay and the Faroes.

2.13 WavePlane

http://www.waveplane.com/

A floating structure. Water entering the device is squeezed through the ducts into the backside of the flywheel tube, where the whole body of water is set into a rotating and flowing motion. The rotation is so forceful that that it continues even after two to three failing waves. Even though the water fed into the WavePlane is pulsating the resulting flywheel ensures an even rotating flow.

3. Tidal Devices

The two main technologies for exploiting tidal power are the use of tidal dams or ocean currents. Dams involve a barrage in a bay or estuaries which have large tidal ranges. The power is generated as the barrage creates a significant head of water, much like a hydroelectric dam. Examples of this technology are at La Rance in France (240MW plant operational since 1966) and Annapolis, Nova Scotia (20MW plant operational since 1984).

3.1 Blue Energy Ocean Turbine

http://www.bluenergy.com/technology.html

Acts as a highly efficient underwater vertical-axis windmill. Four fixed hydrofoil blades are connected to a rotor that drives an integrated gearbox and electrical generator assembly. The turbine is mounted in a concrete caisson which anchors the unit to the ocean floor, directs flow through the turbine thus concentrating the resource supporting the coupler, gearbox, and generator above it. These sit above the surface of the water and are readily accessible for maintenance and repair. The hydrofoil blades employ a hydrodynamic lift principal that causes the turbine foils to move proportionately faster than the speed of the surrounding water. Computer optimized cross-flow design ensure that the rotation of the turbine is unidirectional on both the ebb and the flow of the tide.

3.2 HydroVenturi

http://www.hydroventuri.com/gpage.html

A submarine Venturi is used to accelerate the water and create a subsequent pressure drop which can be made to drive a turbine. The technology does not require impounding large bodies of water to extract energy economically, nor does it require submarine turbines or submarine moving or electrical parts. The technology can be applied to tidal stream, but more obviously also to Run-of-River ('RoR'), existing and future causeways, retrofits of existing hydroelectricity plants and existing and future coastal and riparian civil engineering structures.

3.3 Rotech Tidal Turbine (RTT)

http://www.lunarenergy.co.uk/technology-overview.htm

A horizontal axis turbine using a double venture ducted design to capture and maximize the natural currents of the ocean. The duct accepts flows from both ends to allow for the reverse flow of the tide. A gravity foundation is incorporated to remove the need to pile the device into the sea bed.

3.4 SeaFlow

http://www.marineturbines.com/home.htm

The Seaflow 300kW experimental 11m diameter rotor tidal turbine lies 3km offshore from Lynmouth, Devon, has now been operational for more than two years.

Specific Environmental Issues

Scale of Wave and Tidal Device Installations

When identifying potential environmental impacts, particularly during the consenting process, it is necessary to consider the scale of individual devices and the scale of any array of multiple devices that may be installed. Single devices will have a very different impact to an array, and hence it will be necessary to focus any generic research based on the impacts of these devices in such a way as to take scale into account.

In the short term prototype devices will be initially installed. Such prototypes could be used to investigate impact on birds, mammals and on the sea bed over different temporal scales to account for seasonal effects. It is also apparent that the nature of such assessments is likely to be site specific in many cases irrespective of scale.

Assessment of environmental impacts

In order for developers to produce an appropriate environmental impact assessment of the deployment of prototype devices they request guidance from regulators. Site specific and device specific monitoring is likely to be required as exact knowledge of certain impacts is only likely to be apparent when devices are installed and tested in the water. This leads to the argument that there could be fewer environmental restrictions on the first prototypes to be installed, provided these are adequately monitored. On the other hand it may be argued that the risk to the environment is too great to place a device into an area when the full environmental impact of doing so is not fully understood. It should be borne in mind that the environmental impacts of such devices could be positive.

General Monitoring Issues

The choice of location for renewable energy systems is crucial. For example, sea mammals exhibit different behaviour depending upon the site, and the behaviour changes from year to year. They are unpredictable, which makes monitoring very difficult. Timing of monitoring should be sufficient to highlight these behavioural changes, where this is possible.

The scale of the device and the timing of the installation are also important.

Where appropriate a monitoring programme should consist of three stages i.e. pre, operational and post deployment. Such studies should take into account seasonal variations. However, the purpose and requirements of any monitoring will differ depending upon site and therefore any monitoring requirements would be considered on a case by case basis. Developers consider there is currently a potential conflict as there is a need to deploy devices in the water soon in order to demonstrate technical performance and build investor confidence. It is apparent that developers have not considered the environmental impact of the deployment of such devices, instead concentrating on the engineering implications.

Given that most developers of non-wind renewable energy devices are small scale operations with limited and often insecure financial backing there may be a requirement for some government support for environmental research. Wind exploitation technologies were developed on land where the constraints and overhead costs were much less, this is not a possibility for field testing of non-wind energy devices. This may be of particular relevance to monitoring on a generic level, for example the impact of tidal turbine devices on cetaceans.

Generic and site specific monitoring of potential ‘showstoppers’ associated with deploying prototype devices could form the first tranche of targeted generic monitoring. The largest gaps in knowledge are currently considered to be primarily relating to the impacts on fish and fisheries, birds, Impact on sea mammals, the impact of the energy variation within a tidal channel on the habitat and the restricted access to other marine users. Test centres such as EMEC have a role in determining these impacts from the installation and operation of single devices and later from the trial of small arrays of devices.

Knowledge Gaps

3.5 Ecological Impact and Disturbance to Water Masses

In the UK a number of research groups and institutions are currently working on the ecological impact and water mass disturbance of wave and tidal devices.

- The Supergen consortium is modelling the impact of device arrays on the physical energy resource, but not looking at the ecological impact. The project concentrates on the downstream effects of devices and can model at the device scale.
- CCW and Crown Estates plan to work on determining the impact on of devices on seabed species and predictions based on merging the physical and biological interactions of wave and tidal devices. This work is likely to commence in 2006.
- Aberdeen University has done work linking biology with physical changes in energy flows. This work was carried out in the Forth, and investigated feeding ‘hotspots’ in relation to physical characteristics of sites. The project observed differences in foraging activity of birds, seals and fish as a result of mixing within the water column. The knock-on effects of changes in foraging are unknown. There is clear scope for further investigating the implications of water column mixing as a result of changed energy flow within a system specific to individual devices at test sites such as EMEC.

To further determine the ecological impact of wave and tidal devices in relation to changes in the energy flow associated with such devices, it will be necessary to understand the likely change of energy flow associated with an individual device. In general terms it has been suggested that an individual device can take out 40% of the energy flow from a channel. However, in a simple channel a 20% reduction in kinetic energy flow will lead to approximately a 5% reduction in flow speed and in terms of the energy balance there is very little change as energy within the channel is redistributed (there could be approximately a 0.25% reduction in energy flow). The exact levels of change in energy flow are site dependant but even with such a small change the impact on species is still unknown.

3.6 Colonisation of structures

Work in other sectors shows that any submerged structure will eventually become colonised by marine flora and fauna. It is not known how the generating efficiency of the devices will be affected by this biofouling. The maintenance of the structures may cause disturbance to marine fauna.

3.7 Disturbance to sea bed habitats

At present there is a number of knowledge gaps associated with understanding the impacts on seabed habitat.

- Marine current devices redistribute current flow within a system, which is likely to lead to hot and cold spots in terms of current flow within that specific system. As yet it is not clear what impact this will have and such an impact will predominantly be on a site and device specific level. There is however scope for further research into this area both on the site and device specific level and also linking into changes in energy flow as outlined above.
- The DTI Research Advisory Group is developing studies looking at the consequences of sediment transport and hydrodynamics from non-wind energy devices.
- Guidance is currently available (from Cefas) in relation to offshore wind, which again is likely to be of relevance to the deployment of wave and tidal devices.

3.8 Disturbance to shoreline and landward areas

Work has been carried out in this area already, but would benefit from longer term monitoring of potential coastal effects, particularly in relation to shallow wave devices.

3.9 Behavioural changes in Wildlife and Wildlife Entanglement

The location, scale and timing of devices and their deployment are crucial as the impacts on animal behaviour may differ according to the site characteristics, and may change from year to year. In order to begin to understand the impact of individual devices on behaviour, long term monitoring has to take place before, during and after deployment. In terms of prototype devices, the requirement for such monitoring is considered to provide little incentive to developers who would prefer to test equipment over a much shorter period. Such monitoring is also likely to be particularly site and device specific.

At present, little is known about the behaviour of cetaceans and sea mammals, particularly in relation to underwater structures. Any monitoring would have to take into account the unpredictability of marine mammals as previously mentioned and decisions will have to be made as to whether any useful data can be obtained.

A particular issue in relation to wildlife interaction with wave and tidal devices is the implication of installing animal deterrents around devices to protect against direct strikes. If such deterrents were installed, there may be a number of other consequences associated with the deterrent. Knowledge of the fluid mechanics of tidal devices suggests that animals are only likely to receive a glancing blow from devices, although such blows could lead to later fatalities. Such implications are difficult to measure as part of a dedicated monitoring programme. Tank testing could be undertaken to investigate and demonstrate the impact on floating bodies in a tidal channel with wave and tidal devices installed but full scale monitoring may be prohibitively expensive.

In an analogous area, studies of mammal strikes by high-speed ferries have been shown to be a bigger problem than was first realised. Such studies have produced large amounts of information, which could be of relevance to wave and tidal devices. At present a type of black box recorder is being developed for high-speed ferries to identify strikes. It may be possible to apply such technology to wave and tidal devices. Sonar technology could also be used to determine strikes and impact on devices.

An Engineering and Physical Sciences Research Council project is currently looking at the interactions of devices and impact on marine life. This project aims to look at some generic protection systems which may be attached to devices to minimise strikes.

The temporal effects of a tidal turbine on a local fish and mammal population should also be considered, especially in regard to the spawning season.

3.10 Impacts on conservation areas and protected species

Identification and consideration of protected species and areas are site-specific issues. To minimise the impact on both species and habitats, it is important to site both test and deployment sites carefully and as such programmes such as Strategic Environmental Assessment and marine spatial planning could assist in this process.

3.11 Underwater noise, light and vibration

A number of programmes are currently looking at the impact of underwater noise in relation to marine activity. Developers look to the COWRIE and other funded studies on wind farm related underwater noise for further guidance in this area. Although, this will provide useful information it will not address the fundamental differences in noise that submerged moving parts will have. Further work in this area may be required if the potential impacts are considered likely.

3.12 Electromagnetic and electrical effects

To the work being funded through COWRIE on EMF effects associated with wind farm cables, will inform these and all other sub sea power cables.

3.13 Marine archaeology

COWRIE is about to fund a project producing guidance in relation to impacts of offshore wind on marine archaeology. The British Marine Aggregate Producers Association and Central Dredging Association also have guidance notes available in relation to marine archaeology.

3.14 Navigation sea user interference

Test centres are monitoring vessel movement at their facilities and developers should address issues of adequacy of moorings and exclusion zones around marine devices. Consideration of cumulative impacts of multiple devices should also be included wherever multiple devices are deployed. It should be remembered that there will also be a complex array of subsea power cables on the sea bed, and for certain devices suspended in the water column. Unlike wind farms where the towers above sea level provide a large warning to mariners and which are marked and lit according to international standards, non-wind energy generation devices are submerged and therefore hidden from view. The complex of devices, guy lines, buoys, power cables etc provide a multitude of hidden obstructions below sea level so one can only presume that rights of navigation for all vessels within an array of devices will have to be extinguished. The environmental impact of displacement and possible concentration of fishing activities to other areas must be addressed.

3.15 Seascape and visual impacts

Although many of the devices will be submerged, marker buoys, lighting, possible offshore substations and deployment and maintenance vessels all have the potential to impact other users enjoyment of the marine environment. As such these issues should not be discounted.

4. Summary

Developers of tidal and wave devices need to provide robust baseline data detailing site specific information in relation to deployment of their devices. They should also consider what environmental monitoring should be carried out in advance as part of the consents process and included in the project costs. At present it is apparent that most monitoring and planning considers only the mechanics of wave and tidal devices and not their potential impact on the marine environment.

It is further recognised that there is a need for guidelines on what should be monitored, together with advice on how to do it in advance of any commercial deployments of wave and tidal devices. In the UK guidance on the regulatory process is available for a number of analogous industries including offshore wind, dredging and aggregate extraction, all of which are highly regulated and subject to Environmental Impact Assessment.

In the longer term regulation of the industry should be governed by the best available scientific knowledge. At present, and as highlighted above, there are some clear knowledge gaps, which need to be filled to allow good methodologies to be developed, and to inform the regulatory process.