House of Commons

Science and Technology Committee

Water quality: priority substances: Government Response to the Committee's First Report of Session 2013–14

Fourth Special Report of Session 2013–14

Ordered by the House of Commons to be printed 4 September 2013

HC 648
Published on 12 September 2013
by authority of the House of Commons
London: The Stationery Office Limited
£8.50

Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Government Office for Science and associated public bodies.

Current membership

Andrew Miller (*Labour, Ellesmere Port and Neston*) *(Chair)*
Jim Dowd (*Labour, Lewisham West and Penge*)
Stephen Metcalfe (*Conservative, South Basildon and East Thurrock*)
David Morris (*Conservative, Morecambe and Lunesdale*)
Stephen Mosley (*Conservative, City of Chester*)
Pamela Nash (*Labour, Airdrie and Shotts*)
Sarah Newton (*Conservative, Truro and Falmouth*)
Graham Stringer (*Labour, Blackley and Broughton*)
David Tredinnick (*Conservative, Bosworth*)
Hywel Williams (*Plaid Cymru, Arfon*)
Roger Williams (*Liberal Democrat, Brecon and Radnorshire*)

The following members were also members of the committee during the parliament:
Gavin Barwell (*Conservative, Croydon Central*)
Caroline Dinenage (*Conservative, Gosport*)
Gareth Johnson (*Conservative, Dartford*)
Gregg McClymont (*Labour, Cumbernauld, Kilsyth and Kirkintilloch East*)
Stephen McPartland (*Conservative, Stevenage*)
Jonathan Reynolds (*Labour/Co-operative, Stalybridge and Hyde*)

Powers

The Committee is one of the departmental Select Committees, the powers of which are set out in House of Commons Standing Orders, principally in SO No.152. These are available on the Internet via www.parliament.uk

Publications

The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the Internet at http://www.parliament.uk/science. A list of reports from the Committee in this Parliament is included at the back of this volume.

The Reports of the Committee, the formal minutes relating to that report, oral evidence taken and some or all written evidence are available in printed volume(s). Additional written evidence may be published on the internet only.

Committee staff

The current staff of the Committee are: Dr Stephen McGinness (Clerk); Jessica Montgomery (Second Clerk); Xameerah Malik (Senior Committee Specialist); Victoria Charlton (Committee Specialist); Darren Hackett (Senior Committee Assistant); Julie Storey (Committee Assistant); Henry Ayi-Hyde (Committee Office Assistant); and Nick Davies (Media Officer).

Contacts

All correspondence should be addressed to the Clerk of the Science and Technology Committee, Committee Office, 7 Millbank, London SW1P 3JA. The telephone number for general inquiries is: 020 7219 2793; the Committee's e-mail address is: scitechcom@parliament.uk.

Fourth Special Report

On 13 June 2013 the Science and Technology Committee published its First Report of Session 2013–14, *Water quality: priority substances* [HC 272–I]. On 28 August 2013 the Committee received a memorandum from the Government which contained a response to the Report. The memorandum is published as Appendix 1 to the Report.

Appendix 1: Government response

Water security is key to national well-being. The Government welcomes the report of the House of Commons Science and Technology Committee inquiry into *Water quality: priority substances*. It agrees that issues such as the monitoring of emerging pollutants, the importance of innovation and the need for political support are important for ensuring water security. The Government recognises that a water industry which is innovative and efficient is vital to meet the demands of the future, where increased pressures on water resources will be faced as a result of a growing population and changing climate. To ensure the sector is fit to meet these challenges, the Government has published the Water White Paper, which set out its vision for future water management and a resilient sector, and has recently introduced a Water Bill into Parliament. The Bill will improve resilience by, for example, encouraging the development of new water sources or innovative treatment methods, and by making it easier for water companies to sell water to each other so they can continue to provide water during droughts.

Since the Committee completed gathering evidence, agreement in principle has been achieved at first reading on the European Commission's Priority Substances proposal. The Government is pleased to see that the UK's lead in resisting inclusion of three substances (estradiol, E2, naturally produced as well as used in medicines; ethinylestradiol, EE2, used in the contraceptive pill; and diclofenac, used as an anti-inflammatory) owing to high costs but with a weak benefits case at the current time, was supported by other Member States and the European Parliament. These substances were deleted from the list of priority substances and instead put on a "watch list" for gathering information over their occurrence across the EU. The Government supports this evidence-based approach which should assist in improving the assessment of emerging contaminants.

The Government was also pleased to see that its calls for a more strategic approach towards pharmaceuticals in the environment be taken by the European Commission were reflected in the final proposal text. Greater clarity on the relationship between legislation controlling the sources of chemicals, such as REACH[1], Plant protection products[2] and Biocides[3], and the Water Framework Directive[4] was also set out in the amended proposal.

[1] EC No. 1907/2006

[2] EU No. 1107/2009

[3] EU No. 528/2012

[4] 2000/60/EC

Response to conclusions and recommendations

1. There is clearly cause for concern about the presence of the pharmaceutical substances ethinyl oestradiol, oestradiol and diclofenac in the aquatic environment. These chemicals have been shown to affect the health of aquatic organisms. However, a link to wider population-level effects is difficult to establish for any chemical so we agree that the watch list should be used to gather further evidence on their environmental impact. The Government must consider whether the burden of proof it expects to support designation of these chemicals [E2, EE2 and diclofenac] as priority substances is reasonable. These substances may not be appropriate for designation as priority substances at this time, but their regulation in future should not be ruled out. We recommend that the UK Government should contribute to the collection of further information regarding the environmental impact of these pharmaceuticals on the aquatic environment. The Government should set out how it intends to provide the evidence necessary to clarify the environmental harm caused by these chemicals in the UK in its response to this report. The Government should reconsider adding these three pharmaceuticals to the priority substances list in two years, when the watch list is due to be updated.

The Government recognises that it may become appropriate to regulate concentrations of certain pharmaceuticals in surface waters. Such regulation would be on the basis that the action was proportionate to the risk and that consideration had been given to the full range of socio-economic, environmental and public health concerns.

Pharmaceuticals in the environment is an emerging issue and the derivation of robust evidence on which to make policy decisions is at an early stage. The UK Government is working with the European Commission to try and ensure that DGSANCO's on-going study and the planned strategic view of pharmaceuticals in the environment (by DGSANCO and DGENV) is given sufficient profile and resource. Internationally, opportunities are taken to collaborate with wider research initiatives across the EU and beyond (e.g. *via* the UK-Japan collaboration on endocrine disrupting chemicals in the aquatic environment).

In the UK, the Government is working with a range of stakeholders to identify research needs and the ways to achieve these. For instance, the Government collaborates in research undertaken by academia, consultants and industry to assess the risks and priorities of hazardous substances and pharmaceuticals and in establishing an evidence base for population impacts. Work includes that on integrated approaches to pharmaceuticals in the environment, such as developing techniques for their prioritisation. As elsewhere, the ability to progress this work is constrained by the available resource. However, given the developing nature and potential significance of this research area, **the Government will report to the Committee on progress with its development of the evidence base on pharmaceuticals in the environment in 12 months.**

Following formal agreement of the revised priority substances proposal, the European Commission is expected to draw up the first watch list during 2015, with Member States to provide information within a set timeframe following that (earliest expected deadline, end 2016). This first watch list of ten substances will include E2, EE2 and diclofenac; the process by which other substances will be identified has yet to be developed. Evidence from

the watch list monitoring will be used as part of the Commission's prioritisation process for the next revision of the priority substance list, with the proposal itself expected in 2017. The prioritisation process is led by the Commission with expert input from Member States. As in the past, the UK expects to fully participate in the discussions.

2. Despite the financial cost of improving water treatment being a key element of the arguments presented against the European Commission's proposals, we have not seen a clear estimate of what this cost would be. Different sources have provided different estimates, which have been expressed in different terms, for example per household or per inhabitant. Allegations that official estimates deliberately over-state the cost, through gold-plating the regulations or failing to consider alternative treatment methods, are troubling and the Government should seek to address this. In addition, it is concerning that estimates have focused solely on the cost implications of removing pharmaceuticals from wastewater, despite there being twelve other substances which will be designated as priority substances. The Government has a responsibility to inform the public if these proposals, as negotiated by the EU Presidency, are likely to significantly increase water bills. We recommend that in its response to this report, the Government produces a clear explanation of the costs associated with these proposals, both for the pharmaceuticals and the other 12 proposed substances. The Minister should make a statement clarifying the cost of the proposals adopted by the Commission, the impact this would have on household water bills and the Government's estimate of the extent to which the costs could be reduced through, for example, the development of alternative treatment methods. (Paragraph 16)

The Government's ultimately successful negotiation strategy focused on a few, clear messages to avoid distraction from its significant concerns. Here, the potential costs of the proposal were overwhelmingly dominated by wastewater treatment of E2, EE2 and diclofenac. Other costs were significant (e.g. the revised draft impact assessment estimates costs of £27.3m–£45.3m over 20 years for additional environmental monitoring) but these were relatively small in comparison to the tens of billions of pounds estimated for wastewater treatment of the pharmaceuticals.

The Commission's proposal was not publicly consulted upon in advance of publication. So as to inform Parliament and the negotiation in timely fashion, the Government rapidly developed its response to the proposal using available sources of information. The draft impact assessment for the Commission's original proposal (i.e. includes costs for E2, EE2 and diclofenac) is attached at annex 1. Cost estimates were based on existing technologies because those are the ones which would apply given current knowledge. That the UK was able to derive such information was dependent upon the research efforts of previous years (outlined in response to question 3 below). The Government recognises that such costs might be mitigated over time as innovative approaches are developed.

The Government provided the opportunity for stakeholders to contribute to the production of the draft impact assessment for the proposal. Subsequently (in April 2012) it provided that draft impact assessment to the House European Scrutiny Committees as part of their examination of the proposed EU legislation. The use of many of the listed substances, particularly those used for plant protection or biocides, has already been restricted under earlier source control legislation. This means that there should be no or limited additional costs arising from the new measure in relation to these particular

substances. However, as reported to the Scrutiny Committees, there is uncertainty associated with costs of meeting the standard for BDEs.

The updated impact assessment, based on the amended proposal, will be consulted upon as part of the implementation of the proposal and will set out the associated costs. The Government considers that the time to revise estimates of the costs of wastewater treatment will be in line with the preparation for the next proposal (expected 2017) as further investigations as to the level and type of treatment required in the UK should by then be available.

Differing estimates of costs of wastewater treatment might be expected from differing sources as an evidence base is developed. The Government considers that its estimates of potential costs of wastewater treatment for pharmaceuticals were reasonably consistent. UK Government estimates of £27–30billion over 20 years to treat EE2 are in line with the EU Commission estimate of 18 euros/person/year for the UK to treat E2 (assuming the UK has about 60 million inhabitants). The Commission's impact assessment estimate for Switzerland to treat E2 was 11–18 euros/person/year. The Government has not attempted to further attribute costs to customer bills as additional treatment costs will be dependent upon local conditions: it could be misleading to provide a "per UK customer" cost estimate. Meanwhile, costs reported by some parts of the press appeared to be based on erroneous information.

3. We have not seen evidence to suggest that the water industry's approach to innovation has improved significantly since the Council for Science and Technology's 2009 review described it as "highly variable". It may be that strict regulatory standards, such as those suggested by the European Commission, are required to drive innovation in this sector. Given that the expected changes to the priority substances list will take time to implement, and the regulation of pharmaceuticals in wastewater has now been delayed further, the water industry should take this opportunity to start developing innovative approaches to address this issue. We are disappointed that there has not been more progress in encouraging innovation within the water industry since the Council for Science and Technology's report. We have seen no evidence that the "urgent need for a step-change" recommended in the report has been attempted, let alone delivered, and the Government should address this lack of progress. The Government should take further steps, in conjunction with Ofwat, to address this lack of progress. We recommend that the Government works with Ofwat to evaluate the measures they have taken to encourage innovation in the water industry and the outcomes expected from each of these measures. The Government should update in the Committee in a year's time regarding progress to achieving these outcomes. (Paragraph 22)

The Government is providing strategic leadership for innovation through the refreshed Water Sector Innovation Leadership Group (comprising representatives from water companies, the supply chain, Defra, BIS, Ofwat, the Environment Agency and Technology Strategy Board). The Group is clear that it wants to provide leadership and guidance in order to drive innovation in the water sector by encouraging partnerships, stimulating investment and helping to establish an environment that nurtures progressive innovation. The Group is currently working on several initiatives and aims to run an innovation event at the end of the year.

The Government has recently introduced a Water Bill. The aim is to introduce innovation into the provision of water services, remove barriers to competition and encourage new entrants to enter the market. This will encourage the development of new technologies, enable water resources to be used more flexibly, or to be re-used or treated more efficiently- all increasing our resilience and benefitting the environment.

A Defra Minister will lead a water and waste trade mission later this year to Brazil, to encourage innovation and international trading opportunities of UK skills, knowledge and products. A further water mission is planned to China at the end of the year.

Defra, along with Research Councils, has contributed £1m towards a Technology Strategy Board competition. Feasibility studies and R&D projects funded as part of this competition will help stimulate innovation in the water sector. Separately, UK is represented on a number of Action Groups recently announced under the European Innovation Partnerships (EIP). The EIP aims to speed up innovations that contribute to solving societal challenges, enhance Europe's competitiveness and contribute to job creation and economic growth[5].

The UK Water Research and Innovation Partnership (UKWRIP), chaired by the GCSA brings together industry, policymakers and research funders to provide direction and co-ordination of water research and innovation with the aim of improving UK and global water security, and increasing the UK share of the global water market. The 'Business and Economy' Action Group is currently exploring how the UK can emulate best practice of those countries that make a better job of translating excellent research into products. An UKWRIP representative on the Innovation Leadership Group provides coherence between the initiatives.

Ofwat's approach to the next price review is predicated on incentivising sustainable innovation by water companies, who will be given more ownership of their plans and accountability for delivery. This will be achieved through the emphasis on delivering outcomes rather than outputs, the incentives for outcome delivery, the "totex" approach which will give a boost to options such as working with partners on managing catchments, demand management and green infrastructure, and the expectations around the risk-based review of company business plans. All this means that companies which innovate successfully will stand to be rewarded. **The Government will update the Committee in 12 months with expectations for innovation to be delivered by the water industry.**

The water industry has conducted two major investigation programmes in the last eight years looking at chemicals—including pharmaceuticals—in wastewater effluent, at a total cost of over £40 million. The Endocrine Disruptor Demonstration Programme (2006–2010) focused on steroid oestrogens while the Chemical Investigation Programme (2009–2013)[6], [7] considered a wide range of regulated and emerging substances. Through these investigations, the water industry has a much improved understanding of the chemical composition of treated wastewater, the effectiveness of different treatment technologies and the sources of chemicals entering the sewerage system. It has also piloted new

[5] http://ec.europa.eu/environment/water/innovationpartnership/nine_action_groups_en.htm#TNO

[6] (Gardner et al, 2013, Sci Tot Env http://dx.doi.org/10.1016/j.scitotenv.2013.03.088)

[7] http://www.ukwir.org/site/web/news/news-items/ukwir-chemicals-investigation-programme

treatment technologies and considered costs through options appraisals. This knowledge puts the UK water industry and its regulators at the forefront of understanding the options for, and challenges of managing chemicals in, wastewater. Meanwhile, plans for future chemicals investigations by the water industry are being developed and the Committee's concerns in this area have been noted.

4. We welcome announcements by Unilever and Lush UK to phase out micro-plastics from their products by 2015. The Government should engage with industry to ensure that similar action to that taken by Unilever and to help industry maintain momentum towards phasing out micro-plastics from their products. We expect the Government to publish updated data in six months and to encourage other countries to help eradicate this problem. (Paragraph 27)

The Government has previously commissioned research on the potential harm from microplastics in the marine environment. This work, from Plymouth and Exeter Universities, will report in March 2014. The UK, through Cefas, is also participating in the Interreg project 'MICRO' with neighbouring European countries and local authorities to evaluate the risks and effects of microplastics in the English Channel and southern North Sea area. The Government will update the Committee on the outcomes of these projects when they are complete. In addition, it is exploring with industry what actions might be taken by industry to reduce the volume of microplastics entering the marine environment from cosmetic and other products.

5. The Government must be more pro-active in providing Parliament with sufficient information to effectively scrutinise EU legislation before it is agreed to, particularly when such legislation could result in significant additional costs for UK taxpayers. There needs to be sufficient time given to ensure that the European Scrutiny Committee and our Committee can thoroughly examine progress in this important field. (Paragraph 29)

The Government is committed to the principle of effective scrutiny of European legislation and supports the view that Parliament needs to be able to effectively scrutinise such legislation. Parliamentary Scrutiny Committees play a significant role in examining proposals for EU legislation.

The explanatory memorandum for the priority substances proposal was submitted during February 2012, with the draft impact assessment being provided in April 2012. There were a number of technical complexities with the dossier, so the Government provided informal updates to assist the Committees in their review of the evidence. Clearance of the dossier was achieved from March to June 2013. The Government appreciates the Scrutiny Committees' interest in this technically complex area.

Annex 1: Draft impact assessment for the priority substances proposal – March 2012

Title: Impact Assessment of Proposal to Revise the EQS Directive (2008/105/EC) implementing the Water Framework Directive (2000/60/EC) **IA No:** **Lead department or agency:** **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 23/03/2012 **Stage:** Development/Options **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries**:

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£m	£m	£m	Yes/No	In/Out/zero net cost

What is the problem under consideration? Why is government intervention necessary?

This initial Impact Assessment provides the likely cost and benefits of a Commission proposal to amend the Directive on Environmental Quality Standards (Directive 2008/105/EC) (EQSD) which implements parts of the Water Framework Directive (WFD) in England and Wales. Government intervention to implement the proposal is necessary to (a) provide the right incentives to protect and enhance the water environment; (b) ensure that polluters face the costs of their behaviour; and (c) ensure an appropriate provision of a high quality water environment by the private sector. This is mainly achieved through the introduction of standards, conditions and prescribed management approaches, at EU or UK level.

What are the policy objectives and the intended effects?

The proposed amendment to the EQS Directive (the proposal) has been developed in order to comply with the requirements of Article 16 of the WFD requiring a review after four years of the initial Directive. The proposal includes a revised (second) list of priority substances and provisions to improve the functioning of the legislation. It aims to ensure a high level of protection against risks to or via the aquatic environment attributable to substances and certain other pollutants, which are potentially harmful, by setting EQS that should not be exceeded in the aquatic environment.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

In advance of agreement with other government departments, the focus at this stage in the planning process has been on understanding the strategic implications of the proposal for the UK. Specific policy options have neither been put forward nor withdrawn; although, it is expected that various policy options will be considered in the coming stages ranging from: 'do nothing' to 'reducing the scope of the proposal' or 'using alternative enforcement/compliance mechanisms' and at the extreme, 'adoption/acceptance of the Commission's proposal with no further negotiation'. No preferred option has been identified at this stage. This impact assessment has been designed as a systematic initial assessment of the proposal, aimed at drawing out the practical impacts and implications of the proposal in order to assist an initial cost/benefit analysis.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			Yes / No / N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes/No	**< 20** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate:

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

1) Pharmaceutical Industry: If restrictions (as part of 'source control' measures) are placed on the availability of key pharmaceutical substances (i.e. diclofenac and EE2), losses to manufacturers of hundreds of millions of pounds per year in the UK alone expected
2) Water industry: UK costs of £27 - £31 billion (20 yrs) for removal of EE2 and E2. Higher costs may be incurred relating to pentaBDE removal, however, there are uncertainties as to the scale of the problem.

Other key non-monetised costs by 'main affected groups'

Agricultural Industry: Some costs may be incurred associated with potential loss of quinoxyfen and cypermethrin in some uses
Public authorities: Increased costs of monitoring new PS of between £10 and £24 million PV (over 20 yrs)
Society: Controls on sales of the combined pill (which is based on EE2) could result in an increase in unintended pregnancies with social costs estimated at around £382 million PV (over 20 years).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Benefits associated with the proposal are described, but not fully quantified in the Commissions IA. Wider benefits to biodiversity, cleaner sediments and a level playing-field for industry across the EU are identified as potential benefits. For some substances, it is possible that the development of safer alternatives could provide business opportunities for the UK environmental technology and services sectors, and UK industry as whole. The extent of these benefits is uncertain at this time.

Other key non-monetised benefits by 'main affected groups'

In practice, the extent of benefits would vary by substance and would depend on current levels of releases and the EQS adopted, amongst other factors.
Water industry: May benefit from economies of scale arising from installing advanced tetiary treatment for EE2 removal. In other words, advanced treatment put in place for removing EE2 will effectively remove E2 and contribute significantly to EQS compliance for other PS, such as pentaBDE.

Key assumptions/sensitivities/risks **Discount rate (%)** 4

Key uncertainties surround the extent of failure relating to pentaBDE and the most cost-effective means of achieving the EQS, including 'do nothing'.
SIMCAT models not available for Scotland and Norther Ireland, so potential failures for EE2 and E2 are uncertain. SIMCAT is a mass balance river quality model based on Monte Carlo simulations, used to simulate the flow and quality at any point in a river catchment and useful for estimating the impact of discharges on river quality.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	Benefits:	Net:	Yes/No	IN/OUT/Zero net cost

Evidence Base

Problem under Consideration

The Water Framework Directive 2000/60/EC (WFD) establishes a comprehensive framework for the protection of surface and groundwater, setting environmental objectives including the achievement of good chemical and ecological status and the prevention of deterioration. To meet good chemical status, water bodies must meet the Environmental Quality Standards (EQS) set for Priority Substances (PS) - identified under the WFD as posing a risk to or via the aquatic environment at EU level. Some PS are identified as Priority Hazardous Substances (PHS) because of their persistence, bioaccumulation and/or toxicity (PBT) properties or equivalent level of concern. In addition to the objective of good chemical status, the WFD requires the adoption of control measures aimed at the progressive reduction of PS and at the cessation or phasing out of discharges, emissions and losses of PHS to the aquatic environment within 20 years. The WFD also allows for exemption from meeting good chemical status in specific water bodies on the grounds of technical unfeasibility, disproportionate costs or natural conditions, as long as certain pre-conditions are met.

The WFD (Article 16(4)) requires the Commission to review the list of PS at least every four years. This review was carried out by the Commission with the assistance of the Working Group E on Chemical Aspects (WG E) under the WFD Common Implementation Strategy, including participation of all MS and a wide range of stakeholders.

Three main issues were identified by the Commission (EC, 2012b) as requiring action:

- firstly, new information about risks caused by existing PS and new chemicals has become available and some of this information was not available during the first prioritisation exercise
- secondly, because of the intrinsic properties, widespread use and common potential for long-range transport associated with ubiquitous PBTs (or uPBTs), some of them are still found in the aquatic environment, mostly in sediment and/or biota, at concentrations above the EQS, therefore entailing widespread failures of the objective of good chemical status. This causes three problems:
    - firstly, widespread exceedances of the EQS by ubiquitous PBTs could hide the improvements made in relation to other substances because the chemical status of water bodies under the WFD has to be reported on the basis of all PS;
    - secondly, because PBTs tend to accumulate in sediment and/or biota and may be hardly detectable in water (even with state of the art analytical techniques), MS which apply a water EQS might inappropriately categorise water bodies as having "good chemical status" even when the sediment and/or biota contain PS at levels that still pose a risk; and
    - thirdly, any changes in the environmental concentrations of ubiquitous PBTs are likely to occur only over the long term and a lower monitoring frequency and lower number of monitoring sites than normal under the WFD would seem justified.
- the fact that there is a paucity of relevant monitoring data on which to base assessment of exposure and thus the prioritisation of new PS in future reviews.

The proposal by the Commission is seeking to address these problems. It introduces nine new PS, six new PHS and changes the status of two PS to PHS. Most EQS are set as concentrations in water, although, for twelve substances (existing and proposed), EQS are newly set for measurement in biota. The proposed new substances and changes to existing substances are expected to have an impact in the 2015 updated river basin management plans (RBMPs) and programmes of measures.

Rationale for intervention

Government intervention to implement the proposal is necessary to provide private parties with the right incentives to protect and enhance the water environment. Because the presence of PS and PHS in the water environment is a result of negative externalities, government intervention is required to ensure that polluters face the costs of their behaviour. The proposal also contains administrative requirements for the government, notably with regard to monitoring and reporting requirements.

If the proposal is agreed and the EQS Directive amended based on the current text of the proposals, failure to implement the revised Directive may result in infraction proceedings being brought by the European Commission. It may also result in the UK being unable to meet the objectives and deadlines of the WFD more generally. There is, therefore, an incentive for the UK to aim to obtain the best possible outcome possible in future negotiations.

Policy objective

The EQS Directive is focused on ensuring that hazardous chemicals do not affect the quality of the water environment. In this regard, the proposed amendment to the EQS Directive (the proposal) includes a revised (second) list of priority substances and provisions to improve the functioning of the legislation. By so doing, it aims to ensure a high level of protection against risks to or via the aquatic environment attributable to substances and certain other pollutants, which are potentially harmful, by setting EQS that should not be exceeded in the aquatic environment.

The EQS Directive, in line with the WFD, also requires that other environmental priorities, economic considerations and social issues have to be considered and taken into account when setting water management objectives. Indeed, economic analysis is written into the WFD requirements and a consideration of the positive and negative consequences of achieving environmental objectives is an integral part of WFD objective setting. This is in line with Ministerial objectives of ensuring that the WFD is implemented cost-effectively and that there is a balancing of policy priorities, and hence the needs and interests of different stakeholders.

A key test for adopting alternative objectives is a justification that the measures necessary to achieve the default objective would be “disproportionately costly”. Disproportionate cost analysis brings in considerations of efficiency (costs>benefits), affordability and equity (are there negative distributional consequences from meeting objectives?). Sometimes it will be necessary to balance efficiency and equity criteria and to consider alternative ways in which improvements can be paid for so that the distributional consequences are mitigated. These mechanisms within the WFD will help to ensure that its implementation is in line with government objectives for rural communities, small firms, and competition.

Description of options considered

The focus at this stage in the planning process has been on understanding the strategic implications of the proposal for the UK. Specific policy options have neither been put forward nor withdrawn; although, it is expected that various policy options will be considered in the coming stages ranging from: ‘do nothing’ to ‘reducing the scope of the proposal’ or ‘using alternative enforcement/compliance mechanisms’ and at the extreme, ‘adoption/acceptance of the Commission’s proposal with no further negotiation’. No preferred option has been identified at this stage. This impact assessment has been designed as a systematic initial assessment of the proposal, aimed at drawing out the practical impacts and implications of the proposal in order to assist an initial cost/benefit analysis.

Monetised and non-monetised costs and benefits of each option

Overview

The main features of the proposal are:

- the addition of 15 additional PS, 6 of them designated as PHS;
- stricter EQS for four existing PS and slightly revised EQS for three others;
- the designation of two existing PS as PHS;
- the introduction of biota standards for several substances;
- provisions to improve the efficiency of monitoring and the clarity of reporting with regard to certain substances behaving as uPBTs; and
- a provision for a watch-list mechanism designed to allow targeted EU-wide monitoring of substances of possible concern to support the prioritisation process in future reviews of the priority substances list.

The key **costs** identified to date are associated with:

- pharmaceutical substances (EE2, E2 and diclofenac), which have been designated as PS;
- the change in the EQS for pentaBDE (which is greater than one order of magnitude) and the proposed biota EQS; and
- costs associated with monitoring the new PS.

The key **benefits** will be to users of surface water bodies and water abstractors through improved chemical quality and biodiversity. Water abstractors will benefit from reduced levels of PS and PHS in their water supplies. The development of safer alternatives could also provide business opportunities for the UK environmental technology and services sectors, and UK industry as whole.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

The assessment of costs and benefits is based on literature review, analysis of monitoring data, expert judgement and input and review from stakeholders. As an initial RIA, the information presented in this report should be considered as preliminary and subject to change. However, it does provide some indication of the likely scale of costs accruing to the UK.

Information based on SIMCAT modelling has been used to provide some indication of the likely failures relating to some of the substances. SIMCAT is a mass balance river quality model based on Monte Carlo simulations, used to simulate the flow and quality at any point in a river catchment and useful for estimating the impact of discharges on river quality. Such modelling is, however, intrinsically subject to various uncertainties. Indeed, some of this information (e.g. relating to pentaBDE) is likely to be updated with better information in the coming months.

Costs to Agricultural Industry

Eight substances which are of relevance to the agricultural sector are listed as PS/PHS in the Commission's proposal. For quinoxyfen and cypermethrin, some concerns have been raised regarding the potential loss of 'one component of an effective treatment suite' for dealing with mildews and sea lice respectively ((in the event of resistance developing in future). For quinoxyfen, the exact costs of removal/loss are uncertain due to uncertainties regarding what the actual driver for replacement will be and when this will occur. The Commissions IA (EC, 2010B), however, recognises that "*there would be negative impacts on the producer and on formulators/retailers – and farmers - (although they could be totally or partially compensated by substitutes)"*. As for cypermethrin, it is important to note that loss of cypermethrin is not necessarily required as it is a PS. Cypermethrin is also currently a specific pollutant in the UK with an EQS of 0.1 ng/l (annual mean) (or 0.4 ng/l 95th percentile) and the effects of the UK sheep dip withdrawal programme are yet to be fully felt.

Costs to Water Industry

The main costs for the water industry are likely to come from advanced tertiary treatment which would have to be put in place to remove EE2 and E2. EE2 being a synthetic substance is much harder to treat and breakdown by biological processes than E2 and, as such, the key cost driver in terms of costs to WwTP is EE2, not E2. This is confirmed in UK modelling data (SIMCAT) which shows that where a stretch is modelled as failing for steroid oestrogens, there are never modelled failures for E2 alone, rather E2 failures are always co-incident with EE2 failures. Hence, while around 1,360 sewage treatment works are modelled as contributing to the failures of the EE2 EQS, only around 570 of these are associated with the failures of the E2 EQS alone (EA, 2012).

For EE2, the total costs of treating the ~1,360 WwTP in England Wales with EE2 failures have been estimated at between £27billion and £31 billion, depending on the advanced tertiary treatment which is used. If more efficient methods for removal of EE2 such as ozonation are used (removing around 90% of EE2), this would place the costs at around £27 billion (rather than £31 billion) but at this stage, it is uncertain whether all WwTP can easily fit ozonation without further considerations.

Equivalent modelling for Scotland and Northern Ireland is not available. However, assuming that around 20% of all WwTp require advanced tertiary treatment for EE2 and E2, this would suggest costs of around £300 million for Scotland associated with around 15 works (out of ~70) in Scotland and costs of around £160 million for 8 (out of ~40) works in NI. Please note that these latter costs are mainly indicative costs for scaling purposes only. Total costs to the UK are between **£27billion and £31 billion** (over 20 years).

Costs to Pharmaceutical Industry

Costs to the pharmaceutical industry have been estimated on the assumption that source control measures may be required to achieve the EQS.

Using the estimates provided by ARC (2002) regarding people suffering from osteoarthritis in the UK (~5 million persons of which 2.5 million are treated with Diclofenac), we have estimated a total loss in QALYs to be around £7.5 billion over 20 years (or £516 million per year). There are some uncertainties regarding the exact market share for diclofenac; however, assuming a lesser market share for diclofenac of 33% of NSAIDs would still result in a total loss of QALYs of around **£5 billion** (over 20 years).

The impact of the loss of Diclofenac is, however, not limited to QALYs. There is the loss of working days as well as the loss of QALYs in other acute forms of arthritis or pain treatment for

which Diclofenac is used. The ARC (2002) report notes that 206 million working days were lost in the UK in 1999, equivalent to a loss in production of £18 billion. For osteoarthritis in particular, 36 million days were lost worth around £3 billion in lost production. Assuming that 10% of this lost production is associated with users of Diclofenac who do not obtain equivalent pain reduction from other replacements, this is equivalent to £300 million in lost production per annum. Using this figure, the loss in work sick days over a period of 20 years associated with withdrawal of Diclofenac will be around **£4.5 billion PV (over 20 years).**

There will also be losses to manufacturers and suppliers of diclofenac in the UK. In 2004, the market for diclofenac was estimated at around £100 million (Prnewswire, 2004): this is likely to have increased significantly since then. Pulse (2010) estimates that GPs issued an average of 7.4 million prescriptions for diclofenac every year between 2005 and 2007 and this increased by around 500,000 after it was reclassified as an over the counter drug.

For EE2 (or the combined pill), if it is assumed that all women previously using the combined pill would now use condoms, this would result in around 217,000 additional unintended pregnancies. Using a QALY of £40,000 and a Health Utility State of 0.997, corresponding to a value of £120 (calculated with a Standard Gamble process), the social loss as measured by women's willingness to pay to avoid the unwanted pregnancy would be around £26.2 million per year, equivalent to around **£382 million** over 20 years (discounted at 4%).

There are, however, other significant costs associated with unintended pregnancy, including impacts on working life (lost time) and for those pregnant women that decide to have an abortion, patient costs including direct medical costs (pregnancy test costs, charges), direct non-medical costs (child care, travel, lodging), and productivity losses (value of time away from work or other activities) would also be incurred.

Costs to Authorities

Using the figures provided in the Commissions' impact assessment (EC, 2010b), we have estimated additional costs to the UK associated with monitoring for the new PS at between **£10 and £24 million PV (over 20 years).** These costs have not yet been fully verified at this stage and there are some uncertainties associated with the potential costs (and benefits) of the (additional) monitoring required. For instance, while biota monitoring is more expensive per sample/analysis; as a result of the proposal, fewer sampling locations are needed and at a lower frequency due to the integrative character of biota. Bearing in mind that the default frequency for monitoring in water is monthly (WFD Annex V) and in sediment and biota it is annually, EC (2012) suggests a potential reduction in frequency of analysis for the water matrix could be from 12 samples per annum to 1 or 2 and for biota from 1 per annum to 1 every two or three years for uPBTs. These will be clarified in the next stages.

Table 1: Overall and Unit costs of monitoring existing PS in the EU27 and in UK

	Low	Average	High
Overall costs of monitoring of existing PS – EU27*	€ 41,000,000	€ 69,000,000	€ 97,000,000
Unit costs per PS based on overall monitoring – EU27*	€ 1,025,000	€ 1,725,000	€ 2,425,000
Additional costs for 15 substances – EU27*	€ 15,375,000	€ 25,875,000	€ 36,375,000
UK costs of monitoring of additional 15 PS**	€ 828,820	€ 1,394,843	€ 1,960,866
UK costs of monitoring of additional 15 PS (in £)	£692,993	£1,166,257	£1,639,520
Total cost of monitoring over 20 years	**£10,110,994**	**£17,016,070**	**£23,921,132**

**Figures as presented in Commissions IA (EC, 2010b)*
*** Assuming that there are around 1,160 UK monitoring stations out of 21,500 in EU27*

Risks and assumptions

Uncertainty

A range of different uncertainties affect the ability to predict both the likely costs and the likely benefits of the proposal. The key areas are as follows:

- uncertainty over the extent and source of emissions and losses of the PS and PHS to the environment, as well as uncertainty over the impact that the various measures currently being implemented will have on pressures and trends into the future; and
- uncertainty over what measures may be required to address the problem, in particular the relationship between source control and end-of-pipe controls, the sectors that may be required to take action and the costs of those actions (which may vary significantly depending on the level of action required).

Assumptions

In order to identify measures and estimate costs, a number of assumptions have been made. These include assumptions on:

- the number of water bodies at risk and where action may be required. For instance, for pentaBDE, there are a number of important caveats which have to be applied to the monitoring data. This means that extrapolating the likely failures and thereon costs is subject to significant uncertainties; and

- the costs and effectiveness of the proposed measures. In some cases, meeting the EQS may require the use of techniques or technologies that have not yet been tested or proven at the level of emissions reduction required. Thus, costs may, in practice, be higher or lower depending on site-specific and technical feasibility considerations.

Sustainability Risks

There is a risk that the installation of advanced tertiary treatment at WwTP is likely to result in significant environmental impacts in terms of the carbon costs resulting.

Direct costs and benefits to business calculations (following OIOO methodology)

The UK has transposed the requirements of the WFD into national law. This is, therefore, not ‘new’ legislation, but an amendment to existing legislation.

Wider impacts

See Annexes for further details.

Summary and preferred option with description of implementation plan

To be decided at a future stage.

ANNEX 1

Agricultural Sector

Eight substances which are of relevance to the agricultural sector are listed as PS/PHS in the Commission's proposal. Table 1 overleaf provides an overview of the key issues in terms of how to achieve the EQS (i.e. current level of releases, potential for substitution) for these substances and how these impact on the costs and benefits to the UK. The emphasis, at this stage, has been on bifenox, quinoxyfen and cypermethrin which have been highlighted as being of key concern to the UK.

Overall, a number of preliminary findings are set below:

- in terms of substitution, alternatives are available for all of the substances considered; however, the key concern for quinoxyfen and cypermethrin relates to the loss of what can be considered to be 'one component of an effective treatment suite' in the event of resistance developing in future. For cypermethrin, it is important to note that cessation of use is not required and, in theory, it is possible for critical use (or retention) as part of an 'effective treatment suite' to occur as long as this use is not directly impacting on a specific river basin achieving the EQS;
- cypermethrin products are used in two principal ways within the forestry industry. First, as an electrodyne treatment applied to conifer transplants used in replanting harvested areas in order to protect these plants from being damaged by Hylobius abietis. – a weevil which eats the young trees. Secondly, as a "top-up" spray applied directly to the individual trees after planting using an applicator. Without this treatment, significant damage will typically occur to newly planted trees on harvested sites. An estimated national average of 50% of untreated plants will be killed over the first few years of establishment;
- measures which are in the pipeline may act to reduce the levels of these substances in the water. For instance, under the framework directive on the sustainable use of pesticides (Directive 2009/128/EC), Member states must produce National Action Plans (NAP) to be transposed into national law by 2012. Measures for control of releases (e.g. establishing appropriately-sized buffer zones (Article 11) or prohibition of use in specific areas (Article 12)) are yet to be defined but will be introduced from 2013-2015 and these may act to reduce any current emissions to water of these substances;
- linked to the above, it is important that costs which have already been identified and costed under the PPP Regulation (or relating to NAPs) are not double-counted under the WFD. That said it is important for the Commission to clarify how designation of quinoxyfen as a PHS under the WFD is not intended to "prejudge the outcome of the PPP review" since it acknowledges that "*achievement of the WFD phase-out objective would rely on a decision under the PPP Regulation to refuse reauthorisation*". This indicates that the Commission accepts that the PHS goal of cessation cannot be achieved without restrictions, in which case, the full quantitative costs of listing as a PHS should be provided; and
- in terms of benefits, the actual improvement in UK water quality is quite uncertain, as few failures have been recorded historically for bifenox and quinoxyfen. For cypermethrin, it is unclear whether the additional costs (and possible loss of cypermethrin) exceed the benefits associated with the marginal difference between the UK EQS and the proposed EQS. For Scotland, SEPA currently licenses discharges of cypermethrin using predictive models to set limits on the scale and rate of release to ensure that they meet environmental standards. Breaches of the current standards are therefore unlikely to be occurring from the use and release of fish medicines containing cypermethrin. There is, however, some concern that if

they are required to adopt the new standard, SEPA will no longer be able to license discharges from fish cages as it may not be possible for the standard to be met following release from fish cages. In summary, current levels of use do not pose a specific concern against the currently adopted standards but current levels of use may not be possible were the new standard adopted meaning that cypermethrin would not be available as a fish medicine in the future.

Table 1 summarises the key issues for the eight PS relevant to the agricultural sector.

Table 1: Summary of Key Issues for Agricultural Substances on Priority Substances List	
Substance	**1. Bifenox**
Status	**New priority substance**
Use	Used in control of broad leaved weeds in post-emergence applications in winter cereals. Bifenox is especially active on difficult to control broadleaf weeds like Veronica, Viola and Galium spp. Other species like Lamium spp. are also controlled using Bifenox.
Current level of releases	ENTEC (2011) notes that few failures for bifenox have been recorded historically. This situation could, however, change in the event of improved monitoring which would be required if it is identified as a PS.
How to achieve progressive reduction	ENTEC (2011) notes that wastewater treatment is unlikely to be relevant as a measure for addressing bifenox (as well as dicofol and quinoxyfen), although removal rates may be enhanced by adsorptive tertiary treatment such as sand filters or granulated activated carbon (GAC). Under the framework directive on the sustainable use of pesticides (Directive 2009/128/EC), Member states must produce National Action Plans (NAP) to be transposed into national law by 2012. Measures for control of releases (e.g. establishing appropriately-sized buffer zones (Article 11) or prohibition of use in specific areas (Article 12)) are yet to be defined but will be introduced from 2013-2015.
Potential for substitution	ENTEC (2011) notes that alternatives are available but multiple substances may be required to replace the effect of Bifenox.
Cost to the UK	Minimal. Bifenox has not been highlighted as being of major importance to the UK, according to information from the CRD (HSE).
Benefits to the UK	Overall improvement in water quality **uncertain**, as few failures have been recorded historically and there are/were specific off label approvals (SOLA) required for use of bifenox on oilseed rape, for instance and these SOLAs often entail additional controls on use.
Substance	**2. Quinoxyfen**
Status	**New priority hazardous substance**
Use	A quinoline fungicide used for foliar application in cereals (wheat and barley) and grape vines
Current level of releases	ENTEC (2011) notes that few failures for quinoxyfen have been recorded historically. France provided information to show no EQS failures occurring recently and where failures have been identified, there is a lack of supporting data (tends to partition to sediment). This situation could, however, change in the event of improved monitoring which would be required if it is identified as a PHS.
How to achieve cessation	ENTEC (2011) notes that wastewater treatment is unlikely to be relevant as a measure for addressing quinoxyfen, although removal rates may be enhanced by adsorptive tertiary treatment such as sand filters or GAC. The UK NAP (which is yet to be produced) may contain measures for control of releases (e.g. giving priority to non-chemical alternatives (Article 14) or prohibition of use in specific areas (Article 12)); the specific measures are yet to be defined but will be introduced from 2013-2015.

Table 1: Summary of Key Issues for Agricultural Substances on Priority Substances List	
Potential for substitution	According to the CRD (HSE), restrictions on the use of quinoxyfen would reduce the options available for managing resistance in powdery mildew (particularly in cereals and strawberries). However, the agricultural industry does have access to a "reasonably wide range of actives for the control of mildews" (as noted by ENTEC, 2011) and the key concern relates to the loss of what can be considered to be 'one component of an effective treatment suite' for dealing with mildews (in the event of resistance developing in future). It is important to note that quinoxyfen shows **vPvB** and **PBT** properties and, as such, it is likely, at best (i.e. assuming it is established to have only **PB** properties), to become a "candidate for substitution" under the PPP Regulation 1107/2009.
Cost to the UK	The Commissions IA (EC, 2012) notes that "*achievement of the WFD phase-out objective would rely on a decision under the PPP Regulation to refuse reauthorisation*". This indicates that the Commission accepts that the PHS goal cannot be achieved without restrictions. If designation as a PHS under the WFD is not intended to "*prejudge the outcome of the PPP review*", then it could be argued that quinoxyfen should be listed as a PS, subject to the outcome of the PPP review – bearing in mind that the Commissions IA recognises that "*there would be negative impacts on the producer and on formulators/retailers – and farmers -(although they could be totally or partially compensated by substitutes)"* and possible concerns relating to resistance increasing to powdery mildew (particularly for hops). In terms of quantifying these costs, it is important to note that the UK IA for the PPP Regulation identifies quinoxyfen as one of the active substances which has been assumed will be lost once its current approval expires (in 2014). The costs of possible loss have already been accounted for and should, therefore, not be double-counted. The key issue is, therefore, a matter of principle as to whether the WFD is pre-judging the PPP review, since it is accepted that cessation cannot be achieved without a restriction.
Benefits to the UK	Overall improvement in water quality **uncertain**, as few failures have been recorded historically, this suggests that the changes in water quality, particularly on the EU scale could in fact be minor. While data from FR show isolated exceedances, this highlights the fact that some local measures may be required, particularly in relation to peak concentrations of pesticides (ENTEC, 2011). Assuming that the Commission is right and quinoxyfen is restricted after the PPP Review, then there are costs (with no benefits) associated with monitoring for a substance whose sole use is banned.
Substance	**3. Cypermethrin**
Status	**New priority substance**
Use	Used as a plant protection product, pyrethroid insecticide in large-scale commercial agricultural applications (arable farming), biocide (wood preservative) and veterinary product (in sheep dip and salmon farms).
Current level of releases	As noted in the Commissions IA (EC, 2012), sheep dipping used to be one of the main uses of cypermethrin in the UK – with the UK showing the greatest number of exceedances. This should no longer be the case, although there is no data available showing that exceedances do not still occur from other uses. The Environment Agency (EA) shows that significant improvements in rivers have been seen since 2006. A dramatic drop in the number of serious pollution incidents caused by cypermethrin dips – from 13 serious incidents in 2005 to two in 2006, one in 2007 and none in the past two years has been observed.
How to achieve progressive reduction	The EA anticipates the permanent withdrawal of cypermethrin dips will bring improvements in over 20 stretches of river that currently fail European water quality standards The review programme under the

Table 1: Summary of Key Issues for Agricultural Substances on Priority Substances List	
	Biocidal Products Directive could also lead to change or withdrawal of authorisation of cypermethrin (3 product types). Finally, SOLAs (with additional controls on use) may also apply (or be applied) to existing agricultural uses.
Potential for substitution	In terms of substitution, there are a range of alternative approaches and substances, depending on use (ENTEC, 2011). Organophosphate (OP) **sheep dips** are now back in use but with stricter conditions on packaging and use and which can be used instead of cypermethrin. CRD notes that while cypermethrin is important, it is not considered to be essential as other pyrethroids are available. For use as **sea lice medicines**, alternatives include emamectin benzoate (also known as SLICE), deltamethrinte and flubenzuron, amongst others. Scotland, however, considered it a vital product for the Scottish industry as part of a wider range of products which allows for rotation of treatments to avoid the development of resistance in sea lice. Substitutes exist for other uses in large commercial agricultural operations, as discussed in ADAS (2010).
Cost to the UK	Cypermethrin is a specific pollutant in the UK with an EQS of 0.1 ng/l (annual mean) (or 0.4 ng/l 95th percentile). Only one other country has an EQS; so additional costs should be minimal, taking into account that costs have already been incurred as part of the sheep dip withdrawal programme. Cypermethrin has not been highlighted as being of major importance to the UK, according to information from the CRD (HSE); although Scotland considers it to be 'one component of an effective treatment suite' for dealing with sea lice – and, as such, would wish to avoid complete loss of cypermethrin. Loss of cypermethrin is, however, not necessarily required as it is a PS. Where this to occur, some costs could arise in relation to vine weevil control. ADAS (2010) estimates that poor control of vine weevils – as a result of the loss of <u>both</u> chlorpyrifos and cypermethrin – could result in potential costs to the industry of £13million. Similar to quinoxyfen, it is important to avoid 'double-counting' any possible losses resulting from withdrawal of cypermethrin (which is unlikely). Also, if cypermethrin is lost as a result of the biocidal review programme, this further reduces the need for substitution where it is critical.
Benefits to the UK	Whether there are additional benefits associated with an EQS which is stricter than the current UK one is uncertain. However, listing as a PS would support existing actions in the UK to reduce emissions of cypermethrin into water courses and help ensure a level playing field for other countries with no EQS.
Substance	**4. Aclonifen**
Status	**New priority substance**
Use	A herbicide (nitrophenyl ether herbicide) used on a range of arable crops
Current level of releases	For aclonifen, there is an EU-level requirement since 2008 for buffer strips.
How to achieve progressive reduction	
Substance	**5. Dichlorvos**
Status	**New priority substance**
Use	A highly volatile organophosphate, widely used as an insecticide
Current level of releases	In 2002, the UK suspended the sale of all insecticide products containing dichlorvos and then withdrew the approvals of non-agricultural insecticide products as a precautionary public health measure. See <u>http://www.hse.gov.uk/biocides/copr/dichlorvos.htm</u> Additional **costs** and **benefits** to the UK should be minimal.
How to achieve progressive reduction	PPP legislation is relevant to Dichlorvos, but it is no longer authorised as a PPP.

Table 1: Summary of Key Issues for Agricultural Substances on Priority Substances List	
Substance	**6. Dicofol**
Status	**New priority hazardous substance** **Biota EQS proposed**
Use	An organochlorine pesticide that is chemically related to DDT
Current level of releases	
How to achieve cessation	Dicofol is no longer authorised as a PPP. Dicofol is a possible reprotoxin and, as such, benefits may accrue to spray applicators from its cessation
Substance	**7. Heptachlor/heptachlor epoxide**
Status	**New priority hazardous substance with biota EQS**
Use	Heptachlor is an organochlorine compound that was used as an insecticide. The epoxide, a metabolite, may be more toxic than the parent compound. No longer authorised but secondary emissions possible
Current level of releases	
How to achieve cessation	
Substance	**8. Trifluralin**
Status	**Old priority substance, now priority hazardous substance**
Use	Agriculture
Current level of releases	
How to achieve cessation	Trifluralin is no longer authorised as a PPP.

Pharmaceutical Sector

Three substances which are of relevance to the pharmaceutical sector are listed as PS/PHS in the Commission's proposal. Table 2 overleaf provides an overview of the key issues in terms of how to achieve the EQS (i.e. current level of releases, potential for substitution) for these substances and how these may impact on the costs and benefits to the UK.

Overall, a number of preliminary findings are set out below:

- firstly, the Commission's IA fails to account for the costs of treating EE2 in its own impact assessment and this hugely underestimates the likely total costs of the proposals. It simply states that "*emissions may be reduced due to improvement in waste water treatment driven by the general good status objective of the WFD*". This is not the case, as EE2 being a synthetic substance is much harder to treat and breakdown by biological processes than E2 and, as such, the key cost driver in terms of costs to WwTP is EE2, not E2;

- this is confirmed in UK modelling data which shows that where a stretch is modelled as failing for steroid oestrogens, there are never modelled failures for E2 alone, rather E2 failures are always co-incident with EE2 failures. Hence, while around 1,360 sewage treatment works are modelled as contributing to the failures of the EE2 EQS, only around 570 of these are associated with the failures of the E2 EQS alone;

- in this regard, it is worth noting that the Commission's IA recognises that there will be costs of around €19 billion associated with an upgrade of around 9% of WWTPs (~650 WwTPs) to deal with E2 in the UK alone. Estimates from the Environment Agency suggest a similar number of WwTP failing the E2 standard (~570), however, a much lower cost estimate of around £10.3bn is indicated. Much higher costs would apply in the Commissions IA if the full costs of EE2 removal at WWTP are accounted for;

- for EE2, the total costs of treating the ~1,360 WwTP with EE2 failures have been estimated at between £27billion and £31 billion, depending on the advanced tertiary treatment which is used. If more efficient methods for removal of EE2 such as ozonation are used (removing around 90% of EE2), this would place the costs at around £27 billion (rather than £31 billion) but at this stage, it is uncertain whether all WwTP can easily fit ozonation without further considerations;

- it is also important to note that the figures above are for England and Wales, as the SIMCAT model is still being developed for Scotland. It is not possible to provide specific estimates of the level of failures as populations are likely to be concentrated in a few large areas with the rest more sparsely populated. However, assuming that around 20% of all WwTp require advanced tertiary treatment for EE2 (similar to UK levels), this would suggest costs of around £300 million for Scotland associated with around 15 works (out of ~70) and costs of around £160 million for 8 (out of ~40) works in NI. Please note that these are really indicative costs for scaling purposes only;

- for these pharmaceuticals, it is important to highlight that the impact assessment does not consider the value of the pharmaceuticals in relation to human health;

- using Diclofenac, as an example, the potential health loss associated with loss of Diclofenac is estimated at around £400 million per year or £10 billion (over 20 years at 4% discount rate). This assumes that there are around 2.5 million patients requiring Diclofenac and there is a 0.005 QALY gain compared to alternative pain relief with the value of a QALY is estimated as £40,000;

- In addition to these costs, there are also the direct health care costs, for instance, associated with lost output. Using arthritis as an example, it can be estimated that around £6 billion will be lost in work sick days over a period of 20 years;

- For EE2, a fundamentally misleading assumption in the Commissions IA is that there are alternative contraceptive methods which are equally effective; this is not the case. As shown in Table 2.3, the combined pill is the most popular contraceptive in the UK and the most effective; any alternatives are likely to have a higher rate of unintended pregnancies. As noted in various research , all contraceptive methods are cost-effective and save health care resources by preventing unintended pregnancies. Up-front acquisition costs are inaccurate predictors of the total economic costs of competing contraceptive methods and because no single contraceptive method is clinically recommended to every woman, it is medically and fiscally advisable for public health programs to offer all contraceptive methods;

- For EE2 (or the combined pill), if it is assumed that all women previously using the combined pill would now use condoms, this would result in around 217,000 additional unintended pregnancies. Using a QALY of £40,000 and a Health Utility State of 0.997, corresponding to a value of £120 (calculated with a Standard Gamble process), the social loss as measured by women's willingness to pay to avoid the unwanted pregnancy would be around £26.2 million per year, equivalent to around £382 million over 20 years (discounted at 4%).

- There are, however, other significant costs associated with unintended pregnancy, including impacts on working life. For instance, for the proportion of women (70,000 – 170,000) who will have unwanted pregnancies as a result of switching from the more effective combined pill (EE2) to the slightly less effective IUDs or condoms, if we assume that 60% of these were working full time before birth (~42,000 – 102,000), it is likely that around 30% (~21,000 – 51,000) will stop work after birth. Of the percentage working full time, it is also likely that around 35% would lose around 4,500 hours of work due to nausea and vomiting in pregnancy.

- For those pregnant women that decide to have an abortion, patient costs including direct medical costs (pregnancy test costs, charges), direct non-medical costs (child care, travel, lodging), and productivity losses (value of time away from work or other activities) would also be incurred .

- In terms of source control, there may be possibilities for addressing releases from livestock from E2; however, these are highly uncertain at the moment and depend on the level of adsorption and breakdown of E2 before it reaches water courses.

- Finally, there are likely to be benefits to other substances such as pentaBDE and potentially some pesticides from treatment installed at other WwTP to treat EE2.

Table 2 summarises the key issues for the three PS relevant to the pharmaceutical sector.

Table 2: Summary of Key Issues for Pharmaceutical Substances on Priority Substances List	
Substance	**9. EE2 (17 alpha-ethinylestradiol)**
Use	Man-made steroid oestrogen - the basis of the birth control pill
Current level of releases	The proposed EC EQS standard for EE2 of 0.035 ng/l results in a modelled failure of 11,361km or 23% of the modelled network. 1,353 sewage treatment works are modelled as contributing to these failures (EA, 2012).
How to achieve progressive reduction	**By installing treatment at WwTps failing for EE2**
Potential for substitution	Possibilities for recommending (whether in a regulatory, advisory or voluntary capacity) other types of contraceptives, rather than combined pill; however, large scale shift to alternative forms of contraceptive unlikely to be feasible in the short to medium term. In the UK, there are around 3.5 million women who take the pill (roughly one in three of all females of reproductive age).
Cost to the UK	Estimates of the costs relating to improvements needed for works contributing to failure of the proposed EE2 EQS were between **£27 bn and £30 bn** associated with around **1,353 WwTP (the lower value relates to** ozone treatment installed as opposed to GAC for the higher value). Of these 1,353 works, around 570 also fail the E2 EQS and this pollutant would also be reduced at the same time (EA, 2012).
Benefits to the UK	Improved water quality, although extent of benefits are uncertain as the provision of additional treatment as modelled does not guarantee achievement of the EE2 standard in the river as this will be dependent on the dilution available. Incurring the costs associated with treating EE2 On the other hand, adsorptive tertiary treatment fitted for EE2 removal are likely to improve the removal of other priority substances on the list such as E2, penta-BDE, and some of the pesticides.
Substance	**10. E2 (17 Beta-estradiol)**
Use	Naturally occurring steroid oestrogen, also widely used in hormone replacement therapy
Current level of releases	
How to achieve progressive reduction	**By installing treatment at WwTps failing for E2** for two main reasons: - Modelling by the EA shows that where a stretch is modelled as failing for steroid oestrogens, EE2 is always a failure. Sometimes, E2 fails the EQS too but there are never modelled failures for E2 alone and E2 failures are always co-incident with EE2 failures; - EE2 being a synthetic substance is much harder to treat and breakdown by biological processes than E2. Unlike EE2, GAC or ozonation is not needed to meet the E2 EQS given the effective E2 removal rates for nitrifying activated sludge plants (ASP). **May be possibilities to explore source control relating to livestock emissions**
Potential for substitution	None
Cost to the UK	The costs to achieve the E2 EQS alone are calculated to be **£10.3bn** associated with around **570 WwTP**. These costs are based on the assumption all works identified as

Table 2: Summary of Key Issues for Pharmaceutical Substances on Priority Substances List	
	contributing to E2 failures would need to be improved to nitrifying activated sludge plants – **and that the EQS for EE2 (and possibly pentaBDE) are dropped**. This is based on the findings from the Endocrine Disruptors Demonstration Programme. The model areas most affected by failures are (as previously indicated for EE2): the Thames, Trent and Wash models followed by the Severn, Yorkshire Ouse, Ribble/Mersey and Wash models.
Benefits to the UK	Improved water quality
Substance	**11. Diclofenac**
Status	**New priority substance**
Use	Used as a non-steroidal anti-inflammatory drug (NSAID) taken to reduce inflammation and as an analgesic reducing pain in conditions such as arthritis or acute injury
Current level of releases	
How to achieve progressive reduction	Uncertain
Potential for substitution	
Cost to the UK	
Benefits to the UK	Uncertain. Study presented by Novartis to the Commission concludes that the proposed EQS is over 300 times lower than that which could be concluded from the results of that study.

Other Substances

The other substances identified in the proposals as PS/PHS are summarised in the Table below.

For pentaBDE, it is important to note that although there are considerable uncertainties and assumptions associated with the SIMCAT modelling of the potential failures of the PS (see Table 3), it appears to be the case that there may be more failures associated with the revised EQS for pentaBDE than for EE2. Assuming that both EE2 and pentaBDE mostly come from domestic sources and are likely to be removed by the same treatment processes, it can be assumed that advanced tertiary treatment processes put in place to address EE2 are likely to result in some of the UK river lengths currently modelled to fail the revised EQS for pentaBDE achieving this. It is also expected that emission levels would decline naturally over time (as pentaBDE is banned) and, as such, the number of river length failures would decrease regardless. In addition, it is also possible that, as further information on the behaviour of pentaBDE becomes available (e.g. extent to which it adsorbs to sediments), the level of failures currently identified may be found to over-estimate the actual situation.

Unlike EE2, there is no monitoring data to validate the BDE modelling and, as such, the results are subject to significant uncertainty. This, however, highlights the need for caution in identifying pentaBDE as a major cost driver for the UK.

Overall, for the present purposes, we would assume that the costs incurred for the treatment of EE2 at WwTP would also result in a decrease in modelled pentaBDE failures (however, if EE2 is not treated at WwTP, then it is likely that the costs for pentaBDE would be in £ billions (even if these are associated with speeding up the removal of pentaBDE).

Table 3: Assumptions/Caveats in BDE SIMCAT modelling assessment
1. Uniform STW effluent assumed across all STWs regardless of process type.
2. This uniform effluent was inputted to SIMCAT as a fixed value rather than as a distribution to speed up processing [likely to lead to less reliable result but unable to state which direction any bias would be in results]
3. This fixed value was 0.0019 ug/l. this was obtained by summing the mean effluent values of BDE47 & BDE99 taken from the Chemical Investigations Programme effluent screening work.
4. No in river decay rate or adsorption to sediment rate used. This is a conservative approach [highly likely to lead to more pessimistic assessment of EQS exceedence but unable to state how much]
5. Only two congeners used in the assessment. EQS is based on summed value of six congeners [likely to lead to optimistic assessment of EQS exceedence; difficult to quantify impact on modelling results but evidence from CIP indicates the 4 other congeners adds another 25%-30% to total concentrations]

Table 4: Summary of Key Issues for Other Substances on Priority Substances List	
New PHS and PS	
Substance	**12. Dioxins and DL-PCBs**
Status	**New priority hazardous substance(s) and biota EQS proposed**
Use	A class of organic compounds with 1 to 10 chlorine atoms attached to biphenyl. The chemical formula for PCBs is C12H10-xClx. PCBs were widely used for many applications, especially as dielectric fluids in transformers, capacitors, and coolants Dioxins and dioxin-like compounds are by-products of various industrial processes, and are commonly regarded as highly toxic compounds that are environmental pollutants and persistent organic pollutants (POPs).
Substance	**13. HBCDD**
Status	**New priority hazardous substance with biota EQS**
Use	A brominated flame retardant. Its primary application is in extruded (XPS) and expanded (EPS) polystyrene foam. Currently subject to authorisation under REACH.
Substance	**14. PFOS**
Status	**New priority hazardous substance with biota EQS proposed**
Use	PFOS is a man-made fluorosurfactant and global pollutant. Designated as a POP. Currently included in the Registry of Intentions (by Germany) under REACH for SVHC listing.
Substance	**15. Terbutryn**
Status	**New priority substance**
Use	Biocide, used in coatings for buildings as preservative
Substance	**16. Cybutryne**
Status	**New priority substance**
Use	Algicide or biocide used as anti-fouling agent in coatings for boat hulls
Old PS Reviewed	
Substance	**17. Poly-BDE**
Status	**Old priority substance - change of EQS greater than one order of magnitude and biota EQS proposed**
Use	
Current level of releases	The new standards for Penta BDE move predicted failure against current standards from about 6% of river length to about 43% for the proposed new standards

Table 4: Summary of Key Issues for Other Substances on Priority Substances List	
How to achieve progressive reduction	Treatment at WWTP. Investigation of failures in specific catchment areas.
Potential for substitution	
Cost to the UK	Could be very significant.
Benefits to the UK	
Substance	**18. Nickel**
Status	**Old priority substance - change of EQS greater than one order of magnitude**
Use	Numerous
Cost to the UK	Estimates for the UK in the Commission's IA indicate that approximately 2% of the UWWTPs might need upgrading, requiring whole-life investment of the order of €2 billion and attendant additional running costs. This estimate is based on an EQS bioavailable of 2µg/l^{-1} and is considered to be a worst case as the ambient concentrations of Nickel in the UK are among the highest in the EU. The actual proposed EQS of 4ug/l is unlikely to result in additional cost because the same technology would be needed to address Cu, Zn Cd failures which at the moment are more significant.
Benefits to the UK	
Substance	**19. DEHP**
Status	**Old priority substance, now priority hazardous substance**
Use	Multiple uses, especially in PVC
How to achieve cessation	Although a gradual move away from the use of DEHP in new plastics may be expected, it is unclear that the rate of replacement of common and long-lasting materials (such as plumbing, flooring) will be quick enough to enable cessation of emissions within 20 years.
Cost to the UK	Could be significant taking into account large amounts of PVC recyclate which would contain DEHP.
Benefits to the UK	Currently subject to both restrictions and to authorisation under REACH and, as such, the additional benefits of WFD listing may be questionable. Also, DEHP has a threshold for its main effects and is only a suspected endocrine disruptor.
Substance	**20. Anthracene**
Status	**Old priority substance - minor change of EQS**
Use	
Substance	**21. Lead**
Status	**Old priority substance - minor change of EQS**
Use	
Substance	**22. Naphthalene**
Status	**Old priority substance - minor change of EQS**
Use	
Substance	**23. PAHs**
Status	**Old priority substance - change of EQS greater than one order of magnitude and biota EQS proposed (except for benzo(g,h,i)perylene)**
Use	
Substance	**24. Flouranthene**
Status	**Old priority substance - change of EQS greater than one order of magnitude and biota EQS proposed**
Use	

ANNEX 2 – EE2

Background to 17 alpha-ethinylestradiol (EE2)

EE2 is a synthetic steroid and is most frequently used as the oestrogen component of combined oral contraceptives. It is also used for the treatment of menopausal and post-menopausal symptoms (especially the vasomotor effects) and for other medicinal purposes (e.g. treatment of female hypogonadism, malignant neoplasm of breast and prostate, acne in women and Turners syndrome) (Kerr JF & Benitez JG, 1997).

Reason for Concern

EE2 is an endocrine disrupting substance. Oestrogens have been shown to have significant effects on aquatic life, such as the feminization of male fish, impaired reproduction and abnormal sexual development (Sellin et al, 2009). Concerns about the presence of endocrine disrupting substances within drinking water and the potential impact on human health have also been raised (Björkblom, 2009). For these reasons, EE2 is being proposed for possible inclusion in the EQSD as a priority substance and a progressive reduction in emissions, discharges and losses will be required.

Sources of EE2

EE2 is a synthetic substance and there are no natural sources in the environment. EE2 enters the environment primarily as a result of excretion of the substance by people that consume the substance in pharmaceutical products via the sewerage wastewater system. There may also be releases during manufacture, transport and storage and disposal.

How to achieve the EQS

Two possible methods exist to achieve the EQS:

- the first method involves installing advanced tertiary treatment to treat the wastewater containing EE2 (i.e. end-of-pipe); and/or
- reducing the amount of EE2 which ends up in the sewerage system (i.e. source control), where this could involve substituting use of the combined pill.

This Annex analyses the impact of potential substitution of the combined pill as a means of achieving the EQS.

Calculating Number of Women in the UK potentially affected

In 2011, the UK female population between 15 and 49 years old is around 14.8 million (according to Eurostat figures). It can be assumed that around 75% of these women are sexually active and are using contraceptives of one form or another; effectively, around 11 million women are using contraceptives.

Table 1 provides the estimated popularity of various contraceptives and their effectiveness based on a survey carried out by the UK Office for National Statistics (ONS) on contraception among women aged 16 to 49 and information from the Family Planning Association. We have assumed that the percentage popularity provides a reasonable proxy for the contraceptives being used; on this basis, we have allocated the contraceptives being used across the 11 million women in the UK.

The results (see Table 6) show that around 3.1 million UK women are on the combined pill. It is possible that this figure underestimates the number of women on the pill. UN (2009) suggests a figure of 29% for UK, based on a survey conducted in 2007/2008 and alternative sources (Netdoctor, 2011) suggest that there are around 3.5 million UK women on the combined pill,

Table 5: League Table of Popularity among Various Methods of Family Planning and Effectiveness			
Ranking	**Contraceptive**	**Popularity***	**Effectiveness**
1st equal	The Pill	25 %	Almost 100 %
	The mini-pill		Around 98 %
1st equal	The male condom	25 %	90 to 98 %
3rd	Vasectomy	11 %	Almost 100 %
4th	Female sterilisation	9 %	Almost 100 %
5th	The coil (intra-uterine device or IUD)	4 %	97 to 98 %
6th	Withdrawal method	4 %	
7th	Variations of the rhythm method	3 %	
8th equal	The contraceptive injection ('the Jab')	2 %	Almost 100 %
8th equal	Mirena (intra-uterine system or IUS)	2 %	98 to 99 %
10th equal	The skin patch (Evra)	1 %	
10th equal	The cap or diaphragm	1 %	90 to 96 %
12th	The female condom	<1 %	90 to 98 %
13th	The vaginal ring	<1 %	
http://www.netdoctor.co.uk/sex_relationships/facts/contraception_which.htm			
** Popularity among the various methods of family planning is based on the recent survey carried out by the ONS on contraception among women aged 16 to 49, plus information from the Family Planning Association.*			

Impact on Quality of Life of Women – Unintended Pregnancies

Using the indicated effectiveness of each contraceptive method, we have calculated the likely additional unintended pregnancies per year associated with moving from the combined pill to other contraceptive methods.

Unintended pregnancies impact on the quality of life of women. A study undertaken to assess the potential impact of an unintended pregnancy on women's quality of life indicated that:

- 8% reported pregnancy would make them feel like they were dying and create a health utility state (where 0 represents death and 1 represents perfect health) of **0.487**;
- 28% were willing to trade time from the end of their life to avoid pregnancy, where pregnancy was considered to create a health utility state of **0.992**;
- 16% of women were willing to accept an immediate risk of death, where pregnancy was considered to create a health utility state of **0.997**; and
- 60% of women were willing to pay some amount of money.

Using a QALY of £40,000 (Joore M *et al*, 2010), and a Health Utility State of 0.997, (calculated with a Standard Gamble process (Schwarz EB *et al*, 2008) women's loss of QALY has a value of £120 per year. The social loss as measured by women's loss of QALYs due to the unwanted pregnancy taken over 20 years (discounted at 4%) can be calculated.

Table 6: League Table of Popularity among Various Methods of Family Planning and Effectiveness						
Types of modern contraceptives	**% of Women Using Contraceptives**	**Population of Women using contraceptives**	**Effectiveness of Contraceptive Method (Actual use)**[1]	**Additional Unintended pregnancy from Switching**	**Social loss per year (rounded)**	**Social loss over 20 years (discounted at 4%)**
Women 15-49		**14,822,473**				
Sexually active population using modern contraceptives (75%)		**11,116,855**				
Combined Pill	28%	3,112,719	92%			
Male Condom	27%	3,001,551	85%	217,890	£26.2 million	**£382 million**
Vasectomy	19%	2,112,202	99.85%			
Female sterilisation	9%	1,000,517	99.5%			
IUD	6%	667,011	99.2%			
Injectable or implant	5%	555,843	97%			
Mini pill	1%	111,169	92%			
Other (e.g. female condoms)	5%	555,843	84%	249,018	£29.9 million	**£436 million**
	100%					
1 http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.cfm https://www.optionsforsexualhealth.org/birth-control-pregnancy/birth-control-options/effectiveness						

If it is assumed that all women previously using the combined pill would now use condoms (where it is assumed that the natural move in substitution is to the next most popular protection), this would result in around **217,000 additional unintended pregnancies** and a social cost of around **£26.2 million per year**, equivalent to around **£382 million** over 20 years (discounted at 4%).

In this regard, it is assumed that due to the invasive nature of the procedures required for IUDs and implants (i.e. a trained medical practitioner will need to perform the procedure), it is considered unlikely that many women will switch from the combined pill to these forms of contraceptives, even if they are probably equally or more effective.

Assuming a move to other forms of modern contraceptives (e.g. female condom), would result in around **249,000 additional unintended pregnancies** and a social cost of around **£29.9 million per year**, equivalent to around **£436 million** over 20 years (discounted at 4%).

Impacts in Terms of Lost Output

There are other significant costs associated with unintended pregnancy, including impacts on working life. Recent research shows that while 63% of mothers were working full-time before the birth, this number dropped to 34% after the birth (Changeboard.com, 2009).

Using the figures in Table 5, it can be deduced that for the proportion of women who will have unwanted pregnancies as a result of switching from the more effective combined pill (EE2) to the slightly less effective IUDs or condoms (70,000 – 170,000 respectively), around 60% of these were working full time before birth (42,000 – 102,000) and it is likely that around 30% (**21,000 – 51,000 women**) will stop work after birth. These are costs for the individuals, families and society as a whole of losing this workforce on an annual basis.

Part-time work often brings penalties in terms of pay and promotion and employers also lose, in some instances. For instance, during the pregnancy period, it has been estimated that around

35% of women (Pregnancy Sickness Support, 2012) would lose around 4,500 hours of work due to nausea and vomiting in pregnancy.

Impacts on Abortion Rates

Not all pregnant women will carry their babies to term. For those pregnant women that decide to have an abortion, patient costs including direct medical costs (pregnancy test costs, charges), direct non-medical costs (child care, travel, lodging), and productivity losses (value of time away from work or other activities) would also be incurred (Van Bebber *et al*, 2006).

Impacts on Manufacturers of Combined Pills

The size of the market for combined pills is currently uncertain.

In the US, one company made sales of around $616 million (or around 18% market share) for one contraceptive pill (The New York Times, 2009; Forbes (2003)). This would suggest that the US market for contraceptive pills was worth around $3 billion. The EU population is around 1.5 times the US population; assuming a similar use of the combined pill would suggest an EU market worth around **€4 billion in sales**. This is a rough figure in the absence of quickly available data but highlights the potential size of the market in question. This income could in theory be lost by the pharmaceutical industry if the use of oral contraceptives and other products containing EE2 was to cease.

The Commission assumes that the combined oral pill is likely to be substituted by the mini pill and, as such, the lost sales would relate to the differential production cost between the costs to produce the two products. This may, however, not be the case. If it is assumed more likely that the more popular products are likely to be switched to more (i.e. condoms and IUDs), the impacts on the pharmaceutical industry could be significant. Other costs that could be incurred by the pharmaceutical industry include the costs of provision of medical education and consumer information that would be required to support the substitution of the combined oral pill. Consumer campaigns across the EU-27 can be expected to cost in the **tens of millions of pounds**.

In summary, the inclusion of EE2 needs further consideration in terms of costs. In this regard, it is important to note that medicinal uses (e.g. treatment of female hypogonadism and malignant neoplasm of breast and prostate) have not been captured in the preliminary assessment of costs associated with a potential withdrawal of EE2.

References

ADAS (2010): **Impact of Changing Pesticide Availability on Horticulture**, Report by ADAS UK Ltd, dated 31 March 2010 available from http://www.hdc.org.uk/industry-reports/files/Review%20Document.pdf

ARC (2009): **Arthritis, The Big Picture**, available at http://www.ipsos-mori.com/Assets/Docs/Archive/Polls/arthritis.pdf

Björkblom C., (2009): **Assessment Of Endocrine Disrupting Activities In The Aquatic Environment.** Academic Dissertation. Department of Biology, Åbo Akademi University Finnish Graduate School in Environmental Science and Technology Turku, Finland, available from http://www.doria.fi/bitstream/handle/10024/43821/BjorkblomCarina.pdf?sequence=2

Changeboard.com (2009): **Sidelined Women – 30,000 Lost Jobs Due to Pregnancy/Maternity - £23b Impact on Economy,** Article dated 5th October 2009, available from http://www.changeboard.com/content/1610/Sidelined-women---30,000-lost-jobs-due-to-pregnancy-maternity---23b-impact-on-economy/

EA (2012): Note on the modelled impact of proposed EC standard of the steroid oestrogen ethinyloestradiol on river quality in England and Wales.

EC (2012): **Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards Priority Substances in the Field of Water Policy, COM(2011)876 final, {SEC(2011)1546 final} {SEC(2011)1547 final}, Brussels, 31 January 2012,** Report available from, http://ec.europa.eu/environment/water/water-dangersub/pdf/com_2011_876.pdf

EC (2012b): **Commission Staff Working Paper - Impact Assessment - Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards Priority Substances in the Field of Water Policy {COM(2011) 876 final} {SEC(2011) 1546 final} Brussels, 31.1.2012 SEC(2011) 1547 final,** Report available from http://ec.europa.eu/environment/water/water-dangersub/pdf/sec_2011_1547.pdf

ENTEC (2011): **Technical Support for the Impact Assessment of the Review of Priority Substances under Directive 2000/60/EC,** Final Report for European Commission (DG Environment) by Entec UK Limited, June 2011, available from http://circa.europa.eu/Public/irc/env/wfd/library?l=/framework_directive/thematic_documents/priority_substances/supporting_substances/substance_impacts/anthracenepdf/_EN_1.0_&a=d

Forbes (2003): **Schering AG Storms Birth Control Market**, Article by Aude Lagorce available from http://www.forbes.com/2003/07/11/cx_ad_0710shr.html

Foster DG *et al* (2009): **Cost Savings from the Provision of Specific Methods of Contraception in a Publicly Funded Program**, American Journal of Public Health, Vol 99 No3, March 2009, pp446-451, Article available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661445/?tool=pubmed

Forestry Commission (2001): The Assessment of Site Characteristics as Part of a Management Strategy to Reduce Damage by Hylobius, Available at http://www.forestry.gov.uk/pdf/fcin38.pdf/$FILE/fcin38.pdf

Joore M *et al* (2010): **The Impact of Differences in EQ-5D and SF-6D Utility Scores on the Acceptability of Cost-Utility Ratios: Results across Five Trial-Based Cost-Utility Studies,** Value in Health, Vol 13 No 2, March/April 2010, Article available from http://onlinelibrary.wiley.com/doi/10.1111/j.1524-4733.2009.00669.x/full#f2

Kerr JF & Benitez JG (1997): **Ethinylestradiol,** Available from http://www.inchem.org/documents/pims/pharm/pim221.htm

Netdoctor (2011): **Contraception – the contraceptive pill**, Article by Dr David Delvin available from http://www.netdoctor.co.uk/sex_relationships/facts/contraceptivepills.htm

New York Times (2009): **A Birth Control Pill that Promised Too Much**, Article by Natasha Singer available from http://www.nytimes.com/2009/02/11/business/11pill.html?_r=2

Prnewswire (2004): **Eurand Receives Approval to Market Generic Sodium Diclofenac**, News article published October 25, 2004 and available at http://www.prnewswire.com/news-releases/eurand-receives-approval-to-market-generic-sodium-diclofenac-74940577.html

Pregnancy Sickness Support (2012): **Employment in Relation to NVP. Time Lost from Work,** Available from http://www.pregnancysicknesssupport.org.uk/healthcare-professionals/literature-review/employment-in-relation-to-nvp-time-lost-from-work/

Pulse (2010): **Diclofenac OTC switch confounds efforts to cut NSAID use**, Article by Lilian Anekwe dated 12 January 2010 and available at http://www.pulsetoday.co.uk/newsarticle-content/-/article_display_list/11021547/diclofenac-otc-switch-confounds-efforts-to-cut-nsaid-use

Schwarz EB *et al* (2008): **Measuring the Effects of Unintended Pregnancy on Women's Quality of Life,** Contraception, Vol 78 No 3, September 2008, pp204-210, Article available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2580059/

Sellin MK *et al* (2009) **Estrogenic Compounds Downstream From Three Small Cities In Eastern Nebraska: Occurrence And Biological Effect**. Journal Of The American Water Resources Association. Vol. 45, No. 1 pp14-21.

Trussell J *et al* (1995): **The Economic Value of Contraception: A Comparison of 15 Methods,** American Journal of Public Health, Vol 85 No 4, April 2009, pp494-503, Article available from http://www.ncbi.nlm.nih.gov/pubmed/7702112

UN (2009): **World contraceptive Use 2009,** United Nations – Department of Economic and Social Affairs – Population Division. http://www.un.org/esa/population/publications/contraceptive2009/contracept2009_wallchart_front.pdf

Van Bebber SL *et al* (2006): **Patient Costs for Medication Abortion: Results from a Study of Five Clinical Practices,** Women's Health Issues, Vol 16 No 1, January 2006, pp4-13, Article available from http://www.whijournal.com/article/S1049-3867%2805%2900081-2/abstract

Printed in the United Kingdom by The Stationery Office Limited
9/2013 33035 19585

Distributed by TSO (The Stationery Office) and available from:

Online
www.tsoshop.co.uk

Mail, Telephone, Fax & E-mail
TSO
PO Box 29, Norwich NR3 1GN
General enquiries 0870 600 5522
Order through the Parliamentary Hotline *Lo-call* 0845 7 023474
Fax orders: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone: 0870 240 3701

The Houses of Parliament Shop
12 Bridge Street, Parliament Square
London SW1A 2JX
Telephone orders: 020 7219 3890/General enquiries: 020 7219 3890
Fax orders: 020 7219 3866
Email: shop@parliament.uk
Internet: http://www.shop.parliament.uk

TSO@Blackwell and other Accredited Agents

PEFC
PEFC/16-33-622

ISBN 978-0-215-06225-3
9 780215 062253