



Department
for Environment
Food & Rural Affairs



Department for
Business, Energy
& Industrial Strategy

A consultation on the proposed Control of Mercury (Enforcement) Regulations 2017

October 2017



The Scottish
Government
Riaghaltas na h-Alba



Llywodraeth Cymru
Welsh Government



Department of
Health

An Roinn Sláinte
Mánnystrie O Poustie



Department of
**Agriculture, Environment
and Rural Affairs**



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Contents

Part I – About this consultation	1
1.1 Who is leading this consultation?	1
1.2 Who will be interested in responding?	1
1.3 Northern Ireland rural proofing impact assessment.....	2
1.4 When and where would the new measures apply?	2
1.5 Why is government consulting?	3
1.6 Exiting the EU	3
1.7 Having your say.....	3
1.8 Next steps	3
Part II – Background	4
2.1 Mercury	4
2.2 The Minamata Convention on Mercury	5
2.3 The EU Regulation on Mercury	5
2.4 Impact of the EU Regulation	6
2.5 The proposed UK Mercury Regulations	7
Part III - Consultation	8
3.1 Confidentiality.....	8
3.2 Environmental provisions	8
3.2.1 Enforcement authorities.....	8
Enforcement in Northern Ireland.....	10
3.2.2 Rationale	10
3.2.3 Powers.....	12
3.2.4 Border Force.....	15
3.2.5 Criminal offences.....	16

3.2.6 Monetary penalties (civil, fixed and variable monetary penalties)	17
3.2.7 Appeals.....	20
3.2.8 Applications to import mercury and mixtures of mercury	22
3.2.9 Notifications relating to new mercury-added products and new manufacturing processes using mercury.....	24
3.3 Dental provisions.....	27
3.3.1 England	27
Articles 10(1) and 10(2) in England	27
Article 10(3) in England	28
Article 10(4) in England	28
3.3.2 Wales.....	28
Article 10(1) in Wales.....	28
Article 10(2) in Wales.....	28
Provisions for dental practices only providing private care in Wales	29
Article 10(3) in Wales.....	29
Article 10(4) in Wales.....	30
3.3.3 Scotland.....	30
Article 10(1) In Scotland	31
Article 10(2) in Scotland.....	31
Article 10(3) in Scotland.....	32
Article 10(4) in Scotland.....	32
3.3.4 Northern Ireland.....	32
Article 10(1) in Northern Ireland.....	33
Article 10(2) in Northern Ireland.....	33
Article 10(3) in Northern Ireland.....	34

Article 10(4) in Northern Ireland.....	34
Annex I Confidentiality and Data Protection Information.....	36
Annex II Provisions relating to the environment and relevant dental provisions	38
Annex III Provisions relating to dentistry (and the environment)	40
Annex IV List of consultation questions	41

Part I – About this consultation

1.1 Who is leading this consultation?

This is a joint consultation led in England by Defra and the Department for Business, Energy and Industrial Strategy (BEIS), with input from the Department of Health. In the Devolved Administrations it has been led by the Scottish Government, the Welsh Government, the Department of Agriculture, Environment and Rural Affairs (Northern Ireland) and the Department of Health (Northern Ireland). The departments involved in this consultation will from now on be referred to in this consultation document as “government” unless otherwise specified.

This is a consultation on the proposed UK approach to the implementation of the requirements of European Union (EU) Regulation 2017/852 on Mercury (‘the EU Regulation’). It covers the proposed provisions of the Control of Mercury (Enforcement) Regulations (‘the UK Regulations’) which are intended to implement the environmental requirements of the EU Regulation. It is also proposed that the UK regulations should set out arrangements for the enforcement of the requirement for an amalgam separator as this has been identified as a risk to the environment and public health but not a risk to individual dental patient safety.

Government considers that the provisions in the EU Regulation that relate to the use of encapsulated dental amalgam and the use of dental amalgam fillings should however be managed through the existing regulatory system for dental services. Consequently it is proposed that the UK Regulations would not create any new enforcement powers in respect to these requirements.

1.2 Who will be interested in responding?

This consultation will be of particular interest to:

- i) Those involved in the export of mercury, mercury compounds, mixtures of mercury and waste mercury,
- ii) Those involved in the import of mercury or mixtures of mercury,
- iii) Those involved in the export, import and manufacturing of products containing mercury,
- iv) Organisations that use mercury in manufacturing processes, especially the chlor-alkali industry,

- v) Operators (in particular in the offshore oil and gas exploration / production sector) involved in the cleaning of natural gas and the waste mercury gained from this process,
- vi) Scientists, engineers, technicians or other individuals interested in using mercury in new products or new manufacturing processes,
- vii) Dental practices and dental practitioners,
- viii) Hospitals where dental surgery is undertaken,
- ix) Operators providing hazardous waste management services to dental practices and other organisations that produce waste mercury,
- x) Operators interested in providing temporary or permanent storage facilities for waste mercury,
- xi) Operators interested in mercury waste management, specifically in the conversion and solidification of waste mercury, and
- xii) Environmental groups and individuals interested in the management of chemicals and hazardous waste.

1.3 Northern Ireland rural proofing impact assessment

In Northern Ireland, under Section 75 of the Northern Ireland Act 1998, all government policy is required to have due regard for the need to ensure equality. In addition, all new policies must undergo a Rural Proofing Impact Assessment. Accordingly, screening exercises were carried out to ascertain if the policies contained in this document require full impact assessments and both indicated that full assessments are not required. Further information is available from the Department of Agriculture, Environment and Rural Affairs.

1.4 When and where would the new measures apply?

The EU Regulation will be directly applicable in UK law, but domestic legislation is required in order to designate authorities for the enforcement of the environmental provisions.

The proposed UK Regulations would come into force on 1 January 2018, and would apply across the United Kingdom (including relevant marine areas e.g. territorial waters and the United Kingdom Continental Shelf).

1.5 Why is government consulting?

This consultation requests stakeholders' views on government's proposed approach to implementing the EU Regulation. Government is particularly interested in views on whether the proposed approach is appropriate and proportionate.

1.6 Exiting the EU

On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

1.7 Having your say

If you wish to respond, please submit your comments by 21 November 2017.

You can respond in one of three ways:

- a. Online by completing a questionnaire at: <https://consult.defra.gov.uk/>
- b. E-mail to: chemicals.strategy@defra.gsi.gov.uk
- c. Post to:

DEFRA EU and International Chemicals Team
Area 2A, Nobel House
17 Smith Square
London SW1P 3JR

Our preferred method is online because it is the fastest and most cost-effective way for us to collate and analyse responses.

Unless you specifically request your response to be treated confidentially, your response may be made public. For more information please refer to Annex I.

1.8 Next steps

We will publish the summary of consultation responses within 12 weeks. We plan to lay the UK Regulations in Parliament as soon as practicable, after the consultation closes, so that they can enter into force on 1 January 2018.

Part II – Background

2.1 Mercury

Elemental mercury is a heavy silvery-white metal which is liquid and readily evaporates at room temperature. In nature, mercury is mostly found in deposits of cinnabar but also in deposits of other metals such as lead and zinc. It is also found in smaller amounts in rocks, including coal and limestone.

Mercury can be released naturally from volcanic activity and rock weathering but is also released from a range of anthropogenic sources, including: energy production (in particular, from coal combustion); industrial processes (such as cement production, metallurgical processes, and processes using mercury as a catalyst) and waste management (in particular, incineration). Mercury is used in a variety of applications, such as healthcare, electrical and electronic devices and measuring equipment. Outside Europe, mercury is also widely used in artisanal and small-scale gold mining. Once released into air or water, mercury can travel over long distances and mercury pollution is therefore a global issue. The release of mercury into the environment is problematic for a number of reasons: it does not break down easily and once deposited in soil or sediments it may change its chemical form and become methylmercury. Methylmercury is not readily eliminated from organisms and so accumulates at each step in the food chain, magnifying particularly in aquatic food chains from bacteria, to plankton, through macroinvertebrates, to herbivorous fish and to fish-eating fish. This exposure of fish to sub-lethal mercury concentrations can lead to a wide variety of physiological, reproductive and biochemical abnormalities.

The World Health Organization (WHO) lists mercury among the 'ten chemicals of major public health concern'¹. Mercury may produce harmful effects on the central nervous system, thyroid, kidneys, lungs, immune system, eyes, gums and skin. Human exposure occurs mainly through the consumption of seafood containing methylmercury and through inhalation of elemental mercury vapours released from industrial processes or artisanal and small-scale gold mining. Although all humans are exposed to mercury to some degree, some groups are at a higher risk, in particular foetuses, breast-fed babies and infants exposed through seafood consumption, either directly or through their mother, and people who are chronically exposed to high levels of mercury, for instance due to subsistence fishing or work.

¹World Health Organization (2010) "Preventing disease through healthy environments
http://www.who.int/ipcs/assessment/public_health/mercury/en/

2.2 The Minamata Convention on Mercury

The Minamata Convention on Mercury is named after a Japanese town where the worst recorded case of mercury pollution occurred. The pollution was caused by the release of methylmercury in industrial wastewater from a local chemical factory, which then accumulated in the fish and shellfish consumed by the local population. The factory continued to emit methylmercury between 1932 and 1968. The form of mercury poisoning resulting from this pollution is now known as Minamata disease. As of the end of 2016, nearly 3,000 people in Japan have been officially designated as suffering from Minamata disease, this includes over 1,700 people who have died as a result of the pollution.

The Convention is an international treaty designed to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. It aims to achieve this goal by imposing restrictions on the production, trade in, and use of mercury and mercury-added products and the disposal of mercury wastes worldwide.

The Convention currently has over 128 signatories. 84 countries have ratified the Convention and it entered into force on 16th August 2017.

Government takes the protection of human health and the environment seriously and is committed to being part of international efforts to limit mercury emissions and releases on a global scale. The UK was very active during the Convention negotiations; fully supporting its objectives and signed the Convention in October 2013. Government has expressed its commitment to ratify the Convention once the necessary UK legislation is in place.

2.3 The EU Regulation on Mercury

Regulation 2017/852 was adopted by Member States to fill gaps in existing mercury legislation and enable ratification of the Minamata Convention. It provides a legislative framework with provisions concerning:

- exports of mercury, mercury compounds and specified mixtures of mercury,
- imports of mercury and specified mixtures of mercury,
- export, import and manufacture of specified mercury-added products,
- the production of new mercury-added products,
- the development of new manufacturing processes using mercury,
- the use and interim storage of mercury,

- the use of mercury in artisanal and small-scale gold mining,
- the use of mercury in dentistry,
- the designation of mercury from specified sources as waste,
- the temporary and permanent storage of mercury waste, and
- reporting on the movement, temporary and permanent storage of mercury waste,

The Regulation will fully apply from 1 January 2018², it also repeals a previous mercury regulation (Regulation (EC) No. 1102/2008) which bans exports of metallic mercury and certain mercury compounds and requires the safe storage of metallic mercury.

The EU Regulation does not introduce any new provisions on the regulation of emissions of mercury and mercury compounds from crematoria but there is a requirement on the Commission to report to the European Parliament and to the Council on the outcome of its assessment regarding the need to regulate these emissions by 30 June 2020 (Article 19(1) (a)).

2.4 Impact of the EU Regulation

Mercury is a highly toxic substance, which has been subject to strict control under UK legislation for many years. Industry stakeholders were kept informed of the development and negotiation of the EU Regulation by government through the UK Chemicals Stakeholder Forum. Consequently, government anticipates that there will be negligible impact on UK businesses.

UK businesses that wish to import mercury or mixtures of mercury listed in Annex I of the Regulation will need to apply for import consent. Implementing this provision will result in a small increase in the administrative burden associated with importing mercury or using mercury. In some cases import authorisation may be withheld if criteria relating to the source, origin and intended use of the mercury are not met.

² A provision prohibiting the use of mercury as an electrode in chlor-alkali production applies from 11 December 2017.

Operators that wish to produce new mercury-added products not manufactured prior to 1 January 2018 or develop new manufacturing processes using mercury that were in operation prior to the same date will have to apply through the environmental regulators for approval by the European Commission. Implementing this provision will also result in an increase in the administrative burden associated with developing new products or processes that use mercury. In some cases approval may be withheld by the Commission if the specified criteria are not met.

The use of mercury in manufacturing processes listed in Annex III of the EU Regulation is also restricted and the import, export and manufacturing of mercury-added products listed in Annex II of the EU Regulation is prohibited

Restrictions on the use of dental amalgam will also apply. These include a requirement that dentists only use pre-dosed encapsulated dental amalgam and a requirement for an amalgam separator to be installed in every dental facility where dental amalgam is used or fillings containing amalgam are removed.

The use of dental amalgam in the treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women will also be prohibited, except where deemed strictly necessary by the dental practitioner on the basis of the specific medical needs of the patient. For pregnant and nursing mothers, advice from the Department of Health (England) has been to avoid or delay amalgam restorations in these circumstances.

2.5 The proposed UK Mercury Regulations

Defra Ministers, in agreement with Ministers in the devolved administrations, have decided to introduce a single set of UK-wide regulations that would enable enforcement by the relevant authorities in each devolved administration. This approach is intended to make UK implementation as effective, simple to understand and easy to comply with, as possible.

The proposed UK Regulations would also repeal The Mercury Export and Data (Enforcement) Regulations 2010 (“the 2010 Regulations”).

Further details of the proposed approach to the UK implementing legislation are outlined in Part III of this document.

Part III - Consultation

3.1 Confidentiality

For full confidentiality information, please see the Confidentiality and Data Protection Information in Annex I.

Q1. Do you want your response to this consultation to be confidential?

Yes

No

If you answered yes to this question, please give your reason.

3.2 Environmental provisions

3.2.1 Enforcement authorities

Government proposes that the majority of the provisions in the EU Regulation would be enforced by the environmental regulators (the Environment Agency (EA), Natural Resources Wales (NRW), the Scottish Environment Protection Agency (SEPA) and the Northern Ireland Environment Agency (NIEA).

The proposal is that the EA, SEPA and NRW would be the enforcement authorities for the following provisions:

- restrictions on mercury exports (Article 3) (N.B. this does not apply to intra-EU movements of mercury),
- restrictions on imports of mercury and mixtures of mercury (Article 4) (this also does not apply to intra-EU movements of mercury),
- determining applications for consent to import mercury or mixtures of mercury for use (Article 4),

- restrictions on the export, import and manufacturing of mercury-added products (Article 5),
- restrictions on the use of mercury in manufacturing processes (Article 7),
- restrictions on the placing on the market of new products containing mercury (Article 8(1))
- restrictions on the use of mercury or mercury compounds in new manufacturing processes (Article 8(2)),
- processing and assessment of notifications relating to new mercury-added products and new manufacturing processes using mercury (Article 8(4)),
- restrictions on the use of mercury in artisanal and small scale gold mining (Article 9) (see below),
- requirement for an amalgam separator in dental facilities in which dental amalgam is used or dental fillings or teeth containing such fillings are removed (Article 10(4)),
- requirements on the handling and collection of amalgam waste (Article 10(6)), and
- requirements on the release of amalgam waste into the environment (Article 10(6)).
- disposal requirements for mercury waste from specified large sources (Article 11),
- receiving and collating reports and certificates relating to mercury waste from the operators of large sources of mercury waste (Article 12),
- requirements for the permanent storage of mercury waste (Article 13),
- receiving and collating registers relating to the temporary storage of mercury waste the conversion of mercury waste³ and, if applicable, the solidification of mercury waste from operators of these services (Article 14), and
- preparation and publication of reports relating to implementation (Article 18).

³ Conversion to mercury sulphide (HgS).

Enforcement in Northern Ireland

Government proposes that in Northern Ireland, the Northern Ireland Environment Agency would have responsibility for enforcing all of the above provisions with the exception of the requirement for an amalgam separator (Article 10(4)) and the provisions restricting imports of mercury and mixtures of mercury (Article 4). Government has not yet developed a preference on how these provisions would be best enforced in Northern Ireland and the views of stakeholders are sought.

3.2.2 Rationale

The environmental regulators are currently responsible for enforcing many of the provisions in Regulation (EC) No 1102/2008 and government proposes that they should retain those roles for those provisions that are replicated in the new EU Regulation.

Government considers that the regulators' existing functions could be expanded to include additional responsibilities within their area of expertise with limited cost and resource implications. It is the view of government that as the reporting requirements under the 2010 Regulations on offshore installations engaged in hydrocarbon-related operations relate to mercury waste, it is proposed that the environmental regulators should be responsible for enforcing the relevant offshore provisions of the UK Regulations as this would mirror existing arrangements under other waste legislation (e.g. The Transfrontier Shipment of Waste Regulations 2007 (as amended)).

An alternative approach would be to make BEIS the enforcement authority for the offshore requirements but this isn't considered the most appropriate option as government considers that the proposed approach reflects the fact that BEIS's Offshore Petroleum Regulator for Environment and Decommissioning (OPRED) is not an enforcing authority in respect to other UK waste legislation.

However, to support the environmental regulators it is proposed that BEIS / OPRED should have an 'investigation and evidence gathering' role under the proposed UK Regulations. This would enable BEIS / OPRED to continue to seek information from operators relating to mercury waste generated on offshore installations and the facilities to which this waste is sent for temporary storage and/or permanent disposal. It is proposed that the UK Regulations would also include suitable provisions so that, if requested by the environmental regulators, OPRED Inspectors would be able to visit / board and inspect offshore installations to investigate any alleged contraventions of the Regulations.

Given the existing roles of the environmental regulators in enforcing the environmental permitting of non-ferrous metal (gold) processing (or production) operations government believes they are best placed to enforce the provisions relating to artisanal and small scale gold mining. The Crown Estate and Crown Estate Scotland manage the Mines Royal (gold and silver) throughout the UK⁴ on behalf of the Monarch. The Crown Estate and Crown Estate Scotland are not aware of any use of mercury by existing Mines Royal option holders or lessees. For smaller unregulated operations, such as gold panning, it is understood that the extraction of gold using mercury amalgamation is not used or supported within the UK.

With respect to the requirements of Article 8(4) relating to notifications for new mercury-added products or new manufacturing processes using mercury, the role of the environment regulators would be to determine whether notifications submitted by UK operators meet the criteria specified in Article 8(6). If the environmental regulators are satisfied that the criteria are met, the information provided would be forwarded to the European Commission for its assessment.

Consideration was given to designating the Health and Safety Executive (for Great Britain) and the Health and Safety Executive for Northern Ireland as competent authorities for Article 5, due to their roles in the enforcement of the Prior Informed Consent Regulation (Regulation 649/2012) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (Regulation (EC) No. 1907/2006), on which some of the provisions in the EU Regulation are based. However, given their experience as competent authorities under the Mercury Export and Data (Enforcement) Regulations 2010 and in enforcing the current mercury export ban and requirements on safe storage of mercury, the environmental regulators are considered to be a more appropriate choice.

Q2. Do you have any comments on the proposed enforcement authorities for the provisions detailed in Section 3.2.1?

- Yes
- No

If you answered yes to this question, please provide your comments.

⁴ With the exception of some limited areas in Scotland.

Q3. Do you have any specific views or comments on the enforcement in Northern Ireland of the requirement for an amalgam separator and the provisions restricting the import of mercury and mixtures of mercury?

Yes

No

If you answered yes to this question, please provide your comments and any rationale.

3.2.3 Powers

Government proposes to make use of existing powers of entry available to the UK environmental regulators and provide the environmental regulators with the following new powers:

- serve information notices to obtain information,
- serve enforcement notices requiring individuals or organisations to take steps to comply with one or more of the provisions of the EU Regulation and to recover the costs of this, (see **Annex II**),
- arrange for an enforcement notice to be complied with and to recover the costs of this, and
- a power that would enable the environmental regulators, BEIS / OPRED, the health and social care regulators, Border Force and Her Majesty's Revenue and Customs to share information to support the assessment of compliance and aid enforcement.

In addition, in England and Wales, the UK Regulations could provide the EA and NRW with the following powers to:

- serve civil monetary penalty notices where the regulator is satisfied that one or more of the provisions of the EU Regulation have not been complied with (refer to **Annex II**),
- serve a civil monetary penalty notice for failing to comply with an information notice or an enforcement notice,

- publish information about a civil monetary penalty (the subject of the penalty, the amount, etc.)
- withdraw civil monetary penalties notices,
- recover a civil monetary penalty as a debt,
- take civil proceedings if another remedy under the regulations would be ineffectual, and
- recover costs associated with a civil monetary penalty notice,

In Scotland, the UK Regulations could provide SEPA with powers to ensure compliance with the provisions in the EU Regulation by including the offences (see below) under the UK Regulations in the list of offences in Schedule 4 to the Environmental Regulation (Enforcement Measures)(Scotland) Order 2015. The UK Regulations could also give new powers to SEPA and the regulator would then have:

- a power to serve fixed or variable monetary penalty notices where it is satisfied on the balance of probabilities that one of those offences has been committed,
- a power to accept an enforcement undertaking where it has reasonable grounds to suspect one of these offences has been committed,
- a power to recover any penalty as a civil debt, and
- a power to recover costs associated with a variable monetary penalty notice.

Fixed or variable penalty notices require a person to pay a financial penalty to the regulator, which is then remitted to the Scottish Consolidated Fund. The maximum amount of a variable penalty is the maximum penalty for an offence available on summary conviction. In the UK Regulations, this is proposed to be the statutory maximum (currently £10,000). There are different levels of fixed penalties associated with different offences. It is proposed that in Scotland, in cases where a fixed penalty is appropriate as an alternative to prosecution, the proportionate level of fixed penalty for the majority of these offences is likely to be £600.

In Northern Ireland, current legislation does not provide for the issue of civil monetary penalty notices. Any offence in relation to non-compliance would, therefore, be treated as a criminal offence and would be included within the relevant offences sections of the Northern Ireland legislation as appropriate. However, Article 5A of the Waste and Contaminated Land (Northern Ireland) Order 1997 and regulation 46 of the Hazardous Waste Regulations (Northern Ireland) 2005 both provide for enforcing authorities to serve notices offering the opportunity to discharge any liability to conviction by payment of a fixed penalty. It is proposed that the UK Regulations would amend the Northern Ireland provisions to include the mercury requirements within those offences and penalties.

To ensure parity, the proportionate level of fixed penalty for the majority of these offences would reflect those established in Scotland, currently suggested at £600. Further information in relation to criminal offences in Northern Ireland is contained in Section 3.2.5 of this document.

In England, Wales and Scotland, it is proposed that the environmental regulator would be able to rely on the powers it already has under section 108 of the Environment Act 1995, in order to enforce the UK Regulations. These include the power to enter premises, the power to examine or investigate, the power to direct things to be left undisturbed, to take measurements or photographs, to take samples, to dismantle, test or seize things that are likely to be harmful to the environment or human health, to require specific information and answers to questions to be provided by witnesses, to require records to be produced, to seize documents under warrant, and to require facilities and assistance to be provided. In Northern Ireland Article 72 of the Waste and Contaminated Land (Northern Ireland) Order 1997 provides broadly similar powers of entry and inspection to authorised officers.

Many aspects of the environment are protected by laws and enforced by regulators. Many persons, including businesses, public organisations, landowners or individuals comply with these laws, and most strive to do so. Those who do not comply, put at risk or actually harm the environment, and spoil our quality of life. Non-compliant businesses also undermine law-abiding businesses. The powers proposed by government are considered necessary, appropriate and consistent with existing enforcement powers for similar requirements in environmental legislation relating to hazardous substances.

Government considers that the powers detailed above would give the environmental regulators flexibility to respond in ways proportionate to the seriousness of the non-compliance.

Q4. Do you consider that the powers detailed in Section 3.2.3 would provide the environmental regulators with appropriate powers to effectively enforce the UK Regulations?

- Yes
- No
- Don't know

Please explain your response.

3.2.4 Border Force

Government proposes that enforcement of the environmental provisions would be primarily undertaken by the environmental regulators (see Section 3.2.1).

For seaports, airports and other locations where goods enter or leave the UK, as the environmental regulators are not regularly present; the government considers it prudent to provide appropriate powers to Border Force to take any immediate action required.

Border Force currently has a power to detain exports of mercury under regulation 12 of the Mercury Export and Data (Enforcement) Regulations 2010. The proposed new power would replicate this existing power for exports but would also allow non-compliant imports of mercury, mixtures of mercury and mercury-added products (and exports of non-compliant mercury-added products) to be seized and detained.

Government therefore proposes to provide Border Force officials with the power to seize and detain any material they believe has been imported or which is the process of being imported in contravention of the EU Regulation for a period of up to 5 working days. Border Force would then refer the detained material to the environmental regulators for further investigation

Q5. Do you consider that the powers detailed in Section 3.2.4 would provide Border Force with appropriate powers to assist the environmental regulators in the enforcement of the UK Regulations?

- Yes
- No
- Don't know

Please explain your response.

3.2.5 Criminal offences

Government proposes that the UK Regulations would make it a criminal offence to fail to comply with the provisions listed in Annex II to this consultation document.

Where an operator is convicted of a criminal offence, government proposes they would be liable:

- on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months, or both; or
- on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years, or both.

In the enforcement of these provisions government proposes that the environmental regulators would rely on existing powers under Section 108 of the Environment Act 1995, or, in Northern Ireland, under Article 72 of the Waste and Contaminated Land (Northern Ireland) Order 1997.

Government proposes that the enforcing authority would be able to issue an enforcement notice where one of the provisions in Annex II has been breached (e.g. for not providing information within the requested time). Breach of a requirement under an enforcement notice would be a criminal offence. Failure to comply with an information notice – a requirement to provide specified information to the enforcing authority – would also be a criminal offence. Criminal liability would still apply to breaches of the EU requirements, although the option of using an enforcement notice would be available.

Q6. Do you think the proposed approach to criminal enforcement is appropriate and proportionate?

- Yes
- No
- Don't know

Please explain your response.

3.2.6 Monetary penalties (civil, fixed and variable monetary penalties)

Government supports a proportionate approach to penalties for breaches of the proposed UK Regulations. We therefore propose to enable the EA, SEPA and NRW to bring criminal proceedings where they think it necessary and appropriate to do so, or to serve an enforcement notice or a monetary penalty notice instead where appropriate.

A civil monetary penalty notice (CMPN) is a monetary penalty for an offence imposed by the regulator. Where a CMPN is served, payment of the penalty discharges the liability. Where this happens a record of the payment of the CMPN would be kept. Where a CMPN is imposed but not paid, the EA and NRW would look to recover the penalty as a civil debt. If the breach was ongoing and classified as a new breach the EA and NRW may then look to prosecute.

In Northern Ireland we propose to enable the NIEA to bring criminal proceedings for breaches, or to serve an enforcement notice or a fixed penalty notice. The use of enforcement notices and monetary penalties would be available from the 1 April 2018, to allow sufficient time to develop and implement a suitable system for appeals. Until that date, only the use of criminal proceedings would be available to the environmental regulators. In Scotland, the Crown Office and Procurator Fiscal Service (COPFS) has discretion to prosecute, and provides guidance to the enforcing authority on the use of power to issue penalties. The regulator may report a matter for consideration of criminal prosecution, or decide to apply a financial penalty (as long as a penalty is available for a specific offence). But ultimately the decision to prosecute a case is made by COPFS, not the enforcing authority

In England and Wales, government proposes to set a maximum civil monetary penalty of £200,000 for breaches of the UK Regulations. In practice, the EA and NRW would vary penalties so that the maximum civil monetary penalty would only apply to large organisations with high levels of culpability, with a sliding scale of penalties for smaller organisations and different levels of culpability as set out in the table below (please note that this is an indicative, rather than final penalties scale and penalties may increase or decrease within a range based on numerous factors).

The Environment Agency will shortly be consulting on their Enforcement and Sanctions Policy (ESP). The EA propose having a section in the ESP setting out how they would enforce the UK Regulations.

	Size of organisation (based on turnover or equivalent)			
Breach category	Large £50 million & over	Medium between £10 million and £50 million	Small between £2 million and £10 million	Micro Not more than £2 million
Deliberate	£200,000	£80,000	£20,000	£10,000
Reckless	£110,000	£44,000	£11,000	£6,000
Negligent	£60,000	£24,000	£6,000	£3,000
Low or no culpability	£10,000	£4,000	£1,000	£500

The different levels of culpability may be defined as follows.

Deliberate means one of the following:

- intentional breach of, or flagrant disregard for, the law by person(s) whose position of responsibility in the organisation is such that their acts/omissions can properly be attributed to the organisation; or
- deliberate failure by the organisation to put in place and enforce such systems as could reasonably be expected in all the circumstances to avoid commission of the offence.

Reckless means one of the following:

- actual foresight of, or wilful blindness to, risk of offending but risk nevertheless taken by person(s) whose position of responsibility in the organisation is such that their acts/omissions can properly be attributed to the organisation; or
- reckless failure by the organisation to put in place and enforce such systems as could reasonably be expected in all the circumstances to avoid commission of the offence.

Negligent means failure by the organisation as a whole to take reasonable care to put in place and enforce proper systems for avoiding commission of the offence.

Low or no culpability means an offence committed with little or no fault on the part of the organisation as a whole, for example by accident or the act of a single employee acting in an unauthorised capability and despite the presence and due enforcement of all reasonably required preventive measures, or where such preventive measures were unforeseeably overcome by exceptional circumstances.

The size of an organisation would be defined in terms of its annual turnover, or an equivalent measure, in line with the following categories:

- large - £50 million and over,
- medium - between £10 million and £50 million,
- small – between £2 million and £10 million, and
- micro – not more than £2 million.

In order to serve a civil monetary penalty notice, the regulator would need to be satisfied that it is more likely than not (i.e. the civil standard of proof) that the subject has failed or is failing to comply with one or more of the provisions of the EU Regulation.

In Scotland, it is proposed that the enforcing authority would have the power to issue fixed and variable monetary penalties by extending the range of offences that the Environmental Regulation (Enforcement Measures) (Scotland) Order 2015 applies to so that they include the offences under the UK Regulations. Under the 2015 Order, the maximum variable monetary penalty would be the statutory maximum (currently £10,000), as this is linked to the maximum penalty proposed for the UK Regulations. Fixed monetary penalties are likely to be set at £600 for the majority of offences under the UK Regulations.

The Lord Advocate's guidelines to the enforcing authority in Scotland apply to the use of these enforcement measures, and offences which involve deliberate wrongdoing may not be appropriate for a fixed or variable monetary penalty.

The use of monetary penalties should enable the regulators to enforce provisions in the legislation more effectively. In England and Wales the environmental regulators would adopt guidance governing the application of monetary penalties setting out how they would be used and the circumstances when they would pursue a criminal offence or impose a monetary penalty. As previously stated, in Scotland the COPFS has discretion to prosecute, and provides guidance to the enforcing authority on the use of powers to issue monetary penalties.

In Northern Ireland it is proposed, as set out in Section 3.2.3, that any offence in relation to non-compliance would be treated as a criminal offence and would be included within the relevant offences sections of the NI legislation as appropriate. However, for those offences which are deemed inappropriate for a small fixed penalty, in recommending such cases to the Courts, the Department for Agriculture, Environment and Rural Affairs will provide advice on the various levels of culpability and the associated monetary penalties being applied across the remainder of the UK by way of the above indicative table. However, responsibility for the application of penalties and fines remains solely with the Courts and the Department may only operate in an advisory capacity in such circumstances.

Q7. Do you consider that the proposed approach to monetary penalties is appropriate? If not, what do you consider to be more appropriate and why?

Yes

No

If you answered no to this question, please provide your comments.

3.2.7 Appeals

Government proposes that a person on whom an enforcement notice or a monetary penalty notice is served would be able to appeal if they wish to do so. Appeals against cost recovery notices and information notices would also be available.

In England and Wales, government proposes that appeals would be made to the General Regulatory Chamber of the First-tier Tribunal from 1 April 2018. If the First-tier Tribunal is selected as the appropriate body to hear appeals in these matters then it would operate under the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 which provide flexibility for dealing with individual cases. The General Regulatory Chamber rules can be found at:

<http://www.justice.gov.uk/downloads/guidance/courts-and-tribunals/tribunals/tribunals-rules-2009-at010411.pdf>.

In Scotland, a person on whom a regulator imposes a fixed or variable monetary penalty would be able to appeal if they wish to do so, and appeals should be made to the Scottish Land Court in accordance with the Environmental Regulation (Enforcement Measures)(Scotland) Order 2015. Appeals against enforcement notices would also be available under the UK Regulations, but we propose that these should be made to the Scottish Ministers. In Scotland, there are specific procedures for dealing with appeals to the Scottish Land Court or to the Scottish Ministers, as appropriate⁵.

In Northern Ireland, it is proposed that appeals in relation to fixed penalty notices may be made to the Planning Appeals Commission (PAC), which is an independent body which deals with a wide range of land use planning issues and related matters. Its powers in respect of waste activities mainly derive from the Waste and Contaminated Land (Northern Ireland) Order 1997 (the 1997 Order), which is the key primary vehicle for various subordinate waste legislation in Northern Ireland, including the Hazardous Waste Regulations (NI) 2005 (the 2005 Regulations). Accordingly, it is proposed to amend the 1997 Order and the 2005 Regulations by way of the UK Regulations, to include an appeals provision in relation to fixed penalty notices issued in relation to mercury-related offences.

Q8. Do you consider that the proposed approach on appeals is appropriate and proportionate?

Yes

No

If you answered no to this question, please provide your comments.

⁵ Appeals under the 2015 Order are already designated for Scottish Land Court.

3.2.8 Applications to import mercury and mixtures of mercury

Importers of mercury or mixtures of mercury would be required to apply in writing for consent to import mercury and mixtures of mercury with a mercury concentration of at least 95% by weight for use in mercury-added products or manufacturing processes. A decision would be based on satisfying the circumstances laid out in Article 4 of the EU Regulation. Forms to be used for an application to import mercury or mixtures of mercury will be provided by the European Commission (Article 6).

Based on notifications to the European Chemicals Agency, there are currently thought to be a small number of imports of mercury or mixtures of mercury every year and the impacts of this provision are likely to be limited.

In England, Scotland and Wales it is proposed that the environmental regulators would be the enforcement authorities for determining applications for consent to import mercury and mixtures of mercury in much the same way as the EA, SEPA and NRW are responsible for imports of waste. Government has not yet developed a preference on how this provision would be best enforced in Northern Ireland and the views of stakeholders are sought.

Given government anticipates only a small number of applications for import of mercury and the difficulty in effectively assessing cost recovery for such a small number of applications, government proposes not to specify an application fee in the UK Regulations. Instead, it is proposed to make provision in the UK Regulations for the EA, SEPA and NRW to specify an application determination fee in accordance with their powers to set a charging scheme under the Environment Act 1995. A charging scheme for application fees in Northern Ireland will be finalised once the enforcing authority has been determined. It is anticipated that any fees and charges applied would be congruent with those established in Scotland, England and Wales.

Any fee in respect to imports would be subject to public consultation and the competent authorities would not be able to charge a fee until such time as it is specified in a charging scheme.

Q9. Do you have any views or comments on the appropriate UK enforcement authorities for imports of mercury?

- Yes
- No

If you answered yes to this question, please provide your comments and any rationale for your response.

Q10. Are you involved in the import of mercury or mixtures of mercury?

- Yes
- No

Q11. Do you agree with our assessment that there are relatively few UK imports of mercury and mixtures of mercury?

- Yes
- No
- Don't know

Please provide any further information that you have on imports of mercury.

Q12. Do you have any views on what would be a reasonable fee to charge for determining an application to import mercury or mixtures of mercury?

- Yes
- No

If you answered yes to this question, please provide your views

3.2.9 Notifications relating to new mercury-added products and new manufacturing processes using mercury

Operators that wish to either:

- manufacture or place on the market new mercury-added products that were not being manufactured prior to 1 January 2018, and/or
- use manufacturing processes involving the use of mercury or mercury compounds that were not processes used prior to 1 January 2018,

are required to apply for authorisation from the European Commission (Article 8). The Commission will determine whether the notification demonstrates that the new product or new process would provide significant environmental or health benefits; pose no significant risks either to the environment or human health and that no technically practicable mercury-free alternatives providing these benefits are available.

Government proposes that the environmental regulators would be the competent authorities for this provision and they would be responsible for initially assessing any notifications they receive in respect to Article 8 and forwarding these to the European Commission, provided they are satisfied the notification fulfils the criteria specified above. The European Commission will approve notifications.

Government would welcome views on how the assessment of notifications by the environmental regulators could be supported. Specifically, whether this should be through an application fee that recovers the costs associated with assessing notifications or whether provision should be made in the UK Regulations to enable the environmental regulators to require the submission of a report by an appropriately qualified independent expert.

Given the anticipated small number of such notifications and the difficulty in effectively assessing cost recovery, we would propose not to specify an application fee in the UK Regulations. We would instead propose to make provision in the UK Regulations for the environmental regulators to specify an application determination fee in accordance with their powers to set a charging scheme under the Environment Act 1995, or, in Northern Ireland, under Article 15 of the Waste and Contaminated Land (Northern Ireland) Order 1997. Any fee in respect to notifications proposed by the environmental regulators would be subject to public consultation.

Q13. Are you aware of any new products or new manufacturing processes under development that use mercury?

Yes

No

Please provide any further information.

Q14. Do you have any views on what would be a reasonable fee to charge for assessing whether a notification for a new mercury-added product or a new manufacturing process using mercury meets the required criteria?

Yes

No

Please provide any views you have.

Q15. Do you have any views on whether the environmental regulators have the appropriate skills to assess whether a notification for a new mercury-added product or a new manufacturing process using mercury meets the assessment criteria?

Yes

No

Please provide any views you have.

Q16. Do you consider that a report from an independent expert would be a more effective and efficient method of assessing notifications?

- Yes**
- No**
- Don't know**

Please provide any views you have.

3.3 Dental provisions

The EU Regulation contains the following provisions relating to the use of mercury in dentistry:

- from 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form. **(Article 10(1))**,
- from 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient **(Article 10(2))**,
- a requirement for a national plan on measures to phase down the use of amalgam by 1 July 2019 **(Article 10(3))**, and
- from 1 January 2019 a requirement for dental facilities to be equipped with an amalgam separator **(Article 10(4))**.

Government proposals on the dental provisions are outlined below. With the exception of Article 10(4) on the requirement for an amalgam separator, no new legislative provisions are proposed to fulfil these requirements. Government proposes instead to rely on the existing regulatory arrangements.

3.3.1 England

Articles 10(1) and 10(2) in England

No new regulatory arrangements are proposed for Articles 10(1) and 10(2) in England. Instead health regulators should use their existing processes to determine (where appropriate to their specific regulatory role) whether the requirements set out in these provisions are being met. Where a regulator finds failure to meet the requirements, it would consider action, if appropriate, following its existing processes.

In advance of the implementation dates for Articles 10(1) and 10(2) the Department of Health will ensure guidance is made available in England to support dentists in following the new requirements of these provisions.

Article 10(3) in England

Article 10(3) requires national plans to be developed to phase down the use of dental amalgam. Such plans are being developed in England and include a range of oral health improvement schemes aimed at reducing the prevalence of dental decay amongst children and vulnerable groups. The minimal intervention dentistry approach to restoring teeth, which is existing good practice, is being promoted through undergraduate, post graduate and continuing dental education. Separately, through reform of the existing NHS dental contract, dentists are being encouraged to focus on prevention, thereby further reducing the prevalence of decay.

Article 10(4) in England

Failure to comply with Articles 10(1) and 10(2) presents a potential risk to patients and these provisions are therefore within the remit of health regulators. However, a missing or defective amalgam separator (Article 10(4)) does not present a direct risk to patients but rather an environmental and public health risk. Our view is therefore that it is not for health regulators to enforce. Instead it is proposed that enforcement of the requirement to have an amalgam separator in England (Article 10(4)) would be for the Environment Agency (EA). The EA, as the enforcing authority, would take appropriate enforcement action in cases of non-compliance. Views are welcomed on how intelligence of breaches of Article 10(4) would most effectively be gathered.

3.3.2 Wales

Article 10(1) in Wales

Welsh Government proposes that in practices providing NHS only or NHS and private care, the use of pre-dosed encapsulated amalgam would be verified through the dental practice inspection programme undertaken by Healthcare Inspectorate Wales (HIW) and through completion of the Quality Assurance System (QAS) self-assessment. HIW inspectors and Health Board Dental Practice Advisers would verify and validate the information provided. The HIW inspection documentation, the QAS toolkit and validation of documentation is being amended to mandate the use of encapsulated amalgam.

Article 10(2) in Wales

Government proposes that the HIW inspection programme includes a check of patient records. Health Board Dental Practice Advisers can also undertake random checks of patient treatment. This together with the QAS process would look for non-compliance in the use of amalgam in specific patient groups. Failure to pass all mandatory elements of the practice inspection and/or QAS is a breach of terms of service for a dentist working under general dental service regulations.

This can result in a range of enforcement action. The individual can also be subject to the NHS Disciplinary process which could lead to referral to a performance process (sanctions include removal from a performers' list which in turn would remove the right to work for an NHS provider in Wales) or to General Dental Council (removal of registration and loss of ability to practice dentistry in the UK). In the case of NHS services, the Welsh Ministers also have powers of intervention for serious service failures.

Provisions for dental practices only providing private care in Wales

The HIW inspection process also extends to private only practices. They would also require mandatory encapsulated amalgam usage. The HIW practice inspection team would review dental records as part of the dental practice inspection to look for non-compliant usage of amalgam in specific patient groups and adherence to national clinical guidelines.

HIW has a number of enforcement options, both civil and criminal. This details a spectrum of enforcement orders which range from:

- a requirement to improve,
- conditions on continued operation,
- cancellation of registration, and
- closure of the practice.

Article 10(3) in Wales

Plans to phase down the use of dental amalgam in under 15s, nursing and expectant women are underpinned by investment in a national oral health improvement programme in Wales to reduce the prevalence of decay in young children, the delivery of focussed Wales Deanery quality improvement and contract reform programmes to facilitate a preventive and evidence informed approach to dental care and treatment delivery.

A National Strategic Advisory Forum in Paediatric Dentistry has been established to agree and communicate a national plan for expectations for the provision of dental care and treatment for children. This will include Welsh (and UK) clinical guidelines on the phase down in the use of amalgam in deciduous teeth, in the under 15s and in nursing and expectant woman.

Any medical/clinical justification for its use after July 2018 will be outlined, agreed and widely communicated. The use of alternative restorative treatments such as stainless steel crowns in deciduous teeth will be described. It is proposed that this change will be mandated through Welsh Health Circular guidance. The clinical treatment guidelines will mandate a preventive approach to care delivery. The Wales Deanery quality improvement and training programmes for practices will improve capability and skills in dental care services for children.

Article 10(4) in Wales

It is currently a mandatory requirement for all dental practices to have an amalgam separator. Scrutiny and assurance is delivered through the HIW inspection and Health Board Dental Practice Adviser QAS processes. It is proposed that, the enforcement of the requirement to have an amalgam separator (Article 10(4)) would be divided between HIW and Natural Resources Wales (NRW), with HIW being responsible for verifying compliance with the provisions, and NRW being the enforcing authority in the case of non-compliance.

3.3.3 Scotland

The Scottish Government proposes that the dental provisions would be enforced through existing authorities, namely Health Boards and Healthcare Improvement Scotland, using their existing range of powers. Health Boards and Healthcare Improvement Scotland assess dental services using an agreed national practice inspection process. This process ensures that services deliver dental care that is safe, effective and person-centred.

Health Boards and Healthcare Improvement Scotland are required to include UK law and guidance as information to draw upon in assessing whether dental practices have met essential practice inspection standards. It is proposed that the new provisions on amalgam would be part of the evidence of compliance on the essential standard of safety. Key pieces of legislation and guidance used to assess compliance with the practice inspection standards is set out in guidance to the profession and these examples would be amended to specifically include the three key new provisions (Articles 10(1), 10(2) and 10(3)).

In Scotland, as in the other UK nations, these new provisions would be enforced through the existing range of powers available to the relevant body charged with enforcement. Health Boards and Healthcare Improvement Scotland assess compliance against mandatory elements of the practice inspection.

Actions for NHS only and mixed NHS and private dental practices subject to Health Board enforcement include:

- a requirement to improve,
- referral for NHS Disciplinary proceedings, and

- referral to the NHS Tribunal (which includes removal of the right to work in NHS Scotland).

For entirely private dental practices, Healthcare Improvement Scotland has a range of enforcement penalties which include:

- a requirement to improve,
- conditions on continued operation, and
- cancellation of registration.

If referred to the General Dental Council (the UK professional regulator) this could lead to removal of registration and loss of the ability to practice dentistry in the UK.

Article 10(1) In Scotland

The use of pre-dosed amalgam is already standard practice across the majority of the dental sector but is not a current legislative or guidance requirement and therefore not something that is currently formally monitored. Guidance will be made available to dentists in Scotland in advance of this provision coming into force. Once the Article 10(1) of the EU regulation fully applies the use of amalgam in a pre-dosed form would form part of the practice inspection process. Failure to use amalgam in a pre-dosed form would be regarded as unsafe practice and action would be taken in the event of non-compliance on this basis within Health Board and Healthcare Improvement Scotland's existing powers. It is proposed that compliance with the requirement to use pre-dosed amalgam would be listed as an example of evidence of overall safe practice.

Article 10(2) in Scotland

This is a new requirement. In response, UK-wide guidance is being developed which will include how decisions to, exceptionally, provide an amalgam filling to a patient in the specified groups should be recorded. This guidance will be made available to dentists in Scotland in advance of this provision coming into force in July 2018.

Once Article 10(2) of the EU regulation fully applies failure to record decisions to use amalgam in accordance with the guidance would be regarded as unsafe practice and action would be taken in the event of non-compliance using Health Board and Healthcare Improvement Scotland's existing powers.

Other regulatory bodies are responsible for investigating concerns raised about individual dental clinician's clinical treatment including the General Dental Council which regulates individuals within the dental profession. This would extend to the new provisions on pre-dosing and restrictions on the use of amalgam.

Article 10(3) in Scotland

In Scotland the phase down of amalgam use will best be delivered through improving oral health; our national oral health improvement programme, Childsmile has been in place for some years and is delivering significant improvements. The programme has recently been extended to reduce oral health inequalities in our most deprived communities. By July 2018, guidance will be prepared and widely communicated to dental teams to highlight alternatives to the use of amalgam in under 15s and nursing and expectant women. The approach to be taken by dental teams in cases where the use of amalgam is clinically/ medically justified will also be detailed.

Article 10(4) in Scotland

For dental facilities in Scotland, the proposed new provision reinforces an existing requirement rather than setting a new requirement. The standard to be applied arises from an existing EU Hazardous Waste Directive. This standard is already reflected in the practice inspection process which Health Boards and Healthcare Improvement Scotland apply under their existing powers. The practice inspection process would be amended to reflect the fact that this provision is now incorporated into legislation but the compliance requirement is already clearly set out in Health Boards' and Healthcare Improvement Scotland's process.

In addition to the Health Boards' and Healthcare Improvement Scotland's own powers, both organisations, following practice inspection, would refer any concerns to SEPA about how amalgam waste is being disposed of. Government proposes that SEPA would be the enforcing authority in the case of non-compliance.

3.3.4 Northern Ireland

The Department of Health proposes that the dental provisions (except those relating to the amalgam separator) would be enforced through either the Health and Social Care Board (HSCB) or the Regulation and Quality Improvement Authority (RQIA) using their existing range of penalties, with the exception of amalgam separators as covered below (Article 10(4)). HSCB assess dentists working in the General Dental Services (GDS) against their terms of service which include requirements relating to quality of care. RQIA assess health and social care services against four essential domains. These require that organisations are: well led and provide care that is safe, effective and compassionate. This includes any facility at which private dental care is delivered.

Both the HSCB and RQIA assess the quality of care provided by primary care dentists against the Minimum Standards for Dental Care and Treatment. This includes UK law and guidance as evidence in assessing whether providers have met these minimum standards. The new provisions on amalgam would be part of the evidence of compliance on safety and quality. Key pieces of guidance that the HSCB and RQIA use to assess compliance with the Minimum Standards would be amended to specifically include the two new provisions.

In Northern Ireland, as in the other UK nations, these new provisions will be enforced through the existing range of penalties available to the body charged with enforcement.

Article 10(1) in Northern Ireland

The use of pre dosed amalgam is already standard practice across the dental sector but is not a current legislative or guidance requirement and therefore not something that is currently formally monitored. Once Article 10(1) of the EU regulation fully applies failure to use amalgam in a pre-dosed form would be regarded as unsafe practice and action would be taken in the event of non-compliance on this basis within the HSCB's and RQIA's existing powers. Compliance with the requirement from 1 January 2019 to use pre dosed amalgam would be listed as an example of evidence of overall safe practice.

Article 10(2) in Northern Ireland

This is a new requirement. In response, UK wide guidance is being developed which would include how decisions to, exceptionally, provide an amalgam filling to a patient in the specified groups should be recorded.

This guidance would be made available to dentists in Northern Ireland in advance of this provision coming into force on 1 July 2018. Once Article 10(2) of the EU regulation fully applies, failure to use amalgam in accordance with the guidance would be regarded as unsafe practice. Action taken in the event of non-compliance would use the HSCB's and RQIA's existing powers.

Other regulatory bodies are responsible for investigating concerns raised about individual dental clinicians' clinical judgement including the General Dental Council which regulates individuals within the dental profession. This would also be the position for the new provisions on pre dosing and restrictions on the use of amalgam.

Article 10(3) in Northern Ireland

Plans to phase down the use of dental amalgam in under 15s and nursing and expectant women are being developed in Northern Ireland, including the use of oral health improvement schemes aimed at reducing the prevalence of dental decay amongst children and vulnerable groups, and the promotion of evidence-based preventive therapies in primary dental care. Alternative techniques from within the Minimal Intervention Dentistry philosophy, which is existing good practice, would be promoted through guidance and undergraduate, post graduate and continuing dental education.

Article 10(4) in Northern Ireland

Government policy in respect to inspection and enforcement of the amalgam separator requirement is not settled and the views of stakeholders are invited on how this provision should be enforced and compliance verified in Northern Ireland.

Q17. Do you have any comments on the proposed approach to the dental provisions in the EU Regulation?

- Yes**
- No**

Please provide any comments.

Q18. Do you have any views on the best approach to gathering intelligence on non-compliance with the amalgam separator requirement in England?

- Yes**
- No**

If you answered yes to this question, please provide your comments and any rationale.

Q19. Do you have any views on the body or bodies that are best placed to enforce and inspect the amalgam separator requirement in Northern Ireland and the best approach to gathering intelligence on non-compliance?

Yes

No

If you answered yes to this question, please provide your comments and any rationale.

Annex I Confidentiality and Data Protection Information

1. A summary of responses to this consultation will be published on the UK Government website at: www.gov.uk/defra. The summary will include a list of organisations that responded **but not** personal names, addresses or other contact details.

1.1. Information provided in response to this consultation, including personal information, may be made available to the public on request, in accordance with the requirements of the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (EIRs). Defra may also publish the responses to the FOIA/EIR requests on www.gov.uk/defra.

1.2 If you want your response, including personal information such as your name, that you provide to be treated as confidential, please explain clearly in writing when you provide your response to the consultation why you need to keep these details confidential. If we receive a request for the information under the FOIA or the EIRs we will take full account of your explanation, but we cannot guarantee that confidentiality can be maintained in all circumstances. However, Defra will not permit any unwarranted breach of confidentiality nor will we act in contravention of our obligations under the Data Protection Act 1998 (DPA). An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as a confidentiality request.

1.3. Defra will share the information you provide in response to the consultation, including any personal data, with a third party of contracted external analysts for the purposes of response analysis and provision of a report.

1.4 Defra is the data controller in respect of any personal data that you provide, and Defra's Personal Information Charter, which gives details of your rights in respect of the handling of your personal data, can be found at:

<https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs/about/personal-information-charter>.

1.5 This consultation is being conducted in line with the "Consultation Principles" as set out in the Better Regulation Executive guidance which can be found at:

<https://www.gov.uk/government/publications/consultation-principles-guidance>.

1.6 If you have any comments or complaints about the consultation process, please address them to:

Consultation Co-ordinator
8A, 8th Floor, Nobel House
17 Smith Square,
London, SW1P 3JR.

Annex II Provisions relating to the environment and relevant dental provisions

Provision of Regulation (EU) 2017/852	Subject matter
Article 3(1)	Prohibits the export of mercury
Article 3(2)	Prohibits the export of listed mercury compounds
Article 3(4)	Prohibits the export of mercury compounds not listed under Article 3(2) for the purposes of reclaiming mercury
Article 4(1)	Prohibits the import of mercury and listed mixtures of mercury including mercury waste for purposes other than disposal as waste
Article 4(2)	Prohibits the import of other mixtures of mercury and mercury compounds for purposes of reclaiming mercury
Article 4(3)	Prohibits the import of mercury for use in artisanal and small-scale gold mining and processing
Article 5(1)	Prohibits the export, import and manufacturing of listed mercury-added products
Article 7(1)	Prohibits the use of mercury compounds in listed manufacturing processes
Article 7(2)	Requires that the use of mercury compounds in other listed manufacturing processes shall only be allowed subject to certain conditions
Article 7(3)	Requires environmentally sound management of mercury stored on an interim basis
Article 8(1)	Prohibits manufacturing of new mercury-added products or placing them on the market
Article 8(2)	Prohibits new manufacturing processes involving the use of mercury or mercury compounds
Article 9(1)	Prohibits the use of mercury in artisanal and small-scale gold mining
Article 10(4)	Requires the operators of certain dental facilities to have amalgam separators
Article 10(6) first subparagraph	Requires dental practitioners to ensure that amalgam waste is handled and collected by an authorised waste management establishment

Article 10(6) second subparagraph	Requires dental practitioners not to release amalgam waste into the environment under any circumstances
Article 12(1)	Requires operators in listed industries to report on large sources of mercury
Article 13(3) first subparagraph	Requires operators to convert mercury before its permanent disposal
Article 13(3) second subparagraph	Requires operators to use one of a list of facilities to permanently dispose of mercury
Article 13(3) third subparagraph	Requires operators of permanent storage facilities to store converted mercury separately
Article 14(1) first subparagraph	Requires operators of facilities for the temporary storage of mercury to establish a register
Article 14(1) second subparagraph	Requires operators of facilities for the temporary storage of mercury to issue a certificate for mercury waste leaving temporary storage
Article 14(1) third subparagraph	Requires operators of facilities for the temporary storage of mercury to transmit the certificate about mercury waste leaving temporary storage
Article 14(2) first subparagraph	Requires operators of facilities for the conversion of mercury to establish a register
Article 14(2) second subparagraph	Requires operators of facilities for the conversion of mercury to issue a certificate for mercury waste after the conversion
Article 14(2) third subparagraph	Requires operators of facilities for the conversion of mercury to transmit the certificate about conversion
Article 14(3) first subparagraph	Requires operators of facilities for the permanent storage of converted mercury to issue a certificate relating to its permanent storage/ disposal
Article 14(3) second subparagraph	Requires operators of facilities for the permanent storage of converted mercury to transmit the certificate about the mercury's permanent storage/ disposal

Annex III Provisions relating to dentistry (and the environment)

Provision of Regulation (EU) 2017/852	Subject matter
Article 10(1)	Requires dental amalgam to be used only in pre-dosed encapsulated form and prohibits the use of mercury in bulk form by dental practitioners
Article 10(2)	Prohibits the use of dental amalgam in certain cases – for example where the patient is a child aged under 15 years - except when deemed strictly necessary
Article 10(3)	Requires the setting out a national plan on measures that will be implemented to phase down the use of dental amalgam
Article 10(4)	Requires the operators of certain dental facilities to have amalgam separators
Article 10(6) first subparagraph	Requires dental practitioners to ensure that amalgam waste is handled and collected by an authorised waste management establishment
Article 10(6) second subparagraph	Requires dental practitioners not to release amalgam waste into the environment under any circumstances

Annex IV List of consultation questions

Q1. Do you want your response to this consultation to be confidential?

Q2. Do you have any comments on the proposed enforcement authorities for the provisions detailed in Section 3.2.1?

Q3. Do you have any specific views or comments on the enforcement in Northern Ireland of the requirement for an amalgam separator and the provisions restricting the import of mercury and mixtures of mercury?

Q4. Do you consider that the powers detailed in Section 3.2.3 would provide the environmental regulators with appropriate powers to effectively enforce the UK Regulations?

Q5. Do you consider that the powers detailed in Section 3.2.4 would provide Border Force with appropriate powers to assist the environmental regulators in the enforcement of the UK Regulations?

Q6. Do you think the proposed approach to criminal enforcement is appropriate and proportionate?

Q7. Do you consider that the proposed approach to monetary penalties is appropriate? If not, what do you consider to be more appropriate and why?

Q8. Do you consider that the proposed approach on appeals is appropriate and proportionate?

Q9. Do you have any views or comments on the appropriate UK enforcement authorities for imports of mercury?

Q10. Are you involved in the import of mercury or mixtures of mercury?

Q11. Do you agree with our assessment that there are relatively few UK imports of mercury and mixtures of mercury?

Q12. Do you have any views on what would be a reasonable fee to charge for determining an application to import mercury or mixtures of mercury?

Q13. Are you aware of any new products or new manufacturing processes under development that use mercury?

Q14. Do you have any views on what would be a reasonable fee to charge for assessing whether a notification for a new mercury-added product or a new manufacturing process using mercury meets the required criteria?

Q15. Do you have any views on whether the environmental regulators have the appropriate skills to assess whether a notification for a new mercury-added product or a new manufacturing process using mercury meets the assessment criteria?

Q16. Do you consider that a report from an independent expert would be a more effective and efficient method of assessing notifications?

Q17. Do you have any comments on the proposed approach to the dental provisions in the EU Regulation?

Q18. Do you have any views on the best approach to gathering intelligence on non-compliance with the amalgam separator requirement in England?

Q19. Do you have any views on the body or bodies that are best placed to enforce and inspect the amalgam separator requirement in Northern Ireland and the best approach to gathering intelligence on non-compliance?