

Agenda – Constitutional and Legislative Affairs Committee

Meeting Venue:

Committee Room 2 – Senedd

Meeting date: 21 September 2015

Meeting time: 13.30

For further information contact:

Gareth Williams

Committee Clerk

0300 200 6362

SeneddCLA@Assembly.Wales

1 Introduction, apologies, substitutions and declarations of interest

2 Evidence in relation to the Public Health (Wales) Bill

(Pages 1 – 101)

(Indicative time 13.30)

Mark Drakeford, Minister for Health and Social Services

Chris Tudor-Smith, Welsh Government

Nia Roberts, Welsh Government

Dewi Jones, Welsh Government

CLA(4)-22-15 – Paper 1 – Statement of Policy Intent

**CLA(4)-22-14 – Paper 2 – Letter from the Presiding Officer in relation to the
Public Health (Wales) Bill**

CLA(4)-22-15 – Research Service Briefing

CLA(4)-22-15 – Legal Advice Note



3 Instruments that raise no reporting issues under Standing Order 21.2 or 21.3

(Pages 102 – 104)

CLA(4)–22–15 – Paper 3 – Statutory Instruments with clear reports

Attached Documents:

Negative Resolution Instruments

**CLA576 –The Agricultural Holdings (Units of Production) (Wales) (No. 2) Order
2015**

Negative procedure; Date made: 2 September 2015; Date laid: 4 September 2015;
Coming into force date: 28 September 2015

**CLA577 – The Proxy Purchasing of Tobacco, Nicotine products etc (fixed penalty
notice) (Wales) Regulations 2015**

Negative procedure; Date made: 4 September 2015; Date laid: 10 September
2015; Coming into force date: 1 October 2015

Affirmative Resolution Instruments

**CLA578 –The Human Transplantation (Excluded Relevant Material) (Wales)
Regulations 2015**

Affirmative procedure; Date made: Not stated; Date laid: 11 September 2015;
Coming into force date: 1 December 2015

CLA579 –The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015

Affirmative procedure; Date made: Not stated; Date laid: 11 September 2015;
Coming into force date: 1 December 2015

CLA580 – The Human Transplantation (Appointed Representatives) (Wales) Regulations 2015

Affirmative procedure; Date made: Not stated; Date laid: 11 September 2015;
Coming into force date: 1 December 2015

CLA581 –The Human Tissue Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013

Affirmative procedure; Date made: Not stated; Date laid: 11 September 2015;
Coming into force: Not stated

4 Instruments that raise issues to be reported to the Assembly under Standing Order 21.2 or 21.3

Joint and Composite Negative Resolution Instrument

CLA575 – The Water Environment (Water Framework Directive) (England and Wales) (Amendment) Regulations 2015

(Pages 105 – 122)

Joint and Composite Negative procedure; Date made: 24 August 2015; Date laid: 24 August 2015; Coming into force date: 14 September 2015

CLA(4)–22–15 – Paper 4 – Report

CLA(4)–22–15 – Paper 5 – Regulations

CLA(4)–22–15 – Paper 6 – Explanatory Memorandum

CLA(4)–22–15 – Paper 7 – Transposition Note

5 Papers to Note

(Pages 123 – 126)

CLA(4)–22–15 – Paper 8 – Letter from Bruce Crawford MSP, Convener of the Scottish Parliament’s Devolution (Further Powers) Committee Parliamentary oversight and reporting of intergovernmental relations under the new provisions in the Scotland Bill

CLA(4)–22–15 – Paper 9 – Public Administration and Constitutional Affairs Committee consultation on its Inquiry into the Union and Devolution

6 Motion under Standing Order 17.42 to resolve to exclude the public from the meeting for the following business:

(vi) the committee is deliberating on the content, conclusions or recommendations it proposes to publish; or is preparing itself to take evidence from any person;

Final Report: Environment (Wales) Bill

(Pages 127 – 145)

CLA(4)–22–15 – Paper 10 – Final Report

Draft Report: Historic Environment (Wales) Bill

(Pages 146 – 168)

CLA(4)–22–15 – Paper 11 – Draft Report Historic Environment (Wales) Bill

Draft Report: Making Laws in the Fourth Assembly

(Pages 169 – 274)

CLA(4)–22–15 – Paper 12 – Draft Report

Forward Work Programme

(Pages 275 – 277)

CLA(4)–22–15 – Paper 13 – Forward Work Programme



Mark Drakeford AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Eich cyf/Your ref
Ein cyf/Our ref: LF/MD/0411/15

David Rees AM
Chair of the Health and Social Care Committee
National Assembly for Wales
Ty Hywel,
Cardiff Bay
Cardiff
CF99 1NA

11 June 2015

Dear David,

Public Health (Wales) Bill – Statement of Policy Intent

Following the introduction of the Public Health (Wales) Bill into the National Assembly for Wales on 8 June 2015, I am pleased to enclose the Statement of Policy Intent for the subordinate legislation and other delegated legislative powers contained in the Bill.

The statement provides further information on the policy intent for the subordinate legislation, which could be made under the Bill, if enacted.

I look forward to providing evidence before the Committee in due course.

A copy of this letter and the enclosed statement is also being sent to David Melding, Chair of the Constitutional and Legislative Affairs Committee.

Best wishes,

Mark

Mark Drakeford AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

PUBLIC HEALTH (WALES) BILL

Statement of Policy Intent for Subordinate Legislation

June 2015

PUBLIC HEALTH (WALES) BILL

STATEMENT OF POLICY INTENT FOR SUBORDINATE LEGISLATION

This document provides an indication of the current policy intention for the subordinate legislation that the Welsh Ministers would be empowered or required to make under the provisions of the Public Health (Wales) Bill ('the Bill'). It has been prepared in order to assist committees during the scrutiny of the Bill and should be read in conjunction with the Explanatory Memorandum and Explanatory Notes.

The key purpose of the Bill is to introduce changes that:

- Place restrictions on the use of tobacco and electronic cigarettes (nicotine inhaling devices) in enclosed and substantially enclosed public and work places, and give the Welsh Ministers a regulation-making power to extend the restrictions to open spaces;
- Provide for the creation of a national register of retailers of tobacco and nicotine products;
- Provide the Welsh Ministers a regulation-making power to add to the offences for which a Restricted Premises Order may be sought in Wales;
- Prohibit the handing over of tobacco and/or nicotine products to a person under the age of 18;
- Provide for the creation of a mandatory licensing scheme for businesses/practitioners carrying out "special procedures" (acupuncture, body piercing, electrolysis and tattooing);
- Introduce a prohibition on the intimate piercing of persons under the age of 16;
- Change the arrangements for determining applications for entry onto the pharmaceutical list of Local Health Boards (LHBs), to a system based on the pharmaceutical needs of local communities; and
- Require local authorities to prepare local toilets strategies to plan how they will meet the needs of their communities for accessing toilet facilities.

For ease of reference, this document includes separate information for each provision in the Bill which involves subordinate legislation. However, in reality a number of these areas would be likely to be combined and dealt with, for example, within a set of regulations. A number of these regulations will need to be passed by the Assembly before the corresponding sections of the Bill are brought into force.

Implementation of some parts of the Bill will not involve the production of subordinate legislation. These areas are referenced at relevant points within the document. The contents of this document correspond to the information provided in Chapter 5 of the Explanatory Memorandum.

In developing subordinate legislation, the Welsh Government will work closely with stakeholders in order to ensure the provisions are relevant, valid and proportionate.

PART 2: TOBACCO AND NICOTINE PRODUCTS

Chapter 1 – Smoking and use of nicotine inhaling devices

REGULATIONS RELATING TO	The exemption of a device, or description of a device, from the definition of a 'nicotine inhaling device'
BILL PART	Chapter 1 of Part 2
SECTION	2(2)(b)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power enables the Welsh Ministers to make regulations to exempt a device, or description of a device, from the definition of a 'nicotine inhaling device' provided at Section 2(2). For the purpose of the Bill a 'nicotine inhaling device' is a device that enables the inhalation of nicotine via a mouth piece (whether or not the device also enables any other substance to be inhaled). A device that is intended to be used for the consumption of lit tobacco is already exempted from the definition by Section 2(2)(a).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power allows the Welsh Ministers to make regulations to exempt devices that would otherwise fall within the definition of a nicotine inhaling device for the purpose of the Bill. This would enable devices or descriptions of devices that would otherwise be captured by the definition of a nicotine inhaling device to be used in smoke-free premises.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This regulation-making power enables the Welsh Ministers to provide exemptions for devices that are not intended to be captured by the definition of a nicotine inhaling device. Regulations made under this power are subject to the negative procedure because such regulations will add technical detail to the definition of 'nicotine inhaling device' provided on the face of the Bill. This power may be used to provide clarity to the regime by exempting a device or description of a device from the definition of nicotine inhaling device at Section 2(2) where it is found that such a device is being captured by that definition but their use in public is not undermining the policy rationale behind the provisions.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Specifying further devices that enable the inhalation of a substance, or descriptions of such devices, to which provisions on smoking and the use of nicotine inhaling devices may apply
BILL PART	Chapter 1 of Part 2
SECTION	3(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations that provide for other devices, or descriptions of a device, to be covered by this Chapter where they are satisfied that this is likely to contribute towards the promotion of the health of the people of Wales. Such additional devices may or may not enable nicotine to be inhaled. This power enables the Welsh Ministers to modify how Chapter 1 applies in relation to any such other devices, or description of devices, as they consider necessary or expedient.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The Welsh Ministers could use these powers, for example, should it become apparent that devices which are not currently captured by the definition of a NID are contributing to the renormalisation of smoking behaviours and/or are undermining enforcement of the smoke-free requirements and are therefore having a negative impact on the health of the people of Wales.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>It is possible that some inhaling devices not covered by the definition of 'nicotine inhaling device' in this Chapter may exist or are being/will be developed by industry in the future. This regulation-making power is required to enable the Welsh Ministers to react to any such developments, where they are satisfied that this is likely to contribute towards the promotion of the health of the people of Wales. The Welsh Ministers will need flexibility to respond to these changes in order to ensure the integrity of the provisions on smoking and the use of nicotine inhaling devices is maintained.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Duties regarding additional smoke-free premises and smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	5(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>Section 5 (1) requires managers of smoke-free workplaces and public premises to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in those premises.</p> <p>This power, in Section 5 (2), enables the Welsh Ministers to make regulations to place corresponding duties on a person or description of person in respect of any additional smoke-free premises (designated by virtue of Section 8 of the Bill) and smoke-free vehicles (designated by virtue of Section 9) designated by the Welsh Ministers.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power enables the Welsh Ministers to place a duty on managers of any additional smoke-free premises and those responsible for smoke-free vehicles in Wales to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in their premises/vehicles. This would achieve consistency across the smoke-free regime in Wales for all managers of smoke-free premises.</p> <p>Such regulation-making powers are currently provided for in the Health Act 2006, but only in respect of smoking in additional smoke-free premises and smoke-free vehicles; not for the use of nicotine inhaling devices in such places, which would also be covered by these regulations.</p> <p>In relation to smoke-free vehicles, the Health Act 2006 and the Smoke-free Premises etc. (Wales) Regulations 2007 currently place the duty to take reasonable steps to prevent smoking on the operator, the driver and any person on a vehicle who is responsible for order and safety on it. The policy intention is to continue to make these persons responsible in any vehicles designated as smoke-free.</p> <p>In relation to any additional smoke-free premises designated under Section 8, it is intended to decide on a case by case basis whether or not to place the duty on the manager of those premises. So, for example, if hospital grounds in Wales were designated by the Welsh Ministers as additional smoke-free premises, consideration would be given to placing a duty on hospital managers in Wales to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in the grounds of the hospital(s) for which they are responsible.</p>	
WHY THE REGULATIONS ARE REQUIRED	
<p>This power is required to create the offence of failing to prevent a person from smoking or using a nicotine inhaling device in any additional smoke-free premises and smoke-free vehicles designated by regulations. This will enable enforcement</p>	

authorities to prosecute persons they believe to have committed such an offence, so that they may be liable on summary conviction to a fine on the standard scale.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Section 8(3) of the Health Act 2006 currently provides the Welsh Ministers with powers to make regulations that place a duty on managers of any additional smoke-free places (designated by virtue of Section 4 of the Health Act 2006), and those responsible for smoke-free vehicles in Wales (designated by virtue of Section 5) to cause a person smoking there to stop smoking. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. These powers are used in respect of smoke-free vehicles in regulation 7 of the Smoke-free Premises etc. (Wales) Regulations 2007.

REGULATIONS RELATING TO	The meaning of “enclosed” and “substantially enclosed” for designating smoke-free workplaces and public premises
BILL PART	Chapter 1 of Part 2
SECTION	6(7)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations to define what is meant by “enclosed” and “substantially enclosed” for the purposes of designating smoke-free workplaces and premises that are open to the public.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The power enables the Welsh Ministers to clarify which areas of workplaces and premises open to the public are required to be smoke-free.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>The power is required to provide technical detail to the legislative scheme. The definitions provided in regulations will add precision to the meaning of the words ‘enclosed’ and ‘substantially enclosed’. This detail is relatively minor to the overall legislative scheme and therefore best achieved through regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Section 2(5) of the Health Act 2006 provides the Welsh Ministers with powers to make regulations that specify what “enclosed” and “substantially enclosed” means. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. The current definitions of “enclosed” and “substantially enclosed”, for the purposes of smoke-free premises under the Health Act 2006, are set out at regulation 2 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p>	

REGULATIONS RELATING TO	Additional smoke-free premises
BILL PART	Chapter 1 of Part 2
SECTION	8(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations to designate any place, or description of place, in Wales as smoke-free. The additional smoke-free places need not be enclosed or substantially enclosed and must not already be designated as smoke-free by the Bill. Being 'smoke-free' in these provisions means that smoking and use of nicotine inhaling devices is not permitted, unless an exemption applies. The regulations allow the Welsh Ministers to consider the circumstances, times, conditions and/or areas in which any additional premises should be smoke-free on a case by case basis.</p> <p>The regulations may also provide for exemptions to the smoke-free status of any additional smoke-free premises. The regulations may, for example, allow the person in charge of the additional smoke-free premises to designate areas in which smoking or the use of a nicotine inhaling device is to be permitted. The designation would have to be in accordance with any conditions set out in the regulations.</p> <p>Under this power, the additional smoke-free premises may not be a private dwelling (NB. private dwellings being used as a workplace or open to the public are covered by Sections 6 and 7.)</p> <p>The Welsh Ministers will only be able to designate additional smoke-free premises where they are satisfied that designating that place as smoke-free is likely to contribute towards the promotion of the health of the people of Wales.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will allow the Welsh Ministers to create additional smoke-free premises where doing so is likely to contribute towards the promotion of the health of the people of Wales. The intention is to create additional smoke-free non-enclosed spaces which may include, but are not limited to, hospital grounds, school grounds and children's playgrounds. The regulation-making power will also enable the Welsh Ministers to allow for areas within those additional smoke-free premises to be exempt from the smoke-free requirements where they have been designated as such by the manager of those premises.</p> <p>It is the current policy intention that there will be no obligation on the person in charge of the additional smoke-free premises to designate areas within the premises where the smoke-free requirements do not apply, unless in specific circumstances as determined by the Welsh Ministers. So, for example, if the Welsh Ministers make regulations for smoke-free hospital grounds, the regulations could provide that the manager of those hospitals <u>may</u> designate areas within the grounds in which smoking and/or use of a nicotine inhaling device is permitted. Any designation would have to comply with specific requirements in the regulations.</p>	

The power allows for flexibility to make regulations on additional non-enclosed places in the future if the Welsh Ministers are satisfied that doing so is likely to contribute to the promotion of the health of the people of Wales.

WHY THE REGULATIONS ARE REQUIRED

This power is required to continue to ensure that smoking behaviours are not re-normalised, nor the use of nicotine inhaling devices normalised, by permitting smoking and the use of nicotine inhaling devices in certain non-enclosed places; particularly those where children and young people are commonly present.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

These powers differ to those under Section 4 of the Health Act 2006, whereby the Welsh Ministers may designate an additional smoke-free place (in relation to smoking, not to the use of nicotine inhaling devices) in Wales only if, in their opinion, there is significant risk that, without designation, persons present in the place would be exposed to significant quantities of smoke. Regulations made under Section 4 of the Health Act 2006 are subject to the affirmative procedure. The power for the Welsh Ministers to make such regulations has not yet been used.

REGULATIONS RELATING TO	Smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	9(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations providing for vehicles to be smoke-free. It enables the Welsh Ministers to require certain types of vehicles to be smoke-free, to set the circumstances in which vehicles are smoke-free, to provide that the vehicle is to be smoke-free when located in specific areas, and to make exemptions to any of these requirements. The Welsh Ministers can only designate a vehicle as being smoke-free where they are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales. Smoking and the use of a nicotine inhaling device is prohibited in a smoke-free vehicle, unless the Welsh Ministers make regulations to provide for exemptions (e.g. to allow the use of nicotine inhaling devices).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will allow the Welsh Ministers to establish a smoke-free regime for vehicles in Wales that is specific to certain types of vehicles, and details when and where they must be smoke-free. This allows for flexibility so that the regime for smoke-free vehicles can be adapted for specific scenarios.</p> <p>The policy intention is that all vehicles used for the transportation of the public or for work purposes by more than one person should be smoke-free all of the time.</p> <p>It is not the current policy intention to require private vehicles, including privately rented vehicles, to be smoke-free unless they are carrying persons under the age of 18, and unless the private rental includes a driver, in which case the rental is a workplace and so should be smoke-free.</p> <p>Being 'smoke-free' means that smoking and the use of nicotine inhaling devices is not permitted, unless an exemption applies.</p> <p>This regulation-making power could be used to extend the ban on smoking in cars carrying children, contained in the Smoke-free premises etc. (Wales) (Amendment) Regulations 2015, laid on 5th May 2015 and debated by the National Assembly for Wales 2nd June, to include a ban on the use of nicotine inhaling devices in those vehicles. The Welsh Ministers may only do so if they are satisfied that doing so is likely to contribute to the promotion of the health of the people of Wales.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is required to enable Welsh Ministers to apply the smoke-free requirements to vehicles in a range of settings and scenarios. For example, the regulations may designate vehicles used for public transport as smoke-free (e.g. buses), vehicles that are workplaces (e.g. taxis), and private vehicles carrying persons under the age of 18.</p>	

The restatement of the Health Act 2006 and the extension of the meaning of smoke-free to include the use of a nicotine inhaling device as well as smoking creates a need to re-establish the smoke-free regime for vehicles. This power permits the Welsh Ministers to do this.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

The Smoke-free Premises etc. (Wales) Regulations 2007 continue to apply until such time as the Welsh Ministers use these regulation-making powers. Section 95 of the Children and Families Act 2014 amends Section 5 of the Health Act 2006 to provide enabling powers for the Welsh Ministers to make regulations to prohibit smoking in private vehicles carrying persons under the age of 18. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure.

REGULATIONS RELATING TO	Making exemptions for premises from the smoke-free requirements
BILL PART	Chapter 1 of Part 2
SECTION	10(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power allows the Welsh Ministers to make regulations to exempt premises, or specified areas within premises in Wales, from the requirement to be smoke-free. Exemptions from the smoke-free requirements may be in respect of both smoking and the use of nicotine inhaling devices, smoking only, or the use of nicotine inhaling devices only.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will enable the Welsh Ministers to allow smoking and/or the use of nicotine inhaling devices in certain public premises or workplaces, or specific areas within these premises (i.e. exempt them from the smoke-free requirements). This will achieve some flexibility in the application of the smoke-free regime in Wales.</p> <p>Exemptions from the existing smoke-free regime currently apply to specific rooms within care homes, adult hospices, mental health units, research or testing facilities, hotels, guesthouses, inns, hostels and members' clubs. These are provided for by regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p> <p>There is a commitment in the Tobacco Control Action Plan for Wales to review the exemption from the existing smoke-free requirements for mental health units that provide residential accommodation. It is the intention to review this exemption in respect of smoking when regulations are made under this power. It is also the intention to retain all other existing exemptions in respect of smoking, and to include the use of a nicotine inhaling device in these exemptions. It is intended to provide an exemption in mental health units that provide residential accommodation in respect of the use of a nicotine inhaling device.</p> <p>It is not currently intended to provide any further exemptions for workplaces and public premises to those already provided for by the Smoke-free Premises etc. (Wales) Regulations 2007 in respect of smoking. There are currently two judicial reviews being considered regarding smoking in prisons in England and Wales. The position in prisons relating to smoking and the use of nicotine inhaling devices will be considered following the outcome of these cases. There is no current intention to restrict entirely the use of nicotine inhaling devices in prisons in Wales.</p> <p>It is the intention to provide further exemptions in premises or specified areas of premises in respect of use of a nicotine inhaling device only – i.e. the use of nicotine inhaling devices would be permitted in such premises even though smoking is not permitted. Such additional exemptions could include, but are not limited to; use of a nicotine inhaling device in specific areas of pharmacies (for example, the pharmacy consulting room); or by performers where use of a nicotine inhaling device is required for the artistic integrity of their performance.</p>	

WHY THE REGULATIONS ARE REQUIRED?

This power is required to enable the Welsh Ministers to exclude from the smoke-free requirements settings which may be considered a person's dwelling for the time being. For example, this will be relevant in settings such as a room in a hotel or guesthouse, or where persons may be detained (such as mental health units). This is in line with the policy intention that the smoke-free requirements should not apply to private dwellings.

The power is also required to exclude the application of the smoke-free requirements in workplaces or public premises which have justifiable reasons for allowing smoking and/or the use of a nicotine inhaling device. For example, this may be appropriate in premises where research on smoking cessation or emission testing is being undertaken.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

An equivalent power to exempt premises from the current smoke-free requirements is included at Section 3 of the Health Act 2006. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. Regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007, made under the Health Act 2006, sets out the premises within which managers may designate smoking rooms (i.e. may designate rooms as being exempt from the smoke-free requirements of the Health Act 2006).

The Smoke-free Premises etc (Wales) Regulations 2007 continue to apply until such time as the Welsh Ministers use these regulation-making powers.

REGULATIONS RELATING TO	Smoke-free signs
BILL PART	Chapter 1 of Part 2
SECTION	11(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations that specify requirements for smoke-free signs. Such requirements may include how the signs should be displayed as well as specifications regarding the dimensions of the sign, the minimum text size and font, any graphic or symbol that must be included, and any mandatory warning message.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>Smoke-free signs will communicate the requirement to refrain from smoking and using a nicotine inhaling device in smoke-free premises, places and vehicles. This power will enable the Welsh Ministers to make regulations detailing the technical specification of smoke-free signs. This will ensure consistency in the signs displayed.</p> <p>The intention is to specify requirements for signs in respect of the requirement to refrain from smoking, and for signs in respect of the requirement to abstain from the use of a nicotine inhaling device. The requirements for each sign may differ depending on whether they are to be used in enclosed or substantially enclosed smoke-free premises, in smoke-free vehicles or on non-enclosed or non-substantially enclosed smoke-free premises (referred to as “additional smoke-free premises” in the Bill).</p> <p>For smoke-free enclosed or substantially enclosed premises, the intention is for occupiers/managers of such premises to retain their existing no-smoking signs for the purpose of communicating the requirement to refrain from smoking in enclosed or substantially enclosed smoke-free premises. The current specifications for no-smoking signs for enclosed or substantially enclosed premises are provided for in regulation 5 of the Smoke-free Premises etc. (Wales) Regulations 2007. The specifications for such signs will not change as a result of regulations being made using this new power. The existing no-smoking signs will therefore not need to be updated or replaced. This will reduce waste and enable the internationally recognised no-smoking symbol to be retained. The same will apply to no-smoking signs for smoke-free vehicles, the specifications for which are provided for in regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p> <p>To communicate the requirement to refrain from use of a nicotine inhaling device in enclosed or substantially enclosed smoke-free premises and vehicles, it is intended that regulations will specify requirements for separate signs to the existing no-smoking signs. It is intended that the specifications for this new sign will be very similar to those of the existing no-smoking signs, albeit that the graphic image and text will need to be slightly amended. The graphic image will depict a nicotine inhaling device in a circle with a red bar crossing through it, and the message will reflect the requirement to refrain from using a nicotine inhaling device in the premises. It is intended that such signs should be displayed alongside existing no-smoking signs.</p>	

A new distinctive sign to communicate the requirement to refrain from the use of a nicotine inhaling device in enclosed or substantially enclosed smoke-free premises and smoke-free vehicles will make it clear that the requirements in enclosed or substantially enclosed smoke-free premises have changed.

In addition, separate signs are required to enable exemptions from the smoke-free regime in respect of smoking, use of a nicotine inhaling device, or both. For example, if the Welsh Ministers make regulations to provide for an exemption from the smoke-free regime for pharmacy consulting rooms in respect of use of a nicotine inhaling device, such areas of the premises will require a sign to communicate the requirement to refrain from smoking only. Although it will not be a legal requirement, guidance will advise on the display of a sign to show that the use of nicotine inhaling devices is permitted.

The requirements for the signs to be displayed in non-enclosed or non-substantially enclosed smoke-free premises by virtue of regulations made under Section 8 will differ to those for smoke-free premises as outlined above. It is the current intention to use the same graphic image and message; however, other requirements such as the dimensions and where signs should be placed will differ to reflect the non-enclosed or non-substantially enclosed environment.

WHY THE REGULATIONS ARE REQUIRED?

The power is required to provide technical detail to the legislative scheme. The public need to be aware of which premises, places and vehicles are smoke-free as they will be committing an offence if they smoke or use a nicotine inhaling device in such smoke-free premises, places and vehicles. The negative procedure is used here because the regulations will be of a technical nature.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Section 6 of the Health Act 2006 provides the Welsh Ministers with powers to specify the requirements for no-smoking signs in regulations. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. Regulation 5 of the Smoke-free Premises etc. (Wales) Regulations 2007 establishes the existing requirements for no-smoking signs for smoke-free premises, and regulation 6 provides the existing requirements for no-smoking signs for smoke-free vehicles.

The Smoke-free Premises etc. (Wales) Regulations 2007 will continue to apply until such time as the Welsh Ministers use these regulation-making powers.

It is likely that any regulations that utilise this power will have to be notified pursuant to Article 9(2) of Directive 98/34/EC ("the Technical Standards Directive"), as they will be setting technical standards for the smoke/nicotine inhaling device signs to be used.

REGULATIONS RELATING TO	Signs for additional smoke-free premises and smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	11(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>Smoke-free signs will communicate the requirement to refrain from smoking and the use of a nicotine inhaling device in smoke-free premises in Wales. Section 11(1) requires those who occupy or manage smoke-free public premises or workplaces to display smoke-free signs. The power in Section 11(3) permits the Welsh Ministers to make regulations that place a corresponding duty on those who occupy or manage additional smoke-free premises (designated by virtue of Section 8) and smoke-free vehicles (designated by virtue of Section 9).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will enable the Welsh Ministers to require managers of additional smoke-free premises and smoke-free vehicles to display smoke-free signs.</p> <p>Regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007 places a duty on the operator, driver and any person on a vehicle who is responsible for order or safety on it to ensure no-smoking signs are displayed. There is no intention to change this existing duty. Instead, it is the intention to make the same persons responsible for ensuring signs are displayed relating to refraining from use of a nicotine inhaling device in smoke-free vehicles.</p> <p>Should the Welsh Ministers make regulations under Section 8 to provide for additional smoke-free premises, it is intended to require the manager or occupier of the additional smoke-free premises to ensure appropriate smoke-free signs are displayed. For example, if the Welsh Ministers make regulations to provide for hospital grounds to be smoke-free, the manager of those hospitals will be responsible for ensuring that the required signs are displayed.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is needed to enable the Welsh Ministers to require the managers/occupiers of additional smoke-free premises and smoke-free vehicles to display signs. The power is also required to ensure the public are aware, by way of appropriate signs, that the additional premises or vehicle in question should be smoke-free. The corresponding duty for managers of smoke-free public and work places is on the face of the Bill and therefore subject to full scrutiny by the Assembly. The affirmative procedure is used for regulations made under Section 11(3) to ensure a similar level of scrutiny by the Assembly because the regulations will place a duty on managers of additional smoke-free premises and smoke-free vehicles.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Section 6(2) of the Health Act 2006 provides the Welsh Ministers with powers to require persons or descriptions of persons to display no-smoking signs in places that are smoke-free by virtue of Section 4 of that Act, and vehicles that are smoke-free by virtue of Section 5. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. Regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007 provides the existing requirements for no-smoking signs for smoke-free vehicles. This includes a duty on the operator, driver and any person on a vehicle who is responsible for order or safety on it to ensure no-smoking signs are displayed.

REGULATIONS RELATING TO	Enforcement authorities
BILL PART	Chapter 1 of Part 2
SECTION	12(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power requires the Welsh Ministers to make regulations to designate persons, or descriptions of person, as enforcement authorities for the purposes of this Chapter. The regulations must also specify the descriptions of premises, places or vehicles to which an enforcement authority is designated. An authorised officer is any person authorised by the enforcement authority to carry out its enforcement functions. An authorised officer may or may not be an officer of the enforcement authority.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>Regulations made under this power will establish who is responsible for enforcing the smoke-free requirements and descriptions of the premises, places or vehicle for which the enforcement authority is responsible. It is the intention that county and county borough councils in Wales (local authorities) shall be designated as enforcement authorities for the enforcement of the smoke-free requirements in public premises and workplaces, as well as any additional smoke-free premises. Section 12(4) permits the designated enforcement authority to make arrangements with another enforcement authority for a case dealt with it to be taken over by that authority. This is the same as the current enforcement arrangements under the Health Act 2006.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is required as it adds technical detail to the smoke-free regime. This detail is relatively minor in the overall legislative scheme and therefore best achieved through regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Section 10(1) of the Health Act 2006 provides the Welsh Ministers with powers to make regulations to designate the bodies or descriptions of body as enforcement authorities for the purpose of Chapter 1 of Part 1 of that Act. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. Regulation 8(1) of the Smoke-free Premises etc. (Wales) Regulations 2007 designates county and county borough councils in Wales to enforce the smoke-free provisions of the Health Act 2006 in relation to the premises and the vehicles that are within their area.</p> <p>For smoke-free private vehicles carrying persons under the age of 18, the intention, in draft Regulations laid on 5 May 2015, is to designate the Police in addition to county and county borough councils in Wales as the relevant enforcement authority.</p>	

Chapter 2 - Retailers of tobacco and nicotine products

REGULATIONS RELATING TO	Specifying the registration authority to maintain a register of retailers of tobacco and nicotine products
BILL PART	Chapter 2 of Part 2
SECTION	22(2)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>Section 22 of the Bill places a duty on the registration authority to maintain a register of retailers of tobacco and nicotine products.</p> <p>This power will allow the Welsh Ministers to make regulations to specify which organisation will undertake the role of the registration authority. Section 22(8) provides that the regulations can specify the Welsh Ministers as the registration authority. This may be required to ensure the register remains operational.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will specify a local authority, or other statutory, voluntary, or private organisation, to act as the registration authority for the register of retailers of tobacco and nicotine products.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers require the ability to specify an organisation to maintain the register. The organisation specified within these regulations, referred to as the registration authority, will then be required to fulfil the duties required of the registration authority contained within Chapter 2 of Part 2 of the Bill.</p> <p>The Welsh Ministers will also need to be able to change the organisation which is nominated as the registration authority in certain circumstances. For example, the power will enable the Welsh Ministers to respond to a situation where the organisation nominated as the registration authority becomes unable to continue to perform the role. In addition, the ability to nominate the Welsh Ministers as the registration authority is intended to provide additional flexibility to ensure that the register will remain in operation if there are difficulties in finding a suitable organisation to fulfil this role.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	The application form for the register, information contained within the form and accompanying fee.
BILL PART	Chapter 2 of Part 2
SECTION	23(3)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 23 of the Bill covers applications by retailers of tobacco and nicotine products for entry onto the register. This includes detail about the type of information an application for inclusion on the register must include.</p> <p>This power will enable the Welsh Ministers to provide for the form of an application, the way it is to be submitted, any other information which must be included, and for a fee to accompany the application.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations would provide details regarding how a retailer would be required to submit an application for entry onto the register. It is intended that applicants will be able to complete an application either electronically or in paper format. Engagement will take place with stakeholders (such as trading standards departments and retailers) in order to ensure the relevant information is collected and to keep the application process as straightforward as possible.</p> <p>In relation to other types of information to be included within the register, it is the current intention that additional information requested will only be that which could be useful in reducing access to tobacco products and nicotine products by persons under 18.</p> <p>The regulations will also outline if there is a fee required as part of an application. It is currently intended that applicants will have to pay a small fee as part of a registration application. The precise detail of the fee structure is yet to be determined, but the current intention is for there to be a £30 fee to cover the application and registration of one premises, with a further £10 for each additional initial premises. It is intended that the level of the fee will be kept to a reasonable level which would not be prohibitive for small retailers.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required in order to ensure that the information captured on the register is relevant, and that the registration process is not too burdensome for retailers who need to submit applications. The precise form of the application will need to be developed with input from stakeholders. In addition, following the launch of the register there may be a need to amend the form or format in which an application is submitted to the registration authority, for example to improve the process, or make it quicker and easier for retailers.. Regulation-making powers are considered the most effective way of achieving this as they will provide the required level of flexibility.</p>	

Similarly, there may be a need to set or change the level of the fee in the future. This will provide flexibility for the fee to be increased or reduced, based on variables such as inflation. Any future changes to the fee would need to take account of the need to ensure fees are proportionate and not prohibitive.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Charging a fee in connection with revising the register
BILL PART	Chapter 2 of Part 2
SECTION	26(6)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 26 of the Bill places a duty on the registration authority to revise the register of retailers of tobacco and nicotine products under certain conditions such as;</p> <ol style="list-style-type: none"> 1. upon receiving notice from a registered person to revise the register, in respect of matters detailed in 25 (1); or 2. to correct any inaccuracies in the register of which it becomes aware, other than by notification by a registered person. <p>The Section outlines the process the registration authority must follow when revising the register. This power will enable the Welsh Ministers to make regulations to allow the registration authority to charge a fee in connection with making revisions to the register.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will stipulate if the registration authority can charge a fee to make revisions to the register, as well as the level of the fee. It therefore provides limited further technical detail to the operation of the register.</p>	
WHY THE REGULATION IS REQUIRED	
<p>When the register initially becomes operational, it is intended that any revisions made to the register will not incur a fee. However, it may be necessary to review this position and consider providing for a fee in the future. This will provide flexibility to consider this issue, for example once it is known how many requests are being received to revise details on the register and the administrative burden this places on the registration authority.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Application of the register of retailers of tobacco and nicotine products to moveable structures
BILL PART	Chapter 2 of Part 2
SECTION	28
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>This power provides regulation-making powers to enable the Welsh Ministers to modify the provisions of Chapter 2 of Part 2, including its requirements, when applied to a vehicle, a stall, a tent or a moveable structure (for example, by requiring the application for registration for a stall to include additional information to that which is required for retail premises).</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>Regulations made under this power could specify specific information which must be included in an application for a moveable structure to be included on the register of retailers of tobacco and nicotine products. It is intended that this regulation-making power will only be used if the application process needs to be modified for moveable structures.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Identifying moveable units, particularly stalls, is considered much more difficult than the other types of retail outlet captured by the register. The regulation-making power is therefore intended to enable the application process to be amended to capture specialist information which is unique to moveable structures, and which would assist enforcement agencies in dealing with this type of retail premises. For example, this may include some form of unique trading number for stalls (or other moveable units).</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Definition of 'nicotine product' in respect of the register of retailers of tobacco and nicotine products
BILL PART	Chapter 2 of Part 2
SECTION	39(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 39 of the Bill contains definitions of terms used within Chapter 2 of Part 2. This power will enable the Welsh Ministers to specify in regulations what is included within the definition of "nicotine product" in relation to the register of retailers of tobacco and nicotine products.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will specify what constitutes a "nicotine product" in relation to the register of retailers of tobacco and nicotine products. These regulations would therefore indicate in relation to which products a retailer must register.</p> <p>It is currently intended that the regulations will define "nicotine product" to capture any nicotine product that is subject to an age restriction on sale. Nicotine products which do not have an age of sale restriction, or which are licensed as medicines, will not be included within the definition of "nicotine product" in relation to the register.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Currently the Nicotine Inhaling Products (Age Of Sale and Proxy Purchase) Regulations 2015 provide detail about which nicotine products can only be sold to persons aged 18 or over. It is the intention that the definition of "nicotine product" in relation to the register of retailers of tobacco and nicotine products will mirror these regulations, and will therefore exclude medicinal products (for example nicotine inhaling products that are licensed medicines).</p> <p>In addition, it may be necessary to amend the definition of "nicotine product" in the future to respond to changing circumstances. This will ensure the register remains relevant and effective in the light of future developments in the area of nicotine products.</p> <p>Use of the power will provide appropriate clarity which would otherwise not be provided.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

Chapter 3 - Prohibition on sale of tobacco and nicotine products

REGULATIONS RELATING TO	Adding new tobacco or nicotine offences to the Restricted Premises Order regime
BILL PART	Chapter 3 of Part 2
SECTION	40(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Currently a local authority in Wales can apply to the magistrates' court to impose a Restricted Premises Order on a premises in relation to the following tobacco offences, where they have been committed on three separate occasions over a two year period;</p> <ol style="list-style-type: none"> 1. sale of any tobacco or cigarette papers to a person under the age of 18, whether for their own use or not, or 2. if it is proved to the satisfaction of the courts that an automatic machine for the sale of tobacco kept on premises has been used by any person under the age of eighteen. <p>A restricted premises order prohibits the sale of any tobacco or cigarette papers, to any person, for a set period of time, on the premises to which it relates.</p> <p>Section 40 of the Bill amends Section 12D of the Children and Young Persons Act 1933 to allow the Welsh Ministers to make regulations to amend the definition of tobacco or nicotine offences. This will enable the Welsh Ministers to include additional tobacco or nicotine offences for which a local authority can apply for a Restricted Premises Order for a retail premises in Wales.</p> <p>The Welsh Ministers will only be able to add new offences if they are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine, and is punishable by a level 4 fine on the standard scale or greater.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will allow the Welsh Ministers to add further tobacco and nicotine offences to those which can currently trigger a local authority requesting a Restricted Premises Order. The Welsh Ministers will only be able to add new offences if they are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine, and is punishable by a level 4 fine on the standard scale or greater.</p> <p>In considering this issue, engagement will take place with stakeholders such as Wales Heads of Trading Standards and HM Revenue and Customs to identify the relevant offences which should be included within the Restricted Premises Order regime.</p> <p>Potential offences which could be considered for inclusion, subject to consultation, could include those relating to the sale of illegal tobacco or infringements of the</p>	

display ban.

WHY THE REGULATION IS REQUIRED

Having the power to add new offences will ensure that any future offences which meet the criteria can be added to those for which a Restricted Premises Order can be sought.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

Chapter 4 – Handing over of tobacco etc. to persons under 18

There are no provisions in this Chapter which provide for the production of subordinate legislation.

PART 3 - SPECIAL PROCEDURES

REGULATIONS RELATING TO	Exemption from the requirement to be licensed
BILL PART	Part 3
SECTION	49(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>This power enables the Welsh Ministers to make regulations which provide that a special procedures licence is required by an individual who is a member of a profession set out in paragraphs (a) to (ga) of Section 25(3) of the National Health Service Reform and Health Care Professions Act 2002, and who would otherwise be exempted from the requirement to be licensed, in order for them to practice a specified special procedure. The list of special procedures is provided in Section 46 and comprises: acupuncture, body piercing, electrolysis and tattooing.</p> <p>The professions listed in Section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 are:</p> <ul style="list-style-type: none"> (a) the General Medical Council, (b) the General Dental Council, (c) the General Optical Council, (d) the General Osteopathic Council, (e) the General Chiropractic Council, (f) the General Pharmaceutical Council, (g) subject to Section 26(6), the Pharmaceutical Society of Northern Ireland, (ga) the Nursing and Midwifery Council. 	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power enables the Welsh Ministers to require that members of a specified profession require a special procedures licence in order to practice one or more special procedures. It is the intention that the regulations are tailored to take account of the practices undertaken by individuals within each profession, and are developed in conjunction with the relevant regulatory bodies.</p> <p>For example, the regulations may provide that a member of a specified profession, (such as a chiropractor) may be required to obtain a special procedure licence in order to practice body piercing, electrolysis and tattooing, but will not be required to obtain a licence to practice acupuncture as the relevant regulatory body has determined that the practice of acupuncture is within the scope of practice of its members.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers will retain responsibility for the special procedures that exempt individuals can perform without a special procedure licence. As exempt individuals will perform special procedures without a licence, it is important to ensure they are only performed by individuals who are determined to be competent and acting within</p>	

their scope of practice as determined by their regulating body.

The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Exemption from the requirement to be licensed
BILL PART	Part 3
SECTION	49(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATION	
<p>This power enables the Welsh Ministers to make regulations specifying when a special procedures licence is not required by an individual in order for them to practice a specified special procedure. The list of special procedures is provided in Section 46 and comprises acupuncture, body piercing, electrolysis and tattooing.</p> <p>The Welsh Ministers will only be able to exempt an individual who is:</p> <p>(a) a member of a profession which is specified in or under regulations (but not a profession that is regulated by a body mentioned in paragraphs (a) to (ga) of Section 25(3) of the National Health Services Reform and Health Care Professions Act 2002) or who is a worker of a description specified in or under regulations; and</p> <p>(b) who is registered, in the capacity of a member of that profession or a worker of that description, in a qualifying register. A qualifying register is:</p> <ul style="list-style-type: none"> • a register maintained by the Health and Care Professions Council; or • a voluntary register that is accredited by the Professional Standards Authority for Health and Social Care under Section 25G of the National Health Service Reform and Health Care Professions Act 2002 or that is specified in or under regulations. 	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulations will enable the Welsh Ministers to provide that an individual, who is a member of a profession or is already registered with a qualifying register, is exempt from the requirement to obtain a special procedure licence in order to practice a specified special procedure.</p> <p>It is the intention that the regulations are tailored to take account of the practices undertaken by individuals within each profession and are developed in conjunction with the regulatory body/ registering authority. For example, it is the intention that a</p>	

physiotherapist who is a member of a register maintained by the Health and Care Professions Council will be exempt from the requirement to obtain a licence in order to practice acupuncture. It is also the intention for members of the British Acupuncture Council (BAcC) to be exempt from the requirement to obtain a licence to practice acupuncture (subject to the BAcC maintaining its accreditation with the Professional Standards Authority for Health and Social Care).

WHY THE REGULATION IS REQUIRED

The Welsh Ministers will retain responsibility for the special procedures that exempt individuals can perform without a special procedure licence. As exempt individuals will perform special procedures without a special procedures licence, it is important to ensure special procedures are only undertaken by individuals who are determined to be competent and acting within their scope of practice as determined by their regulating body or authority.

The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Health and Care Professions Council: <http://www.hpc-uk.org/>
 Professional Standards Authority for Health and Social Care: <http://www.professionalstandards.org.uk/about-us>

REGULATIONS RELATING TO	Licensing criteria
BILL PART	Part 3
SECTION	51(1), 51(3), 51(4)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>These powers require the Welsh Ministers to prescribe in regulations the licensing criteria that must be met upon application for a special procedures licence in order for the application to be granted. The licensing criteria may relate to (among other things):</p> <ul style="list-style-type: none"> (a) an individual’s eligibility for a licence; (b) the premises or vehicle at or in which a special procedure is to be performed, or at or in which equipment or material used in the special procedure is to be stored or prepared (including, among other things, facilities available there and standards of hygiene); and (c) the equipment used in, or in connection with, the performance of a special procedure. <p>Regulations made under this Section may also require that the local authority undertakes an inspection of the premises or vehicle identified in the application before a licence is issued or renewed. This is to enable the local authority to determine the premises’ or vehicle’s compliance with the licensing criteria before a</p>	

licence is granted.

In addition, the regulations may make different provision for different descriptions of premises and vehicles, for different special procedures, and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed.

The licensing criteria may also address the basis upon which the special procedure will be performed (i.e. whether the special procedure is performed on a peripatetic basis, on a fixed site basis, on a mobile basis, on a temporary basis, or otherwise), and specify the requirements in relation to each practice. Further detail on the basis is provided in Section 77(3).

Before the regulations are made, Section 53 requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and if so to consult with them if appropriate. This will ensure that those who are affected by the regulations are consulted and have their views considered before they are put in place.

WHAT CAN THE REGULATION ACHIEVE?

The regulations will provide the Welsh Ministers with the ability to develop tailored and specific licensing criteria that relate to an individual special procedure, the location it is practiced from (i.e. a premises or vehicle), and the basis upon which it is performed. As the practice of special procedures varies significantly, the licensing criteria will be developed to take account of the variance. For example, it is expected that the licensing criteria will be different for an individual practicing tattooing from a single premises than those for a practitioner practicing acupuncture peripatetically.

It is the intention that the licensing criteria will specify the standards of competence that an individual must have in order to be granted a licence. For example, a requirement may be that the individual is able to demonstrate that they have specific knowledge or have undertaken training in relation to infection control in order to undertake the special procedure safely. The criteria may also relate to the equipment to be used in, or in connection with, the performance of a special procedure for example the presence of non-hand operated taps at the location from which special procedures will be performed.

It is therefore the intention to specify in these regulations the licensing criteria in relation to each type of practice. It is also the intention to address the licensing criteria required for performing special procedures during conventions in these regulations.

WHY THE REGULATION IS REQUIRED

In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, they will also provide consistency in relation to the licensing criteria and ensure that the same criteria are applied across Wales. The regulations will ensure that the requirements to be met by those applying for a special procedure licence are transparent and

obtainable.

The regulations are also needed to provide flexibility and ensure that the licensing criteria can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS	Mandatory licensing conditions
BILL PART	Part 3
SECTION	52(1), 52(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>Section 52 requires the Welsh Ministers to make regulations that set out the mandatory licensing conditions in relation to special procedure licences. The mandatory licensing conditions will detail the requirements that the holder of a special procedure licence must adhere to. The mandatory licensing conditions may relate to (among other things):</p> <ul style="list-style-type: none">(a) the premises or vehicle at or in which a special procedure is to be performed, or at or in which equipment or material used in a special procedure is to be stored or prepared;(b) the way in which a special procedure is to be performed (including, among other things, equipment used in connection with its performance, protective clothing etc.);(c) information to be provided by and to the licence holder, and consultation to be carried out before, and after a special procedure is performed;(d) record keeping;(e) displaying a licence;(f) circumstances in which an application for variation of a licence is to be made; and(g) the return of a licence, on its expiry, to the authority by which it was issued. <p>In addition, the regulations may make different provision for different descriptions of premises and vehicles, for different special procedures, and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed.</p> <p>Before the regulations are made, Section 53 requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and if so, to consult with them as appropriate. This will ensure that those who are affected by the regulations are consulted and have their views considered before the regulations are put in place.</p>	

WHAT CAN THE REGULATION ACHIEVE?

The policy intention is to ensure that the physical condition of the premises or vehicle used in connection with special procedures will not provide a risk of harm to human health. Details about how the licence holder must maintain their records, display their licence, the circumstances in which an application for variation of a licence is required, and how the licence must be returned on its expiry, will all be specified in the conditions.

The mandatory licensing conditions may also specify the way in which a specified special procedure is to be performed. This may include details about the equipment that should be used, how the procedure should be performed, and the requirements in relation to protective clothing to be worn by the licence holder. The provision of information by the licence holder to clients both before and after a special procedure is carried out may also be specified in the conditions.

It is the intention to specify in these regulations the mandatory licensing conditions in relation to each type of practice. It is also the intention to address the conditions governing practice of special procedures during conventions in these regulations.

WHY THE REGULATION IS REQUIRED

In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, the regulations will also provide consistency in relation to the mandatory licensing conditions and ensure that each local authority in Wales requires the same conditions in relation to specified special procedures. The regulations will also ensure that the requirements of those holding a special procedure licence are transparent and obtainable.

The regulations are also needed to provide flexibility and ensure that the licensing conditions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Performance of special procedure In course of business: approval requirement
BILL PART	Part 3
SECTION	58(6)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Section 58 establishes that a person carrying on a business, in the course of which a special procedure is performed, must comply with two approval requirements. The first requirement is that the procedure is performed at premises or in a vehicle that has been approved by the local authority under Section 59. The second requirement ensures that, once approved, a premises or vehicle complies with the applicable mandatory conditions of approval (provided for in secondary legislation - Section 59(3)(c)).</p> <p>This power provides the Welsh Ministers with the ability to make regulations to exempt certain premises or vehicles from the approval requirements.</p> <p>The premises or vehicle may be described in the regulations by way of reference to the persons by whom they are managed or controlled; the nature of activities carried on, at or in them; the different circumstances in which a special procedure is performed at or in them; or the number of individuals performing special procedures.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>This power will enable the Welsh Ministers to exempt specific premises or vehicles from either or both of the approval requirements. For example, the premises from which a special procedure is performed by an exempted individual may be exempt. The regulations may also provide that specific types of premises, such as GP surgeries or hospitals, are exempt from the requirement to be approved.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers will retain responsibility for determining which descriptions of premises and vehicles are exempt from the requirement to be approved. As the local authority will not be required to approve exempted premises or vehicles and will therefore have little or no role in overseeing the practice of special procedures from them, it is important to ensure special procedures are only undertaken in premises or vehicles that are deemed to be suitable.</p> <p>The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Approval of premises and vehicles in respect of performance of special procedure
BILL PART	Part 3
SECTION	59(3), 59(7), 59(8)
METHOD OF BRINGING INTO FORCE	59(3)- Affirmative 59(7), 59(8) - Negative
DESCRIPTION OF THE REGULATION	
<p>This Section requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles.</p> <p>Regulations made under Section 59(3) must cover the criteria to be met in order for the application to be granted, the circumstances in which an application for approval is to be granted, and the process for an applicant to appeal against a refusal of an application. In addition, the regulations will specify the conditions (the “mandatory approval conditions”) which must be complied with in order for an approval to be retained.</p> <p>Regulations made pursuant to Section 59(7) may also make provision about the way in which an application for approval is made and is dealt with (including the payment of a fee), the circumstances in which an application for approval must not be granted, or may be granted at the local authority’s discretion, and the process that will apply to the renewal of an approval.</p> <p>In addition, regulations made under Section 59 may make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulation-making power in Section 59(3) will allow the Welsh Ministers to make specific provision in relation to the performance of special procedures from premises and vehicles. As the regulations will enable the Welsh Ministers to take account of different descriptions of premises and vehicles, different descriptions of special procedures and different circumstances, the requirements specified by the regulations, including the criteria and mandatory approval conditions, may be tailored to the specific practice of special procedures. For example, the regulations may require that the premises has an adequate and constant supply of hot and cold running water, that there are suitable hand cleansing facilities (for example non-hand operated taps), and that any surface that may be contaminated with blood or other body fluids must be impermeable and suitable for effective cleaning.</p>	
WHY THE REGULATION IS REQUIRED	
<p>In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, the regulations will provide consistency in relation to approved premises and vehicles and ensure that each local authority in Wales has the same requirements in relation to specified special procedures. The regulations will also ensure that the</p>	

requirements in relation to approved premises and vehicles are transparent and obtainable.

The regulations are also needed to provide the flexibility required to respond to changing circumstances.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Adding or removing special procedures from the list
BILL PART	Part 3
SECTION	76(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATION	
<p>This power enables the Welsh Ministers to amend the list of special procedures in Section 46 by adding or removing a type or description of procedure to or from the list, or by varying a reference to a type or description of procedure.</p> <p>The procedure may be described by reference to (amongst other things) the individual who carries out the procedure, or the individual on whom it is carried out.</p> <p>In order for a procedure to be added to the list, the Welsh Ministers must consider that the procedure is capable of being performed for aesthetic or therapeutic purposes and the performance of the procedure for those purposes is capable of causing harm to human health. Harm to human health is defined in Section 77(4) and includes harm to an individual's physical or mental health.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>This power will enable the Welsh Ministers to amend the list of special procedures in future. The Welsh Ministers could use the power if it was clear that a specific procedure performed for aesthetic or therapeutic purposes was causing harm to human health. For example, due to the increase in popularity of tattooing, it may be the case that demand for tattoo removal procedures may soon increase. This power could therefore potentially be used to add tattoo removal to the list of special procedures in Section 46.</p>	
WHY THE REGULATION IS REQUIRED	
<p>It is possible that other procedures carried out for aesthetic or therapeutic purposes and with the potential to cause harm to human health exist or are being developed by the industry. The regulation-making power is required to enable the Welsh Ministers to react to developments within the special procedures sector, and ensure that the list of special procedures remains up to date and relevant. The power will</p>	

therefore ensure the licensing requirements take account of changing practices and trends, within a quickly evolving sector. It also therefore provides a mechanism for making appropriate amendments to the list more easily than amending primary legislation on each separate occasion.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Interpretation of “body piercing”
BILL PART	Part 3
SECTION	77(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>This Section provides the Welsh Ministers with a power to amend the definition of “body piercing” by describing objects that may be implanted in an individual’s body.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power will enable the Welsh Ministers to extend the definition of “body piercing” so that it captures the attachment of objects, other than jewellery to an individual’s body. Objects such as a “flesh plugs” may be inserted into the body to progressively stretch the skin, for example the ears. Therefore, the regulations may include “flesh plugs” so that these objects are included in the definition of “body piercing” in the future.</p>	
WHY THE REGULATION IS REQUIRED	
<p>There are a range of objects, other than jewellery, that may be attached to an individual’s body. In order for the definition of “body piercing” to remain effective and reflect the range of objects that may be implanted into the body, the regulation-making power is required to enable the Welsh Ministers to react to changing trends and ensure the definition remains up to date.</p> <p>The regulation-making power also therefore provides a mechanism for amending the definition more easily than by amending primary legislation, as this is a technical matter which may need updating from time to time.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

PART 4 - INTIMATE PIERCING

There are no provisions in this Part which provide for the production of subordinate legislation.

PART 5 - PHARMACEUTICAL SERVICES

REGULATIONS RELATING TO	The preparation and publication of an assessment of needs for pharmaceutical services in its area by a Local Health Board
BILL PART	Part 5
SECTION	89
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This Section inserts Section 82A in to the National Health Service (Wales) Act 2006. Section 82A places a duty on Local Health Boards to prepare and publish an assessment of needs for pharmaceutical services in its area.</p> <p>Section 82A also includes a regulation-making power. The Welsh Ministers must by way of regulations, specify a date by which a Local Health Board is to prepare and publish its first assessment; make provision about the circumstances in which a Local Health Board should review and if appropriate revise its assessment; and make provision about the way in which an assessment is to be published.</p> <p>Regulations may make further provision about the preparation, publication, review and revision of an assessment, which could include things such as the information to be contained in the assessment, the extent to which the assessment should take account of future needs and of other matters, the requirements for consultation, and procedural requirements.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The regulations will ensure that every Local Health Board has made and maintains an assessment of the needs for pharmaceutical services in its area.</p>	
WHY THE REGULATIONS ARE REQUIRED	
<p>The Welsh Ministers must make regulations that require each Local Health Board to make arrangements for the provision of pharmaceutical services to persons within its area by a specific date. In order to maximise the public health role of community pharmacies it is necessary for a Local Health Board to fully understand the need for pharmaceutical services within its area when making arrangements for their provision.</p> <p>The regulations will also provide consistency in relation to the pharmaceutical needs assessment and ensure that each Local Health Board in Wales provides the same level of information, and abide by the same procedural requirements.</p> <p>Providing further technical detail about the process surrounding the preparation of pharmaceutical needs assessment through regulations will provide appropriate flexibility for details of the process to be amended from time to time, without the need to amend primary legislation.</p>	

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)
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N/A

REGULATIONS RELATING TO	The determination of applications by persons seeking to provide NHS pharmaceutical services within the area of a Local Health Board
BILL PART	Part 5
SECTION	90(3), (4), (5), (6), (7), (8), (10)
METHOD OF BRINGING INTO FORCE	Negative procedure
DESCRIPTION OF THE REGULATIONS	
<p>The powers within this Section relate to regulation-making powers currently located in Section 83 of the NHS (Wales) Act 2006. The provisions in this Section amend that existing regulation-making power.</p> <p>Section 90(3) inserts a new Section 2B in Section 83 of the National Health Service (Wales) Act 2006. Section 2B provides that unless specified otherwise in regulations, applications for inclusion on a pharmaceutical list by a person not already on a list, or applications by a person already included on a list for inclusion may only be granted if the Local Health Board is satisfied, if having regard to their most recent pharmaceutical needs assessment and to any matters specified in the regulations, that the granting the application would meet a need in its area for the services applied for.</p> <p>Section 90(7) gives the Welsh Ministers powers to make regulations which specify the circumstances in which a Local Health Board may invite persons to make an application for inclusion in a pharmaceutical list.</p> <p>Section 90(7) also enables the Welsh Ministers to make regulations that specify circumstances in which a Local Health Board may, or must, remove a person from its pharmaceutical list for breaches of a term or condition of arrangements made with the Local Health Board for the provision of pharmaceutical services. The regulations will place conditions on such a removal, in particular that before removing a person from the pharmaceutical list a Local Health Board must issue that person with a notice detailing the breach and the action required to remedy it, and that person has then failed to comply with that notice.</p> <p>Section 90(10) provides that if regulations made under Section 83 of the NHS (Wales) Act 2006 contain provisions about the removal or a person from a pharmaceutical list, the regulations must make provision about the giving of notice of a Local Health Board's intention to remove and the right to make representations.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The regulations will ensure that the provision of pharmaceutical services is closely aligned to the needs of the citizens who use community pharmacies in Wales, in particular by ensuring that persons wishing to provide pharmaceutical services seek to do so in areas where a Local Health Board has identified a need for those services, and where necessary, by allowing Local Health Boards to issue invites to provide services in areas with unmet need.</p> <p>The regulations will also ensure that where, by breaching their terms of service,</p>	

persons providing pharmaceutical services fail to do so effectively, that the Local Health Board can take graduated action to improve the provision of pharmaceutical services. This will improve the consistency and quality of services.

WHY THE REGULATIONS ARE REQUIRED

The Welsh Ministers must make regulations that require each Local Health Boards to make arrangements for the provision of pharmaceutical services to persons within its area. In order to maximise the public health role of community pharmacies it is necessary for a Local Health Board to take account of the need for pharmaceutical services within its area when making arrangements for their provision, and for them to take action to remedy poor performance.

Providing further technical detail about the process for determining applications seeking to provide pharmaceutical services, and the process for removal from a pharmaceutical list, will provide appropriate flexibility for details of the process to be amended from time to time, without the need to amend primary legislation.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

PART 6 - PROVISION OF TOILETS

There are no provisions in this Part that confer regulation-making powers on the Welsh Ministers.

PART 7 – GENERAL

REGULATIONS RELATING TO	Consequential and transitional provisions
BILL PART	7
SECTION	100(1)
METHOD OF BRINGING INTO FORCE	Negative or affirmative
DESCRIPTION OF THE REGULATION	
<p>Section 100(1) provides a regulation-making power to allow Welsh Ministers to make supplementary, incidental, or consequential provisions or any transitional, transitory or saving provisions as appropriate in connection with the Bill.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulations will permit the Welsh Ministers to make amendments to provisions as outlined above in order to give full effect to the provisions of the Bill</p>	
WHY THE REGULATION IS REQUIRED	
<p>These regulations are required to allow the Welsh Ministers to make supplementary, incidental, consequential, transitional or saving provisions if it is considered necessary for the purposes of giving full effect to the provisions of the Bill. Such changes would be relatively minor and making them through regulations will provide appropriate flexibility for such provisions to be made without the need to amend primary legislation.</p> <p>If the regulations amend or repeal any provision of an Act of Parliament or Measure or Act of the National Assembly for Wales, then they will be subject to the affirmative procedure. Otherwise, they will be subject to the negative procedure.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Commencement provisions
BILL PART	7
SECTION	101(2)
METHOD OF BRINGING INTO FORCE	No procedure applicable to commencement order
DESCRIPTION OF THE POWER	
<p>Section 101(2) provides that the Welsh Ministers may appoint by order that provisions not listed in Section 101(1) shall to come into force on a specified date.</p> <p>Section 101(1) provides that the following Sections will come into force on the day Royal Assent is received:</p> <ul style="list-style-type: none"> • Section 1; • Sections 96 to 100; • Section 101; and • Section 102. <p>The enforcement date for the remaining Sections will be determined by Welsh Ministers by statutory instrument.</p>	
WHAT CAN THE POWER ACHIEVE?	
<p>The power will enable the Welsh Ministers to appoint by order a date other than that of Royal Assent for some of the Bill's provisions to come into force.</p>	
WHY THE POWER IS REQUIRED	
<p>This power is required to allow the Welsh Ministers to set commencement dates by order, as noted above. Such orders will be confined to commencement and are technical in nature.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

SCHEDULE 1 – FIXED PENALTIES

REGULATIONS RELATING TO	Provisions on content and form of Fixed Penalty Notices
BILL PART	Schedule 1
SECTION	Paragraph 5
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 makes provision about the fixed penalty notices that may be issued for offences under Chapter 1 of Part 2 (smoking and use of nicotine inhaling devices) and Chapter 2 of Part 2 (register of retailers of tobacco and nicotine products), including requirements relating to content. Paragraph 5 of Schedule 1 provides the Welsh Ministers with the power to make further provision in relation to the details that a fixed penalty notice must contain. The regulations will also state the form in which a fixed penalty notice must be issued.</p>	
WHAT CAN THE POWER ACHIEVE?	
<p>The regulations will state the form of a fixed penalty notice issued in relation to Part 2, Chapter 1 (Smoking and use of nicotine inhaling devices) and Part 2, Chapter 2 (Retailers of tobacco and nicotine products). The regulations can also make further provision about the content required on the fixed penalty notice.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required in order to ensure that the information included on the fixed penalty notice remains accurate. This will enable the Welsh Ministers to include additional information to be included on the fixed penalty notice if required.</p> <p>In addition, should it become necessary to include additional information on the fixed penalty notice, the penalty form will have to be amended. In order to achieve this, the Welsh Ministers will require regulation-making powers relating to the penalty form.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 4 of that Schedule gives powers to the Welsh Ministers to specify the form of the penalty notice in regulations. The Schedule to the Smoke-free Premises etc. (Wales) Regulations 2007 sets out the fixed penalty notice forms for existing smoke-free offences.</p> <p>The Schedule to the Smoke-free Premises etc. (Wales) Regulations 2007 continues to apply until such time as the Welsh Ministers use these regulation-making powers.</p>	

REGULATIONS RELATING TO	Amount of penalty for fixed penalty notices
BILL PART	Schedule 1
SECTION	Paragraph 6
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 covers fixed penalty notices. Paragraph 6 of Schedule 1 provides the Welsh Ministers with the power to make regulations to prescribe the amount set for a fixed penalty notice issued for the offences below.</p> <p>Part 2, Chapter 1 (smoking and use of nicotine inhaling devices)</p> <ul style="list-style-type: none"> • Smoking or use of a nicotine inhaling device in smoke-free premises or a smoke-free vehicle. • Not displaying signs in smoke-free premises or a smoke-free vehicle. • Failing to take reasonable steps to cause a person to stop smoking or using a nicotine inhaling device in any smoke-free private vehicles. <p>Part 2, Chapter 2 (retailers of tobacco and nicotine products)</p> <ul style="list-style-type: none"> • A registered person carrying on a tobacco or nicotine business at premises in Wales other than those stated in the person's entry in the register. • A registered person carrying on a tobacco or nicotine business at premises consisting of a moveable structure, a stall, a tent or a vehicle in the area of a local authority other than one stated in the persons entry on the register. • A person who fails, without reasonable excuse, to comply with Section 25 (duty to notify certain changes). 	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power will allow the Welsh Ministers to set fixed penalty notice levels across the relevant offences in Part 1, Chapters 1 and 2 to ensure consistency across the requirements regarding smoking and use of nicotine inhaling devices, and to consider appropriate levels for all offences.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required as there could be a requirement in the future to alter the penalties linked to the offences above. Taking a regulation-making-power through an affirmative process is therefore the most appropriate way to meet this requirement, as this provides an appropriate level of flexibility whilst also providing additional security that the amount set for fixed penalty notices will not be determined without full consideration and opportunity for debate.</p> <p>.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 5 of that Schedule gives the Secretary of State powers to specify the amount of the penalty in regulations. Regulation 2 of the Smoke-free (Penalties and Discounted Amounts) Regulations 2007 sets out the penalty amounts for existing smoke-free offences. These are:

- £200 (discounted to £150) for offences relating to failure to display smoke-free signs; and,
- £50 (discounted to £30) for offences relating to smoking in a smoke-free place.

The Smoke-free (Penalties and Discounted Amounts) Regulations 2007 continue to apply in Wales until such time as the Welsh Ministers use these regulation-making powers.

REGULATIONS RELATING TO	Discounted amount of penalty for fixed penalty notices
BILL PART	Schedule 1
SECTION	Paragraph 9
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 of the Public Health Bill covers fixed penalty notices. Paragraph 9 of Schedule 1 provides the Welsh Ministers with the power to make regulations to state the discounted penalty for a fixed penalty notice issued for the offences below.</p> <p>Part 2, Chapter 1 (smoking and use of nicotine inhaling devices)</p> <ul style="list-style-type: none"> • Smoking and use of a nicotine inhaling device in smoke-free premises or a smoke-free vehicle. • Not displaying signs in smoke-free premises or a smoke-free vehicle. • Failing to take reasonable steps to cause a person to stop smoking or using a nicotine inhaling device in any smoke-free private vehicles. <p>Part 2, Chapter 2 (retailers of tobacco and nicotine products)</p> <ul style="list-style-type: none"> • A registered person carrying on a tobacco or nicotine business at premises in Wales other than those stated in the person's entry in the register. • A registered person carrying on a tobacco or nicotine business at premises consisting of a moveable structure, a stall, a tent or a vehicle in the area of a local authority other than one stated in the persons entry on the register. • A person who fails, without reasonable excuse, to comply with Section 25 (duty to notify certain changes). <p>A discounted amount is payable if the penalty is paid within 15 days, beginning with the day the fixed penalty notice is issued.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power will allow Welsh Ministers to set fixed penalty notice levels across the relevant offences in Part 2, Chapters 1 and 2 to ensure consistency across the requirements regarding smoking and use of nicotine inhaling devices, and to consider appropriate levels for all offences.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required as there could be a requirement in the future to alter the penalties linked to the offences above. If the penalty amount is changed then there may be a requirement to alter the discounted amount as well. In addition, there may be a requirement to only change the discounted amount (for example if it is considered that the discounted amount is not sufficient to encourage prompt payment). Taking a regulation-making power through an affirmative process is the most appropriate way to meet this requirement, as this provides an appropriate level of flexibility whilst also providing additional security that the discounted amount set for fixed penalty notices will not be determined without full consideration and opportunity for debate.</p>	

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 8 of that Schedule gives the Secretary of State powers to specify the amount of the discounted penalty in regulations. Regulation 2 of the Smoke-free (Penalties and Discounted Amounts) Regulations 2007 sets out the penalty amounts for existing smoke-free offences. These are:

- £200 (discounted to £150) for offences relating to failure to display smoke-free signs; and,
- £50 (discounted to £30) for offences relating to smoking in a smoke-free place.

The Smoke-free (Penalties and Discounted Amounts) Regulations 2007 continue to apply in Wales until such time as the Welsh Ministers use these regulation-making powers.

**SCHEDULE 2 – SMOKING AND NICOTINE INHALING DEVICES:
CONSEQUENTIAL AMENDMENTS**

REGULATIONS RELATING TO	Fixed penalty notices
BILL PART	Schedule 2
SECTION	Paragraph 17(2)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 91 of the Children and Families Act 2014 makes Schedule 1 to the Health Act 2006, which covers fixed penalty notices (FPNs), applicable in relation to the offence of the purchase of tobacco etc. on behalf of persons under 18 (the so called “proxy purchase” offence).</p> <p>However, paragraph 15 of Schedule 2 to the Public Health (Wales) Bill amends paragraph 4 of Schedule 1 to the Health Act 2006, such that the reference to “appropriate national authority” is changed to “Secretary of State”. Thus the power in the Health Act 2006 to specify in regulations the form of the FPNs becomes applicable to England only.</p> <p>The consequential amendment at Paragraph 17(2) of Schedule 2 further amends Schedule 1 to the Health Act 2006 so as to retain the Welsh Ministers’ powers to specify in regulations the form of the FPN in relation to the proxy purchase offence.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power enables the Welsh Ministers to prescribe in regulations the form of the FPN in relation to the proxy purchase offence.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Without this regulation-making power, the repeal of Part 1 of Chapter 1 of the Health Act 2006 in relation to Wales would remove the power for the Welsh Ministers to prescribe in regulations the form of the FPN in relation to the proxy purchase offence, powers for which are provided by Section 91 of the Children and Families Act 2014.</p> <p>Whilst the proxy purchase offence is not directly relevant to the content of the Bill, Paragraph 17(2) of Schedule 2 is required to maintain the status quo in relation to the Welsh Ministers’ powers to prescribe the form of the FPN for the proxy purchase offence. This consequential amendment does not, therefore, constitute additional powers for the Welsh Ministers.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Regulations on the form of the FPN for the proxy purchase offence, drafted under the provisions of the Health Act 2006, will be laid shortly and will come into force on 1st October 2015.

These regulations, once in force, will continue to apply until such time as the Welsh Ministers use these regulation-making powers.

SCHEDULE 3 – FURTHER PROVISION IN CONNECTION WITH SPECIAL PROCEDURE LICENCES

REGULATIONS RELATING TO	Application for special procedure licence
BILL PART	Schedule 3
SECTION	Paragraph 4(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraphs 1-4 of Schedule 3 provide details of the process that an applicant for a special procedure licence must follow, including the information that they must provide to the local authority to obtain a licence. This information includes the special procedure(s) to which the application relates, and details on the basis that the procedure is to be performed (for example, a peripatetic basis).</p> <p>Paragraph 4(4) enables the Welsh Ministers to make regulations to make further provision about the procedure that the local authority must follow in dealing with an application for a special procedure licence, which could include any additional information that is to be included in an application.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power enables the Welsh Ministers to prescribe the process that the local authority must follow in dealing with an application for a special procedure licence. For example, the regulations may establish the timeframe within which the local authority must determine the application and how they must inform the applicant of their decision. The regulations could also require that additional information is supplied with an application, such as a photograph of the applicant.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The power is required to ensure that applications for a special procedure licence are dealt with consistently by local authorities. The power also provides the Welsh Ministers with the flexibility to respond to different circumstances or changes in practice. For example, whilst a special procedure licence must bear a photograph of the licence holder, the process by which the photograph is supplied to the local authority may vary depending upon the facilities available within the local authority. Some local authorities may have photography facilities, whereas others may require a passport style photograph to be supplied by the applicant. The regulations will therefore enable provision to be made to take account of this type of variation.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

REGULATIONS RELATING TO	Contents of special procedure licence
BILL PART	Schedule 3
SECTION	Paragraph 5(3)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraph 5 of Schedule 3 specifies the content of a special procedures licence. The licence must, amongst other things, state the name of the licence holder, name the authority by which the licence is issued and the special procedure that is authorised by the licence.</p> <p>Paragraph 5(3) provides the Welsh Ministers with a regulation-making power to make further provision about the form and contents of special procedure licences.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power will enable the Welsh Ministers to specify further details in relation to special procedures licences. For example, the form of the licence (i.e. its dimensions and style) may be prescribed so that all special procedures licences issued in Wales have a consistent appearance and are recognisable by the public.</p> <p>The regulations may also specify the content of the licence, for example whether it contains a special procedure licence number, or information about the applicable mandatory licensing conditions that the holder of the licence must adhere to. For example, the licence may specify that the licence holder is only permitted to undertake body piercing of the ear using a “hygienic piercing instrument” or is only permitted to practice acupuncture if they use single-use needles.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The regulations will provide the Welsh Ministers with the ability to adapt the form and contents of the special procedure licence to changing circumstances. In addition, it is expected that the information to be contained on the licence in relation to the mandatory licensing conditions is likely to be dependent upon the conditions developed under Section 52; therefore flexibility is required in these regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

REGULATIONS RELATING TO	Delegation of functions
BILL PART	Schedule 3
SECTION	Paragraph 20(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraph 20 of Schedule 3 delegates the specified functions of a local authority to its licensing committee. This allows the licensing committee to make the decisions in relation to those functions listed under paragraph 20 (1).</p> <p>Paragraph 20(4) provides the Welsh Ministers with a regulation-making power to make provision about the procedures applicable to licensing committees and their sub-committees for the purpose of the exercise of the delegated functions under this paragraph, including public access and the availability of records. Subject to any regulations made by the Welsh Ministers, paragraph 20(5) enables each licensing committee and its sub-committees to regulate its own procedure.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulation-making power enables the Welsh Ministers to require that the licensing committee or sub-committee considering cases in relation to Part 3 of the Bill (for example, the refusal of an application for a special procedure licence) has specified procedures in place. The regulations may therefore require that the committee has procedures in place to take valid decisions (for example the number of committee members required to take a valid decision), and to ensure the public has access to committee proceedings and its records.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Ensuring the licensing committee has provisions in place to ensure proper exercise its functions will provide transparency in relation to the local authority's exercise of their powers under this Part. The regulations will also ensure that a consistent approach to the consideration of cases in relation to provisions in this Part is adopted by all local authorities in Wales.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Schedule 4 – Provision of toilets: consequential amendments

There are no provisions that confer powers on the Welsh Ministers to make subordinate legislation in Schedule 4 to the Bill.

OTHER SECONDARY LEGISLATION

PART 6 – PROVISION OF TOILETS

GUIDANCE RELATING TO	Delegation of functions
BILL PART	Part 6
SECTION	91(8)
METHOD OF BRINGING INTO FORCE	Guidance
DESCRIPTION OF THE GUIDANCE	
<p>Section 91 requires a local authority to prepare and publish a local toilets strategy. To assist local authorities with their duty, the Welsh Ministers may issue guidance to local authorities about the matters which they should take into consideration when preparing, reviewing or publishing a local toilets strategy. A local authority must have regard to any guidance issued.</p>	
WHAT CAN THE GUIDANCE ACHIEVE?	
<p>It is intended that the guidance will comprehensively cover the issues that local authorities may wish to consider when preparing, reviewing or publishing their local toilets strategy. The guidance will provide information on the mechanisms the local authority could employ to assess the need for toilets in their area, as well as suggested parties that are likely to be interested in the provision of local toilets. The guidance will also provide information on the methods by which the local authority could publicise those toilets that are available in their area for use by the public.</p>	
WHY THE GUIDANCE IS REQUIRED	
<p>The power enables the Welsh Ministers to issue guidance in relation to local toilets strategies and provide details upon the issues the local authority should take into consideration when preparing, reviewing or publishing a local toilets strategy.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Power to make byelaws in relation to toilets
BILL PART	Part 6
SECTION	94(1)
DESCRIPTION OF THE BYELAWS?	
<p>Section 93(1) enables a local authority (including a community council) to provide toilets in its area for use by the public. Section 94(1) provides these authorities with the power to make byelaws in relation to the conduct of persons using or entering any toilets provided by them.</p>	
WHAT CAN THE BYELAWS ACHIEVE?	
<p>The byelaws powers are exercisable by local authorities and may be introduced by them if they see fit to do so. The byelaws enable the local authority to make provision about the conduct of persons using or entering any toilets provided by them, and enable the local authority to take action (by way of issuing a fixed penalty notice) for contravention of the byelaws. An example of the conduct that may be specified in the byelaws is that no person is permitted to write on or deface the toilet; a person also must not affix any picture or written material to it.</p>	
WHY THE BYELAW-MAKING IS REQUIRED	
<p>Section 93(1) restates the existing byelaw-making power provided to local authorities (including community councils) in Wales by Section 87 of the Public Health Act 1936. The process to make these byelaws is to be provided by the Local Government Byelaws (Wales) Act 2012.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Local Government Byelaws (Wales) Act 2012 - http://www.legislation.gov.uk/anaw/2012/2/contents/enacted</p>	

David Melding AM
Chair
Constitutional and Legislative Affairs Committee
National Assembly for Wales
Ty Hywel
Cardiff Bay
Cardiff
CF99 1NA

23 June 2015

Dear David

Public Health (Wales) Bill - legislative competence

Further to my statement on the legislative competence in respect of the Public Health (Wales) Bill, published on 8 June, I am writing to draw your attention to the Secretary of State consent and human rights issues I took into account in reaching my view. The issues in relation to human rights are not straightforward and they will require careful consideration during Stage 1. Furthermore, as I explain below, careful consideration by the Assembly, and its Committees, is in itself an important factor in reassuring the courts that human rights have been fully respected, and, therefore, that the Bill is within competence.

Provisions requiring Secretary of State consent

In my view, although the Bill is mostly within the legislative competence of the Assembly, sections 4(7), 5(6), and 11(7) and paragraphs 6 and 9 of Schedule 1 would not be within competence. This is because these provisions require the consent of the Secretary of State, pursuant to Part 2 of Schedule 7 of the Government of Wales Act 2006 (GoWA), to bring them within the Assembly's competence and this necessary consent has not been obtained at this time.

This is consistent with the way I have previously interpreted section 110(3) of GoWA, as requiring me to reflect whether the Bill would be within competence if it were passed as drafted when introduced. You will be aware that GoWA does not debar a Bill from being introduced even if my view is that it would not be within competence.



The Member in charge of a Bill also has to form a view as to whether the Bill is within competence. In contrast to the position regarding my own view, section 110(2) of GoWA does debar introduction where that Member does not positively state that the Bill would be within competence.

As I understand it, the Minister for Health and Social Services, as the Member in charge of the Bill, has relied on a different interpretation of the GoWA, which has enabled him to state that, in his view, all of the Bill's provisions "would be" within competence, in the sense that they would be if the necessary consents were received by the time the Bill was passed.

Human rights

Background

Under Section 108(6)(c) of GoWA, a provision of a Bill is outside the Assembly's competence if it is incompatible with the European Convention on Human Rights.

Part 2, Chapter 1 of the Bill contains provisions that make enclosed and substantially enclosed public premises and shared workplaces smoke-free. These are referred to as 'smoke-free premises'. In this context, 'smoke-free' means that smoking and the use of nicotine inhaling devices (commonly known as 'electronic cigarettes') is banned, unless the premises are exempted by regulations made under section 10 of the Bill.

In terms of workplaces, section 6 of the Bill provides as follows.

Workplaces have to be smoke-free. For these purposes, "workplace" means a place:

- where more than one person works (whether at the same time or not);
or
- where only one person works but is somewhere that the public may have access to.

Where only part of the premises is a workplace, only that part has to be smoke-free. And if part of the workplace is not enclosed or substantially enclosed, that part does not have to be smoke-free either.

But all workplaces have to be smoke-free all of the time – i.e. even outside working hours – except for workplaces that are also dwellings (homes) or within dwellings (section 6(5) of the Bill). In that situation, the workplace does not have to be smoke-free when it is not being used as a place of work.

Section 6(5) raises competing human rights between:

- (a) smokers whose homes are also workplaces; and
- (b) workers who are employed at such workplaces and who wish to have their health protected from smoke (“workers”).

To be within competence, the Bill has to strike the balance between these rights in a way that is “proportionate” to the legitimate aim of protecting public health, in the context of a person’s private home. Both these rights are protected by Article 8 of the European Convention on Human Rights and thus by the Human Rights Act 1998.

We sought a specialist opinion from a leading human rights barrister on whether the Bill does strike this balance appropriately. She advised that the Assembly would have a wide discretion when balancing the Article 8 rights of these different groups of individuals. (This discretion is often called the “margin of appreciation”). However, she stressed that the courts will be much more likely to respect that discretion if the Assembly has carefully considered where to strike the balance, on the basis of relevant evidence. This is consistent with what the majority of the Supreme Court said in the recent judgment in the *Recovery of Medical Costs of Asbestos Diseases (Wales) Bill* case.

Given:

- (a) that the impact on workers is likely to fall within the margin of appreciation of the Assembly (subject to medical evidence); and
- (b) the way the Bill balances the rights of smokers;

I concluded that section 6(5) of the Bill would be within competence.

(a) Workers’ rights

A highly relevant matter for the Assembly to consider, when balancing the rights of smokers and non-smokers in the context of employment in the smoker’s home, is the effects of third-hand smoke and residual vapours from NIDs, respectively. I believe it would be helpful for your Committee to take medical evidence, during Stage 1, on these matters.

The fact that a worker has a degree of choice as to where to work can be taken into account by the Assembly in its considerations as to the balance of rights.



Llywydd
Presiding Officer



(b) Rights of smokers who, in their own home, employ others

Limiting what people can do in their home is a significant infringement of their enjoyment of that space, especially when it can result in a criminal penalty. The Bill extends the right of to smoke in a home that is also used as a workplace, by allowing the resident to smoke even in the parts that are used as a workplace, provided that this is outside working hours.

However, if you take account of the present position under secondary legislation, the Bill balances out this move in favour of smokers by further restricting the right to smoke in other parts of the home.

This is a very short summary of the issues. If you would like further information and advice on these, or any of the other competence tests I applied to the Bill, the officials supporting your inquiry will be pleased to assist.

I am writing in similar terms to the Chair of the Health and Social Care Committee and I am copying this letter to the First Minister and to the Member in charge of the Bill.

A handwritten signature in blue ink that reads "Rosemary".

**Dame Rosemary Butler AM,
Presiding Officer**

By virtue of paragraph(s) vi of Standing Order 17.42

Document is Restricted

By virtue of paragraph(s) vi of Standing Order 17.42

Document is Restricted

National Assembly for Wales Agenda Item 3 Constitutional and Legislative Affairs Committee Statutory Instruments with Clear Reports 21 September 2015

CLA576 -The Agricultural Holdings (Units of Production) (Wales) (No.2) Order 2015

Procedure: Negative

This Order prescribes units of production for the assessment of the productive capacity of agricultural land situated in Wales. It sets out the amount which is to be regarded as the net annual income from each such unit for the year 12 September 2014 to 11 September 2015 for certain purposes of the Agricultural Holdings Act 1986. This Order revokes the Agricultural Holdings (Units of Production) (Wales) Order 2015 (S.I. 2015/1020 (W.73)) (“the 2015 Order”). The figures contained in the Schedule to this Order differ from those in the Schedule to the 2015 Order. This Order relates to the same period as the 2015 Order.

CLA577 - The Proxy Purchasing of Tobacco, Nicotine products etc (fixed penalty notice) (Wales) Regulations 2015

Procedure: Negative

These regulations provide for the Penalty Notice form to be used where an adult is alleged to have committed the offence of purchasing tobacco, cigarette papers or a relevant nicotine product on behalf of a person under the age of 18.

CLA578 -The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015

Procedure: Affirmative

The Human Transplantation (Wales) Act 2013 (“the Act”) provides a change to the way in which consent, for the purposes of transplantation, is to be given for organ and tissue donation in Wales.

The Act introduces two concepts: that of “express consent” and that of “deemed consent”.

The Act does not specify the types of tissues and organs which are to be donated but refers to “relevant material”. Certain material - gametes, embryos outside the body, hair and nails form the body of a living person – are not considered to be “relevant material” for the purposes of the Act but all other material is included.



The Act provides that material may be excluded from the deemed consent regime such as material used in novel forms of transplants. In these instances express consent will be required.

The Regulations define excluded composite tissues and excluded relevant material. They set out those parts of excluded composite tissues which are not to be regarded as excluded relevant material.

CLA579 -The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015

Procedure: Affirmative

The Human Transplantation (Wales) Act 2013 (“the Act”) provides for exceptions to deemed consent including those persons who lack capacity to understand the notion of deemed consent; in such a case, express consent is required.

These Regulations ensure that the arrangements for living persons who lack the capacity to consent to organ or tissue donation will remain the same after the commencement of the Act as the current arrangements under the Human Tissue Act 2014, i.e an activity involving the storage or use of relevant material from a human body for the purposes of transplantation which involves material from the body of a person who lacks capacity to consent (“P”) will be deemed to have been undertaken with P’s consent where the activity was undertaken by a person who is acting in what he or she reasonably believes to be in P’s best interests.

CLA580 - The Human Transplantation (Appointed Representatives) (Wales) Regulations 2015

Procedure: Affirmative

The Human Transplantation (Wales) Act 2013 (“the Act”) provides that a person may appoint a representative whose role it would be to make a decision on organ donation after the death of the person making the appointment.

These Regulations make provision as to the description of persons who may not act as an appointed person for the purposes of the Act.

CLA581 -The Human Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013

Procedure: Affirmative

This Code of Practice has been prepared by the Human Tissue Authority to provide advice and guidance on the circumstances in which consent is deemed under section 4 of the Human Transplantation (Wales) Act 2013. It is intended for use by specialist nurses for organ donation and other clinicians and professionals working in the transplantation sector in Wales.



The Assembly may approve or reject the code but may not amend it. If approved by the Assembly the Code is required to be approved by the UK Parliament.

The Code has been prepared by the Human Tissues Authority in English only. It is understood that following confirmation of the UK Parliament's approval, a Welsh translation will be prepared.



**CLA575 - The Water Environment (Water Framework Directive)
(England and Wales) (Amendment) Regulations 2015**

Procedure:

Negative

Background

These Regulations amend the Water Environment (Water Framework Directive) (England and Wales) Regulations (SI 2003/3242) 'the 2013 Regulations' to transpose aspects of Directive 2013/39 as regards priority substances in the field of water policy ('the Priority Substances Directive').

The Priority Substances Directive itself amends the Environmental Quality Standards Directive 2008/105 which, is a daughter Directive of the Water Framework Directive 2000/60 ('the WFD'). The Priority Substances Directive identifies and sets environmental quality standards in surface waters for a list of priority substances identified under the WFD as presenting a significant risk to or via the aquatic environment.

These Regulations are made by the Welsh Ministers and the Secretary of State jointly in respect of areas partly in Wales and partly in England and compositely otherwise. They also make miscellaneous amendments to the 2003 Regulations.

Technical Scrutiny

The following point is identified for reporting under Standing Order 21.2(ix) – that the instrument is not made in both English and Welsh.

1. Being composite regulations subject to a parliamentary procedure at Westminster, these Regulations have been made in English only.

Merits Scrutiny

No points are identified for reporting under Standing Order 21.3 in respect of this instrument

Legal Advisers
Constitutional and Legislative Affairs Committee
27 August 2015



STATUTORY INSTRUMENTS

2015 No. 1623

WATER RESOURCES, ENGLAND AND WALES

The Water Environment (Water Framework Directive) (England and Wales) (Amendment) Regulations 2015

Made - - - - 24th August 2015
Laid before Parliament 24th August 2015
Laid before the National Assembly for Wales 24th August 2015
Coming into force - - 14th September 2015

The Secretary of State, acting in relation to river basin districts that are wholly in England, and the Welsh Ministers, acting in relation to river basin districts that are wholly in Wales, and the Secretary of State and the Welsh Ministers acting jointly in relation to river basin districts that are partly in England and partly in Wales, make these Regulations in exercise of the powers conferred upon them by section 2(2) of the European Communities Act 1972(a).

The Secretary of State is designated for the purposes of that section in relation to matters relating to the environment(b), and the Welsh Ministers are designated for the purposes of that section in relation to water resources(c).

Citation and commencement

1. These Regulations may be cited as the Water Environment (Water Framework Directive) (England and Wales) (Amendment) Regulations 2015 and come into force on 14th September 2015.

Amendments to the Water Environment (Water Framework Directive) (England and Wales) Regulations 2003

2. The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003(d) are amended in accordance with regulations 3 to 13.

Regulation 2 (interpretation)

- 3.—(1) In regulation 2(1)—
- (a) omit the definition of “the Assembly”;
 - (b) for the definition of “the Directive”, substitute—

(a) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c. 51), section 27(1)(a), and the European Union (Amendment) Act 2008 (c. 7), Part 1 of the Schedule.
(b) S.I. 2008/301.
(c) S.I. 2003/2901, to which there are amendments not relevant to these Regulations.
(d) S.I. 2003/3242, amended by S.I. 2013/755 (W.90); there are other amending instruments but none is relevant.

““the Directive” means Directive 2000/60/EC of the European Parliament and of the Council of 23rd October 2000 establishing a framework for Community action in the field of water policy(a);”;

- (c) in the definition of “environmental objectives”, after “(waters used for the abstraction of drinking water)”, insert “, and the EQS Directive”;
- (d) in the definition of “public body”, for “or the Assembly” substitute “, the Welsh Ministers, the First Minister for Wales or the Counsel General to the Welsh Government”;
- (e) insert each of the following in the appropriate place—

““the EQS Directive” means Directive 2008/105/EC of the European Parliament and of the Council on environmental quality standards in the field of water policy(b);”;

““existing obligations” means the obligations (on environmental quality standards in the field of water policy) under Directive 2008/105/EC (“the original Directive”) before it was amended by Directive 2013/39/EU including, in particular, the achievement of good surface water chemical status in relation to the substances and the associated environmental quality standards listed in the original Directive;”;

““the table of priority substances” means the table in Part A of Annex I to the EQS Directive;”.

(2) In regulation 2(1B)—

- (a) in the opening words and in paragraphs (a) and (b), omit each “and each of its principal regional offices”; and
- (b) in paragraph (c), omit “and each of their principal regional offices”.

Regulation 3 (the general duties)

4.—(1) In regulation 3(1)—

- (a) for “the Assembly”, substitute “the Welsh Ministers”; and
- (b) after “of the Directive”, insert “and the EQS Directive”.

(2) In regulation 3(2), for “of the Directive for the achievement of its environmental objectives”, substitute “of the Directive and the EQS Directive for the achievement of the environmental objectives”.

Regulation 9 (monitoring)

5. In regulation 9, after paragraph (4) insert—

“(5) By 22nd December 2018, the appropriate agency must establish, for each river basin district, a monitoring programme in respect of substances 34 to 45 in the table of priority substances.”.

Regulation 10 (environmental objectives and programmes of measures)

6. In regulation 10, after paragraph (5) insert—

“(6) Without prejudice to the existing obligations, the appropriate authority must ensure that a programmes of measures updated by 22nd December 2015, or subsequently, under paragraph (5)(a)(iii) includes measures for the purpose of aiming to achieve good surface water chemical status by 22nd December 2021 in relation to substances 2, 5, 15, 20, 22, 23 and 28 in the table of priority substances.”.

(a) OJ No L 327, 22.12.2000, p1, as last amended by Commission Directive 2014/101/EU (OJ No L 311, 31.10.2014, p32). The effect of section 20A of the Interpretation Act 1978 (c.30) is that the updated reference to Directive 2000/60/EC is to that Directive as last amended by Commission Directive 2014/101/EU.

(b) OJ No L 348, 24.12.2008, p84, as last amended by Directive 2013/39/EU (OJ No L 226, 24.8.2013, p1).

New regulation 10A (further programmes of measures)

7. After regulation 10 insert—

“Further programmes of measures in relation to certain priority substances

10A.—(1) The appropriate agency must, by 22nd December 2018, establish a preliminary programme of measures for each river basin district in relation to substances 34 to 45 in the table of priority substances.

(2) For the purposes of a programme of measures to be updated under regulation 10(5)(a)(iii) by 22nd December 2021, the appropriate agency must, by such date as the appropriate authority directs, prepare and submit to the appropriate authority proposals for a final programme of measures for the purposes of aiming to achieve good surface water chemical status in relation to substances 34 to 45 in the table of priority substances by 22nd December 2027 and preventing deterioration in the chemical status of each body of surface water in relation to those substances.

(3) Regulation 10(2) applies to the preparation by the appropriate agency of its proposals under paragraph (2) as it does to proposals under regulation 10(1).

(4) Without prejudice to the existing obligations, the appropriate authority must ensure that, for each river basin district, the programme of measures updated under regulation 10(5)(a)(iii) by 22nd December 2021 contains measures for the purposes of aiming to achieve good surface water chemical status in relation to substances 34 to 45 in the table of priority substances by 22nd December 2027 and preventing deterioration in the chemical status of each body of surface water in relation to those substances.

(5) Regulation 10(3) and (4) applies in relation to proposals for a programme of measures submitted to the appropriate authority under paragraph (2) as it does to proposals submitted under regulation 10(1).

(6) The appropriate authority must ensure that the measures referred to in paragraph (4) are made operational as soon as possible after 22nd December 2021, and at the latest by 22nd December 2024.”.

Regulation 11 (river basin management plans)

8.—(1) In regulation 11(2)(b), after “the Directive” insert “and the EQS Directive”.

(2) After regulation 11(3) insert—

“(3A) The relevant provisions of the EQS Directive for the purposes of this regulation are—

- (a) Article 3(5) (information about monitoring and analysis, including alternative matrices);
- (b) Article 4(2) (information relating to mixing zones);
- (c) Article 5(4) (updated inventories).”.

Regulation 18 (publication of information)

9. In regulation 18, after paragraph (3) insert—

“(4) The appropriate authority must ensure that an interim report describing progress in the implementation of the planned programme of measures required to be produced under Article 15(3) of the Directive is made available via a central portal which is accessible to the public electronically in accordance with Article 7(1) of Directive 2003/4/EC of the European Parliament and of the Council on public access to environmental information(a).”

(a) OJ No L 41, 14.2.2003, p26.

New regulation 18A

10. After regulation 18 insert—

“Coordination

18A.—(1) This regulation applies where the results of a report under Article 7a of the EQS Directive show that additional measures at European Union or member State level may be necessary in order to facilitate compliance with the Directive in relation to a particular substance approved pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market^(a) or Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products^(b).

(2) The competent authority must apply Article 44 of Regulation (EC) No 1107/2009 or Article 48 of Regulation (EU) No 528/2012, as appropriate, to the relevant substance referred to in paragraph (1), or products containing that substance.

(3) In applying the provisions referred to in paragraph (2), the competent authority must take into account any risk evaluations and socio-economic or cost-benefit analyses required under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012, including as regards the availability of alternatives.

(4) The competent authority for the purposes of this regulation is the person defined as the competent authority for England or Wales—

- (a) in respect of Regulation (EC) No 1107/2009, under regulation 3 of the Plant Protection Products Regulations 2011^(c);
- (b) in respect of Regulation (EU) No 528/2012, under regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013^(d).”.

Schedule 1 (Directive definitions)

11. In Schedule 1, in the appropriate place insert—

““Good surface water chemical status” means the chemical status required to meet the environmental objectives for surface waters established in Article 4(1)(a), that is the chemical status achieved by a body of surface water in which concentrations of pollutants do not exceed the environmental quality standards established in Annex IX and under Article 16(7), and under other relevant EU legislation setting environmental quality standards at EU level.”.

Schedule 2 (enactments in relation to which duties in regulation 3 apply)

12.—(1) In Part 1 of Schedule 2—

- (a) renumber paragraphs 4 to 6 as paragraphs 3 to 5;
- (b) after newly numbered paragraph 5 insert—

“6. The Land Drainage Act 1991^(e).”;

- (c) renumber paragraph 7A as paragraph 8; and

(a) OJ No L 309, 24.11.2009, p1, as last amended by Regulation (EU) No 652/2014 (OJ No L 189, 27.6.2014, p1).
 (b) OJ No L 167, 27.6.2012, p1, as last amended by Regulation (EU) No 334/2014 (OJ No L 103, 5.4.2014, p22).
 (c) S.I. 2011/2131, to which there are amendments not relevant to these Regulations.
 (d) S.I. 2013/1506, to which there are amendments not relevant to these Regulations.
 (e) 1991 c.59.

(d) after newly numbered paragraph 8 insert—

“9. The Flood and Water Management Act 2010(a).”.

(2) For Part 2 of Schedule 2, substitute the Part in the Schedule to these Regulations.

Further miscellaneous amendments

13.—(1) For regulation 4, substitute—

“4.—(1) The areas shown on the official map are identified as river basin districts for the purposes of these Regulations.

(2) In this regulation, “the official map” means the map of river basin districts produced by the Agency and published on its website.

(3) The NRBW must ensure that the official map is published on its website.

(4) The Agency and the NRBW must ensure that the official map is made available to the public at their principal offices.”.

(2) In regulation 12(5)(a), for each “English Nature” substitute “Natural England”.

(3) In regulation 16(3), for “Agency” substitute “appropriate agency”.

(4) In regulation 17, for “the Assembly” substitute “the Welsh Ministers”.

(5) In the following regulations, omit each “and each of its principal regional offices”—

(a) regulation 12(2)(a);

(b) regulation 13(1)(a);

(c) regulation 14(3)(a).

24th August 2015

Rory Stewart
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

20th August 2015

Huw Lewis
On behalf of Minister for Natural Resources
One of the Welsh Ministers

(a) 2010 c.29.

SCHEDULE

Regulation 12(2)

New Part 2 of Schedule 2 to the 2003 Regulations

“PART 2

Subordinate instruments

- 10.** The Sludge (Use in Agriculture) Regulations 1989**(a)**.
- 11.** The Urban Waste Water Treatment (England and Wales) Regulations 1994**(b)**.
- 12.** The Surface Waters (Shellfish) (Classification) Regulations 1997**(c)** and the Surface Waters (Shellfish) Directions 2010**(d)**.
- 13.** The Water Protection Zone (River Dee Catchment) (Procedural and Other Provisions) Regulations 1999**(e)**.
- 14.** The Water Resources (Environmental Impact Assessment) (England and Wales) Regulations 2003**(f)**.
- 15.** The Urban Waste Water Treatment (England and Wales) (Amendment) Regulations 2003**(g)**.
- 16.** The Environmental Damage (Prevention and Remediation) (Wales) Regulations 2009**(h)**.
- 17.** The Environmental Permitting (England and Wales) Regulations 2010**(i)**.
- 18.** The Water Resources (Control of Pollution) (Silage, Slurry and Agricultural Fuel Oil) (England) Regulations 2010**(j)**.
- 19.** The Water Resources (Control of Pollution) (Silage, Slurry and Agricultural Fuel Oil) (Wales) Regulations 2010**(k)**.
- 20.** The Natural Resources Body for Wales (Establishment) Order 2012**(l)**.
- 21.** The Bathing Water Regulations 2013**(m)**.
- 22.** The Nitrate Pollution Prevention (Wales) Regulations 2013**(n)**.
- 23.** The Keeping and Introduction of Fish (Wales) Regulations 2014**(o)**.

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- (a)** S.I. 1989/1263, amended by S.I. 1990/880, 1996/593, 2000/656, 2010/1159, 1820 (W.177) and 2013/755 (W.90).
- (b)** S.I. 1994/2841, amended by S.I. 2003/1788, 2005/2035, 2010/675, 2011/556 and 2013/755 (W.90).
- (c)** S.I. 1997/1332, amended by S.I. 2009/1266 and 2013/755 (W.90).
- (d)** The Directions are available at:
<http://webarchive.nationalarchives.gov.uk/20130402151656/http://archive.defra.gov.uk/environment/quality/water/waterquality/shellfish/2010surfacewatershellfish.pdf> and at:
<http://gov.wales/legislation/subordinate/nonsi/epwales/2010/3815653/?skip=1&lang=en>
- (e)** S.I. 1999/916, amended by the Countryside and Rights of Way Act 2000 (c.37), section 73(2) and by S.I. 2013/755 (W.90).
- (f)** S.I. 2003/164, amended by S.I. 2006/3124, 2010/1159, 2011/1043 and 2013/755 (W.90).
- (g)** S.I. 2003/1788, amended by S.I. 2013/755 (W.90).
- (h)** S.I. 2009/995 (W.81), amended by S.I. 2011/556, 971, 1043, 2131, 2012/630, 2013/755 (W.90) and 2015/1394.
- (i)** S.I. 2010/675, amended by the Energy Act 2013 (c.32), Schedule 12, Part 2, paragraph 30 and by S.I. 2010/676, 2172, 2011/600 (W.88), 988, 2043, 2933, 2012/630, 811, 2013/390, 755 (W.90), 766, 2952, 2014/255, 571 (W.60), 2852, 2015/324, 664, 918 and 934.
- (j)** S.I. 2010/639, amended by S.I. 2010/1091.
- (k)** S.I. 2010/1493 (W.136), amended by S.I. 2013/755 (W.90).
- (l)** S.I. 2012/1903 (W.230), amended by S.I. 2013/755 (W.90).
- (m)** S.I. 2013/1675, amended by S.I. 2014/1067 (W.106) and 2363.
- (n)** S.I. 2013/2506 (W.245).
- (o)** S.I. 2014/3303 (W.336).

24. The Keeping and Introduction of Fish (England and River Esk Catchment Area) Regulations 2015**(a)**.

25. The Nitrate Pollution Prevention Regulations 2015**(b)**.

26. The Environmental Damage (Prevention and Remediation) (England) Regulations 2015**(c)**.”

(a) S.I. 2015/10.

(b) S.I. 2015/668.

(c) S.I. 2015/810, amended by S.I. 2015/1391.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 (S.I. 2003/3242) (“the 2003 Regulations”). They transpose aspects of Directive 2013/39/EU 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 (OJ No L 226, 24.8.2013, p1).

The Regulations also make miscellaneous amendments to the 2003 Regulations, including updating the list of enactments in Schedule 2 to which certain duties in regulation 3 of the 2003 Regulations apply.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen. A transposition note is annexed to the Explanatory Memorandum which is available alongside the instrument on www.legislation.gov.uk.

Explanatory Memorandum to The Water Environment (Water Framework Directive) (England and Wales) (Amendment) Regulations 2015.

This Explanatory Memorandum has been prepared by the Department for Economy, Skills and Natural Resources and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Water Environment (Water Framework Directive) (England and Wales) (Amendment) Regulations 2015.

Huw Lewis
On behalf of minister for Natural Resources
One of the Welsh Ministers

20 August 2015

Description

1. This instrument amends certain provisions of the Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 to transpose aspects of Directive 2013/39/EU (“the Priority Substances Directive”).
2. The Priority Substances Directive itself amends the Environmental Quality Standards Directive¹ (“the EQS Directive”), which is a daughter Directive of the Water Framework Directive² (“WFD”), and identifies and sets environmental quality standards (EQS) in surface waters for a list of priority substances identified under the WFD as presenting a significant risk to or via the aquatic environment.

Matters of special interest to the Constitutional and Legislative Affairs Committee

3. These Regulations will apply to England and Wales and are subject to negative resolution procedure in the National Assembly for Wales and in both Houses of the UK Parliament. The Regulations are made by the Welsh Ministers and Secretary of State jointly in respect of areas partly in Wales and partly in England, and compositely otherwise. Because the Regulations will be subject to UK Parliamentary scrutiny, it is not considered reasonably practicable for this instrument to be made or laid bilingually.
4. To date, Welsh Government has tended towards transposing Directives compositely with DEFRA. This was due in part, to the fact that the Environment Agency acted as the main environment regulator for both the Welsh Government and UK Government.
5. With the creation of Natural Resources Wales in 2013, there is more scope to operate differently in Wales; however with respect to this particular Directive, there is limited scope to transpose directions differently due to the river basin areas that are partly in Wales and partly in England.
6. The Welsh Ministers have the power to give NRW directions for the implementation of EU obligations such as this. However, that power only covers river basin districts wholly in Wales. In effect this would mean if Welsh Government was to resource a separate transposition it would only apply to the Western Wales river basin, the Severn and Dee River Basins would still need to be directed jointly with DEFRA.
7. Transposing the Directive jointly also ensures there is consistency in delivery, and this is something that the European Commission is keen to see with regards to the overall Water framework Directive.

¹ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.

² Directive 2000/60/EC of the European Parliament and Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

8. These Regulations are made in reliance on section 2(2) of the European Communities Act 1972. By virtue of section 59(3) of the Government of Wales Act 2006, the Welsh Ministers are to determine whether an instrument made in exercise of the section 2(2) powers is to be subject to the negative or affirmative procedure.
9. This statutory instrument is subject to annulment of the Assembly (negative procedure). The Regulations do not amend any provision of an Assembly Act or Measure. They do not impose obligations of special importance. Accordingly, the Welsh Ministers have determined that these Regulations are to be subject to the negative resolution procedure.

Legislative background

10. The Water Framework Directive establishes an integrated approach to water management, based on river basin planning, and sets environmental objectives which are designed to protect and improve the ecological health of aquatic eco-systems as a whole.
11. The list of priority substances forms Annex X to the WFD. The list was reviewed in accordance with Article 16(4) WFD and updated by the EQS Directive which also set standards for each of those substances. Following a further review of the list of priority substances the European Commission proposed to revise a number of the standards set by the EQS Directive and add twelve new substances to the list. The resulting Priority Substances Directive, which this instrument partially transposes) amended the EQS Directive to revise the list and some of the standards and established some new monitoring and reporting requirements in addition to those already required by the WFD.
12. The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 (“the 2003 regulations”) transposed many of the obligations of the WFD. The key amendments made to the 2003 Regulations by this instrument are set out below.
13. Regulation 3 of the 2003 regulations provide for the Secretary of State, the Welsh Ministers, and the environment agencies in England and Wales³ to exercise their relevant functions so as to secure compliance with the requirements of the WFD. The amendment to Regulation 3 provides for this requirement to apply also in relation to the requirements of the EQS Directive as amended by the Priority Substances Directive. The “relevant functions” are the functions under the 2003 Regulations and those listed in Schedule 2 to the 2003 Regulations (which this instrument updates – see below).
14. Regulations 9 and 10 of the 2003 Regulations are amended, and a new regulation 10A inserted, to transpose the new monitoring requirements of

³ The Environment Agency and the Natural Resources Body for Wales.

the Priority Substances Directive and to ensure that revised programmes of measures established for the purposes of the WFD include measures which take into account the new priority substances and the revised standards from the appropriate dates.

15. Regulation 11 is amended to set out new requirements from the Priority Substances Directive for matters to be included in river basin management plans under the WFD. Regulation 18 is amended to require the interim progress report required by the WFD to be published. Regulation 18A is inserted which sets out further requirements relating to certain substances approved under other EU instruments (relating to biocidal products and plant protection products).
16. As well as the amendments to the 2003 Regulations for the purposes of transposing the Priority Substances Directive, the instrument makes other minor updating amendments to the 2003 Regulations. These are to update the list of 'relevant functions' in Schedule 2 to the 2003 Regulations, changes references from "the Assembly" to "the Welsh Ministers", and from "English Nature" to "Natural England", where appropriate, and to remove references to the regional offices of the environment agencies.
17. These composite Regulations will apply to England and Wales and are subject to negative resolution procedure in both Houses of the UK Parliament and the National Assembly for Wales.
18. The Welsh Ministers have the power to amend the The Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 under section 2(2) of the European Communities Act 1972, having been designated in relation to water resources.

Purpose & intended effect of the legislation

19. The Water Framework Directive (WFD) 2000/60/EC⁴ provides a strategic framework for protecting and improving the water. Specific environmental objectives and measures for individual bodies of water are identified through a 6-yearly river basin planning process. All key stages in the river basin planning process are subject to stakeholder engagement and extensive public consultation.
20. Water body quality ("status") is assessed in terms of how closely the water body resembles conditions unaffected by human activity. There are five ecological status classes (ranging from high to bad). Chemical status is classed as "good" or "failing to achieve good". Assessment of compliance with the standards set for the priority substances determines whether a

⁴ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02000L0060-20090113:EN:NOT>

water body is at good chemical status or not. Member States are required to prevent deterioration in status and aim to achieve good status (where it does not already exist) by December 2015. The deadline can be extended to December 2021 or 2027 for reasons of technical feasibility, disproportionate cost or natural conditions.

21. Standards for general ecological indicators such as dissolved oxygen and nutrient concentrations are set by each Member State to reflect local environmental conditions. Setting of standards for the priority substances (chemicals with a high level of toxicity that are identified under Article 16.4 WFD as presenting a significant risk to the aquatic environment or to people and which are widely used across the EU) is coordinated by the European Commission.
22. Implementation of the EQS Directive as amended by the Priority Substances Directive will help ensure that standards for toxic chemicals are sufficiently protective of the environment and human health by preventing them reaching dangerous concentrations in water bodies by means of controls on discharges and emissions.

Consultation

23. These amending Regulations affect functions of the environment agencies, the Secretary of State and the Welsh Ministers. Since they do not have implications for industry or the public, there has been no consultation exercise. The UK, through the Water Framework Directive Technical Advisory Group adopted an approach of continuing engagement through a stakeholder group of industries likely to be affected by revised and new standards (which will be implemented through Directions to the environment agencies) from the time of the proposal to adoption of the Priority Substances Directive.

Regulatory Impact Assessment (RIA)

24. Since the amending Regulations have no direct impact on statutory duties or statutory partners, a separate impact assessment has not been prepared for this instrument.
25. Any specific measures to achieve standards for priority substances in individual water bodies will be determined through the river basin planning process, which itself involves an assessment of the costs and benefits. The revised standards for the existing priority substances that apply to the period 2015 to 2027 have been used to develop draft updated river basin management plans, to be submitted by the agencies to the respective Ministers in England and Wales this autumn for approval and published by 22nd December 2015. An impact assessment is being prepared for these updated river basin management plans.

**TRANSPOSITION NOTE FOR DIRECTIVE 2013/39/EU REGARDING PRIORITY SUBSTANCES IN THE FIELD OF WATER POLICY,
AMENDING DIRECTIVES 2000/60/EC AND 2008/105/EC.**

Directive 2013/13/EU¹ (“the PSD”) amends Directive 2000/60/EC² (“the WFD”) and Directive 2008/105/EC³ (“the EQSD”). The EQSD sets environmental quality standards (“EQS”) in relation to priority substances. The PSD amends the requirements of the EQSD, adds new substances to the list of priority substances and sets EQS for these, and revises some of the EQS for the existing priority substances.

Provision of Directive⁴	Requirement		Transposition
Article 2(2) replaces Article 3 of Directive 2008/105 (the	In addition to previous requirements, new article 3.1a of the EQSD	(i) the application of revised EQS for certain existing priority substances (“revised substances”) from 22nd December 2015 with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2021. This must	Regulation 6 amends regulation 10 of the Water Environment (Water Framework Directive) (England and Wales) Regulations 2003 (“the 2003 Regulations”) to require the Secretary of State, or Welsh Ministers, as appropriate, to ensure that the programmes of

¹ Directive 2013/13/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

² Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy.

³ Directive 2008/105/EC of the European Parliament and the Council on environmental quality standards in the field of water policy.

⁴ Some EQSD requirements are transposed through Ministerial Directions to the appropriate agency. These include the requirements (or relevant parts of the requirements) under: article 2 (definitions); article 3 (applying the EQS) in particular articles 3.2 and 3.3 (applying biota, water or alternative EQS), articles 3.3a, 3.3b, 3.4 (monitoring and analysis), and article 3.6 (long term trend analysis); articles 4.1 and 4.3 (mixing zones); articles 5.1, 5.2 and 5.4 (inventory of emissions, discharges and losses of priority substances); article 8a.2 (also on monitoring); articles 8b.3 and 8b.4 (the watch list); and Annex 1 (the standards and their application). A number of these are based on, or are amended versions of, requirements in the version of the EQSD that was in force on 13 January 2009.

EQSD).	requires :		measures updated in December 2015 include measures for the purpose of aiming to achieve good surface water chemical status in relation to the revised substances by 22 nd December 2021.
(ii)	<p>be done by means of programmes of measures in the updated river basin management plans⁵.</p> <p>the application of EQS for 12 new priority substances (new substances) from 22nd December 2018, with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2027 and preventing deterioration in the chemical status of surface water bodies;</p> <p>the establishment of a supplemental monitoring</p>	<p>Regulation 7 inserts new regulations 10A(2) and 10A(4) into the 2003 Regulations to, respectively:</p> <p>-require that the relevant environmental regulator (“the appropriate agency”)⁶ includes in the proposals for a final programme of measures for the update in December 2021 (see below) measures for the purpose of aiming to achieve good surface water chemical status in relation to the new substances by 22nd December 2027 and preventing deterioration in the chemical status of water bodies.</p> <p>- require the Secretary of State, or Welsh Ministers, as appropriate, to ensure that the final programmes of measures updated in December 2021 include measures for the purpose of aiming to achieve good surface water chemical status in relation to the new substances by 22nd December 2027 and preventing deterioration in the chemical status of water bodies.</p> <p>Regulation 5 amends regulation 9 of the 2003</p>	

⁵ River basin management plans are required to be produced and periodically updated under the Water Framework Directive 2000/60/EC.

⁶ For England, the Environment Agency and, for Wales, the Natural Resource Body for Wales.

		<p>programme for the new substances by 22 December 2018;</p> <p>the establishment of a preliminary programme of measures for the new substances by 22 December 2018;</p> <p>the establishment of a final programme of measures for those substances by 22 December 2021;</p> <p>that the final programme of measures must be made fully operational by December 2024 at the latest.</p>	<p>Regulations on monitoring, to require the appropriate agency to establish the monitoring programme for the new substances by 22 December 2018.</p> <p>New regulation 10A(1), inserted into the 2003 Regulations by regulation 7 (see above), requires the appropriate agency to establish a preliminary programme of measures for the new substances by 22nd December 2018.</p> <p>New regulation 10A(2), inserted into the 2003 Regulations by regulation 7 (see above), requires the appropriate agency to prepare proposals for a final programme of measures by 22nd December 2021; and new regulation 10A(4) requires the Secretary of State or Welsh Ministers, as appropriate, to ensure that the final programmes of measures contain appropriate measures (see above).</p> <p>New regulation 10A(6) requires the Secretary of State, or Welsh Ministers, as appropriate, to ensure that the measures in the programme of measures updated in December 2021 are made operational as soon as possible and no later than 22nd December 2024.</p> <p>General: Regulation 2 and regulation 4 amend regulation 3 of the 2003 Regulations to ensure that the general duties on the Secretary of State, Welsh Ministers, and the appropriate agency include the duty</p>
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		<p>to exercise their relevant functions to ensure compliance with the EQSD as amended by Directive 2013/39/EU.</p>
<p>Article 2(4) inserts new article 7a into the EQSD.</p>	<p>New article 7a(imposes requirements for priority substances falling within scope of other specified EU instruments (on plant protection products and biocidal products).</p>	<p>Regulation 10 inserts new regulation 18A into the 2003 Regulations to transpose the relevant requirements under new article 7a(3).</p>
<p>New article 3(5) requires additional information about the EQS, monitoring and methods of analysis to be included in the updated river basin management plans.</p>	<p>Regulation 8 amends regulation 11 of the 2003 Regulations (which sets out the requirements for river basin management plans) to require the additional information to be included.</p>	<p>Regulation 9 amends regulation 18 of the 2003 Regulations on monitoring, to ensure that the interim report is published electronically in accordance with new article 3(5a). Further transposition of the obligation to electronically publish the river basin management plans is not necessary as the plans are already required to be published in the appropriate way, including on the appropriate agency's website (regulation 14 of the 2003 Regulations).</p>
<p>New article 3(5a) requires electronic publication of the updated river basin management plans and interim report required under article 15(3) of the WFD.</p>	<p>Regulation 9 amends regulation 18 of the 2003 Regulations on monitoring, to ensure that the interim report is published electronically in accordance with new article 3(5a). Further transposition of the obligation to electronically publish the river basin management plans is not necessary as the plans are already required to be published in the appropriate way, including on the appropriate agency's website (regulation 14 of the 2003 Regulations).</p>	<p>Regulation 10 inserts new regulation 18A into the 2003 Regulations to transpose the relevant requirements under new article 7a(3).</p>



The Scottish Parliament
Pàrlamaid na h-Alba

Devolution (Further Powers) Committee

Mr David Melding AM
Chair
Constitutional and Legislative Affairs
Committee
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7 September, 2015

Dear Mr Melding,

Re. Parliamentary oversight and reporting of intergovernmental relations under the new provisions in the Scotland Bill

As you are aware, the UK Government's Scotland Bill is making progress in its passage through the UK Parliament. A significant component of the Bill involves the transfer of further financial powers and, for the first time, also certain welfare powers to the Scottish Parliament.

In doing so, this greatly increases the intergovernmental dialogue that will need to take place on such matters both as the Bill completes its passage – for example, through agreement to a new fiscal framework – and also in future years to take forward the new powers in a co-ordinated fashion with the UK Government. Such matters will also therefore have an impact I believe on how the other devolved nations interact with the UK Government. Indeed, this was an area specifically highlighted by Lord Smith of Kelvin in the Final Report of the Smith Commission as being in considerable need of reform and improvement.

The Devolution (Further Powers) Committee, which I chair, has been charged with scrutinising the Scotland Bill. In addition, we have been reviewing how the Scottish and UK Government will reach a bilateral agreement on future relations in tax and welfare and, more generally, how the reform of the quadrilateral structures of intergovernmental relations (IGR) across the UK is progressing through the review of the current review of the Memorandum of Understanding and the Joint Ministerial Committees being led by the UK Cabinet Office.

My Committee is very keen to contribute to the question of how the Scottish Parliament expects to have a degree of oversight of IGR in the future and how it can be appropriately informed of the major discussions between the two governments and any agreements being reached or disputes that require resolution.

At a recent discussion between Committee members, it was agreed that I should write to other committees in other legislatures across the UK that may share an interest as legislatures in this matter.

We are expecting to produce a report on this issue in October and would be pleased to send you a copy. This may in turn lead to the start of a dialogue between us on how we may all benefit from each other's experience in holding respective governments to account and in how we could share information on how parliaments may be best informed of future IGR in the shared space of devolution across the UK.

I would be interested in hearing from you as to whether this may be an area you would be happy to explore as a matter of common interest.

Yours sincerely,

A handwritten signature in black ink that reads "Bruce Crawford". The signature is written in a cursive, slightly slanted style.

Bruce Crawford MSP
Convener

From: EVANS, Adam [mailto:evansab@parliament.uk]
Sent: 16 September 2015 14:36
Subject: *Extended deadline*: EVEL and the Future of the Union Inquiry
Importance: High

Dear colleagues,

You are probably aware that the Public Administration and Constitutional Affairs Select Committee has launched an inquiry into English Votes for English Laws and the Future of the Union. While the deadline for submissions was initially the 8th September, I wanted to alert you to the fact that, in light of the high interest in this subject, this has now been extended until mid-October with an intention to begin oral evidence sessions in November. Please find the terms of reference below:

“The Public Administration and Constitutional Affairs Select Committee (PACAC) has just launched a major inquiry into the constitutional implications of the Government’s proposed amendment to House of Commons Standing Orders which will introduce 'English Votes for English Laws.'

This inquiry focusses on the broader constitutional implications of the Government’s proposal to establish a system of ‘English Votes for English Laws’.

This is in response to the desire for more consideration and reflection on the implications of this proposal. While the Procedure Committee will focus on the changes to Standing Orders on the House of Commons, PACAC’s inquiry will seek to evaluate the effect of the change on the UK constitution as a whole.

The Committee therefore invites written evidence on the following questions, dividing the inquiry into two parts:

Part 1 (England)

1. What are the constitutional anomalies which English Votes on English Laws seeks to address?
2. What are the political and constitutional effects of the introduction of ‘English Votes for English Laws via Standing Orders, including on such matters as the durability of the post-referendum settlement between Scotland and the rest of the UK, and on the relationship between the two Houses of Parliament?
3. How consistent is English Votes for English Laws with the House of Commons’ status as a United Kingdom legislature?
4. What is the impact of devolution to Scotland, Wales and Northern Ireland (both in its current form and by way of the Scotland Bill currently awaiting Report Stage in the House of Commons and the forthcoming draft Wales Bill) on making legislation for England?
5. What are the political and constitutional effects for the Union of devolving further tax raising powers to devolved Parliaments and Assemblies?
6. What are the political and constitutional effects for the Union of the continued use of the Barnett Formula?
7. What other factors could destabilise the UK, for example, uncertainty about the UK’s relationship with the EU caused by the forthcoming EU referendum, or renewed demands for a further Scottish independence referendum?

It is possible that, as part of these deliberations, Committee members may also be interested in responses that touch on some additional points:

- 1) *The compatibility of English Votes for English Laws with the continued existence of the Barnett formula*
- 2) *Proposed Standing Order 83J(6) would enable the Speaker to certify a Bill as “relating exclusively to England or England and Wales” should it contain schedules or clauses that have “minor or consequential effects” on other parts of the United Kingdom (including the amendment of Scottish or Northern Irish legislation). What is a “minor or consequential effect” and what are the potential implications or this for the conduct of business at Westminster and more broadly for the Union?*

Part 2 (The future of the Union)

1. What are the alternative means of addressing the constitutional anomalies identified of asymmetric devolution, while taking account of the difference between the four parts of the UK, in size, population, and economic viability?
2. What alternative mechanism could be established for determining the distribution of UK resources between the four constituent parts of the UK?
3. What might the effects be of granting Scotland ‘full fiscal responsibility’? What does this term mean?
4. How could a permanent and durable settlement between the four parts of the United Kingdom best be achieved, taking account of the need to address decentralisation within England?
5. What might be the best means of achieving a consensus across the whole of the UK for such a new settlement?

Deadline for written evidence

The deadline for submissions is **Tuesday 8 September 2015**. Evidence sessions will start in the Autumn.

Where to submit evidence

Written submissions should be submitted via the English Votes for [English Laws and the Future of the Union inquiry page](#), where further guidance and information can also be found.”

Kind regards,

Adam

Adam Evans, Committee Specialist, Public Administration and Constitutional Affairs Select Committee (PACAC)
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Agenda Item 6.2

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