

## Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol

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Lleoliad:  
Ystafell Bwyllgora 2 – y Senedd

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Dyddiad:  
Dydd Llun, 25 Chwefror 2013

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Amser:  
14:30

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Cynulliad  
Cenedlaethol  
Cymru

National  
Assembly for  
Wales



I gael rhagor o wybodaeth, cysylltwch â:

**Gareth Williams**  
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### Agenda

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1. Cyflwyniad, ymddiheuriadau, dirprwyon a datganiadau o fuddiant
2. Offerynnau nad ydynt yn cynnwys unrhyw faterion i'w codi o dan Reol Sefydlog 21.2 neu 21.3

Offerynnau'r Weithdrefn Penderfyniad Cadarnhaol

#### **CLA216 – Rheoliadau Cynllun Gostyngiadau'r Dreth Gyngor (Canfod Twyll a Gorfodi) (Cymru) 2013**

Y weithdrefn negyddol. Ni nodwyd y dyddiad y'u gwnaed. Ni nodwyd y dyddiad y'u gosodwyd. Yn dod i rym ar ddyddiad sy'n unol â rheoliad 1.

3. Offerynnau sy'n cynnwys materion i gyflwyno adroddiad arnynt i'r Cynulliad o dan Reol Sefydlog 21.2 neu 21.3

Offerynnau'r weithdrefn penderfyniad cadarnhaol

#### **CLA215 – Gorchymyn Ystadegau Swyddogol (Cymru) 2013 (Tudalennau 1 – 8)**

Y weithdrefn negyddol. Fe'i gwnaed yn 2013. Ni nodwyd dyddiad gosod. Yn dod i rym yn unol ag erthygl 1.

**4. Cynnig y Comisiwn Ewropeaidd i ddiwygio'r Gyfarwyddeb Cynhyrchion Tybaco (Cyfarwyddeb 37/2001/EC)** (Tudalennau 9 – 14)  
CLA(4)-07-13(p4) – Cynnig y Comisiwn Ewropeaidd i ddiwygio'r Gyfarwyddeb Cynhyrchion Tybaco (Cyfarwyddeb 37/2001/EC)

**5. Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y canlynol:**  
Caiff pwyllgor benderfynu gwahardd y cyhoedd o gyfarfod neu unrhyw ran o gyfarfod:

(vi) lle mae'r pwyllgor yn cyd-drafod cynnwys, casgliadau neu argymhellion adroddiad y mae'n bwriadu ei gyhoeddi; neu'n ymbaratoi i gael tystiolaeth gan unrhyw berson; neu

(ix) lle mae unrhyw fater sy'n ymwneud â busnes mewnol y pwyllgor, neu fusnes mewnol y Cynulliad, i gael ei drafod.

**Adroddiad drafft terfynol ar y Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru)** (Tudalennau 15 – 48)  
CLA(4)-07-13(p5) – Adroddiad drafft terfynol

# Eitem 3.1

## **Constitutional and Legislative Affairs Committee**

**CLA(4)-07-13 Paper 1**

**CLA215 – The Official Statistics (Wales) Order 2013**

**Procedure: Affirmative**

This Order is made under section 6(1)(b) and (2) of the Statistics and Registration Service Act 2007, which allows orders to be made to specify other persons as producers of official statistics.

This Order designates the statistics produced, or to be produced, by the persons listed in the Schedule as official statistics. These are the Arts Council of Wales, Natural Resources Body for Wales, Public Health Wales National Health Service Trust, Sports Council for Wales and the Welsh Language Commissioner.

### **Technical Scrutiny**

*No points are identified for reporting under Standing Order 21.2 in respect of this instrument*

### **Merits Scrutiny**

*The following points are identified for reporting under Standing Order 21.3(ii) (that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Assembly) in respect of this instrument.*

*The Explanatory Memorandum to the Order states:-*

*“This is the first time that this order-making power has been exercised by the Welsh Ministers. The Order applies to wholly Welsh devolved statistics. Welsh devolved statistics are defined under section 66(3) of the Act. The Order designates the statistics produced, or to be produced by five bodies listed in the Schedule as official statistics. These are the Arts Council of Wales, Natural Resources Body for Wales, Public Health Wales National Health Service Trust, Sports Council for Wales and the Welsh Language Commissioner”.*

### **Legal Advisers**

**Constitutional and Legislative Affairs Committee  
February 2013**

*Draft Order laid before the National Assembly for Wales under section 65(7) of the Statistics and Registration Service Act 2007, for approval by resolution of the National Assembly for Wales.*

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W E L S H S T A T U T O R Y  
I N S T R U M E N T S

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**2013 No. (W. )**

**OFFICIAL STATISTICS,  
WALES**

**The Official Statistics (Wales)  
Order 2013**

**EXPLANATORY NOTE**

*(This note is not part of the Order)*

Section 6(1)(a) of the Statistics and Registration Service Act 2007 (“the Act”) provides that statistics produced by the Statistics Board, a government department, the Scottish Administration, a Welsh Ministerial authority (the Welsh Ministers, the First Minister for Wales, or the Counsel General to the Welsh Assembly Government), a Northern Ireland department, or any other person acting on behalf of the Crown are official statistics.

This Order is made under section 6(1)(b) and (2) of the Act, which allows orders to be made to specify other persons as producers of official statistics. This Order designates the statistics produced, or to be produced, by the persons listed in the Schedule as official statistics. This Order applies to Welsh devolved statistics as defined in section 66 of the Act.

*Draft Order laid before the National Assembly for Wales under section 65(7) of the Statistics and Registration Service Act 2007, for approval by resolution of the National Assembly for Wales*

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W E L S H S T A T U T O R Y  
I N S T R U M E N T S

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**2013 No. (W.)**

**OFFICIAL STATISTICS,  
WALES**

**The Official Statistics (Wales)  
Order 2013**

*Made*

*2013*

*Coming into force in accordance with article 1*

The Welsh Ministers make this Order in exercise of the powers conferred by section 6(1)(b) and (2) of the Statistics and Registration Service Act 2007.

In accordance with section 6(3) of that Act, the Welsh Ministers have consulted the Statistics Board.

In accordance with section 65(7) of that Act, a draft of this Order has been laid before and approved by resolution of the National Assembly for Wales.

**Title and commencement**

**1.** The title of this Order is the Official Statistics (Wales) Order 2013 and it comes into force on 1 April 2013.

**Official Statistics – wholly Welsh devolved official statistics**

**2.** To the extent that they are not otherwise official statistics by virtue of section 6(1)(a) of the Statistics and Registration Service Act 2007, the wholly Welsh devolved statistics<sup>(1)</sup> produced, or to be produced, by the persons listed in the Schedule to this Order are

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(1) “Welsh devolved statistics” is defined in section 66(3) of the Statistics and Registration Service Act 2007.

specified as official statistics for the purposes of section 6(1)(b) of that Act.

*Name*

Minister for Finance and Leader of the House, one of the Welsh Ministers

Date

## SCHEDULE

### Article 2

Arts Council of Wales  
Natural Resources Body for  
Wales  
Public Health Wales National  
Health Service Trust  
Sports Council for Wales  
Welsh Language Commissioner

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## **Explanatory Memorandum to the Draft Official Statistics (Wales) Order 2013**

This Explanatory Memorandum has been prepared by Knowledge and Analytical Services 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 Official Statistics (Wales) Order 2013.

*Jane Hutt*

Minister for Finance and Leader of the House

14 February 2013

### **1. Description**

This Order designates the statistics produced by certain bodies as “official statistics” for the purposes of the Statistics and Registration Services Act 2007 (“the Act”). The effect of designation as official statistics is set out in section 4 below.

### **2. Matters of special interest to the Constitutional and Legislative Affairs Committee**

It is considered that the draft Order does not raise any matters of special interest to the Committee which are not referred to elsewhere in the Memorandum.

### **3. Legislative background**

Under section 6(1)(a) of the Act, all statistics produced by government departments, the Scottish Administration, a Welsh Ministerial authority, a Northern Ireland department or any other person acting on behalf of the Crown are official statistics. “Official statistics” is defined in section 6(1) of the Act. The power of the Welsh Ministers to make this Order is contained in section 6(1)(b) and (2) of the Act, which allows orders to be made to specify other persons as producers of official statistics. This Order designates the statistics produced, or to be produced, by the bodies listed in the Schedule as official statistics.

The Order is subject to approval by the Assembly (the affirmative resolution procedure).



#### **4. Purpose & intended effect of the legislation**

The Act which received Royal Assent in July 2007 created a new non-ministerial department, the Statistics Board (which operates under the name 'UK Statistics Authority'). The Act conferred a number of functions on the Statistics Board to promote and safeguard the quality and comprehensiveness of official statistics. The Statistics Board is required to monitor the production and publication of official statistics and to report relevant concerns to the person responsible for those statistics (section 8 of the Act). The Statistics Board may publish its findings or report under that section. At the request of the appropriate authority (defined in section 12(7) of the Act), the Statistics Board must assess and determine whether the Code of Practice for Official Statistics ("the Code") has been complied with in relation to any official statistics and, if so, to designate those statistics as "National Statistics" (section 12 of the Act).

The impact of designation as official statistics on the producers of such statistics is that:

- a) the production and publication of official statistics is subject to monitoring and reporting by the Statistics Board (section 8 of the Act);
- b) the persons producing official statistics which have not been designated as "National Statistics" are expected to comply with the standards set out in the Code, which sets out the procedures to be followed in producing and publishing National Statistics. Official statistics designated as National Statistics requires the producers of those statistics to fully comply with the Code, in order to maintain that designation. For other official statistics compliance with the Code is not a formal requirement but is best practice to be observed;
- c) the persons producing official statistics must comply with the relevant rules and principles relating to the granting of pre-release access to official statistics to the extent applicable to them and, in relation to official statistics designated as National Statistics, must do so as if these rules and principles are part of the Code;
- d) the person responsible for any official statistics in respect of which an assessment is being made under section 12 of the Act must provide the Statistics Board with such information about the statistics as the Statistics Board may reasonably require.

This is the first time that this order-making power has been exercised by the Welsh Ministers. The Order applies to wholly Welsh devolved statistics. Welsh devolved statistics are defined under section 66(3) of the Act. The Order designates the statistics produced, or to be produced by five bodies listed in the Schedule as official statistics. These are the Arts Council of Wales, Natural Resources Body for Wales, Public Health Wales National Health Service Trust, Sports Council for Wales and the Welsh Language Commissioner.

Each of the bodies that are listed in the Schedule produce important statistics but over which the Statistics Board has no control, or power to make assessments against its Code. If the Statistics Board is to be able to fulfil its duty to build trust in official statistics, these bodies need to be specified in the Order.

## **5. Consultation**

Bodies that have been included in the Order have agreed to be named within it, following direct discussions with the statistical Head of Profession.

As required by the Act, the Statistics Board has been consulted on this order. No comments were received on the draft Order.

## **6. Regulatory Impact Assessment (RIA)**

A Regulatory Impact Assessment has not been prepared in respect of this Order. The Order only has an impact on those bodies listed in the Schedule. Two of those bodies are registered charities and the other three bodies are from the wider public sector. No impact on businesses, individuals and the voluntary sector is foreseen. The impact on the public sector is expected to be negligible. .

The Order has no impact on the Welsh Ministers statutory duties set out under sections 77- 79 of the Government of Wales Act 2006 or the local government, voluntary sector and business schemes made under sections 73, 74 and 75 of the Government of Wales Act 2006 respectively.

## Constitutional and Legislative Affairs

### European Commission proposal to revise the Tobacco Products Directive (Directive 37/2001/EC)

#### Briefing

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Date of paper:

25 February 2013

This briefing has been produced by the Research Service for use by the Constitutional and Legislative Affairs Committee.

For further information, contact Owain Roberts in the Research Service  
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Research  
Service



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## 1. Introduction

On 19 December 2012, the European Commission published a proposal to revise Directive 37/2001/EC ('the Tobacco Products Directive').<sup>1</sup> The Tobacco Products Directive dates back to 2001 and sets down requirements in relation to tobacco products (their manufacture, presentation and sale) in order to align the laws, regulations and administrative provisions of all the EU's members states. The new proposal published by the Commission in December 2012 revises this legal framework and proposes new and strengthened rules on tobacco products.

An Explanatory Memorandum was prepared by the UK Government's Department of Health in response to the Commission's proposal on 21 January 2013.<sup>2</sup>

## 2. The proposed Directive

The objectives of the proposed Directive were summarised in a press release issued by the European Commission:

All citizens will benefit from the revision foreseen as they will receive more accurate information about the products. Young people will be discouraged from taking up tobacco consumption, as the possibilities to render the products "attractive" will be limited. Current tobacco users will benefit from the measures proposed in the Directive as they will be in a better position to take informed decisions about the products and on quitting if they so wish and thus benefit in terms of health.

Manufacturers of tobacco products will benefit from clearer rules, an improved functioning of the internal market and a level playing field. The new rules take particular account of the specific needs of small and medium-sized companies.<sup>3</sup>

In particular, one of the proposed Directive's main aims is to extend the scope of the Tobacco Products Directive to encompass **non-tobacco nicotine-containing products** ('NCP') (e.g. **e-cigarettes**) below a certain nicotine threshold.

Although there is no suggestion that the proposed Directive will seek to ban e-cigarettes, the intention is that NCP products which contain above a certain level of nicotine, will be regulated as 'medicinal products' in a similar way to nicotine replacement therapies ('NRT') which are used as aids in smoking cessation (patches, gum etc.). NRT products are currently available on prescription from GPs and can also be purchased in pharmacies and larger supermarkets. NCP products with nicotine levels below the threshold could continue to be sold as consumer products (but must feature an adapted health warning). The nicotine threshold would be based on nicotine content in medicinal products already authorised for smoking cessation.

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<sup>1</sup> EUROPA, [\*Questions and answers: Towards a new EU law on Tobacco Products\*](#), 19 December 2012 [accessed 20 February 2013]

<sup>2</sup> Department of Health, [\*Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products\*](#), 21 January 2013 [accessed 20 February 2013]

<sup>3</sup> EUROPA, [\*Questions and answers: Towards a new EU law on Tobacco Products\*](#), 19 December 2012 [accessed 20 February 2013]

The proposal is expected to reinforce the character of NCP as smoking cessation rather than 'leisure', and aims to make tobacco products and tobacco consumption less attractive, therefore discouraging more young people from starting to smoke.

At present, NCP products fall outside the scope of the Tobacco Products Directive, and Member States have taken different approaches to these products, including regulating them as medicinal products, applying certain provisions that are used for tobacco products, or having no specific legislation. The proposal aims to remove the current legislative divergence between Member States, and the differential treatment of NCP and NRT.

According to the accompanying European Commission Press Release, the proposal has been adopted following extensive consultation with stakeholders, including a public consultation.<sup>4</sup> It also states that an impact assessment was also carried out and a number of external studies were commissioned.<sup>5</sup>

### 3. Subsidiarity

The Subsidiarity Protocol provides all national parliaments of the EU's member states with an **eight-week** early warning period to submit a reasoned opinion stating why it considers that the draft legislative proposal in question does not comply with the principle of subsidiarity.

Turning such objections into practice however is dependent on the following procedures:

- **Yellow card procedure:** Triggered if one third of the EU's national parliaments (currently 9 out of the 27 member states) contest the conformity of a draft legislative proposal on grounds of subsidiarity. The procedure requires the EU Commission to re-examine the draft and explain why it is maintaining it. A different threshold of a quarter of member states (either 6 or 7 member states) applies if the draft legislation in question relates to the area of freedom, security and justice.
- **Orange card procedure:** Triggered if a simple majority of the EU's national parliaments (currently 14 member states) challenges the conformity of a draft legislative proposal on grounds of subsidiarity and if the European Commission maintains its original proposal. The procedure requires the matter to be referred to the European Parliament and the Council, which will issue a decision at first reading. If they believe that the legislative proposal is incompatible with the principle of subsidiarity, they may reject it subject to a 55 per cent Council majority or a majority vote in the European Parliament.

In addition to these procedures, the **Committee of the Regions** is also empowered to refer cases where the principle of subsidiarity is breached by one of the main EU institutions directly to the Court of Justice of the European Union.

Because the National Assembly is considered a 'regional' rather than a national parliament at the EU level, it has no direct legal grounds to question EU legislative proposals on the basis of subsidiarity. Nevertheless, the Assembly's Standing Orders enable a 'responsible

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<sup>4</sup> EUROPA, *Tobacco products: towards bigger health warnings and ban of strong flavourings*, 19 December 2012 [accessed 20 February 2013]

<sup>5</sup> Ibid

committee' (currently the Constitutional and Legislative Affairs Committee) to raise formal concerns about a draft legislative proposal introduced by the European Commission, within the Assembly's legislative competence or the Welsh Ministers executive powers, on the grounds that it breaches the subsidiarity principle.

If the Committee decides that the draft legislative proposal in question does not comply with the subsidiarity principle, Standing Orders allow it to make written representations on behalf of the National Assembly within the eight week early warning period to the relevant committees in the House of Commons and the House of Lords, who may take account of those representations in reaching their own conclusions.

The eight week deadline for reasoned opinions from national parliaments in relation to the proposed Directive is **4 March 2013**. To date, only two reasoned opinions (by the national parliaments of Italy and the Czech Republic) have been expressed on the proposal.<sup>6</sup> Possible concerns may also be raised by the Swedish Riksdag.<sup>7</sup> According to the Committee of the Regions' Subsidiarity Monitoring Network, no concerns have been raised in relation to the proposed Directive by any of the regional or sub-state legislatures of the EU's member states.<sup>8</sup>

### 3.1. *The role of the Assembly*

Although Welsh Ministers were consulted by the Department of Health in preparing the EM to the proposed Directive,<sup>9</sup> a copy was not received by the Assembly upon its publication.

The proposed Directive was not initially identified from the 'batch list' (i.e. a list prepared by the Foreign and Commonwealth Office of all the proposals published by the European Commission) as relevant to the work of the Assembly by Assembly officials upon its introduction. This was on the basis that its provisions would fall outside the scope of the Welsh devolutionary settlement as 'Human medicines and medicinal products, including authorisations for use and regulation of prices' is included as an exception to the Assembly's legislative powers, as outlined in Schedule 7 to the *Government of Wales Act 2006*.<sup>10</sup>

### 3.2. *The UK Government's position*

The Department of Health's EM does not provide a specific view on whether the UK Government will oppose the proposal on the grounds of subsidiarity or not, stating instead that:

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<sup>6</sup> IPEX, [Document: COM/2012/0788](#), 3 January 2013 [accessed 20 February 2013]

<sup>7</sup> Ibid

<sup>8</sup> See Subsidiarity Monitoring Network, [REGPEX](#) [accessed 20 February 2013]

<sup>9</sup> Department of Health, [Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products](#), 21 January 2013, paragraph 5 [accessed 20 February 2013]

<sup>10</sup> [Government of Wales Act 2006](#) (Chapter 32)



The UK Government recently consulted on the standardised packaging of tobacco products and retains an open mind on this issue. The Government would wish to see a final text which leaves this option open for Member States.<sup>11</sup>

No reasoned opinion has been issued by either the House of Commons or the House of Lords in relation to the proposal to date.

#### 4. Next steps

On the basis that no further objections on the grounds of subsidiarity will be made by other member states before 4 March 2013, the proposal will be passed on for discussion in the European Parliament and in the Council of Ministers. It is expected to be adopted in 2014, and would come into force sometime in 2015–2016.

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<sup>11</sup> Department of Health, *[Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products](#)*, 21 January 2013, paragraph 15 [accessed 20 February 2013]



# Eitem 5.1

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon