

Constitutional Affairs Committee

Report: CA(3)-05-11 : 17 February 2011

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Time: 9.30 am

Venue: Committee Room 4, Ty Hywel

Assembly Members in attendance

Janet Ryder, North Wales (Chair)
Alun Davies, Mid and West Wales
William Graham, South Wales East
Rhodri Morgan, Cardiff West
Kirsty Williams, Brecon and Radnorshire

Apologies.

There were no apologies.

The Committee reports to the Assembly as follows:

Instruments and Draft Instruments in respect of which the Assembly is not invited to pay special attention under Standing Order 15.2 or 15.3

Instruments subject to annulment pursuant to a resolution of the Assembly (Negative Procedure)

CA529 - The Bee Diseases and Pests Control (Wales) (Amendment) Order 2011

Procedure: Negative

Date made: 1 February 2011.

Date laid: 7 February 2011.

Coming into force date: 28 February 2011

CA533 - The Local Curriculum in Higher Education Institutions (Wales) Regulations 2011.

Procedure: Negative.

Date made: 8 February 2011.

Date laid: 9 February 2011.

Coming into force date: 4 March 2011

Draft Instruments subject to approval pursuant to a resolution of the Assembly (Affirmative Procedure)

CA530 - The Children Act 1989 (Higher Education Bursary) (Wales) Regulations 2011

Procedure: Affirmative
Date made: Not stated
Date laid: 7 February 2011
Coming into force date: In accordance with regulation 1.

CA534 - The Flood and Coastal Erosion Risk Management Information Appeal (Wales) Regulations 2011

Procedure: Affirmative Procedure.
Date made: Not stated.
Date laid: 10 February 2011.
Coming into force date: 6 April 2011

Instruments and Draft Instruments in respect of which the Assembly is invited to pay special attention under Standing Orders 15.2 and/or 15.3

Instruments subject to annulment pursuant to a resolution of the Assembly (Negative Procedure)

CA532 - The Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011

Procedure: Negative.
Date made: 5 February 2011.
Date laid: 8 February 2011.
Coming into force date: 1 March 2011

Draft Instruments subject to approval pursuant to a resolution of the Assembly (Affirmative Procedure)

CA531 - The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

Procedure: Affirmative.
Date made: not stated.
Date laid: 8 February 2011.
Coming into force date: In accordance with the provisions of regulation 1(2)

The Committee agreed the Reports under S.O.15.2 and S.O.15.3 on these statutory instruments, which are attached as Annexes 1-2.

Resolution to Meet in Private

In accordance with Standing Order 10.37(vi) the Committee resolved to exclude the public from the remainder of the meeting to discuss to consider Draft Supplementary Report on the Local Government (Wales) Measure 2011.

Janet Ryder AM
Chair, Constitutional Affairs Committee

17 February 2011

Annex 1

Constitutional Affairs Committee

(CA(3)-05-11)

CA532

Constitutional Affairs Committee Report

Title: The Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011

Procedure: Negative

These Regulations amend the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009, as previously amended by S.I. 2010/2288 (“the principal Regulations”) in order to provide for the implementation in Wales of transitional arrangements contained in Commission Directive 2011/8 EU amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, (“the new Commission Directive”). These Regulations amend the principal Regulations to provide for the implementation of the transitional arrangements in the new Commission Directive.

Technical Scrutiny

The following point is identified for reporting under S.O. 15.2 in respect of this instrument:-

These Regulations specify the exercise by the Welsh Ministers of the power contained within sub-section (2) (a) of section 26 of the Food Safety Act 1990, which imposes a requirement upon persons carrying on any activity to which the regulations apply to keep and produce records and provide returns. There is no use of the power within sub-section (2) (a) of these Regulations and so this power is superfluous to the requirements of these Regulations.

Standing Order 15.2 (ii) that it appears to make unusual or unexpected use of the powers conferred by the enactment under which it is made or to be made.

Merits Scrutiny

No points are identified for reporting under Standing Order 15.3 in respect of this instrument:

Janet Ryder AM

Chair, Constitutional Affairs Committee

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The Government has responded as follows:

**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD
(WALES) (AMENDMENT) REGULATIONS 2011**

**GOVERNMENT RESPONSE TO THE POINT IDENTIFIED BY THE LEGAL
ADVISERS TO THE COMMITTEE**

Point raised by Legal Advisers

1. The Legal Advisers identify the following point for reporting under S.O 15.2:

“These Regulations specify the exercise by the Welsh Ministers of the power contained within sub-section (2) (a) of section 26 of the Food Safety Act 1990, which imposes a requirement upon persons carrying on any activity to which the regulations apply to keep and produce records and provide returns. There is no use of the power in sub-section (2) (a) within these Regulations and so this power is superfluous to the requirements of these Regulations. ”

2. It is accepted that the reference to sub-section 26(2)(a) in these Regulations (while appropriate in the principal regulations which they amend) was superfluous for the reason given by the Legal Advisers. As this does not affect the substance of these Regulations, it is not considered that any further action is required.

Annex 2

Constitutional Affairs Committee

(CA(3)-05-11)

CA531

Constitutional Affairs Committee Report

Title: The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

Procedure: Affirmative

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Regulations”) make new arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales. They implement the provisions of the NHS Redress (Wales) Measure 2008 (“the Measure”).

Technical Scrutiny

Under Standing Order 15.2 the Assembly is not invited to pay special attention to this instrument.

Merits Scrutiny

The Committee makes the following report to the Assembly under Standing Order 15.3(ii) that these draft regulations are of political or legal importance and give rise to issues of public policy likely to be of interest to the Assembly.

Background

The NHS Redress Measure 2008 was the first Assembly Measure to be passed by the Assembly and these draft Regulations are the first to be made under that Measure (although some provisions in the draft Regulations are made under powers conferred on Welsh Ministers by Westminster legislation).

The Measure enables Welsh Ministers to make Regulations, which allow for redress to be provided in circumstances where there is a qualifying liability in tort in relation to the provision of qualifying services. Redress may encompass apologies, explanations, action plans, remedial treatment and, if appropriate, financial compensation.

The objective of the *National Health Service (Concerns, Complaints and Redress) (Wales) Regulations 2011* is to make it easier for patients to raise concerns if they are dissatisfied or if things go wrong with their NHS care. They will also ensure that the NHS approach to such situations is more consistent and results in a fairer outcome for patients and staff.

In 2007, the then Subordinate Legislation Committee took evidence and reported on the Measure. Its report noted that:

“The Proposed Measure sets very wide parameters for what the Regulations must contain, leaving the substance of the Scheme to be dealt with by the Regulations which will deal with matters under the following broad headings:

- *Redress under the regulations*
- *Access to redress*
- *Potential application of redress arrangements*
- *Delivery of redress*
- *Provision of legal advice and the services of medical experts and other assistance for those seeking redress*
- *Functions with regard to redress arrangements”*

The Subordinate Legislation Committee accepted at the time that there were valid reasons for a ‘Framework’ Measure being justified in this case. However, the Committee also considered that the approach taken by this particular Measure should not set a precedent.

The Committee recommended a strong level of scrutiny for Regulations made under the Measure and that there **should be widespread consultation on the Regulations.**

Consideration by the Constitutional Affairs Committee

We have considered the current Regulations in relation to the issues raised above, particularly whether the Regulations have been subject to adequate consultation and whether the Regulations as presented adequately reflect issues raised during consultation.

Attached as an Annex to this report is our understanding of the consultation arrangements for the draft Regulations as well as of changes made to them in response to consultation responses.

While we believe that the general concerns about ‘Framework’ Measures remain valid (and while we note the considerable amount of time that has elapsed since the Measure was passed), we are content that consultation in respect of these draft Regulations has in our view been thorough, inclusive and responsive to concerns raised during it.

Both committees scrutinising the Measure and the Finance Committee raised concerns at the time about the information on the cost of the Measure (see Annex). It is not for us to say whether the information set out in the Financial Impact Assessment, which accompanies the draft Regulations would have addressed those concerns. However, we note that the estimates have now been refined from an estimated range at the time of £2.4m-£3.6m to budgeted provision for 2011-12 of £2.514m and of £2.388m in 2012-13. A budget of £1.8m has been available in the current financial year for development and preparatory work.

Janet Ryder AM

Chair, Constitutional Affairs Committee

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Annex to CA531: The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

Consultation Arrangements

The Explanatory Memorandum states that there has been a “significant amount of engagement with stakeholders undertaken in the development of the policy”. These included patient groups; staff interest organisations and stakeholder groups.

An earlier draft of the Regulations was subject to a twelve-week consultation from 11 January 2010 until 2 April 2010, which generated 119 responses. A consultation report was issued on 2 August 2010. A further short technical consultation was held between 6 and 30 September 2010, on a revised version of the draft Regulations. The short consultation covered two specific aspects relating to the financial limits for compensation for redress and the cross border application of the redress arrangements, and 16 replies were received.

Responses to the [consultation on Draft Regulations in 2010](#) raised a number of issues:

- Independence: NHS bodies should not be allowed to investigate complaints and concerns about themselves.

The Welsh Government commented that it was not “realistic to remove the responsibility for investigating concerns from the NHS organisations themselves. This goes against all current thinking about learning and improving.”

- A significant number of responses were about the time limits allowed in the Regulations for raising a concern or the timescales for the handling of a concern once it had been raised.

The Regulations have been amended to address concerns about time limits.

- A proportion of respondents felt that the Regulations did not adequately deal with primary care issues.

The Welsh Government commented that the draft Regulations would be clarified to make it clear that the redress element does not apply to primary care practitioners.

Patients will be able to raise a concern about a primary care practitioner either with the practice direct, or with their local health board, but not both. LHBs will not be able to make decisions about the liability of primary care practitioners. Patients who wish to pursue

claims against their primary care practitioner would need to obtain their own legal advice on how to proceed.

In cases where the same complaint covers primary and secondary care, the Regulations only provide for the liability of the hospital provider to be considered. However, the Welsh Government will set out in guidance how we expect the parties to proceed on issues relating to liability if the concern spans primary and secondary care.

- Some respondents were concerned about the relationship between the arrangements and whistle blowing policies and felt that more clarity was needed.

The Welsh Government commented that arrangements are not a substitute for proper HR processes which deal with instances of “whistle blowing”. The process is meant to enable people to report incidents so that they can be properly investigated. If the investigation reveals a concern about the competence of a member of staff, then this will be dealt with according to the normal professional processes. It stated that this will be made clear in guidance.

Amendments following consultation

A number of amendments have been made to the Regulations to take account of the comments received during the consultation. These include the following:

- Amendments have been made to the Regulations (Regulation 23) to strengthen independence in the process and involvement of individuals, namely:
 - the more effective and routine involvement of the person raising the concern;
 - the need to consider the securing of independent clinical or other advice and
 - the use of alternative means of resolving a matter using independent services such as mediation or facilitation.
- Further amendments (Regulation 15) have been made to clarify the time limits for bringing forward a concern as well as the need to communicate clearly and regularly with those raising a concern if the investigation is taking longer than it should (Regulations 24 and 26).
- The Regulations are now clear that the NHS Redress element of the arrangements does not apply in primary care (Definitions and, for example, Regulations 23(1)(i), 23(2), 25, 34, 35, 37, 38 and 39 where obligations in respect of NHS Redress are only placed on NHS bodies).

- An amendment has been made to suspend the limitation period from the date that the concern was first notified to the NHS organisation (Regulations 30 and 45).
- The Regulations are now clear that the NHS Redress element of the arrangements does not apply to independent providers (Definitions and, for example, Regulations 23(1)(i), 34, 35, 37, 38 and 39 where obligations in respect of NHS Redress are only placed on NHS bodies).
- An amendment has been made to set the overall financial limit for any compensation for redress to £25,000 (Regulations 29 and 44).
- The Regulations now set out more clearly how the redress arrangements will operate in terms of care provided by an NHS provider in England, Scotland or Northern Ireland (Part 7).

Financial Costings

Both the committee scrutinising the Measure and the [Finance Committee](#) expressed concerns about the costings in the Measure, the latter stating:

“The Committee were disappointed that the information to assess the cost of the implementing the Measure was so weak. While they accepted that there were difficulties in making judgements in this regard, they felt it should have been possible to provide more robust information so the Committee could test the assumptions that had been made. They consider this important not just in relation to the NHS Redress Measure itself but because any under- or over-estimate of its costs would have a consequent effect on the budgets for other Welsh Assembly Government policies.

The Committee noted that Officials are to continue to work on the figures and that this work would be informed by the working groups that have been set up. They were disappointed that the Measure had been brought forward before the assessment its financial impact had been adequately completed.”

The Financial Impact Assessment accompanying the Regulations states:

“A similar Financial Impact Assessment was prepared for the passage of the NHS Redress (Wales) Measure 2008. At that time, we were of the view that potential additional costs arising from the introduction of new arrangements would range from £2.4m to £3.6m. With the reorganisation of the NHS in Wales, we have

now been able to considerably refine the estimates. In particular we are now of the view that we can revise downwards the estimate required for investment in staffing, given that the opportunities for staff restructuring and redeployment that the reform programme affords. Financial provision of £2.514m has been made for 2011/12 to embed the new arrangements and £2.388m for 2012/13. A budget of £1.8m has been available in 2010/11 for development and preparatory work. In light of the above we are of the view that the programme can be delivered within these amounts.”