The Committee will meet at 10.30am in Committee Room 6.

1. **Inquiry into the regulatory framework in Scotland:** The Committee will take oral evidence from—

   Bill Adamson, Branch Head – Strategy and Coordination, Food Standards Agency Scotland;
   Sandy McDougall, Branch Head – Contaminants, Hygiene, Additives and Shellfish, Food Standards Agency Scotland;
   Dave Gorman, Operations Manager, Scottish Environment Protection Agency;
   Campbell Evans, Director of Government and Consumer Affairs, Scotch Whisky Association; and
   David Williamson, Public Affairs Manager, Scotch Whisky Association.

2. **Delegated powers scrutiny:** The Committee will consider a response from the Executive on the delegated powers provisions in the following bill —

   Management of Offenders etc. (Scotland) Bill as amended at Stage 2.

3. **Delegated powers scrutiny:** The Committee will consider a response from the Executive on the delegated powers provisions in the following bill —

   Human Tissue (Scotland) Bill at Stage 1.

4. **Executive responses:** The Committee will consider responses from the Executive to points raised on the following—

   the Regional Transport Partnerships (Establishment, Constitution and Membership) (Scotland) Order 2005 (*SSI 2005/draft*)

   the Civil Partnership Act 2004 (Consequential Amendments) (Scotland) Order 2005 (*SSI 2005/draft*)

   the Tryptophan in Food (Scotland) Regulations 2005, (*SSI 2005/479*)
the Food Hygiene (Scotland) Regulations 2005, (SSI 2005/505)


5. Draft instruments subject to approval: The Committee will consider the following—

the Civil Partnership (Jurisdiction and Recognition of Judgments) (Scotland) Order 2005 (SSI 2005/draft)


6. Instruments subject to approval: The Committee will consider the following—


7. Instruments subject to annulment: The Committee will consider the following—


the Additional Support for Learning (Placing Requests and Deemed Decisions) (Scotland) Regulations 2005, (SSI 2005/515)


the Additional Support for Learning (Co-ordinated Support Plan) (Scotland) Amendment Regulations 2005, (SSI 2005/518)

the Mental Health Tribunal for Scotland (Practice and Procedure) (No.2) Rules 2005, (SSI 2005/519)

the National Assistance (Assessment of Resources) Amendment (No.2) (Scotland) Regulations 2005, (SSI 2005/522)


8. Instruments not laid before the Parliament: The Committee will consider the following—

Act of Sederunt (Rules of the Court of Session Amendment No.8) (Miscellaneous) 2005, (SSI 2005/521)
The following papers are relevant to this meeting:

**Agenda Item 1**

Briefing paper (Private)  
Food Standards Agency Submission  
Scottish Environment Protection Agency Submission  
Scotch Whisky Association Submission

**Agenda Items 2 – 8**

Legal brief (Private) – to follow

**Agenda Item 2**

Executive response

**Agenda Item 3**

Executive response

**Agenda Item 4**

Executive responses

**Agenda Items 5 – 8**

Copies of instruments (circulated to Members only)
RESPONSE BY THE FOOD STANDARDS AGENCY SCOTLAND TO THE SUBORDINATE LEGISLATION COMMITTEE’S (SLC’s) CONSULTATION PAPER ON PHASE 2 OF ITS INQUIRY INTO THE REGULATORY FRAMEWORK IN SCOTLAND

1. The Scottish arm of the Food Standards Agency (FSA Scotland) welcomes the opportunity to supplement the response it provided to the SLC during phase 1 of its inquiry. The Agency continues to support the objectives of improving the quality of new regulation and is fully engaged as a UK body, working in a devolved area, of both the Westminster better regulation agenda and the very complimentary agenda in Scotland. The Agency’s legislative work is principally one of public health protection and therefore can require robust immediate enforcement deterrents to be in place to achieve the necessary lever of public protection. In addition, much of the Agency’s legislative agenda is derived from directly applicable EU legislation which normally has a requirement for uniform implementation dates. The following response therefore reflects these policy drivers.

Nature of supervision by the Parliament

Negative and Affirmative Procedures. Whether they should continue to exist?

2. Currently, the vast majority of subordinate legislation initiated by the Agency falls into two areas, either:

2.1 Emergency legislation designed to provide immediate public protection from exposure to a food hazard, or:

2.2 Subordinate legislation designed to provide enforcement arrangements, and offences and penalties, for directly applicable EU Regulations.

3. Emergency control legislation is designed to ensure the immediate protection of the public from exposure to unsafe foods. As has been identified in your background ‘link’ paper these are made, either under Section 1 (1) of the Food & Environment Protection Act 1985 (FEPA) by class 3 affirmative procedures, or under section 13 of the Food Safety Act 1990 by class 5 negative procedures. (NB the reference in footnote 15 of the background paper appears incorrect. The cited order is not made under the Food Safety Act.) We note that you have suggested that this situation may appear inconsistent and speculate whether negative procedures under Class 5 would be sufficient for both. There are certainly some attractions to the Agency in this proposition, principally the time saving for officials and ministers appearing on each occasion before the health committee under the current Class 3 procedures for FEPA. However, we are acutely aware that food emergencies do not obey strict geographical boundaries, and therefore there is an obvious need for cross border consistency in the timing of application and revocation. (see also comments on timing para’s 10-15)

4. In relation to non-emergency legislation, an increasing amount of the Agency’s work relates to providing for adequate enforcement of directly applying EU legislation. For the most part these SSIs are derived from the European
Communities Act 1972, although the Food Safety Act 1990 may also be used. In these cases the relevant SSIs are normally subject to negative procedures. This seems appropriate since the instrument in policy terms is principally giving effect to directly applying EU law, which Scottish Ministers have obligations to facilitate. Once more, as a UK wide Agency operating in a devolved area, consistency of application across the UK is important. (see also comments on timing)

5. In relation to legislative provisions which are not covered by those matters highlighted in paragraphs 3 & 4 above, the Agency would support in principle the use of super-affirmative procedures, where appropriate, for major policy issues, so long as issues of consistency are fully considered for matters of food law.

6. In summary, we can see the place for both affirmative & negative procedures, but believe that the chosen procedure should fit individual circumstances.

Amendment

7. As described above, for most of the Agency's area of responsibility the law is either of an emergency nature, or giving effect to directly applicable EU legislation and therefore the scope for amendment, by the Parliament in these circumstances, seems limited.

Consultation

8. We were unclear from the consultation document how in practice the Parliament would actually consider consultations and respond, other than via the use of 'super-affirmative' procedures as described. We would require greater clarity as to what is proposed before responding in detail on this point. However, we believe it would be inappropriate to impose a general requirement to consult since this may not always be practical.

Definition of SSIs

9. It is our belief that it would be counterproductive for all guidelines and codes of conduct to be considered to be SSIs. We believe that there are so many such instruments that might fall into this category, that it would be impossible for the Parliament to consider them in this way. There is statutory provision within certain Acts, requiring Codes to be made by Ministers and laid before Parliament. Enforcement Codes made under the Food Safety Act fall into this category, and this appears to be sufficient parliamentary scrutiny. We do, however, believe that all such instruments should be exposed to full and meaningful public consultation before adoption, and we follow this principle in relation to any Code or Guidance with a statutory basis, developed by or on behalf of the Agency.

Existing Parliamentary Procedures

Timing of negative and affirmative considerations

10. The Agency accepts in principle the rationale in correlating the laying period and annulment period, so that they coincide for class 5 negative procedures.
However, our UK status means it is important that, as far as possible, our food law is given effect throughout the whole of the UK at the same time. Any extension to the laying date, may therefore cause problems, if the laying periods for Westminster and other devolved Parliaments were not all consistent.

11. Any agreed harmonisation and extension to laying dates, should be without prejudice to the ability to arrange for the 21 day rule to be broken where there is good reason, such as, emergencies, or the need to ensure common commencement dates for application of directly applicable EU regulations.

12. In relation to emergency instruments subject to class 5 negative procedures, the Agency currently has to explain to the Presiding Officer the reason for the need to break the 21 day rule on each occasion an emergency order is required. Should class 3 procedure FEPA orders be changed to class 5 procedures, as hypothesised in paragraph 3 above, such requests would require to be made on a relatively frequent basis, albeit this may diminish significantly with new control arrangements due to come into force on 1st January 2006. We would request consideration of a policy which allows that where an emergency situation has previously been accepted as requiring immediate effect, there is no need to seek permission from the Presiding Officer in writing thereafter for the same scenario on every occasion.

13. The Agency finds itself frequently drafting SSIs whose sole purpose is to give enforcement effect to directly applicable EU regulations. Occasionally the EU drafting and publishing timeframe on these Regulations is very late. This means that in order for the SSI to be laid in time, to ensure enforcement provisions are in place by the EU implementing date, once more a request to break the 21 day rule has to be made. The Agency appreciates that other regulators may also be placed in a similar positions with respect to implementation of directly applicable EU law, however this is exacerbated for us as a UK body involved in regulating business operating within a UK and international market.

14. Any procedural change, which increase the time between the signing of instruments, their laying before Parliament, and the coming into force date will clearly exacerbate the problems highlighted in paras 12 & 13 above. The Agency, therefore, would have concerns about these particular types of situation being covered by extended scrutiny provisions.

15. One solution to the problem of late deadlines on SSIs, giving effect to directly applicable EU law, might be for the subordinate legislation committee to be given the opportunity of commenting on the SSIs at the consultation draft stage. There is a requirement in EU law that any food Regulation, apart from urgent matters, must be the subject of public consultation. The Agency in furtherance of its policy of openness and transparency ensures that wherever possible this consultation period is for a minimum of 3 months. This should afford the SLC a reasonable opportunity to comment on any proposal.
Instruments not subject to procedure

16. The Agency has no experience in the use of these instruments therefore feels unable to comment on the discontinuation of class 7 procedures.

Numbering, classification and publication of SSIs

17. The Agency is happy with the current publication arrangements for SSIs

Consequences of not laying

18. It would appear appropriate, that there was a requirement, for instruments to be laid as soon as practicably possible after making, nevertheless, there may be a danger in making the instrument automatically invalid if not laid within a specified time. If there were evidence that information was being deliberately withheld from parliament this would clearly be a serious matter. However, if a technical administrative error was made, and the failure to lay was without prejudice to any affected person, the consequences might be significant if action on the back of an invalidated instrument was ruled technically incompetent in court.
1. Introduction

1.1 The Scottish Environment Protection Agency (SEPA) welcomes the opportunity to comment on Phase 2 of the Committee’s Inquiry into the Regulatory Framework in Scotland.

1.2 SEPA is the principal environmental regulator for Scotland. SEPA has a wide range of powers and duties to protect and improve the environment across air, land, water and waste, as well as to protect human health. SEPA is committed to the principles of better regulation much as set out in the Hampton report.

1.3 SEPA’s activity largely flows from requirements set out in primary and secondary legislation, and it is therefore vital to SEPA’s interests, on behalf of government, implementing environmental legislation, that such secondary legislation is well structured and clear, with sound objectives and an effective scrutiny process. At the same time SEPA does not wish to see an overall increase in the timescales for making secondary legislation.

1.4 Our comments on the consultation paper are set within the context of a commitment to better regulation and a requirement for proportionate and transparent regulation. Reference should also be made to the views expressed in our responses to Phase 1 of the inquiry.

2. Specific Comments on the Consultation Paper

2.1 The comments offered below mirror the structure set out in the consultation paper.

(a) Nature of Supervision by the Parliament

Comments are invited on:-

- The current negative and affirmative procedures and whether they should continue to exist for the Parliamentary consideration of subordinate legislation;
- The role of the subordinate legislation committee and the subject Committees in examining subordinate legislation;
- Whether the procedure chosen should rely on the parent Act or whether the Parliament should consider a procedure which allows the significance of the instrument to dictate the procedure adopted.

2.2 SEPA believes that the existing twofold distinction of positive and negative procedures works reasonably well. For example, the recent adoption of the Controlled Activity Regulations 2005, made under the affirmative procedure followed an intensive scrutiny process, whereas the Pollution Prevention and Control (Scotland) Amendment (No 2) Regulations 2005 (Scottish Statutory Instrument 2005 No 340) made under the negative procedure were non contentious and did not require a similar level of scrutiny.
2.3 SEPA does believe there is a case however for a procedure which allows the significance of the instrument to dictate the procedure adopted, as it may not always be possible at the time of drafting the parent Act to predict the significance of, or stakeholder interest that may arise from a proposal. Such a procedure would also allow for flexibility in departing from the requirement of the parent Act. SEPA believes that the means by which significance could be judged would need careful consideration.

2.4 SEPA believes that the subject committees and subordinate legislation committee have complementary roles. The subject committees have a particular role in scrutinising the ‘content’ of regulation, whereas the subordinate legislation committee should focus more on the structure, clarity and ease of use of the regulation. Both types of committee should scrutinise the impact of regulations, particularly examining the Regulatory Impact Assessment where it exists.

(b) Amendment

Comments are invited on:–

- Whether the Scottish Parliament should be given powers to amend instruments or drafts, or to recommend such amendments; and
- Whether the Scottish Parliament should be given the power to recommend certain changes being made to an instrument, before the instrument will achieve Parliamentary approval.

2.5 SEPA would share the view that the current ‘all or nothing’ approach to approval does not always lead to a proportionate outcome, and that there could be cases where the power to propose amendments would be useful. SEPA offers this view without prejudice to the constitutional, policy and procedural questions that may arise. SEPA would also be concerned to ensure that any changes to process did not extend the overall timescales for law-making. A further point to be considered would be the impact of proposed changes late in the process in terms of legislative clarity, policy impact or business costs.

2.6 Most UK or Scottish environmental law arises from EU Directives which normally have fixed transposition deadlines. The ability therefore for a degree of amendment at scrutiny stage, would seem to offer a sensible approach that would offer more opportunity for consensus to be reached, whilst keeping to transposition timescales. Again SEPA would stress the need to ensure overall timescales for law-making are not affected.

(c) Consultation

Comments are invited on:–

- Imposing a general requirement to consult the Parliament on draft instruments;
- The use of ‘super-affirmative’ procedure and examples of where it could be used effectively.

2.7 SEPA believes the ‘super-affirmative’ procedure is a valuable one, particularly in cases where regulations may have a significant impact.

2.8 SEPA is cautious about the imposition of a general duty to consult the Parliament on draft instruments. SEPA believes that this could impose an unnecessary burden on the Scottish Executive, particularly in cases where the avoidance of
infraction at EU level is required, or where emergency regulations or otherwise swift action is required. A better approach would seem to be to allow for amendment or agreement on amendments prior to approval, as suggested in section 1.5 of the consultation paper.

(d) Definition of SSIs

Comments are invited on:-

- Where all instruments of a legislative character, for example, guidelines and codes of conduct, should require to be SSIs.

2.9 SEPA believes that the impetus for better regulation provided by actions at the EU and UK level e.g. the Hampton Report, will result in greater use of alternative forms of regulation over time. SEPA believes therefore that ‘rules about rules’ are required e.g. the scope and extent of rule making powers on matters such as codes of practice, schemes etc. However SEPA believes that the importance of transparency in the use of such instruments should be balanced against the need for proportionality, and therefore further consideration is needed before a general requirement to make such instruments SSIs is imposed. There will clearly be certain forms of guidance and codes that are not statutory in nature and care will be needed in defining the differences.

2.10 SEPA agrees that a central register of all directions, and greater scrutiny of directions with potentially significant impact is required as it is often not possible to fully understand a regulatory implementation package without considering the directions issued as part of that regulatory package.

(e) Existing Parliamentary Procedures

Comments are invited on:-

- The existing procedures for scrutinising SSIs
- Increasing the time allowed for the Parliament to consider SSIs
- Extending the 21 days given for negative instrument to come into force to something that would allow the Parliament to consider all negative instruments before they came into force.

2.11 SEPA believes a case can be made for use of affirmative, negative and super affirmative procedures but has no comments on the detailed arrangements set out in the table.

2.12 SEPA agrees in principle that further time should be given to the SLC to consider and report on SSIs, subject to an overall assessment of the effect on the law making process. As Phase 1 of the Committee’s inquiry highlighted, there is an increasing need to consider the form and structure of regulation as well as its content. SEPA’s comments are again assuming no overall increase in the timescales for lawmaking.

2.13 SEPA considers it vital that the regulatory environment is as transparent and proportionate as possible for all stakeholders. The examples of the difficulties arising from annulment under the negative procedure do not contribute to good law making, and SEPA would therefore support the extension of the 21 day rule in these cases.
(f) **Instruments Not Subject to Procedure**

Comments are invited on:-
- The use of these procedures;
- Whether the use of Class 7 should be discontinued, with class 6 being used so that general instruments should be laid before Parliament in all cases.

2.14 SEPA would agree that the continued use of these procedures, in particular Class 7, would appear to be anomalous and should be avoided and possibly eliminated.

(g) **Numbering, Classification and Publication of SSIs**

Comments are invited on:-
- The current publication system of SSIs;
- Whether there should be a requirement for the QPS to publish drafts which are laid before Parliament and subject to affirmative procedure.

2.15 In line with the Committee's conclusions from Phase 1 of the inquiry, SEPA believes that at the very least all SSIs should be published via the internet. SEPA believes that this should include the drafts of instruments laid before parliament under the affirmative procedure.

(h) **Consequences of Not Laying**

Comments are therefore invited on:-
- Whether an instrument should be required to be laid as soon as practicably possible;
- Whether failure to lay an instrument, when this is required to be laid, should make the instrument invalid.

2.16 SEPA believes that as a principle of good practice, instruments should be required to be laid as soon as practicably possible. In addition, it must be right that failure to lay an instrument when this is required to be laid, should invalidate the instrument. Clarity is required as to liabilities that may arise for regulators should they in the meantime regulate according to an instrument that later turns out to be invalid.

SEPA
23 September, 2005
Committee Inquiry into the Regulatory Framework in Scotland – Phase 2

The Scotch Whisky Association (SWA) is the trade association representing the Scotch Whisky industry at home and abroad.

In representing the industry in its 200 markets, the SWA has extensive experience of different legislative approaches, both in terms of primary and secondary legislation.

Subordinate legislation can have far reaching implications. The Association believes it is vital such legislation is subject to rigorous scrutiny to ensure that it is necessary, appropriate and proportionate. Certain aspects of the existing arrangements in the Scottish Parliament for the scrutiny of subordinate legislation could be improved to better ensure these objectives.

We broadly agreed with the conclusions of the Committee’s Phase 1 report and welcome the opportunity to provide evidence on the Phase 2 consultation paper on the regulatory framework in Scotland.

a. **40-day rule**

The Parliament’s standing orders limit to 40 days the time available to consider a statutory provision laid under the affirmative procedure (‘Class 1’ procedure). The SWA does not believe this is a sufficient length of time to allow adequate consideration of potentially contentious issues arising in the subordinate legislation.

a. Lead committee scrutiny cannot start until such time as the Subordinate Legislation Committee has itself reported. This restricts the time available for discussion and scrutiny of the substance of the subordinate legislation.

b. Lead committees already have busy work programmes. Our experience has been that, as a result, little time may be available to consider in any detail issues that may arise in draft subordinate legislation. The text, for example, may only feature on the lead committee’s agenda after a significant amount of the 40 day period has elapsed.

c. Faced by such constraints, and with power only to approve or reject legislation under the affirmative procedure, the lead committee is unlikely to be able to schedule evidence sessions with stakeholders.
To allow a full assessment of draft legislation, and an opportunity for the lead committee to take evidence if necessary, we would support an amendment to the Parliament’s standing orders to extend the time available to consider the subordinate legislation. We would agree that 60 working days would appear to be an appropriate length of time. Alternatively, the 40 day period should not commence until the Subordinate Legislation Committee has completed its work.

It would make little sense to extend the period from 40 to 60 days if draft legislation continues to be heard only once a significant period of that time has elapsed. We would therefore suggest that the lead committee, as a matter of good practice, include the draft text on its agenda according to a prescribed timescale, early in the 60 day period. By requiring the committee to consider the text by, for example, the 20th day of that period, it would still have the opportunity to arrange for further evidence to be received from stakeholders.

b. Amendment of draft legislation

The Parliament cannot amend or propose an amendment to a draft instrument. Instead, it must either approve an instrument in its entirety or recommend that it is not approved.

The SWA considers that the Parliament’s inability to recommend amendments encourages what might be termed a ‘fait accompli’ approach to the text. Faced with limited options and time constraints, there is a reluctance to reject draft legislation in its entirety, despite concerns over a specific provision.

In this context, it would be in the interests of effective scrutiny to grant Parliament powers to recommend approval subject to amendment of the draft instrument. This would be particularly appropriate in circumstances where commitments given to the Parliament at the primary legislation stage are not followed up in the draft secondary legislation, or when discussion in the lead committee with the responsible Minister leads to changes in approach or even policy amendment.

Whilst noting that this might be considered inconsistent with the concept of primary legislation having delegated power to the Executive, Parliament should continue to have the ability to oversee the application of that power in practice, and recommend amendments to subordinate legislation where necessary.

c. Consultation

Earlier consultation with the Parliament on draft subordinate legislation could assist in identifying potential problem issues, help build consensus, and ensure full consideration is given to the range of stakeholder views.

It may therefore be that further consideration should be given to more frequent use of the ‘super affirmative’ option where there is a likelihood that contentious issues will arise. This would also be preferable to a more general requirement to consult Parliament on draft instruments before they are made or laid, which could potentially overburden the system.
That said, if other changes allow for more satisfactory scrutiny once the final instrument is laid, by a revised affirmative or negative procedure, it may be that this in itself would be adequate to ensure appropriate examination of the regulations.

We believe strongly that a Regulatory Impact Assessment (RIA) and policy statement relative to the proposed legislation should be given to Parliament six months before the draft statutory instrument is laid to allow MSPs the opportunity to weigh up the need for and proportionality of the proposed legislation.

Great care should be taken to rigorously adhere to the RIA guidelines. Genuine consideration should be given to alternative policy options and robust cost/benefit analysis provided. If not, there is a danger the process becomes no more than a box ticking exercise justifying a pre-determined policy choice.

We believe it would also be appropriate for the lead committee, where it is dissatisfied, to be allowed to challenge and amend the RIA, and report on the reasons why it has decided to do so.

d. General comments

(i) Availability of subordinate legislation

The SWA welcomed the committee’s recommendation at Phase 1 that up to date texts of primary and secondary legislation should be available to the public on line and free of charge. While not considered in the Phase 2 consultation document, we would also like to raise a further practical issue in relation to the availability of subordinate legislation.

Currently, the Parliament does not make draft subordinate legislation available on its website. Often the draft legislation as laid before Parliament is different from earlier drafts circulated to stakeholders.

The arrangements result in stakeholders encountering difficulty in obtaining the most up to date version of what is often detailed draft legislation. Not only does this delay stakeholders being able to assess the implications of the legislation, it exacerbates the time constraints highlighted above and prevents views being made available to the lead committee in order that it can consider the legislation fully cognisant of the implications at the earliest opportunity.

(ii) Better Regulation Principles

The Association fully supports the recommendations of the Hampton Report and the Better Regulation Task Force (BRTF), as accepted by the UK Government earlier this year.

We hope the Parliament will press the Scottish Executive to explicitly state its support for, and adherence to, the recommendations of the Hampton
Report and BRTF, thereby ensuring best regulatory practice is routinely followed, for example in relation to the RIA process and post-implementation reviews; and that the Executive’s performance against these recommendations will be monitored and reported on.

Needless to say, we would be happy to provide clarification or further information on the above.

Yours sincerely

Campbell Evans
Director of Government & Consumer Affairs
SUBORDINATE LEGISLATION COMMITTEE

29th Meeting, 2005 (Session 2)

Tuesday 1st November, 2005

Executive Response

Management of Offenders etc. (Scotland) Bill as amended at Stage 2

On 25 October 2005 the Committee asked for an explanation of the following matters –

1. **Section 7(2): Transfer of functions to CJA**

   The Committee noted that the Bill has been amended at Stage 2 to include a duty on Ministers to consult with relevant local authorities and with the Community Justice Authority before laying a draft Order before the Parliament. The issue of consultation was raised by this Committee during its consideration of the delegated powers at Stage 1. At that time, the Executive indicated that it did not consider that it was necessary to include specific duties to consult in the Bill.

   The Committee, therefore, asks why the Executive has changed its approach in relation to this matter.

2. **Section 11(1B) – New section 1AA (release of certain sexual offenders) of the Prisoners and Criminal Proceedings (Scotland) Act 1993**

   The Committee seeks clarification of the full impact that the new section 1AA in section 11(1B) will make to the existing 2003 Act in relation to the release of sexual offenders.

The Scottish Executive responds as follows –

1. In her letter dated 3 May 2005 the Clerk to the Committee reported that the Committee wished to have an explanation of the Executive’s proposals for consultation in relation to subordinate legislation under 4 separate provisions, namely sections 2(1), 5(12), 7(2) and 14(1)(b).

   In its reply to that letter the Executive stated that it did not consider it appropriate to impose a statutory requirement to consult before making subordinate legislation although, as a matter of practice, consultation is normally undertaken. That remains the position as regards sections 2(1), 5(12) and 14(1)(b). The specific requirement regarding consultation highlighted by the Committee in the letter dated 25 October 2005 relates only to Orders made under section 7(2).
The Executive has had regard to comments made by the Subordinate Legislation Committee, by members during the Parliamentary Stages of this Bill and by stakeholder groups and partner bodies. Taking all of these comments together the Executive has concluded that as regards Orders made under section 7(2) it would be appropriate to include in the Bill a requirement to consult with affected local authorities and the Community Justice Authority and only to proceed with the making of the Order if those consulted have confirmed their agreement. This represents a departure from the Executive’s normal practice as regards consultation before making subordinate legislation but it is satisfied that in the particular circumstances of this case the measures proposed in section 7 of the Bill are appropriate.

2. Section 11(1B), which was added to the Bill at Stage 2, inserts new section 1AA in the 1993 Act. This provides that certain short-term prisoners, who would otherwise be released unconditionally after serving one half of their sentence, will instead be released on licence and will be subject to supervision and other conditions. The new section does not alter the point of release, but simply the post-release regime. The section applies only to prisoners who are subject to the notification requirements of Part 2 of the Sexual Offences Act 2003 (ie those who are on the “Sex Offenders Register”).

In contrast, section 11(3) of the Bill inserts a new section 3AA in the 1993 Act to provide for Home Detention Curfew (HDC). Prisoners granted HDC would be released before they become eligible for automatic early release at half-sentence, but would be subject to licence conditions including an electronically monitored curfew. The scheme is intended for low risk prisoners, and section 3AA specifically excludes certain classes of prisoner. One such exclusion (section 3AA(5)(d)) is for any prisoner subject to the notification requirements of Part 2 of the Sexual Offences Act 2003.

The provisions are therefore mutually exclusive. Sex offenders are automatically ineligible for HDC and are instead covered by the new release arrangements in section 1AA.

Scottish Executive Justice Department
SUBORDINATE LEGISLATION COMMITTEE

29th Meeting, 2005 (Session 2)

Tuesday 1st November, 2005

Executive Response

Human Tissue (Scotland) Bill at Stage 1

1. On 25th October 2005 the Committee requested an explanation of the following matters which are answered below.

Section 15(3) – Restrictions on transplants involving live donor

2. The Committee noted that the power at section 15(3) is very wide and it concerns a sensitive issue. While the Committee is content with the use of delegated powers in this instance, the Committee questioned whether negative procedure provides the correct degree of control. Paragraph 7 of the Delegated Powers Memorandum on the bill states that affirmative procedure is used where there is significant public interest. The Committee considered that these sensitive issues merit the more detailed scrutiny afforded by affirmative procedure. The Executive is asked for comment.

3. The Executive thanks the Committee for its comments in this respect and agrees, on reflection, that in light of the fact that the power under section 15(3) concerns a sensitive issue it would be appropriate to make regulations under this section subject to the more detailed scrutiny afforded by affirmative procedure. The Executive notes that the equivalent regulation making power in section 33(3) of the Human Tissue Act 2004, applicable to England and Wales, is subject to affirmative procedure and would wish to be consistent with this approach. The Executive will amend section 53(3) as soon as is practicable, so as to make clear that regulations made under section 15(3) will be subject to affirmative procedure.

Section 16(1) – Records, information etc.: removal and use of parts of human bodies for transplantation etc.

4. The Committee noted that section 16(1)(a) gives the Scottish Ministers powers to make regulations requiring persons to maintain records in connection with the removal of human parts for transplantation and the use or retention of parts, while section 16(1)(b) gives Ministers the powers to make regulations requiring persons to make information available to Ministers or to a specified body.

5. The Committee questioned whether the powers as drafted would provide sufficient vires for any relevant confidentiality provision in regulations made under the section. The Committee acknowledges that it may be that the position is covered adequately under other legislation such as Data Protection or Freedom of Information legislation. The Executive is asked to comment.
6. The Executive explains that it is currently considering the issue of confidentiality generally in relation to the Bill. If, as a result of that consideration, the Executive forms the view that the specific issues covered in the Bill are not already adequately covered by existing legislation such as Data Protection and Freedom of Information legislation, and that a specific confidentiality provision requires to be included on the face of the Bill, then it will bring forward a suitable amendment to the Bill at Stage 2. If the view is ultimately that an amendment is required then the question of whether it is necessary to amend section 16(1) or to introduce a new separate provision will be assessed at that time.

Section 35(2)(c) – Use of organ no longer required for procurator fiscal purposes

Section 43(2) – Use of organ removed before day on which section 35 comes into force

7. The Committee noted that these powers allow for the specification of persons who may give approval to carry out research on an organ removed from a deceased person. Whilst it is clear from the Delegated Powers Memorandum that the policy intention is that a Research Ethics Committee will provide approvals, the Committee was concerned that the powers as drafted leave the choice of persons or groups granting approval wide open and asks for further clarification in relation to how it is intended that these powers will work in practice. The Executive is asked to comment.

8. The Executive explains that the current practice as regards approval to carry out research on any organ removed from a deceased person is that the Research Ethics Committees (“RECs”) provide independent advice on the extent to which proposals for any research studies comply with recognised ethical standards. Accordingly, if a research proposal fails to gain REC approval, it would have to be abandoned. It is the intention of the Executive that specifying RECs in the Regulations will ensure that this existing role of the REC would continue so that the clear rules for RECs considering any research proposal involving human material, as set out in the Phase 3 report of the Review Group on Retention of Organs at Post-Mortem, would continue to apply to the consideration of all such cases in Scotland.

9. As regards the way in which the powers have been drafted to give effect to this policy intention, the Executive further explains that the regulation making powers are framed as widely as they are in order to reflect firstly the fact that the types of research that may be approved may change over time, and secondly that the identity of the body that approves them may also change over time. The Executive does not wish to specify RECs in these provisions because if they change their names in the future, this would necessitate amending the Act that the Bill will become. The Executive wishes to re-affirm to the Committee that the only bodies that it currently intends to specify in regulations made under these provisions are RECs and that it is not aware of any other body that could be specified either at present or in the foreseeable future.
Part 3: General point

10. The Committee also raised a more general point on Part 3 of the Bill, relating to the delegated powers. The Committee has been unable to ascertain what, if any, sanctions there are for failure to comply with the requirements of this Part of the Bill. The Executive is asked to comment.

11. The Executive explains that no provision is made in the Bill for failure to comply with the requirements of Part 3. The penalties that apply for failure to comply with the requirements of Parts 1 of the Bill relate to the removal and use of parts of the body of a deceased person for the purposes of transplantation, etc. The penalties that apply for failure to comply with the requirements of Part 2 of the Bill relate to the carrying out of a post-mortem examination, the removal of an organ during a post-mortem examination or the subsequent retention of any such organ.

12. However, the provisions of Part 3 of Bill relate only to the use of organs and tissue sample which have already been removed from a deceased person’s body as part of an examination which has been instructed by a procurator fiscal. The Bill does not extend to the carrying out of fiscal examinations and the provisions of Part 3 therefore relate only to tissue sample or organs that are no longer required for the purposes of the fiscal. As there is no question of a person removing an organ or tissue sample from a deceased person’s body in terms of Part 3 of the Bill, the Executive does not consider it appropriate to impose penalties for failure to comply with the requirements of that Part of the Bill.

Section 47 – Power to prescribe forms and descriptions of persons who may act as witnesses

13. The Committee noted that section 47(a) gives Ministers powers to prescribe the form in which authorisation for certain activities under Parts 2 and 3 of the Bill can be given by nominees, relatives or persons with parental rights and responsibilities. Section 47(b) gives Ministers powers to prescribe persons who are eligible to act as witnesses to authorisation in certain cases. However, the Committee was unclear whether it is mandatory for forms to be used when they are prescribed or whether their use is optional. The Executive is asked to comment.

14. For Part 2 authorisations (hospital post-mortem examinations), the Executive confirms that the policy intention is that the forms prescribed under section 47(a) will be mandatory. In relation to Part 3 authorisations (tissue samples or organs no longer required for procurator fiscal purposes), however, the Executive confirms that the policy intention is that it will not be mandatory for the forms that are prescribed under section 47(a) to be used by a person when they are providing authorisation by virtue of the specified Part 3 sections. It is intended in that regard that where an authorisation does not replicate the exact form which is prescribed then the examination will not be prevented and the pathologist will not be at risk of committing an offence provided that the form otherwise complies with the Part 3 authorisation provisions. However, the intention is that the forms prescribed by Scottish Ministers for Part 3 will, in practice, be used universally and the Executive is in the process of developing a mechanism to achieve this consistency. The Executive thanks the Committee for its comments. The Executive will ensure that the necessary
amendment is brought forward at Stage 2 to make clear on the face of the Bill the proper status of each of the forms for Parts 2 and 3 respectively.

**Section 48(13) – New section 8A(2)(a) and (b) of the Anatomy Act 1984**

15. The Committee observed that while subsection (7) provides that failure to observe a provision of the code of practice will not of itself render a person liable to prosecution, the drafting of subsection (7) seems to imply that it could tend to establish guilt of a substantive offence. Subsection (8) also provides that in granting licences the Scottish Ministers can take into account observance or otherwise of the code. The Executive is therefore asked for clarification of the intention of this drafting.

16. The Executive clarifies for the Committee that the intention behind the drafting of subsection (7) of new section 8A of the Anatomy Act 1984 is that no person will be rendered liable to any proceedings, either civil or criminal, for failure, of itself, to observe a provision of the code of practice. Subsection (1) of new section 8A is clear that the purpose of the code is to provide practical guidance to persons who are to have regard to the code. Subsection (7) provides that the code of practice will be guidance which must be had regard to, but there is no statutory duty to observe any particular provisions of the code in itself.

17. However, while there is no statutory duty to observe any provisions of the code in itself, failure to do so may be important to other civil or criminal proceedings. Those who have a duty to have regard to the Code should, if departing from the provisions of the Code, have cogent reasons for doing so. Accordingly, where the guidance set out in the Code may be relevant to any civil or criminal proceedings, the terms of subsection (7) allow the person’s failure to observe the code’s provisions, and the reasons for doing so, to be considered.

18. In relation to subsection (8) the Executive clarifies for the Committee that Scottish Ministers are to be able to take into account the observance of, or failure to observe, the code where a person applies for one of the licenses referred to in that subsection (8)."

**Section 50(1) – Power to give effect to Community obligations**

19. The Committee queried why it has been decided to take a specific power for this purpose, rather than rely on section 2(2) of the European Communities Act 1972. The Committee therefore asks for the reasons behind the taking of this power.

20. The Executive acknowledges that the general power under section 2(2) of the European Communities Act 1972 enables regulations to be made for the purpose of giving effect to Community obligations of the United Kingdom. The Executive explains that the specific power to give effect to Community obligations included at section 50(1) of the Bill was included initially primarily as a marker to denote that the Bill or Act would be subject to further amendment as a result of requiring to implement the particular requirements of the EC Directive 2004/23/EC of 31 March 2004 on settings standards of quality and safety for the donation, procurement,
testing, processing, preservation, storage and distribution of human tissues and cells ("the Tissue and Cells Directive"). The implementation date for the Tissue and Cells Directive is 7th April 2006, when it is intended that the Bill itself will be brought into force if passed by the Parliament. However, the Tissues and Cells Directive itself was not complete at the date of introduction of the Bill and is still awaiting completion of its framework by completion and inclusion of its technical annexes by the European Commission. It is the Executive's intention to implement the Tissue and Cells Directive so far as it can at the moment, but it is recognised that further amendment may be necessary to the Bill subsequently once the technical annexes are finalised by the European Commission.

21. Whilst the Executive accepts, therefore, that the inclusion of the power to make regulations under section 50(1) is, in one sense, merely a confirmation of the general power under section 2(2) of the European Communities Act 1972, it nevertheless considers it appropriate in light of the ongoing issues surrounding the Tissue and Cells Directive to make specific provision for this power in this Bill and to provide that this power is to be exercised using affirmative procedure. The Executive would point out in that regard that whilst the 1972 Act would give the option of allowing either the affirmative or negative procedure to be used, section 53(3) of the Bill commits Scottish Ministers to exercising the power to make any regulations required to further implement the Tissue and Cells Directive by means of the affirmative procedure.

22. The Executive further explains that the inclusion of the power in section 50(1) is consistent with a similar power at section 46 of the Human Tissue Act 2004, applicable to England and Wales, which the Executive presumes would have been included for the same reasons as are explained above.

Scottish Executive Health Department
The Regional Transport Partnerships (Establishment, Constitution and Membership) (Scotland) Order 2005 (SSI 2005/draft)

On 25th October 2005 the Committee asked the Executive for an explanation of the following matters:

"In article 3(5) of the Order it is provided that a Regional Transport Partnership may determine to amend its standing orders to require that certain specified decisions be determined by a two-thirds majority. The Committee is not clear whether this is compatible with the enabling power at section 1(2)(e)(iii) of the Transport (Scotland) Act, and seeks further clarification from the Executive as to the vires of article 3(5).

The Committee also seeks clarification of the use of the word “they” at article 4(1) of the Order. The Committee notes that a Partnership is referred to in the singular throughout the rest of the Order and seeks explanation of the use of “they” in this instance."

The Scottish Executive responds as follows:

1. In relation to the Committee’s first point, we are of the opinion that paragraph 3(5) of Schedule 2 to the Order is intra vires. We view this provision as being within the enabling power at section 1(2)(e) of the Transport (Scotland) Act 2005 which states that the Scottish Ministers “shall provide as to the determination of questions for decision by the Transport Partnership.” The mechanism provided at paragraph 3(5) which allows a Partnership to determine “by a two-thirds majority of the votes cast, subject to sub-paragraph (4) above, to amend its standing orders to require that certain specified decisions be determined by a two-thirds majority of the votes cast” is within that enabling power – it is providing as to the determination of questions for decision by the Partnership.

2. We have met the requirement at section 1(2)(e)(iii) (i.e. securing that the minimum voting capacity of all the councillor members of the Partnership is not less than two-thirds of that of its whole membership) in our provision for the number of other members and in our provision as to the weighting of votes of councillor members in Schedule 1 to the Order. The numbers in columns 3 to 5 in that Schedule comply with the requirement at 1(2)(e)(iii) in relation to minimum voting capacity for councillor members. Also, paragraph 3(5) of Schedule 2 to the Order is subject to sub-paragraph (4), the provision on weighting for councillor member votes.
3. The provision at 3(5) allowing Partnerships to change their standing orders to apply a two-thirds majority to certain decisions is a separate issue to the securing of a minimum voting capacity for councillor members which we have secured elsewhere in the Order at Schedule 1.

4. In relation to the Committee’s point about the use of the word “they” at paragraph 4(1) of Schedule 2 to the Order, we concede that this is a grammatical error and is not in keeping with the references in the singular throughout the rest of the Order. However, this point will not affect the legal or practical application of the Order. Accordingly we do not intend to amend the Order to deal with this point at this stage.
The Civil Partnership Act 2004 (Consequential Amendments) (Scotland) Order 2005 (SSI 2005/draft)

On 25th October 2005 the Committee asked the Executive for an explanation of the following matters –

“The Committee notes that articles 5 to 7 of this Order amend the Marriage (Scotland) Act 1977 to provide for civil partnerships to equate with marriage, as regards relationships between persons within specified degrees of affinity.

The Committee is aware of the recent decision of the European Court of Human Rights in B and L v UK which found the UK position in this respect to be in breach of the Convention. Given this decision, the Committee would welcome clarification from the Executive as to whether it considers articles 5 to 7 to be compatible with the Convention and therefore within devolved competence.

The Committee also seeks an explanation of how the Executive considers ECHR matters in the drafting of instruments such as this.”

The Scottish Executive responds as follows –

The Executive is aware of the decision in B and L v UK. In that case the European Court of Human Rights found provisions in the Marriage Act 1949 which acted to prohibit a marriage between a former father-in-law and daughter-in-law to be in breach of Article 12 of the Convention. The Executive’s position is that Article 12 of the Convention does not extend to the status created in the Civil Partnership Act 2004. However, it is recognised that the effect of article 6 and the second part of article 7 of the draft Order amends the law in relation to marriage in section 2(1B) and paragraph 2A of Schedule 1 of the Marriage (Scotland) Act 1977. The Executive intends to withdraw this Order and re-lay it omitting article 6 and the second paragraph of article 7.

Separately the Committee will wish to note the terms of section 1 of the Family Law (Scotland) Bill which is currently at stage 2 in the Scottish Parliament. Section 1 will repeal both section 2(1B) and paragraph 2A of Schedule 1 to the Marriage (Scotland) Act 1977. This repeal will extend to both marriages and civil partnerships. If passed, it is expected that this Bill will receive Royal Assent in January 2006 and come into force in spring of next year.

The Executive confirms that ECHR compliance is always considered in the drafting of instruments and thanks the Committee for its letter.
The Tryptophan in Food (Scotland) Regulations 2005, (SSI 2005/479)

On 25 October, the Committee requested an explanation of the following matters–

“The Executive is asked for clarification as to why the relevant provisions of S.I. 1990/2625 have not been revoked by these Regulations. The Committee would also welcome explanation of whether the drafting of the equivalent UK Regulations affected the drafting of this instrument.”.

The Food Standards Agency responds as follows–

First question
The Agency acknowledges that relevant provisions of S.I. 1990/2625 are not revoked by these Regulations. Although express revocation of spent provisions does not affect the substantive changes made, the Agency agrees that such revocation is good practice. Accordingly it will take the next suitable legislative opportunity to rectify this omission.

Second question
The Agency takes the reference to UK Regulations to mean equivalent Regulations promulgated in respect of England. The Agency’s policy instructions in England and Scotland were identical and hence the form of the Regulations in each case was broadly similar. However, drafting differences appear for example in relation to definitions contained in regulation 2(1) and the application of provisions of the Food Safety Act 1990 in regulation 8.
The Food Hygiene (Scotland) Regulations 2005, (SSI 2005/505)

In its letter of 6 October to Catherine Hodgson, the Committee requested an explanation for the following matters.

1. The Committee requests an explanation of the legal basis of regulation 24, given that it provides for a code of practice to be issued by the Scottish Ministers that has legislative effect. In relation to this matter, the Committee is mindful of the restriction in paragraph 1(c) of Schedule 2 to the enabling power and asks for further explanation.

2. The Committee asks the Executive to confirm that all necessary consents required under the EC legislation have been obtained in respect of the domestic provisions contained in the Regulations and, in particular, in relation to the sale of raw milk.

3. The Committee also asks the Executive to confirm that regulation 23 as drafted is sufficient to achieve its stated purpose, as members note that, where it has been desired to attract section 9 in other Regulations, a fuller adaption has been required.

The Food Standards Agency responds as follows.

1. The power taken to issue a code of practice relates to the guidance of enforcement authorities under the Regulations and is not a power to legislate of new. It is envisaged that a code will demonstrate best practice in the enforcement of the Regulations rather than in any way add to or otherwise alter the effect of the Regulations. The power to direct authorities in regulation 24(2) is consistent with the description in paragraph 1(2) of Schedule 2 to the European Communities Act 1972.

2. The domestic provisions to which the Committee refers are contained in Schedules 3-6 of the Regulations. Schedules 3 and 4 were made pursuant to the discretion afforded to Member States to maintain national rules under Article 17(3) of Regulation 852/2004. Schedule 5 is a national measure made pursuant to Article 1(4) of Regulation 853/2004 in respect of the activities described in Article 1(3)(d) of that Regulation. Schedule 6 is made pursuant to the derogation available to Member States to establish national rules prohibiting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption contained in Article 10(8)(a) of Regulation 853/2004. All of the above measures were notified to the Commission by the Department of Trade and Industry under the Technical Standards Directive on 24 September 2004. The Agency received no comments from the Commission in relation to the proposed measures.

3. The Agency is satisfied that regulation 23 as drafted is sufficient to achieve its stated purpose. In other circumstances it has proved necessary to provide for additional modifications to section 9 to enable it to operate effectively. However, that was not necessary in the present circumstances.
The Smoking, Health and Social Care (Scotland) Act 2005 (Commencement No.1) Order 2005, (SSI 2005/492)

1. On 25th October 2005 the Committee requested an explanation of the following matters which are answered below.

2. The Executive is asked to explain why section 43(4) of the parent Act (Smoking, Health and Social Care (Scotland) Act 2005) has not been cited as an enabling power in the above order.

3. The Executive thanks the Committee for its letter and responds as follows.

4. The Executive accepts that it is normal practice to refer to a provision such as section 43(4) when making a commencement order which appoints different days for the coming into force of different sections of the parent Act.

5. However, while accepting that it may have been preferable to refer to section 43(4) the Executive would draw attention to the following three points -

   Firstly the power to make the commencement order is contained in section 43(3) of the parent Act which was cited in the preamble. Section 43(4) is merely an ancillary provision. It extends the power in section 43(3) to enable different days to be appointed for different purposes. It is not a stand alone power. Accordingly it is not strictly necessary to include it in the preamble and in one view it might be appropriately relegated to a footnote.

   Secondly the Executive considers that if it is necessary to refer to section 43(4) in the preamble this is achieved by the inclusion of the words “and all other powers enabling them in that behalf” in the preamble to the order.

   Thirdly the Executive wishes to make it clear that the fact that section 43(4) was not expressly cited does not invalidate the commencement order. There is no law which provides that an instrument is only valid if all the powers under which it is made are cited in the preamble.