EXPLANATORY MEMORANDUM TO

THE BOVINE SEMEN (ENGLAND) REGULATIONS 2007

2007 No. 1319

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument provides for the collection, processing and distribution of bovine semen within England and for intra-Community trade. In particular, it:

- replaces the Artificial Insemination of Cattle (Animal Health) (England and Wales) Regulations 1985, as amended;
- implements Council Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species;
- simplifies the licensing regime for centres where bovine animals may be quarantined and semen may be collected for intra-Community trade, and use within England;
- simplifies the licensing regime whereby only approved bovine animals may enter collection centres;
- regulates how semen may be processed, stored and transported; and
- Incorporates new fees and charges for services to industry.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The Artificial Insemination of Cattle (Animal Health) (England and Wales) Regulations 1985 had been amended several times as a result of changes to EC Directives.

4.2 They governed the collection, storage, and supply of bovine semen for the domestic market, as well as the training of laypersons in Artificial Insemination (AI) and the carrying out of AI by such persons. The artificial insemination

industry and market has changed significantly since the making of those Regulations, which are now out of step with modern industry practices.

4.3 The last time fees payable under the revoked Regulations were reviewed was in 1992. Further, those fees were not calculated to cover full cost for services rendered to the industry. New fees associated with the new Regulations replace the old Fees regulations

4.4 Annex 1 contains a transposition note for Council Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species, which the 2007 Regulations implement.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 Wales, Scotland and Northern Ireland have agreed to issue similar instruments.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 These Regulations control the collection, processing and storage of semen eligible for trade in England and with other member States of the European Union. It also ensures the health status of donor animals. The revoked Regulations were no longer in line with modern industry procedures and practices. Further, the fees charged have not been reviewed since 1992.

7.2 A working group which consisted of Defra officials, SVS, Devolved Administrations and industry representatives was set up to carry out this review and prepare the Bovine Semen (England) Regulations 2007 and its associated new Fees and charges.

As well as having industry representatives on the working group, once a draft of the new Regulations was available it was discussed with a wider, but selected, industry group as a “litmus test” at a meeting on 7 April 2004. The proposals were welcomed although there was mixed views about the two additional regulatory measures due to the increased costs they would impose. It was decided that the whole industry should be given the opportunity to air their views on issues raised by the select group.

A public consultation was then carried out between 16 July and 8 October 2004. From the responses received, the industry generally supported the proposals although issues were raised with regard to the increased costs which would be

involved, due to the introduction of 2nd series tests for diseases and the level of record keeping. Further meetings were held with industry to discuss these issues and revised sets of proposals were constructed following decisions made in light of the consultation responses, meeting with industry and meetings held with both senior veterinary and policy officials. We have continued to keep the industry informed of progress and decisions by issuing several Customer Information Notes.

A copy of the response to the public consultation and analysis is available Defra Information Resource Centre, Lower Ground Floor, Ergon House, c/o 17 Smith Square, London SW1P 3JR.

7.3 We will be informing the industry of the coming into force of the new regulations by issuing a Customer Information Note (CIN) six (6) weeks before the regulations are due to come into force. The guidance sets out all the changes involved in the process of gaining approval both for bovine animals and centres.

7.4 The new Regulations do not themselves create new offences, although non-compliance will be an offence under section 10(6) of the Animal Health and Welfare Act 1984.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum which contains the new requirements for which bovine semen trade within England were negotiated.

9. Contact

Simon Qasim at the Department of Environment, Food and Rural Affairs Tel: 020 7904 6941 or e-mail: simon.qasim@defra.gsi.gov.uk can answer any queries regarding the instrument.

Annex 1

6 March 2007

Council Directive 88/407/EC laying down the animal health requirements applicable to intra-community trade in and imports of semen of domestic animals of the bovine species

TABLE SHOWING TRANSPOSITION OF THE DIRECTIVE BY THE BOVINE SEMEN (ENGLAND) REGULATIONS 2007

Note: Where Directive article refers to Directive schedule, and the schedule is transposed in schedules to the Regulations, the Regulation schedule is shown against the Directive schedule, not against the cross referring Directive article

Directive Article	**Regul-ation reg**	**Subject**	**Comments**
1	-	Introduction	
2	2	Interpretation	
3(a)	4, 30	Collection, processing, and/or storage in approved collection or storage centres	Export qualifications
3(b)	7, 19, and 21 (Reg 21 for teaser animals)	Health status of bulls	
3(c)	20, 24, 25, 26, 27	Collection, processing, storage and/or transport	
3(d)	30(2)	Animal health certificates	
4		Admission to England of semen form bulls vaccinated against foot and mouth disease	Admin action (Products of Animal Origin Regulations)
5(1) first para	4(a), (b)(i), (c)(i)	MS to licence collection & storage centre only where Annex A & rest of Directive observed	
5(1) second para	40 34, 35	Supervision by official vet; Suspend licence if Directive not complied with	
5(2) first para	6(1)	Centres to be registered and given licence number.	Administrative action: inform Commission and other member States
5(2) second para	-	EC legislative procedure	
6	-	Admission of semen from another	Administrative

		member State	action
NO ARTICLE 7			
8	-	Imports from 3rd countries	Administrative action (Products of Animal Origin Regulations)
9	-	Imports from 3rd countries	EC action
10	-	Imports from 3rd countries	Administrative action (Products of Animal Origin Regulations)
11	-	Imports from 3rd countries	Administrative action (Products of Animal Origin Regulations)
12	-	Imports from 3rd countries	Administrative action (Products of Animal Origin Regulations)
NO ARTICLE 13			
NO ARTICLE 14			
15		Checks in member State of destination	Administrative action (Animal and Animal Products Regulations)
16(1)	-	Checks by EC vets authorised	Administrative action
16(2)	-	Implementation procedure	EC action
17	-	Legislative procedures	EC action
18	-	Legislative procedures	EC action
NO ARTICLE 19			
20(1)	3(4)	Not apply to semen collected before 1 Jan 1990	
20(2)	-	No preferential treatment for third country semen	Administrative action (Products of Animal Origin Regulations)
21	-	Implementation by 1 Jan 1990	Admin action
22	-	Addressed to MS	Admin action

ANNEX A CHAPTER I			
Para			
1(a)	6(1)(d), 15(1)(a), (b)	Semen collection centre permanently supervised by authorised centre vet	
1(b)-(f)	Schedule 1 Part 2	Requirements for EC collection centre	
2(a)	6(1)(d), 15(1)(a), (b)	Semen storage centre permanently supervised by authorised centre vet	
2(b)-(c)	Reg 16 (c), Sched 1 Part 3	Requirements for EC storage centre	

ANNEX A CHAPTER II			
1(a) first sentence	Reg 12(1)	Only bovines in centre.	
1(a) second sentence	Reg 12(2)	Other species admitted if no risk and authorised by centre vet.	
1(b)	Reg 13(2)	Record of bovines at centre	
1(c)	Reg 40	Centre inspected twice a year by official vet	
1(d)	Reg 11	Only authorised persons enter & must comply with conditions of centre vet	
1(e)	Reg 15(2)	Employ technically competent staff suitably trained	
1(f)(i) first sentence	Sched 3 Part 3 paras 1(a)(i) & (ii), 1(c)	Only certain semen processed at EC collection centre	
1(f)(i), second sentence, first indent	Sched 3, Part 3, para 1(a)(iii)	Tests on bulls whose semen not collected in centre but can be processed there	
1(f)(i), second indent	Reg 25; Sched 3, Part 3, para 1(b)	Separate equipment used, or at a different time and the equipment is cleaned and sterilised after use	
1(f)(i), third indent	Reg 30(1)(a)(i) Sched 3 Part 3 para 1 (c)	Such semen cannot be traded with other member States "EC" semen not come into contact with nor stored with other semen processed at the centre	
1(f)(i), fourth indent	Sched 3 Part 3 1(b)(ii)	Non – "EC" semen identified by distinct mark	
1(f)(i) final para and three indents	Sched 4, para 2	Embryos may be stored at storage centres	

1(f)(ii)	Reg 4 (b)(i), (c)(i), Reg 30	Collection, processing, storage only takes place on licensed premises.	
1(f)(ii)	Reg 15 (1)(c), (d)	Hygiene standards maintained	
1(f)(iii)	Reg 25	Instruments disinfected/sterilised before use; single use instruments	
1(f)(iv)	Sched 3 Part 3 para 1(d)	Products of animal origin used in processing to present no risk.	
1(f)(v)	Reg 26	Storage and transport containers are sterilised or disinfected before use, apart from single use container.	
1(f)(vi)	Sched 3 Part 3, para 1(e)	Cryogenic agent not used for other products of animal origin	
1(f)(vii)	Sched 3, Part 1, para 2 Sched 3 Part 3 para 1(f)	Marking of semen	Communication of marking to Commission and other MS – admin action
1(f)(viii)	Reg 4(b)(i), Sched 1 Part 2, para (a)(iv), Regs 26, 27	Storage unit of collection centre must comply with conditions for storage centre	General conditions relating to EC storage centres are captured since they also apply to EC collection centres.
2(a)	Reg 14	Records of semen movement and health status of bulls	
2(b)	Reg 40	Bi-annual inspections	
2(c)	Reg 11	Unauthorised persons not enter; comply with centre veterinarian's instructions	
2(d)	Reg 15(2)	Competent, trained staff	

2(e)(i) first para	Sched 4 para (1)(b)(i)	Only semen at EC collection centres may be stored in EC storage centres	
2(e)(i) second para	Sched 4 para (1)(b)(ii) Reg, 26 & 27	Movement between EC storage centres Conditions of transport into storage centre	
2(e)(i) third para	Sched 4 para 2	Deep frozen embryos may be stored at storage centres	
2(e)(ii)	Reg 4(c)(i), Reg 15(1)(c), (d)	Only stored on licenced premises under appropriate levels of hygiene	
2(e)(iii)	Reg 25	Instruments disinfected/sterilised	
2(e)(iv)	Reg 26	Transport and storage containers disinfected/sterilised/single use	
2(e)(v)	Sched 4, para 1(c)	Cryogenic agent has not been used previously for products of animal origin	
2(e)(vi)	Sched 4 para 1(d)	Marking of semen	Communication of marking to Commission and other MS is admin action

ANNEX B, CHAPTER I			
Para 1(a)	Reg 22(3), Sched 8 Part 1 para (a)	Quarantine before movement to EC collection centre	
Para 1(b)	Reg 22(2)	Herd officially brucellosis and tuberculosis-free before movement to quarantine.	
Para 1(c) first para	Sched 2, para 1(1) and 1(2)	Tests – EBL	
Para 1(c) second para	Sched 3 Part 4, para 4	Semen quarantine on account of EBL	
Para 1(d) first para, and sub-paras (i) – (v)	Sched 2, para 2(1)	Tests before quarantine	
Para 1(d) second para	Sched 2, para 2(2),(3), (4)	Consequence of positive results	NB consequence of positive serological test for BVD/MD is in Sched 2 para 4
Para 1(e)(i)	Sched 2, para 3(1)(a)	Test - brucellosis	
Para 1(e)(ii)	Sched 2, para 3(1)(b)	Test – IBR/IPV	
Para 1(e)(ii) second para	Sched 2, para 3(2)	Consequences of positive test	
Para 1(e)(iii)	Sched 2, para 4, 5	Test – BVD/MD	NB record keeping and transmission requirement
Para 1(e)(iv)	Sched 2, para 3(1)(c)	Test – Campylobacter fetus ssp. Venerealis	
Para 1(e)(v)	Sched 2, para 3(1)(d)	Test – Trichomas foetus	
Para 1(e) final part	Sched 2, para	Consequences of positive tests	

	3(2)		
Para 1(f)	Sch 3 Part 4, para 1	Further tests for BVD/MD, consequences of positive result	
Para 2	Reg 18	Tests only in approved laboratory	
Para 3, first sentence	Regs 12(1), 22(1)	Introduction of bovine animals to be expressly authorised by centre vet	
Para 3, second sentence	Reg 13	Movement of bovine animal to be recorded	
Para 4, first sentence	Reg 19 (c)	No admission if clinical signs of disease	
Para 4, the rest	Reg 22(3), (6) Sched 8 Part 1, para (a)	Condition of quarantine centre (ie, isolated from disease)	
Para 5, first sentence	Reg 22(3), Sched 8 Part 1, para (b)	Movement of bovine animal between centres	
Para 5, second sentence	Reg 23(1)	Means of transport of bovine animal	
Para 5, last sentence	Reg 23(2)	Movement of bulls between member States	

ANNEX B, CHAPTER II			
Para 1	Sched 3 Part 2	Routine annual tests	
Para 1(a)	Sched 3 Part 2 para 1(1)(a)	Test – tuberculosis	
Para 1(b)	Sched 3 Part 2 para 1(1)(b)	Test – brucellosis	
Para 1(c)	Sched 3 Part 2 para 1(1)(c)	Test – enzootic bovine leukosis	
Para 1(d)	Sched 3 Part 2 para 1(1)(d)	Test – IBR/IPV	
Para 1(e) first para	Sched 3 Part 2 para 1(1)(e)	Test – BVD/MD	
Para 1(e) second para	Sched 3 Part 2 para 1(4)	Consequence of positive BVD/MD test	
Para 1(f)	Sched 3 Part 2 para 1(2), (3)	Test – campylobacter fetus ssp venerealis	
Para 1(g)	Sched 3 Part 2 para 1(2), (3)	Test – Trichomonas foetus	
Para 2	Reg 18	Tests only in approved laboratory	
Para 3, first para.	Sched 3 Part 2, paras 2(1), 3	What to do in event of positive test	
Para 3, second para.	Sched 3 Part 2, para 2(2)	Treatment of semen in event of positive test (other than for BVD/MD)	

ANNEX C			
Para 1(a)	Reg 19 (c)	No clinical sign of disease when semen is collected	
1(b)	Sched 3, Part 4, para 5	Effect of foot and mouth vaccination between 30 days and 12 months before collection	
1(c)	Reg 19(d)	Not vaccinated against foot and mouth vaccination within 30 days before collection	
1(d)	Reg 19 (f)	Conditions with regard to supply of fresh semen	
1(e)	Reg 19 (e)	Cannot serve naturally	
1(f)	Reg 20(2)(a), (b) Sched 3, Part 4 para 3	Collection centre or unlicensed premises which are free from foot and mouth. Semen quarantine to ensure that premises of collection remain free of foot and mouth post collection	
1(g)	Reg 20(2)(c) Sched 3 Part 4 para 3	Collection centre or unlicensed premises which are disease free. Semen quarantine to ensure that premises of collection remain free of foot and mouth post collection	
Para 2, first & second para	Sched 3 Part 3 , para 3	Adding antibiotics	
Para 2, final para	Sched 3 Part 3 , para 4	Temperature control	
Para 3(a)	Sched 3 Part 4 para 2	30 days' quarantine for frozen semen before dispatch	
Para 3(b)	Reg 26 Sched 4, para 1(d)	Clean/ disinfected/ sterilised containers Doses identified.	
Annexes D	-	Form of certificates	Admin action

Annex 2

Regulatory Impact Assessment

1. Title of Proposal

The Bovine Semen (England) Regulations 2007.

2. Purpose and intended effect of measures

(i) The Objective

The Bovine Semen (England) Regulations 2007 (hereinafter referred to as the "control regulations") (Appendix 1) seek to minimise the animal health risks that are potentially associated with the collection, processing and storage of bovine semen for the domestic (UK) market. In doing so, the control regulations aim to be proportionate to the disease risks involved, to be guided by the best scientific information available and to avoid the imposition of unnecessary burdens (whether these be financial costs or other restrictions) upon the industry. The control regulations endeavour to clearly set out what is required of those to whom they apply whilst being both fair and enforceable.

The control regulations also introduce transparency into the monitoring and enforcement mechanisms for EU controls on bovine semen production etc. intended for intra-Community trade (as laid down in Council Directive 88/407 as amended and implemented via The Animal and Animal Products (Import and Export) (England) Regulations 2004 and the Products of Animal Origin (England) Regulations 2004) and enforced by the Artificial Insemination of Cattle (Animal Health)(England and Wales)(Amendment)(England) Regulations 2004. Such mechanisms had not previously been suitably set out. These measures are not the subject of this RIA, having previously been assessed and agreed during discussions to amend Council Directive 88/407.

The new control regulations now contain fees that have been constructed to be equitable and transparent on how industry would be charged for any official services provided as a result of requirements coming from the control regulations. The aim of the fees and charges is to achieve full economic cost recovery as laid down in Treasury Guidance, subject to cost sharing principles laid out in the Animal Health and Welfare Strategy for Great Britain published on 24 June 2004.

(ii) The Background

a. Current Legislation

This regulatory impact assessment is associated with the revision of two pieces of legislation:

1. The Artificial Insemination of Cattle (Animal Health) (England and Wales) Regulations 1985 (as amended).

2. The Artificial Insemination (Cattle and Pigs) (Fees) Regulations 1987 (as amended).

Despite their respective amendments both of these pieces of legislation are now outdated. There have been marked changes in both the structure of the bovine semen industry and the environment in which it operates since the 1985 Regulations were introduced (and amended).

There have been parallel advances in both scientific knowledge and the techniques employed by the industry. Therefore there is an urgent need for the revision of the 1985 Regulations (as amended) to bring them back into alignment with the environment within which they must function.

The details for approval and content of AI training courses has also been reviewed and a new Exemption Order will be introduced at the same as the new Bovine Regulations under the Veterinary Surgeons Act (VSA). This will regularise and put on a legal footing the status of non-veterinarians performing AI in terms of the VSA and will mean that all controls on the carrying out of AI are in one place rather than being split between the two pieces of legislation.

Controls on the advertisement in England of semen from bulls of dairy breeds and the specific information to be included in such advertisements are detailed in the new regulations and will revoke the Artificial Insemination of Cattle (Advertising Controls etc.) (Great Britain) Regulations 1987. These Regulations are out of date and have not been enforced for some time. Instead, action on misleading or inaccurate advertising can be taken under trading standards legislation

The 1987 Fees Regulations have not been updated or amended since 1992. As such, they do not provide for the full recovery of the financial costs to Government of regulating the bovine and porcine semen industries. With the new control regulations being proposed it would seem sensible to review those costs to Government associated with the regulation of the bovine semen industry. Following Cabinet Office guidelines on better regulation, the need for separate legislation detailing the fees has been deemed to be no longer necessary and this information will now be contained within the main body of the control regulations.

b. The Industry (licences: Chief Veterinary Officers Report – 2006 Figures)

The bovine semen industry is effectively structured around the flow of semen from its point of collection, through processing and various stages of supply and storage to its use in inseminating a recipient cow, usually on farm.

In contrast to semen eligible for intra-Community trade, which may only be collected at a semen collection centre (SCC) approved to EC defined standards, semen which is eligible for domestic trade may be collected either on an approved domestic SCC or on farm.

(See Appendix 2 for diagrams of current and proposed regulated cover for Industry. See Appendix 3 for the glossary of terms)

There are currently two domestic SCCs in England. The demand for domestic SCCs arises primarily from the inability of some bulls to comply with the full requirements demanded for the collection of semen for intra-Community trade (as laid down in Council Directive 88/407/EEC as amended), primarily with respect to Bovine Tuberculosis (TB) and also Infectious Bovine Rhinotracheitis (IBR). Stricter EC controls mean that any donor animal that has ever been in a herd of a lower health status, e.g. TB restrictions having been applied, means that they will never be able to be collected from. Domestic controls applying to domestic SCCs will allow for such animals to be collected from, provided that the semen is traded only within the UK (the new regulations will maintain this domestic arrangement).

IBR is endemic in the UK national herd and the requirement that, for the purposes of intra-Community trade, a donor bull must be tested with negative results for antibody to IBR effectively excludes many bulls from which the industry wish to collect semen from EC approved SCCs. Domestic SCCs may contain IBR positive animals with the condition that

samples of each ejaculate are tested to ensure the absence of the virus causing IBR. Both domestic SCCs in England contain only IBR positive animals (– the new regulations will deregulate testing for this disease at domestic centres). Seventy-six bulls were moved onto domestic SCCs in England during 2006.

On-farm semen collection represents the alternative to sending a bull to a SCC where semen is not intended for intra-Community trade. Forty bulls were approved for on-farm collection in England during 2006. Semen collected on-farm is subject to such limited processing as is necessary to maintain it during transport to the laboratory where it is to be processed for long term storage.

The laboratories processing bovine semen are associated with collection centres. Here the semen is evaluated before being diluted with a solution containing a variety of compounds including an energy source and antibiotics required to support the spermatozoa and protect the health status of the semen during the period before its use. The vast majority of semen used in bovine artificial insemination is then frozen as individual doses in narrow sealed tubes called 'straws'. It is in this form that such semen is distributed.

The structure within which bovine semen is distributed to the domestic market has evolved to assume its current complex state over a number of years. Most semen is initially stored in a main store (of which there are 4 in England). From here semen may be transferred to a semen supply centre (40 in England), a semen shop (13 in England) or a farm storage unit (6463 in England). The exact route of distribution may involve one or more of these latter types of unit. However, in most instances, distribution of semen and the operation of those carrying out insemination, may currently only take place within designated geographical zones. Zones were originally introduced as a precautionary measure to limit the risk of spread of diseases. In particular the risk of Foot and Mouth Disease was the greatest concern due to the ease with which it spreads. Zones can also be seen as an anti-competitive measure by allowing businesses to set up a monopoly with regard to the supply of semen or insemination services.

(iii) Risk assessment

A number of diseases of cattle can be transmitted in semen. **Appendix 3.2.1** of the Office International Epizooties (OIE) Terrestrial Animal Health Code (2006) recommends the testing of all bulls whose semen might enter international trade for the following diseases:

- Bovine brucellosis
- Bovine tuberculosis
- Bovine viral diarrhoea-mucosal disease (BVD-MD)
- Infectious bovine rhinotracheitis – infectious pustular vulvovaginitis (IBR/IPV)
- *Campylobacter fetus* subsp. *venerealis*
- *Trichomonas foetus*.

All of these diseases will have significant animal health and production costs in any bovine herd in which they occur. Great Britain is currently officially free of bovine brucellosis and an outbreak of this disease would have significant cost implications, including international trade, for both Government and the cattle industry as a whole.

By far the most likely mechanism by which semen itself may become the means of transmission of one of the above diseases is if it is collected from a bull at the time of an active infection in that animal. It therefore follows that if the donor animal can be tested prior to collection such that the risk of it being infected is negligible then the animal health risk associated with the

collected semen is also negligible provided that the collection and processing of the semen takes place under high standards of hygiene.

Once semen is frozen within a straw, it is largely protected from internal contamination with a pathogen. Any animal health risk associated with the subsequent use of such semen is the same as that associated with the movement of any item susceptible to surface contamination between livestock units. As such it would be inappropriate to subject bovine semen to restrictions not placed upon other comparable entities of equivalent risk.

The principle therefore adopted by the proposed control regulations is to seek to minimise, in so far as is reasonably possible, the health risks associated with the collection of semen from donor animals at SCCs and at unlicensed premises (e.g. On-farm collection). It is also to ensure the hygienic collection and processing of bovine semen whilst removing the majority of the current controls on the distribution of such semen on the domestic market, including the restriction of movement within specified zones.

The compulsory quarantine of frozen semen for a minimum of 30 days before use or distribution acts as a further safeguard against the risk of disease not identified in the donor animal at the time of collection.

Fresh semen (i.e. semen that has been processed but is not frozen) represents a greater animal health risk than frozen semen since it cannot be quarantined, having an effective life of only a few days. In the case of fresh semen collected from animals resident in an SCC this potential risk is mitigated by the high health status of the centre and the high levels of bio-security that effectively minimise the risk of the exposure of the donor animal to pathogens of concern.

Fresh semen collected from bulls' on-farm presents an even greater problem. Experience has shown that it is impossible to guarantee the same levels of bio-security on-farm that can be maintained on a SCC. In the case of fresh semen and consideration of the animal health risk involved has led to the proposal that the distribution of semen, collected on-farm (unlicensed premises) should be limited to frozen semen.

3. Consultation

(i) Within Government

The National Assembly of Wales, Scottish Executive Environment and Rural Affairs Department, Department of Agriculture and Rural Development Northern Ireland, the States of Jersey Department of Agriculture and Fisheries, Cabinet Office, Small Business Service and Office of Fair Trading have been consulted and their comments taken on board.

(ii) Public consultation

Comments on the proposals through informal consultation were sought from selected industry representatives. The industry generally supported the proposals and the improved health status of the animals it would bring. The public consultation exercise was carried out between 16 July and 8 October 2004.

Resulting from responses received from the consultation exercise, and in discussions on these responses with industry representatives held on the 10 November 2004, the proposals have been revised to make industry more responsible for assuring the quality of their bovine semen products. Testing for notifiable diseases (TB, Brucellosis and EBL) will remain under statutory control for bull approvals (including teaser animals) and for tests at routine inspection of animals at approved collection centres. Testing for non-notifiable diseases including IBR, BVD/MD, Campylobacter and Trichomonas (and for any other possible pathogens) will be deregulated and be made the industry's responsibility whether to test for (as best practice) or not – as this is purely a commercial decision they could make to assure the quality of their semen products (although these tests could be included with any future farm health plans). Therefore separate guidance is to be issued (Customer Information Note) in tandem with the regulations being agreed by Ministers for industry to prepare for the introduction of the new regulations. This guidance will:
1: instruct those concerned on what testing is legally required for AI purposes, and
2: what testing would be best practice to better assure quality of their semen products.
Another issue of concern brought up in some responses received was the issue of record keeping. Record keeping requirements have been tightened so that any person who receives supplies or uses semen for AI shall keep those records for a period of at least two years. This is essential for tracing purposes in the event of any major disease outbreak – and will be enforced through the regulations.

Updates

In order to ensure that the industry and stakeholders are aware of the issues and areas of work being taken forward in our proposal, we have continued to send out Customer Information Notes and hold formal and informal meetings on a regular basis. The industry is therefore fully armed with the proposals as outlined within the new Bovine Semen Regulations.

4. Options

(i) The Bovine Semen Regulations (England) 2007

Option 1: Do nothing, i.e. make no revisions to the existing AI of cattle regulations.

> This option would do nothing to resolve the existing tensions arising from the imposition of regulations that are markedly out of step with the industry that they regulate. The need to revise the existing regulations has been publicly acknowledged for several years and the continued failure to deliver this work would be the source of significant criticism, both from the industry itself and from those working with it.

Option 2: Introduce new control regulations, which seek to minimise the risk to the health status of donor animals for major notifiable diseases, along with the hygienic collection, processing and storage of semen produced for the domestic market; these regulations will also introduce proportionate risk based controls that will allow for a reduced level of regulation or deregulation where possible for certain areas within the bovine semen industry's production and supply chain.

This option has the benefits of addressing current concerns regarding flaws in the current requirements for the testing of bulls from which semen is collected for domestic trade, whilst permitting a significant reduction in the level of regulation imposed upon what is, a large proportion of the industry. It provides the opportunity to align the legislation with both the environment within which it operates and with the best current scientific knowledge available. Discussions to date indicate that this is the preferred option for the vast majority of stakeholders and it is therefore the recommended option to take forward. This option is in accordance with the Animal Health and Welfare Strategy and reflects the Department's commitment towards working in partnership with industry to achieve our main goal of improving the health status of donor animals without the burden of regulations.

Option 3: Withdraw from all regulation of bovine semen collection, processing and storage for the domestic market - effectively handing over all responsibility to controlling the animal health risks associated with these practices to the industry.

While potentially attractive to Government, this option would only be viable if it can be certain that complete separation can be maintained between semen collected for the domestic market and that collected for international trade. Any significant failure to do so would potentially compromise the latter. Similarly, there remains a need for a reliable audit trail regarding supplies of bovine semen. Should there be a disease outbreak (such as FMD or a possible new zoonotic disease) it will become vitally important to identify the whereabouts of possible "at risk" semen. Such certainty does not exist at this time. Moreover it is questionable as to whether the industry is ready to accept such a position at this time and it may be better to consider this a long-term goal rather than a current option.

(ii) Revise Fees and Charges

Option 1: Do nothing, i.e. make no revisions to the existing Artificial Insemination (Cattle and Pigs) (Fees) Regulations 1987 (as amended).

This option will not provide up to date costs for administrative and veterinary time and other overheads spent in bull approvals, licensing of premises and in inspection. This option would not provide full economic cost recovery.

Option 2: Introduce the new fees and charges so as to ensure that the full financial costs of regulation to Government with regard to bovine semen controls are recovered.

This option will provide up to date charges and rates in which to retrieve full costs for official services provided. The fees will be calculated to be fair and transparent, subject to cost sharing principles laid out in the Animal Health and Welfare Strategy for Great Britain. In accordance with better regulation requirements, the principles for the new fees and charges are now included in the new Bovine semen Regulations.

5. Cost and Benefits

(i) The Bovine Semen Regulations (England) 2007

Option 1: Do nothing, i.e. make no revisions to the existing AI of cattle regulations.

- This option would not alter the animal health risk nor would it reduce the risk of a disease outbreak on the domestic market due to bovine semen.

Option 2: Introduce the new control regulations.

- This option would benefit the industry by better assuring the health status of donor animals with regard to the major notifiable diseases and therefore the semen collected and processed for the domestic market.
- Reduced amount of testing required for the domestic market by the new regulations**.** This decision was reached after a risk assessment was carried on the three (TB, Brucellosis and EBL) of the statutory tests out of the six tests usually carried out on animal for domestic collection. TB, EBL and Brucellosis will continue to be tested for compulsorily while the remaining three will be tested for on commercially basis – thus making it the industry's responsibility to test for any other pathogen outside the regulations to assure quality of their products e.g. testing for IBR, BVD, Trichomonas and Campylobacter (that have been removed from regulatory control).
- The removal of geographical zones on the movement of semen would both remove unnecessary restrictions and open up the industry for competition.
- The proposal allows for the option for bull owners/Centre operators to have the choice which veterinarian (either the Centre Vet named on the licence of the Centre, Local Vet Inspector or a SVS Official Vet) they wish to employ to carry out sampling depending on their business preferences.
- The distribution chain, after the main store down, would be largely deregulated, with the exception of record keeping requirements, as they present a significantly lower disease risk. The result would be that deregulated businesses would no longer require licences; would no longer be subject to routine official inspection and would not have to pay fees associated with the obligations previously placed upon them.

The distribution chain being largely deregulated would mean that if you look at licences previously issued in the table below there would be a cost saving (as a total) of £564,822.00 (of those licences issued to date – end 2005). There would be annual savings to all those businesses of £7,490.00 in routine inspections – from all those currently licensed and inspected on a routine basis (see table below). Note these figures are all based on 1992 prices – these would be significantly higher if they were brought up to date - in line with inflation, rises in overheads etc.

Table to Show Cost Saving to Industry through the Deregulation (removal of licensing and inspection requirements) of the Distribution Chain

Note: Figures are composite figures (see 7 below) with no reduced fees considered - from the current Fees regulations. The number of licences and inspection figures taken from the Chief Veterinary Officer's Report – to date end 2006.

Activity (Service provided)	**Current Cost**	**Proposed Cost**	**Potential Cost Savings to Industry**
Licences Approved = 6530	40 (supply shops) @ £208.00 = £8,320.00 + 13 (semen shops) @ £208.00 = £ 2,704.00 + 14 (Farm storage servicing licenses) @102.00 = £1,428.00 + 6463 (Bovine semen storage unit + Note the record of all storage units to date) @ £91.00 =£588,133.00	Deregulated – No costs incurred	**£600,585.00** (Overall Approximation)
Inspection of licensed premises	40 Supply centre @ £70 x 2 (inspected twice a year)= £5600.00 + 13 Semen shops @ £70 (inspected once a year) = £ 910.00 + 14 Farm storage servicing licenses @ £70 (inspected once a year) = £980.00	Deregulated – No costs incurred	**£7,490.00** (Annual Approximation)

(Current costs calculate all those premises licensed under the current regulations being multiplied by the current full cost of approval and inspection. Based on current charges which are at the 1992 rates: of the current fees regulations)

Option 3: Withdraw from all regulation of bovine semen collection, processing, storage and supply.

This would benefit those producing semen for the domestic market, as they would not be tied to any fixed set of testing requirements, record keeping, inspection etc. But this would put into question the clear distinction necessary between production for the domestic market and production for the international market. Without such a clear distinction the highly lucrative international market could be jeopardised.

(ii) Revise Fees and Charges

Option 1: Do nothing, i.e. make no revisions to the existing Artificial Insemination (Cattle and Pigs) (Fees) Regulations.

- The benefits to industry of doing nothing are that they would continue to gain access to the services currently provided by government without being charged the true costs of these services.

Option 2: Introduce new fees and charges.

- Cost-recovery - would allow for full cost recovery. The costs will be borne by the economic beneficiary rather than by the taxpayer.
- Fees would be both fair and transparent - under the present regulations, there is one fixed fee covering both administrative and test costs. With the new Bovine Semen Regulations, the charges are fixed for both Departmental administrative services, and Departmental veterinary services. The veterinary sampling and inspection service will be charged for at an hourly rate. This breakdown allows for an accurate calculation of costs for those receiving the services provided. Note: the additional fieldwork charge only applies when Departmental officials are engaged to provide services, when CVs or LVIs are engaged the beneficiary only incurs an administrative charge.
- Those parts of the industry that present a very low risk with regard to disease spread, and which under the proposed control regulations would be largely deregulated, would not have to pay for licences, inspections etc.

(iii) Sectors affected

The introduction of the new control and fees regulations will have an effect on all currently licensed operators/premises. The new regulations propose to largely deregulate the distribution chain of the semen market down from the main stores. This would have a positive affect on those businesses presently licensed to perform the function of: semen shop, semen shop store, supply centre, supply centre store, farm storage servicing facilities, transfer of bovine semen and special farm storage movement licences. Licensing and inspection requirements, along with fees charged, would be removed.

All businesses that receive, supply or use semen for AI will be required to keep a record of all semen kept in their possession for a period of at least two years to ensure effective traceability of the product in case of a disease outbreak. Whilst this is unlikely to affect the larger centres that will have recording procedures in place, it is likely to impose an additional burden on the smaller businesses, although this should be in place anyway for effective herd management.

Domestic SCC and collection on-farm will be affected by the new control requirements, as there will now be a reduction in the amount of official tests required. New testing requirements will cover only tests for TB, Brucellosis and EBL. It is proposed that it will be the industry's responsibility to assess the need to control pathogens or controls not covered by the legislation and to define and implement such interventions (for example pre-collection quarantine and health testing for other diseases) as and where considered appropriate by them.

In summary the main sectors of the industry (trading for the domestic market) that would be affected are:

- *Domestic Collection Centres – which also carry out processing (2***)**
- On-Farm collection – (40 bull approvals)
- Main Store (4)
- Semen Shops (13 – to be deregulated except record keeping)
- Supply Centres (40 – to be deregulated except record keeping)
- Bovine Semen Farm Storage Units (approx 6463 – to be deregulated except record keeping)
- Bovine Farm Storage Servicing Licences (14 – to be deregulated except record keeping)

(In brackets: The above are total licence figures as at 31 December 2006 ref: Chief Veterinary Officers Report)

Costs

Introductory Notes: It must be emphasised that any comparison between the current and proposed fees regulations would in no way be accurate. This is due to the difference in the way that each set of fees have been calculated and presented – it follows that there could not be any sort of creditable comparison between these sets of costs. With the current fees regulations costs are a composite of many different factors that include actual VLA test costs, vet sampling time and travel, Department administration, overheads etc.

The new fees regulations have been constructed to break composite costs down to be fair, transparent and equitable. Departmental administrative time has been calculated to give an accurate fixed figure to charge the beneficiaries.

Official veterinary time spent on travelling to and from premises, and spent on inspection and sampling varies greatly from case to case so that the most practical way to calculate the field work fee, is to provide chargeable rates for the service that include travelling expenses. This makes the costs invoiced to individuals or businesses more accurately reflect the actual time spent providing the service.

In the worked examples that follow, relating to bull approvals, it is presumed that the applicant chooses to use a Veterinary Officer of the SVS to carry out sampling. Where the applicant decides to use either the LVI or centre vets, as a new option available to the industry, the costs are likely to be different and may be either higher or lower than those highlighted in the examples.

(i) The Bovine Semen Regulations (England) 2007

Option 1: Do nothing, i.e. make no revisions to the existing AI of cattle regulations

The costs would remain at the current level, presuming the associated fees regulations were not revised also. Presuming licence applications etc. remained the same in future years, as they were in 2004, the industry would pay a total of some £14, 500 per year (approximation as 10% - for the domestic market only - of the annual income: from the Out Turn Memorandum Trading Account 2003/4). However, the cost to the Department, to bridge the gap between receipts and costs, would be £30, 000 per year (approximation as 10% - for the domestic market only - of the annual full costs incurred: from the Out Turn Memorandum Trading Account 2003/4) and would continue to increase with inflation.

Option 2: Revise the existing AI of cattle regulations.

a. Sampling costs

Under the new proposals the industry will have the choice of contracting either a Veterinary Officer of the SVS, a LVI or a centre veterinarian. As the employment of a LVI or centre veterinarian will be subject of a private commercial agreement it is not possible to estimate sampling costs using these service providers. When an SVS Veterinary Officer is chosen, the cost would depend on the time spent on the task and time travelled to the premises. As such fees would be calculated on a case-by-case basis. **An example scenario is given under "typical costs to business"**

b. Laboratory (VLA test) costs

b. (i) Domestic Semen Collection Centre

Under the current testing regime the costs incurred to the collection centre of the pre-entry tests in laboratory charges is £207 in total per animal including both administrative cost and actual test costs (VLA - Domestic Test Charges**)**. With the proposal - only testing for TB, Brucellosis and EBL would be required. The new testing regime would mean that total costs incurred would be approximate (as there is no exact figure for TB Test kits – estimate £6) of £24.31 per animal. It is unlikely that bulls would remain on Domestic SCC to be charged the compulsory routine test costs (for the same diseases – TB, Brucellosis and EBL) of £24.31 per animal.

Example of test cost to industry:

a. Domestic Semen Collection Centre

76 Bulls went onto a Domestic SCC last year at a cost of £207 each
207 X 18 =£15,732.00.

Under the new proposal the cost for the same number of bulls will be:

76 X £106 (administrative fees + VLA tests costs) = £8,056.00.00 plus
Charge for field work approximately 5 hours per bull = 5hours at the rate of £82 per hour = 5 X 76 X £82 = £31,160.00

Total cost would be £8,056.00 + £31,160.00 =£39,216.00.

Therefore the estimate cost for a bull approval under the new regulations using an official veterinarian is approximately £516

Please Note: the cost will reduce if more than one bull is tested on a visit, as this will reduce time used by VO.

b. Collection at Unlicensed Premises ("On-farm")

Under the current testing regime the costs incurred to the collection at an on-farm centre (including VLA test costs) is

£207 in total per animal. 40 Bulls were collected from last year.

40 bulls X £207 = £8,280.00

Under the new proposal the cost for the same number of bulls would be:

40 Bulls X 106 (administrative fees, + VLA tests costs) = £4,240.00 plus
Charge for field work approximately 5hours per bull = 5hours X 40 X £82 per hour = £16,400.00

Total Cost would be = £4,280 + £16,400.00 = £20,640.00

Please Note:

- Bull Approval and Centre Licence costs have not been increased in the past fourteen (14) years.
- A high percentage of the cost is for the veterinary official who has to carry out the sampling and also return 3 days later to check the result of the Tuberculin skin test.
- Three out of the five hours estimated for each bull hours have been allocated for travel. Travel time may be less depending on the location of centre, and so if travel time is less then the cost will reduce accordingly.
- The farmer/operator now has the choice of using either an LVI or Centre Vet instead of a veterinary official, which should reduce the cost.

c. Other Recurring Costs

Option 3: Withdraw from all regulation of bovine semen collection, processing, storage and supply.

These costs could not be quantified. A number of different scenarios could arise as a result of deregulation of the domestic bovine semen market, each with different economic consequences.

The obvious one is the outbreak of a notifiable disease and its spread through infected semen. Another could be the loss of lucrative international markets due to the inability to satisfy foreign governments' requests for certain health, auditing and stock separation requirements.

(ii) New Bovine Semen fees and charges as included in the New Bovine Semen Regulations 2007

Option 1: Do nothing, i.e. make no revisions to the existing Artificial Insemination (Cattle and Pigs) (Fees) Regulations.

The fees levied to the Domestic AI industry for services provided would remain at present costs indicated in the present regulations (see 5 (i) Option 1 above).

Option 2: Introduce new fees regulations.

Costs to those sectors of the domestic bovine semen industry, which will continue to be regulated (remembering a significant proportion of the industry is to be largely deregulated) would naturally increase, as fees have not been revised since 1992. However these costs will be fair and reflect current costs that would reflect the services provided to the industry. Actual costs are difficult to estimate as many will be calculated on a case by case basis; however, bearing in mind the assumptions made in the "introductory notes" to this section the following gives some indications of costs to typical businesses:

Costs to typical businesses

The following assessment has been made of proposed costs that give some sort of quantitative measurement of the proposals introduced. These are only very rough estimates and the explanation given, under section 5 "Costs", should be taken into consideration.

Approval for licence of a Domestic Semen Collection Centre

<u>Assumptions</u> – fixed admin price + veterinary official travelling time to and from a centre: 2 hour + 1 hour inspection of premises. Plus any extra inspection required.

Bull approval for collection at unlicensed premises e.g. on-farm

<u>Assumptions</u> – fixed admin and tests cost price + veterinary official travelling time to and from a centre: 2 hour + 1 hour for sampling + 2 hour three days later for Tuberculin skin test.

<u>Table (2) to Show Present and Proposed Costs</u>

Activity	**Present Cost £**	**Proposed Cost £**
EC Bull Approval (bull less than 6 months old)	207	617 (admin + VLA tests costs + 5 hrs of VO's time)
EC Bull Approval (bull over 6 months old)	207	743 (admin + VLA tests cost + 5 hrs of VO's time)
Domestic Bull Approval	207	516 (admin + VLA tests costs + 5 hrs VO's time)
Unlicensed Premises Bull Approval	207	516 (admin + VLA tests costs + 5 hrs VO's time)
EC Quarantine Centre	Part of processing centre	277 (admin + V0's time)
EC Collection Centre	327	617 (admin + VO's time)
Domestic Collection Centre	327	617 (admin + VO's time)
EC Processing Centre	Now part of collection centre	N/A
Domestic Processing Centre	Now part of collection centre	N/A
EC Storage Centre	N/A	236 (admin + VO's time)
Domestic Storage Centre	N/A	236 (admin + VO's time)
EC Main Store	208	N/A
Domestic Main Store	208	N/A
Routine testing of animals at a domestic collection centre	Private arrangement	89
Routine testing of animals at an EC collection centre	Private arrangement	168

6. Consultation with small business: the Small Firms' Impact Test

A Working Group was set up to carry out this review and prepare new Regulations. The group consisted of representatives from Defra, SVS, and the Devolved Administrations and, in line with the aims of the Animal Health and Welfare Strategy of working in partnership, representatives from the bovine semen industry.

The guiding principle for the Working Group was to consider the need for controls, and the possibilities for deregulation, based on perceived veterinary risk. Discussions led us to conclude that by applying proportionate disease control measures at the collection, processing and main storage levels of the production chain, it would be possible to deregulate to a greater extent below these levels within the distribution side of the industry. This has been accepted and included within the proposal.

As well as having industry representatives on the working group, once an acceptable draft of the new Regulations was available it was discussed with a wider, but selected, industry group as a "litmus test" at a meeting on 7 April 2004 (and at a further meeting held to discuss issues during consultation on the 14 September 2004). A further meeting was held post consultation on the 28 November 2004 to further develop the proposed controls.

7. Competition Assessment

The Competition Filter has been applied and the conclusion is that there is no significant risk of impact on competition. A detailed assessment has therefore not been prepared.

In applying the filter the market identified was the Domestic semen industry. Knowledge of this sector indicates that in the whole of the national bovine semen industry the domestic (including On-farm) sector holds only about 20% of the market share, whereas the majority of the market is semen collected for intra-community trade (80%). There is no firm that dominates the domestic semen market and the requirements of the new regulations proposed would fall evenly across the market. The regulations may have some impact on the current market structure, but should not adversely affect new firms compared to existing ones.

Deregulation of the distribution chain and the removal of geographical zones for the movement of semen should open up the market for competition.

Finally, the introduction of these proposed regulations should have no impact on the choice of firms in respect of price, quality, range or location of their products.

8. Enforcement and Sanctions

The proposals update and amend existing controls on bovine semen for Domestic trade. These controls are enforced by Defra through the use of field officers (State Veterinary Service) who approve the licensing of the centres and also carry out routine inspections as required by the new regulations and where suspected breaches of the regulations have

occurred. Defra (through the powers of the Secretary of State) will have the right to suspend or revoke the licence of the offending party, meaning they will not be able to market their products.

9. Implementation and delivery plan

The arrangement is for guidance to be issued to the industry weeks before the new regulations is to be effected. They will also receive flowcharts of the different procedures that will be required by the new regulations. The task of implementing the new policies and ensuring full cost is covered for all services will then be passed to the State Veterinary Services.

10. Post Implementation Review

The arrangement for monitoring and evaluating the effectiveness of the proposal's enforcement regime is to be agreed by senior officers. There is also the need to set a time and a mechanism for recording any complaints received from those affected by the proposals.

The cost of providing these services will be reviewed periodically and appropriate fees/rates applied. Increases in rates will not exceed the level needed to recover the costs of the services concerned and industry will be given reasonable notice of any change.

11. Summary and Recommendation

(i) The Bovine Semen Regulations (England) 2007

Option	Total Cost per year	Benefit
1. Do nothing	Would remain at current levels and would require the Department to continue subsidising the industry.	This option would not alter the animal health risk from trade in bovine semen nor would it reduce the risk of a disease outbreak
2. Review the current Artificial Insemination of Cattle Regulations	The costs could not be realistically quantified due to the new system of calculating fees. However there would be increased costs if VOs are used for taking samples for testing requirements being proposed.	This option would improve the animal health risk from domestic trade in bovine semen and help in reducing the risk of a disease outbreak to a minimum. Deregulation of distribution chain and removing zones for semen movement would benefit the industry
3. De-regulate the domestic industry	There would be no cost to the Department but would have cost implications for	The industry would prefer this but would then be out of official control.

	industry - which could not be quantified. (The loss to industry – as intra-community trade in semen would cease, as this must be under official controls as per the Directives. It would be hard to guarantee any separation between EC and Domestic semen)	

Option 2 is recommended Introducing the new testing regime (controls on the major notifiable diseases only: TB, Brucellosis and EBL) in the regulations and with the industry taking greater ownership for quality assurance of their semen (commercial decision to test for any other pathogens – including those diseases no longer requiring regulatory control e.g. BVD, IBR, Campylobacter and Trichomonas – as there is no national control programs so there little sense in obligating the industry to test for them) would result in significant improvements in biosecurity of Domestic and Unlicensed Premises (e.g. collection on-farms), improve confirmation of health status of animals, and to reduce the risk of a disease outbreak associated with such Centres for which financial consequences could be severe. This would provide better quality assurance and therefore a better guarantee for purchasers of the semen, and may benefit trade. The proposal is proportionate to the disease risk and removes burdens, such as the deregulation of the distribution chain, which does not bring any advantage in disease control terms.

(ii) Bovine Semen Fees and Charges as included in the new regulations

Option	Total Cost per year	Benefit
1. Do nothing	Would remain at current levels and would require the Department to continue subsidising the industry which is running at only a 47.5% recovery rate for the whole AI Industry (Domestic Bovine Industry is approx. 10% of the AI market place)	The benefits of doing nothing are that industry would continue to gain access to the services currently provided without being suitably charged.
2. Review the Artificial Insemination of Cattle and Pigs Fees and Charges Regulations	The costs could not be quantified due to the new system of calculating fees.	This would allow for full economic cost recovery for services provided.

Option 2 is recommended Introducing the updated charging regime would allow for full economic cost recovery for services provided to industry as laid down in Treasury guidance, and in line with the cost sharing principles laid out in the Animal Health and Welfare Strategy for Great Britain published on 24 June 2004 by the Department. These new fees have been calculated to be fair, transparent and equitable. The breakdown of SVS Veterinary Official's time being put into rates incurred by officers providing services, allows for the accurate calculation of costs for those being invoiced for the services provided.

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

***Signed* …Ben Bradshaw**

Date 9th April 2007

Minister's name, title, department

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