

<b>Title:</b> <b>Commission Regulation (EU) No 1276/2011 - Treatment to kill viable parasites in fishery products for human consumption</b>  <b>IA No:</b> FOODSA0033  <b>Lead department or agency:</b> Food Standards Agency  <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>		
	<b>Date:</b> 21/06/2012		
	<b>Stage:</b> Final		
	<b>Source of intervention:</b> EU		
	<b>Type of measure:</b> Secondary		
<b>Contact for enquiries:</b> Steve Hardie			

**Summary: Intervention and Options** **RPC Opinion:** RPC Opinion Status

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as One-Out?
£77.8m	£77.8m	£-8.6m	No
			N/A

**What is the problem under consideration? Why is government intervention necessary?**  
 Freezing is an effective means of killing any parasites in raw fishery products that may pose a risk to consumer health. However, recent scientific evidence and practical experience suggests that the risks to human health from parasites in farmed fish are minimal and there is no longer a clear public health case for continuing to require the freezing of farmed fishery products intended to be consumed raw or almost raw. Government intervention is needed to ensure that EU legislation on parasites in fishery products fully reflects the available evidence and that freezing controls are risk based and proportionate. Government intervention is also required to ensure the UK is fully compliant with EU legislation.

**What are the policy objectives and the intended effects?**  
 The Commission Regulation updates the existing requirements in Regulation (EC) No. 853/2004 concerning parasites in fishery products and introduces a specific freezing exemption for farmed fishery products reared under specified controlled conditions. This will reduce burdens on the UK fish farming industry and address a long standing issue for the UK farmed salmon sector by ensuring that freezing controls are kept to the minimum necessary to provide adequate public health protection.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**  
Option 1: Do nothing - leave current freezing requirements unchanged.  
Option 2a: Support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing.  
Option 2b: Support the amendments to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria.  
  
 A combination of Options 2a and 2b is the preferred option. This will ensure public health controls for fishery products intended to be consumed raw or almost raw are proportionate and in line with scientific evidence and ensure the UK is compliant with EU legislation.

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> 12/2016					
Does implementation go beyond minimum EU requirements?				No	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		<b>Micro</b> Yes	<b>&lt; 20</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)				<b>Traded:</b> N/A	<b>Non-traded:</b> N/A

**I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.**

Signed by the responsible Minister:  Date: 2 July 2012

# Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing - leave current freezing requirements unchanged

## FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) N/A		
			Low: Optional	High: Optional	Best Estimate: N/A

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	N/A	N/A	N/A

### Description and scale of key monetised costs by 'main affected groups'

There are no incremental monetised costs associated with this option. This is the baseline against which the other options are assessed.

### Other key non-monetised costs by 'main affected groups'

There are no incremental non-monetised costs associated with this option. This is the baseline against which the other options are assessed.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	N/A	N/A	N/A

### Description and scale of key monetised benefits by 'main affected groups'

There are no incremental monetised benefits associated with this option. This is the baseline against which the other options are assessed.

### Other key non-monetised benefits by 'main affected groups'

There are no incremental non-monetised benefits associated with this option. This is the baseline against which the other options are assessed.

### Key assumptions/sensitivities/risks

Failure to provide for adequate enforcement provisions in the UK will result in the UK being liable for EU infraction proceedings

Discount rate (%)

N/A

## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: N/A	Benefits: N/A	Net: N/A	No	NA

# Summary: Analysis & Evidence

# Policy Option 2a

Description: Amendment to Regulation (EC) No. 853/2004 – extended freezing controls

## FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: Optional	High: Optional	Best Estimate: £-30,291

COSTS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£30,291	N/A	£30,291

### Description and scale of key monetised costs by 'main affected groups'

Total cost of policy option 2a: £30,291 (Present Value (PV))

Cost to industry: One-off familiarisation cost to fish processing industry of £12,530 (EAC of £1,456).

Cost to enforcement authorities (Local Authorities): One-off familiarisation to enforcement authorities of £17,761 (EAC of £2,063)

### Other key non-monetised costs by 'main affected groups'

Ongoing freezing costs: fish processors of wild cold smoked fish products will now be covered by the extension of the freezing controls

BENEFITS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	N/A	N/A	N/A

### Description and scale of key monetised benefits by 'main affected groups'

There are no incremental monetised benefits associated with this option.

### Other key non-monetised benefits by 'main affected groups'

- The extension of freezing controls to all wild cold smoked fishery products may provide reputational benefits to businesses producing these products as customers and consumers can be reassured that appropriate public health controls have been applied for at-risk species that have not undergone processing sufficient to kill any viable parasites that may be present.
- The introduction of more risk-based controls for cold smoked fishery products will ensure that consumers are provided with an appropriate level of public health protection in relation to cold smoked products derived from wild species that will now need to be frozen to kill any viable parasites that may be present in the product.

### Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

- Under Option 2a we estimate that approximately 240 businesses will be affected by this proposal on the assumption that this will only impact on processors of wild cold smoked fish products. Though data is available on the number of cold smoked fish processors; we have been unable to separate out the proportion of processors that handle wild fish. This means number of businesses actually affected by the legislation is likely to be an overestimate.
- We also envisage that approximately 434 local authorities (LAs) will be required to familiarise themselves with the proposal. We assume one hour would be required per LA for one Environmental Health Officer (EHO) to read and familiarise, plus an additional hour to disseminate this information to staff.

## BUSINESS ASSESSMENT (Option 2a)

Direct impact on business (Equivalent Annual) £m:	In scope of OIOO?	Measure qualifies as
Costs: 0.0015      Benefits: 0      Net: 0.0015	No	N/K

# Summary: Analysis & Evidence

# Policy Option 2b

Description: Amendment to Regulation (EC) No. 853/2004 – freezing exemption

## FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: Optional	High: Optional	Best Estimate: £77,807,196

COSTS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£4,964,991	N/A	£4,964,991

### Description and scale of key monetised costs by 'main affected groups'

Total cost of policy option 2b: £4,964,991 (Present Value (PV))

Cost to industry: One-off familiarisation costs to industry of £4,947,230 (EAC of £574,746) ;

Cost to enforcement: £17,761 in one off familiarisation costs

### Other key non-monetised costs by 'main affected groups'

There are no incremental non-monetised costs associated with this option.

BENEFITS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	N/A	£9,616,078	£82,772,186

### Description and scale of key monetised benefits by 'main affected groups'

Benefits Industry: Freezing cost savings to industry of £49,895,247(Present Value (PV)); Value Increase Benefits to industry of £32,872,163 (PV); resulting in a total benefit to business of £82,767,410

Benefits Enforcement: Enforcement cost savings of £4,778 (PV)

### Other key non-monetised benefits by 'main affected groups'

- Quality improvements of products intended to be consumed raw/almost raw;
- Reduced barriers to entry to 'ready to eat' market;
- Reputational benefits to industry producing fresh products;

Key assumptions/sensitivities/risks

Discount rate (%)

3.5%

- We estimate that approximately 94,760 businesses (fish farms, fish processors, retailers, wholesalers and food business operators) will be affected by this proposal.
- Familiarisation costs to Local Authorities are already calculated as per sub-option 2a. This is strictly to avoid the risk of double counting this one-off cost under both sub-options (2a and 2b).
- Limited data is available on potential monetised benefits; estimates should therefore be interpreted as indicative and treated with caution.

## BUSINESS ASSESSMENT (Option 2b)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.58	Benefits: 9.62	Net: -9.04	No	

## Summary: Analysis & Evidence Policy Option 2a and 2b

**Description:** Amendment to Regulation (EC) No. 853/2004 – extended freezing controls and freezing exemption

### FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: Optional	High: Optional	Best Estimate: £77,807,196

COSTS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£4,964,991,	N/A	£4,964,991

#### Description and scale of key monetised costs by 'main affected groups'

Costs to Industry: (Option 2a+2b): One-off familiarisation costs to industry of £4,947,230 (EAC of £574,746)

Costs to Enforcement; (Option 2a+2b): One-off familiarisation cost to enforcement authorities of £17,761 (EAC of 2,063)

#### Other key non-monetised costs by 'main affected groups'

Option 2a: Ongoing freezing costs to industry affecting fish processors of wild cold smoked fish products

BENEFITS	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	N/A	£9,616,078	£82,772,186

#### Description and scale of key monetised benefits by 'main affected groups'

Benefits to Industry: (Option 2b): Freezing cost savings to industry of £49,895,247(PV); Value Increase Benefits to industry of £32,872,163 (PV); resulting in a total benefit to industry of £82,767,410;

Benefits to Enforcement: (Option 2b): Enforcement cost savings of £4,778 (PV)

#### Other key non-monetised benefits by 'main affected groups'

Option 2b:

- Quality improvements of products intended to be consumed raw/almost raw;
- Reduced barriers to market entry to 'ready to eat' market;
- Reputational benefits to industry producing fresh products

#### Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

This option is a combination of Option 2a and 2b. This means that the familiarisation costs under this option will be the same as under option 2b, i.e. calculated based on the whole industry.

Option 2a: Option 2a only applies to processors of *wild* cold smoked fish products of which we estimate approximately 240 businesses will be affected by this proposal. We have data on the number of fish processors that process cold smoked fish, however, we have been unable to separate out the proportion of those processors that handle wild fish. Instead we have used the whole category, which may mean that there is a risk that this category has been overestimated. We also envisage that approximately 434 local authorities will be required to familiarise themselves with the proposal.

Option 2b: We estimate that approximately 94,760 businesses (fish farms, fish processors, retailers, wholesalers and food business operators) will be affected by this proposal. Risk - there is little data available on potential benefits under option 2b – numbers should be interpreted as indicative and be treated with care.

### BUSINESS ASSESSMENT (Option 2a and 2b)

Direct impact on business (Equivalent Annual) £:			In scope of OIOO?	Measure qualifies as
Costs: 0.58	Benefits: 9.62	Net: -9.04	No	

# Evidence Base (for summary sheets)

## REASON FOR INTERVENTION

1. EU food hygiene legislation introduced in January 2006 required that fishery products intended to be consumed raw or almost raw, and certain cold smoked and marinated/salted fishery products, must undergo a freezing treatment to kill any parasites that may pose a risk to consumers, unless there is sufficient epidemiological evidence to demonstrate there that there is no health hazard with regard to parasites. To be efficient, these controls need to be risk-based, flexible, and proportionate, with all the costs of compliance fully justified by the benefits.
2. Recent scientific evidence generated by the FSA<sup>1</sup> and confirmed by an EFSA opinion<sup>2</sup>, as well as practical experience, suggests that the risks to human health from parasites in farmed fish are minimal and there is no longer a clear public health case for continuing to require the freezing of farmed fishery products intended to be consumed raw or almost raw. Government intervention is therefore needed to update EU legislation to allow food business operators to adapt the freezing controls applicable to farmed fishery products to reflect the risks and available evidence. Intervention is also required to ensure that freezing requirements for cold smoked fishery products are risk-based and extended to cover all species of fish that have not undergone a sufficient heat treatment to kill viable parasites.
3. Intervention will also ensure that the UK is fully compliant with EU law.

## INTENDED EFFECT

4. The main change contained in Commission Regulation (EU) No 1276/2011 is an amendment to the requirements in Annex III of Regulation (EC) No. 853/2004 to allow food business operators to make evidence-based freezing exemptions for farmed fishery products reared under certain controlled conditions. A freezing exemption will be available for farmed fishery products exclusively reared in an environment that is free from parasites, or where food business operators can verify through procedures, approved by the competent authority, that they do not present a health hazard. The introduction of this specific freezing exemption for farmed fishery products will reduce regulatory burdens on the UK fish farming industry and address a long term issue for the UK salmon farming sector which, under the current legislation, is required to freeze raw 'ready to eat' products derived from farmed salmon such as sushi, sashimi and gravadlax. Research carried out by the FSA in Scotland found that the risks to human health from *Anisakis* nematodes in farmed Atlantic salmon are negligible, a conclusion also reached by EFSA following their evaluation of the FSA research. This provides the necessary evidence that will enable food business operators to apply the freezing exemption to farmed salmon.
5. The Commission Regulation maintains the existing national flexibility that allows competent authorities in Member States to authorise a freezing exemption for fishery products when sufficient epidemiological evidence is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites, although this now specifically relates to wild catches. Retention of this national flexibility enables the UK to authorise such an exemption for wild catches provided the fishing grounds of origin do not present a health hazard with regard to the presence of parasites.
6. Freezing requirements for cold smoked fishery products have also been updated to ensure they are risk-based without compromising public health protection and extended to cover all species of fish that have not undergone a heat treatment of at least 60°C, unless there is sufficient evidence of negligible risk to allow a freezing exemption to be applied. Previously, Regulation (EC) No. 853/2004 only required that cold smoked herring, mackerel, sprat and wild Atlantic and Pacific salmon needed to be frozen before consumption.

---

<sup>1</sup> Petrie, A, et al. A Survey of *Anisakis* and *Pseudoterranova* in Scottish fisheries and the efficacy of current detection methods: Food Standards Agency in Scotland, Study S14008, 2007

<sup>2</sup> <http://www.efsa.europa.eu/en/scdocs/doc/1543.pdf>

7. There is no change in the requirements applicable to marinated/salted fishery products. They will continue to be required to undergo a freezing treatment if the processing of such products is insufficient to kill viable parasites.
8. The Regulation maintains current documentation requirements for fishery products that are subject to a freezing treatment. These must be accompanied by a document from the food business operator performing the freezing treatment stating the type of treatment they have undergone, except when supplied to the final consumer. However, the Regulation introduces a new obligation on food business operators to ensure that any wild or farmed fishery products placed on the market without having undergone a freezing treatment to kill parasites originate from a fishing ground or fish farm that complies with the specific conditions set out in the exemptions. This may be met by information in commercial documentation or any other information accompanying the fishery products. Both of these requirements will ensure food business operators maintain traceability throughout the food chain and apply appropriate freezing controls to protect consumer health.
9. The updated freezing controls will ensure that adequate public health protection is maintained and the least burdensome arrangements are placed on food business operators and Local Authorities enforcing the legislation.

## BACKGROUND

10. Regulation (EC) No. 853/2004 applied from 1 January 2006 and lays down specific hygiene rules for food of animal origin, including those applicable to fishery products. Annex III, Section VIII, Chapter III, Part D.1 requires certain fishery products to be frozen under specific conditions to reduce the risk to public health from parasitic infection. These include fishery products intended to be consumed raw or almost raw, cold smoked fishery products (derived from herring, mackerel, sprat and wild Atlantic and Pacific salmon), and marinated and/or salted fishery products where the processing is insufficient to kill nematode larvae. Regulation (EC) No. 853/2004 also includes a national flexibility allowing Competent Authorities to authorise a freezing exemption for fishery products when sufficient epidemiological evidence is available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites.

### EFSA Opinion

11. Following a request from the European Commission the EFSA Panel on Biological Hazards was asked to deliver a scientific opinion on food safety related to parasites in fishery products. They were asked to set criteria, if any, for when products intended to be eaten raw, almost raw or cold smoked from wild catch fishing grounds and from aquaculture do not present a health hazard with regard to the presence of parasites. They were specifically asked to assess the available documentation for farmed Atlantic salmon which included an evaluation of the data from a study jointly funded by FSA in Scotland and the Scottish Salmon Producers' Organisation (SSPO) published in 2007 which found that the public health risks from anisakid nematodes from pellet-fed farmed Atlantic salmon in Scottish waters are negligible.
12. The panel presented its opinion on 11 March 2010 and concluded that the main parasitic risks to human health from fishery products were from the presence of cestodes, trematodes and nematodes. Anisakid worms are nematodes. The panel also concluded that only *Anisakis simplex* had been implicated in allergic reaction and that consumption of products containing viable *A. simplex* larvae presents a greater risk for allergy than consumption of products containing non-viable larvae.
13. EFSA determined that the risk to human health from parasitic nematodes from Atlantic salmon fed controlled compound diets and farmed in raised sea cages or onshore tanks is negligible. No conclusion was reached for any other farmed species as it was determined that there was insufficient monitoring evidence available. This conclusion applied only to farmed salmon and not wild salmon as the EFSA opinion indicates that, for wild catch fish, no fishing grounds can be classed as 'parasite-free', meaning that all wild-caught seawater and freshwater fish must still be considered at risk of containing viable parasites of human health concern if to be consumed raw or almost raw.

14. EFSA identified that freezing or heat treatments remain the most effective processes to guarantee the killing of parasitic larvae. Many traditional marinating and cold smoking methods are not sufficient to kill *A. simplex* larvae. They also concluded that there is insufficient evidence to indicate whether alternative treatments such as high hydrostatic pressure, irradiation, drying or low voltage currents are effective in killing viable larvae.
15. Following publication of the EFSA opinion the Food Standards Agency wrote to enforcement authorities advising them to take account of the opinion and the Commission's ongoing review of the legislation regarding parasites in fishery products when considering whether it is appropriate to take any enforcement action where fully traceable farmed Atlantic salmon is supplied raw or almost raw to consumers without first having been frozen.

#### Working Group Discussions

16. Based on this EFSA opinion, the Commission proposed a legislative amendment that would specifically exclude farmed Atlantic salmon from the freezing requirements applied to fish to be eaten raw. This amendment was supported by Member States and was fully in line with the findings of the FSA funded study. The Commission also tabled a proposal to remove the flexibility for Competent Authorities to authorise exemptions from the requirement for freezing. This prompted a strong negative reaction from several Member States, particularly those that had already made use of this flexibility for certain fishing grounds. The UK was strongly in favour of retaining the flexibility as it considered it was more appropriate for risk assessments to be made at a national level so local conditions can be considered. The UK also considered it was not an appropriate use of resources for all decisions to be made at an EU level, as many derogations would be relevant for either individual or a small number of Member States, and this would also delay the introduction of proportionate controls. Following discussions, the Commission agreed to consider and redraft the legislation, and set up a restricted technical Working Group to progress the dossier. The UK participated in that Working Group and was very active in securing changes to the proposal to obtain the most favourable outcome for the UK.
17. Subsequent drafts of the proposal retained the national flexibility for wild catches and extended the freezing exemption for farmed Atlantic salmon to all farmed fishery products reared under controlled conditions which meet specific criteria. The freezing requirement for cold smoked fish was also extended to all species, subject to any exemptions that may be applied. The UK was supportive of these proposed changes to the current legislation on the basis that they were introducing more risk based and proportionate public health controls, providing adequate public health protection while minimising burdens on business.
18. A final draft Commission Regulation was presented for vote at the Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 12 July 2011 and received the support of the majority of Member States, including the UK. In collaboration with Member States the Commission also produced a guidance document to accompany the updated legislation and clarify the criteria food business operators must meet before a freezing derogation can be applied. This was presented for vote at SCOFCAH on 16 November 2011 and endorsed by Member States.

#### Risk Assessment

19. The risk assessments carried out by EFSA and the FSA in Scotland provide the necessary evidence to enable the UK farmed salmon sector to make use of the new freezing exemption for farmed fish, and we do not expect there to be a need for any further risk assessment on parasites in farmed salmon assuming there are no changes in farming practices.
20. Unlike the salmon sector, EFSA concluded that there is insufficient monitoring data available to provide a robust assessment of the risk from viable parasites in other species of farmed fish.<sup>3</sup> However, EFSA have established criteria for considering when fishery products from aquaculture do not present a health hazard with regard to the presence of parasites - principally where fish are reared in raised cages and fed on a controlled artificial diet that cannot be infected with larval parasites. If the same rearing procedures based on these criteria are followed, farmed fishery products other than Atlantic

---

<sup>3</sup> The FSA in Scotland has now commissioned research to assess the risks from parasites in farmed marine trout and halibut in the UK



salmon may be considered to present a negligible risk for parasites that may be a risk to the health of the consumer, allowing a freezing derogation to be applied.

21. The UK farmed trout sector uses four types of production system – open sea pens, open freshwater pens, freshwater ponds, and freshwater tanks and raceways. Sea reared trout and trout reared in open freshwater pens are produced using the same production methods as farmed salmon, thereby meeting the EFSA criteria set out above. Therefore it is considered that fishery products derived from this type of farmed trout production will also present a negligible risk and will be exempt from the freezing requirements if intended to be consumed raw. As such, no additional risk assessment or verification monitoring for this type of production is considered necessary, assuming there is no change in farming practices.
22. With regard to onshore freshwater systems, EFSA concluded that trout reared in freshwater tanks, ponds or raceways are very rarely parasitized by helminths that present a risk to humans. In cases where water used for culture is drawn from lakes and reservoirs without filtration EFSA indicate that there may be a risk of infection with *Diphyllobothrium* since copepods containing infective stages may enter the system and be preyed upon by trout. Fish reared in cages in still water bodies may be at more risk of infection if they feed on infected copepods. However, scientific experts consulted by the FSA consider that there are no convincing records of the presence of *Diphyllobothrium* in the UK, and where appropriate filtration is used it is considered that onshore freshwater systems will be able to demonstrate that trout have been reared in an environment that is free from viable parasites. Therefore we anticipate that freshwater trout production will also benefit from the freezing exemption.
23. Farmed species other than salmon and trout are also reared using a mixture of floating sea pens and onshore tank based systems which are likely to meet the EFSA criteria for considering when fishery products from aquaculture do not present a health hazard with regard to the presence of parasites. Therefore it is anticipated that these production methods will enable food business operators rearing these species to meet the exemption criteria and apply a freezing derogation for any product that is supplied for raw consumption.

## SECTORS & GROUPS AFFECTED

### Industry

24. The introduction of a **freezing exemption** for farmed fish will affect food business operators supplying farmed fishery products intended to be consumed raw, cold smoked or marinated/salted. UK fish farming companies, fish processors, and retailers are all involved in this trade to a greater or lesser degree, and the freezing derogation will enable these businesses to make cost savings by removing the need to freeze affected fishery products.
25. Fish processors and smokers may also be affected by the **extension of freezing controls** to all cold smoked fishery products not intended to undergo further processing (such as cooking) before consumption. However, the impact of this change will be mitigated by the introduction of the freezing exemption for farmed fish and will only affect businesses supplying certain species of wild cold smoked fish such as trout, halibut, and cod.

### Fish Aquaculture

#### *Farmed Salmon*

26. In terms of production volumes the UK fish farming industry is dominated by the Scottish farmed Atlantic salmon industry which will be the main sector to benefit from the **freezing exemption**. The Scottish Salmon Producers' Organisation (SSPO) has confirmed that the Scottish farmed salmon sector supplies a significant proportion of the UK market in raw 'ready to eat' products such as

gravadlax, sushi and sashimi, products that previously required to be frozen before consumption. The SSPO estimate this market to be valued at £46.1M and growing at 3.3% annually<sup>4</sup>.

27. Potentially all of the larger salmon farming companies are involved in this trade, either through manufacturing of their own products, supplying to processors who manufacture raw 'ready to eat' products, supplying through wholesalers who sell product to customers involved in these different areas, or direct supply to larger sushi / sashimi restaurant chains. Although precise volume cannot be verified due to the many different routes that the raw material takes to the consumer, the SSPO estimates that between 3 – 5% of total production of Scottish farmed salmon goes for raw 'ready to eat' consumption and will benefit from the new freezing derogation.
28. A significant proportion of farmed Atlantic salmon is also supplied cold smoked although these products will not be directly affected by the freezing exemption as cold smoked farmed fishery products did not need to be frozen previously. Salmon farming businesses will also be unaffected by the extension of freezing controls for cold smoked fish as these will only affect processors cold smoking certain wild species (see below).
29. There are currently 30 Scottish companies spread across 249 sea pen sites authorised for salmon production in the UK (only 20 companies are currently active), plus one further company in Northern Ireland. In 2010 production was concentrated in 9 Scottish companies, which between them accounted for over 95% of total salmon production in Scotland.<sup>5</sup> The total production of farmed Atlantic salmon in Scotland in 2010 was 154,164 tonnes, with a projected tonnage of 157,385 tonnes for 2011.<sup>6</sup>
30. The total number of salmon fish farming companies by size of business is shown in Table 1 below. Total numbers for Scotland were sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey 2010 Report*<sup>7</sup>, with data on size of business provided by SSPO. Data for Northern Ireland was provided by the Department of Agriculture and Rural Development (DARD).

**Table 1 – UK Salmon Fish Farming Businesses by Country and Size**

	Micro	Small	Medium	Large	Total
England	0	0	0	0	0
Wales	0	0	0	0	0
Scotland	20	5	1	4	30
Northern Ireland	0	0	1	0	1
<b>UK Total</b>	<b>20</b>	<b>5</b>	<b>2</b>	<b>4</b>	<b>31</b>

Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Note: totals may not sum due to rounding

### *Farmed Trout*

31. It is anticipated that the UK farmed trout industry will also look to benefit from the **freezing exemption** for farmed fish when the product is supplied for raw consumption, although the extent of the trade in farmed trout for the raw 'ready to eat' market and the likely benefits of an exemption are less clear. The British Trout Association (BTA) has been unable to confirm the amount of farmed trout that is supplied for raw consumption by trout aquaculture businesses, but an assumption can be made that similar proportions to the salmon sector are supplied, i.e. 3-5% of total farmed trout production.
32. A proportion of UK farmed trout will also be supplied cold smoked, but, as with salmon, these fishery products did not require to be frozen previously and any cold smoking is likely to be carried out by processors rather than trout farmers.

<sup>4</sup> Source: Scottish Salmon Producers' Organisation

<sup>5</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>6</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>7</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

33. The UK farmed trout industry is more diverse than the farmed salmon sector and the BTA have estimated that there are 199 businesses in the UK currently engaged in table production (excluding restocking sites and trout fisheries), with 90% of production concentrated in 85 businesses. They estimate that the majority of businesses are micro businesses in England with an annual turnover of less than £1M. According to farmed finfish production data published by CEFAS there were 15,531 tonnes of farmed trout produced in the UK in 2009.<sup>8</sup> As with salmon, production volumes for farmed trout are greatest in Scotland, with 5,208 tonnes produced in 2010 spread across 40 companies and 59 sites.<sup>9,10</sup> There is less production data available for the other UK nations, but the BTA have estimated that in 2008 there was 4,981 tonnes of trout produced in England, 530 tonnes in Northern Ireland, and 500 tonnes in Wales.
34. The total number of trout fish farming companies by size of business is shown in Table 2 below. Total numbers for Scotland were sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey 2010 Report*<sup>11</sup>, with numbers for the rest of the UK and information on size of business provided by BTA:

**Table 2 – UK Trout Fish Farming Businesses by Country and Size**

	Micro	Small	Medium	Large	Total
England	128	2	0	0	130
Wales	25	0	0	0	25
Scotland	39	1	0	0	40
Northern Ireland	4	0	0	0	4
<b>UK Total</b>	<b>196</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>199</b>

Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Note: totals may not sum due to rounding

#### *Other Commercially Farmed Species*

35. In addition to salmon and trout there are a number of other farmed species cultured in the UK, including arctic charr, cod, halibut, carp, catfish, sea bass and tilapia, and food business operators rearing these species may also take advantage of the **freezing derogation** when product is supplied for raw consumption.<sup>12</sup> The 2009 production data published by CEFAS indicates that the total UK production of farmed finfish species other than salmon and trout was 793 tonnes.<sup>13</sup> Discussions with the British Marine Finfish Association (BMFA) have confirmed that this sector is comprised mainly of small scale businesses.

#### *Total Number of UK Fish Farms*

36. The total number of fish farming companies in the UK by species is shown in the Table 3 below. Data for Scotland has been sourced from the Marine Scotland Science *Scottish Fish Farm Production Survey 2010 Report*.<sup>14</sup> Data for England and Wales was obtained during individual meetings with UK trade organisations – SSPO, BTA, and BMFA – and extrapolated from production data in the CEFAS annual production survey for 2009. Data for Northern Ireland was obtained from DARD.

**Table 3 – Total UK Fish Farming Businesses by Species**

<sup>8</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>9</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>10</sup> This comprised 5,139 tonnes of rainbow trout produced by 25 companies (with freshwater production accounting for 3,533 tonnes and seawater production for the remaining 1,606 tonnes) and 69 tonnes of brown/sea trout produced by 15 companies

<sup>11</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>12</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>13</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>14</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

Country	Salmon	Trout	Arctic Charr	Cod	Halibut	Other	Total
England	0	130	0	0	0	4	134
Wales	0	25	0	0	0	1	26
Scotland	30	40	5	2	3	0	80
Northern Ireland	1	4	0	0	0	0	5
<b>UK Total</b>	<b>31</b>	<b>199</b>	<b>5</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>245</b>

N.B. All freshwater salmon farms are hatcheries only as they are then transferred to seawater pens before going for human consumption.

Note: totals may not sum due to rounding

37. Table 4 below shows total UK fish farms that will be affected by the freezing extension, by country and firm size.

**Table 4 - Total UK Fish Farms (Firm Size)**

	Micro	Small	Medium	Large	Total
<b>England</b>	131	3	0	0	134
<b>Wales</b>	26	0	0	0	26
<b>Scotland</b>	67	8	1	4	80
<b>Northern Ireland</b>	4	1	1	0	5
<b>UK Total</b>	<b>228</b>	<b>11</b>	<b>2</b>	<b>4</b>	<b>245</b>

Note: totals may not sum due to rounding

## Fish Processors

38. Fish processing businesses will benefit from the new **freezing derogation** if they are supplying farmed fishery products intended to be consumed raw, cold smoked or marinated/salted, whether as 'fresh' product or pre-packaged products for grocery multiples. When a freezing derogation is applied processors will need to ensure that raw product is derived from fish farms that meet the freezing exemption criteria, and appropriate commercial documentation may be required to verify this.
39. Processors smoking fish may also be affected by the **extension of freezing controls** to all cold smoked fish intended to be consumed without further processing. However, the impact of these changes will be limited to those processors cold smoking certain species of wild fish, as no species of cold smoked farmed fish were required to be frozen previously under the EU hygiene legislation and farmed fish will continue to be exempt due to the new freezing derogation. Cold smoked wild trout is the main species likely to be affected by the extended freezing requirement. Other wild species that may be affected include cold smoked cod and Atlantic halibut if they are not intended to undergo further processing before consumption, but the production volumes for these species are estimated to be minimal. Cold smoked wild Atlantic and Pacific salmon will not be affected by the changes as these at-risk wild species were already required to be frozen.
40. The majority of cold smoked wild fish on sale in the UK is intended to be cooked before consumption. Whitefish species treated in this way include haddock, herring, cod, whiting, hake, saithe and ling. As these products are traditionally cooked before consumption, a heat treatment that will kill viable parasites, they are not subject to the Community freezing controls. Therefore processors supplying this type of cold smoked fishery product will be unaffected by the new proposals.
41. The total number of approved fish processors in the UK is shown in the table below, drawn from the list of approved premises on the FSA website.<sup>15</sup> No precise data is available on the number of approved processors supplying product for the raw, cold smoked or marinated/salted markets, and an assumption on the likely number of affected businesses has been made based on information held by the FSA on the associated activities for each premises in Scotland, Wales and Northern Ireland (this information is potentially commercially sensitive and is not publicly available on the FSA website). Information on associated activities is not available for approved premises in England, and estimated numbers have been extrapolated from the data available for approved plants in rest of the UK:

<sup>15</sup> <http://www.food.gov.uk/foodindustry/farmingfood/fishapprove/>

**Table 5 – UK Approved Fish Processors**

	To be Consumed Raw	Cold Smoked	Marinated/Salted	Total
England	118	177	59	354
Wales	6	9	3	18
Scotland	31	47	16	94
Northern Ireland	5	7	2	14
<b>UK Total</b>	<b>160</b>	<b>240</b>	<b>80</b>	<b>480</b>

Note: totals may not sum due to rounding

42. There are a total of 480 approved fish processors in the UK that will be affected by the proposal. All approved processors will be affected by the freezing exemption; whilst the freezing extension will only affect the 240 processors of cold smoked products. Table 6 below presents the number of approved fish processing business by location and size of firm.

**Table 6 – Total UK Approved Fish Processors by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	186	106	53	9	354
Wales	16	2	0	0	18
Scotland	49	28	14	2	94
Northern Ireland	7	4	0	0	14
<b>UK Total</b>	<b>258</b>	<b>141</b>	<b>69</b>	<b>12</b>	<b>480</b>

Note: totals may not sum due to rounding

### Retail and Wholesale

43. All retail and wholesale businesses that undertake activities with fishery products intended to be consumed raw, cold smoked or marinated/salted will need to ensure that they are **familiar** with the new Regulation when buying in or selling on affected fishery products. This will include fish wholesalers and grocery multiples. In particular, retail businesses selling farmed fishery products that have not undergone a freezing treatment will need to ensure that farmed fish originate from production sites that meet the exemption criteria, and appropriate documentation may be required to verify this.
44. The total number of major retail and wholesale stores supplying sushi and chilled smoked fish is shown in the table below (note – this does not differentiate between hot and cold smoked fish):

**Table 7 –UK Retailers and Wholesalers Selling Raw and Smoked Fishery Products by Country<sup>16</sup>**

	Sushi	Chilled Smoked Salmon	Chilled Smoked Cod	Chilled Smoked Trout	Total
England	856	847	414	258	2,375
Wales	32	32	16	10	90
Scotland	186	184	90	56	515
Northern Ireland	34	34	17	10	95
<b>UK Total</b>	<b>1,108</b>	<b>1,097</b>	<b>536</b>	<b>334</b>	<b>3,075</b>

Note: totals may not sum due to rounding

45. Table 8 below shows the number of retailers and wholesalers affected by the proposal by country and size of firm.

<sup>16</sup> Source: Nielsen Scantrack MAT to May 2011

**Table 8 - Retailers and Wholesalers Selling Raw and Smoked Fishery Products by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	2,039	286	50	0	2,375
Wales	77	11	2	0	90
Scotland	442	62	11	0	515
Northern Ireland	82	11	2	0	95
<b>UK Total</b>	<b>2,640</b>	<b>370</b>	<b>65</b>	<b>0</b>	<b>3,075</b>

### Food Service Businesses

46. Food service businesses selling affected fishery products will need to **familiarise** themselves with the revised legislation. In addition, larger businesses that source farmed fish for raw consumption direct from UK production sites and currently freeze on site are likely to achieve freezing cost savings from the new **freezing exemption**. One major UK sushi restaurant chain has confirmed in discussions with the FSA that approximately 70-80% of the sushi/sashimi served in their restaurants is fresh Scottish farmed salmon sourced direct from the producer, and the company has welcomed the proposals to provide a freezing exemption for farmed fishery products.<sup>17</sup> These businesses will also be required to ensure that farmed fishery products are sourced from production sites that meet the exemption criteria before they can be sold without freezing.
47. The type of food service businesses likely to be affected by the proposal is set out below in table 9 using Standard Industrial Classification (SIC) codes taken from the Office for National Statistics (ONS) Inter Departmental Business Register (IDBR). Note that this is likely to be an overestimate of the number of affected businesses as only a proportion of these businesses will serve raw fish.

**Table 9 - Type of Food Service Businesses Affected<sup>18</sup>**

SIC Code	Business Type
56.10	Restaurant & Mobile Food Services
56.21	Event Catering Activities
56.29	Other Food Service Activities

48. Table 10 below shows these food business operators by Country and Firm Size.

**Table 10 – Number of affected businesses by country and size<sup>19</sup>**

	Micro	Small	Medium	Large	Total
England	58,346	16,117	1,839	92	76,395
Wales	2,910	804	92	5	3,810
Scotland	6,026	1,665	190	10	7,890
Northern Ireland	2,188	604	69	3	2,865
<b>UK Total</b>	<b>69,470</b>	<b>19,190</b>	<b>2,190</b>	<b>110</b>	<b>90,960</b>

**Notes:**

- Totals may not sum due to rounding
- Figures are the sum of premises listed under SIC codes as per table 4.
- Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

<sup>17</sup> Other wild species served by this business as sushi/sashimi are yellow fish, tuna and halibut, all of which are already supplied block frozen.

<sup>18</sup> Source: The Inter Departmental Business Register (IDBR) - accessible via the Office for National Statistics (ONS), <http://www.statistics.gov.uk/idbr/idbr.asp>

<sup>19</sup> Source: IDBR (ONS)

## Total Number of Affected Businesses

49. Under sub-option 2a the extension of freezing controls is limited to processors of cold smoked produce handling certain species of wild fish such as trout, halibut, and cod. However, using the only data available, we are unable to separate out the activity of processors handling cold smoked fish according to species. We therefore use the category of cold smoked fish handling in its entirety; aware this could be overestimating the impact for this particular sub-sector.
50. More extensively the freezing exemption under sub-option 2b will affect a number of businesses including fish farming companies, fish processors, retailers (fish wholesalers, grocery multiples) and food service businesses. A summary of the total number of affected businesses under respective sub options 2a and 2b are presented in tables 11 and 12 below:

**Table 11: Policy Option 2a - fish processors supplying certain species of wild cold smoked fish**

	Micro	Small	Medium	Large	Total
England	93	53	27	4	177
Wales	5	3	1	0	9
Scotland	25	14	7	1	47
Northern Ireland	4	2	1	0	7
<b>UK Total</b>	<b>126</b>	<b>72</b>	<b>36</b>	<b>6</b>	<b>240</b>

Note: totals may not sum due to rounding

**Table 12: Policy Option 2b - fish farming companies, fish processors, retailers and food service businesses**

	Micro	Small	Medium	Large	Total
England	60,689	16,524	1,944	101	79,258
Wales	3,026	819	94	5	3,944
Scotland	6,588	1,763	216	12	8,579
Northern Ireland	2,281	621	73	4	2,979
<b>UK Total</b>	<b>72,584</b>	<b>19,727</b>	<b>2,327</b>	<b>122</b>	<b>94,760</b>

Note: totals may not sum due to rounding

## Consumers

51. Consumers of raw and cold smoked fishery products will also be affected by the revised freezing controls. There is growing consumer demand in the UK for raw 'ready to eat' fishery products such as sushi and sashimi which is seen as a healthy option. The Commission Regulation will ensure that public health measures designed to protect consumers from the risks associated with this type of raw product are risk-based and targeted. The Regulation also includes more explicit obligations on food business operators to ensure that raw fishery products that have been placed on the market without freezing have been sourced from fishing grounds or fish farms that meet the exemption criteria. This will ensure that consumers are only able to eat raw fishery products that have not undergone a freezing treatment when there is sufficient evidence to demonstrate that the risks are negligible.

## Enforcement

52. Enforcement of the revised freezing controls across the UK will be carried out by Local Authorities who will be required to verify that freezing has taken place where necessary to ensure public health remains protected. They will also be required to verify that farmed fishery products subject to a freezing exemption are compliant with the exemption criteria. This will require an understanding of the risks associated with parasites across various aquaculture production methods and fish species and an up-to-date knowledge of the latest scientific risk assessments. The guidance document produced by the

Commission to accompany the new Regulation will assist Local Authorities in assessing FBO compliance with the revised legislation. Local Authorities will also need to verify and check relevant food business operator documentation as necessary.

## CONSULTATION

53. The FSA held ongoing discussions with affected industry sectors as negotiations on the Commission proposal progressed, including individual meetings with the three main farmed fish industry bodies - SSPO, BTA and BMFA. All three organisations are supportive of the changes and proposed freezing exemption for farmed fish.
54. An early draft of the proposal was circulated for comment to all interested parties across the UK in January 2011. This was sent to industry, consumer, and enforcement stakeholders. Four responses were received which indicated general support for the changes, although a number of questions were raised regards the scope of the proposal, requirements for monitoring data, and alternative treatments. These points were addressed in subsequent drafts of the proposal and draft Commission guidance. In addition, officials from the FSA in Scotland met face to face with a number of individual affected businesses from the production, processing and retail sectors to discuss the impact of the proposals and inform the UK negotiating position.
55. A shortened 4 week public consultation was issued in England on the draft Impact Assessment (16 March 2012 – 14 April 2012). Two responses were received both in support of the amendment to the regulation and in agreement that the changes would lift unnecessary burden on industry. Parallel consultation exercises were carried out in Scotland, Wales and Northern Ireland.
56. A summary of responses to the consultation will be published on the Agency's website at: <http://www.food.gov.uk/news/consultations/consulteng/2012/iacommissionregeu12762011eng>

## OPTIONS

57. The Options considered were:
  - **Option 1:** Do nothing and leave current freezing requirements unchanged. There would continue to be a legal obligation to freeze all farmed and wild fishery products intended to be consumed raw or almost raw, unless the competent authority authorises a national exemption based on epidemiological data.
  - **Option 2a:** In line with Commission Regulation (EU) No 1276/2011 support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing
  - **Option 2b:** In line with Commission Regulation (EU) No 1276/2011 support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria.
58. Options 2a and 2b are the preferred options. This would bring freezing controls for cold smoked and farmed fishery products into line with current scientific evidence ensuring they are risk-based and proportionate.

## COSTS AND BENEFITS

### COSTS

**Option 1** – is the 'do nothing' option. There are no additional costs to business and the public sector associated with this option. This option provides the baseline to which all other options are compared.



**Option 2a** - support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing

## Industry

### One-Off Familiarisation Cost

59. Food business operators processing cold smoked fishery products would be required to familiarise themselves with the new freezing requirement. It is envisaged that 1 hour would be required per business to read and familiarise themselves with the new legislation, plus an additional hour to disseminate this information to staff<sup>20</sup>. This means a total of 2 hours per business to become familiar with the revised controls. There are currently 240 'cold smoked' fish processing businesses operating in the UK which are directly affected by the proposal (see Table 11).
60. The total familiarisation cost is quantified by multiplying the median hourly wage rate of a manager of £26.10<sup>21</sup> by the time required to familiarise themselves with the policy (2 hours) by the total number of approved 'cold smoked' fish processing businesses affected in the UK (240); resulting in a familiarisation cost to the sector of £12,530<sup>22</sup>. Table 13a below shows the familiarisation cost to Fish Processors by country and firm size.

**Table 13a: One-Off Familiarisation Costs to Fish Processors, by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	£4,851	£2,772	£1,386	£231	£9,241
Wales	£247	£141	£70	£12	£470
Scotland	£1,288	£736	£368	£61	£2,454
Northern Ireland	£192	£110	£55	£9	£365
UK	£6,578	£3,759	£1,879	£313	£12,530

Note: totals may not sum due to rounding

61. In order for one-off costs to be compared with annual costs on an equivalent basis across the entire time span of the policy, one-off costs are transformed into Equivalent Annual Costs (EAC) by dividing the one-off cost by an annuity factor.<sup>23</sup>
62. The total one-off cost to industry in the UK affected by this proposal is estimated to be £12,530 which yields an equivalent annual cost of £1456 over a time period of 10 years. Table 13b shows the breakdown of EACs by UK country

**Table 13 b: Annual Equivalent Costs (EANC) by UK Country**

	EAC
England	£1,074
Wales	£55
Scotland	£285
Northern Ireland	£42
UK	£1,456

<sup>20</sup> While we recognise that dissemination of information will result in an opportunity cost in terms of time of key staff members we anticipate that this will be minimal and the additional hour will cover these costs.

<sup>21</sup> Wage rate obtained from the Annual Survey of Household Earnings (ASHE) 2011. Median hourly wage rate of 'Production Manager', £20.08, uplifted by 30% to account for overheads (20.08\*1.3) = 26.10

<sup>22</sup> 240\*2\*1\*£26.10=£12,518

<sup>23</sup> The annuity factor is essentially the sum of the discount factors across the time period over which the policy is evaluated. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left( \frac{1}{1+r_i} \right)$$

## Ongoing Freezing Costs

63. With regard to cold smoked fishery products derived from **farmed** fish, no freezing was required previously under the EU hygiene legislation. As indicated above, it is fully expected that all aquaculture production methods currently in operation in the UK will be able to demonstrate that they meet the freezing exemption criteria, therefore farmed cold smoked fish will continue to be exempted from the freezing requirements and no additional freezing costs are expected for businesses supplying these products as a result of this policy option.
64. Based on the data available we are unable to separate out the activity of processors handling cold smoked fish derived from **wild** species. However, our assumption is that production volumes of affected wild cold smoked fishery products that will now require freezing for the first time are likely to be small. The main species likely to be affected are wild trout, cod and halibut. The UK's largest trout processor (who process approximately 80% of UK trout) has confirmed that they do not produce any cold smoked wild trout. They also confirmed that there is likely to be minimal amounts of cold smoked wild trout, cod and halibut produced commercially in the UK. We therefore assume that any additional freezing costs to UK industry are likely to be minimal.

## **Enforcement**

### One-Off Familiarisation Costs

65. Local Authorities enforcing the revised freezing controls would be required to familiarise themselves with the revised legislation. We assume that 1 hour would be required per Local Authority for one Environmental Health Officer (EHO) to read and familiarise themselves with the new legislation, plus an additional hour to disseminate this information to staff. It is envisaged that 434 Local Authorities will be affected by the proposed changes in the UK.
66. To calculate the total familiarisation cost we first need to quantify the familiarisation cost per LA. The familiarisation cost per LA is calculated by multiplying the hourly wage rate of an EHO (£20.46<sup>24</sup>) by the number of hours required for familiarisation and dissemination (2 hours), resulting in a familiarisation cost per LA of £40.92 (assuming that one official per LA will be required to familiarise themselves with the new policy). The total familiarisation cost for enforcement authorities in the UK is calculated by multiplying the familiarisation cost per LA (£40.92) by the number of LAs in the UK (434), resulting in a familiarisation cost in the UK to enforcement authorities of £17,761<sup>25</sup>. Table 14a displays the familiarisation cost to enforcement authorities broken down by country.

**Table 14a – Familiarisation cost to enforcement authorities by country**

	Number LAs	Familiarisation Cost
England	354	£14,487
Wales	22	£900
Scotland	32	£1,310
Northern Ireland	26	£1,064
<b>UK</b>	434	£17,761

Note: totals may not sum due to rounding

67. As with the one off familiarisation costs to industry it is necessary to equivalently annualise the one off familiarisation costs for enforcement authorities (see paragraph 60). The total one-off cost to enforcement authorities under Option 2a is estimated at £17,761, which yields an equivalent net annual cost of £2,063 over a time period of 10 years. Table 14b below shows the breakdown of EACs by UK country

<sup>24</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2011. (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Environmental health officers' £15.74 + 30% to cover overheads = £20.46).

<sup>25</sup>  $434 * 1 * 2 * 20.46 = 17,761$

**Table 14b: Equivalent Annual Costs (EAC) by UK Country**

	EANC
England	£1,683
Wales	£105
Scotland	£152
Northern Ireland	£124
UK	£2,063

**Total Costs under Option 2a (Freezing Extension)**

68. In order to assess the costs over the life time of this policy it is standard HM Treasury practice to sum costs/benefits over a period of 10 years and discount to obtain the present value of these costs and benefits. Discounting adjusts for the general principle that people prefer to receive goods/services now to later.<sup>26</sup> The total one-off costs associated with policy Option 2a are estimated at £30,291, as set out in Table 15 below.

**Table 15: Total Costs under Option 2a (PV)**

One-Off Costs: Familiarisation	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	PV
Industry	£12,530	£0	£0	£0	£0	£0	£0	£0	£0	£0	£12,530	£12,530
Enforcement	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	<b>£30,291</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£30,291</b>	<b>£30,291</b>

Note: totals may not sum due to rounding

**Option 2b** - Support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria

**Industry****One-Off Familiarisation Costs**

69. Food business operators wishing to make use of the freezing exemption would be required to familiarise themselves with the new freezing exemption. It is estimated that 1 hour would be required per business to read and familiarise themselves with the new legislation, plus an additional hour to disseminate this information to staff. It is estimated that 94,760 food businesses will be affected by the proposed changes (see Table 12), resulting in 189,520 hours of industry time required to become familiar with the changes. Assuming the median hourly wage rate of a food business manager of £26.10<sup>27</sup> per hour, and that one manager per FBO will be required to familiarise themselves with the policy, this would result in a familiarisation cost to industry of £4,947,230. Table 16 below shows the familiarisation costs associated with preferred sub-option 2b to Industry.

**Table 16a: One-Off Familiarisation Costs to Industry by Country and Firm Size**

	Micro	Small	Medium	Large	Total
England	£3,168,458	£862,674	£101,484	£5,285	£4,137,902
Wales	£157,978	£42,781	£4,909	£241	£205,908
Scotland	£343,945	£92,067	£11,260	£621	£447,892
Northern Ireland	£119,110	£32,401	£3,818	£199	£155,528
UK	£3,789,490	£1,029,922	£121,472	£6,346	£4,947,230

Note: totals may not sum due to rounding

<sup>26</sup> Discounting is a technique used to compare costs and benefits that occur in different time periods. It is a separate concept from inflation, and is based on the principle that, generally, people prefer to receive goods and services now rather than later. This is known as 'time preference'.

<sup>27</sup> Wage rate obtained from the Annual Survey of Household Earnings (ASHE) 2011. Median hourly wage rate of 'Production Manager', £20.08, uplifted by 30% to account for overheads (20.08\*1.3) = 26.104

70. One-off costs need to be transformed into EACs (see paragraph 60). The total one-off cost to UK industry affected by Option 2b is estimated to be £4,947,230 which yields an equivalent annual cost of £574,746 over a time period of 10 years. Table 16b below shows the breakdown of EACs by UK country.

**Table 16b: Equivalent Annual Costs to Industry under Option 2b**

	EAC
England	£480,722
Wales	£23,921
Scotland	£52,034
Northern Ireland	£18,068
UK	£574,746

### Risk Assessment & Verification Costs

71. The freezing exemption for farmed fishery products is available where fish are cultured from embryos and fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and are either exclusively reared in an environment that is free from parasites, or where food business operators can verify through procedures, approved by the competent authority, that they do not present a health hazard with regard to parasites. As outlined above, it is expected that all aquaculture production methods currently in operation in the UK will meet these exemption criteria. On this basis, we envisage no additional costs to UK fish aquaculture businesses resulting from the need to carry out additional risk assessment or verification monitoring, assuming there is no change in farming practices.

### **Enforcement**

#### Familiarisation Costs

72. No additional Local Authority familiarisation costs are envisaged for Option 2b in addition to those calculated for Option 2a, as EHO's will familiarise themselves with new Commission Regulation as a whole. Familiarisation costs to enforcement under Option 2b are therefore the same as under Option 2a; £17,761 (see Table 14a).

### **Total Costs under Sub-option 2b (Freezing Exemption)**

73. The total one-off cost (Present Value (PV)) associated with policy Option 2b is estimated at £4,964,991 (see table 17).

**Table 17: Total Costs under Option 2b (PV)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	PV
<b>One-Off Costs: Familiarisation</b>												
<b>Industry</b>	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£4,964,991	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,964,991	£4,964,991

### **Total Costs under Sub-options 2a and 2b (Freezing Extension and Exemption)**

74. The total one-off cost (PV) associated with policy Sub-Options 2a and 2b is estimated at £4,964,991 (see table 18). Note that in calculating the total one-off familiarisation costs to industry the familiarisation costs of £12,530 under Sub-Option 2a are included in the familiarisation costs of £4,947,230 under Sub-Option 2b as all affected businesses are contained within Sub-Option 2b.

Similarly, as explained in paragraph 71, familiarisation costs to Local Authorities are the same under both Sub-Options and are only calculated once, giving total familiarisation costs of £17,761.

**Table 18: Total Costs under combined Sub-Options 2a and 2b (PV)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	PV
One-Off Costs: Familiarisation												
Industry	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
Enforcement	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	<b>£4,964,991</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£4,964,991</b>	<b>£4,964,991</b>

## **BENEFITS**

**Option 1** is the ‘do nothing’ option. There are no additional benefits to business and the public sector associated with this option. This option provides the baseline to which all other options are compared.

**Option 2a** - support the amendments to Regulation (EC) No. 853/2004 to extend freezing controls to all cold smoked fishery products intended to be consumed without further processing

### **Industry**

75. The extension of freezing controls to all wild cold smoked fishery products may provide reputational benefits to businesses producing these products as customers and consumers can be reassured that appropriate public health controls have been applied for at-risk species that have not undergone processing sufficient to kill any viable parasites that may be present.

### **Enforcement**

76. No additional benefits to enforcement authorities have been identified for this option.

### **Consumers**

77. The introduction of more risk-based controls for cold smoked fishery products will ensure that consumers are provided with an appropriate level of public health protection in relation to cold smoked products derived from wild species that will now need to be frozen to kill any viable parasites that may be present in the product.

**Option 2b** - Support an amendment to Regulation (EC) No. 853/2004 to provide a specific freezing exemption for farmed fishery products that meet the relevant exemption criteria

### **Industry**

#### **Freezing Cost Savings**

78. The Commission Regulation will enable food business operators in the UK to make cost savings by removing the need to freeze raw, cold smoked and marinated/salted fishery products derived from farmed fish where the new exemption criteria are met. It is, however, difficult to attribute any potential cost savings to individual sectors – aquaculture, processing, retail and wholesale – as the obligation to freeze affected products is placed on the sector as a whole. Both the previous and revised legislation specifies that a freezing treatment must be applied to raw materials or finished product, but does not specify where in the supply chain any freezing treatment must take place. This is left to the discretion of individual food business operators who will seek to maximise efficiencies in the supply chain.

79. In addition, food business operators supplying fishery products may not necessarily know if a product is destined for raw consumption, and therefore subject to freezing controls, as this decision may be made later in the supply chain. For these reasons, estimated cost savings resulting from the new freezing

exemption have been aggregated for all affected industry sectors as a whole based on total UK production data for farmed fish and an estimate of the volume entering the raw 'ready to eat' market.

80. The published CEFAS production data for 2009 indicates a total UK farmed finfish production of 160,988 tonnes.<sup>28</sup> However, this data indicates a total Atlantic salmon production 144,663 tonnes, whereas more recent Scottish data for 2010 confirms this to be 154,164 tonnes.<sup>29</sup> Therefore total UK farmed finfish production has been calculated using the latest 2010 Scottish data for farmed salmon, and 2009 CEFAS data for all other production, giving a total UK production of 170,488 tonnes. If it is assumed, based on SSPO estimates, that 3 – 5% of total production is supplied for the raw 'ready to eat' market, this would equate to between 5,114 – 8,524 tonnes per annum of farmed fish going for raw consumption that previously had to be frozen and would now benefit from a freezing exemption.<sup>30</sup>
81. Most of the UK farmed salmon industry currently use third party companies to freeze gutted, head-on salmon when required. The SSPO have indicated that the basic cost of freezing is between £0.70 and £1.00 / Kg (October 2011) plus storage costs and potentially higher distribution costs. If an average freezing cost of £0.85 / Kg is used as an estimate, the freezing exemption in the Commission Regulation would result in estimated freezing cost savings to UK industry of between £4.3M per annum (based on 3% of production going for raw consumption) and £7.2M per annum (based on 5% of production going for raw consumption). On this basis we estimate that the per annum cost saving to the UK fish industry would range from £4,347,444 to £7,245,740 with a central estimate of £5,796,592. Table 19a below shows annual freezing cost savings broken down by country and firm size, whilst Table 19b shows the cost to the UK industry (discounted) over a period of 10 years.

**Table 19a: Freezing Costs Savings per Country and Firm Size (£, per annum, Central Estimate)**

	Micro	Small	Medium	Large	Total
England	£3,712,433	£1,010,781	£118,908	£6,193	£4,848,315
Wales	£185,100	£50,126	£5,752	£282	£241,260
Scotland	£402,995	£107,873	£13,193	£727	£524,789
Northern Ireland	£139,559	£37,964	£4,474	£233	£182,229
UK	£4,440,086	£1,206,744	£142,327	£7,435	£5,796,592

Note: totals may not sum due to rounding

**Table 19b: Freezing Costs Savings to UK Industry (£ constant prices, discounted over 10 years)**

Industry	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Freezing Costs Savings to UK Industry</b>													
<i>Upper Bound</i>	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£72,457,400	£7,245,740	£62,369,058
<i>Lower Bound</i>	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£43,474,440	£4,347,444	£37,421,435
<i>Central/ Best Estimate</i>	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£5,796,592	£49,895,247

Note: totals may not sum due to rounding

82. Potentially these savings could be even higher. One major salmon farming company representing around 24% of the total production of farmed Atlantic salmon in Scotland have estimated that as much as 25% of the total salmon they supply may be consumed raw or almost raw either as sushi/sashimi or cold smoked, therefore potential freezing cost savings could be much higher. Although a significant proportion of this is likely to be exported.

<sup>28</sup> <http://www.cefass.defra.gov.uk/publications/finfishnews/FFN11-Web.pdf>

<sup>29</sup> Scottish Fish Farm Production Survey: 2010 Report, Marine Scotland, The Scottish Government, 2011

<sup>30</sup> These estimated production volumes include raw and marinated/salted farmed fishery products only. No freezing savings have been calculated for cold smoked farmed fishery products as these products did not require to be frozen previously.

<sup>31</sup> Central Estimate obtained by: £5,796,592 = (£4,347,444 + £7,245,740) / 2

## Product Value Increase to Industry from Freezing Exemption

83. A freezing derogation will also increase the value of farmed fish supplied for raw consumption, as freezing turns a high quality fresh product into a cheaper frozen commodity product. Based on information provided by SSPO, the average UK spot price in 2010 for fresh salmon was £4.25 / Kg, and £3.69 / Kg for frozen salmon, giving a price differential of £0.56/Kg. If it is assumed that the price differential for fresh and frozen product is similar across all farmed species, and assuming between 5,114 and 8,524 tonnes are supplied annually to the raw 'ready to eat' market, this would result in an increase in value of between £2.8M and £4.7M for farmed fishery products intended to be consumed raw as a result of applying a freezing derogation.
84. On this basis we estimate a per annum incremental benefit from an increase in the value of raw farmed fish of £2,864,198 - £4,773,664 with a central estimate of £3,818,931<sup>32</sup>. Table 20a below shows the per annum benefit derived from an increase in product value as a result of the freezing exemption, based on central estimates and broken down by country and firm size. Table 20b shows the total benefits to industry discounted over a 10 year period.

**Table 20a: Product Value Increases from Freezing Exemption, by UK Country and Firm Size, (£, Central Estimate, per annum)**

	Micro	Small	Medium	Large	Total
England	£2,445,838	£665,927	£78,339	£4,080	£3,194,184
Wales	£121,948	£33,024	£3,790	£186	£158,947
Scotland	£265,502	£71,069	£8,692	£479	£345,743
Northern Ireland	£91,945	£25,011	£2,947	£154	£120,057
UK	£2,925,233	£795,031	£93,768	£4,899	£3,818,931

Note: totals may not sum due to rounding

**Table 20b: Product Value Increases to UK Industry (£ constant prices, discounted over 10 years)**

Industry	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Product Value Increase to UK Industry</b>													
<i>Upper Bound</i>	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£47,736,640	£4,773,664	£41,090,203
<i>Lower Bound</i>	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£28,641,984	£2,864,198	£24,654,122
<i>Central/ Best Estimate</i>	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£3,818,931	£32,872,163

Note: totals may not sum due to rounding

## **Enforcement Freezing Exemption Cost Savings**

85. We assume that the freezing exemption for farmed fish will reduce the level of enforcement action required to be taken against companies supplying farmed fishery products intended to be consumed raw. This will free up scarce Local Authority resources to focus on more high risk food safety issues. To calculate any potential cost savings from reduced levels of enforcement we first need to quantify the level of enforcement activity related to the previous freezing requirements.
86. Of the 32 Local Authorities in Scotland we are aware that 2 have spent time enforcing the previous freezing requirements. Assuming this is a typical level of enforcement across the UK, it can be estimated that around 27 of the 434 Local Authorities in the UK (6%) may have spent time to enforce the freezing requirements. Anecdotal evidence indicates that individual EHOs will spend between 0.5 – 1.5 hours on activities such as considering legislation and guidance, completion of enforcement reports, and liaising with the FSA.
87. We assume that one EHO per Local Authority will be required to spend time on these enforcement issues, resulting in a range of between 13.5 – 40.5 hours of total enforcement time spent on enforcing

<sup>32</sup> Central Estimate obtained by: £3,818,931 = (£2,864,198 (Lower Bound) + £4,773,664 (Upper Bound))/ 2

freezing requirements across the UK. The potential cost savings from applying a freezing exemption is then derived from multiplying the total amount of enforcement time (2 hours) by the hourly wage rate of an EHO (£20.46<sup>33</sup>), resulting in potential cost savings to UK enforcement authorities ranging between £278 - £833, with a central estimate of £555 per annum<sup>34</sup>. Table 21a below shows lower and upper bound estimates including a central estimate of these freezing exemption cost savings to Local Authorities broken down by country. Table 21b shows the total discounted freezing exemption cost savings to enforcement over a 10 year period.

**Table 21a – Freezing Exemption Cost Savings to Enforcement Authorities by UK Country)**

	No. of Affected LAs	Cost Saving		
		lower bound	upper bound	Central Estimate
England	22	£226	£679	£453
Wales	1	£14	£42	£28
Scotland	2	£20	£61	£41
Northern Ireland	2	£17	£50	£33
UK	27	£278	£833	£555

**Table 21b – Freezing Exemption Cost Savings to UK Enforcement Authorities (£, discounted over 10 years)**

Enforcement	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Freezing Costs Savings to Enforcement</b>													
<i>Upper Bound</i>	£833	£833	£833	£833	£833	£833	£833	£833	£833	£833	£8,325	£833	£7,166
<i>Lower Bound</i>	£278	£278	£278	£278	£278	£278	£278	£278	£278	£278	£2,775	£278	£2,389
<i>Central/ Best Estimate</i>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778

Note: totals may not sum due to rounding

## Non-monetised benefits

### *Quality Issues*

88. All industry representatives and affected business consulted in the development of this impact assessment have stressed that freezing of farmed salmon intended to be consumed raw or almost raw results in significant deterioration in the quality of the fish due to the soft, oily nature of the flesh, making it very difficult to slice into sashimi. The introduction of a freezing derogation will ensure that product can be supplied fresh, avoiding this quality issue and any potential deterioration in demand for raw product.

### *Reduced Barriers to Market Entry*

89. The freezing exemption may reduce barriers for new companies entering this raw 'ready to eat' market by removing the need to invest in freezing equipment and infrastructure. The SSPO has indicated that individual quick freezing (IQF) of raw material at the initial processing stage (immediately after gutting) is the best way to ensure optimum quality for finished raw products such as sushi and sashimi. The

<sup>33</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2011. (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Environmental health officers' £15.74 + 30% to cover overheads = £20.46)

<sup>34</sup> Central Estimate obtained by: £555 = £278 (Lower Bound) + £833 (upper Bound) / 2



freezing exemption removes the potential need for any new salmon companies entering the market to invest in IQF equipment at production sites.

### *Reputational Benefits*

90. It is likely that the new freezing exemption will help reinforce confidence in the ability of the UK farmed salmon industry to deliver premium fresh product in a timely manner. The SSPO have indicated that the freezing process introduces additional variability and costs into the supply chain that is not consistent with the supply of standard fresh product, and that freezing results in a loss of all the benefits of Scottish provenance and marketing. They highlight that the supply chain needs consistency and certainty of supply to operate effectively and when this consistency is compromised by additional processes, such as freezing, processors may seek alternative options to UK supply resulting in potential market deflection towards Norwegian imports. The ability of producers to carry out the freezing process also becomes a factor in the decision by retailers and food service businesses to buy UK farmed salmon. These factors have the potential to dilute the 'locally grown' and sustainability messages promoted by the Scottish industry, and could result in a fall in consumer confidence with respect to the quality of UK farmed salmon. The new freezing exemption will remove this additional variability in the supply chain and mitigate any potential impact on the reputation of the Scottish industry that may have otherwise occurred if freezing continued to be a legal requirement.

### **Consumers**

91. Provision of a freezing derogation for farmed fishery products intended to be consumed raw will provide consumers with a level of public health protection that is appropriate to the risks. The proposal only allows for fishery products to be exempted from the freezing requirements when there is sufficient evidence or risk assessment to show there are no risks to public health from parasitisation, or where those risks are shown to be negligible, ensuring that consumers are not exposed to products that may contain live parasites without first having been frozen. The freeing up of scarce Local Authority resources to focus on more high risk food safety issues will also enable the delivery of greater long-term benefits for consumers.

### **Government**

92. The introduction of a freezing exemption for farmed fish in the UK will remove any potential reputational costs to the UK Government of not applying risk-based controls. As outlined above current scientific opinion considers the risks to public health from parasites in farmed fish to be negligible when certain conditions are met, and supporting this amendment will ensure that food safety policy in the UK continues to be science and evidence based.

### **Total Benefits under Option 2b (Freezing Exemption)**

93. The total benefit associated with policy Option 2b is estimated at between £62m and £103m over 10 years with a best estimate of £83m; an annual average benefit of £9.6m. Once these benefits are discounted at a rate of 3.5% over 10 years we obtain a present value total benefit of £80m. Total on-going benefits associated with option 2b are presented in table 22.

**Table 22: Summary of All Monetised Benefits under Option 2b**

Total Benefits	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Benefit	Average Annual Benefit	NPV
<b>Enforcement</b>													
<u>Freezing Costs</u>													
<u>Savings</u>													

Upper Bound	£833	£833	£833	£833	£833	£833	£833	£833	£833	£833	£8,325	£833	£7,166
Lower Bound	£278	£278	£278	£278	£278	£278	£278	£278	£278	£278	£2,775	£278	£2,389
Central/ Best Estimate	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778
Total Enforcement	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£555	£4,778
Industry													
Freezing Costs Savings													
Upper Bound	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£7,245,740	£72,457,400	£7,245,740	£62,369,058
Lower Bound	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£4,347,444	£43,474,440	£4,347,444	£37,421,435
Central/ Best Estimate	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£5,796,592	£49,895,247
Product Value Increase													
Upper Bound	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£4,773,664	£47,736,640	£4,773,664	£41,090,203
Lower Bound	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£2,864,198	£28,641,984	£2,864,198	£24,654,122
Central/ Best Estimate	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£3,818,931	£32,872,163
Total Industry	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£96,155,232	£9,615,523	£82,767,409
Total Benefit													
Upper Bound	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£12,020,237	£120,202,365	£12,020,237	£103,466,428
Lower Bound	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£7,211,920	£72,119,199	£7,211,920	£62,077,946
Central/ Best Estimate	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£96,160,782	£9,616,078	£82,772,187

## Total Net Benefits

### Option 2a

94. Total costs outweigh the total benefits of preferred policy sub-option 2a generating a net negative benefit of £30,291 presented in table 23 below.

**Table 23: Total net benefit under Option 2a (Freezing Extension, central estimate)**

Net Benefit	Yr0	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Total Net Benefit	PV
Industry	-£12,530	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£12,530	-£12,530
Enforcement	-£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£17,761	-£17,761
Total	-£30,291	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£30,291	-£30,291

### Option 2b

95. Total benefits outweigh the total costs of preferred policy sub-option 2b generating a net positive benefit over 10 years of £77,807,196. Table 24 below displays the net benefit of this option 2b.

**Table 24: Total net benefit under Option 2b (Freezing Exemption, central estimate)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	PV
Net Benefits												
Industry	£4,668,293	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£9,615,523	£91,208,002	£77,820,179
Enforcement	-£17,206	£555	£555	£555	£555	£555	£555	£555	£555	£555	-£12,211	-£12,983
Total	£4,651,087	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£91,195,791	£77,807,196

Note: totals may not sum due to rounding

## Total net benefit under sub-options 2a and 2b (Freezing Extension and Exemption)

### Options 2a and 2b

96. Total benefits outweigh the total costs of preferred policy sub-options 2a and 2b generating a net positive benefit of £77,807,196 (central estimate) over ten years. Table 25 below displays the net benefit of the preferred option.

**Table 25: Total net benefit under Options 2a and 2b (Freezing Extension and Exemption, central estimate)**

UK	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	PV
<b>One-Off Costs: Familiarisation</b>												
<b>Industry (Options 2a+2b)</b>	£4,947,230	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,947,230	£4,947,230
<b>Enforcement</b>	£17,761	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,761	£17,761
<b>Total</b>	£4,964,991	£0	£0	£0	£0	£0	£0	£0	£0	£0	£4,964,991	£4,964,991
<b>Ongoing Benefits</b>												
<b>Industry (Freezing cost savings)</b>	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£5,796,592	£57,965,920	£49,895,247
<b>Industry (Increase in product value)</b>	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£3,818,931	£38,189,312	£32,872,163
<b>Enforcement (Cost savings)</b>	£555	£555	£555	£555	£555	£555	£555	£555	£555	£555	£5,550	£4,778
<b>Total</b>	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£96,160,782	£82,772,187
<b>Net Benefits</b>												
<b>Total</b>	£4,651,087	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£9,616,078	£91,195,791	£77,807,196

Note: totals may not sum due to rounding

## RISKS AND ASSUMPTIONS

97. Key stakeholders were invited to comment on our assessment of the costs and benefits to industry and enforcement bodies. Overall, respondents to consultation were mainly supportive of the assumptions used to obtain these estimates.
98. Under Option 2a we estimate that approximately 240 businesses will be affected by this proposal on the assumption that this will only impact on processors of wild cold smoked fish products. Though data is available on the number of cold smoked fish processors; we have been unable to separate out the proportion of processors that handle wild fish. This means number of businesses actually affected by the legislation is likely to be an overestimate.
99. Under Option 2b we estimate that approximately 94,760 businesses (fish farms, fish processors, retailers, wholesalers and food business operators) will be affected by this proposal. Familiarisation costs to Local Authorities are already calculated as per sub-option 2a. This is strictly to avoid the risk of double counting this one-off cost under both sub-options (2a and 2b).
100. Limited data is available on potential monetised benefits; estimates should therefore be interpreted as indicative and treated with caution.

## PROPORTIONALITY

101. We have been unable to obtain evidence on the number of processors handling wild fish including on-going freezer costs associated with the extension of freezing controls. To address these data gaps it is possible to develop a questionnaire and disseminate it to key industry and enforcement

stakeholders to obtain this information. However, taking account of the proportionality principle, it is our assessment that the time cost and resources needed to gather this information would far outweigh the benefits.

## **ADMINISTRATIVE BURDEN COSTS**

102. The documentation requirements in the new Commission Regulation are the same as those previously required by the EU hygiene legislation – affected fishery products must be accompanied by a document issued by the food business operator performing the freezing treatment stating the type of treatment applied, except when supplied to the final consumer. Therefore they will not impose any new additional administrative burdens on industry.
103. Where fishery products that have not undergone a freezing treatment are placed on the market the new Regulation requires that food business operators ensure that they originate from a fishing ground or fish farm that meet the exemption criteria. The new Regulation does not set down any mandatory requirements for how this obligation should be met; only indicating that this provision may be met by information in commercial documentation or by any other information accompanying the fishery products. It would be a commercial decision for food business operators as to whether additional documentation is provided. Therefore no additional administrative cost burdens have been calculated for this aspect of the revised legislation.
104. Any reduction in the level of enforcement action resulting from the freezing exemption for farmed fishery products would also reduce administrative burdens on Local Authorities.

## **ENFORCEMENT**

105. Local Authorities will be responsible for enforcing Commission Regulation (EU) No 1276/2011.
106. Domestic enforcement of the Commission Regulation will be provided by The Food Hygiene (England) (Amendment) Regulations 2012. Parallel legislation will apply in the other UK countries. This Regulation is due to come into force on 9 July 2012 and will be communicated to stakeholders by email, letter and via the Agency's website etc.

## **SIMPLIFICATION**

107. The Commission Regulation simplifies EU freezing controls applicable to fishery products intended to be consumed raw or almost raw by making a clearer distinction between the risks associated with parasites in wild and farmed fishery products. Both the Regulation and accompanying guidance set out clear criteria on when a freezing derogation can now be applied which will assist both affected food business operators and Local Authorities to understand risk factors and apply the legislation consistently across the UK.
108. The introduction of a freezing derogation for farmed fishery products will also reduce the regulatory burden on food business operators supplying these products to the raw 'ready to eat' market without compromising public health protection. It is fully expected that the revised freezing controls will result in an overall net reduction in the regulatory burden on UK industry which is fully in line with the Government's reducing regulation agenda.

## **IMPLEMENTATION & REVIEW**

109. Commission Regulation (EU) No. 1276/2011 applied directly in the UK from 29 December 2011 (i.e. 20 days after being published in the EU Official Journal on 9 December 2011).
110. A review to establish the actual costs and benefits and the achievement of the desired effects will take place in December 2016 (i.e. 5 years from the direct application of the Commission Regulation in the UK). A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

**COMPETITION ASSESSMENT**

111. The requirements of Commission Regulation (EU) No 1276/2011 are not expected to either directly or indirectly limit the number or range of UK suppliers of affected fishery products. The introduction of a freezing exemption for farmed fishery products may increase the competitiveness of food business operators supplying the raw ‘ready to eat’ market by removing additional processes and variability in the supply chain. This may help affected UK businesses compete against farmed fish imports from other third countries, particularly imports of farmed salmon from Norway.

**SMALL FIRMS IMPACT TEST**

112. As outlined above, during development of the Commission Regulation the FSA met with a range of affected small firms from the production, processing and retail sectors to discuss the impact of the planned changes on their business. All of those consulted were supportive of the freezing exemption for farmed fish which was viewed as a positive step in which European legislation was ‘catching up’ with the latest scientific evidence. All small businesses consulted were supportive of the Commission proposals being put forward.

**SUSTAINABLE DEVELOPMENT**

113. No impact on sustainable development is anticipated.

**RACE, GENDER & DISABILITY EQUALITY ISSUES**

114. No impact on race, gender or disability is anticipated.

**SPECIFIC IMPACT TESTS**

Type of test and link to guidance (Double click on each of the headings to follow link)	Click on a box for EACH row to show if the test is relevant or not:	
	Relevant	Not relevant
<a href="#">Competition assessment</a>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<a href="#">Small firms impact test</a>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b><a href="#">Sustainability:</a></b> Economic impact Social impact <a href="#">Environmental impact</a>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
<a href="#">Carbon impact</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<a href="#">Equality impact</a>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

<u>Justice impact</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<u>Rural proofing</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<u>Human rights</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<u>Privacy impact</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<u>Creation of new criminal offence</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<u>Impact on powers of entry</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

