

FINAL REGULATORY IMPACT ASSESSMENT

1. TITLE OF THE REGULATORY PROPOSAL

THE FEEDING STUFFS (SCOTLAND) AMENDMENT (No 3) REGULATIONS 2003

Implementation of:

Commission Directive 2003/7/EC of 24 January 2003 amending the conditions for authorisation of canthaxanthin in feedingstuffs in accordance with Council Directive 70/524/EEC (OJ No L22, 25.1.2003, p.28)

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

2(i) Objective

These Regulations will reduce the permitted maximum content in complete feedingstuffs of canthaxanthin; a colourant authorised for use in animal feedingstuffs. The reduction was adopted by the European Commission following an opinion from the Scientific Committee on Animal Nutrition (SCAN) which noted that canthaxanthin intakes would be too high in a theoretical diet modelling high level consumption of foods containing this colourant. SCAN therefore concluded that the permitted maximum inclusion rates in feed should be reduced.

The feed industry, particularly the producers of feed for farmed fish and (to some extent) laying hens, will be most heavily affected by the measure, and will have to reduce the use of this colourant and/or switch to an alternative.

2(ii) Devolution

These Regulations will apply only in Scotland. Separate but parallel regulations will be made in England, Wales and Northern Ireland.

2(iii) Background

Canthaxanthin is a naturally-occurring pigment belonging to a group of substances called carotenoids, which themselves are related to a group of substances called carotenes. These provide the red-orange pigment in carrots, red peppers, and marine algae and shrimps. Beta carotene itself is related to vitamin A. In nature, wild salmon and trout derive their pinkish-coloured flesh from the carotenoids in their natural diet.

Canthaxanthin is also a feed additive, authorised in EC feed legislation for use as a colourant in certain feeds manufactured for poultry and for farmed salmon and trout. Its purpose is to provide additional pigmentation to egg yolks and to the flesh of fish and poultry in order to make the products appear more attractive to the consumer. For salmon and trout, another colourant, astaxanthin, may also be used – alone or in combination with canthaxanthin – to help colour the fish flesh. Farmed salmon and trout would otherwise consume lower quantities of carotenoids, and their flesh would

have less pigmentation. Other colourants are also authorised for use in feed for laying hens.

Canthaxanthin has been used in this way for many years, although there have been concerns – prompted by the use of so-called “tanning pills” (now withdrawn) which incorporated the colourant as their active ingredient – that excessive levels may cause retinal deposits in humans. In 1995, the FAO/WHO Joint Expert Committee on Food Additives (JECFA) recommended an acceptable daily intake (ADI) for consumers of no more than 0.03mg per kg of human bodyweight. (The ADI is the amount of a substance that can be ingested daily over a lifetime without appreciable health risk. It is expressed in relation to the bodyweight (bw) in order to allow for different body sizes, such as for children of different ages.) The Commission’s Scientific Committee on Food adopted the JECFA recommendation in 1997 and the UK’s Committee on Toxicology and the Food Advisory Committee endorsed this recommendation the following year.

The Commission subsequently asked SCAN to review the levels of canthaxanthin permitted in feedingstuffs with particular regard to vulnerable groups of consumers eating certain foods. SCAN noted that canthaxanthin intakes would be too high in a theoretical diet modelling high level consumption of foods containing this colourant, and therefore concluded that the permitted maximum inclusion rates in feed should be reduced.

The maximum inclusion rates currently permitted for canthaxanthin are as shown in the table below:

Species	Maximum content (mg/kg) in complete feedingstuff	Conditions
Poultry	80 mg/kg	Alone or with other carotenoids and xanthophylls*
Salmon, trout	80 mg/kg	Use permitted from the age of 6 months onwards. The mixture of canthaxanthin with astaxanthin is allowed provided that the total concentration of the mixture does not exceed 100mg/kg in the complete feedingstuff.
Dogs, cats, ornamental fish	---	---

*Carotenoids and xanthophylls are categories of colourants.

The new measure reduces these limits to those shown in the following table:

Species	Maximum content (mg/kg) in complete feedingstuff	Conditions
Poultry other than laying hens	25 mg/kg	The mixture of canthaxanthin with other carotenoids and xanthophylls is allowed provided that the total concentration of the mixture does not exceed 80 mg/kg in the complete feedingstuff.
Laying hens	8 mg/kg	

Salmon, trout	25 mg/kg	Use permitted from the age of 6 months onwards. The mixture of canthaxanthin with astaxanthin is allowed provided that the total concentration of the mixture does not exceed 100 mg/kg in the complete feedingstuff.
Dogs, cats, ornamental fish	---	---

NB: There are no limits or conditions for the use of canthaxanthin in feed for dogs, cats and ornamental fish. However, these species are included in the table to indicate that (unlike other animals not so listed) it is permissible to use the colourant in their feed.

2(iv) Risk Assessment

An informal consultation was conducted in the summer of 2002, when the proposal was still in draft. Consumer groups were generally content with the proposed new levels, although producer interests considered that they were not proportionate to the actual risk. The SCAN calculations were based on an assumed consumption of 300g of salmon and trout per day. By contrast, average UK consumption, as shown by the National Diet and Nutrition Survey published in December 2002, is around 86g of oily fish (salmon and tuna) per week (12g per day). Extreme UK consumption, as shown by the same survey, was still less than 100g per day – less than a third of the SCAN assumption.

The UK therefore argued during negotiation of the measure that although it was content to have reduced limits on canthaxanthin in feed for farmed fish, those proposed were too low and disproportionate to the actual risk to consumers. The UK argued that consumer health would be better protected by the adoption of risk-based maximum residue limits (MRLs) for the levels of canthaxanthin in fish flesh for human consumption, which would apply to all fish products marketed in the EU. This approach would also cover imports from third countries, which would not be subject to the same controls on feed, and thus ensure that UK fish producers would not be disadvantaged relative to third country producers – see 2(v) below. The UK argued that to enhance consumer choice, foods (both fish and eggs) which had been coloured by the feed consumed should be labelled to indicate this. However, the Commission and some other Member States did not accept these arguments, and a qualified majority carried the proposal, with the UK abstaining in the final vote.

Nevertheless, the Commission has agreed to consider the UK suggestion of setting maximum residue levels for canthaxanthin in fish flesh. The UK, motivated by consumer choice considerations, is also continuing to press for the labelling of foods coloured by the canthaxanthin in the feeds consumed.

2(v) Business Sectors Affected

Canthaxanthin is no longer used extensively in feed for laying hens and other poultry – some egg-producers' codes of practice prohibit its use – so the reduced inclusion rates are unlikely to have much impact on that sector. However, current inclusion rates of canthaxanthin for farmed fish are generally much higher than the new

maximum level of 25 mg/kg for complete feeds, and the aquaculture sector will therefore be faced with the need to either reduce the use of canthaxanthin and/or switch to the alternative colourant astaxanthin.

Aquaculture interests, particularly Scottish salmon producers who are regular users of canthaxanthin, have claimed a possible loss of export markets, particularly in North America and Japan. Customers in these countries are said to regard highly pigmented fish flesh as of higher quality than flesh of a paler hue; canthaxanthin-coloured fish flesh therefore commands a higher price. Third country producers would not be subject to the same controls, and could therefore take an increased share of these markets. Aquaculturists could also face competition in the domestic market from third country imports produced under regimes that permit inclusion rates of greater than 25 mg/kg.

Aquaculturists have advised that for those currently using 100% canthaxanthin the cost of switching to 25 mg/kg canthaxanthin and making up the balance from astaxanthin would be 2p-4p per kilo of final product, rising to 7p per kilo of final product for those switching to 100% astaxanthin. This could not be absorbed and would have to be passed on to consumers of farmed salmon and trout, with a consequent impact on sales. The United Kingdom Agricultural Supply Trades Association estimated that the annual cost to industry of a complete switch from canthaxanthin to the more expensive astaxanthin could amount to £3.3 million.

Much of this information was provided in response to the informal consultation. Stakeholders, particularly aquaculture interests, were invited to comment further on these issues as part of the public consultation on the draft Regulations, and to provide further financial and other information on the potential impact of the measure on their activities. However, no further comments were forthcoming.

2(vi) Issues of Equity and Fairness

UK producers of farmed fish will clearly be disadvantaged relative to imports of fish for human consumption from third countries not subject to the same feed controls, and will face increased costs for the feed they use because of the higher cost of astaxanthin. This could adversely affect both the domestic and the export markets. The export market for Scottish salmon in 2002 was worth £140 million, which represented about half of all Scottish agriculture and fisheries exports in that year.

The UK feed industry is unlikely to be disadvantaged directly by the reduced inclusion rates for canthaxanthin, because the reduction will apply to both feed manufactured in the UK and feed imported from third countries, which has to conform to EU feed legislation to be legally sold here. UK compounders estimated, however, that they would be unable to absorb the higher costs of astaxanthin, which could increase the cost of finished feed from around £65 per tonne to £80-£85 per tonne and which would have to be passed on to their customers.

Stakeholders, particularly feed industry interests, were invited to comment further on these points and to provide further financial and other information on the potential impact of the measure on their activities. As before, however, no further comments were forthcoming.

3. OPTIONS

There would appear to be four possible options:

- (i) non-implementation or partial implementation of the measure; or
- (ii) full implementation of the measure; or
- (iii) full implementation of the measure plus continued pressure on the Commission to bring forward proposals for maximum residue levels (MRLs) for canthaxanthin in fish flesh for human consumption; or
- (iv) delayed implementation of the measure.

4. BENEFITS AND COSTS

4(i) Policy Considerations

Option 1

Non-implementation or partial implementation of Directive 2003/7 (perhaps by adopting a maximum inclusion rate for canthaxanthin in fish feed of less than the present 80 mg/kg but above 25 mg/kg) could represent a saving in the costs of this measure to both the manufacturers and the users of feed for farmed fish. Manufacturers would not be faced with the need to source alternative colourants or to pay the higher price for astaxanthin; and aquaculturists, in addition to not having to pay higher prices for feed containing astaxanthin, would retain both their existing export markets in North America and Japan and their current share of the domestic market relative to imports of farmed fish for human consumption from third countries.

However, both non-implementation and partial implementation could give rise to perceptions that feed safety and consumer protection measures were being ignored. Non-implementation or partial implementation would also result in undoubtedly successful legal proceedings against the UK in the European Court of Justice, as the terms of the Directive require implementation of all its provisions. The costs of non-implementation would include the costs of infraction proceedings to the UK Government. There could also be a loss of EU markets to both UK feed companies, which might be unable to market fish feeds in other Member States because they could not demonstrate compliance with EU requirements; and to UK aquaculturists, who might be unable to sell fish products in other EU countries because of consumer fears about the links between canthaxanthin and retinal damage in humans (albeit at much higher levels of consumer exposure).

Option 2

Full implementation of Directive 2003/7 would meet the UK's mandatory obligation to implement EC measures. UK feed manufacturers and aquaculturists could benefit from this, as both would be able to demonstrate that their products met EU feed safety and consumer protection requirements. However, the paler hued fish flesh

which could result from the reduced use of canthaxanthin might lead to some loss of export markets, particularly for Scottish salmon in North American and Japan. There could also be a reduction in domestic sales for UK producers of farmed fish should UK customers prefer the colour of imported fish flesh from third countries not subject to the same feed controls.

Option 3

This would have similar benefits and costs as Option 2. In addition, UK consumers would benefit, should continued pressure on the Commission lead to risk-based maximum residue levels that would be consistently applied to livestock products for human consumption – i.e., at the point where the colourant enters the human food chain. This could also have longer-term benefits for UK producers of farmed fish, who – once MRLs had been agreed – would no longer be disadvantaged in the domestic market relative to imports from third country producers working to different feed controls.

Option 4

Delaying implementation might defer any implementation costs. However, this would still leave the UK open to infraction proceedings and there could be concerns that a measure intended to ensure the safety and integrity of the feed chain and the protection of consumers was being delayed.

4(ii) Economic Considerations

Increased Production Costs

These come from the reformulation of feed for farmed salmon and trout; reducing canthaxanthin and increasing astaxanthin use to maintain flesh colour. This has been assumed to increase production costs by £40 per tonne, based on the upper range of industry estimates. These costs (fish and feed) fall differently on producers, retailers and consumers for each option, and are estimated to sum to an annual total of £0.78 million for options 2, 3, and 4.

Potential Market Losses

This affects options 1 and 4 as non-implementation will effectively bar UK exports of fish for human consumption from EU markets. This trade is worth approximately £120 million per annum.

Infraction Costs

Non-implementation – options 1 and 4 – could bring infraction proceedings against the UK. Because of the lack of precedent in this area, no costs associated with these have been included in the formal calculations.

Avoidance of Health Costs

While in theory the human health costs associated with potential retinal damage due to high exposure to canthaxanthin could be avoided by implementation of this Directive, it is unlikely that any sector of the UK population is at risk. In practice, even “extreme” UK consumers are highly unlikely to approach intake levels that might correspond to deposition of canthaxanthin on the retina. This is because “extreme” UK consumption is estimated to be less than a third of that assumed in the SCAN model, which also had a wide safety margin built in.

The Food Standards Agency does not believe that consumption of livestock products coloured with canthaxanthin, even at currently permitted levels, presents a risk of retinal damage to UK consumers. We are however required to present a worst case scenario in our economic analysis of the costs and benefits of each option. The calculations in the summary table below have therefore assumed for illustrative purposes that 2.5% of the population may be at risk and will therefore benefit from the new lower limits for canthaxanthin.

It is also difficult to estimate an exact economic cost for each case; Department for Transport estimates (for avoiding different health states¹) have been used.

Summary of Economic Costs and Benefits

Option	Discounted Costs (£ million)	Discounted Benefits (£ million)	Net Present Value (£ million)
1. Do Nothing; Non-implementation	993.2	0	-993.2
2. Full Implementation	5.93	0.24	-5.69
3. Full Implementation plus introduction of MRLs	7.17	0.24	-6.93
4. Delayed Implementation	338.1	0.15	-338.0

All figures are calculated over 10 year period using discount rate of 3.5%.

Overall Summary and Recommendations

Options 1 and 4 produce highly negative economic values mainly because of the large industry losses that could be associated with the loss of EU export markets for fish for human consumption. If the UK were not to implement this Directive then UK producers of farmed salmon and trout would effectively be barred from other EU markets. For this reason these options are not recommended.

Options 2 and 3 also produce negative economic values but these are of a much lower magnitude. Both options avoid potential losses in the EU export market while

¹ In particular avoidance of health state F: slight to moderate pain; some restrictions to work and/or leisure activities for several weeks/months; return to normal health with no permanent disability; £22,367 per case.

generating human health benefits. However, these benefits are very small in relation to the costs that will be imposed on industry. In order for the costs to equal the benefits (i.e., reach break-even point), 60% of the UK population would need to be at risk (i.e., consuming very large quantities of farmed salmon and trout.) The actual proportion of the population consuming at this level is known to be less than 2.5%; even where a higher valuation is placed on each retinal damage case² this proportion would still need to reach 22%.

Option 3 represents the best overall approach despite a slightly more negative economic value than option 2. This is because the future introduction of maximum residue levels would remove some of the negative competition effects (with all producers now facing the same feed costs) from non-EU producers selling into the UK market, and enable some cost sharing along the supply chain. Salmon and trout producers' costs associated with this Directive could be reduced under option 3, with the other fractions passed to others in the supply chain.

All of the economic calculations in this RIA are based on the implicit assumption that consumers want, and are prepared to pay for, livestock products coloured via a feed additive. However, attitudes to additives have changed and will continue to evolve over time. It may be that producers will not have to meet these added costs if consumers cease to be concerned about flesh colour and look for lower levels of additives in general.

Stakeholders were invited to provide further information on any evidence that consumers in the UK and the major export markets would be prepared to pay more for livestock products coloured via a feed additive. However, no comments were forthcoming in response to the consultation, and it is not therefore possible to derive any conclusions with respect to consumer willingness to pay extra for livestock products coloured via a feed additive.

5. COSTS FOR BUSINESS, CHARITIES & VOLUNTARY ORGANISATIONS

5(i) Compliance Costs

Charities and voluntary organisations will be unaffected by this measure. The costs of compliance for business are difficult to quantify, although some estimates are given in sections 2(v) and 2(vi) above. Stakeholders were requested to provide further information on the potential costs to them of this measure as part of the consultation but as before, no comments additional to those already provided in response to the informal consultation were forthcoming. As stated in 2(v) above, much of the information provided in response to the informal consultation was incorporated in the partial Regulatory Impact Assessment drawn up for the formal consultation on the draft Regulations. Also as stated in 2(v) above, the United Kingdom Agricultural Supply Trades Association estimated in response to the informal consultation that the annual cost to industry of a complete switch from canthaxanthin to the more expensive astaxanthin could amount to £3.3 million.

² Health state V: moderate to severe pain; some pain gradually reducing but may recur when taking part in some activities; some restrictions to leisure and possibly some work activities for rest of life; £61,501 per case.

5(ii) Costs for a Typical Business

As for 5(i) above.

6. CONSULTATION WITH SMALL BUSINESS (THE “LITMUS TEST”)

Approximately one-third of the companies that manufacture prepared feedingstuffs claim small company status. The impact of this measure on small business competitiveness and profitability is likely to be high. Small business stakeholders were accordingly requested to provide information on the potential impact of this measure on them as part of the consultation on the draft Regulations, but once again no comments additional to those already provided in response to the informal consultation on the proposal when it was still under negotiation were received.

7. COMPETITION ASSESSMENT

The markets supplying farmed salmon and trout will be affected by these Regulations. Most concern is generated by the impact they may have on the competitive position of UK producers with regard to export markets (both EU and non-EU) and from imports to the domestic market.

The farming of Atlantic salmon (based predominantly in Scotland) is dominated by multinational corporations with more than 100 producing companies involved. In a recent ruling, the Competition Commission (CC) found that the appropriate market for farmed Atlantic salmon was the whole of the European Economic Area (EEA), in which it appears that no producer has more than a 10% market share. The trout farming industry (with more than 350 registered farms) is much smaller than the salmon farming industry, more geographically dispersed, and appears to be dominated by smaller companies. Trout production ranges from a few tonnes up to 1000 tonnes, with no one producer having greater than a 10% market share in the UK (the most narrow market definition).

Option 1, not implementing the Directive and saving producer costs, will effectively prevent access to the EU market for UK producers; this market is worth around £120 million annually. Option 2 will allow access to all export markets but will increase UK (and EU) producers' costs by 2-7p per kilo (representing between 1% and 3.5% of current wholesale prices for both salmon and trout), placing them at a competitive disadvantage to non-EU producers. Producers would be faced with the choice of meeting these costs or losing market share. Option 3 will have the same competition implications for UK producers in the short-term; however, pressing for a switch to MRLs in the longer-term will affect all producers equally and remove the bias against EU producers. Option 4 is identical to option 2 in its effects, which are simply delayed by 4 years.

The Regulations have negative competition implications for all the considered options. Only option 3 moves towards addressing these and putting all producers on an equal competition footing, and is therefore the recommended choice.

It is understood that many aquaculturists contract directly with feed compounders, and that both parties to the contract are reluctant to divulge information on volumes and prices to third parties in case it is of use to their competitors. Aquaculture and feed industry interests were nevertheless invited to provide information on the volume and value of the trade in feed for farmed fish, to permit compilation of a more refined competition assessment, as part of the consultation on the draft Regulations. An assurance was given that any data supplied would be anonymised, but in the event no such data was forthcoming.

Approximately one-third of the companies that manufacture prepared feedingstuffs claim small company status (see section 6 above) and could therefore be disproportionately affected, vis-à-vis larger firms, by the cost increases they would face as a consequence of the measure. The measure could also have some effect on the structure of the markets for both feed and aquaculture products, and it is possible that some small firms could merge or cease operations.

The reduction in the permitted maximum inclusion rates for canthaxanthin will directly affect all feed producers, who will be required to obtain alternative colourants or perhaps cease using them altogether.

Stakeholders, particularly aquaculture and feed industry interests, were accordingly invited to provide information on the potential impact of the measure on their activities, including the likely costs to them, as part of the consultation on the draft Regulations. However, as advised in 2(v), 2(vi) and 5(i) above, no information additional to that already provided in response to the earlier informal consultation was forthcoming.

8. ENFORCEMENT AND SANCTIONS

8(i) Enforcement

Enforcement of animal feedingstuffs legislation is the responsibility of local authority Trading Standards Departments in Great Britain, and the Department of Agriculture and Rural Development in Northern Ireland. Enforcement includes the taking of samples of animal feed and the testing of them for the presence of various ingredients. In theory, enforcement authorities should not face additional costs as a consequence of the reduction in the permitted maximum content of canthaxanthin, as testing for its presence in feed should already be part of their enforcement activity.

Enforcement authorities were invited to provide information on possible additional costs to them as part of the consultation on the draft Regulations. The Local Authorities Co-ordinators of Regulatory Services (LACORS) has advised that it does not anticipate that the new requirements would present enforcement authorities with any significant additional resource burdens.

8(ii) Sanctions

The penalties for non-compliance with feedingstuffs legislation are set out in the Agriculture Act 1970 and the Feeding Stuffs (Scotland) Regulations 2000.

9. MONITORING AND REVIEW

The Food Standards Agency welcomes comments by the feed industry; enforcement authorities and other stakeholders which will help evaluate their experience of the new legislation and its effectiveness. This could include requests for a future review of the new MPLs for canthaxanthin. However, stakeholders should note that potential requests for increases in the permitted maximum content, particularly in feed for salmon and trout, would need to be supported by scientific evidence to demonstrate that this would not entail additional risks to animal or human health.

Food Standards Agency Scotland is committed to ensuring that all Regulations introduced are, and remain, proportionate and fit for purpose. In line with Scottish Executive guidance provided by Improving Regulations in Scotland (IRIS) Unit we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment. This will be completed within 10 years of the date of the Regulation coming into force.

10. CONSULTATION

10(i) Within Government

The Food Standards Agency in England, Wales and Northern Ireland has been consulted on the implementation of the measure. Agriculture Departments have similarly been consulted.

10(ii) Public Consultation

The measure was the subject of informal consultation with stakeholder interests while it was still under negotiation in Brussels. After adoption and publication of the measure in the *Official Journal*, statutory consultation with stakeholder groups – the feed industry, aquaculturists, enforcement authorities and consumer groups – commenced on 6 May and lasted for twelve weeks. Stakeholders were invited to comment on the draft Regulations and the draft Regulatory Impact Assessment, including information on costs and benefits (both monetary and non-monetary).

A total of eight responses were received in response to this consultation. Three – from the Malt Distillers Association of Scotland, the Meat and Livestock Commission and the Scottish Association of Meat Wholesalers – advised that they had no comments to make. One response, from the Halal Food Authority, made general comments about the need for feedingstuffs to be suitable and wholesome. The fifth response, from the Scottish Agricultural College, suggested that a reduction in the use of canthaxanthin, particularly in poultry diets, could lead to a reduction in the purchase and consumption of animal products because of increased variability in

their appearance; but also, on the other hand, that any publicity given to the claimed health benefits of a reduction in the additive content could lead to an increase in the consumption of such products. The sixth response, from LACORS, is summarised in 8(i) above.

A seventh response, from the Salmon Farm Protest Group – a group campaigning for (at the minimum) the labelling of aquaculture products to show the additives included in fish feed as a prelude to (at the maximum) the phasing out of aquaculture altogether – argued that although the reduction in the permitted inclusion rates of canthaxanthin is welcome, the Agency has not gone far enough and should instead be moving towards a blanket prohibition on the use of this and other colourants. It has been explained in response that because feed legislation is a harmonised area under EU law, it would be difficult for the UK to take unilateral action in this area without first making an application to the Commission for a derogation, which would be very unlikely to be granted unless supported by strong scientific evidence to demonstrate any health risks to animals and the consumers of animal products at the new, lower inclusion rates.

The eighth response came from the United Kingdom Agricultural Supply Trades Association, reprising comments made by its Fish Feed Sub-Committee in response to the informal consultation on the proposal when it was still under negotiation in Brussels. This argued that the only safety issue which had arisen with respect to canthaxanthin had been its inclusion at very high rates in so-called “tanning pills” which, as pointed out in section 2(iii), have since been withdrawn. By contrast, there is no evidence that the use of this colourant in feed, even at the present maximum inclusion rate of 80 mg/kg, has given rise to any animal or human health concerns. The Fish Feed Sub-Committee accordingly considered that the rationale advanced by the Scientific Committee on Animal Nutrition for the reduction in the maximum inclusion rate of canthaxanthin was flawed because it grossly overestimated the quantity of fish consumed, took no account of the fact that producers in third countries would not be subject to the same constraints as those within the EU, and overlooked the increased costs the feed industry and aquaculturists would face because of the switch to the more expensive astaxanthin necessary to maintain the colour of the finished product. UKASTA has been advised in response that the UK raised these points during the negotiations on the proposal, but that they failed to carry weight with other Member States.

11. SUMMARY AND RECOMMENDATIONS

Option	Total Cost	Total Benefit
Option 1: Non-implementation or partial implementation	Costs of infraction proceedings (which would be ongoing); loss of EU markets for both UK feed manufacturers and UK fish farmers.	No loss of exports to third countries or UK markets for UK producers of farmed salmon and trout.
Option 2: Full implementation	Possible loss or reduction of export and	UK aquaculturists could continue selling farmed salmon and trout

	domestic markets for farmed salmon and trout. Additional costs of fish and feed	into EU markets.
Option 3: Full implementation plus pressure on Commission to propose MRLs for canthaxanthin in fish flesh	As for Option 2 (in the shorter term).	As for Option 2 (in the shorter term). In the longer term: no disadvantage to UK producers of farmed fish relative to imports from third countries, which would have to meet the same MRLs, plus unquantifiable benefits to consumers from setting MRLs (see section 2(iv)).
Option 4: Delayed implementation	Costs of infraction proceedings (which would be ongoing).	Maintenance of existing inclusion rates for canthaxanthin until implementation of the measure.

The reduction of the permitted maximum inclusion rates for canthaxanthin, particularly in feed for farmed fish, could have a major effect on both the producers of such feed and its users, the aquaculture industry. Producer and user interests have already said that they do not consider the new, reduced levels proportionate to the actual risk. The UK took a similar line in negotiations on the proposal, arguing that consumer health would be better protected by the adoption of maximum residue limits for the levels of canthaxanthin in fish flesh for human consumption, which would apply to all fish products marketed in the EU, including imports from third countries which would not be subject to the same controls on feed.

Other Member States did not accept this argument and the UK therefore abstained in the final vote, although the Commission has indicated that it will consider the UK argument for the setting of maximum residue levels for canthaxanthin in fish flesh. It could accordingly be possible for the UK to delay – or even defer altogether – implementation of the measure pending agreement on MRLs. However, there could be perceptions that a measure intended to enhance feed safety, and thus the consumers of farmed livestock products, was being delayed. In any case, the measure has been adopted at European level and the UK is legally obliged to implement it in domestic legislation.

We therefore recommend Option 3 – i.e., the implementation of Directive 2003/7 in Scotland by the Feeding Stuffs (Scotland) Amendment (No. 3) Regulations 2003, allied to continued pressure on the Commission to bring forward proposals for setting MRLs for canthaxanthin in fish flesh for human consumption. Stakeholders were invited to comment on this recommendation but none did so.

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Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister _____

Date _____