

FULL REGULATORY IMPACT ASSESSMENT

Title of measure

1. The Sweeteners in Food (Amendment) (England) Regulations 2004.

Purpose and intended Effect of the Measure

2. To update the rules relating to the use of sweeteners in foodstuffs by implementing in England the provisions of European Parliament and Council Directive 2003/115/EC of 22 December 2003 amending Directive 94/35/EC on sweeteners for use in foodstuffs, and also Commission Directive 2004/46/EC of 16 April 2004 amending Directive 95/31/EC establishing purity criteria for sweeteners.

Devolution

3. The Regulations relate to England only. Separate, parallel legislation has been made in Scotland, Wales and Northern Ireland.

Background

4. The Sweeteners in Food Regulations 1995 (as amended) provide current UK Regulations in this area. These Regulations implement EC Directive 94/35/EC (as amended) and Commission Directive 95/31/EC (as amended).

5. The Framework Directive 89/107/EEC on food additives provides for the adoption of specific Directives to harmonise the use of different categories of additives in foodstuffs. Directive 94/35/EC on sweeteners for use in foodstuffs sets out a list of authorised sweeteners, the foodstuffs in which they may be used and their conditions of use. The Directive was adopted in June 1994 and first amended in 1996. It has been amended on this occasion in light of recent technical and scientific developments.

6. The main amendments introduced by Directive 2003/115/EC are:
 - Changes to the text of the Directive in order to bring it into line with other food additive Directives; and to reflect recent changes in Standing Committee procedures.
 - Changes to the conditions of use for two currently permitted sweeteners, cyclamic acid and its sodium and calcium salts (E952; "cyclamate"), and aspartame (E951).

- The addition of two new substances, sucralose (E955) and salt of aspartame –acesulfame (E962) to the list of sweeteners approved for use in the EU.

7. Following the revised opinion of the Scientific Committee on Food (SCF) on cyclamate (E952) in March 2000, setting a full Acceptable Daily Intake (ADI) of 0-7 mg/kg bw/day, Member States accepted that there was a need for a reduction in the maximum usable dose of cyclamate in soft drinks. The Commission's original proposal reduced the maximum permitted dose from 400 mg/l to 350 mg/l. On first reading of the proposal, the European Parliament adopted a reduction in the levels of cyclamate in water-based flavoured drinks energy-reduced or with no added sugar to 100 mg/l.

8. The Commission rejected this amendment and proposed a level of 250 mg/l with an extension of this reduction to include 'milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar'. In addition, the Commission agreed to enter the following minute statement "The Commission undertakes to keep under review the maximum usable doses of cyclamic acid and its sodium and calcium salts (E952 "cyclamate") taking account inter-alia of information on intakes from Member States."

9. Political agreement was reached (on first reading) at the Competitiveness Council on 19 May 2003. On their second reading (21 October 2003), the European Parliament adopted three amendments to the common position and Council adopted the common position (final) at second reading on 1 December 2003. The proposed level of 250 mg/l was adopted for cyclamate.

10. Commission Directive 2004/46/EC amends Directive 95/31/EC for the fourth time and lays down specific purity criteria for sucralose and salt of aspartame-acesulfame in the EU. Sucralose and salt of aspartame-acesulfame were each given two-year temporary national authorisations (in 2002 and 2003 respectively) to be marketed in the United Kingdom prior to their EU-wide approval. These authorisations are permitted under Article 5 of the Food Additives Framework Directive (89/107/EEC). Article 3 of Directive 89/107/EC specifies the need to establish purity criteria for all additives used in food. Purity criteria for sweeteners exist at International level and these are taken into consideration when establishing purity criteria for sweeteners approved in the EU.

11. The temporary national authorisation granted to sucralose incorporated the International purity criteria for this sweetener as set out at pages 119 to 124 of the Food and Agriculture Organisation's Compendium of Food Additives Specifications Addendum 2 (1993) FAO Food and Nutrition Paper 52 Addendum 2. The temporary national authorisation granted to salt of aspartame-acesulfame

incorporated the International purity criteria for this sweetener as set out at pages 19 to 21 of the Food and Agriculture Organisation's Compendium of Food Additives Specifications Addendum 8 (2000) FAO Food and Nutrition Paper 52 Addendum 8. The purity criteria established for salt of aspartame-acesulfame at EU level is identical to the International specifications. However, the EU specifications for sucralose outlined in Commission Directive 2004/46/EC stipulate a particular pH value for the sweetener whereas the International specifications do not. This difference does not in practice alter the specifications for sucralose or present any changes to its permitted use.

12. The temporary national authorisations for these sweeteners will be revoked as a result of the Sweeteners in Food (Amendment) (England) Regulations 2004 coming into force and although they will continue to be permitted to be used under the new Regulations, some changes to the conditions of use of sucralose in a small number of categories of foodstuffs will occur as a result.

Risk assessment

13. Studies have shown that cyclamate fed to rats can be metabolised to cyclohexylamine in their bodies and, at high doses, this can cause slight damage to their testicles. Some humans can also convert unabsorbed cyclamate to cyclohexylamine, a metabolite of cyclamate. However, experts have concluded that studies show that cyclamate has no similar effect in humans.

14. The ADI for this additive of 7 milligrams per kilogram bodyweight (mg/kg) was set on a precautionary basis to protect the most sensitive individuals and allow for uncertainties in the scientific evidence. Due to the safety margins in the ADI, it is not a threshold value above which harmful effects will occur in humans.

15. Directive 2003/115/EC offers consumers increased protection through the reduction in use and levels of use of cyclamate, in line with the SCF's revised opinion published on 9 March 2000. Cyclamate intakes have not hitherto been regarded as a problem in the UK since, until recently, cyclamate was not used by UK manufacturers - it was in fact not permitted to be used in this country from 1970 until 1995. However, soft drinks containing cyclamate are now known to be on the UK market.

16. The Food Standards Agency's 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks' published in 2003 (Food Surveillance Information Sheet 36/03) recorded diaries of consumption of soft drinks over one week for a total of 1110 young children. Approximately 10% of these children consumed drinks containing cyclamate, of which, one quarter consumed cyclamate at levels above the ADI. This data also indicated that young children who are high-level consumers, drinking five or more glasses or beakers

(averaging about 180mls) of squash containing cyclamate each day, exceed the ADI of this intense sweetener by a factor of two. A reduction of the maximum permitted limit of cyclamate in soft drinks was therefore required to ensure that high-level consumers of cyclamate-containing soft drinks do not exceed the ADI.

17. Directive 2003/115/EC also offers consumers the choice of the newly permitted sweeteners, sucralose and salt of aspartame – acesulfame, which provide a number of advantages over those currently permitted. Manufacturers of these sweeteners are now able to market these sweeteners throughout the European Union.

18. The SCF issued a statement on salt of aspartame-acesulfame in March 2000: "Considering that a) the salt represents an alternative source of aspartame and acesulfame ions to the two already permitted sources (E951 and E950), b) potential exposure is the same with an equivalent blend of aspartame and acesulfame-K, c) the use of this substance raises no additional safety considerations, the Committee regards as acceptable the use of aspartame-acesulfame salt as an additive. It should be ensured that consumption of this substance is taken into account when estimating intakes of aspartame and acesulfame-K in relation to the ADIs for these substances."

19. The Committee published its opinion on the safety of sucralose in September 2000, which concluded that: "sucralose is acceptable as a sweetener for general food use and that a full Acceptable Daily Intake level (ADI) of 0-15mg/kg body weight can be established". This is in line with the ADI set for sucralose by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1990.

Business sectors affected

20. **Food and food additives manufacturers:** All sectors of the food industry using sweeteners in the manufacture of foods, as well as the manufacturers of the new sweeteners, will benefit from the permitted uses of the new sweeteners, and the new permitted use of aspartame. As cyclamate is not used widely in the UK, the only UK manufacturers likely to be affected by the changes to the conditions of use for cyclamate are those who produce soft drinks. We are aware of only one major UK manufacturer who uses cyclamates to any significant degree in its dilutable soft drinks products.

21. The Agency became aware of two small manufacturers of soft drinks who were using cyclamates in their products. It was originally thought that these manufacturers would be required to reformulate their products. However following consultation with the companies concerned, it is apparent that reformulation will not be required.

22. **Retailers (including larger retailers):** larger retailers who manufacture “own-brand” produce will be affected in a similar way to other manufacturers using sweeteners in foods (see above). Those retailers who simply sell on pre-packed produce are not affected.

23. **Restaurants and other catering establishments:** are not affected.

Issues of equity and fairness

24. The provisions of Directive 2003/115/EC apply to all businesses throughout the Community. There is no disadvantage for businesses in England.

Options

25. The following options were proposed before Directive 2003/115/EC was adopted:

Option 1 – Do nothing i.e. oppose all aspects of the new proposal to amend Directive 94/35/EC.

Option 2 – Support the Council's Common Position, with the levels of cyclamate in water-based, milk- and milk-derivative-based, or fruit-juice-based drinks reduced from 400 mg/l to 250 mg/l.

Option 3 – As Option 2, except press for a reduction in the level of cyclamate in dilutable soft drinks from 400 mg/l to 200 mg/l in accordance with the results of the recent Food Standards Agency 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks'.

Option 4 – Support the European Parliament's amendment to reduce the levels of cyclamate in dilutable soft drinks from 400 mg/l to 100 mg/l.

26. Options 2, 3 and 4 would all permit the use of the two new sweeteners, sucralose and salt of aspartame-acesulfame, bring about a reduction in the maximum permitted levels of cyclamate, and allow the use of aspartame to be extended to one new foodstuff category.

Benefits

Option 1 – Do nothing

27. Under this option, the current rules would continue unchanged, with no new sweeteners or additional uses of sweeteners permitted and no reduction in uses or

levels of cyclamate. No changes in product composition would be necessary.

Disadvantages

28. This option would not afford consumers the increased protection, which would be brought about by the reduction in use and levels of use of cyclamate. The results of the 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks' conducted by the Food Standards Agency indicate that, at the current permitted level of 400 mg/l, the intake of cyclamate by children who are high level consumers exceeds the ADI level by over 100%. This option will also not permit manufacturers and consumers to benefit from the new sweeteners, sucralose and salt of aspartame-acesulfame, and the additional use of aspartame. Manufacturers of sucralose and salt of aspartame-acesulfame would be particularly disadvantaged as these sweeteners have been the subject of national authorisations in the UK. Manufacturers of other sweeteners would not be affected. **This is therefore not a viable option.**

Option 2 – Support the Council's Common Position, with the levels of cyclamate in water-based, milk and milk-derivative-based and fruit-juice based soft drinks reduced from 400 mg/l to 250 mg/l.

29. This option would permit consumers and manufacturers to benefit from the new sweeteners and additional uses of sweeteners.

Disadvantages

30. Industry has indicated that some reformulation of products containing cyclamate will be necessary at 250 mg/l. Cyclamate is almost always used in conjunction with another sweetener, and additional sweeteners may be required. Some changes to product labelling will be required. Results from the Food Standards Agency 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks' indicate that children consuming high levels of soft drinks containing cyclamate at 250mg/l would be consuming around 33% above the ADI for this sweetener. **This is therefore not a desirable option.**

Option 3 – As Option 2, except press for a reduction in the level of cyclamate in dilutable soft drinks from 400 mg/l to 200 mg/l in accordance with the results of the recent Food Standards Agency 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks'.

31. The Agency's 'Diary Survey of the Intake of Intense Sweeteners by Young Children from Soft Drinks' has indicated that a reduction in the level of cyclamate in dilutable soft drinks to 200 mg/l is necessary to afford an adequate level of protection to children who are high level consumers of cyclamate-containing soft

drinks.

Disadvantages:

32. Industry has indicated that some re-formulation of products containing cyclamates will be necessary at 200 mg/l. Cyclamate is almost always used in conjunction with another sweetener, and additional sweeteners may be required. Some changes to product labelling will be required.

Option 4 – Support the European Parliament’s amendment to reduce the levels of cyclamate in soft drinks from 400 mg/l to 100 mg/l.

33. Reducing the maximum permitted limit will benefit consumers by ensuring they do not exceed the recommended safe level for cyclamate. At this level even high level consumers of cyclamate-containing drinks would be very unlikely to exceed the ADI for cyclamate.

Disadvantages

34. The European Commission rejected the European Parliament’s proposed amendment. Industry have indicated that cyclamate would have insufficient technological effect in soft drinks at this level and would need to reformulate their soft drinks that currently contain cyclamate with alternative, more costly, sweeteners. Changes to product labelling would also be required. **This is therefore not a viable option.**

35. *The UK initially supported option 3 prior to the adoption of Directive 2003/115/EC. However, option 2 was adopted and should be sufficient to prevent high-level consumers exceeding the ADI, as reformulation of products will be required.*

Summary of Options

	Costs	Effect
Option 1	None	Would not permit manufacturers and consumers to benefit from the newly permitted sweeteners. Would not deliver improved consumer protection measures of the new Directive.
Option 2	Less than £80,000	Would deliver full benefits to manufacturers and consumers wishing to use the new sweeteners. Additional cost to industry from reduced levels of cyclamate in dilutable soft drinks. At a level of 250 mg/l in soft drinks, a percentage of high level UK consumers of soft drinks could still exceed the Acceptable Daily intake level for cyclamate.
Option 3	Less than £80,000	Would deliver full benefits to manufacturers and consumers wishing to use the new sweeteners. Additional cost to industry from reduced levels of cyclamate in dilutable soft drinks. Reducing the limit for cyclamate to 200 mg/l would safeguard consumers from exceeding recommended safe levels for cyclamate.
Option 4	Not known	Would deliver full benefits to manufacturers and consumers wishing to use the new sweeteners. Reducing the limit for cyclamate would safeguard consumers from exceeding recommended safe levels for cyclamate. However, it would be disproportionately costly to industry with no clear benefits over option 3 in terms of consumer safety. The costs of withdrawal of brands cannot be quantified. Any transitional costs associated with the changes in market shares of different producers also depend on the uncertain reaction of consumers.

Costs for charities and voluntary organisations

36. None are expected.

Compliance costs for industry

(i) Reformulation costs

37. One-off reformulation requirements (applies to options 2, 3 and 4): A reduction in cyclamate levels to 200 mg/l or 250 mg/l will require reformulation of

existing products as additional, more expensive, sweeteners will need to be used to compensate for reduced levels of cyclamate. Industry has indicated that any ongoing costs would be reflected in the price of the product on a longer term basis, but one-off costs would not. At a level of 100 mg/l existing brands would require complete reformulation using more expensive sweeteners. The cost of reformulation is likely to amount to less than £75,000 for a decrease in cyclamate levels to 200 mg/l or 250 mg/l.

38. The recipe re-formulations would result in a change in the taste profile of the products and may therefore imply a loss of market share for this producer (but potentially a gain to other soft drinks producers). This is very uncertain and difficult to evaluate, as it will depend on the reaction of consumers. Any transitional costs associated with the changes in market shares of different producers also depend on the uncertain reaction of consumers.

39. Labelling requirements: (applies to options 2, 3 and 4): Changes to product labelling will be required if additional sweeteners are used, or currently used sweeteners are withdrawn. This is likely to amount to less than £5,000 in total.

(ii) Costs for a typical business

40. Only one UK soft drinks company is understood to use cyclamate to any significant degree in its dilutable drinks products. As such any costings are commercially sensitive and cannot be given in this document.

Additional costs to enforcement bodies

41. Local authority enforcement bodies currently have responsibility for the enforcement of the Sweeteners in Food Regulations. There is unlikely to be any significant additional resource implications for enforcement.

Consultation with small firms impact test

42. Industry has confirmed that only one UK soft drinks company uses cyclamate to any significant degree in its dilutable drink products. However, the Agency became aware that two other small manufacturers of soft drinks may be using cyclamate in their products and therefore could also be affected by the new Regulations.

43. The Agency consulted the Small Business Service who were content for us to include these manufacturers in the consultation on the proposal to amend Directive 94/35/EC as well as the draft Regulations to determine if they would be affected by the changes in use of cyclamate.

44. When consulting on the draft Regulations to implement Directive 2003/115/EC, Trade Associations were contacted in order to determine if other companies would also be affected by the changes in the use of cyclamate. It was concluded that the two smaller manufacturers would not be disproportionately affected by the changes in use of cyclamate. The Small Business Service are content that the impact on small businesses has been fully explored through the consultation and acknowledge that the need for a sufficient transition (implementation) period was considered and has been incorporated in the attached Regulations.

Competition Assessment

45. As the Regulations only impose restrictions in relation to the sweetener cyclamate, the competition assessment will focus only on that aspect of the Regulations.

46. Cyclamate is currently thought to be used only by one major producer of squash with a market share of less than 10%. Overall, there are 16 producers of squash who are members of the British Soft Drinks Association. The Britvic Soft Drinks Category Report 2003 puts the annual market for squash at 603 million litres. In value terms this amounts to at least £569m (the leisure and catering category was not valued). This information is mainly based on AC Nielsen data.

47. Given these figures and given the intense competition, with strong demand and supply-side substitution between most categories of soft drinks (e.g. carbonates, fruit juices, etc.), and given that the Regulations will not impose new barriers to entry into the market (other sweeteners are used by all other producers), it can be concluded that the Regulations will not restrict competition.

Enforcement and Sanctions

48. Enforcement of the Regulations in England will be the responsibility of Local Authority Trading Standards or Environmental Health Departments.

49. The penalty on conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale (currently £5,000).

Monitoring and review

50. Member States are obliged under the provisions of Directive 94/35/EC to monitor and review the consumption and use of sweeteners. To fulfil this obligation, the UK undertakes a programme of surveys to gather information on actual levels of use of additives in foodstuffs. This information not only helps to refine intake estimates of additives, including sweeteners, but it may be used to

check that industry complies with permitted limits. The UK submits this information to the European Commission, for inclusion in its period reports on dietary food additive intake in the European Union.

Consultation

Within Government

51. The new measures do not impact significantly on the work of other Government Departments. However, the Agency consulted DEFRA and the Small Business Service on the impact to industry of the reduced levels of cyclamate.

Public consultation

52. Prior to the adoption of Directive 2003/115/EC, the Food Standards Agency held discussions with the British Soft Drinks Association (BSDA) and the principle company manufacturing cyclamate-containing soft drinks. The principal company concerned was also consulted on the draft Regulations that implement the provisions of Directive 2003/115/EC. Two full public consultations were conducted on the proposal to amend Directive 94/35/EC and on the draft Regulations. A summary of each consultation exercise can be found below.

Summary – Consultation on the proposal to amend Directive 94/35/EC

53. Five responses were received to the first consultation. One of the respondents did not comment on the options presented. Two of the respondents supported option 3 and two supported option 4. Option 3 was supported due to the findings of the Agency's survey on sweetener intake by young children (paragraph 31 above refers). Option 4 was supported due to the proposed level of cyclamate. However, option 2 was ultimately adopted by all Member States.

Summary – Consultation of the Draft Sweeteners in Food (Amendment) (England) Regulations 2004.

54. Six responses were received to this consultation. Overall, the responses demonstrated that there was no disproportionate impact on businesses (including small businesses) as a result of the new Regulations coming into force. None of the responses indicated changes to the reformulation costs outlined in the original consultation.

55. One of the respondents did not comment on the draft Regulations. One of the responses highlighted the benefits of UK manufacturers being able to market their products containing the newly permitted sweeteners throughout the European Union and re-iterated that the changes to the use of cyclamate is unlikely to affect

UK manufacturers as compared to other Member States. Another respondent suggested the consolidation of all the amendments to the Sweeteners in Food Regulations 1995, enabling enforcement officers to provide advice to businesses more easily and applying the controls in practice. Another respondent suggested an extension to one of the existing food categories.

56. Two respondents provided their comments via the Consultation Feedback Questionnaire. One respondent confirmed that any of the options outlined in the original consultation was acceptable and the other confirmed that the changes in the cyclamate levels will have little impact on their business due to the low levels of cyclamate they use.

57. The provisions of Directive 2004/46/EC are identical to the measures introduced for salt of aspartame-acesulfame by the Sweeteners in Food Regulations 2003 (as amended), for which a full public consultation was previously undertaken. With regard to sucralose, the provisions are almost identical (other than the pH) to the measures introduced by the Sweeteners in Food Regulations 2002 (as amended), for which a full public consultation was previously undertaken. As previously mentioned in paragraph 11, the inclusion of the pH value in Directive 2004/46/EC does not in practice alter the specifications or present any changes to the permitted use of sucralose.

Minister’s Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the responsible Minister.....

Date.....

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