Introduction

Please read this note carefully before you proceed to the questions and data collection.

This online consultation and data collection takes place in the framework of a study launched by the European Commission to support the evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on food (the NHC Regulation) with regard to the following provisions:
1.Nutrient profiles for determining whether products high in certain nutrients (in particular, salt, sugar and fat) can bear claims; and,
2.Claims made on plants and their preparations, as well as the general regulatory framework for their use in foods.

The study, which was commissioned to the Food Chain Evaluation Consortium (FCEC) in May 2016, is being carried out by Agra CEAS Consulting in association with Areté.

Following the Better Regulation Communication of 19 May 2015[1] the Commission announced that, as part of its REFIT programme, it will carry out an evaluation of the NHC Regulation with regard to the above aspects. It is noted that both of the aspects under study have not to date been applied as foreseen in the NHC Regulation.

Thus, the purpose of the study is to provide an evidence base to feed into the Commission's evaluation by assessing whether nutrient profiles and health claims on plants and their preparations and the more general regulatory framework for their use in food can be considered "fit for purpose". In particular, it aims to analyse the current situation, effectiveness, efficiency, relevance coherence, and EU added value of the legislative framework introduced by the NHC Regulation. The analysis places the implementation of the above provisions in the context of developments with other relevant legislation, as well as non-legislative initiatives, which are further detailed in the background to each section of this questionnaire.

As outlined in the PAFF Working Group meeting of 21 June, the FCEC team has developed a detailed list of questions addressed to Member State Competent Authorities (MS CAs), with a view to collecting relevant information and data to feed into the FCEC analysis which is due to be presented in its final report to the European Commission in autumn 2017.

The aim of this survey is to consult your organisation and collect specific information and data on the implications of the various issues considered in the study. This questionnaire is composed of two sections corresponding to the two subjects covered by this study. Please select and complete the section that is relevant for your organisation as the national Competent Authority, or complete both if your organisation is the only national Competent Authority for both issues.

We invite you to read the background to each section, before proceeding to the examination of the various issues raised in this questionnaire. Further comprehensive description of the various themes of the study is provided in the Terms of Reference (ToR), which you can find here:
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/docs/tor_266-1061_en.pdf

Please note that the following abbreviations are used in this questionnaire:

-CA/s: Competent Authority/ies
-EU: European Union
-FBO/s: Food Business Operator/s
-FIC Regulation: Regulation (EC) No 1169/2011 on food information to consumers
-MS/s: Member State/s
-NHC Regulation: Regulation (EC) No 1924/2006 on nutrition and health claims made on food
-SME/s: small-medium enterprise/s
-ToR: Terms of Reference (of the study)

The study covers any sector/product falling into the definition of food (Article 2 of the General Food Law Regulation (EC) No 178/2002), in particular pre-packed products.

Please provide the **most recent studies/data** that you have at your disposal. This is important to ensure that the results and findings, on which our conclusions will be based, derive from the most up-to-date data.

The information you provide will be treated on a strictly confidential basis. All data collected through the survey will be used by the FCEC for statistical analysis of the impacts related to the examined issues under study only. A **privacy statement** regarding data protection can be found in:
http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en

WARNING: Filling in this questionnaire online needs to be performed in a continuous session (*otherwise there is risk of losing data*) . Therefore, we strongly recommend that you fill in the questionnaire **only after all replies are ready** so that you can complete it in one session.

To facilitate your response, we have also provided a PDF version of this questionnaire to use in your consultation with the relevant services/departments within your organisation or other relevant organisations, prior to filling in the on-line questionnaire. Please note that your response to this questionnaire needs **to be submitted online** (PDF versions of the questionnaire will not be accepted).

This questionnaire is available in English.

If you have any additional documents, reports and other data that you wish to submit for consideration in this study, please send by e-mail at: **health.claims@ceasc.com**

You can reply to this survey by 17 February 2017.

THE FCEC THANKS YOU IN ADVANCE FOR YOUR COOPERATION

If you have any questions on this questionnaire or need any further clarifications of the issues raised and/or the consultation process, please contact us by e-mail at:

health.claims@ceasc.com

[1]COM(2015) 215 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Better regulation for better results - An EU agenda.

Identification data

* 1. Identification Data

Competent Authority:

Contact person:

Email address:

Telephone number:

* 2. Member State

* 3. *This questionnaire is composed of two sections corresponding to the two subjects covered by this study. Please select and complete the section that is relevant for your organisation as the national Competent Authority, or complete both if your organisation is the only national Competent Authority for both issues.*

- [ ] Section 1: Nutrient profiles for food bearing claims
- [ ] Section 2: Health claims on plants and their preparations and the general regulatory framework for their use in foods
- [ ] Both, section 1 and section 2

Section 1: Nutrient profiles for foods bearing claims

Background

The objective of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (the NHC Regulation) with regard to setting harmonised nutrient profiles across the EU for foods bearing claims is to provide a high level of consumer protection from untruthful and misleading claims and facilitating consumers' healthier food choice whilst ensuring fair competition in the area of foods bearing nutrition and health claims. In particular, the application of nutrient profiles as a criterion for determining whether a product can bear claims and the conditions of use of such claims aims to avoid a situation where claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. Thus, in the context of the Regulation, nutrient profiles provide maximum levels ('thresholds') of nutrients such as saturated fat, salt and sugars above which nutrition claims are restricted and health claims are prohibited.

Article 4(1) of the NHC Regulation envisaged the adoption of nutrient profiles, by 19 January 2009, in consultation with EFSA and stakeholders. EFSA adopted a scientific opinion on the setting of nutrient profiles in 2008[2]. However, the setting of nutrient profiles was postponed due to the complexity of the subsequent discussions, where certain sectors of the food industry pointed to alleged economic losses and lower competitiveness expected from an implementation of the proposed system.

Given that the nutrient profiles provided for in the Regulation have not yet been adopted, the purpose of the study (Section 1) is to examine the current situation - as it has evolved in the absence of harmonised nutrient profiles - and to assess the extent to which harmonisation remains necessary to ensure the overall objectives of the Regulation.

In making this assessment, the study will consider the effects of the current situation and whether there are alternative and less burdensome solutions to achieve the Regulation's objectives, including other existing harmonised legislation and non-harmonised, national, initiatives (including consideration of alternative approaches adopted in non-EU countries).

Although nutrient profiles have not been adopted at EU level for determining whether food can bear claims and the conditions of use of such claims, other existing measures may contribute to the Regulation's objectives – in particular:

- *Provisions in the **current EU regulatory framework** impose **mandatory nutrition labelling,** as follows:*

*- Chapter IV, section 3 of Regulation (EU) No 1169/2011 (the Food Information to Consumers (FIC) Regulation) imposes **'back-of-pack' nutrition declaration[3] on food:** this is applied today on a voluntary basis, but will become mandatory as from 13 December 2016;*
*- Article 7 of the NHC Regulation imposes **mandatory nutrition labelling on foods bearing claims[4]**. Nutrition or health claims can only be made on food labelled with a nutrition declaration, in accordance with the requirements of the FIC Regulation[5].*

- *In addition, **initiatives/schemes** may have been developed **at the level of Member States on a voluntary basis,** as follows:*

*- National schemes providing additional, **front-of-pack[6] nutrition information**, as envisaged by Recital (41) and in Article 35(2) of the **FIC Regulation** ('additional forms of expression and presentation', using graphical forms or symbols in addition to words or numbers). Generally, such schemes tend to indicate the status of products in relation to key nutrients (such as energy, saturated fat, total fat, sugar, salt). An example is the UK traffic light labelling, which classifies individually the energy and each nutrient into three different categories (green, yellow and red) based on thresholds on the amount of energy, salt, sugar, fat and saturated fat they contain.*
*- National legislation on nutrition claims, notified under **Article 23 of the NHC Regulation.** Such initiatives sometimes use a logo to identify healthier nutritional options; this logo may be considered as a nutrition claim. Examples include: the Nordic keyhole logo, which packaged foods are eligible to carry provided they fulfil certain conditions (based on the Nordic Nutrition Recommendations), as specified by the authorities in Sweden, Denmark, Norway and Iceland; and, the Healthy Choice scheme, which has national programmes in The Netherlands, Poland and Czech Republic, defining conditions of use based on international dietary guidelines.*
*- **Nutrient profiles** may be developed at national level for other specific purposes, such as for imposing restrictions for the marketing of foods to children, for imposing taxes, as a general guideline to the industry in the context of food reformulation initiatives etc.*

*The development of the above schemes/initiatives at the level of Member States is **voluntary**. There may b e **national (regulatory) schemes/initiatives** developed by authorities, or developed by the industry and/or other stakeholders and endorsed by authorities. There may also be **private schemes/initiatives,** developed by the industry and/or other stakeholders but not (or not yet) endorsed by authorities.*

The purpose of this questionnaire is:

- *to map what measures have been taken to date at national level on a voluntary basis;*
- *to understand their characteristics, their objectives and their effects;*
- *to establish the extent to which the objectives sought by the NHC Regulation are being fulfilled by existing measures (national and EU) and the effects of the absence of EU nutrient profiles; and lastly,*
- *in view of the current situation, to evaluate whether the setting of harmonised nutrient profiles at EU level is still considered relevant and necessary.*

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[2]**https://www.efsa.europa.eu/en/efsajournal/pub/644**

[3]The nutrition declaration for a food is a factual indication of its nutritional content, in particular information on the energy value and content of certain nutrients (fat, saturates, carbohydrate, sugars, protein and salt) (Article 30(1) of the FIC Regulation).

[4]**Nutrition labelling of foods bearing claims was always mandatory:** Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs lays down rules on the content and presentation of nutrition information on pre-packed foods. According to those rules, the inclusion of nutrition information is voluntary unless a nutrition- related claim is made concerning the food.

[5]As specified in Article 49 of the FIC Regulation, the information to be provided shall consist of that specified in Article 30(1) of the Regulation, i.e. the energy value and the content of fat, saturates, carbohydrate, sugars, protein and salt.

[6]The principal field of vision on the label is commonly known as the *'front of pack'*.

Current situation: mapping of existing schemes/initiatives

* 4.
Are there in place, in your country, any national regulatory schemes/initiatives having nutritional objectives?

National regulatory: as described in the background to Section 1, this refers to schemes/initiatives developed by authorities, or developed by the industry and/or other stakeholders and endorsed by authorities. Please consider all national schemes/initiatives of relevance applying in your country; this may include:

i. additional forms of expression, applied front of pack (Recital (41) and Article 35 of the FIC Regulation)
ii. measures notifiable under Article 23 of the NHC Regulation, including nutrition claims in the form of pictorial, graphic or symbolic representations
iii. setting of nutrient profiles for specific purposes (e.g. for restrictions of advertising to children, for taxation purposes, for food reformulation etc.)

- ◯ Yes: adopted and already implemented
- ◯ Yes: adopted but not yet implemented
- ◯ No: schemes/initiatives are planned but not yet adopted
- ◯ No: there are no national regulatory schemes/initiatives

Current situation: mapping of existing schemes/initiatives (2)

Please select up to three major national regulatory schemes/initiatives that are the most important for your country and for which you can provide the details requested below.

What are the characteristics of these national regulatory schemes/initiatives in place, in your country?
Please, provide the details requested below for up to three examples of major national regulatory schemes/initiatives.

Example 1

* 5. Name of scheme/initiative

* 6. Year of introduction

* 7. Developed by: *(multiple tick if developed by cooperation)*

- [ ] authorities
- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 8. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ measures notifiable under Article 23 of the NHC Regulation
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 9. Legal basis of scheme/initiative (national; EU)

* 10. Notified to the Commission

- ◯ Yes
- ◯ No

If yes, please specify under which legal base/procedure it was notified to the Commission (i.e. what was followed).

* 11. Is the scheme/initiative research or science based?
E.g. based on nutrition recommendations founded on scientific research and/or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 12. Application

- ◯ Voluntary rules
- ◯ Guidelines (i.e. not detailed rules but general recommendations)

Please provide details.

* 13. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 14. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 15. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category (e.g. Nordic key hole)
- ◯ Threshold for each nutrient across all product categories (e.g. UK traffic light)
- ◯ Other (please specify)

Please provide details.

* 16. Why was this scheme/initiative introduced in your country?

* 17. What were the objectives of this scheme/initiative?

* 18. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, provide further details.

* 19. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot

Please provide the % of products in categories covered.

* 20. Do you have more examples of schemes/initiatives?
If you do, please provide similar details.

- ◯ Yes
- ◯ No

Current situation: mapping of existing schemes/initiatives (3)

Example 2

* 21. Name of scheme/initiative

* 22. Year of introduction

* 23. Developed by: *(multiple tick if developed by cooperation)*

- [ ] authorities
- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 24. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ measures notifiable under Article 23 of the NHC Regulation
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 25. Legal basis of scheme/initiative (national; EU)

* 26. Notified to the Commission

- ◯ Yes
- ◯ No

If yes, please specify under which legal base/procedure it was notified to the Commission (i.e. what was followed).

* 27. Is the scheme/initiative research or science based?
E.g. based on nutrition recommendations founded on scientific research and/or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 28. Application

- ◯ Voluntary rules
- ◯ Guidelines (i.e. not detailed rules but general recommendations)

Please provide details.

* 29. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 30. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 31. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category (e.g. Nordic key hole)
- ◯ Threshold for each nutrient across all product categories (e.g. UK traffic light)
- ◯ Other (please specify)

Please provide details.

* 32. Why was this scheme/initiative introduced in your country?

* 33. What were the objectives of this scheme/initiative?

* 34. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, provide further details.

* 35. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot

Please provide the % of products in categories covered.

* 36. Do you have more examples of schemes/initiatives?
If you do, please provide similar details.

- ◯ Yes
- ◯ No

Current situation: mapping of existing schemes/initiatives (4)

Example 3

* 37. Name of scheme/initiative

* 38. Year of introduction

* 39. Developed by: *(multiple tick if developed by cooperation)*

- [ ] authorities
- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 40. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ measures notifiable under Article 23 of the NHC Regulation
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 41. Legal basis of scheme/initiative (national; EU)

* 42. Notified to the Commission

- ◯ Yes
- ◯ No

If yes, please specify under which legal base/procedure it was notified to the Commission (i.e. what was followed).

* 43. Is the scheme/initiative research or science based?
E.g. based on nutrition recommendations founded on scientific research and/or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 44. Application

- ◯ Voluntary rules
- ◯ Guidelines (i.e. not detailed rules but general recommendations)

Please provide details.

* 45. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 46. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 47. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category (e.g. Nordic key hole)
- ◯ Threshold for each nutrient across all product categories (e.g. UK traffic light)
- ◯ Other (please specify)

Please provide details.

* 48. Why was this scheme/initiative introduced in your country?

* 49. What were the objectives of this scheme/initiative?

* 50. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, provide further details.

* 51. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot

Please provide the % of products in categories covered.

Current situation: mapping of existing schemes/initiatives (5)

* 52. Why have no national regulatory schemes/initiatives been developed in your country? (select all that apply or specify other reasons if relevant)

- [ ] **There is no need for the introduction of schemes/initiatives having nutritional objectives in my country**
- [ ] **The need was identified but no action was taken as** (1) there were already industry-led schemes/initiatives in place
- [ ] **The need was identified but no action was taken as** (2) the complexity of the subject and the divided positions of the various affected stakeholders
- [ ] **The need was identified but no action was taken as** (3) the lack of scientific basis for developing such schemes/initiatives at national level
- [ ] **The need was identified but no action was taken as** (4) waiting for harmonised regulatory action, e.g. nutrient profiles to be established at EU level

Please provide further details on the reasons why schemes/initiatives have not been developed in your country.

Current situation: mapping of existing schemes/initiatives (6)

* 53. Are there any major private schemes/initiatives in place in your country, developed by producers or retailers, concerning the nutritional status of food products?

*Private: as described in the background to Section 1, this refers to schemes/initiatives developed by the industry and/or other stakeholders, but not (or not yet) endorsed by authorities. Please consider all **major** private schemes/initiatives of relevance in place in your country, i.e. that are used by multiple actors (rather than by individual companies) and across a national (rather than regional) scope. This may include:*

- *additional forms of expression, applied front of pack (Recital (41) and Article 35 of the FIC Regulation)*
- *setting of nutrient profiles for specific purposes (e.g. for restrictions of advertising to children, for food reformulation etc.)*

- ◯ Yes
- ◯ No
- ◯ Do not know

Current situation: mapping of existing schemes/initiatives (7)

Please select up to three major private schemes/initiatives that are the most important for your country and for which you can provide the details requested below.

What are the characteristics of these private schemes/initiatives in place, in your country?
Please, provide the details requested below for up to three examples of major private schemes/initiatives.

Example 1

* 54. Name of scheme/initiative

* 55. Developed by:

- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 56. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 57. Were Competent Authorities consulted on this scheme/initiative?

- ◯ Yes
- ◯ No

If yes, please provide details.

* 58. Is the scheme research/science based? E.g. based on nutrition recommendations founded on scientific research and or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 59. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 60. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 61. Reasons for introduction

Why was this scheme/initiative introduced?

* 62. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category
- ◯ Threshold for each nutrient across all product categories (e.g.UK traffic light)
- ◯ Other (please specify)

Please provide details

* 63. What were the objectives of this scheme/initiative?

* 64. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, please provide details.

* 65. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot
- ◯ Do not know

Please provide details.

* 66. Do you have more examples of schemes/initiatives?
If you do, please provide similar details.

- ◯ Yes
- ◯ No

Current situation: mapping of existing schemes/initiatives (8)

Example 2

* 67. Name of scheme/initiative

* 68. Developed by:

- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 69. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 70. Were Competent Authorities consulted on this scheme/initiative?

- ◯ Yes
- ◯ No

If yes, please provide details.

* 71. Is the scheme research/science based? E.g. based on nutrition recommendations founded on scientific research and or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 72. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 73. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 74. Reasons for introduction

Why was this scheme/initiative introduced?

* 75. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category
- ◯ Threshold for each nutrient across all product categories (e.g.UK traffic light)
- ◯ Other (please specify)

Please provide details

* 76. What were the objectives of this scheme/initiative?

* 77. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, please provide details.

* 78. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot
- ◯ Do not know

Please provide details.

* 79. Do you have more examples of schemes/initiatives?
If you do, please provide similar details.

- ◯ Yes
- ◯ No

Current situation: mapping of existing schemes/initiatives (9)

Example 3

* 80. Name of scheme/initiative

* 81. Developed by:

- [ ] industry (producers; retailers etc.)
- [ ] other stakeholders (e.g. consumers; public health NGOs etc.)

Please provide details.

* 82. Type of scheme/initiative

- ◯ additional forms of expression (Article 35 of the FIC Regulation)
- ◯ setting of nutrient profiles for specific purposes

Please provide details.

* 83. Were Competent Authorities consulted on this scheme/initiative?

- ◯ Yes
- ◯ No

If yes, please provide details.

* 84. Is the scheme research/science based? E.g. based on nutrition recommendations founded on scientific research and or consumer studies

- ◯ Yes
- ◯ No

Please explain the underpinning scientific basis.

* 85. Product categories covered

- ◯ All categories of food products
- ◯ Foods for specific groups
- ◯ Specific food product sectors (please specify)

Please provide details.

* 86. Nutrients covered

- ◯ Sodium
- ◯ Fat (total; saturated; trans fatty acids)
- ◯ Sugars
- ◯ Other (please specify)

Please provide details.

* 87. Reasons for introduction

Why was this scheme/initiative introduced?

* 88. Approach of classification used by the scheme/initiative is based on:

- ◯ Threshold for each nutrient by product category
- ◯ Threshold for each nutrient across all product categories (e.g.UK traffic light)
- ◯ Other (please specify)

Please provide details

* 89. What were the objectives of this scheme/initiative?

* 90. Was the purpose of this scheme/initiative linked to any restrictions on the basis of the level of nutrients (in particular: salt, sugar, fat) that food products contain? (e.g., restrictions on whether a product can bear claims, restrictions on advertising to children etc.)

- ◯ Yes
- ◯ No

If yes, please provide details.

* 91. To what extent is the scheme/initiative taken up by the industry?

- ◯ Not at all
- ◯ A little
- ◯ A fair amount
- ◯ Quite a lot
- ◯ A lot
- ◯ Do not know

Please provide details.

Current situation: mapping of existing schemes/initiatives (10)

* 92. Why have no (major) private schemes/initiatives been developed in your country? (*select all that apply or "do not know")*

- [ ] There were already schemes/initiatives developed by the authorities
- [ ] There were already schemes/initiatives developed by stakeholders in other Member States and/or at international level
- [ ] The complexity of the subject and the divided positions of the various affected stakeholders
- [ ] The lack of scientific basis for developing such schemes/initiatives
- [ ] Waiting for harmonised regulatory action, e.g. nutrient profiles to be established at EU level
- [ ] Other reason/s (please specify)
- [ ] Do not know

Please provide further details on the reasons why private schemes were not developed in your country as indicated above.

Current situation: mapping of existing schemes/initiatives (11)

* 93. Following the introduction of the above schemes/initiatives (whether national regulatory or private) has there been any research on their effectiveness?

	Yes	No	Do not know/ not applicable
National regulatory	○	○	○
Private	○	○	○

If yes, please specify for which scheme/initiative and provide further details of the research as well as available literature, if any. Research on the effectiveness of the schemes may cover e.g. consumer awareness, effect on food purchasing behaviour, food choice and prices.

***Note**: As specified in the background to Section 1, nutrition declaration on food, in accordance with Chapter IV section 3 of the FIC Regulation, becomes a mandatory obligation on 13 December 2016. We would like to understand the extent to which nutrition declaration has been applied by operators in your country before 13 December 2016:*

* 94. To what extent has nutrition declaration been applied by operators in your country before 13 December 2016?

	Fully	Partially	Not at all	Do not know
Back-of-pack nutritional declaration, as applied on a voluntary basis (Chapter IV, section 3 of the FIC Regulation) before 13 December 2016	○	○	○	○

If partially/not at all, why? Please provide reasons why current application is incomplete, and data on the extent of application, if any; please highlight differences between product sectors, if any, and explain the reasons why.

Current situation: assessment of effectiveness, efficiency, relevance and coherence

* 95. Given the current situation in your country, as described in the previous section, are there any problems stemming from the non-setting of nutrient profiles at EU level?

- ◯ Yes
- ◯ No
- ◯ Do not know

If yes, why? Please provide further details, and reasons for, any identified problems.

* 96. In your experience, are any product sectors particularly affected (whether positively or negatively) by the non-setting of nutrient profiles at EU level? Please identify up to five (5) cases of the most affected product sectors and explain the reasons why they are particularly affected. Please focus on broader product categories rather than specific products.

	Potentially negatively affected (disadvantaged)	Potentially positively affected (advantaged)	Do not know
Product sector - #case 1	○	○	○
Product sector - #case 2	○	○	○
Product sector - #case 3	○	○	○
Product sector - #case 4	○	○	○
Product sector - #case 5	○	○	○

Please specify here the product sectors and provide further details on the above identified cases. Please indicate how these sectors are affected (whether positively or negatively) and reasons why. If impacts have been quantified / are quantifiable, please provide elements in this respect (estimated figures, references to independent studies, etc.)

* 97. In your experience, are SMEs and micro-enterprises[7] particularly/disproportionately affected by the non-setting of nutrient profiles at EU level? *If negatively affected*, are any measures taken to mitigate the effects? *Please explain the reasons why SMEs have been particularly/ disproportionately affected and, if negatively affected, whether/what measures are taken to mitigate negative the effects.*

	Particularly negatively affected (disadvantaged)	Particularly positively affected (advantaged)	Not particularly affected	Do not know
SMEs	◯	◯	◯	◯
Micro-enterprises	◯	◯	◯	◯

If yes, why? Please provide reasons why SMEs/micro-enterprises have been particularly/ disproportionately affected, what measures are taken if SMEs/micro-enterprises are negatively affected, and examples, if any.

[7]The category of micro, small and mediumsized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million. Commission Recommendation of 6 May 2003, 2003/361/EC

* 98. In your experience, to what extent has the nutrition declaration (defined in chapter IV section 3 of FIC regulation), as applied in your country to date, fulfilled the objectives listed below in the absence of EU nutrient profiles?

	Fully	Partially	Not at all	Do not know
Ensuring accurate and reliable information to consumers regarding nutrition and health claims	○	○	○	○
Facilitating consumers' healthier food choice	○	○	○	○
Limiting the use of claims on foods high in fat, sugar and salt	○	○	○	○
Enabling the free circulation of foods bearing nutrition and health claims	○	○	○	○
Ensuring fair competition of food business operators	○	○	○	○
Stimulating food reformulation	○	○	○	○

If partially/not at all, why? Please explain the reasons why any of the above objectives has not been achieved to date.

* 99. To what extent will the entry into force of the obligation for food business operators to provide the nutrition declaration (defined in chapter IV, section 3 of FIC Regulation), as fully applied from 13 December 2016, fulfil the objectives listed below in the absence of EU nutrient profiles?

	Fully	Partially	Not at all	Do not know
Ensuring accurate and reliable information to consumers regarding nutrition and health claims	○	○	○	○
Facilitating consumers' healthier food choice	○	○	○	○
Limiting the use of claims on foods high in fat, sugar and salt	○	○	○	○
Enabling the free circulation of foods bearing nutrition and health claims	○	○	○	○
Ensuring fair competition of food business operators	○	○	○	○
Providing legal certainty for food business operators, on the use of claims	○	○	○	○
Stimulating food reformulation	○	○	○	○
Protecting and promoting innovation	○	○	○	○

If partially/not at all, why? Please explain the reasons why any of the above objectives may not be achieved.

***Note**: We would like you to think about the effects - on consumers and on the industry - of the schemes/initiatives currently taken in your country (whether national regulatory or private, as identified in section 1) compared to the use of nutrient profiles set at EU level (as a criterion for determining whether a product can bear claims and conditions of use of such claims). Please bear in mind that nutrition labelling on foods bearing claims applies in any case on a mandatory basis, and that nutrition declaration on foods (whether bearing claims or not) becomes fully mandatory on 13 December 2016.*

* 100. To what extent do you consider that the national regulatory schemes/initiatives currently taken in your country, as identified in section 1, are fulfilling the objectives listed below in terms of foods bearing claims?

	Fully	Partially	Not at all	Do not know / not applicable
Ensuring accurate and reliable information to consumers regarding nutrition and health claims	○	○	○	○
Facilitating consumers' healthier food choice	○	○	○	○
Limiting the use of claims on foods high in fat, sugar and salt	○	○	○	○
Enabling the free circulation of foods bearing nutrition and health claims	○	○	○	○
Ensuring fair competition of food business operators	○	○	○	○
Providing legal certainty for food business operators, on the use of claims	○	○	○	○
Stimulating food reformulation	○	○	○	○
Protecting and promoting innovation	○	○	○	○

If partially/not at all, why? Please explain the reasons why the national regulatory schemes/initiatives are not fulfilling the objectives and from which point of view.

* 101. To what extent do you consider that the private schemes/initiatives as identified in section 1, are fulfilling the objectives listed below in the absence of EU nutrient profiles?

	Fully	Partially	Not at all	Do not know / not applicable
Ensuring accurate and reliable information to consumers regarding nutrition and health claims	○	○	○	○
Facilitating consumers' healthier food choice	○	○	○	○
Limiting the use of claims on foods high in fat, sugar and salt	○	○	○	○
Enabling the free circulation of foods bearing nutrition and health claims	○	○	○	○
Ensuring fair competition of food business operators	○	○	○	○
Providing legal certainty for food business operators, on the use of claims	○	○	○	○
Stimulating food innovation	○	○	○	○
Protecting and promoting innovation	○	○	○	○

If partially/not at all, why? Please explain the reasons why the private schemes/initiatives are not fulfilling the objectives and from which point of view.

* 102. Are there any advantages/benefits of relying on schemes/initiatives (whether national regulatory or private, as identified in section 1) rather than EU-level nutrient profiles?

	Yes	No	Do not know
For consumers	○	○	○
For the industry	○	○	○

If yes, what are the advantages/benefits? Please identify and justify advantages/benefits

* 103. Are there any disadvantages/shortcomings of relying on schemes/initiatives (whether national regulatory or private, as identified in section 1) rather than EU-level nutrient profiles?

	Yes	No	Do not know
For consumers	○	○	○
For the industry	○	○	○

If yes, what are the disadvantages/shortcomings? Please identify and justify disadvantages/shortcomings.

* 104. To what extent can other initiatives taken at EU or international level address any problems associated with the non-setting of EU-nutrient profiles, as identified in Q37?

	Fully	Partially	Not at all	Do not know
EU Platform on Diet, Physical Activity and Health (e.g. EU Pledge)	○	○	○	○
WHO Nutrient Profiles in relation to advertising to children	○	○	○	○
Other initiatives: please specify	○	○	○	○

If partially/not at all, why? For each initiative: please provide further details on any problems identified that cannot be addressed by the initiative and reasons why.

Need for action at EU level

* 105. Given the current situation, does the setting of nutrient profiles at EU level, as envisaged by Article 4(1) of Regulation (EU) No 1924/2006, continue to be:

	Yes	No	Do not know
Relevant	○	○	○
Necessary	○	○	○
Feasible	○	○	○

Please provide any further reasons/comments for your answer.

* 106. To what extent are you likely to change the national regulatory schemes currently applying in your country, in the event where harmonised nutrient profiles are established at EU level?

No change	Small change	Moderate change	Complete change	Complete removal	Do not know/not applicable
◯	◯	◯	◯	◯	◯

Please provide any further reasons/comments for your answer.

* 107. What would be the potential impacts of setting nutrient profiles at EU level, compared to the continuation of the current situation, on each of the following aspects?

	Considerable deterioration	Deterioration	Neutral	Improvement	Considerable improvement	Do not know
Level of harmonisation	◯	◯	◯	◯	◯	◯
Cost-effectiveness for the Competent Authorities (development, application and control)	◯	◯	◯	◯	◯	◯
Avoiding misleading labelling for products bearing claims	◯	◯	◯	◯	◯	◯
Governing the conditions for use of claims on products high in fat, sugar or salt	◯	◯	◯	◯	◯	◯
Consumer trust in the EU food chain	◯	◯	◯	◯	◯	◯
Legal certainty for food business operators	◯	◯	◯	◯	◯	◯
Fair competition for food business operators	◯	◯	◯	◯	◯	◯

	Considerable deterioration	Deterioration	Neutral	Improvement	Considerable improvement	Do not know
Free circulation of products bearing claims	○	○	○	○	○	○
Marketing potential of products bearing claims	○	○	○	○	○	○
Food innovation	○	○	○	○	○	○
Coherence with other national initiatives, such as nutritional guidelines and objectives for contributing to healthier, more balanced diets	○	○	○	○	○	○
Coherence with other EU initiatives, such as the EU Platform on Diet, Physical Activity and Health or WHO nutrient profiles for advertising to children	○	○	○	○	○	○
Other potential impacts: please specify	○	○	○	○	○	○

Please, explain the reasons behind your position.

* 108.

To what extent would the setting of nutrient profiles at EU level be likely to result in changes in **costs for enforcement authorities** (e.g. costs of controls, other costs/burden), compared to the current situation? To what extent would the level of controls need to be increased?

Note: It could be the case that there are currently no controls, but if harmonised EU nutrient profiles were established, controls may be needed and costs occur; on the other hand, it could be the case that currently there are costs for controls and costs related to the development of national rules and guidelines, but if harmonised EU nutrient profiles are established there would be savings in these costs.

	Increase	No impact	Decrease	Do not know
Level of controls	○	○	○	○
Level of costs	○	○	○	○

If change in costs is expected, please explain why and what is the estimated level of change (i.e. % change on current costs)

* 109.

Do you have any other experience that can be compared to the introduction of nutrient profiles at EU level in terms of impacts on costs and burden for enforcement authorities in your country? What has been the impact on costs? *Please consider any previous experience you may have had from the introduction of nutrition declaration (FIC Regulation) or, more generally, other labelling rules in the food and drinks sector., that could be compared? Please indicate the impact on costs in these comparable cases.*

	Increase	No impact	Decrease	Do not know / not applicable
Comparable case 1: *please specify*	○	○	○	○
Comparable case 2: *please specify*	○	○	○	○

Please specify here the identified comparable case/s. If change in costs was incurred in any of these cases, please explain why and what was the actual level of change (i.e. % change on costs incurred prior to the introduction of the rules).

Need for action at EU level (2)

* 110. Should the existing provision for setting nutrient profiles at EU level be withdrawn from Regulation (EC) 1924/2006?

- ◯ Yes
- ◯ No
- ◯ Do not know

Please provide any further reasons/comments for your answer.

* 111. What would be the consequences of withdrawing the provision for setting nutrient profiles at EU level from Regulation (EC) 1924/2006?

	Yes	No	Do not know
In terms of further action your country would take at national level: • My country would consider taking further action to develop initiatives at national level	◯	◯	◯
In terms of potential advantages compared to the current situation: • It would improve clarity of the EU regulatory framework	◯	◯	◯

	Yes	No	Do not know
• It would improve coherence with national nutritional policy objectives, guidelines and/or rules in this field	○	○	○
• Other advantages (please specify below)	○	○	○
In terms of potential disadvantages compared to the current situation: • It would increase differences / reduce coherence in current approaches/rules applying at national level	○	○	○
• It would reduce coherence with the objectives of the EU regulatory framework, including the NHC Regulation	○	○	○
• Other disadvantages (please specify below)	○	○	○

Please specify

* 112. Please provide further explanation, and reasons why, any of the above consequences would be expected to occur.

* 113. Are you replying to section 2 of this survey (plants and their preparations used in foods) ?

- ◯ Yes
- ◯ No

Section 2: Health claims made on plants and their preparations

Health claims made on plants and their preparations and the more general regulatory framework for their use in foods.

Background

Regulation (EC) No 1924/2006 (the Nutrition and Health Claims Regulation) is intended to regulate all health claims, including the health claims on plants and their preparations used in foods. Since the Regulation entered into force many health claims on plants and their preparations were submitted to EFSA for an assessment under the procedure laid down in Article 13(1). However, the first 500 health claims on plants and their preparations assessed by EFSA received an unfavourable scientific opinion. The main reason for this is that, as a general rule, EFSA's scientific assessments for health claims require evidence at the "highest possible standard", and EFSA considers human studies to be an essential part of the required evidence. This implies that evidence collected solely on the basis of traditional use is not, on its own, deemed sufficient by EFSA to substantiate a health claim on plants and their preparations used in foods.

In September 2010, the decision was taken to put the authorisation of health claims on plants and their preparations on hold. This applied both to already assessed claims, and to those whose assessment was pending (EFSA was asked to suspend their assessment): as a result, a total of 2078 health claims for plants and their preparations submitted under Article 13(1) are currently on hold. Health claims which are on hold are currently used under the transitional measures foreseen in Article 28(5) of the Regulation on nutrition and health claims made on foods, which provide that these claims are made under the responsibility of food business operators provided that they comply with the general principles and conditions of Regulation (EC) No 1924/2006 and with existing national provisions applicable to them.

More in general, the use of plants and their preparations in foods, including food supplements, is not harmonised by means of specific legislation at EU level. These food products are covered by various EU legislative texts of general/horizontal application such as Regulation (EC) No 178/2002 on the general principles of food law, and other legal acts applicable to certain categories of foods, such as Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

In the absence of specific harmonised EU rules, certain Member States adopted national rules to regulate the use of such substances in foods. This has led to a situation where food business operators and Member States' Competent Authorities face inconsistencies between the practices in the different Members States. Furthermore, where there are no specific harmonised provisions, the principle of mutual recognition of national rules applies, i.e. the free movement of such goods is governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), subject to national restrictions or bans within the limits laid down by Article 36.

In addition, a number of Member States and stakeholders highlighted the presence of two parallel legal frameworks applying to products containing plants and their preparation bearing similar

health claims and therapeutic indications on the basis of their classification as "food" or as "medicine" at Member State level: Regulation (EC) No 1924/2006 on health claims and Directive 2004/24/EC on traditional herbal medicinal products (THMPs).

Under the current EU rules, Member States may decide on the classification of a product as food or as THMP on a case-by-case basis, taking into account all the characteristics of the final product. In practice, as stated on several occasions by the Court of Justice of the EU, differences exist between Member States in the classification of plants and their preparations. Such differences not only have implications for the approach to be applied to claims made on such products (with different conditions of use depending on whether they are a food or a THMP), but more broadly for the overall safety and regulatory framework. For plants and their preparations used in both foods and medicines, differences in the applicable legislation and different approaches in the classification among Member States could lead to different treatment of the same substance, according to whether it is present in a food or in a medicine. This might create distortions on the market, inconsistencies and lack of clarity for food business operators and Competent Authorities, as well as cause confusion and safety concerns for consumers.

The objective of the study is to investigate the impacts - on consumers, business operators and other stakeholders - stemming from the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods and the absence of specific EU harmonised rules for the use of plants and their preparations in foods.

In relation to the evaluation of the Nutrition and Health Claims Regulation, given that health claims on plants and their preparations are currently on hold, and that the Regulation (EC) No 1924/2006 has not been fully implemented on this, the study will also assess the need, and potential impacts, of introducing alternative provisions for addressing health claims on plants and their preparations. In making this assessment, the study will consider the impacts of the full entry into force of the relevant provisions of the Regulation and whether the scientific assessment of health claims could recognise the notion of "traditional use" as an adequate element for the substantiation of a claim.

In relation to the general regulatory framework for the use of plants and their preparations in foods, the purpose of the study is to understand whether legislative measures have been taken at Member State level and what have been their impacts on involved stakeholders. The study will also investigate whether the setting of harmonised legislative framework on plants and their preparation at EU level is considered as necessary and which are its potential advantages and disadvantages.

Current situation:

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 114. Do you have national legislation on the use of plants and their preparations in foods?

Please consider that national legislation (if any) can include one or more of the following relevant aspects (non-exhaustive list):

- procedures of notification/authorisation of food products containing plants and their preparations;
- positive or negative lists of plants / of their preparations for use in foods;
- safe use of plants and their preparations in foods, and establishing / regulating the related alert system;
- sales of foods containing plants and their preparations (including those imported from third countries);
- internet sales of foods containing plants and their preparations (including those imported from third countries);
- the implementation of the on-hold list of health claims on plants and their preparations used in foods;
- other forms of national provisions (e.g. guidelines, recommendations)

◯ Yes

◯ No

Current situation (2):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 115. Does the national legislation cover procedures of notification for marketing of food products containing plants and their preparations?

- ◯ Yes
- ◯ No

Please provide any further reasons/comments for your answer.

Current situation (3):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 116. Please provide a short description of the procedure of notification for marketing of food products containing plants and their preparations (based on Article 10 of Directive 2002/46/EC and Article 15 of Regulation (EC) No 1925/2006).

Current situation (4):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 117. Does the national legislation cover positive lists of plants / of their preparations for use in foods?

- ◯ Yes
- ◯ No

Please provide any further reasons/comments for your answer.

Current situation (5):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 118. Which of the following characterises the*positive* lists of plants / of their preparations for use in foods developed in your country?

	Yes	No
The lists have been compiled on a scientific basis (scientific literature, scientific evidence from clinical tests, etc.)	○	○
The lists have been compiled taking also into consideration the concept of “Traditional use”	○	○
The lists are legally binding	○	○
The lists are notified to the Commission	○	○

Lists have been compiled on the basis of other criteria (please specify).

Current situation (6):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 119. Does the national legislation cover negative lists of plants / of their preparations for use in foods?

- ◯ Yes
- ◯ No

Please provide any further reasons/comments for your answer.

Current situation (7):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 120. Which of the following characterises the*negative* lists of plants / of their preparations for use in foods developed in your country?

	Yes	No
The lists have been compiled on a scientific basis (scientific literature, scientific evidence from clinical tests, etc.)	○	○
The lists have been compiled taking also into consideration the concept of “Traditional use”	○	○
The lists are legally binding	○	○
The lists are notified to the Commission	○	○

Lists have been compiled on the basis of other criteria (please specify)

Current situation (8):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 121. Which of these aspects are covered by national legislation on the use of plants and their preparations in foods? (select all that apply)

- [ ] Procedures of *authorisation* for marketing of food products containing plants and their preparations
- [ ] Ensuring safety in the use of plants and their preparations in foods
- [ ] Establishing / regulating the alert system covering the use of plants and their preparations in foods
- [ ] Sales of foods containing plants and their preparations (including those imported from third countries)
- [ ] *Internet* sales of foods containing plants and their preparations (including those imported from third countries)
- [ ] The implementation of the on-hold list of health claims on plants and their preparations used in foods
- [ ] Other forms of national provisions (e.g. guidelines, recommendations)
- [ ] Other aspects (*please specify below)*

Please provide any further reasons/comments for your answer.

Current situation (9):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 122. Why was national legislation on the use of plants and their preparations in foods developed in your country? (tick all that apply)

- [ ] Because it fulfils strategic national objectives and priorities (*please specify*)
- [ ] Due to a need as a result of the absence of an EU harmonised legislation on the use of plants and their preparations in foods
- [ ] Due to the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods (Regulation (EC) No 1924/2006)
- [ ] National legislation was introduced for other reasons (*please specify*)

Please provide any further reasons/comments for your answer.

Current situation (10):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 123. Why was no national legislation on the use of plants and their preparations in foods developed in your country? (select all that apply)

- [ ] There was/is no need for the introduction of national legislation on the use of plants and their preparations in foods in my country
- [ ] The need for the introduction of national legislation on the use of plants and their preparations in foods was identified but no action was taken, due to: **the complexity of the subject and the divided positions of the various affected stakeholders**
- [ ] The need for the introduction of national legislation on the use of plants and their preparations in foods was identified but no action was taken, due to: **waiting for a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods (Regulation (EC) No 1924/2006)**
- [ ] Other reason/s (please specify)

Current situation (11):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 124. Does your country plan to develop or to further expand the scope of national legislation on the use of plants and their preparations in foods?

Please consider that national legislation (if any) can include one or more of the following relevant aspects (non-exhaustive list):

- procedures of notification/authorisation of food products containing plants and their preparations;
- positive or negative lists of plants / of their preparations for use in foods;
- safe use of plants and their preparations in foods, and establishing / regulating the related alert system;
- sales of foods containing plants and their preparations (including those imported from third countries);
- internet sales of foods containing plants and their preparations (including those imported from third countries);
- the implementation of the on-hold list of health claims on plants and their preparations used in foods;
- other forms of national provisions (e.g. guidelines, recommendations)

◯ Yes

◯ No

Current situation (12):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 125. Which of these aspects will be covered by the planned national legislation on the use of plants and their preparations in foods? (select all that apply)

- [ ] Procedures of *authorisation* for marketing of food products containing plants and their preparations
- [ ] Procedures of *notification* for marketing of food products containing plants and their preparations
- [ ] Positive lists of plants / of their preparations for use in foods
- [ ] *Negative* lists of plants / of their preparations for use in foods
- [ ] Ensuring safety in the use of plants and their preparations in foods
- [ ] Establishing / regulating the alert system covering the use of plants and their preparations in foods
- [ ] Sales of foods containing plants and their preparations (including those imported from third countries)
- [ ] *Internet* sales of foods containing plants and their preparations (including those imported from third countries)
- [ ] The implementation of the on-hold list of health claims on plants and their preparations used in foods
- [ ] Other forms of national provisions (e.g. guidelines, recommendations)
- [ ] Other aspects (please specify below)

Please provide any further reasons/comments for your answer.

* 126. Why does your country plan to develop or to further expand the scope of national legislation on the use of plants and their preparations in foods?(select all that apply)

- [ ] Because it fulfils strategic national objectives and priorities (*please specify below*)
- [ ] Due to a need as a result of the absence of an EU harmonised legislation on the use of plants and their preparations in foods
- [ ] For the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods (Regulation (EC) No 1924/2006)
- [ ] For other reasons (*please specify below*)

Please provide any further reasons/comments for your answer.

Current situation (13):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 127. Why national legislation on the use of plants and their preparations in foods is not planned / not further expanded in your country? (select all that apply)

- [ ] There is no need for the introduction / further development of national legislation on the use of plants and their preparations in foods in my country (*please specify the reasons for this below*)
- [ ] The need for the introduction of national legislation on the use of plants and their preparations in foods has been identified, but no action will be taken, due to: **the complexity of the subject and the divided positions of the various affected stakeholders**
- [ ] The need for the introduction of national legislation on the use of plants and their preparations in foods has been identified, but no action will be taken, due to: **waiting for a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods (Regulation (EC) No 1924/2006)**
- [ ] Other reason/s (*please specify below*)

Please provide any further reasons/comments for your answer.

Current situation (14):

Mapping of national (MS) legislation on the use of plants and their preparations in foods

* 128. Please provide a short description of the provisions which determine/regulate the procedures for classifying products as “foods” or “medicines”, in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2002/46/EC on the approximation of the laws of Member States relating to food supplements and established case law.

* 129. Please provide a short description of how you implement the on-hold list of health claims on plants and their preparations used in foods in your country.

* 130. Prior to the introduction of Regulation (EC) No 1924/2006, was there any national legislation on health claims on plants and their preparations used in foods?

- ◯ Yes
- ◯ No

Current situation (15):

* 131. If yes, please provide a short description of the provisions of national legislation on health claims on plants and their preparations used in foods in force before the implementation of Regulation (EC) No 1924/2006.

Current situation: assessment of its effectiveness, efficiency, relevance and coherence

Note: the current situation includes the following elements:

- Absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods in the context of Regulation (EC) No 1924/2006
- Absence of harmonised regulation on the use of plants and their preparations in foods at EU level
- Adopted national legislation on the use of plants and their preparations in foods in certain Member States

* 132. Is the current situation on the use of plants and their preparations in foods as described above considered to be satisfactory with respect to the following objectives?

	Fully satisfactory	Partially satisfactory	Unsatisfactory	Do not know
Ensuring the smooth functioning of the internal market	○	○	○	○
Ensuring a high level of consumer protection	○	○	○	○
Ensuring fair trading practices in trade of such products	○	○	○	○
Placing safe food on the EU market	○	○	○	○
Ensuring an effective approach to the Member States competent authorities controlling activities	○	○	○	○

Please provide any further reasons/comments for your answer.

* 133. In your experience, how has the current situation on the use of plants and their preparations in foods as described above had an effect on consumers, the food and pharmaceutical industry, and public health? *(Please give an impact description for each category)*

Main impacts for consumers (e.g. in terms of consumers choices, consumer protection, retail price of products, labelling)

Main impacts for food industry operators (e.g. in terms of revenues, limits to communication, obstacles to competition, barriers to trade, market dimension, innovation rate)

Main impacts for pharmaceutical industry operators (e.g. in terms of revenues, limits to communication, obstacles to competition, barriers to trade, market dimension, innovation rate)

Main impacts for public health (e.g. in terms of health risks, procedure for ensuring safety, controlling activities)

* 134. *If any of the above impacts have been quantified / are quantifiable for your country, please provide elements in this respect (estimated figures, references to independent studies, etc.)*

* 135. How has the current situation on the use of plants and their preparations in foods as described above affected your organisation (e.g. in relation to enforcement of the legislation, controlling activities, administrative burden)?

* 136.
How has the absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods had an effect on consumers, the food and pharmaceutical industry, and public health? *(Please give an impact description for each category)*

Main impacts for consumers (e.g. in terms of consumers choices, consumer protection, retail price of products, labelling)

Main impacts for food industry operators (e.g. in terms of revenues, limits to communication, obstacles to competition, barriers to trade, market dimension, innovation rate)

Main impacts for pharmaceutical industry operators (e.g. in terms of revenues, limits to communication, obstacles to competition, barriers to trade, market dimension, innovation rate)

Main impacts for public health (e.g. in terms of health risks, procedure for ensuring safety, controlling activities)

* 137. *If any of the above impacts have been quantified / are quantifiable for your country, please provide elements in this respect (estimated figures, references to independent studies, etc.)*

* 138. How has the absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods affected your organisation (e.g. in relation to enforcement of the legislation, controlling activities, administrative burden)?

* 139. To what extent are the original needs addressed by the Regulation (EC) No 1924/2006 in terms of consumer protection, information to consumers and fair competition still relevant in relation to the use of health claims made on plants and their preparations used in foods?

	Fully relevant	Partially relevant	Not relevant	Do not know
Ensuring a high level of consumer protection	◯	◯	◯	◯
Giving the consumer the necessary information to make choices in full knowledge of the facts	◯	◯	◯	◯
Creating equal conditions of competition for the food industry	◯	◯	◯	◯

Please, explain the reasons behind your position including also a description of current needs that the objectives of the Regulation No 1924/2006 do not address (if any).

* 140. The 2008 Report of European Commission on the use of substances other that vitamins and minerals in food supplements concludes that the *Community legal instruments already constitute a sufficient legislative framework and does not consider it opportune to lay down specific rules for substances other that vitamins or minerals for use in foodstuffs (including substances derived from plants).*

In your experience, do the conclusions of the EC Report of 2008 still correspond to the current needs and trends within the EU in relation to overall legislative framework on plants and their preparations used in foods?

◯ **Yes**: there is no need to lay down specific rules for the use of plants and their preparations in foods at EU level

◯ **No**: it is necessary to lay down specific rules for the use of plants and their preparations in foods at EU level

Current situation: assessment of its effectiveness, efficiency, relevance and coherence (2)

* 141. If no, please, provide further explanations and reasons why there is no need to lay down specific rules for the use of plants and their preparations in foods at EU level and thus the conclusions of the EC Report of 2008 are still valid.

Current situation: assessment of its effectiveness, efficiency, relevance and coherence (3)

* 142. If yes, which are the main reasons/issues behind your call to lay down specific rules for the use of plants and their preparations in foods at EU level?

- [ ] Issues related to the classification of products
- [ ] Absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods (Regulation (EC) No 1924/2006)
- [ ] Issues related to consumer protection
- [ ] Issues related to fair competition for food business operators
- [ ] Free circulation of food products containing plants and their preparations (e.g. mutual recognition principle and its exemptions)
- [ ] Issues related to food safety
- [ ] Issues relating to competent authorities' controlling activities
- [ ] Other (please specify below)

Please, provide further explanation and reasons why a harmonised legislation is needed in order to address the above issues.

Need for action at EU level

NOTE: the following section contains questions which allow the investigation of the need, and potential impacts, of introducing alternative provisions on plants and their preparations used in foods, both for addressing health claims (i.e. in the NHC Regulation) and in terms of the overall framework applying on these products.

* 143.

In your experience, under the current legislative framework on the use of plants and their preparations in foods, what would be the main impacts (positive and negative) for consumers, the food and pharmaceutical industry, and public health, associated with the full application* of Regulation (EC) No 1924/2006?

*According to the Regulation (EC) 1924/2006 health claims shall be based on and substantiated by generally accepted scientific data. Traditional use alone cannot be considered sufficient to allow for the scientific substantiation. In the framework of a fully implementation of Regulation (EC) No 1924/2006, human studies would be essential for the substantiation of claims, given that such studies allow the drawing of scientific conclusions at the highest possible standard.

	Strong positive impact	Moderate positive impact	No impact	Moderate negative impact	Strong negative impact	Do not know
Overall consumers' protection	○	○	○	○	○	○
Safety of products placed on the market	○	○	○	○	○	○
Availability of adequate information on products	○	○	○	○	○	○
Overall impacts on food industry operators	○	○	○	○	○	○
Overall impacts on pharmaceutical industry operators	○	○	○	○	○	○
Overall impacts on public health	○	○	○	○	○	○

Please provide any further reasons/comments for your answer.

* 144.

In your experience, would SMEs and micro-enterprises[1] be particularly/disproportionately affected by the full application of authorisation procedures required for health claims?

- ◯ Yes
- ◯ No
- ◯ Do not know

If yes, please explain the reasons why SMEs are likely to be particularly/ disproportionately affected and what measures could be taken to mitigate impacts.

[1]The category of micro, small and mediumsized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million. Commission Recommendation of 6 May 2003, 2003/361/EC

* 145.

What would be the potential impacts of the inclusion of traditional use* as evidence for the scientific substantiation of health claims made on foods for consumers, food and pharmaceutical industry, public health.

*EFSA considered that the evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations *('traditional use')* alone cannot be considered sufficient to allow for the scientific substantiation of a health claim made on foods. On the other hand, evidence of traditional use is given a different consideration in the case of therapeutic indications on herbal substances used in Traditional Herbal Medicinal Products (THMPs). In this respect the traditional use is defined as medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Union.

	Strong positive impact	Moderate positive impact	No impact	Moderate negative impact	Strong negative impact	Do not know
Consumers	○	○	○	○	○	○
Food industry operators	○	○	○	○	○	○
Pharmaceutical industry operators	○	○	○	○	○	○
Public health	○	○	○	○	○	○

Please provide any further reasons/comments for your answer.

* 146. To what extent is it necessary to take action to harmonise at EU level the following provisions on the use of plants and their preparations in foods?

	No need for harmonised regulation at EU level	Need for harmonised regulation at EU level
Positive lists of substances	○	○
Negative lists of substances	○	○

	No need for harmonised regulation at EU level	Need for harmonised regulation at EU level
Authorisation procedure for marketing of food products containing plants and their preparations	○	○
Notification procedure for marketing of food products containing plants and their preparations	○	○
Procedures for assessing on a case-by-case basis the classification of products containing plants and their preparations as “foods” or “medicines”	○	○
Safety requirements for production and marketing of the products	○	○
Information to consumers (i.e. labelling, conditions of use)	○	○
Other (*please specify*)	○	○

Please provide any further reasons/comments for your answer.

* 147. *Please, describe the main advantages (if any) of a harmonised EU level legislation on the use of plants and their preparations in foods compared to the current situation of absence of harmonised regulation on the use of plants and their preparations in foods at EU level.*

* 148. *Please, describe the main disadvantages (if any) of a harmonised legislation on the use of plants and their preparations in foods compared to the current situation of absence of harmonised regulation on the use of plants and their preparations in foods at EU level.*

Your response is complete

If you have any additional documents, reports and other data that you wish to submit for consideration in this study, please send by e-mail at:

health.claims@ceasc.com

THANK YOU!