

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

## Background

Plant substances are widely available on the EU market and are used in various food products, including food supplements. Examples include ginkgo, garlic, St. John's Wort and ginseng. Such products are generally labelled as natural foods and bear a variety of claims regarding their possible health benefits.

The use of plant substances in foods is not harmonised in specific legislation at EU level. Although food products containing these substances are covered by general EU legislation on food, including food supplements, some Member States have adopted specific rules to regulate the use of these substances in foods. This has led to different practices followed in different EU countries.

Some plant substances can be used as components of various product categories, including foods and medicines. EU countries may decide to classify a product as food or as a medicine on a case-by-case basis. Depending on how products are classified, different rules apply. Consequently, the same plant substance used in the same product may be treated in a different way within the EU.

The NHC Regulation requires that manufacturers who want to make any health claims on their products must submit scientific evidence on these claims for their evaluation by the European Food Safety Authority (EFSA). On the basis of the scientific opinion of EFSA the Commission takes a decision to authorise, or not, the claim in question.

## *What is this survey about?*

The Commission is currently evaluating the issue of health claims on plants added to foods. This evaluation will also consider the more general regulatory framework for the use of plants in foods. In particular the evaluation will be looking into whether the current rules concerning health claims on plants used in foods are adequate, and how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparation.

This consultation is an opportunity for your company to influence any possible changes to the legislation concerning the use of health claims on plant substances in foods (under Regulation (EC) 1924/2006 on nutrition and health claims made on food – the NHC Regulation) and the more general regulatory framework on the use of plant substances in foods.

This consultation aims at finding out how Regulation (EC) 1924/2006 (EU rules on the use of nutrition and health claims) affects smaller businesses in the sector.

The Commission is keen to hear from SMEs about their experiences – good and bad – on the current situation and how they are complying with the relevant rules.

SMEs feedback will help the Commission assess the effectiveness of the law, and possibly make changes to it.

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Enterprise Europe Network Partner identification

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Please enter your 7 digit EEN partner code:

*Text of 7 to 7 characters will be accepted*

You find it next to your name in Merlin forums. Example: BE00268

## SME panel questionnaire: general respondent profile

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1. Does your company manufacture and/or trade in food or medicinal products containing plant substances?

	Yes	No
My company manufactures and/or trades in <b>food</b> products containing plant substances	<input type="radio"/>	<input type="radio"/>
My company manufactures and/or trades in <b>medicinal</b> products containing plant substances	<input type="radio"/>	<input type="radio"/>

**IF ANSWER IS 'NO' TO ALL QUESTIONS, QUESTIONNAIRE STOPS HERE**

2. In which of the following sectors is your company mainly active? (please tick all that apply)

- Food supplements
- Sports nutrition
- General food and drinks (other than above)
- Pharmaceutical
- Other sector

Other sector (please specify)

**3. In which country is your company established?**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom

**4. What is the size of your company?**

- self-employed
- 1-9
- 10-49
- 50-249
- $\geq 250$

## General regulatory framework on plants and their preparations used in foods

Currently, the use of plant substances in foods is not harmonised in specific legislation at EU level. The same substance used in the same product may be treated in a different way across the EU, depending on whether the product is classified as a food or as a medicine. We would like to understand whether and how your business operations may be affected by the absence of specific harmonised rules at EU level on the use of plant substances in foods.

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**5. Is your company affected by the absence of specific harmonised rules at EU level on the use of plant substances in foods?**

- Yes
- No

**6. How has your company been affected, in terms of the following aspects?**

	Strong increase	Moderate increase	No impact	Moderate reduction	Strong reduction	Do not know	Not applicable
Changes in production costs (e.g. manufacturing)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changes in marketing costs (e.g. labelling, advertising)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Innovation potential (i.e. launch of new products, use of new ingredients)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trading opportunities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Competitive position on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sales potential	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other impacts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other impacts (please specify)

**7. Where does your company trade in products containing plant substances?**

	Yes	No
National market	<input type="radio"/>	<input type="radio"/>
EU/EEA market	<input type="radio"/>	<input type="radio"/>
Markets outside the EU/EEA	<input type="radio"/>	<input type="radio"/>

**8. Does your company face any of the following difficulties in trading with other EU countries? (please tick all that apply)**

- Difficulties due to classification issues as food or as medicine
- Difficulties due to the absence of specific EU rules such as positive lists of permitted plant substances
- Difficulties due to existing national rules for placing a given substance on the market
- Other difficulties
- No difficulties

Other difficulties (please specify)

**9. Given the current situation, do you believe that any of the following aspects of legislation on plant substances used in foods should be harmonised at EU level?**

	Yes	No	No opinion
List of substances that can be used in foods (positive lists)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
List of substances that cannot be used in foods (negative lists)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Authorisation procedure before marketing food products containing plants and their preparations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Classification of products containing plants and their preparations as “foods” or “medicines”	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Specific additional information to consumers (e.g., conditions of use, warning statements)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Health claims made on plants and their preparations used in foods

**THIS SECTION IS ONLY ADDRESSED TO THOSE TICKING ‘FOOD’ IN Q1.**

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**10. What is the approximate percentage of your sales value of food products containing plant substances that make claims on the health effects of these substances?**

- less than 10%
- 11-25%
- 26-50%
- 51-75%
- 76% and more
- Don't know



**11. If none of your products makes claims, why does your company not make any claims on the health effects of the plant substances contained in your food products?**

	Yes	No
Not interested: health claims do not influence my consumers' purchasing habits	<input type="radio"/>	<input type="radio"/>
Regulatory obligations are too complicated to comply with	<input type="radio"/>	<input type="radio"/>
Regulatory obligations are not clear enough	<input type="radio"/>	<input type="radio"/>
Too expensive to comply with regulatory obligations	<input type="radio"/>	<input type="radio"/>
Other reasons	<input type="radio"/>	<input type="radio"/>

Please specify "other reasons"

**12. Has your company ever submitted, or considered submitting, an application for the authorisation of a new health claim on your food products, in line with the current rules? The current rules require scientific evidence of the highest possible standard (i.e. human clinical trials) in order to substantiate a health claim on a plant substance contained in food products.**

- Yes, my company has submitted an application
- Yes, my company has considered to submit an application
- No

**13. What are the types of costs for including a new health claim on a plant substance in your food products? Please consider both internal and external costs (if some of the tasks indicated below are carried out on your behalf by external consultants/companies).**

- Familiarising with the regulatory obligations, including training (if needed)
- Production of new data and/or processing of existing data (including clinical trials)
- Other administrative tasks, e.g. meetings , filling in information/application templates etc.
- Buying equipment and other supplies, including for modifying labels
- Other type(s)
- Do not know

Please specify "other types":

**14. What is approximately the total amount of costs for including a new health claim on a plant substance in your food products?** *Please provide an estimate if you have considered submitting an application but have never done so.*

- < €100,000
- €100,001-200,000
- €200,001-300,000
- €300,001-400,000
- €400,001-500,000
- > €500,000
- Do not know

**15. What are the benefits for your company, in terms of sales, of obtaining the authorisation for a new health claim on plant substances contained in foods?**

- Presenting new products on the market
- Attracting new costumers
- Developing new geographical markets
- Do not know

**16. To what extent are the costs proportionate to the benefits?**

- Benefits are higher than costs
- Benefits are more or less equal to costs
- Costs are higher than benefits
- Do not know

Evidence on traditional use is evidence collected on the experience gained over time with the actual consumption of plant substances. Currently, such type of evidence is not considered sufficient on its own for the scientific substantiation of a health claim made on foods containing these substances.

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**17. If traditional use was considered in the scientific assessment of health claims, would your company intend to submit application(s) for the authorisation of health claims made on plant substances used in foods?**

- Yes
- No
- Do not know

**18. If traditional use was considered in the scientific assessment of health claims, the overall costs for your company for including a new health claim on a plant substance in your food products would be:**

- Much higher than now
- Higher than now
- About the same
- Lower than now
- Much lower than now
- Do not know

**19. If traditional use was considered in the scientific evaluation of health claims, how would your company be affected in terms of:**

	Increase	No change	Decrease	Do not know
Innovation potential (i.e. launch of new products, use of new ingredients)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Export opportunities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Competitive position on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other impacts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>