The REFIT Platform has considered the two submissions, one from Mr Loosen, a member of the Stakeholder Group and another one from a business association through LTL, on Nutrition and Health Claims (Reg EC 1924/2006).

The Stakeholder group agrees with the submissions and proposes to enlarge the scope of the ongoing Evaluation to include 1) more transparent procedures for the authorisation of health claims; 2) less scientific and more consumer-friendly wording of health claims; and 3) the possibility to market products with the same claims in all Member States. With regard to Nutrient Profiles, the Stakeholder group proposes to wait for the outcome of the Evaluation, expected in 2018.

The majority of Member States that contributed to the opinion supports the recommendations of the Stakeholder group regarding both submissions; some Member States stress the need to protect consumers against misleading messages on labels and consider a rigorous risk assessment function is crucial for this purpose. The role and responsibility of the National Food Agency to find appropriate wordings taking into consideration local conditions and traditions is also highlighted by some Member States.
1. Submission XI.11.a by a Member of the Stakeholder Group (Mr Loosen)

The “Claims Regulation”, adopted in 2006, has been designed to ensure that only authorized nutrition and health claims which have been scientifically substantiated can be used on foods throughout the EU. Whereas the Regulation to a certain degree has improved legal certainty, harmonization and trade within the EU, and significant improvements have been made with regard for example to the claims authorisation process over the years, it has also resulted in important challenges for European food business operators that make it an obvious candidate for a fitness-check.

Regulation (EC) 1924/2006 sets a high standard for the authorisation of health claims. While the industry supports a high standard, as this promotes consumer trust, complying with it implies significant costs and burdens, particularly for SMEs, who comprise 99% of the food and drink manufacturing sector. This in turn challenges the competitiveness of the EU market versus that of third countries, placing additional burdens on EU operators.

The main issues and burdens for food business operators with the Claims Regulation have been, amongst others:

- **Obstacles to research and innovation:** The rather long and complex authorisation process for health claims is a major burden for research and innovation. Although important improvements have been made over the last nine years in the risk assessment and risk management processes, both are rather slow, lengthy and with limited visibility of timing and expected outcome. Furthermore, since decisions on the authorisation of a claim/on the conditions and restrictions of use applying to it can be taken based on other legitimate factors other than EFSA’s opinion, any decision is very unpredictable, to the detriment of legal certainty, impartiality and transparency. Both the risk assessment and the risk management process would profit from exchanges with the applicant that would significantly strengthen the principles of transparency, visibility and predictability, while allowing both the applicant and EFSA/Commission and Member States to save time and resources.

- **Consumer information and understanding of health claims:** Due to the limited flexibility that is allowed in the wording of claims, a rather scientific language has to be used,
which can make the understanding by consumers difficult. In addition, the interpretation of “understandable to consumers” and the degree of flexibility in claims wording to enable that understanding varies from country to country; this is increasing the cost and complexity across the EU Internal Market, while serving no beneficial purpose to consumers. Another issue is represented by the fact that there is rather limited possibility to explain the underlying science and the context of the claim. This situation discourages the industry from investing in R&D and affects consumer information and ability to select food/food ingredients which can be beneficial for their health, nullifying the positive impact that the Regulation could have on public health.

- Interpretation and harmonization of the EU Single Market: The dimension of implementation and interpretation by Member States is key. Without common guidelines and common practices by Member States regarding implementation and interpretation, the idea “to improve the free movement of foods with nutrition and health claims within the internal market and to increase legal certainty for economic operators” is hampered. The Commission’s Guidance on Regulation (EC) 1924/2006 has never been revised/updated since its first adoption in 2007 while the application and interpretation of the Regulation has become quite divergent.

**Suggestion for simplification**

It is proposed that the aforementioned burdens for FBOs are addressed by the following:

- Obstacles to research and innovation: The procedures for the authorization of health claims should be streamlined and made more transparent and accessible to communication and exchange with risk assessors and managers (e.g. through pre-submission meetings). This would ensure less costly, lengthy and unpredictable decisions. A more transparent, streamlined process would also facilitate research and innovation, with positive repercussions on jobs and growth, unlocking the untapped potential for SMEs. Clear procedural rules and Commission assistance and guidance for applicants would lead to shorter and more effective risk assessment and risk management processes. The principle that decisions on the authorisation of a claim/on the conditions and restrictions of use applying to it should be primarily based on science (i.e. on EFSA’s opinion) should be recognised, in order to ensure legal certainty, impartiality and transparency.

- Consumer information and understanding of health claims: Authorized health claims should be less scientific and more consumer-friendly; a greater degree of flexibility of wording should be allowed. A common interpretation of what is “understandable to consumers” and the degree of flexibility in claims wording to enable that understanding is needed.

- Interpretation and harmonization of the EU Single Market: Commission guidance should ensure that diverging practices by EU Member States regarding implementation and interpretation of the Regulation cease to exist in view of re-affirming the idea “to improve the free movement of foods with nutrition and health claims within the internal market and to increase legal certainty for economic operators”.
Policy context

According to its Article 27, Regulation (EC) No. 1924/2006 should have been evaluated by 19 January 2013 at the latest, in particular with regard to its relevance on the evolution of the market in foods in respect of which nutrition or health claims are made and on the consumers’ understanding of claims, together with a proposal for amendments if necessary.

In the nine years of its application, the issues and concerns raised above have, amongst others, led to considerable burden on food business operators with an interest, first, to communicate on the nutrition and health effects of their foods and, secondly, to invest in research and innovation connected to the nutrition and health properties of foods. Those issues should have been addressed in the evaluation foreseen by Article 27 of the Regulation by January 2013. Food businesses do not share the Commission’s earlier view that the nine years of the application of the Regulation in general and the four years since the establishment of the list of authorized claims would make such evaluation premature.

Current State of Play

Despite the evaluation foreseen in Article 27 of the Regulation and ample experience with its application, the ongoing fitness check of the Regulation will only assess two parts of the Regulation that have not been applied in the last nine years: nutrient profiles and botanicals. A broader evaluation of the application of the Regulation is therefore proposed to address all the issues that have occurred during its application.

Annex (To open the attachment please click the paper clip)

2. Submission XI.11.b by a business association (LtL 553)

Nutrient Profiles pursuant to art. 4 of the Nutrition and Health Claims Regulation [EC] 1924/2006:

Art. 4 of Regulation [EC] 1924/2006 provides for so-called nutrient profiles. These “wanted” food profiles are to determine which foods may be advertised using health and nutrition claims in future. The chosen nutrients are limited to salt/sodium, saturated fatty acids, and sugar, for which tolerance limits are to be set per food category. If at least two of these three nutrients exceed their set limit, nutrition or health claims will be banned. If only one of the nutrients exceeds its respective limit, a nutrition claim will only be possible by adding a notice regarding the nutrient whose limit has been exceeded. These Nutrient Profiles should have been developed by 2009. Today, 2016, we are convinced that the Nutrient Profiles are no longer necessary and should therefore not be pursued.
since the new European Food Information Regulation EU(No) 1169/2011 now comprehensively covers all information required by consumers. Nutrient profiles are scientifically untenable and impracticable and no more than a politically motivated concept. Nutrient profiles fail to achieve their purpose, ignore the amounts of food consumed, fail to reflect the manifold eating cultures of Europe, and stigmatise traditional products. Nutrient profiles are not fit for purpose in protecting consumers from being misled and preventing overweight. Nutrient profiles will, according to experts in the field, not stand up to legal scrutiny by the European Court of Justice. The nutrient profile concept is an impediment to innovation. In summary once elaborated they would be an unjustified and disproportional burden, especially for SME.

3. Policy Context

The issue at stake is the application of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, which harmonises the use of nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. This Regulation aims in particular at enabling consumers to make healthier choices by protecting them from misleading information and at ensuring a level playing field for food business operators within the internal market and legal security.

This Regulation applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods delivered to consumers.

The Regulation provides for the definitions of nutrition claims and health claims as well as for the general principles and conditions for their use. It lays down the lists of permitted nutrition and health claims and also provides for specific procedures for introducing new claims. More specifically, the Regulation stipulates that nutrition and health claims made on food must be based on and substantiated by generally accepted scientific evidence and that health claims should only be authorised for use in the Union after a thorough scientific assessment by the European Food Safety Authority (EFSA).

In addition, the Regulation obliges the Commission to set nutrient profiles, after consulting EFSA, which are thresholds of nutrients such as fat, salt and sugars, above which nutrition claims would be limited and health claims prohibited, thus preventing a positive health message on foods high in these nutrients.

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods was adopted on 20 December 2006. The Regulation progressively harmonises the governance of nutrition and health claims since its entry into application from 1 July 2007.

The list of permitted nutrition claims came into application from 19 July 2010, and a first list of permitted health claims started to apply in December 2012. Since then these lists have been regularly updated. Under the current legal framework on nutrition and health claims, flexibility of wording is allowed provided that the adapted wording has the same meaning for consumers as that of the permitted nutrition or health claim in question and the related conditions of use are complied with.

A long list of health claims concerning plants and their preparations in foods remains
unregulated since December 2012 and the nutrient profiles required by the Regulation are still not established.

**State of Play**

The Commission announced its plan to carry out a REFIT evaluation of this Regulation in its Better Regulation Communication of 19 May 2015. The REFIT evaluation will focus on nutrient profiles and health claims on plants and their preparations added to foods, which are the two elements raising most difficulties in the application of the Regulation. It will also consider the more general regulatory framework for the use of plants and their preparations in foods.

The purpose of this REFIT evaluation is to assess whether these two specific elements required for the implementation of the Regulation have proven to be “fit for purpose” and whether the Regulation, to date, with respect to these elements, has achieved, at minimum burden, its overall objectives on truthful information to consumers and the facilitation of the free movement of foods bearing claims.

In addition, on 12 April 2016, the European Parliament by adopting its resolution on REFIT, called on the Commission to review the scientific basis of the Claims Regulation (how useful and realistic it is) and, if appropriate, to eliminate the concept of nutrient profiles considering that information and specific indications on fat, sugar and salt content are now required by Regulation (EU) No 1169/2011 on the provision of food information to consumers. However, the Commission will be in a position to address such demand only once the ongoing REFIT evaluation has been completed.

On 15 January 2018, the Commission completed the Fitness Check on the General Food Law Regulation (Regulation (EC) No 178/2002). The Commission is currently reflecting what changes should be made to the GFL Regulation to improve the quality of studies submitted in support of an application for EU authorisation including applications on health claims.

**What actions would be required to implement this suggestion?**

With regard to the Submission XI.11.a, no action on Regulation (EC) No 1924/2006 would be required for the following reasons:

- This issue of more transparency and accessibility and exchange with risk assessors and managers is currently being considered following the completion of the Fitness Check on the General Food Law (Regulation (EC) No 178/2002) on 15 January 2018 and the Commission Communication on the European Citizens' Initiative (ECI) "Ban glyphosate and protect people and the environment from toxic pesticides". The Commission is currently reflecting what changes should be made to the GFL Regulation to improve the quality of studies submitted in support of an application for EU authorisation including applications on health claims;

- On the more consumer-friendly wording of health claims, Regulation (EC) No 1924/2006 already allows flexibility for the wording of nutrition and health claims provided that the
adapted wording has the same meaning for consumers as that of the permitted nutrition or health claim in question and the related conditions of use are complied with.

- On possible divergent practices at national level, since the adoption of the Regulation (EC) 1924/2006, the Commission and the Member States are meeting regularly in the context of the Working Group on Nutrition and Health Claims to exchange views and facilitate the harmonised application of the Regulation in the EU market.

With regard to the Submission XI.11.b, no action would be required as the setting of nutrient profiles is currently assessed under the ongoing Refit Evaluation of Regulation (EC) No 1924/2006.
1 Opinion of the REFIT Platform

1.1 Considerations of the REFIT Platform Stakeholder group

The Stakeholder group recognises the concerns raised by the submissions.

With regard to Submission XI.11.a and the request made to address the issues of concern in the evaluation foreseen the Stakeholder Group recognises that those issues have not been part of the on-going REFIT evaluation and should be addressed in the outstanding evaluation of the Regulation (EC) No. 1924/2006 foreseen in its Article 27.

With regard to the Submission XI.11.b and the question of whether or not nutrient profiles are still needed, the Stakeholder Group recognises that the REFIT evaluation that the Commission has announced in 2015 and that has been finalised in 2017 will deliver the necessary elements for deciding inter alia the very question whether nutrient profiles are required for the implementation of the Regulation. The Stakeholder Group therefore proposes to await the results of the REFIT evaluation that are expected in 2018.

1.2 Considerations of the REFIT Platform Government group

Thirteen Member States have contributed to this Opinion.

Nine out of the thirteen contributing MS support the recommendations of the Stakeholder group regarding submission XI.11.a; some of them stress the need to protect consumers against misleading messages on labels and consider a rigorous risk assessment function is crucial for this purpose.

Two Member States highlight the role and responsibility of the National Food Agency to find appropriate wordings taking into consideration local conditions and traditions.

Four Member States do not consider the need to take any action on Regulation EC No. 1924/2006 to address the concerns expressed in the submission. Specifically HU is not in favour of relaxing the current system as well as transferring the role and functions of business organisations into government actors.

Twelve out of the thirteen contributing MS partially or fully support the recommendations of the Stakeholder group regarding submission XI.11.b on nutrient profiles and agree to wait for the outcome of the planned Evaluation.

One Member State supports the current situation in which nutrient profiles have not been set.
Individual contributions from MS

Member State 1

Member State 1 agrees with the final draft opinion.

The Member State 1 welcomes the proposals.

Protecting consumers lies at the heart of this legislation and looking at ways to make the process more transparent and consumer-friendly would be of benefit.

The Member State 1 is aware of the concern from certain parts of industry in respect of the application and evaluation process for nutrition and health claims. However, MS1 remains of the opinion that a rigorous risk assessment function is a crucial part of the process to ensure consumers are protected from potentially misleading claims (i.e. when there is no scientific evidence to substantiate the claim). The Member State 1 can support changes to the administrative processes if these will help businesses, but the overriding consideration must be consumer protection. Additionally, Member State 1 supports the proposal made by other member states of the need for an urgent update of the Commission’s Guidance on this Regulation, as it has not been updated since 2007.

Member State 6

With regard to Submission XI.11.a: Member State 6 supports the opinion of the REFIT platform stakeholder group. For MS6 the interpretation of Regulation 1924/2006 by Member States is the key point. Member State 6 proposes an urgent updated of Commission’s Guidance on Regulation that has never been updated since 2007, in light of the difficulties encountered in these nine years of application of the regulation.

With regard to the Submission XI.11.b: Member State 6 agrees with the opinion of the REFIT platform stakeholder group because MS6 is convinced that nutrient profiles are untenable and impracticable because ignore the amounts of food consumed, fail to reflect the different manifold eating cultures of Europe and stigmatize some traditional products.

Moreover now, for information and specific indications on fat, sugar and salt content of individual foods to the consumer, there is the Regulation 1169/2011 that supports consumers in informed choices.

Member State 13

Member State 13 agrees with the related REFIT draft opinion. Nutrient profiles should not be
wholly abandoned and some workable variation should still be developed for the foreseeable future. The rates of incidence of NCDs in the European general population will continue to rise and information to the consumer should be strengthened and not weakened through all the means necessary; until the aforementioned trends are shown to be decreasing if not reversed. The above opinion reinforces what is stated in the REFIT platform draft opinion whereas:

This issue of more transparency and accessibility and exchange with risk assessors and managers is currently being considered following the completion of the Fitness Check on the General Food Law (Regulation (EC) No 178/2002) on 15 January 2018 and the Commission Communication on the European Citizens' Initiative (ECI). The Commission is currently reflecting what changes should be made to the GFL Regulation to improve the quality of studies submitted in support of an application for EU authorisation including applications on health claims;

On the more consumer-friendly wording of health claims, Regulation (EC) No 1924/2006 already allows flexibility for the wording of nutrition and health claims provided that the adapted wording has the same meaning for consumers as that of the permitted nutrition or health claim in question and the related conditions of use are complied with.

With regard to the Submission XI.11.a, no action on Regulation (EC) No 1924/2006 would be required for the following reasons: On possible divergent practices at national level, since the adoption of the Regulation (EC) 1924/2006, the Commission and the Member States are meeting regularly in the context of the Working Group on Nutrition and Health Claims to exchange views and facilitate the harmonised application of the Regulation in the EU market.

With regard to the Submission XI.11.b and the question of whether or not nutrient profiles are still needed, the Stakeholder Group recognises that the REFIT evaluation that the Commission has announced in 2015 and that has been finalised in 2017 will deliver the necessary elements for deciding inter alia the very question whether nutrient profiles are required for the implementation of the Regulation. The Stakeholder Group therefore proposes to await the results of the REFIT evaluation that are expected in 2018

**Member State 2**

MS 2 believes that consumers should be protected against misleading messages on labels. Past experience has shown that it is necessary to draw up regulations on the use of health claims. Therefore, health claims must be sufficiently scientifically proven and established by the EU Commission. And in addition the Dutch Government is in favour to establish harmonized nutrient profiles at EU level to prevent nutrient claims and health claims from being made on unhealthy products.
**Member State 3**

Member State 3 supports the considerations of the REFIT Platform Stakeholder group.

**Member State 4**

Member State 4 shares the view given in the point 2.4 Policy context justifying that with regard to the Submission XI.11.a, no action on Regulation (EC) No 1924/2006 would be required. Likewise, MS4 also share that with regard to the Submission XI.11.b, no action would be required until the assessment under the ongoing Refit Evaluation of Regulation (EC) No 1924/2006 on the setting of nutrient profiles is finalised.

**Member State 12**

Regarding Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods ("Claims Regulation"), Submission XI.11.a by member of the REFIT Platform Stakeholder Group (Mr. Loosen), the Member State agrees with the opinion.

**Member State 8**

Member State 8 can support the considerations of the Stakeholder Group

**Member State 7**

Nutrient profiles: Member State 7 rather supports the current situation that nutrient profiles have not been set yet. Foodstuffs could be divided into "good" and "bad", depending on whether they meet the conditions of defined nutrient profiles, but regardless of the total daily diet of consumers. Consequently, consumers could start to see national specialties and products with protected designations or other high-quality products as negative.

Health claims relating to plants: In our opinion, health claims relating to plants are not to be approved by the procedure laid down in Regulation (EC) No. 1924/2006, because it is not possible in some plants to establish a scientific substantiation of a relevant health claim. Therefore, MS7 believe that in case of the authorization of health claims related to the plants, the tradition of use of specific plant should be reflected. However, MS7 disagree with the fact that no regulatory framework for plants is set. The regulation of this issue could be dealt, for
example, with Regulation No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, or it would be appropriate to create own regulatory framework for this issue.

**Member State 9**

The current system contains a wealth of mechanisms for reasons of transparency. There is plenty of continuously updated guidance supporting the work of applicants. MS9 also ensures consultations for interested stakeholders before forwarding their individual applications. The suggestions in the text are too general. In light of precise proposals can be decided whether or not they can be supported.

In general, the wording of health claims is consumer friendly and flexible, however, there are some health claims, e.g. platelet aggregation, where it is difficult to find a plain/simple wording. It is the responsibility of FBO to find a simple wording with the same content/meaning.

Member States and the Commission make numerous efforts to harmonize the interpretation and implementation of this Regulation, though, certain problems are unique, which can be resolved only by taking into account local conditions (e.g. the use of the term ‘healthy’ in the wording of health claims).

The nutrient profile is subject to a current REFIT evaluation and cannot be substituted by any other labelling element. A properly designed nutrient profile could be an important factor in preventing the promotion of foods with an unfavourable nutrient profile by claims and, this way, misleading and deceiving the consumer.

**Member State 10**

Member State 10 does not support the submission.

*Comments:* Member State 10 views regarding the submissions related to Regulation 1924/2006 on nutrition and health claims is reflected under the heading “What actions would be required to implement this suggestion?” MS10 does not consider that any action would need to be taken on Regulation (EC) No 1924/2006 to address the concerns expressed in the submissions.

As mentioned under “What actions would be required to implement this suggestion?”, the issue of more transparency and accessibility and exchange with risk assessors and managers is currently being considered following the completion of the Fitness Check on Regulation 178/2002. The Commission is currently reflecting on what changes should be made to that Regulation to improve the quality of studies submitted in support of an application for EU
authorisation, including applications on health claims. It should be noted that the decision whether a health claim should be authorised or not is primarily based on the Efsa-opinion. However, a claim needs to fulfil the requirements of the Regulation in order to be authorised, and therefore other legitimate factors such as nutrition recommendations, safety concerns and consumer understanding, have to be considered in the decision making. Our view is that these considerations are made carefully in order to take proportionate and justifiable measures.

On the more consumer-friendly wording of health claims, Regulation 1924/2006 already allows flexibility for the wording of claims provided that the wording has the same meaning for consumers as that of the permitted claim in question and the conditions of use are fulfilled. Hence, it is necessary to have the wording in the authorisations properly reflecting the scientific evidence in order to ensure that the claims appearing on the market also do so and are not misleading. The National Food Agency considers that the acceptable level of flexibility could be subject to discussions with the Commission and the Member States. MS10 also wishes to stress the possibility to use unspecific health claims in accordance with Article 10(3) of Regulation 1924/2006, which offers an additional opportunity for the food business operators in the use of health claims.

As explained under “What actions would be required to implement this suggestion?” the Commission and the Member States are meeting regularly in the context of the Working Group on Nutrition and Health Claims to exchange views and facilitate the harmonised application of Regulation 1924/2006. There is also common guidance on the implementation of the Regulation.

With regards to the Submission XI.11.b, Member State 12 agrees that no action would be required as the setting of nutrient profiles is currently assessed under the ongoing REFIT of Regulation (EC) No 1924/2006.

**Member State 14**

The Draft opinion XI.11.a asks for clear procedural rules, flexibility of wording, improvement of the free movement of goods and a broader evaluation of the Regulation. These objectives are sensible. However, Member State 14 is currently not in favour of any actions as the regulation itself has already dealt with the objectives and the report of the REFIT evaluation will give a good basis for discussion about possible adjustments. With regard to the procedural rules it is necessary to have in mind that the outcome of an application of a health claim might be different to the scientific established cause and effect relationship between the consumption of the food and the claimed effect. This is due to safety reasons or nutritional advice. Safety reasons have to be considered to ensure consumer safety, no changes should be made in Regulation (EC) No. 1924/2006. Nutritional advice has to be respected to ensure consumers are not misled by health claims in food with an unfavourable overall composition.
of a food. The unpredictability of the outcome of applications with regard to nutritional advice is partly due to the lacking implementation of nutritional profiles – a question dealt within the REFIT-evaluation already. The question of flexibility of wording was discussed several times. As it is necessary to ensure not to mislead consumers there is little space for flexibility of wording. The free movement of goods will be enhanced by decisions about handling claims on botanicals on EU level – a question dealt within the REFIT-evaluation already. A broader evaluation of the Regulation would hamper the important decisions about nutrient profiles and botanicals and would delay a better predictability of the outcome of applications and the free movement of goods. Furthermore part of the burden to industry is due to high consumer protection and the need of having scientific based health claims that are in line with Regulation (EC) No. 1924/2006. MS14 has no remarks to 'What actions would be required to implement this suggestion?' with regard to Submission XI.11.b.

**Member State 17**

The submitted comments have their justification. According to Art. 27 of Regulation (EC) No 1924/2006, the Commission was to present a report to the European Parliament and the Council on the application of this Regulation together with a possible proposal for amendments. However, to date, the Commission has not submitted such a report regarding the whole regulation. What is more, no work has begun to assess the functioning of the entire Regulation.

However, the REFIT evaluation was undertaken in relation to two selected areas covered by the Regulation - health claims regarding plants and nutrient profiles. This evaluation, carried out by an external institution, was completed at the end of 2017. The external institution presented its report, however, the Commission has not yet referred to it and has not proposed any further action.

In view of the above, the scope of the comments made in the submission XI.11.a should be taken into account in the framework of the overdue evaluation of Regulation (EC) No 1924/2006, referred to in its Art. 27. The comments made in the submission XI.11.b have already been covered by the completed REFIT evaluation regarding health claims on plants and nutrient profiles. At the moment, the position of the Commission on the results of the evaluation and the action plan in these two areas covered by the evaluation should be expected.