JHCI

Joint Health Claims Initiative
PO Box 43, Leatherhead
Surrey, KT22 7ZW
UNITED KINGDOM
Ph: 01372 224 027
Fax: 01372 224707
melanieruffell@jhci.org.uk
www.jhci.org.uk

Review of JHCI Guidelines for the Substantiation of Health Claims

---

An internal evaluation report

31st March 2006

Melanie Ruffell
JHCI Executive Director

Acknowledgements

JHCI wishes to thank all those who participated in completing the questionnaire or attending the focus group meeting. Thanks also to Dr Mike Rayner, Director, British Heart Foundation Health Promotion Group, for his assistance in the development of the questionnaire.

CONTENTS

EXECUTIVE SUMMARY

BACKGROUND

In light of the forthcoming European Regulation on Nutrition and Health Claims Made on Foods[1] the Joint Health Claims Initiative (JHCI) was commissioned by the Food Standards Agency (FSA) to review its Guidelines for Preparing Dossiers to Substantiate Health Claims[2], to help inform the development of EU-wide guidance on dossier requirements under the proposed rules.

This review has generated the recommendations shown below for improving the effectiveness and efficiency of Guidelines for the substantiation of health claims for food. The JHCI undertook this work because of its unique experience in writing and operating guidelines specifically designed for this purpose. The recommendations are based on a combination of the following inputs:

- The participants' responses to a questionnaire about the effectiveness and efficiency, and strengths and weaknesses of the JHCI Guidelines.
- The author's 5 years of experience working exclusively with submitters, assessors and dossiers.
- Feedback from the Expert Committee (JHCI assessors) on aspects of the Guidelines that affect the dossier assessment procedure.

PARTICIPANTS AND THE SCOPE OF THE REVIEW

Submitters, the JHCI Secretariat and Expert Committee were interviewed for their attitudes and opinions on the JHCI Guidelines for Substantiation. Results are presented in detail in the Annexes to this report. The research focussed solely on the usability of the Guidelines and did not review:

- the JHCI claims assessment process
- the JHCI decision-making process
- the JHCI Code of Practice for applying health claims to products
- the proposed EU Nutrition and Health Claims Regulation.

RECOMMENDATIONS

1. Split Guidelines into two stand-alone documents; one on ‘Preparing Dossiers for the Substantiation of Health Claims’ the other on ‘The Application of Health Claims’.

2. Clearly identify the Purpose and Objectives of the Guidelines in order to provide a reference point for their effectiveness.

3. Provide upfront an ‘at-a-glance’ flowchart of the overall claim submission process, including the relationship between substantiation and application; what needs to be done when and by whom, and any estimations of timelines, deadlines, dates and likely costs.

4. Clarify the minimum knowledge, in particular of the aspects of systematic reviews, that submitters should have to work with and understand the requirements of the Guidelines.

5. Keep the main body of the text focused on the salient points only, in a clear and concise manner. Use the Annexes for the bulk of explanatory notes and further details.

6. Succinctly state the requirements for what needs to be done and provide explicit instructions for meeting the requirements.

7. Include all key information within the one document, with clear internal referencing. Minimise the need for external cross-referencing by ensuring the Guidelines are comprehensive and complete (within reason, so not to overwhelm the reader).

8. Provide clear explanations as to the importance, relevance and application of the requirements.

9. Clearly indicate which areas are non-negotiable requirements and which areas are explanations or help notes.

10. Present the step-by-step processes clearly and concisely, ideally in flowchart format.

11. Include specific diagrams, graphs, tables and schematics to illustrate requirements and minimise room for interpretation.

12. Use clear, plain language and avoid technical jargon as appropriate. Include a glossary for explicit definitions of terms and phrases.

13. Provide checklists, help notes and recommended external sources of additional information and expertise to support the effective completion of the dossier by the submitter.

In addition, ideally:

14. Allow for dialogue with a Secretariat or advisors to clarify process requirements set out in the Guidelines.

15. Provide models of dossiers previously submitted to demonstrate how the requirements are translated into the finished product.

16. Provide an online interactive broad template, accessible by both the submitter and the assessors, to aid preparation and assessment of the dossier.

OVERVIEW OF RESULTS

Effectiveness and efficiency

- 86% of respondents felt that the guidelines had been effective in helping them prepare a dossier for consideration by JHCI, regardless of the outcome of their submission.
- 85% of participants were either 'very confident' or 'mostly confident' that they had met the process requirements for the submission (although this was also attributable to verbal guidance from the Secretariat and access to a model dossier).
- 64% of participants found it 'very easy' or 'mostly easy' to meet the requirements of the Guidelines, because they were, for example, *'concise'*, *'fully comprehensive'* and *'provided a clear step-by-step process for reviewing the evidence'*. Of the 36% who found it 'mostly difficult' to meet the requirements, many recognised that the difficulty was attributed to the overall process rather than the actual Guidelines.
- 79% of participants found the Guidelines to be 'very helpful' or 'mostly helpful' in the preparing and submitting the dossier. One person commented that *"The Guidelines are aimed at the right level for getting an independent answer and are set very well to ensure the evidence is compiled objectively and independently"*.
- 86% of participants felt that the Guidelines were missing some information and that they would have benefited from additional guidance.

Strengths and weaknesses

Although most participants found the Guidelines to be effective and efficient overall, when asked about the detail everyone thought that at least some improvement was required. For the purposes of this report, suggested improvements were recorded as a 'weakness'. The key findings were that:

- There was a broad range of responses suggesting that, rather than highlighting any dominant areas for priority attention, the finer details would benefit from improvement.
- 'Strength' and 'weakness' responses were highly subjective and often conflicting between participants. For example *'no template'* was both a high rating strength and weakness.
- The top rating strengths and weaknesses were the subgroup headings (which were broken down to individual comments further down the results Table 3):
  - '*overall preparation guidance'* e.g. step-by-step process
  - *'explanations'* e.g. types of claims; statistical help
  - *'requirements'* e.g. study criteria; hand search

CONCLUSIONS

All participants acknowledged the usefulness of the Guidelines but in response to particular questions about effectiveness and efficiency they agreed that improvements could be made.

The broad range of perceived strengths and weaknesses show that whilst there is room for overall improvements, one size doesn't fit all. Contradictions in the results show the difficulty in trying to satisfy all needs of all parties. The variation in opinion amongst participants appeared to be influenced by the submitter's background experience and familiarity with the JHCI submission process and Guidelines, and the type and nature of the claim which was the subject of their submission. In order to make best use of the Guidelines ideally submitters should have a minimum knowledge of the aspects involved in conducting a systematic review and an appreciation of science. Reference to model dossiers, together with explanations on how the Guidelines can be applied to different types of claims, will help indicate what is required.

The most commonly reported weaknesses were in relation to the need for more detailed requirements, explanations and definitions, particularly about the scientific and statistical standards. Yet many participants acknowledged that in providing more detail the Guidelines would become more prescriptive and restrictive, which would be an undesirable consequence, given that *'flexibility and room for interpretation'* was one of the more commonly mentioned strengths. Inevitably some of this flexibility in translation of the Guidelines will need to be sacrificed in favour of providing clearer instructions and more detailed requirements. Based on JHCI experience, it seems that submitters ultimately want clearer rules for the criteria and presentation of the science (validation of facts), yet greater flexibility in their approach to applying the science (as a health claim) to their products.

It is also the author's view that many of the reported tensions between flexibility and prescriptiveness was because the current Guidelines require the process to begin with a specified health claim. Thus a recommendation has been made to develop two separate guidelines in relation to the science and the application, whereby suitable emphasis on flexibility and restrictiveness can be applied as appropriate.

Verbal guidance from the JHCI Secretariat was considered by submitters to be a strength. The author believes that the availability of verbal confirmation increases the effectiveness and efficiency of guidelines, which is ultimately beneficial to both submitters and assessors of dossiers. However, whether or not dialogue is available to submitters in the future, guidelines should contain explicit instructions to minimise misinterpretation of the requirements by submitters and to support standardised verbal advice, particularly when translating future guidelines into different European languages.

Effective and efficient guidelines are essential for submitters, assessors and law enforcers. Submitters need to plan their submissions and have confidence that they can navigate their way through the requirements; authorities and assessors need to identify if the dossiers are viable for assessment and enforcement officers investigating breaches of the law need to be able to recognise, in the procedural sense, whether or not

companies have met a minimum standard. In addition, publicly available guidelines for the substantiation and application of health claims can also help reassure consumers that a robust, transparent authorisation system exists to protect them from false and misleading claims.

This review is based on submitters' feedback and the JHCI's unique practical experience in developing and administering guidelines for substantiation, provides a timely and well-grounded summary of positive attributes and lessons learnt in the UK as new guidance is prepared for Europe.

INTRODUCTION

BACKGROUND

The European Commission (EC) has recently adopted a proposed Regulation on 'Nutrition and Health Claims Made on Foods'[1], which intends to provide a more consistent and structured approach to the control of health claims in the countries of the European Union. In the absence of this legislation, the Joint Health Claims Initiative (JHCI), a tripartite alliance of consumer, enforcement, and commercial interests, published voluntary Guidelines for Preparing Dossiers to Substantiate Health Claims[2] in February 2002, preceded by the launch of its voluntary Code of Practice on Health Claims on Foods[3] in December 2000. The purpose of JHCI has been to provide an opinion on the scientific validity of health claims and to offer guidance on the wording and responsible use of health claims.

In preparing the JHCI Guidelines, comparable procedures in other countries were considered and drawn upon, largely those in Sweden, The Netherlands, USA, Canada, New Zealand and Australia. At the time of writing, JHCI has considered 14 health claims (7 public, 7 proprietary/confidential) and worked closely with many more companies during their initial preparations, but who ultimately chose not to submit to the JHCI Expert Committee (some multinational companies may also have submitted to other European Member State authorities, e.g. Sweden, The Netherlands, and France).

The JHCI has already been influential in the development of the proposed EC Regulation[1]. Many of the JHCI Code principles are reflected in the EC proposal and in 2003 JHCI undertook a Food Standards Agency (FSA) project in the UK to develop a process to 'Identify and define well-established Health Statements'[4].

PURPOSE

The purpose of this project was to undertake a process evaluation to assess the workability and efficiency of the JHCI Guidelines for Substantiation, and to identify areas requiring improvement. The recommendations offered are intended to support future revisions to the JHCI Guidelines and potential use by the FSA and the European Food Safety Authority (EFSA) in the development of new Guidelines for Europe.

AIM AND OBJECTIVES

In order to help inform how the UK might contribute to the development of new substantiation procedures for Europe, the aim was to identify any advantages and disadvantages of the current JHCI Guidelines. These are tried and tested and reputed to be helpful and informative in what is generally seen as a tough process with high standards for the substantiation of health claims.

Food companies, currently marketing products with health claims, are eager to prepare for the new rules, particularly in cases where commercial protection could be offered

for proprietary data or to ensure that their products are not withdrawn from the market unnecessarily. Understanding the substantiation requirements and procedures is important for food companies if they are to begin preparations to comply with the Regulation.

The objective of this review was to form recommendations based on an internal evaluation of the JHCI Guidelines for Substantiation, by collecting, categorising and summarising the attitudes and opinions of three key groups:

a) Industry members who have followed JHCI guidance to prepare and/or submit dossiers (including relevant interested parties who declined to submit to JHCI for reasons linked to the Guidelines (by specific invitation only)).
b) The JHCI Secretariat advising submitters on the application of the Guidelines.
c) The JHCI Expert Committee assessing dossiers of evidence that have been prepared following the JHCI Guidelines for Substantiation.

SCOPE

This research focuses on the strengths and weaknesses on the JHCI Guidelines for Substantiation. A number of comments received from participants, although closely related to the Guidelines, were about the overall process requirements, dictated either by the JHCI Code of Practice or European legislation. Either way, a review of these documents, or the overall process, are not within the scope of this report. Therefore this report is limited to the usability and effectiveness of the Guidelines alone, rather than the process it aims to support.

METHODOLOGY OVERVIEW

1. 14 participants (12 previous submitters and 2 JHCI Secretariat staff) completed a questionnaire via interviews.
2. 6 participants (JHCI Expert Committee members) attended a focus group meeting to provide Committee comments on the Guidelines.
3. Attitudes and opinions were summarised and categorised to enable data analysis.
4. Comments were rated as a ‘strength’ or ‘weakness’ when they were either clearly described by the participant to be a strength/weakness; or when they were reported to be an element of the Guidelines that was satisfactory/unsatisfactory, missing, or requiring improvement or development.
5. Strengths and weaknesses reported were analysed by their frequency to identify areas of the Guidelines for priority attention and any areas of inconsistency in reports of strengths and weaknesses.
6. The effectiveness and efficiency and areas requiring improvement were reported based on the questionnaire results.

A full methodology including further details about the, participants, categorisation and rating of strengths and weaknesses is presented in Annex 1.

RESULTS

Participants completed a questionnaire that sought their opinions on:

- the overall effectiveness and efficiency of the Guidelines, and
- the strengths and weaknesses of the content and format of the Guidelines

A summary of the results relating to these two key areas is presented below and further details can be found in Annex 2a and 2b.

EFFECTIVENESS AND EFFICIENCY

The majority of participants found the Guidelines to be both effective in helping them to prepare a dossier and efficient in expediting the preparation process:

- 86% of respondents felt that the guidelines had been effective in helping them prepare a dossier for consideration by JHCI, regardless of the outcome of their submission.
- 78% thought that the guidelines were either 'very clear' or 'mostly clear' in explaining the JHCI submission process requirements for evidence presentation and content. However many felt that understanding the Guidelines was experience dependent. Some examples of improvements suggested by participants included *"More guidance and clarity on forest plots and statistics, ideally with recommended software packages or statistical experts"; "More pictorial examples of statistical analyses; tables; schematics and flowcharts; example dossiers";* and *"More guidance on how to choose and define inclusion and exclusion criteria, especially in relation to quality criteria for evidence, human studies etc"*.
- 85% of participants were either 'very confident' or 'mostly confident' that they had met the process requirements for the submission, although this was also due to verbal guidance from the Secretariat and access to a model dossier.
- 64% of participants found it 'very easy' or 'mostly easy' to meet the requirements of the Guidelines and commented that they were concise and provided a clear step-by-step process for reviewing the evidence. Others in this group noted that the Guidelines were fully comprehensive and did not refer the submitter to other documents, which would have interrupted their flow of work.
- Of the 36% who found it 'mostly difficult' to meet the requirements, many recognised that the difficulty was attributed to the process itself rather than the actual Guidelines.
- 79% of participants found the Guidelines to be 'very helpful' or 'mostly helpful' in preparing and submitting the dossier. One person commented that *"The Guidelines are aimed at the right level for getting an independent answer and are set very well to ensure the evidence is compiled objectively and independently"*. Although another noted that *"The Guidelines do not explain if and how to handle emerging evidence… This is harsh because it doesn't acknowledge the changing nature of the evidence."*
- 86% of participants felt that the Guidelines were missing some information and that they would have benefited from additional guidance.

STRENGTHS AND WEAKNESSES

Although most participants seemed satisfied with the Guidelines, everyone thought that at least some aspect of the Guidelines required revision which would improve their effectiveness and efficiency. Each participant comment was rated as either a 'strength' or a 'weakness', and any aspect thought to require improvement was rated by the researcher as a weakness. Table 3, Annex 2b provides a detailed list of the comments rated as a strength or weakness. Overall the results showed that:

a. There was no single aspect of the Guidelines that was consistently reported as a strength or weaknesses. As such, revision of all aspects, with improvement where necessary, would be of greatest benefit.

b. 'Strength' and 'weakness' responses were highly subjective and often conflicting between participants. For example *'no template'* was both a high rating strength and weakness.

c. The top rating strength was '*overall preparation guidance'*. For example one participant commented that the *'step by step systematic review'*, and *'filtering process'*, helped submitters to boil down often unwieldy numbers of studies to the totality of evidence relevant to the claim.

d. Some of the other higher rating strengths were about the format of the Guidelines, for example that the main body of text was brief and reader-friendly, with further detail in the *'Annex'*.

e. The fact that the Guidelines do not follow a *'grades of evidence'* approach also rated highly as a strength. This was because most participants felt that the submission '*process should be universal'* for all grades of evidence and that such detail would be *'too restrictive'*, involve too much *subjectivity* and negate the role of the Expert Committee by '*pre-judging the evidence'*. The proportion of weaknesses reported in relation to [the lack of] a *'grades of evidence'* approach was significantly lower.

f. The top rating weakness was [that the Guidelines were missing] '*explanations'*. For example participants considered that further guidance was required in relation to [how to handle different] *'Types of claims'* and *'Statistical help'* and in relation to the *'claim wording/development/context'* and the '*totality of evidence'*.

g. Other higher rating weaknesses were that the Guidelines were *'overburdensome'*, that they required more *'Examples, diagrams, tables'* and that their effectiveness and efficiency was *'Experience dependent'* (both in terms of the submitter's experience of JHCI and prior to JHCI).

(Note: Text in italics on this page relates to the comment categories presented in Table 3).

DISCUSSION

The results have highlighted a number of key issues relating to perceived strengths and weaknesses of the JHCI Guidelines for Preparing Dossiers to Substantiate Health Claims[2]. These issues are discussed in more depth under the following headings:

- Effectiveness and efficiency vs strengths and weaknesses
- The consistency of results
- The need for balance between clear requirements and prescriptiveness
- The difference between 'Requirements' and 'Explanations'
- The value of dialogue
- Separate Guidelines for 'Substantiation' and 'Application'?
- Conclusions

Effectiveness and efficiency vs strengths and weaknesses

Overall it appears that participants were satisfied that the Guidelines were mostly effective and efficient (Annex 2a), although they indicated by their comments that there was room for improvement (Annex 2b). This suggests that although a minimum level of effectiveness was achieved with the current Guidelines (probably given that the alternative was no Guidelines), it would be preferable to revise and improve the Guidelines to help maximise these outcomes.

Table 3, Annex 2b presents detailed comment categories of strengths and weaknesses. Although the percentages shown are small (they are a proportion of the total number of strengths or weaknesses, which was considerably larger than the total number of participants) all comments are valuable because they help to compare and contrast the attitudes and opinions of the 20 participants. Because each participant has spent a considerable amount of time working with the Guidelines to prepare their dossier(s), their input was essential to help form recommendations for the development of practical and effective guidance in the future.

The consistency of results

The results indicate that the overall effectiveness and helpfulness of the Guidelines varies from submitter to submitter and from submission to submission. This demonstrates the subjective nature of working with the Guidelines, which themselves may currently be too flexible and open to interpretation which invites subjectivity (even though flexibility and room for interpretation was one of the more commonly mentioned strengths).

From the author's experience, the variation in opinion amongst participants is likely to be influenced by:

- The submitter's background experience and scientific knowledge prior to working with the JHCI Guidelines.

- The submitter's familiarity with the JHCI submission process and dossier preparation requirements, that is, whether they are first time submitters.
- The type and nature of the claim which is the subject of the submission and the submitter's confidence on how to apply the Guidelines to their claim.

Such variation needs to be taken into account in the development of new guidance, which, to help address problem areas early on, should involve a group representing the experience and characteristics of likely submitters.

Comments about the Guidelines were often inconsistent between participants, for example where some felt that the '*step-by-step process for undertaking the systematic review was clear, concise and helpful'*, others said that it was '*onerous and confusing'* to follow. But some participants also contradicted themselves as they recognised the complexities of providing guidance for the substantiation of claims. For example, submitters said that '*guidance should not be too prescriptive as this would appear restrictive and burdensome'*. Yet the same submitters also felt that '*clearer requirements were needed on the type and number of studies'* required to substantiate their claim.

Submitters were generally aware of this contradiction and noted that it was '*not possible to prepare guidance that would cover every eventuality'*. The availability of verbal advice would be one way around this.

The need for balance between clear requirements and prescriptiveness

Responses were closely matched on whether the Guidelines needed to be more specific about the submission requirements, particularly in terms of study quantity and quality criteria, or that they should be unprescriptive and flexible.

Those who thought that '*more explicit guidance was necessary'* commented that such information would help them *to 'plan, prepare and decide if their submission was viable and worth the financial cost and effort'*. Feedback from participants indicated that '*potential submitters may have been discouraged'* because seeking JHCI approval is voluntary and because the Guidelines do not provide enough clarity about the requirements to enable the submitter to determine the likely outcome of their submission. Yet others felt that the requirements were clear, which at best was thought to be *'very helpful'*, at worst *'overly burdensome'* and *'daunting'*.

As noted above, the inconsistency in whether aspects of the Guidelines were found to be a strength or a weakness shows that guidance for the substantiation of health claims can never meet everyone's needs. The current JHCI Guidelines were found to suit some submitters but not others, and submitters of more than one claim found that the Guideline's effectiveness and usability varied from claim to claim. Participants felt that this was largely due to a '*lack of clarity, explanation and definition'* (which can be developed and improved in a revision), however it is impossible to provide a 'one-size fits all' document that is both explicit in its requirements but not overly prescriptive and restrictive (another commonly reported weakness).

Whilst it has been desirable to cover as many eventualities as possible, the current system of claim submission involves scientific validation of a specific health claim submitted upfront, which varies considerably from submitter to submitter (and these claim possibilities are likely to widen significantly when 25 Member States begin to develop and translate health claims under the proposed new rules[1]).

The current JHCI Guidelines are one document containing two sections: Section 1 focuses on guidance for undertaking a systematic review of evidence to validate a claim; Section 2 provides advice on how to demonstrate how the claim will be marketed in the UK context. This approach means that the health claim is both the starting and finishing point of the submission and was designed specifically to comply with the remit of JHCI, which was to 'provide an opinion on the validity of a health claim presented to it'. However, it is the author's opinion that given the opportunity to revise this approach and based on JHCI experience, it is more logical to begin with a proposed relationship on food and health, from which a health claim could be devised that accurately reflects the scope of valid evidence. It is also the author's view that many of the reported tensions between flexibility and prescriptiveness were because the current Guidelines require the process to begin with a specified health claim.

Table 3, Annex 2b, shows that flexibility was regarded more often as a strength than as a weakness so a degree of interpretation was found to be preferable, however the need for greater clarity about the requirements also featured more often than others, once again demonstrating the tension in views. Bearing this in mind the development of future guidelines will need to weigh up the submitters need for clear scientific requirements with their desire for enough flexibility to encourage innovation and new submissions. Overall the author believes that the Guidelines would be improved if the '*scientific requirements were more specific'* and the *'wording requirements were less specific'*. Below is a discussion on an option to facilitate this improvement by preparing separate guidelines for 'Substantiation' and for 'Application' of health claims.

The difference between 'Requirements' and 'Explanations'

There was a perceived lack of clarity in the JHCI Guidelines about the process requirements. This may be due to the voluntary nature of the system. That is, although it is a legal requirement that health claims are substantiated, submitting to JHCI is not. However once a submission to JHCI has been initiated, aspects of the submission process reflected in the Guidelines are non-negotiable. Based on the feedback from both submitters and the JHCI Secretariat, this distinction was not explicit. Undoubtedly it would have helped submitters if the Guidelines had simply been named 'Submission Requirements', with clearly marked explanations to support it.

The most commonly reported weaknesses were that more explanations were needed to describe the reasons behind the requirements and their instructions. In a revision of the Guidelines, 'requirements' should be clearly distinguishable from 'explanations' to curtail misinterpretations about what is necessary to satisfy the process. For example page 4 of the current JHCI Guidelines[2] presents a list of headings, preceded by the statement, *'It is suggested that the dossier follows the format below:'* whereas it would have been unmistakable if the statement read, *'It is <u>necessary</u> that the dossier follows the format below:'*.

The value of Secretariat dialogue

Dialogue with the JHCI Secretariat was a frequently reported strength, which, although is complimentary to the JHCI and clearly seen as helpful to submitters, suggests that perhaps the Guidelines alone did not adequately describe and explain the requirements. This is consistent with other results, particularly that the highest number of weaknesses reported in Table 3 were both in relation to the need for clearer 'requirements' and more 'explanations'. Secretariat assistance and feedback has formed a significant part of the JHCI's service to help companies identify if sufficient evidence exists to substantiate their health claims. It has also been essential to ensure that submitters have met all the process requirements before dossiers are submitted to the Expert Committee. However, whether or not dialogue is available to submitters in the future, guidelines should contain explicit instructions to minimise misinterpretation of the requirements by submitters and to support standardised verbal advice, particularly when translating future guidelines into different European languages.

Separate Guidelines for 'Substantiation and 'Application'?

The current JHCI submission process requires marketing material to be developed and submitted with the dossier to show how the company intends to use the claim in food labelling (the development of the claim is somewhat of a chicken and egg scenario, but logically it begins with an understanding of the valid science available on which to base a claim). The following three steps are an oversimplified version of the current JHCI process, whereby the company has been required to refine and resubmit their claim if the initial proposal was deemed to be inappropriate or inaccurate in relation to the evidence:

1. Define and develop health claim
2. Find and submit substantiating evidence based on the totality of evidence
3. Refine and resubmit health claim

To help develop guidance that is more specific about the scientific requirements, and less specific on the proposed wording of health claims, the author suggests that new guidelines could be refocused and reformatted into two separate documents, along the lines of:

1. Guidelines for Substantiation
   Whereby a 'health statement' about a diet/food/health relationship, is the subject of substantiation.

And

2. Guidelines for Application
   Whereby the scientifically substantiated health statement is applied in a responsible way as a health claim to a food product.

With this distinction, 'Guidelines for Substantiation' can be as clear, explicit and defined as scientific principles allow, of which many of the standards are already universally agreed. For example, the ILSI Europe PASSCLAIM[6] initiative recently

published its consensus on criteria for how markers should be identified, validated and used in well designed studies to explore the links between diet and health.

'Guidelines for Application' need to be equally robust, so not to defy the point of a harmonised central system, but adapted as appropriate to suit local needs and allow for degrees of flexibility in wording and application for submitters across different markets. This flexibility will be essential under the new European system to take local variation into consideration. Therefore an approved health 'statement' would encapsulate the parameters to help define and develop a specific health 'claim' for a food product. In other words this approach would encourage submitters to first understand the base of evidence, before preparing marketing material and labels to carry the claim.

To summarise, two sets of guidelines, one for substantiation, the other for application, would have the following benefits:

- They would not be an over-simplified or over-restrictive compromise in an attempt to be a 'one-size-fits-all' document.
- Assessment of the science first would enable a range of conditions for use to be published in relation to the use of the authorised health statement, from which a suitable health claim could be devised.
- Decisions about the suitable wording of the health claim would be made at the end of the process and in light of the scientific opinion, together with the Guidelines for Application of the science to the food label. Thus addressing many of the concerns about the need for flexibility in the use of health claims.
- This order of claim assessment would bypass the need for a resubmission (unless new evidence was to be presented).

Conclusions

Based on the findings of this research and the JHCI's experience in working with submitters, their dossiers and the claim assessment panels, the key conclusion has been that we separate the Guidelines into two documents. The first (i.e. Guidelines for Substantiation) starting with the science to establish the health statement, which encapsulates the parameters for converting it into a specific health claim for a food product (i.e. the Guidelines for Application', which takes into account consumer, nutrition and legal principles).

In addition the following conclusions have also been reached by the author about ensuring the effectiveness and efficiency of future guidelines:

i. The overall effectiveness and efficiency of guidelines is influenced largely by the content and, to a lesser degree, the format which helps the user to navigate and find the key points of the document. These aspects, together with the user's subjectivity and previous experience seemed to determine the overall usefulness of the guidelines (although it seems likely that JHCI Secretariat advice boosted the Guidelines effectiveness).

ii. To help set the scene for submitters, it is imperative that the purpose of the Guidelines is stated explicitly at the beginning of the document, together with an overview of the entire process.

iii. All requirements should be rooted in the purpose, and the instructions designed to reflect these. Guidelines must be more of a help than a hindrance to the reader, especially if they are being used to encourage submissions. In some cases guidelines can easily lose or discourage the reader if they are too detailed, yet imprecise guidelines that miss the finer points of clarification may daunt readers if they feel they have to second-guess the requirements.

iv. All terms and phrases should be clearly defined and consistently used throughout the document. Any room for misinterpretation will interfere with the user's understanding of the task at hand and is likely to generate confusion and frustration at the requirements set out in the Guidelines.

The broad spread of strengths and weaknesses reported, together with the contradictory results, indicates that a revision of the JHCI Guidelines, or the development of any new guidance, will need to carefully find the balance between clear requirements and prescriptiveness. However, under a mandatory system[1] for Europe, prescriptiveness may be received more favourably, and therefore act less as a deterrent, than within a voluntary system for approval of claims. The JHCI voluntary Guidelines were published in February 2002, shortly after the organisation's launch. Practical guidance of a similar degree had not been issued at the time, so the current version (Version 1) was invented by JHCI in its early days and as such was based mostly on theory. Guidelines can now be substantially improved with refinements based on JHCI's four years of experience in processing dossiers, and, particularly with the feedback obtained via this research.

In preparing an inventory of necessary improvements, there is a need to recognise the difference between whether areas of preference and dissatisfaction are about the Guidelines themselves, or whether they are more to do with the underlying policy and legal framework that dictates the content of the Guidelines. Ultimately guidelines can only provide instructions and advice on how to satisfy the procedural requirements, and some strengths and weaknesses will simply be a symptom of the over-arching rules that may not be subject to change in the short or medium term.

With a new EU 'claims' Regulation[1] due for adoption in the coming months, the JHCI Guidelines are likely to be superseded by EU-wide guidelines to help submitters meet the new legal requirements. However as many of the scientific substantiation requirements are likely to remain, it is anticipated that the lessons learnt by organisations such as JHCI can be shared in the development of EU-wide guidance, and the identification of their strengths and weaknesses will help new guidelines to be as workable and efficient as possible.

Food companies, currently marketing products with health claims, are eager to prepare for the new rules, particularly in cases where commercial protection could be offered for proprietary data and to ensure that their products are not withdrawn from the market unnecessarily. Understanding the substantiation requirements and procedures is

important for food companies if they are to begin preparations to satisfy all requirements for application for the authorisation of a health claim in the Regulation.

Clear guidance not only helps submitters to navigate their way through the legal and scientific requirements but also helps enforcement officers investigating breaches of the law to recognise, in the procedural sense, whether or not companies have followed guidelines on application. In addition, publicly available guidelines for the substantiation and application of health claims can also help reassure consumers that a robust, transparent authorisation system exists to protect them from false and misleading claims. This in turn will help maintain consumer confidence in products carrying health claims and 'enable informed choice' about their diet.

The findings in Table 3 and recommendations set out in this report, based on feedback from those who have used or worked with the JHCI Guidelines, should help pave the way for the development of new guidance and help ensure that future guidelines are effective in achieving their objectives and user-friendly and helpful for those who have to work with them.

RECOMMENDATIONS

1. Split Guidelines into two stand-alone documents; one on 'Preparing Dossiers for the Substantiation of Health Claims' the other on 'The Application of Health Claims'.

2. Clearly identify the Purpose and Objectives of the Guidelines in order to provide a reference point for their effectiveness.

3. Provide upfront an 'at-a-glance' flowchart of the overall claim submission process, including the relationship between substantiation and application; what needs to be done when and by whom, and any estimations of timelines, deadlines, dates and likely costs.

4. Clarify the minimum knowledge, in particular of the aspects of systematic reviews, that submitters should have to work with and understand the requirements of the Guidelines.

5. Keep the main body of the text focused on the salient points only, in a clear and concise manner. Use the Annexes for the bulk of explanatory notes and further details.

6. Succinctly state the requirements for what needs to be done and provide explicit instructions for meeting the requirements.

7. Include all key information within the one document, with clear internal referencing. Minimise the need for external cross-referencing by ensuring the Guidelines are comprehensive and complete (within reason, so not to overwhelm the reader).

8. Provide clear explanations as to the importance, relevance and application of the requirements.

9. Clearly indicate which areas are non-negotiable requirements and which areas are explanations or help notes.

10. Present the step-by-step processes clearly and concisely, ideally in flowchart format.

11. Include specific diagrams, graphs, tables and schematics to illustrate requirements and minimise room for interpretation.

12. Use clear, plain language and avoid technical jargon as appropriate. Include a glossary for explicit definitions of terms and phrases.

13. Provide checklists, help notes and recommended external sources of additional information and expertise to support the effective completion of the dossier by the submitter.

14. Allow for dialogue with a Secretariat or advisors to clarify process requirements set out in the Guidelines.

15. Provide models of dossiers previously submitted to demonstrate how the requirements are translated into the finished product.

16. Provide an online interactive broad template, accessible by both the submitter and the assessors, to aid preparation and assessment of the dossier.

REFERENCES

1. European Regulation on nutrition and health claims made on foods. Latest version can be viewed at:
   http://www.europarl.europa.eu/oeil/file.jsp?id=235102

2. Joint Health Claims Initiative (Feb 2002): *Guidelines for Preparing Dossiers to Substantiate Health Claims.*
   http://www.jhci.org.uk/

3. Joint Health Claims Initiative (2000): *Code of Practice on health claims on foods.*
   http://www.jhci.org.uk/info/code.pdf

4. Joint Health Claims Initiative (2003): *Final Technical Report: A Process to Define and Identify Well Established Health Statements and a list of Well Established Nutrient Function Statements.*
   http://www.food.gov.uk/multimedia/pdfs/jhci_healthreport.pdf

5. Food Standards Agency (2004): *2005-2010 Strategic Plan. Putting Consumers First.*
   http://www.food.gov.uk/aboutus/publications/busreps/strategicplan

6. ILSI Europe (2005): *Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM).*
   http://europe.ilsi.org/NR/rdonlyres/F6442FB4-767E-45E3-BDC3-533455B5E713/0/PASSCLAIMConsensusonCriteria.pdf

7. Swedish Nutrition Foundation (2004): *Health Claims in the Labelling and Marketing of Food Products. The Food Sectors Code of Practice.*
   http://www.hp-info.nu/SweCode_2004_1.pdf

ANNEX 1

METHODOLOGY

METHODOLOGY OVERVIEW

- 14 participants (12 previous submitters and 2 JHCI Secretariat staff) completed a questionnaire via interviews, 12 out of 14 over the phone.
- 6 participants (JHCI Expert Committee members) attended a focus group meeting to provide Committee comments on the Guidelines.
- Attitudes and opinions were summarised and categorised to enable data analysis.
- Comments were rated as a 'strength' or 'weakness' when they were either clearly described by the participant to be a strength/weakness; or when they were reported to be an element of the Guidelines that was satisfactory/unsatisfactory, missing, or requiring improvement or development.
- Strengths and weaknesses reported were analysed by their frequency to identify areas of the Guidelines for priority attention and any areas of inconsistency in reports of strengths and weaknesses.
- The effectiveness and efficiency and areas requiring improvement were reported based on the questionnaire results

1. THE QUESTIONNAIRE

Structured questionnaires were developed, in consultation with an advisor experienced in qualitative research methods, to seek the views of those who have been involved in the preparation of dossiers. That is, Submitters of dossiers (Group A participants) and the JHCI Secretariat advising on application of the Guidelines (Group B participants). Participants were encouraged to report their views on the Guidelines' strengths and weakness, and were invited to suggest improvements. Relevant interested parties who declined to submit to JHCI were specifically invited to participate, if they identified that their reasons for not submitting related to the Guidelines.

A copy of the questionnaire is presented in Annex 2. To help the participants consider strengths and weaknesses of all aspects of the Guidelines, the questions were assigned to one of five categories:

- Effectiveness
- Efficiency
- Content
- Format
- General

2. THE PARTICPANTS AND DATA COLLECTION

To undertake the first formal internal evaluation of the JHCI Guidelines for Substantiation of Health Claims, the attitudes and opinions of the following key groups were collected, categorised and summarised:

2.1. Group A Participants – Submitters (n=12)

Industry representatives who have followed JHCI guidance to prepare and/or submit dossiers).

- Total number of people APPROACHED to participate in this research = 16
  Of which: People who had completed at least one final submission = 12
  And: People who had not reached final submission = 4

- **Total number of people AGREED to participate in this research = 12**
  Of which: People who had completed at least one final submission = 10
  And: People who had not reached final submission = 2

The questionnaire was sent to participants in advance of an agreed interview date and time. Interviews took up to 1.5 hours to complete and were conducted from 13th to 24th February 2006. All but one of the interviews were conducted via telephone, largely to save travelling time for both the interviewer and the interviewee. All interviews were undertaken by the JHCI Executive Director.

2.2. Group B Participants – JHCI Secretariat (n=2)

JHCI Secretariat staff who have advised submitters on the application of the Guidelines.

The current JHCI Executive Director and a former Acting Executive Director met and completed the questionnaire together on 14th February 2006 to provide the JHCI Secretariat view. Individual responses have been reported separately and counted together with the Submitter results because both Group A and Group B participants completed the same questionnaire.

2.3. Group C Participants – JHCI Expert Committee (n=6)

JHCI Expert Committee members who have had experience assessing dossiers of evidence that have been prepared following the JHCI Guidelines for Substantiation.

The JHCI Expert Committee met on 26th January 2006 for a focus group meeting. The full Committee membership, excluding the Chairman, comprises seven members. Six members attended the focus group meeting to provide the Expert Committee view. It should be noted that:

- The Committee did not complete the questionnaire. Committee views were sought, via a focus group discussion, on the effectiveness of the Guidelines in helping Submitters to prepare a complete and proportionate dossier to substantiate the claim under question.

- The Committee views have been reported as one because the view reflects an agreed position of the Committee, rather than of individual members.
- The Committee comments were summarised and categorised into the same categories described in Section 1 above and whether they were a strength or weakness. This enabled strengths and weaknesses identified by the Committee to be counted together with those of Submitters and the Secretariat.

3. CATEGORISING AND SUMMARISING ATTITUDES / OPINIONS

3.1 Categories of responses

All participant responses were logged, summarised and categorised, to enable data analysis, in the following manner:

Category	*Description*
Ref #:	Response reference number
Participant type:	'Submitter'; 'Secretariat'; or, 'Expert Committee'
Q #:	Questionnaire question number to which the comment relates
Question category:	As shown in Section 1, Methodology, above
Question subject:	Abbreviated version of each question in the questionnaire
Strength/Weakness:	Comment rated as 'Strength'; 'Weakness'; 'n/a'*; or, 'EU Context'**
Broad response:	Broad description of attitude or opinion
Detailed response:	Detailed description of attitude or opinion

* *'n/a' was used in cases where comments were about the overall process, which is not the subject of this research.*

** *'EU Context was used in cases where comments were in relation to the proposed EU Nutrition and Health Claims Regulation*

For example, the response, '*the language is not very user friendly for someone with limited experience'*, was summarised and categorised as follows:

Ref #	Participant Type	Q #	Question Category	Question Subject	Strength / Weakness	Broad response	Detailed response
62	Submitter	1.3	Effectiveness	Clear requirements?	Weakness	Terminology	Not user friendly

3.2 Definition of 'strength' and 'weakness' ratings

Responses were rated as a **'strength'** when they were:
- Clearly described by the participant as a strength or positive attribute, or
- Reported by the participant to be a satisfactory element of the Guidelines.

Responses were rated as a **'weakness'** when they were:
- Clearly described by the participant as a weakness or negative attribute, or
- Reported by the participant to be an element of the Guidelines that was unsatisfactory, missing, or requiring improvement or development.

4. DATA ANALYSIS AND PRESENTATION OF RESULTS

Detailed responses to the questionnaire are presented in two parts as follows:

- **Annex 2a: Actual responses to the questionnaire**
  ➲ To demonstrate whether the Guidelines were effective and efficient

- **Annex 2b: All comments rated as strengths and weaknesses**
  ➲ To identify the strengths and weakness of the Guidelines

Strengths and weaknesses reported were analysed by their frequency against Question Category (Table 1); Question Subject (Table 2); and Range of Responses (Table 3), each to identify areas of the Guidelines for priority attention and any areas of inconsistency in reports of strengths and weaknesses. Table 3 also presents a de-duplicated list of all the strengths and weaknesses reported, on which detailed future improvements could be based.

ANNEX 2a

ACTUAL RESPONSES TO THE QUESTIONNAIRE

A summary of the participants' responses.
Group A (submitters, n=12) and Group B (secretariat staff, n=2).

1. EFFECTIVENESS
Of the Guidelines to help you meet dossier submission requirements

1.1 What was your understanding of the Guideline's purpose?

All respondents understood that the Guideline's purpose was to help them prepare a dossier of the totality of evidence, in a standardised format, to substantiate their health claim. Some also considered that the Guidelines we there to *"help JHCI do its job"; to "make the assessment process more efficient";* or *"to help determine whether the claim will fly or not".*

1.2 Overall, how effective do you think the Guidelines were, in providing submitters with a step-by-step approach for the preparation of a dossier of evidence for the substantiation of health claims for food? In particular, did the Guidelines help you to present a systematic review of evidence relevant to the claim, and information regarding its application and likely impact in the UK, so that the JHCI Expert Committee could assess the claim and form a recommendation based on the totality of the facts?

Very effective	**36%**
Mostly effective	**50%**
Mostly ineffective	**14%**
Very ineffective	**0%**

More than three-quarters of respondents felt that the Guidelines had been effective in helping them prepare a dossier for consideration by JHCI, regardless of the outcome of the submission. Of the two people that thought they were 'mostly ineffective', one felt that a model dossier was essential in order to clarify and demonstrate the Guidelines requirements.

1.3 Overall, how clear do you think the Guidelines were for explaining JHCI submission process requirements for evidence presentation and content?

Very clear	**21%**
Mostly clear	**57%**
Mostly unclear	**14%**
Very unclear	**7%**

The majority of participants had found the Guidelines to clearly set out the requirements for the submission content and presentation, however many felt that understanding the Guidelines was experience dependent. Some examples of improvements suggested by participants included:

- More guidance and clarity on forest plots and statistics, ideally with recommended software packages or statistical experts.
- More pictorial examples of statistical analyses; tables; schematics and flowcharts; example dossiers.
- More guidance on how to identify salient points of evidence and how to present

succinctly.

- More detail on the overall process including timelines, deadlines and the process for submitting draft dossiers and JHCI response timeframes.
- The addition of a glossary to help explain technical terminology and consistent use of terms.
- Links to more detailed advice on minimum study requirements (e.g PASSCLAIM) and tips for acceptable evidence as deemed by the Expert Committee.
- More guidance on how to choose and define inclusion and exclusion criteria, especially in relation to quality criteria for evidence, human studies etc.
- More guidance on how to handle data that didn't appear to fit the Guidelines suggested approach.
- More clarity on how to handle different areas of science in relation to the same food component.

1.4 When the dossier was presented to the Expert Committee, how confident were you that you had met the process requirements for the submission (regardless of the outcome)?

Very confident	**14%**
Mostly confident	**71%**
Mostly unconfident	**7%**
Very unconfident	**0%**

Participants commented that other important factors were involved in their levels of confidence, such as:

- Receiving verbal guidance and feedback from the Secretariat.
- Checking their work against the model dossier.
- Lack of familiarity with the JHCI process on a first submission.

2. EFFICIENCY

Of the Guidelines to expedite the dossier preparation process

2.1 Overall, how easy or difficult was it to meet the requirements of the Guidelines?

Very easy	**14%**
Mostly easy	**50%**
Mostly difficult	**36%**
Very difficult	**0%**

36% of participants found it 'mostly difficult' to meet the requirements of the Guidelines. The 64% who found it 'mostly easy' or 'very easy' commented that the Guidelines were concise and provided a clear step-by-step process for reviewing the evidence. Others noted that the Guidelines were fully comprehensive and did not refer the submitter to other documents, which would have interrupted their flow of work.

Much of the difficulty was attributed to the process itself rather than the actual Guidelines.

2.2 Overall, how helpful were the Guidelines in the preparing and submitting the dossier?

Very helpful	**50%**
Mostly helpful	**29%**

Mostly unhelpful	**14%**
Very unhelpful	**0%**

As with section 1.4, participants noted that the model dossier, Secretariat feedback and the Guidelines were all helpful in equal measure, to help minimise individual interpretation. Comments included:

- The Guidelines are aimed at the right level for getting an independent answer and are set very well to ensure the evidence is compiled objectively and independently.
- Although the Guidelines were mostly helpful on how to prepare dossier, they were mostly unhelpful on how to submit the dossier and the process.
- The Guidelines do not explain if and how to handle emerging evidence…This is harsh because it doesn't acknowledge the changing nature of the evidence.
- You have to study the Guidelines to understand what you need to do overall, rather than just follow from start to finish.
- The model dossier gives a yardstick measure of your own interpretation of the Guidelines. It's hard to turn words from a page into a physical entity.
- Helpful on how to do the process, but that doesn't make the process easy to do.

3. FORMAT

Strengths and weaknesses of the presentation of the Guidelines

3.1 Overall, how easy or difficult was it to navigate the Guidelines, particularly in terms of looking for and finding information you needed?

Very easy	**36%**
Mostly easy	**57%**
Mostly difficult	**7%**
Very difficult	**0%**

Overall the Guidelines format was favoured because of their brevity (supported by additional detail in the Annex), lay out and the step-by-step process for undertaking a systematic review of the evidence. However some submitters felt that the format could be improved in a number of ways, for example:

- Mention the key requirements of the JHCI Code within the Guidelines.
- Improve referencing to other sections within the document.
- Include help notes from the Annex in the main text.
- Include Annex information on 'Hierarchy of Evidence' within relevant steps of the systematic review process.
- Include more diagrams, tables, examples.
- Provide a flowchart upfront to set out the overall process at-a-glance and to help to show that the submission is a multidisciplinary approach that involves technical and marketing input.

3.2 Do you think that dossier preparation would be easier to complete, or that the requirements would be clearer, with an online form or CD-ROM template?

Easier to complete:	
Yes	**64%**
No	**36%**
Requirements clearer:	
Yes	**50%**

No **50%**

Overall there was not a consistent preference for an online form or template, or a consistent view that this would make the requirements any clearer. One participant explained that *"the Guidelines would be easier to access if online, but not necessarily easier to complete because it is the process that is burdensome, not the Guidelines"*. A number of the participants also noted that there would be no difference in their interpretation of the requirements if the Guidelines were in a template or online form compared to the current version.

Although many participants considered that broad headings would be a helpful guide for the presentation of the dossier, there was concern that a template would make the Guidelines too restrictive and prescriptive and force submitters to fill in boxes, even if they felt the data didn't fit. Some suggested that it is impossible to create a 'one size fits all' form for submitting evidence.

One submitter suggested that *"an interactive online process would be best, especially if the submitter and Secretariat or assessors could look at the work in progress online at the same time and provide feedback. This would help to reduce paperwork, cost and time"*.

3.3 What do you think are the <u>strengths</u> of the Guidelines format?

Submitters responded as follows:

- Step-by-step summary of systematic review process.
- Annex notes helpful.
- Overall layout.
- Brief body with more detail in annexes.
- Summary up front is helpful.
- Example tables (e.g search results) are helpful, but could be more.
- Format and set out helpful and neat.
- Step-by-step process self evident.
- Clearly set out.
- Checklist very helpful.
- At a glance can take in all the elements.
- Would be prescriptive if any bigger.
- Don't have to refer to other documents.
- Tells you to follow standard format, e.g how to summarise individual papers.
- Comprehensive coverage of all points.

3.4 What do you think are the <u>weaknesses</u> of the Guidelines format?

Submitters responded as follows:

- More examples of diagrams, tables, forest plot.
- Electronic version on web - perhaps could have been updated more frequently.
- Not easy to navigate.
- Not easy to find information.
- Lack of helpful references to other info/tables in the document.
- Could be improved if consumer friendly by developing glossy and attractive version.
- Put at front that claims must be substantiated by human data and that food must deliver the benefit in the right quantities.
- Lots of information - would be easier to follow by flowchart.

- Add timeline up front for idea of overall process.
- Good that brief and succinct, but that means can't cover every eventuality. Will be very difficult to manage in 25 Member States under the new legislation.

4. CONTENT

Strengths and weaknesses of the information provided in the Guidelines

4.1 Do you think any information is missing from the Guidelines?

Yes	**86%**
No	**14%**

Nearly all participants thought the Guidelines were missing some information and thought that the following should be added:

- Recommended statistical software for the creation of forest plots and/or more explicit guidance on how to prepare a forest plot.
- More references to example dossiers previously submitted to JHCI.
- 'AOB' section to include information that doesn't fit elsewhere in the dossier.
- More visuals, schematics, diagrams to illustrate the requirements.
- Tips on presenting the dossier contents concisely and effectively.
- Cross references to helpful external sources of information (e.g PASSCLAIM).
- Quality criteria for study types and evidence.
- More explanation about the 'weight of evidence' concept and guidance for the submitter to identify where their data lies.
- More guidance on how to define a 'scientific question' on which to base the systematic review of evidence.
- Further information about how to address issues relating to the food matrix.
- More information on the overall process, timescales, dates, deadlines, draft submissions etc.
- Add information on the copyright laws and how JHCI handles this.
- Guidance on how to handle publication bias.
- Guidance on using meta analyses as the basis for claim submissions.
- Further explanation on substantiating evidence vs supporting evidence.
- Guidance on the usefulness and limitations of mechanistic data.
- Guidance on how to address safety issues.
- More details regarding innovative claims and the submission of proprietary data.
- Recommended experts in the specific areas of nutrition.
- Information about claim changes during the submission process.

4.2 Do you think any sections of the Guidelines are unnecessary or redundant?

Yes	**50%**
No	**50%**

Participants responded as follows:

- Types of Evidence' (page 8 of the Guidelines) is surpassed by Annex 3, on the 'Source and Nature of Scientific Evidence', so page 8 isn't necessary.
- The requirement to summarise individual studies (page 9) is unnecessary when the full text of the paper is included anyway.
- The hand search is highly laborious with little yield, so is it really necessary? Emerging evidence is most often on the internet before published in hard copy and wide coverage can be achieved in the internet search by using broad search

terms and alternative words.

- The requirement for dose-response relationship data shouldn't be included because it is too medicinal. But a minimum effective amount is necessary [to show the amount needed in the food product to deliver or contribute to the effect]. So why request dose-response data if information on the minimum amount is provided?
- The requirement for to set the claim in the UK context and the range of foods carrying claim etc is unnecessary and irrelevant. The application needs flexible treatment.
- Some parts of the Guidelines are redundant for people who know what they are doing.

4.3 Do you think any sections of the Guidelines are too wordy or confusing in their meaning?

Yes	**71%**
No	**29%**

A number of the responses to this question were answers repeated in previous questions that relate to the clarity of the Guidelines. Additional comments included:

- Terminology used inconsistently and interchangeably. Glossary would also help.
- Confusing how the different study types should be reviewed and clustered.
- Too wordy; more visuals.
- Step-by-step process confusing, especially Step 2 (page 6 of Guidelines) on developing a scientific question and the requirement for the different Reference lists.
- Lack of detailed study quality criteria created uncertainty and confusion.
- Unsure how to handle evidence published in a foreign language.
- Guidelines confusing on how to approach different claim types, e.g. health maintenance vs nutrient function vs disease risk factor reduction.

4.4 Did you find that the Guidelines clearly explained how you should present your dossier?

Yes	**50%**
No	**50%**

The people who said 'no' suggested that the presentation requirements would be improved by:

- Viewing model dossiers.
- A template for headings and sections.
- More examples and visuals in the Guidelines.
- More guidance on where to put other information that isn't seen to fit in with the systematic review data, such as mechanistic and safety data or other information considered by the submitter to be necessary for inclusion.
- Explicit instructions not only on where to put the content, but the role of that content.
- A list of example or suggested headings from which the submitter could choose as they felt appropriate.

4.5 Do you think that the Guidelines were sufficiently detailed to cover the submission of different types of claims (e.g nutrient function; health maintenance; disease risk factor reduction (e.g. cholesterol))?

Yes	**64%**
No	**36%**

All of the 64% who said 'yes' thought that the process for reviewing and submitting the evidence should be the same, regardless of the claim type. Some noted that claim type differentiation only became an issue after the scientific basis had been agreed and that each product needed to be considered on a case-by-case basis.

The people who said 'no' commented that:

- The Guidelines didn't clarify how JHCI would handle disease risk factor reduction claims, but that this would be assisted by the inclusion of a clear definition of 'health claim' within the Guidelines, and what types of claims this covers, with examples.
- More information on recognised risk factors would be helpful.
- It would be helpful if JHCI came up with more pre-approved claims, like the 'well-established' nutrient function statements for vitamin and mineral claims.
- The Guidelines need to be updated to include how biomarkers are handled, with warnings about not implying a medical or therapeutic benefit.
- The Guidelines need more information on generic vs innovative claim submissions, as each require different levels of evidence.
- It wasn't clear from the Guidelines which type of claim best suited the evidence. Further guidance is required on the types of claims that can be submitted, and those that have the best chance of approval, although this could end up overly restrictive.
- It would be helpful to have more guidance on how JHCI interprets claims. There could be an agreement up front between the submitter and assessment body on the claim to be considered.

4.6 Do you think that Guidance should be separated into sections relating to claims based on varying strengths of evidence (e.g. 'unlikely'; 'possible'; 'probable'; 'convincing')?

Yes	**43%**
No	**57%**

Participants were divided reasonably equally in response to the 'strengths of evidence' question. Those who said 'yes' suggested that:

- The systematic review is a common process, but a flowchart in Section 2 (regarding the application of the claim to the product) would help refine the claim. It would be helpful to know how to handle once evidence considered, for example, how to handle mostly epidemiology; mostly RCT's or a combination of both.
- Examples of claims previously considered would help explain this is how the strength/type of evidence is handled and what is considered 'unlikely', 'possible' etc
- It would be helpful to include criteria behind categories such as 'convincing' or 'probable' but only if the guidance reflects what evidence is acceptable by the assessors. However categorising based on grades of evidence could seem too high a standard for SMEs to achieve so might prevent submissions.
- It would provide the applicant with an early idea of the chance of success because you can judge against the strength of evidence and knowledge of how many studies you need. It would help with confidence levels.
- It would help you to plan and decide which claims to go for, together with discussions with the Secretariat.
- We don't want to go down the route of the USA qualified claims, which is too restrictive and prescribed. The JHCI broader approach encourages innovation. A compromise could be, "as a guide, this type of evidence is needed for this type of

claim…"

Of the 57% who said 'no' some felt that the guidance would become *"too restrictive and prescriptive"* or *"not reflect the complexities of science"*. One person noted that *"it would create more uncertainty for submitters who had to decide where the evidence fits"*, but another thought that *"it would be useful to include an 'emerging evidence' chart to see where the evidence is likely to fit"*. Others commented that it was *"the role of the Expert Committee to assess the evidence strength and advise submitter"*, and that, *"to protect consumers, claims should be approved only when substantiated by convincing evidence"* and that *"the guiding principle should be that submitters look only for highest level of evidence to substantiate claims"*.

4.7 What do you think are the <u>strengths</u> of the Guidelines content?

Responses included:

- A clear, concise step-by-step process for systematic review.
- The suggested sections are helpful.
- Good plain English generally used.
- Clear to understand - misinterpretation of instructions happened only in a couple of places.
- The required information is all there, but needs to be rephrased and represented in more user-friendly way.
- A very 'hands on' document and easily understood.
- Helps you to boil down the evidence.
- The checklists and format systematically sets out the requirements for consistency of presentation and how to ensure that you have completed the review of the totality of available data.
- The checklists are very good.
- Concise and complete. Does a good job of guiding the submitter.

4.8 What do you think are the <u>weaknesses</u> of the Guidelines content?

Responses included:

- Lack of pictorial examples to enhance understanding of the requirements.
- The quantity and quality of studies required to substantiate the claim is not covered sufficiently. Need better clarity regarding the hierarchy of evidence. The table on page 8 needs to be improved and clarified to include proprietary data.
- Lack of a glossary for technical terminology and definitions.
- The scientific approach requires better explanation.
- Lack of definitions. For example there are references to a 'high standard of evidence', but this is not clearly defined.
- Need to focus more on diet-health relationships and less on the specific marketing of the claim. The requirements are too demanding if you haven't formulated information at the time of submission.
- Need to put more emphasis on statistical outcome of the forest plot within the overall decision.
- Lacking guidance on the proposed wording and likely consumer acceptance.
- The table on page 8 is unclear; it seems to wrongly assume that RCTs provide most of what you need to substantiate claims and misses the point that evidence is less precise.
- The requirement to filter gives an end result that implies there is only certain evidence in existence and prevents adequate consideration of inter-related

evidence.

- Needs more of a stepwise approach to presentation and format.
- Too burdensome, especially the requirement for a forest plot. Could suggest alternative options in case the evidence doesn't fit this type of pictorial analysis.
- Lack of prescriptiveness is a strength, but that means it's hard for the submitter to gauge the likelihood of success. Can't have a 'one size fits all' document.
- The Guidelines are too detailed for people who don't know about science.
- The Guidelines need a warning along the lines of "you need to read this document at least twice!"

5. GENERAL QUESTIONS

5.1 Could you please explain any reasons that you are aware of, relating to the Guidelines, which have prevented submissions of dossiers to JHCI (by you or another submitter)?

Responses included:

- Lack of clarity about how JHCI handles the different types of claims, especially disease risk factor reduction claims, so uncertain about the outcome.
- Some companies are already confident that they have enough evidence and that they are meeting the legal requirement for due diligence.
- Requirements are too onerous and too expensive to complete the process. The temptation is to make softer claims and see if they can get away with it, especially when companies see that the cowboys can get away without a dossier.
- The perception in the vast majority is that the system and process is overwhelmingly demanding and time consuming.
- The step-by-step approach could be daunting, but the process is going to be arduous anyway so not really to do with the Guidelines. But can assume that companies weigh up the costs and chance of success and the work involved.
- There is confusion about what JHCI will accept and approve or not.
- If it is a function claim only and they're not attaching a benefit then they are not likely to submit.
- Some companies have expressed that JHCI is voluntary so the outcomes have no regulatory teeth.
- An online interactive process would help make the Guidelines more user-friendly.

5.2 How did the Guidelines help you to understand the submission process?

Nearly half of the respondents felt that the Guidelines required more detail about the process, including a likely timeline of the overall process; dates and deadlines; JHCI response turnaround times; and more clarity about what is expected for the draft submission to the Secretariat. In addition, participants commented that:

- Most advice regarding the process was received verbally from the Secretariat but this should be included in the Guidelines.
- Consultants are likely to be used more and more in the preparation of dossiers.
- The steps in the process helped.
- Table 8 helped.
- The Guidelines were very clear and good because they highlighted up front how complex the substantiation process is. They make you consider the complete picture and focus the mind on who and what to involve, constraints, time and costs. This is vital knowledge for the industry.

5.3 Do you have any comments in relation to the Guidelines impact on either SMEs or multinational companies?

- Collaboration is important for SMEs, especially for a generic claim, because there will be a mutual benefit to everyone anyway, so no one company wants to foot the bill. But there are trade-offs within a collaboration.
- Pre-approved lists of claims are very helpful for SMEs.
- Both SMEs and multinationals consider the requirements to be too onerous.
- Cost and lack of in-house resource makes it prohibitive to most SMEs, even if they do decide to go ahead with it the uncertainty about the outcome may stop people submitting. Therefore some of them try to do as little as they can get away with.
- The Guidelines are very daunting and technical for SMEs. Without technical expertise in-house many get caught out by the complexity of the process. Multinationals are better placed to have the funds to consult with experts.
- Overly burdensome for SMEs – they don't have sufficient time or money.
- The benefits of doing a submission could be clarified in the Guidelines to help encourage submitters.
- The standard of evidence seems too high for SMEs to achieve so prevents submissions.
- It depends on the company policy on innovation and research. There is a political argument because SMEs are quicker to research but they lack the funds. If they are really innovative then they can access research funds.

5.4 Do you have any comments on confidentiality issues in relation to the Guidelines?

Participants were happy with the JHCI policy on confidentiality, but felt that this needed to be added to the Guidelines, especially in relation to how all outcomes are handled regardless of whether they are approved or rejected; generic or proprietary data. One person suggested that "*the Guidelines should clarify the benefits of making the submission public rather than keeping it quiet*". Another respondent felt that "*the authorities mainly accept published data because those studies have gone through a peer review process. The Guidelines could explain that it is only the compilation and evaluation and the resulting claim that is confidential"*.

5.5 Do you have any other comments on the strengths or weakness of the Guidelines, or recommendations for improvement, which are not covered elsewhere?

Responses included:

- The Guidelines could recommend that there is an executive summary at front of dossier, given that it is written last so in a good position to identify all the salient points.
- The Guidelines have stood the test of time.
- It would be helpful to have more information about the factors influencing the Expert Committee's opinion.
- There is a lack of clarity about what happens when the dossier is being considered by the Expert Committee.
- The process set out in the Guidelines didn't favour our case because the dossier made the evidence appear very limited when it's actually very broad. So Guidelines can't be too narrow.
- Only one proposed claim should be submitted. The Guidelines invite the submitter to present a list of alternative claims that they might wish to make if the lead claim is rejected. We thought the alternatives would help our case, but all were rejected and the most extreme ones were highlighted in the feedback.
- No real way of assessing how much work and cost involved in preparation of

dossier and submission. Always will be an element of gambling and can't legislate for that unknown quantity. Would be ideal to be able to prepare a planning proposal based on the Guidelines, but that would be extremely difficult. Would be helpful to do skeleton submission initially.

- The Guidelines really make you look at the totality of evidence, everything, and doesn't let you just cherry pick the 'ripe' data.
- Need to keep confidence up to encourage the industry to invest in research. The Guidelines shouldn't be limited to well-established claims only as this will not encourage research in emerging areas.
- More information on the wording of claims is required.
- Don't want to go down USA route of qualified claims. JHCI's broader approach is better, as long as good evidence provided. A compromise could be, "as a guide, this type of evidence is needed…" Risk is that puts off submitters and stifles innovation if the system seems too restrictive and prescribed. The JHCI approach encourages innovation.
- The Guidelines need to be updated to reflect new EU rules especially in relation to disease risk reduction claims, but to clarify that medicinal claims will still be prohibited.
- Makes you realise up front work required and decide to proceed or not, as well as actually guiding you through the process. Therefore it has a dual purpose.
- It's an expensive process to follow, especially with copying papers etc, but worthwhile doing because it allows the company to recoup the research investments already made by company

5.6 Based on your experience of preparing a dossier of evidence, what advice could you offer the European Authorities on the development of EU-wide Guidelines for the preparation of dossiers for consideration?

Responses included:

- Clarify the types of claims that can be approved and how they will be handled. Provide guidance on the range of claims that will be accepted.
- More information on recognised risk factors and nutrient functions would be helpful and it would be helpful to know which of these are likely to be accepted by the authorities.
- A clearly defined short format for both the Guidelines and dossiers.
- Lots of examples and schematics are most important to make Guidelines user-friendly.
- Feedback and dialogue will be necessary; the earlier in process the better. For example the Novel Foods Secretariat provides feedback throughout. Offer the opportunity for dialogue in the first stage of the submission otherwise it's very difficult. No dialogue at all will mean only small group of consultants will become experts in dossier submissions. Devolve to Member States if need be to enable dialogue to occur – there must be model dossiers and Secretariat advice to support the Guidelines.
- Include key minimum requirements for substantiation and study criteria and the process must be explained clearly.
- Make the Guidelines less restrictive in terms of the kind of evidence that will be considered acceptable.
- Keep the Guidelines short, simple and broad – there is the risk of being too restrictive and prescriptive.
- Provide as much guidance as possible on the consumer perceptions of claims.
- Amalgamate the JHCI Guidelines with PASSCLAIM and relate Articles in the law to the relevant sections of the Guidelines.
- The European Authorities should listen to the Member State advice and recommendations on the preparation of Guidance.
- Will need model dossiers, in different languages to ensure consistent interpretation

of guidelines in 25 different Member States.

- Have Secretariat to flesh out bare bones of brief guidelines. No substitute for a person to explain but must be professional and helpful. Would depend on the person in the role.
- Downside will be rejected dossiers vs lack of inspiration to submit.
- Start with JHCI as gold standard and work backwards. Doesn't address emerging products.
- Look at the JHCI system vs Swedish system. JHCI requirement for meta-analysis very onerous. The Swedish system doesn't ask for this. Is there some other way of doing e.g. a forest plot if you've shown a transparent approach and followed steps and presented summaries of evidence?
- Need to explain the validity of a meta-analysis on small studies after the exclusion and inclusion criteria.
- Don't be too prescriptive but have consistency and flexibility to help innovation. Small companies can be faster and easier to innovate.
- How will claims be approved and policed? Very important that there is consistency in approval between the Member States.
- Guidelines need to be self-explanatory and fairly simple.
- Need a publicity campaign and education on how the Guidelines can be approached and how to work with them. PR will be critical. Need concerted education for food companies first, and consumers second. Writing the legislation and guidelines is just the beginning. EU will not reap the benefits of the legislation if it is not well publicised and will not achieve its potential and purpose. Have regular forums between the Authority and the industry with invited sessions during the development process. Then have a roadshow outlining the new rules.
- Have to ensure that the expert panel agrees with the different grades of evidence, then design guidelines around the criteria.
- Get clear advice on how the scientific substantiation should look.
- Define generally accepted scientific data.
- Clarify the debate on food matrix vs general ingredient.
- Quantification issue requires clarity.
- Regulation is so general it lacks any clarity about substantiation so guidelines will be essential.
- Use the JHCI Guidelines as a baseline and add amendments.
- Don't reinvent the wheel.

ANNEX 2b

ALL COMMENTS RATED AS STRENGTHS OR WEAKNESSES

Findings based on comments in relation to the questionnaire from all participants (Submitters; Secretariat and Expert Committee) rated as strengths or weaknesses.

OVERVIEW ANALYSIS

1. Total responses

The total number of comments from all participants (Submitters; Secretariat and Expert Committee) after they had been summarised and categorised, was 664. Of these 388 were rated as weaknesses and 184 as strengths of the Guidelines. A further 92 comments were not rated as a strength or weakness of the Guidelines and therefore not included in the tables below:- 56 were about the future EU context and 36 were about the overall JHCI process.

2. 'Strength' and 'weakness' frequency by question categories

Table 1 shows that the 184 comments about the strengths of the Guidelines were relatively evenly spread between 'content'; 'format' 'effectiveness' and 'efficiency' (26%, 25%, 21%, and 14% respectively). Over a third of all the 388 comments about weaknesses were in relation to the Guidelines 'content' (39%).

TABLE 1: 'Strength' and 'Weakness' frequency by Question Category

Question Category	Strength n=184	Weakness n= 388
Effectiveness	21%	13%
Efficiency	14%	09%
Format	25%	15%
Content	26%	39%
General	12%	22%

3. Overview of 'strength' and 'weakness' by question subjects

Table 2 simplifies the participants' answers to the questionnaire and rates them as a strength or weakness, whereas Table 3 focuses on the detailed comments.

Overall, this broad analysis shows that the two strongest points of the Guidelines were that they helped submitters to prepare a dossier as required by JHCI and the overall format of the Guidelines. The three main weaknesses were that the Guidelines were missing some information or explanations; that the requirements were unclear; and that they did not take into account the cost, resource and expertise issues faced by SME's. This last point raises issues beyond the Guidelines, however, guidance could include references to helpful resources and advice. Overall Table 2 shows that every question answered included some mention of a weakness, suggesting that every aspect of the Guidelines requires some degree of improvement.

TABLE 2: 'Strength' and 'Weakness' frequency by Question Category & Subject

Question Category	Question Number	Question Subject	Strength n=175	Weakness n= 350
Effectiveness	1.1	Guidelines purpose	n/a	n/a
Effectiveness	1.2	Meet purpose	11%	03%
Effectiveness	1.3	Requirements clear	02%	08%
Effectiveness	1.4	Confident met requirements	07%	02%
Efficiency	2.1	Easy/difficult to meet req's	09%	05%
Efficiency	2.2	Helpful in meeting requirements	05%	03%
Format	3.1	Navigation	06%	05%
Format	3.2a	Template	03%	04%
Format	3.2b	Online	03%	02%
Format	3.3	Strengths	12%	<01%[1]
Format	3.4	Weaknesses	01%[2]	04%
Content	4.1	Missing	<01%	11%
Content	4.2	Unnecessary	<01%	03%
Content	4.3	Too wordy or confusing	01%[3]	04%
Content	4.4	Presentation	02%	03%
Content	4.5	Types of claims	03%	04%
Content	4.6	Grades of evidence	08%	03%
Content	4.7	Content strengths	09%	<01%[4]
Content	4.8	Content weaknesses	00%	07%
General	5.1	Prevented submissions	00%	05%
General	5.2	Understand process	04%	03%
General	5.3	SME's vs multinationals	00%	08%
General	5.4	Confidentiality	02%	02%
General	5.5	Other general comments	05%	05%
General	5.6	EU context	n/a	n/a

[1] number that reported "no strengths" in relation to Guidelines format, thus recorded as a weakness
[2] number that reported "no weakness" in relation to Guidelines format, thus recorded as a strength
[3] number that reported that the Guidelines were not too wordy or confusing, thus recorded as a strength
[4] number that reported "no strengths" in relation to Guidelines content, thus recorded as a weakness

DETAILED ANALYSIS

4. Range and frequency of strengths and weaknesses reported

4.1 Points to note about Table 3 (below)

The purpose of undertaking this detailed analysis of comments was to spot any trends or relationships between the strengths and weaknesses reported. It was also to help distinguish between positive and negative attributes of the Guidelines versus those of the process, which was not the subject of this evaluation.

Therefore, this analysis helped to highlight:

- any key strengths or weaknesses and priority areas for consideration (indicated by clear leaders at the top of the table);
- the overall satisfaction with the Guidelines and whether general improvement is required (indicated by a large number of comments all with lower frequency of reporting); and

- any inconsistencies between the participants in their reporting of strengths/weaknesses (to indicate subjectivity and the degree of allowable interpretation promoted by the Guidelines by lack of definition).

Table 3 provides a detailed breakdown of responses by all participants (Groups A, B and C) rated as a strength or weakness, and how often that response was received (shown as a percentage to give an indication of the strengths and weakness reported most often). Cases where at least one strength or weakness was not recorded are shown with '-'.

The strengths and weaknesses have been listed individually, apart from the following three groups, which provide both a subgroup total, highlighted with grey panel, and an individual total (to reflect the detail of the comments):

- *'Annex'*
- *'Explanations'*
- *'No to grades of evidence'*
- *'Requirements'*

4.2 Key findings from Table 3 (below)

Table 3 provides not only a list of results, but also a list of areas for improvement to the JHCI Guidelines. Table 3 also shows that:

a. There are no obvious strengths or weaknesses that clearly stand out from the rest of the list, which would highlight any dominant areas for priority attention (particularly weaknesses).

b. The broad range of responses, all with lower rates of frequency, suggest that, rather than highlighting any dominant areas for priority attention, numerous areas and the finer details of the Guidelines require attention and improvement. However, it is possible to identify, albeit with small differences, the higher rating strengths and weaknesses.

c. The top rating strength, *'overall preparation guidance'* (15% of all responses rated 'strength') is relatively non-specific. Similarly the top rating weakness, *'explanations'* (25% of weaknesses), and the next item, *'requirements'* (07% of weaknesses) are subheadings for more specific comments further down the list. Therefore the most frequently mentioned <u>specific</u> strengths and weaknesses in the list provide the greatest indication to where development and improvements on the current Guidelines would be required.

d. There are inconsistencies in the participants' responses as to whether aspects of the Guidelines were regarded as a strength or weakness (for example, responses about the *'requirements'* of the Guidelines were the second most frequently reported strength AND the second most frequently reported weakness. Similarly, some participants found that *'no template'* was a strength, whilst others thought it was a weakness).

e. *'Explanation – Types of claims'* was one of the more commonly mentioned weaknesses (5%). Actual responses from participants included requests for better explanations on:

- The difference between generic vs innovative claims and how to submit each
- Different types of claims and those included in, or covered by, the Guidelines
- How the JHCI categorises and handles different types of claims
- The legal acceptability and legal boundaries of different types of claims

f. *'Statistical help'* was also mentioned several times (3% of all weaknesses) and detailed responses highlighted that participants considered that further guidance was required in the following areas:

- How to prepare a meta-analysis/forest plot/ odds ratio
- How to undertake baseline comparisons
- Other alternatives if the data is inappropriate for a forest plot
- Recommendations for statistical software
- Recommendations for statisticians
- How and when to report statistical differences
- How to use meta analyses as a base for a submission

g. Both *'Explanation: Claim wording / development / context'* and *'Explanation: Totality of Evidence'* were reasonably frequently noted as weaknesses (2% each). These broad responses were made up of the following detailed responses, which requested better a better explanation of:

'Claim wording / development / context':

- How to develop a specific, defined and measurable health claim on the base of evidence available. For example claims that are based on epidemiological studies that show associations only, or claims that are based on intervention trials that demonstrate cause and effect. Include acceptable phraseologies and examples of actual claims approved.

- How to avoid developing an ill-defined and meaningless claim that is open to interpretation by consumers and too vague to measure actual effects and thus substantiate.

- How claims can be developed and tweaked during the submission process.

- The differences in, and examples of, acceptable phraseologies for different types of claims, such as, nutrient function; health maintenance; enhanced function; disease risk factor (biomarker) reduction; and disease risk reduction (currently prohibited but likely to be permitted under the new Regulation[1].)

- The differences in, and examples of, direct; indirect; implied; generic and product specific health claims.

- The different approaches to making health claims, e.g. one step claim or two-step claims (refer to Swedish Food Sector's Code of Practice[7], page 8, for examples).

- Further information on the factors affecting consumer perception and suggest model wordings.

- Provide a non-exhaustive list of model wordings most likely to be acceptable to help submitters choose or develop their own.

- Highlight the importance and relevance of the wording, context and overall application of the health claim.

'Totality of Evidence':

- The concepts and meaning of 'totality of evidence', 'weight of evidence', 'emerging evidence' and 'evolution of science'
- How to inter-relate the different types of evidence within one submission to represent the totality of evidence
- What is likely to be acceptable within the totality of evidence
- How to understand the weight of evidence and present appropriately
- Provide more information on the weight of evidence, emerging evidence, totality of evidence
- Show how different types of evidence work together
- Clarify that 'totality of evidence' does not mean 'submit all available evidence'

h. The fact that the Guidelines do not follow a *'grades of evidence'* approach rated 8% of all strengths reported. Reasons for this were largely attributable to the opinion that the submission *process should be universal* for all grades of evidence and that such detail would be *too restrictive*, involve too much *subjectivity* and negate the role of the Expert Committee by *pre-judging the evidence*. The proportion of weaknesses reported in relation to *'grades of evidence'* was significantly lower at <1%.

i. *'Experience dependent'* rated as 3% of all strengths and 3% of all weaknesses. This was aspect was regarded by participants to be a double edged sword because although the Guidelines had not been seen as sufficient to help them through their first submission (weakness), participants felt that they were very likely to help them (strength), in combination with their experience, in future submissions.

j. Some of the higher rating strengths were positive attributes about the format of the Guidelines, suggesting that these attributes should remain in any revision or new development:

- Step by step systematic review
- No strict template
- No external cross references
- Annex – checklist
- Annex – help notes
- User friendly

k. Another frequently recorded strength, akin to *'step by step systematic review'*, was *'filtering process'* (2% of all strengths) which, based on participant comments, helped submitters to boil down often-innumerable studies to the totality of evidence relevant to the claim.

l. Overall the frequency and range of strengths and weaknesses show that numerous changes and improvements can be made to the Guidelines. However the degree of inconsistency in these views must also be taken into account as they demonstrate that one size doesn't fit all.

TABLE 3: The range of Strengths and Weaknesses reported and their frequency

RANGE OF STRENGTHS REPORTED	Strength Frequency n=184 (%)	RANGE OF WEAKNESSES REPORTED	Weakness Frequency n=388 (%)
Overall preparation guidance	15%	'Explanations' Subgroup total (see detail below)	25%
Clear requirements	09%	'Requirements' Subgroup total (see detail below)	07%
'No to grades of evidence' Subgroup total (see detail below)	08%	Explanation: Types of claims	05%
Step by step systematic review	07%	No to template	05%
'Annex' Subgroup total (see detail below)	05%	Clear requirements	04%
No to template	05%	Examples, diagrams, tables	03%
Secretariat dialogue	05%	Experience dependent	03%
Visual example of model dossiers	05%	Expertise/resources	03%
Concise and clear	04%	Overall submission guidance	03%
Annex – checklist	03%	Requirements: Study criteria - quality and quantity	03%
Experience dependent	03%	Statistical help	03%
Flexible / open to interpretation	03%	Voluntary guidance	03%
No external cross references	03%	Explanation: Claim wording / development / context	02%
Confidentiality policy and procedure	02%	Explanation: Totality of evidence	02%
Filtering process	02%	Flowcharts	02%
'Requirements' Subgroup total (see detail below)	02%	Inclusion and exclusion criteria – need help	02%
User friendly	02%	Overburdensome	02%
Annex – detailed	01%	Presentation advice	02%
Annex – help notes	01%	Terminology	02%
Comprehensive	01%	Too restrictive	02%
Cost vs success	01%	Annex Subgroup total	01%
Links to/augments JHCI Code	01%	Daunting	01%
No to grades of evidence - but more help in claim refinement	01%	Definitions	01%
No to grades of evidence - substantiation process universal	01%	Explanation: Collaboration	01%
No to grades of evidence - too restrictive	01%	Explanation: How to handle emerging data	01%

RANGE OF STRENGTHS REPORTED	Strength Frequency n=184 (%)	RANGE OF WEAKNESSES REPORTED	Weakness Frequency n=388 (%)
No to interactive online	01%	Explanation: JHCI policy & process on confidentiality and outcomes	01%
Overall preparation process	01%	Explanation: Supporting / mechanistic / safety data	01%
Overall submission guidance	01%	No to interactive online	01%
Overview section	01%	Overall preparation guidance	01%
Requirements shown upfront	01%	Overall preparation process	01%
Section 2, supplementary information guidance	01%	Step by step systematic review	01%
Standardised format	01%	Table 1 page 8 (Types of Evidence)	01%
Terminology	01%	Timelines/deadlines	01%
Annex – hierarchy of evidence	<01%	User friendly	01%
Assists in planning and preparation	<01%	Yes to grades of evidence – need to clarify grades criteria	01%
Diet and health relationship explained	<01%	'No to grades of evidence' Subgroup total (see detail below)	<1%
Easily understood	<01%	Add appeals process	<01%
Examples, diagrams, tables	<01%	Add model letter of engagement	<01%
General Requirements	<01%	Add publication of information policy	<01%
No to grades of evidence - always aim for highest	<01%	Annex – checklist	<01%
No to grades of evidence - but give examples of convincing claims	<01%	Annex – help notes	<01%
No to grades of evidence - but more help planning	<01%	Annex – hierarchy of evidence	<01%
No to grades of evidence - convincing claims only	<01%	Benefits unclear	<01%
No to grades of evidence - emerging evidence chart	<01%	Concise and clear	<01%
No to grades of evidence - Ex Com role to decide	<01%	Explanation: Acceptability of pre-approved claims eg. US FDA	<01%
No to grades of evidence - prejudging evidence	<01%	Explanation: acceptable risk factors	<01%
No to grades of evidence - too subjective	<01%	Explanation: Comparing data and what's acceptable	<01%
No to grades of evidence	<01%	Explanation: Confidentiality policy	<01%
Open and transparent	<01%	Explanation: Consumer perception	<01%
Presentation advice	<01%	Explanation: Copyright laws and procedure	<01%
Requirements: Define claim upfront	<01%	Explanation: Different areas of science with same food component	<01%
Table 1 page 8 (Types of Evidence)	<01%	Explanation: Don't try to dress up a 'no-goer'	<01%

RANGE OF STRENGTHS REPORTED	Strength Frequency n=184 (%)	RANGE OF WEAKNESSES REPORTED	Weakness Frequency n=388 (%)
Types of claim suited Guidelines	<01%	Explanation: Ex Com decision influences and process	<01%
Add appeals process	-	Explanation: Food matrix	<01%
Add model letter of engagement	-	Explanation: Foreign language studies	<01%
Add publication of information policy	-	Explanation: Funding sources	<01%
Benefits unclear	-	Explanation: Grades of Evidence	<01%
Daunting	-	Explanation: How to handle AOB, where to put	<01%
Definitions	-	Explanation: How you know that you have met requirements	<01%
Expertise/resources	-	Explanation: Meta analyses	<01%
Explanation: Acceptability of pre-approved claims eg. US FDA	-	Explanation: More Well Established Nutrient Function Statements	<01%
Explanation: acceptable risk factors	-	Explanation: Decision tree	<01%
Explanation: Claim wording / development / context	-	Explanation: Proprietary data	<01%
Explanation: Collaboration	-	Explanation: Publication bias	<01%
Explanation: Comparing data and what's acceptable	-	Explanation: Purpose of content	<01%
Explanation: Confidentiality policy	-	Explanation: Recommendations for statistical software	<01%
Explanation: Consumer perception	-	Explanation: Requirements for 'background info'	<01%
Explanation: Copyright	-	Explanation: Scientific question	<01%
Explanation: Different areas of science with same food component	-	Explanation: Substantiation process - how and why	<01%
Explanation: Don't try to dress up a no-goer	-	Explanation: Synopses	<01%
Explanation: Ex Com decisions and process	-	Explanation: Universal process	<01%
Explanation: Food matrix	-	Flexible / open to interpretation	<01%
Explanation: Foreign language studies	-	Glossary	<01%
Explanation: Funding sources	-	Internal references	<01%
Explanation: Grades of Evidence	-	Links to/augments JHCI Code	<01%
Explanation: How to handle AOB, where to put	-	No external cross references	<01%
Explanation: How to handle emerging data	-	No to grades of evidence - but more help in claim refinement	<01%
Explanation: How you know that you have met requirements	-	Overall submission process	<01%
Explanation: JHCI policy & process on confidentiality and outcomes	-	Planning and preparation	<01%

RANGE OF STRENGTHS REPORTED	Strength Frequency n=184 (%)	RANGE OF WEAKNESSES REPORTED	Weakness Frequency n=388 (%)
Explanation: Meta analyses	-	Recommended experts	<01%
Explanation: More Well Established Nutrient Function Statements	-	Reformat with chapters	<01%
Explanation: Decision tree	-	Rename ‘Guidelines’ to ‘Requirements’	<01%
Explanation: Proprietary data	-	Requirements: Consumer research	<01%
Explanation: Publication bias	-	Requirements: Content instructions	<01%
Explanation: Purpose of content	-	Requirements: Country and language issues	<01%
Explanation: Recommendations for statistical software	-	Requirements: Decision tree for inclusion/exclusion criteria codes	<01%
Explanation: Requirements for 'background info'	-	Requirements: Define claim upfront	<01%
Explanation: Scientific question	-	Requirements: Dose response info	<01%
Explanation: Substantiation process - how and why	-	Requirements: Explain non-negotiable areas	<01%
Explanation: Supporting / mechanistic / safety data	-	Requirements: Hand search	<01%
Explanation: Synopses	-	Requirements: More step by step instructions	<01%
Explanation: Totality of evidence	-	Requirements: Need more detail	<01%
Explanation: Types of claims	-	Requirements: Need to be clear on amount of info expected	<01%
Explanation: Universal process	-	Requirements: Prerequisites need to be upfront	<01%
‘Explanations’ Subgroup total	-	Requirements: Representative subjects	<01%
Flowcharts	-	Requirements: Requirements need more detail	<01%
Glossary	-	Requirements: Scientific question	<01%
Inclusion and exclusion criteria – need help	-	Secretariat dialogue	<01%
Internal references	-	Section 2, supplementary information guidance	<01%
Needs warnings	-	Staff dependent	<01%
Overall submission process	-	Too detailed	<01%
Overburdensome	-	Yes to grades of evidence – helps with planning	<01%
Planning and preparation	-	Yes to grades of evidence – need examples of each grade	<01%
Recommended experts	-	Needs warnings	<01%
Reformat with chapters	-	Annex – detailed	-
Rename ‘Guidelines’ to ‘Requirements’	-	Assists in planning and preparation	-

RANGE OF STRENGTHS REPORTED	Strength Frequency n=184 (%)	RANGE OF WEAKNESSES REPORTED	Weakness Frequency n=388 (%)
Requirements: Consumer research	-	Comprehensive	-
Requirements: Content instructions	-	Confidentiality policy and procedure	-
Requirements: Country and language issues	-	Cost vs success	-
Requirements: Decision tree for inclusion/exclusion criteria codes	-	Diet and health relationship explained	-
Requirements: Dose response info	-	Easily understood	-
Requirements: Explain non-negotiable areas	-	Filtering process	-
Requirements: Hand search	-	General Requirements	-
Requirements: More step by step instructions	-	No to grades of evidence - always aim for highest	-
Requirements: Need more detail	-	No to grades of evidence - but give examples of convincing claims	-
Requirements: Need to be clear on amount of info expected	-	No to grades of evidence - but more help planning	-
Requirements: Prerequisites need to be upfront	-	No to grades of evidence - convincing claims only	-
Requirements: Representative subjects	-	No to grades of evidence - emerging evidence chart	-
Requirements: Requirements need more detail	-	No to grades of evidence - Ex Com role to decide	-
Requirements: Scientific question	-	No to grades of evidence - prejudging evidence	-
Requirements: Study criteria - quality and quantity	-	No to grades of evidence - substantiation process universal	-
Staff dependent	-	No to grades of evidence - too restrictive	-
Statistical help	-	No to grades of evidence - too subjective	-
Timelines/deadlines	-	No to grades of evidence	-
Too detailed	-	Open and transparent	-
Voluntary guidance	-	Overview section	-
Yes to grades of evidence – helps with planning	-	Standardised format	-
Yes to grades of evidence – need examples of each grade	-	Types of claim suited Guidelines	-
Yes to grades of evidence – need to clarify grades criteria	-	Visual example of model dossiers	-
Too restrictive	-	Requirements shown upfront	-