Food Safety
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Identifying Appropriate Peer Reviewed Scientific Publications

Identifying appropriate peer reviewed scientific publications

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Contents

List of Tables

List of Figures

Abbreviations

CAT	critical appraisal tools
EFSA	European Food Safety Authority
ELS	extensive literature searches
FSAI	Food Safety Authority of Ireland
GM	genetically modified
IF	Impact Factor
JCR	Journal Citation Report
RCT	randomised controlled trial
SR	systematic review

Background

The Food Safety Authority of Ireland (FSAI) is a statutory, independent and science-based organisation. The FSAI's vision is "safe and trustworthy food for everyone". The FSAI aims to achieve this vision by 'protecting consumers and raising compliance through partnership, science and food law enforcement'. To accomplish this, the FSAI developed their *Science Strategy 2020-2024*. This guidance document has been developed in line with strategic objective 4.3, in the *FSAI Science Strategy 2020-2024:*

> "Explore and exploit opportunities to actively communicate FSAI science to stakeholders in a tailored approach".

The purpose of Regulation (EC) 178/2002 on the general principles of food law is to provide 'the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety'. Regulation (EC) 178/2002 also defines risk assessment as 'a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation'.

These references to the legislation highlight the importance of being able to critically review scientific literature in order to use an evidence-based approach for risk-centred decisions, providing technical expertise and assessing products developed for all consumers including vulnerable groups.

Purpose

To provide food business operators (FBOs) and/or scientific experts advising FBOs with a systematic and effective method of appraising the quality of peer reviewed scientific publications. This will enable the determination of appropriate science on which to base risk assessment and establish the appropriateness of claims on food.

Scope

The scope of this document is restricted to peer-reviewed scientific publications.

How to use this document

This guidance document is divided into the following sections:

- Section 1: The scientific publication process
- Section 2: Key elements of a peer reviewed scientific publication (title page, abstract, introduction, methods, results, discussion/conclusion and references)
- Section 3: Tools for appraising peer reviewed scientific publications

It should be acknowledged that this document is merely a guide, and FBOs and/or scientific experts advising FBOs should use their own discretion and experience in reviewing scientific articles relevant to their area of expertise.

Section 1: Scientific publication process

This section gives an overview of how a scientific paper comes to be published. It also explains some key terminology in this area.

Peer review process

When a scientific paper is submitted to a scientific journal for publication[1], it usually undergoes an initial screening process by the journal editor and if successful, continues through the peer review process (Lovejoy, Revenson and France, 2011). The peer review process involves 'evaluating research findings for competence, significance and originality by qualified experts in the same field' (Manchikanti *et al.*, 2015). Peer review establishes whether the scientific paper is suitable for publication in the journal and, if deemed suitable, the improvements/changes that should be made to the paper. For further information on the peer review process, please refer to the following publications (Lovejoy, Revenson and France, 2011; Newton, 2010; Twaij, Oussedik and Hoffmeyer, 2014).

In recent times, there has been increased popularity in publishing preprints which is a version of a scientific paper available before it has undergone peer review (Peiperl, 2018). However, while the publication of preprints can accelerate scientific developments, they are not on their own, a sufficient basis for risk assessment or claim substantiation (Glasziou, Sanders and Hoffmann, 2020).

Traditionally published journals versus open access

The traditional publishing process involves free submission, peer-review and publication in a journal (Cuschieri, 2018). The reader is only granted access to the article through a subscription fee to the journal, which are largely paid for by universities or institutional libraries. In contrast to this, open access (OA) is where the author pays for the publication of their article and therefore, the published research paper is freely available to the reader (Bjork, 2017). Many traditional journals now offer hybrid models where the author can opt to publish for free but with licence restrictions or pay a fee for immediate open access. Initially, the OA model was met with criticism

[1] A 'publication' is a piece of writing which has been published and could refer to a research paper, a conference proceedings paper, an article, a book, leaflet or report. A 'research paper' is the output of research and could be published or not. If it is published in a scientific journal, then it is a published research paper, or a publication. It is always a good idea to ask the question 'has the research been published' as this will lend support to the robustness and quality of the research conducted. If published, it is important to note where the research has been published i.e. is it a recognised scientific journal with a track record of publishing related articles and a rigorous and transparent peer review process.

due to doubts over the peer review process, such journals not being indexed[2] and the lack of scientific prestige (Cuschieri, 2018). Nowadays, several well recognised publishers, such as PLOS ONE and BioMed Central, have adopted this method of publishing which has led to the indexing of journals and improved the reputation of OA.

Impact factor of the journal

The impact factor (IF) of a journal is a measure reflecting the annual average number of citations[3] to recent articles published in that journal. The IF varies yearly and, in a given year, it is calculated by counting the number of citations that year to articles published in the previous two years and dividing that by the total number of articles published in the journal in those two previous years. (Greenwood, 2007).

For example, 2019 IF would be calculated as:$= \frac{\text{Citations in 2019 to articles published in 2018 and 2017}}{\text{Total number of articles published in 2018 and 2017}}$

The higher the IF, the more highly ranked the journal. The IF is a tool used to compare journals within their field/subject category. It is important to understand what is considered a high impact factor within the specialist area that the paper is published. Journals such as 'Nature' and 'Cell', have current IF's of 43.070 and 36.216 (Clarivate Analytics, 2019). In the area of nutrition and dietetics, a high IF would be considered around 6 (as per Journal Citation Report (JCR) 2019: n = 89 journals, highest IF: 15.083, lowest IF: 0.018, median IF = 2.937). For example, the 'American Journal of Clinical Nutrition' currently has an impact factor of 6.568. Review journals generally have high impact factors as these types of publications are routinely cited e.g. 'Proceedings of the Nutrition Society' has an impact factor of 5.017 (Clarivate Analytics, 2019).

In certain instances, more weight could be given to publications in journals with higher IFs; however, it is important to remember that the IF of the journal is only one aspect of judging a scientific paper. For a journal to receive an impact factor, it must be submitted to Clarivate Analytics (previously known as Thomson Reuters) and accepted following review. If an impact factor is absent from a journal, this may indicate that it did not meet the minimum standard in this review process and may reflect the quality of the journal. A newly established journal will also not have an impact factor as the measure is calculated on the average number of citations over the previous number of years. To view impact factors, Clarivate Analytics InCites Journal Citations Report (JCR) is a prime resource, however users must pay for access to this site. Alternatively, articles are usually accompanied by the journal's impact factor on different platforms e.g. PubMed.

[2] An indexed journal means that it has been added to a database e.g. Medline, Pubmed Central, Thomas ISI's Journal Citation Reports. Once a journal is indexed, it is available to the users of that database. Some databases index titles of scientific research papers only, some index the full scientific publication while others index the abstract of a scientific publication along with the references.

[3] A citation is reference to a source of information e.g. a scientific paper.

Another useful site for checking journal rankings is Scimago where you can search a journal to see how it ranks within its field and compare with other journals, using a metric called SCImago Journal Rank (SJR).

Section 2: Key elements of a peer reviewed scientific publication

This section explains the various elements of a peer reviewed scientific publication and provides guidance on how to judge the quality of a publication. Please note that a checklist containing all elements of this section is available in Appendix 1.

Title page

Title

The title reflects the content of the paper. An inaccurate or inappropriately titled publication may suggest a poorly written article.

Authors' list, affiliations and contributions

The first author listed is usually the researcher who has undertaken the majority of the research work and was the primary author of the article. The last author is usually the principal investigator on the project who provides direction, intellectual input and approves the protocols to be followed and often the author who sourced the funding. The other authors listed would usually have been involved with the work in areas such as gathering the data, statistical analysis, contributing to the writing etc. Many journals require a section at the end of the paper listing each author's contribution. If you wish to contact the research group about the publication, communication is made through the corresponding author. In general, the corresponding author is the first and/or last author on the publication.

When critically reviewing a paper, it is important to look at the authors' affiliations (institution, research group) as this may have an impact on the findings of the paper. For example, if one of the authors works or is affiliated with a company who funded the research, this should be acknowledged in the "conflicts of interest" section of the publication. However, it is worth noting that research conducted by company funded research institutes is often undertaken because the subject matter is solely of commercial interest. In most cases, an author's affiliation with a company is clearly stated. However, an author's affiliation with a company may not be obvious if they are hired by that company as a consultant. It is important to establish the author's affiliation and to distinguish between affiliations with a 'Centre for …' or '… Research Laboratories', which may be given less weight if they are not recognised organisations with a proven track record, in comparison with affiliations with Universities, Technical Institutes or government organisations which are publicly funded. The affiliations of the authors should always be declared for transparency purposes. If these affiliations are not declared, this could cast doubt on the independent nature of the publication. If there is doubt over the credibility of the authors of the study, a search of previous publications by those authors will give an indication as to whether they

are experts in that field. Online platforms such as Scopus, ResearchGate, academia.edu or Google Scholar can be used to check an author's publications list. These platforms often provide the author's *h*-index which is a measure of the impact of the author's scientific publications in terms of citations, similar to an impact factor for a journal (see the section below on "Author impact - *h*-index" for more information).

Article impact - citations

One of the most basic citation metrics is how often an article has been cited in other articles, books, etc. The number of citations is heavily dependent on the discipline and the number of researchers working in that area. For instance, more researchers work in neuroscience than in mathematics, and neuroscientists publish more papers than mathematicians, hence neuroscience papers are more frequently cited than papers in mathematics. Similarly, review papers are more frequently cited than regular research papers because they summarise results from many papers. One method to track citations is through Google Scholar which is free to access.

Author impact - *h*-Index

While the impact factor for a journal assesses the influence of a journal, the *h*-index (created by Jorge E. Hirsch, 2005), gives an estimate of the importance, significance, and broad impact of an author's cumulative research contributions (Hirsch, 2005). The author's *h*-index is a number reflecting the highest number of their papers that have had at least the same number of citations. Therefore, a *h*-index of 20 signifies that an author has published 20 articles each of which has been cited at least 20 times. If using ISI's Web of Science database to assess a *h*-index, it is important to remember that Web of Science uses only those citations in the journals listed in Web of Science. It is important to note that an author's work may be published in journals not covered by Web of Science. Furthermore, the h-index on a researcher's Google Scholar page will be higher than on Web of Science or Scopus as Google identifies and includes publications which are not indexed elsewhere, e.g., preprints. In terms of an author's impact, it is also important to be aware of the practice of self-citation[4] (Ioannidis *et al.*, 2019).

[4] Self-citation is the practice whereby an author cites their own previous publications.

A number of the sections below are based on the following publication:
https://www.science.mcmaster.ca/biopharm/images/files/handouts/critanal.pdf.

Abstract

The abstract should provide a summary of the objectives, methods, results and conclusions of the research study (Brown *et al.*, 2017). Similar to the title, an abstract which is poorly written and not very informative, may indicate that the paper is of poor quality.

Some general questions to ask when reviewing the abstract section of a publication are:

- Is the abstract clear and easy to understand?
- Does the abstract include data that is not presented in the body of the paper?
- Does the abstract include material that cannot be substantiated?

Introduction

In the introduction, the authors should set the scene for the reader in terms of the current state of knowledge and give the rationale for the study i.e. why it is needed (du Prel, Rohrig and Blettner, 2009). All central arguments should be supported with appropriate and up-to-date references. The reader should be confident that the author has read the papers cited i.e. vague phrases such as 'inconsistent findings' should not be used (du Prel, Rohrig and Blettner, 2009). An overly long introduction section containing irrelevant information and information included for the purpose of self-citation may indicate a poorly written article. The introduction section should conclude with the research question the study is proposing to answer i.e. aims and objectives.

Some questions to consider when reviewing the introduction section of a publication include:

- Are the aim and objectives of the study clear?
- Why was the study undertaken? (i.e. the rationale)
- Why now, in this context?
- Is there a link to theory?
- Are the main arguments supported by appropriate references?

(Adapted from (Jesson, Matheson and Lacey, 2011)

Methods

When reviewing this section of a scientific publication, it is important to be aware that there are several different types of research methods that can be used by the researchers. This often depends on the type of research question asked.

A non-exhaustive list of types of study design*

Study type	Explanation of study design
Mechanistic studies	These are studies which aim to investigate a particular mechanism of action in a system. They are designed in a structured way to identify the mechanism of interest supported by theory.
Case reports, case studies	A descriptive study of a single individual, while a case series is a study of a small group.
Cross-sectional studies	Measures cause and effect at the same time but does not tell us the relationship i.e. which one is the cause, and which one is the effect.
Case-control studies	Patients who have a certain condition (cases) are compared with individuals who do not have the condition.
Cohort studies	A group of individuals who are followed up for a period of time for the occurrence of disease. These can be prospective, historical or a combination of both.
Ecological studies	A group of individuals from a particular region e.g. subjects living in a country.
Randomised controlled trials (RCTs)	Subjects are randomly assigned to an experimental group and a control group and followed up for the variables of interest.

	RCTs are considered gold standard in terms of research.
Systematic review	A type of literature review that uses systematic methods to collect secondary data, critically appraise research studies, and synthesise findings qualitatively or quantitatively.
Meta-analysis	The data from individual studies is collected and statistically integrated to identify an overall effect.

(*Some of these definitions have been adapted from (Parab and Bhalerao, 2010)

A well written methods section should resemble a cookbook i.e. the description of the materials used and procedures should be detailed enough (similar to 'recipes') to allow the reader to repeat the study and reproduce the results (du Prel, Rohrig and Blettner, 2009). This section should describe the planning, study sample, how the study was conducted and how the results were analysed. A methods section which lacks sufficient detail may conceal weaknesses in the study design, sample selection criteria or how the study was conducted, and results analysed.

Some questions to ask when reviewing the methods of a publication are:

- Did the study design chosen facilitate the aims of the study?
- Was the study's endpoint precisely defined?
- Was the geographical area, the population, the study period (including duration of follow-up), and the intervals between investigations described in detail?
- If standard methods were used, were adequate references given?
- Was the chosen methodology and/or experimental design appropriate?
- Where relevant, were applicable test guidelines followed (e.g. OECD guidelines)?
- Where relevant, were good laboratory practice requirements followed?
- If methods were adapted from another study and modified, were the modifications described carefully? (The word "modified" should not be used to describe major changes that leave little of the original method.)
- Have the sources of the drugs/chemicals/reagents/foods/supplements been provided?
- Have the specifications of the test material (e.g. purity) been clearly defined?
- If a control group was included, are the conditions applied to this group adequate and clearly defined?
- Have the authors specified the statistical procedures used?
- Are the statistical methods used appropriate?
- If the study involved animals or humans, was appropriate ethical approval sought?

More detailed criteria for various study types are listed in Appendix 2.

Statistical approach

It is important to understand whether the statistics were appropriate to the research question asked. However, it is difficult to define generally appropriate statistics for all scenarios as this will be dictated by the research questions asked. However, as a guide, it is useful to compare the statistics used in a similar paper which is recognised as an important paper in that research area. Similar to the methods section, sufficient detail should be given to allow the reader to repeat the statistical analysis e.g. statistical software used (including version), statistical tests/models implemented, treatment of outliers and to which results they have been applied.

Results

The findings of the research study should be presented clearly and objectively, i.e. no interpretation should be provided by the author in this section and it should directly address the study objectives. It is important to ensure that the results presented have been correctly collated and displayed.

Some questions to ask when reviewing the results of a publication:

- Were the experiments performed appropriately with respect to the objectives of the study?
- Do the results obtained make sense? i.e. comply with generally recognised principles.
- Are the legends to the figures clear?
- Can the figures be understood independently of the text of the manuscript?
- Do the scales on graphs coincide with the results obtained?
- Has appropriate scaling been used on graphs?
- Have appropriate metrics been used when presenting numerical results?
- Are the data, presented in tabular form, clear?
- Are the legends to the tables clear?
- Can the tables be understood independently of the text of the manuscript?
- Is the whole dataset represented or do the results presented relate to a specific sub-sample?

In the results section, information on statistical significance, confidence intervals and effect sizes should be given. Where results are summarised in tables or graphs, consideration should be given to any potential bias which may be introduced by the authors. Are the graphical/tabular elements appropriate for their purpose or have they been deliberately used to conceal significant or unexplained findings? Graphs can give a clear visual overview of the results, however, the use of varying scales (i.e. uneven scales, scales not starting at 0, broken scales, etc.) and the use of logarithmic, power (or otherwise transformed) scales should be examined. The absence of certain graphical/tabular elements that have been used in other similar papers may identify a weakness in

the study. For example, if a meta-analysis is being considered, a funnel plot should be present in the article. This plot would diminish any concerns related to bias that may be introduced into the analysis by the author through study selection.
When the results are presented in conjunction with the discussion in a combined "Results and Discussion" section, special attention should be made to differentiate between the actual results of the research and the results from the referenced published literature.

Discussion/Conclusion

These sections should discuss how the results prove/disprove the chosen research question. The authors should compare the study findings with other reported findings in this area, present the advancement to the research field and critically analyse the study's limitations (du Prel, Rohrig and Blettner, 2009). If the study is focussing on an emerging area, where few other studies may be available for comparison, particular focus should be placed on the strength of the data used to support the arguments made by the authors. These sections should not attempt to answer research questions which were not identified in the objectives of the study or make conclusions that are not supported by its findings.

The discussion section attempts to place the results obtained in perspective. The information gathered is assessed in relation to the objectives of the study and the context in which the study was undertaken. Any discrepancies between anticipated and observed results are explained and elaborated upon. Often there is some repetition of the background material given in the introduction, but the discussion is more elaborate. To many readers, the discussion section is critical since the investigators go beyond mere data gathering and attempt to provide explanations. Critical assessment should clearly identify reasoned interpretation of the results and avoid undue speculation.

Study strengths, weaknesses and uncertainties

These should be discussed by the authors and should be taken into account when judging the quality of the paper.

Some questions to ask when reviewing the discussion/conclusions section of a publication are:

- Were the objectives of the study met?
- Do the authors discuss their results in relation to available information?
- Do the authors indulge in needless speculation?
- If the objectives were not met, do the authors provide an explanation?
- Do the authors adequately interpret their data?
- Have the authors indicated the reasons why particular procedures were used?
- Do the authors discuss the limitations of the methods used?
- Do the authors discuss only the data presented or do they refer consistently to unpublished work?

The conclusion should reflect the outcome of the research question / hypothesis posed in the aim(s) at the start of the article. There may be exceptional cases where unexpected findings may lead the author to make conclusions that are not covered in the original research question. In these cases, the author should emphasise that the findings are unexpected in the discussion section and provide adequate explanation as to why they occurred. Often, this section highlights avenues for future research and these would be indicative of current knowledge gaps which the paper itself does not cover.

References section

The bibliography (references section) is a crucial part of the published article. Rarely are studies conducted in isolation and often arise from actual or perceived problems or gaps in the published literature and it is important to adequately reference the context of the study. Scanning the bibliography/references list will give the reader an appreciation of the relevance of the current study in terms of content and date i.e. are most of the articles recently published / are the publications mostly novel publications or reviews?

Some questions to ask when reviewing the references section of a publication are:

- Do the authors cite appropriate papers to support arguments made in the study?
- Do the authors cite their own publications needlessly?
- Do the authors cite inappropriate sources, e.g. Wikipedia, etc.

Section 3: Tools for appraising peer reviewed scientific publications

In the previous section, the different aspects of a scientific publication were explained, and guidance was given to aid the reader when assessing the quality of a scientific publication. This section builds on this information by giving an overview of tools which can be used to systematically appraise scientific peer-reviewed publications. This section will also introduce tools to appraise epidemiological studies, such as the hierarchy of evidence and critical assessment tools.

EFSA and the PROMETHEUS Project

The European Food Safety Authority (EFSA) is the agency of the European Union that provides independent scientific advice and communicates on existing and emerging risks associated with the food chain. In order to improve and increase consistency of the methods used in its scientific assessments, EFSA launched their PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments) project in 2014 (EFSA, 2015a).

As part of this project, EFSA has published critical appraisal tools (CATs) for appraising: i) systematic reviews of interventions (SR), ii) randomised controlled trials (RCT) relevant for food and feed safety assessments; iii) Genetically Modified (GM) plant equivalence studies and iv) the methodological quality of extensive literature searches (ELS) (EFSA, 2015a).

Critical appraisal tool (CAT) - allows the methodological quality of a study (or a process) to be assessed, which influences the reliability of the evidence produced by such a study (EFSA, 2015b).

Reliability refers to **precision** - the extent to which random error is minimised and the outcome of the process is reproducible over time and **internal validity** – refers to the extent to which systematic error (bias) is minimised (EFSA, 2015a).

There are a number of different types of bias that can occur dependent on the type of study conducted which are described elsewhere (OHAT/NTP, 2019). CATs take into account the different types of biases which can occur.

EFSA has also published a number of other useful resources for reviewing scientific evidence including guidance on conducting systematic reviews (EFSA, 2010), uncertainty analysis (EFSA, 2017c), biological relevance of data (EFSA, 2017a), weight of the evidence approach (EFSA, 2017b), process for dealing with data (EFSA, 2015a). Recently, EFSA has published a draft guidance on appraising and integrating evidence from epidemiological studies (EFSA, 2020).

EFSA guidelines related to authorisation procedures in Europe

Concerning regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union, EFSA provides several resources on the applications section of their webpage, such as information on the regulatory framework, administrative and scientific guidance, and application procedure overviews.

Hierarchy of evidence used to appraise epidemiology studies

A hierarchy of evidence aims to judge the quality of the study bearing in mind the level of bias. The following hierarchy of evidence as illustrated in Figure 1, was developed by Yetley and colleagues to visualise the quality of evidence and risk of bias of studies used to establish dietary reference intakes (Yetley *et al.*, 2017). It indicates that the quality of evidence is likely to improve, and the risk of bias of studies decreases with each ascending level of the pyramid.

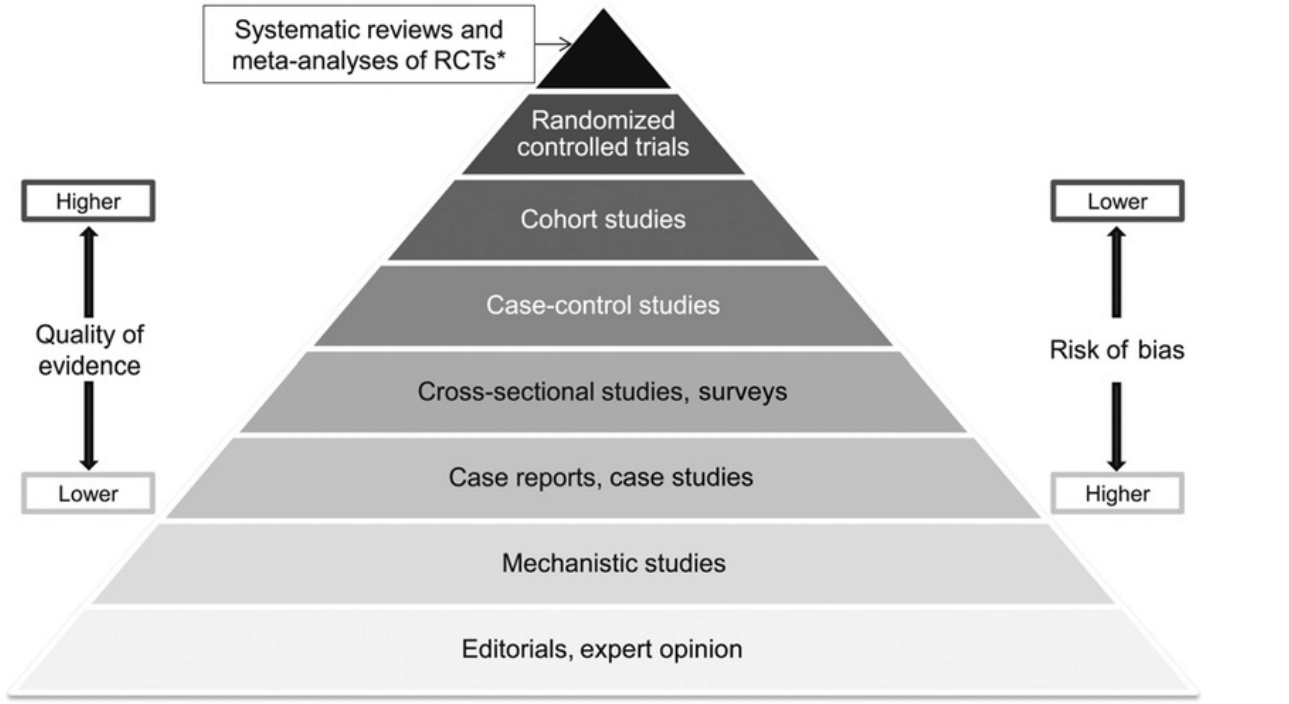

Figure 1 Hierarchy of evidence pyramid

*Meta-analysis and systematic reviews of observational studies and mechanistic studies are also conducted. Adapted from Yetley *et al.* 2017. The definition of each of these types of studies was previously explained in the "Methods" part of Section 2.

Randomised controlled trials (RCTs) are considered the highest level of evidence as they are designed to be unbiased. They have less risk of systematic errors as subjects are randomised to the two or more treatment groups which in turn randomises the confounding factors that may bias results (Yetley *et al.*, 2017). In contrast to this, there can be bias introduced in a case series or

expert opinion based on the author's own experiences or opinion (Burns, Rohrich and Chung, 2011). However, the quality of the studies varies within the levels and therefore it is important to scrutinise the study design to have confidence in the level of evidence (Burns, Rohrich and Chung, 2011). Editorials include sources of information such as handbooks, textbooks which provide a good background to the subject. Editorials are short, invited opinion pieces that discuss an issue of immediate importance to the research community. They would be considered the lowest quality of evidence in health research.

Critical assessment tools for appraising epidemiology studies

There have been several critical assessment tools (CAT) developed for health research, some of which are listed below:

GRADE

Grading of Recommendations Assessment, Development and Evaluation (GRADE).

RoB 2

Version 2 of the Cochrane risk-of-bias tool for randomised trials (RoB 2) is the recommended tool to assess the risk of bias in randomised trials included in Cochrane Reviews.

CASP

Critical Appraisal Skills Programme (CASP) have designed a set of eight critical assessment tools for systematic reviews, RTCs, cohort studies, case control studies, economic evaluations, diagnostic studies, qualitative studies and clinical prediction rule.

Health Service Executive (HSE)

The Health Service Executive (HSE) have also published a number of CATs.

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Appendix 1 General checklist for appraising peer reviewed scientific publications

Initial consideration should be given to these factors:

- Journal
- Impact factor
- Publishing status e.g. open access etc.
- Title
- Authors' list, affiliations and contributions
- Study sponsorship
- Acknowledgements
- Author contributions
- Article impact – citations
- Author impact h-Index

The following should be considered for each section of the journal article:

Abstract

- Is the abstract clear and easy to understand?
- Does the abstract include data that is not presented in the body of the paper?
- Does the abstract include material that cannot be substantiated?

Introduction

- Are the aim, objectives and hypothesis of the study clear?
- Why was the study undertaken? (i.e. the rationale)
- Why now, in this context?
- Is there a link to theory?
- Are the main arguments supported by appropriate references?

Methods

- In terms of the study design chosen, did it permit the aims of the study to be addressed?
- Was the study's endpoint precisely defined?
- Was the geographical area, the population, the study period (including duration of follow-up), and the intervals between investigations described in detail?
- If standard methods were used, were adequate references given?
- Was the chosen methodology and/or experimental design appropriate?
- Where relevant, were applicable test guidelines followed (e.g. OECD guidelines)?
- Where relevant, were good laboratory practice requirements followed?

- If methods were adapted from another study and modified, were the modifications described carefully? (Often the word "modified" is a euphemism for major changes that leave little of the original method but saves the investigator much difficulty by referring to a published procedure).
- Have the sources of the drugs/chemicals/reagents/foods/supplements been provided?
- Have the specifications of the test material (e.g. purity, carriers) been clearly defined?
- If a control group was included, are the conditions applied to this group adequate and clearly defined?
- Have the authors specified the statistical procedures used?
- Are the statistical methods used appropriate?
- If the study involved animals or humans, was appropriate ethical approval sought?

Results

- Were the experiments performed appropriately with respect to the objectives of the study?
- Do the results obtained make sense? i.e. comply with generally recognised principles.
- Are the legends to the figures clear?
- Can the figures be understood independently of the text of the manuscript?
- Do the scales on graphs coincide with the results obtained?
- Has appropriate scaling been used on graphs?
- Have appropriate metrics been used when presenting numerical results?
- Are the data, presented in tabular form clear?
- Are the legends to the tables clear?
- Can the tables be understood independently of the text of the manuscript?
- Is the whole dataset represented or do the results presented relate to a specific sub-sample?

Discussion/Conclusion

- Were the objectives of the study met?
- Do the authors discuss their results in relation to available information?
- Do the authors indulge in needless speculation?
- If the objectives were not met, do the authors provide an explanation?
- Do the authors adequately interpret their data?
- Have the authors indicated the reasons why particular procedures were used?
- Do the authors discuss the limitations of the methods used?
- Do the authors discuss only the data presented or do they refer consistently to unpublished work?

References

- Do the authors cite appropriate papers to support arguments made in the study?
- Do the authors cite their own publications needlessly?
- Do the authors cite inappropriate sources, e.g. Wikipedia, etc.

Appendix 2 Guidelines on assessing different types of studies

In the subsequent tables, key parameters used to assess specific study types are listed – **however, please note that these lists are non-exhaustive and relate primarily to studies relevant to food science**. These lists have been devised based on expert knowledge of the study types unless otherwise indicated.

Table 1 Studies evaluating the presence/absence/number of microorganisms in food samples (prevalence data)

Methods Section	
Considerations	**What to look for:**
Number of food samples	• Check that appropriate number of food samples were collected for the study to be conducted and for the subsequent statistical analyses • Replicate experiments carried out to address sources of variability that may induce differences in microbial growth behaviour and to demonstrate reproducibility of the results and standard deviations given.
Sampling	• Consider sampling type (e.g. random, targeted, etc.) and collection timeframe in line with/representative of the type of study to be conducted
Transportation and storage of food samples	• Ensure appropriate transportation and storage conditions (including time, temperature, atmosphere) between the sampling point and the point of analysis
Sample suitability	• Laboratory to check the suitability of the samples to be analysed
Recovery (enumeration or presence/absence tests)	• Search for the appropriate recovery method in terms of laboratory media and incubation time/temperatures. • Is the method a standard method? E.g. is it based on the most recent edition of an ISO method or an internationally recognised alternative method validated and certified as equivalent by a third party.
Laboratory scope of accreditation (if appropriate)	• Check whether the laboratory has accreditation (e.g. ISO 17025). • Check whether the specific method is accredited for the substance and matrix. • Check whether the laboratory is accredited for performing the specific test in the specific sample type
Statistical analysis	• Have appropriate statistical analyses been employed?

Table 2 Studies evaluating the growth and/or inactivation of microorganisms in food or laboratory media (including or not a processing step e.g. thermal treatment

Methods Section	
Considerations	**What to look for:**
Artificial contamination: Microbial strain(s)	• Source: Check if they come from a reputable culture collection or not. Whether they are isolates from clinical, food or environmental samples. • Common uses: Whether they are commonly used as surrogate microorganisms or, for instance, as control for bacterial antimicrobial susceptibility testing. • Single versus mixtures: Whether the study involves the inoculation of single strains at a time or a pool (mixture) of different strains from the same or different species.
Artificial contamination: Cultivation	• Search for the appropriate cultivation method in terms of laboratory media and incubation time/temperatures.
Artificial contamination: Inoculation method (surface or centre)	• How appropriate is the inoculation method for the food type and the study to be conducted?
Recovery (enumeration or presence/absence tests)	• Search for appropriate recovery method in terms of laboratory media and incubation time/temperatures. • Watch out for the possibility of the recovery of damaged cells. (if samples have been exposed to any processing step e.g. thermal treatments)
Kinetics of growth or inactivation	• Appropriate mathematical model(s) and parameters to describe the kinetics of growth or inactivation.
Timing	• Examine the time and storage conditions between the artificial inoculation and the actual processing step (if applicable) – this may help cells to adapt to, and even grow in, the new environment or to die. • Examine the time and storage conditions between the actual processing step (if applicable) and the recovery – this may help damaged cells to recover, and even grow, or to die.
Control samples	• Does the study have control (unprocessed) samples? • Have the control samples been handled as the processed ones (except for the processing step itself)?
Number of samples	• Appropriate number of samples for the study to be conducted and for the subsequent statistical analyses. • Replicate experiments carried out to address sources of variability that may induce differences in microbial growth behaviour and to demonstrate reproducibility of the results and standard deviations given.

Statistical analysis	• Have appropriate statistical analyses been employed?
Laboratory accreditation	• Check whether the laboratory has general accreditation (e.g. ISO 17025).
Laboratory scope of accreditation (if appropriate)	• Check whether the laboratory is accredited for performing the specific test in the specific sample type.

Table 3 Studies investigating the occurrence (presence/absence) or behaviour of a substance/food in a medium (food, environmental samples, biological sample, etc.)

Methods Section	
Considerations	**What to look for:**
Consumables (Reagents)	• All reagents used should be clearly stated including where they were obtained. • The quality of the reagent (purity and whether it complies with a standard, e.g. ISO) should be included.
Number of food samples	• Check that an appropriate number of food samples collected for the study to be conducted and for the subsequent statistical analyses. • Replicate experiments carried out to address sources of variability and to demonstrate reproducibility of the results and standard deviations given. • Where relevant, have legislative sampling and analysis procedures been followed.
Sampling	• The sampling procedure should be clear and repeatable. • Measures taken to protect the sample from degradation or contamination should be included, when applicable. • The number of samples taken, where/when/by whom and the sampling frequency should be stated. • Examine the sampling type (e.g. random, targeted, etc.) and collection timeframe in line with/representative of the type of study to be conducted. • Check that the origin or sampling location (e.g. retail, on farm, etc.) should be recorded. • Where relevant, check that the legislative sampling and analysis procedures been followed.
Transportation and storage of samples	• Consider what environmental conditions (time, temperature, humidity, UV light, etc.) the samples were stored prior to analysis. • Where applicable, appropriate transportation and storage conditions (including time, temperature, atmosphere) between the sampling point and the point of analysis should be taken into account.

Methods Section	
Considerations	**What to look for:**
Sample suitability	• Laboratory to check the suitability and relevance of the samples to be analysed.
Sample preparation	• All steps from sample collection to final sample analysis should be stated.
Laboratory accreditation	• Check whether the laboratory has general accreditation (e.g. ISO 17025).
Analytical methods	• Check whether the laboratory method is accredited for the specific substance and matrix. • The details of the method used (instrument/configuration/autosampler or manual/instrument consumables/manufacturer of the instrument and instrument model, etc.), the analytical procedure from sample introduction to waste collection including the calibration procedure, the method performance information (LOD, LOQ, recovery of spiked sample, number of control samples, internal standards, etc.) should be stated. • It may not be necessary to report as much of this information if a recognised standard is rigidly followed. Alternatively, for new or emerging techniques far more detail would be required on the mechanisms of the technique and its validation.
Statistical analyses	• The software used and provider should be stated. • The statistics calculated (mean, median, P95, etc.) and the samples they apply to should be stated. • If statistical tests are applied (t-test) or a regression analysis is performed, the significance ($P < 0.05$) should accompany reported correlation coefficients in the results/discussion section. • The number of samples included in the regression, the coefficient of determination and fitting equation should accompany any regression analysis.

Table 4 Studies investigating a new substance/food/process

Methods Section	
Considerations	**What to look for:**
Substance/food/process manufacture	• A clear and detailed description of how the new substance/food was produced should be provided. • What starting materials and/or ingredients were used in the food and how they were prepared? • A list of relevant processing aids and other agents (e.g. extraction solvents) used during production should be provided. • What steps were included in the process and its operating conditions? • Did the procedures follow the principles of Hazard Analysis & Critical Control Point (HACCP), Food Laboratory Practice (GLP), Good Manufacturing Practice (GMP) or other guidelines where relevant?
Substance/food/process characterisation	• An appropriate approach should be included to sufficiently identify, characterise and quantify the new substances/foods/processes.
Substance/food/process safety	• Information on stability, reaction and fate in food should be provided. • Biological and toxicological data following international/EU guidelines and/or requirements should be provided. • Information on proposed uses and population exposure should be provided.

Table 5 Studies investigating a mechanistic/mathematical relationship

Methods Section	
Type	**Considerations**
Mathematic model	• All inputs and outputs to the model should be identified and whether they are variable/constants. • Constant values should be stated. References should be given for all input values taken from the literature, unless they are widely recognised values, e.g. Avogadro's number. • Reference should be made to where the model was originally adapted from. • The study that originally proposed the model should be referenced and if there has been significant adaptions by other studies these should also be referenced. Reviews should not be referenced as a source for models.
Experimental data/model validation	• The experimental design should aim to validate/invalidate only the proposed mathematical model. • The limitations of the experiments should be stated, e.g. maximum/minimum temperature/time ranges, etc. • If some parameters of the model are being formulated from experimental data, then a sub-set of the data should be excluded and used instead to validate the model. • If there is insufficient data to validate the model this should be clearly stated in the discussion section.

Table 6 Experimental animal studies

Methods Section	
Considerations	**What to look for:**
Ethics	• All experiments involving live animals should have appropriate ethical approval and comply with ethical guidelines and legislative requirements (Directive 2010/62/EU as amended).
Experimental design	• Where appropriate, check that international (e.g. OECD TG[5]) or EU (e.g. REACH[6]) agreed test guidelines have been used and studies carried out according to the principles of GLP. • Animal models (rational/limitations) and sample size suitable to the research question should be used, including appropriate control groups. • Information on group size and characteristics (e.g. breed, species, age, gender, weight) and group allocation (e.g. random) of experimental and control animals should be provided. Are the groups comparable; did all animals complete the study? • Animal housing/husbandry (e.g. cage size and location) and care (e.g. blind) conditions should be described. • The testing protocol and SOPs in place should be clearly described. • The test substance, and any vehicles used should be fully characterised, and treatment of controls should be clearly outlined. • The doses administered and type of administration to each group should be clearly described. • The study duration/schedule should be relevant to the research question studied.
Results analysis	• Study outcomes for both groups (including assessment thereof (e.g. blind)) should be clearly reported, in line with the research question asked and statistical considerations be detailed.

[5] https://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm
[6] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Table 7 Studies assessing the safety and suitability of infant and follow-on formula[7]

Methods Section	
Type	**Explanations/Considerations**
Study objectives	• To assess the effects of the newly developed formula on measures of growth as compared to accepted growth standards. • To assess an existing formula complying with the compositional requirements laid down in the EU legislation (control formula).
Study products	• Control formula composition should be as close as possible to the composition of the newly developed formula.
Study design	• Bearing in mind the Hierarchy of Evidence, a randomised controlled trial (RCT) is gold standard (see below for more information). • RCT should be well-designed e.g. using a placebo[8], double- blind[9], intention-to-treat analysis[10], trial registration[11], CONSORT[12]. • To detect similarity in growth between new formula and control, an equivalence study using a pre-defined margin of equivalence/non-inferiority is necessary. It is important to pre-define (at the protocol phase) the equivalence/non-inferiority margin used to calculate the number of subjects needed to ensure sufficient power of the study and to provide a rationale why such margin has been considered appropriate for that purpose. • Study duration – at least 3 months. • Based on appropriate power calculation.

[7] This guidance is adapted from EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies),Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI,Mangelsdorf I, McArdle HJ, Naska A, Neuh€auser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Sjödin A, Stern M, Tome D, Van Loveren H, Vinceti M, Willatts P, Fewtrell M, Przyrembel H, Titz A and Valtueña Martınez S, 2017. Scientific and technical guidance for the preparation and presentation of anapplication for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates. EFSA Journal 2017;15(5):4779, 24 pp.https://doi.org/10.2903/j.efsa.2017.4779. Please note that infant formula and follow-on formula containing only mixtures of free amino acids which are intended for the dietary management of infants with a diagnosed disease/disorder or a medical condition and are covered by EU legislation on food for special medical purposes are considered out of scope in this EFSA guidance.

[8] A placebo is anything that seems to be a "real" medical treatment -- but isn't. It could be a pill, a shot, or some other type of "fake" treatment.

[9] Double-blind is where both the researcher and participants are not aware which participants are in which research groups e.g. control group, intervention group. Therefore, neither party can bias the results.

[10] Intention-to-treat analysis is where all participants who were randomised to the trial are analysed in the research group they were originally assigned. This method allows the researcher to draw unbiased conclusions regarding the effectiveness of the intervention.

[11] Trial registration creates a public record of all clinical trials that researchers are planning and what they intend to do, e.g. which intervention(s) they will be testing, the comparator(s) they will use, and what outcomes they will be measuring.

[12] CONSORT Statement is an evidence-based, minimum set of recommendations for reporting randomised trials.

Study group	• Should be representative of the target population for which the product is intended e.g. healthy infants
Main outcome variables	• For infant formula, measures of growth should include body weight, body length, head circumference and be compared to accepted national or international growth standards. • These variables should be measured with a sufficient frequency during the study to establish the growth pattern of infants, ideally every 4 weeks, and provided as absolute values, as changes from baseline, and as the variable-for age z-scores at each assessment time point and for each study group, together with an indication of the growth standard used to calculate z-scores and the reasons for that choice. • Other outcome variables include: intake of infant formula, together with information on the methods used to ascertain formula intake, intake of complementary foods, where appropriate, together with information on the methods used to ascertain food intake, tolerance of the study products and adverse events.
Basic data set	All subjects should be well characterised (see EFSA opinion for more information)[13].
Statistics	• Results should be provided for comparisons between the intervention and control groups for all outcome variables assessed. • Growth patterns of the study groups should also be compared with accepted growth standards. • Include descriptive and inferential statistics for each assessment time point for both the intention-to-treat (ITT) or the full analysis set (FAS) and the per protocol (PP) analyses; number of infants analysed at each time point for each analysis; point estimate and the associated confidence interval for continuous outcome variables; covariates used in the analysis, with appropriate justification for their use; results of both the adjusted and the unadjusted analysis; reasons for drop-outs or withdrawal of infants from the study by the investigators, together with an assessment/discussion of the impact of drop-outs/withdrawals on the study results.
Publication bias	• Often there can be publication bias i.e. only trials which resulted in a positive outcome are published.

[13] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies),Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI,Mangelsdorf I, McArdle HJ, Naska A, Neuh€auser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Sj€odin A,Stern M, Tome D, Van Loveren H, Vinceti M, Willatts P, Fewtrell M, Przyrembel H, Titz A and Valtue~naMartınez S, 2017. Scientific and technical guidance for the preparation and presentation of anapplication for authorisation of an infant and/or follow-on formula manufactured from proteinhydrolysates. EFSA Journal 2017;15(5):4779, 24 pp.https://doi.org/10.2903/j.efsa.2017.4779

Table 8 Epidemiological studies

Methods Section	
Considerations	**What to look for:**
Sample group	• Eligibility criteria (inclusion and exclusion) should be defined. • Sociodemographic characteristics should be reported as this allows for a judgement on whether there was selection bias where differences in the groups at baseline may account for the effects observed. • High participation rates suggest a study group that is representative of the initial population to be studied. • Attrition or loss to follow up should be reported and explained. • Exclusion numbers should be reported. • Any differences between the exposed and control group should be examined in relation to potential effect on outcome.
Randomisation	• Method of randomisation should be reported.
Study duration	• Have participants been followed up for a sufficient length of time to observe an effect?
Potential bias due to data collection	• Data should be collected in such a way that it is objective, reliable, accurate and reproducible. • Validated questionnaires should be used to collect data.
Potential bias from observers	• Double-blinding (i.e. both researcher and participant) can help reduce bias.
Potential bias from participants	• This is bias due to inaccurate reporting by participants. • Blinding the participants to the objectives of the study can help reduce this bias.
Statistical analysis	• Confidence intervals as well as p values should be reported. • Attributable risk and relative risk should be reported.

Table 9 Dietary studies

Methods Section	
Considerations	**What to look for:**
Sample group	• Should be representative of the country population in terms of socioeconomic class, gender, age etc. • Eligibility criteria should be defined.
Food intake data collection	• Gold standard method adopted e.g. 4 day weighed food diary, 24 hour recall on two non-consecutive days[14]. • If necessary, training should be provided to participants. • Detailed information regarding amount and types of all foods, beverages and nutritional supplements consumed, cooking method, brand names of the foods consumed, and details of recipes should be recorded. • Other relevant information that should be collected includes time of each eating or drinking occasion, participant's definition of each eating or drinking occasion (e.g. morning snack, lunch) and the location of the preparation of the meal or snack consumed (e.g. home, takeaway).
Food quantification and coding	• Adequate detail on how the foods were quantified should be given e.g. weighed, use of food atlas, household measures etc.
Nutrient composition and estimation of nutrient intake	• Software programme used to estimate the nutrient intakes based on food intakes should be given.
Questionnaires	• Additional health and lifestyle information that should be collected includes socio-demographic, education, sun exposure, supplement usage, smoking status and alcohol intake, physical activity.
Anthropometry	• Protocol and equipment used to take measurements should be given.
Blood pressure	• Procedure to taken measurement should be described in detail.
Blood and urine analysis	• If collected, detailed information on the methods of collection and analysis should be described in detail.
Quality control	• Information should be given on what measures were taken to minimise error e.g. research training, participants asked not to change their diet during the study, was each researcher solely in change for the collection, quantification and data entry of an assigned set of food diaries, were over-range checks for portion sizes included in the software programmes etc.

[14] EFSA (2014) Guidance on the EU Menu methodology *EFSA Journal* **12**(12), 3944

Table 10 Meta-analysis of studies

Methods Section	
Considerations	**What to look for:**
Study question	• The scope and study question should be clearly stated.
Study selection	• The criteria for selection of studies should be clear in such a way not to introduce bias. • The search terms and sources used (e.g. Pubmed, etc.) for the literature search should be included. • Any exclusions to the literature search should also be given, i.e. English language publications only. • The criteria for excluding studies should be stated.
Summary of studies	• Like the inputs to a mathematical model, the various factors (e.g. number of participants, age, gender, etc.) in each of the selected studies should be summarised.
Study integration	• The statistical methods used to combine the studies should be included.
Results/discussion section	
Evaluation of literature search	• The integration of the data should be discussed.
Meta-analysis results	• Was the integration process for the various studies into the model successful or were the studies incompatible for the purposes of meta-analysis? • Are the results appropriately displayed? • Has a sensitivity analysis been performed? • Is a funnel plot displayed and has any asymmetry been identified, i.e. has study bias been identified?
Interpretation of funnel plot	• If asymmetry has been identified, has the author considered its sources: reporting biases (publication bias, selective outcome reporting, selective analysis reporting), poor methodological design, etc.?

Contributions

This guidance document has been developed by the FSAI Food Science and Standards, CEO Office and Information teams with advisement from members of the FSAI Scientific Committee.

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