

PROSPERO International prospective register of systematic reviews

Systematic review of nutrient profile models developed for nutrition-related policies and regulations aimed at noncommunicable disease prevention

Marie-Eve Labonte, Mavra Ahmed, Mike Rayner, Mary L'Abbe

Citation

Marie-Eve Labonte, Mavra Ahmed, Mike Rayner, Mary L'Abbe. Systematic review of nutrient profile models developed for nutrition-related policies and regulations aimed at noncommunicable disease prevention. PROSPERO 2015:CRD42015024750 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42015024750

Review question(s)

The overall aim of this systematic review is to build an accessible resource that summarizes and discusses key characteristics of nutrient profile models with applications in government-led nutrition policy and regulation, to ultimately assist public health actors in the selection of a model that is appropriate to the use for which it is intended.

More specific questions to be addressed include the following:

How many nutrient profile models have been developed or endorsed by government bodies worldwide for nutrition policy and regulation?

Which specific applications/uses of nutrient profile models developed for nutrition policy and regulation are the most predominant?

What are the key components of the models (e.g. food categories, nutrients included, etc.) and are some components more predominant than others?

How many of the included nutrient profile models have been formally validated?

Do the characteristics/components of validated models differ from non-validated models?

Searches

The search strategy comprises a 3-step process. It will be performed independently by two review team members (MEL and MA) to enhance objectivity and avoid mistakes:

1. Collection of information from a key review carried out previously:

It has been decided by the research group that the most efficient approach to identify NP models would be first to build on and update work undertaken previously by one of the coauthors, Dr. Rayner. As indicated earlier, Dr. Rayner and colleagues have built a "catalogue" of existing NP models which was last updated in November 2012 [1]. A total of 119 models were identified at that time through a systematic search based on: 1) information obtained from five reviews of nutrient profile models conducted between the end of 2007 and 2010 [2-6]; 2) Internet searches carried out in PubMed, Google and Google Scholar for papers published since January 2008; 3) information obtained from key individuals and organisations following a joint WHO/International Association for the Study of Obesity technical meeting on nutrient profiling held in London on 4-6 October 2010; and 4) information from the developers/owners of included models to ensure accuracy (Summer 2011). Of the 119 models, 54 were included in the catalogue and 65 were excluded based on pre-defined eligibility criteria.

In the present systematic review, the review team will start from the total of 119 models initially identified by Dr. Rayner and reassess each of the models based on the inclusion and exclusion criteria defined later in this document.

2. Search of the peer-reviewed literature:



Searches will be carried out in electronic databases including PubMed, EMBASE and Scopus to identify relevant peerreviewed publications. The following search terms will be used: nutrient profil* OR nutritional profil* OR nutrition profil*. Articles containing these terms in the title or abstract will be retained for further evaluation, except when it will be clear that an article is not relevant to the objective being pursued (e.g. articles about the nutrient profile of animal diets; nutrition intervention studies comparing the impact of different diets on health outcomes; studies in the field of agriculture, such as comparisons between the nutrient profile of different varieties of plants/seeds).

The search will be limited to papers published between January 2008 and the date the searches will be run (Fall 2015). The same start date as the one used to build the 2012 catalogue will be used to ensure that models with applications in nutrition policy or regulation that go beyond those identified in the catalogue have been appropriately retrieved (e.g. models with applications in nutritional surveillance or food fortification). No restriction on language will be imposed during the search, but only models with full details available in English or in French will be included in the systematic review. Retrieved models with full details available in another language will however be indicated in a list of excluded models.

3. Search of the grey literature:

Electronic searches of the grey literature will be a key factor in the realisation of this systematic review considering that relevant and valuable sources of information about nutrient profile models may not necessarily be found in the peer-reviewed literature, particularly when models have been developed by governmental or inter-governmental organisations. Following a consultation with a highly qualified librarian at the University of Toronto, a list of grey literature search engines to be considered has been established (see below). Wherever possible, searches will be carried out using the same terms and limits developed for the peer-reviewed literature.

Grey literature search tools to consider:

- PAIS International, a search engine offering access to the literature from more than 120 countries worldwide in public affairs, public and social policies, and international relations.

- WHO e-Library of Evidence for Nutrition Actions (eLENA), an online library representing a single point of reference for the latest nutrition guidelines, recommendations and related information including supporting materials such as scientific evidence, background materials and commentaries from invited experts.

- Google Custom Search: Canadian Government Documents, which may be useful to retrieve information at the federal and provincial levels of government.

- Science.gov, which may be useful to retrieve authoritative US government science information.

- Google Custom Search: Intergovernmental Organization Search Engine, which will primarily be useful to search the European grey literature.

- OpenGrey, another database of European grey literature.

- ProQuest Dissertations & Theses Global, the largest repository of graduate dissertations and theses offering significant and growing international coverage.

- Scopus and Web of Science with the selection of "Conference" in the filter/document type menu, useful to search for conference papers/proceedings.

References for this section:

1. Rayner M. Nutrient Profiling Catalogue of Nutrient Profile Models: Summary Report. March 04, 2013 [Unpublished report prepared for the World Health Organization].

2. Stockley L, Rayner M, Kaur A. Nutrient profiles for use in relation to food promotion and children's diet: Update of 2004 literature review. Food Standards Agency, London. 2007; Available at:



http://multimedia.food.gov.uk/multimedia/pdfs/publication/npliteraturereviewupdate.pdf (Accessed: July 21, 2014).

3. American Heart Association/International Food Information Council. Nutrient Profiling/Dietary Criteria Matrix: A compilation of programs applying a nutrient-based approach to communicate food guidance (Discussion document). 2009; Available at: http://www.americanheart.org/presenter.jhtml?identifier=3057554 (Accessed: February 2011).

4. Hawkes C. Defining "Healthy" and "Unhealthy" Foods: An International Review. 2009 [Unpublished report prepared for the Office of Nutrition Policy and Promotion, Health Canada].

5. Wartella EA, Lichtenstein AH, Boon CS. Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report. Institute of Medicine. The National Academies Press. 2010.

6. Wentzel-Viljoen E, Jerling J, Badham J. Evaluation of existing nutrient profiling models. Centre of Excellence for Nutrition North-West University South Africa. 2010.

Types of study to be included

There will be no restriction on the type of study design eligible for inclusion, as long as at least one nutrient profile model that meets the inclusion criteria detailed above is described in the retrieved publication.

Condition or domain being studied

Public health nutrition (i.e. policies and regulations aimed at NCD prevention).

Participants/ population

No specific type of participants/populations will be included or excluded considering that nutrient profile models with applications in nutrition-related policies and regulations are generally developed for use in wide segments of the population (e.g. children, adolescents, adults and/or elderly people).

Intervention(s), exposure(s)

As indicated in the 'Review question' (above), we will review the key characteristics of nutrient profile models with applications in government-led nutrition policy and regulation.

Considering that the purpose of nutrient profiling is basically to provide an evaluation of the nutritional quality of a food product based on the amounts of multiple nutrients and other related components, each model identified in the searches will be assessed against the following inclusion and exclusion criteria:

Inclusion criteria:

a) Models allowing for the classification or categorisation of individual foods

b) Models integrating data from more than one nutrient or food component to produce a single overall score or categorisation, or, models with separate sets of criteria for multiple nutrients or food components (e.g. Traffic Light System in which the levels of each of the nutrients considered are interpreted separately)

c) Models with a food focus that also use criteria based on nutrients and other food components

d) Models in which the output (score or classification) includes at least a modest interpretative element

e) Models developed or endorsed* by governmental or inter-governmental organisations and having applications in government-led nutrition policy and regulation, including, but not limited to:

-Food certification schemes/front-of-pack labelling

- -Standards for food advertising or marketing
- -Regulation of health and nutrition claims

-Food procurement regulations/food quality standards for public institutions (e.g. schools, workplaces, hospitals, armed services, prisons, elderly care homes)

-Food taxation

- -Food subsidies
- -Welfare support schemes
- -Food fortification
- -Nutritional surveillance

*For the purpose of the review, "endorsed" refers to models that are used by governmental or inter-governmental organisations or that are made reference to in government publications in relation to one or more of the above applications, but that were not developed by such organisations

f) Models intended for national or international use, or for use in a jurisdiction with responsibility for the relevant food policy or regulation (e.g. models developed by states or provinces responsible for school food standards)

g) Details of the model are publicly available in the peer-reviewed or grey literature (e.g. government documents/websites, theses, etc.)

h) Final versions of models which are currently in use or have been proposed for use within the last 3 to 5 years

i) Models that do not duplicate information included previously

j) Full details of the model are available in English or in French

Exclusion criteria (linked to each of the inclusion criteria above):

a) Models only allowing for the classification or categorisation of combinations of foods (i.e. meals or diets, such as the Healthy Eating Index)

b) Models in which only a SINGLE nutrient or food component is used, as focussing on only one aspect of the nutritional composition can mask the overall nutritional quality of a food product (e.g. nutrient content claim; reformulation targets for single nutrients such as sodium; Whole Grain Stamp)

c) Models with a food focus that do not use criteria based on nutrients and other food components (e.g. a model which only states that soft soda cannot be advertised to children without considering the underlying nutritional composition of the products)

d) Models in which the output shows little or no interpretative element (e.g. models only repeating the amounts of some nutrients found in the Nutrition Facts Table, or models showing a percentage of Guideline Daily Amounts (GDAs), a percentage of Daily Values (DVs) or the GDAs/DVs themselves)

e) Models developed by different types of organisations (e.g. commercial; non-governmental; academic; etc.) that are not endorsed* by government bodies (e.g. models developed by the food industry for their own voluntary marketing restrictions; models developed by heart foundations for food-certification schemes)

f) Models intended for use at a very specific / narrow level (e.g. municipal)

g) Details of the model are not publicly available

h) Discontinued models no longer in use

i) Models duplicating information included previously (e.g. a same model is described in multiple documents, but



under a slightly different name)

j) Full details available in another language than specified above

Comparator(s)/ control

Not applicable.

Context

Here is the background explaining why the present work is undertaken:

Nutrient profiling is defined by the World Health Organization as "the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health" [1-2]. Nutrient profile models therefore consist of algorithms (set of rules or operations) that use a number of inputs (e.g. amounts of nutrients and other related components) to generate outputs (scores or classifications) providing an evaluation of the nutritional quality, or degree of "healthiness", of a food product [3]. Nutrient profile models can support a broad number of public health initiatives, policies or regulations, when there is a need to define clearly and objectively what constitutes "healthy" or "unhealthy" food [4]. Applications of nutrient profiling include, among others, assisting consumers in food-selection decisions in the supermarket through product or shelf labelling logos or symbols highlighting "healthier" and/or "less healthy" choices, restricting the marketing of unhealthy foods to children, food procurement regulations or guidelines for public institutions (e.g. schools and hospitals) and food taxes or subsidies for producers and consumers [5-7]. Overall, nutrient profile models are useful for ensuring regulations and programs are consistent with national dietary guidance and public health objectives in a clear and transparent manner, and to ensure that they are consistent with national objectives to reduce risk of obesity and chronic disease.

A catalogue of existing nutrient profile models and its accompanying report built by Dr. Mike Rayner and colleagues and last updated in November 2012 indicated that such models are increasingly being developed worldwide [8]. Indeed, 28 new models were included in that review as compared with a review of nutrient profile models published 5 years earlier [9], when the same inclusion criteria were applied to both reviews. However, it is stressed that the proliferation of nutrient profile models can "lead to confusion, inconsistencies between models, and possibly loss of credibility for nutrient profiling with regulators, consumers and researchers" [8, 10, 11].

To limit risks associated with the proliferation of nutrient profile models as well as time and cost constraints associated with the development and validation of a new model, it is increasingly recommended to adopt or adapt an existing model. However, an up-to-date and accessible resource summarizing existing nutrient profile models developed for public health initiatives (nutrition policy and regulation) is currently unavailable. Such a resource would be highly valuable for assisting health and nutrition professionals and policy makers in the selection of an appropriate nutrient profile model when the establishment of specific nutrition-related policies or regulations require the use of nutrient profiling.

References for this section:

1. World Health Organization. (in press) Guiding principles and framework manual for the development or adaptation of nutrient profile models (1st ed). Geneva: WHO.

2. World Health Organization. Nutrient Profiling. Available at: http://www.who.int/nutrition/topics/profiling/en/ (Accessed: August 11, 2015).

3. Scarborough P, Rayner M, Stockley L. Developing nutrient profile models: a systematic approach. Public Health Nutr 2007;10:330-6.

4. Scarborough P, Rayner M, Stockley L, Black A. Nutrition professionals' perception of the 'healthiness' of individual foods. Public Health Nutr 2007;10:346-53.

5. Lobstein T, Davies S. Defining and labelling 'healthy' and 'unhealthy' food. Public Health Nutr 2009;12:331-40.

6. Sacks G, Rayner M, Stockley L, Scarborough P, Snowdon W, Swinburn B. Applications of nutrient profiling:

potential role in diet-related chronic disease prevention and the feasibility of a core nutrient-profiling system. Eur J Clin Nutr 2011;65:298-306.

7. Rayner M, Scarborough P, Kaur A. Nutrient profiling and the regulation of marketing to children. Possibilities and pitfalls. Appetite 2013;62:232-5.

8. Rayner M. Nutrient Profiling Catalogue of Nutrient Profile Models: Summary Report. March 04, 2013 [Unpublished report prepared for the World Health Organization].

9. Stockley L, Rayner M, Kaur A. Nutrient profiles for use in relation to food promotion and children's diet: Update of 2004 literature review. Food Standards Agency, London. 2007; Available at: http://multimedia.food.gov.uk/multimedia/pdfs/publication/npliteraturereviewupdate.pdf (Accessed: July 21, 2014).

10. Emrich TE, Qi Y, Cohen JE, Lou WY, L'Abbe ML. Front-of-pack symbols are not a reliable indicator of products with healthier nutrient profiles. Appetite 2015;84:148-53.

11. Emrich TE, Cohen JE, Lou WY, L'Abbe MR. Food products qualifying for and carrying front-of-pack symbols: a cross-sectional study examining a manufacturer led and a non-profit organization led program. BMC Public Health 2013;13:846.

Outcome(s)

Primary outcomes

This systematic review aims to summarize and discuss key characteristics of nutrient profile models with applications in government-led nutrition policy and regulation, including whether these models have been validated or not, to ultimately assist public health actors in the selection of a model that is appropriate to the use for which it is intended.

Not applicable.

Secondary outcomes Not applicable.

Not applicable.

Data extraction, (selection and coding)

To enhance objectivity and avoid mistakes, the selection of studies will be performed independently by two review team members (MEL and MA). Data extraction will be performed by one team member (MEL) and verified by another (MA). Disagreements will be resolved by consensus or by involving a third review team member (MR or ML).

As indicated in 'Searches' (above), in step 1 of the search strategy (collection of information from a key review carried out previously), the two team members will start from the total of 119 models initially identified by Dr. Rayner in his November 2012 review of nutrient profile models and independently reassess each of the models based on pre-determined inclusion and exclusion criteria. Those criteria have been defined above.

In step 2 (search of the peer-reviewed literature) and step 3 (search of the grey literature), publications containing the terms "nutrient", "nutritional" or "nutrition" combined with the truncated term "profil*" in the title or abstract/summary will be retained for further evaluation, except when it will be clear that a publication is not relevant to the objective being pursued (e.g. articles about the nutrient profile of animal diets; nutrition intervention studies comparing the impact of different diets on health outcomes; studies in the field of agriculture, such as those comparing the nutrient profile of different varieties of plants/seeds). Retrieved publications that include nutrient profile models not already identified in step 1 will be assessed based on the established inclusion and exclusion criteria. Retrieved publications that include nutrient profile models already identified as part of step 1 will also be retained for evaluation as they may potentially contain additional or updated information about the models.

The data for all included models will be extracted into an Excel Workbook. Data extraction fields will be based on work undertaken previously by Dr. Rayner and colleagues and will include:

-Identifier (Model No.): All models will be given a number as they are listed (included and excluded models)

-Model name

-Does the model A) integrate data from more than one nutrient or food component to produce a single overall score or categorisation (summary indicator system) or is it B) a model that has separate sets of criteria for different nutrients and/or food components (nutrient specific system)

-Organisation (name and type) which developed the model

-Country where the model was developed

-Year of introduction or of seminal publication

-Intended Application 1

-Intended Application 2

-Target population

-No. of foods and types of foods "excluded" from consideration by the model (e.g. alcoholic drinks, food supplements)

-No. of foods and types of foods "exempted" from the model (e.g. fresh fruit and vegetables)

-Number of food categories

-List of food categories

-Does the model contain A) – positive and negative components B) – only negative components or C) – only positive components?

('Positive' means 'nutrient or food components which contribute towards a positive weighting in the context of a specific model' = nutrients or food components to encourage; 'Negative' means 'nutrient or food components which contribute towards a negative weighting in the context of a specific model' = nutrients or food components to limit)

-Positive components (e.g. vitamins/folic acid, minerals, protein, fibre, long chain fatty acids, fruit and vegetables, fish, energy)

-Negative components (e.g. total fat, SFA, TFA, cholesterol, Na, sugars, energy)

-Reference amount (e.g. per serving/per 100g/per calories)

-Further information on the "Reference amount" if needed

-Is the model intended to use compositional data before or after fortification

-Do the criteria apply to the food 'as sold' or 'as eaten'

-Outputs (score or definition(s) or both)

-If outputs are definitions then list of definitions (e.g. 'eligible to make health claim')

-Validation of the model (yes/no)

-Reference giving the model algorithm (including web-link if possible)



-Reference(s) to the development of the model

-Reference(s) to validation and/or reviews of the model

-Other references (if needed)

-Other comments (if needed)

-Date accessed

Finally, a list of excluded models including the model name, source reference and reason for exclusion will also be built.

Risk of bias (quality) assessment

Risk of bias assessment is not applicable.

Strategy for data synthesis

In the publication that will derive from this work, the information extracted from each model (detailed above under 'Data extraction') will be separated into different tables to facilitate reading and understandability. For example, the first table may include characteristics of the development of each model such as country, type of organisation, name of organisation, year of introduction, and primary applications; the second table may include key characteristics of the models such as foods exempted or excluded, food categories, nutrients included; a third table may present details of the validation of the models (i.e. validated or not, and how). We will also provide a narrative synthesis of the included nutrient profile models structured around the characteristics highlighted in the tables.

Analysis of subgroups or subsets

An overall comparison between nutrient profile models that have been validated and nutrient profile models that have not been validated may be performed to highlight potential differences in their components and constructs. This may reveal whether some types of models appear to be easier to validate than others. The same type of comparison may be performed within specific applications of the models, wherever possible.

Dissemination plans

A paper will be prepared and submitted to a scientific journal for publication. In addition, an online database will be built to permit easy comparison of the components and construct of different models and facilitate the selection by knowledge users of a nutrient profile model that is appropriate for the use it is intended (e.g. application in food labelling vs. regulation of health and nutrition claims vs. taxation), when the establishment of specific nutrition-related policies or regulations require the use of nutrient profiling.

Contact details for further information

Dr Labonte

Department of Nutritional Sciences,

Faculty of Medicine, University of Toronto,

FitzGerald Building, 150 College Street,

Toronto, ON, Canada, M5S 3E2

marieeve.labonte@utoronto.ca

Organisational affiliation of the review

University of Toronto (Department of Nutritional Sciences, Faculty of Medicine), with collaborators at the British Heart Foundation Centre on Population Approaches for Non-Communicable Disease Prevention, Nuffield Department of Population Health, University of Oxford and at the World Health Organisation

Review team

Dr Marie-Eve Labonte, Department of Nutritional Sciences, Faculty of Medicine, University of Toronto, Canada Mrs Mavra Ahmed, Department of Nutritional Sciences, Faculty of Medicine, University of Toronto, Canada Dr Mike Rayner, British Heart Foundation Centre on Population Approaches for Non-Communicable Disease Prevention, Nuffield Department of Population Health, University of Oxford, United Kingdom Dr Mary L'Abbe, Department of Nutritional Sciences, Faculty of Medicine, University of Toronto, Canada

Details of any existing review of the same topic by the same authors

This review builds on and updates work undertaken previously by one of the authors, Dr. Rayner. As detailed in Field 16, Dr. Rayner and colleagues have built a "catalogue" of existing nutrient profile models and an accompanying report which were last updated in November 2012 (Rayner M. Nutrient Profiling Catalogue of Nutrient Profile Models: Summary Report. March 04, 2013 [Unpublished report prepared for the World Health Organization]). It is stressed that inclusion and exclusion criteria used to assess the eligibility of nutrient profile models differ between this earlier review and the present review.

Anticipated or actual start date

08 September 2015

Anticipated completion date

31 May 2016

Funding sources/sponsors

This review is funded through a grant of the Burroughs Wellcome Foundation. Additionally, MEL is funded by a postdoctoral fellowship of the Canadian Institutes of Health Research (CIHR) to work on nutrient profiling.

Conflicts of interest

MR has given talks on the topic of nutrient profiling at workshops, seminars, and conferences for which travel and accommodation has been paid for by the organisers which have included the World Health Organisation. Funding for MR's research centre (including his salary) comes from the British Heart Foundation.

ML has given talks on the topic of nutrient profiling at workshops, meetings or conferences for which the registration and/or travel expenses have been paid for by the organisers: 1) World Health Organization Meeting on the "Development of a single Regional nutrient profiling model for purposes of reducing marketing of foods high in fat, sugar and salt to children" Copenhagen, Denmark, December 16 - 17, 2013; 2) IUNS 20th International Congress of Nutrition, Granada, Spain, September 19, 2013; 3) FAO/WHO Codex Committee workshop to provide information to Codex Committee on Food Labelling delegates and observers regarding various issues related to front-of-pack labelling (FOP), Charlottetown, Canada, 2013.

MEL and MA declare that they have no known conflicts of interest.

Other registration details None.

Language English

Country England, Canada

Subject index terms status Subject indexing assigned by CRD

Subject index terms

Food; Humans; Models, Theoretical; Nutrition Policy

Any other information

Worldwide, government bodies increasingly recognize the importance of using objective and transparent methods for distinguishing between different foods according to their nutritional quality for policy and regulatory purposes (e.g. Reports from the Institute of Medicine on Front of Pack Labelling [1], Canadian Standing Committee on Health [2], WHO [3], US Federal Trade Commission recommendations on marketing to children [4]). Nutrient profiling fits this purpose, but as indicated earlier, an up-to-date and accessible resource summarizing existing nutrient profile models developed for or used in various public health and policy or regulatory initiatives is currently unavailable. The resource that we are developing will be highly valuable for assisting public health actors (e.g. health and nutrition professionals, policy makers) in the selection of a model that is appropriate for the use it is intended (e.g. application in food labelling vs. regulation of health and nutrition claims vs. taxation). Based on the recent proliferation of nutrient profile models, this resource will help to identify models that could be adapted for a specific purpose instead of undertaking the creation of a new model and permit easy comparison of the components and construct of different models. This resource will also help to identify gaps that need to be addressed in the area of nutrient profiling, such as the potential lack of demonstrated validity for many of the existing models.

References for this section:

1. Institute of Medicine. Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices: Washington DC: The National Academies Press, 2011;

2. The Standing Committee on Health. Healthy Weights for Healthy Kids. 2007; Available at: http://www.sportmatter s.ca/files/Groups/SMG%20Resources/Health/2007-Healthy%20weights%20for%20healthy%20kids.pdf (Accessed: July 21, 2014);

3. World Health Organization. Nutrient profiling: report of a technical meeting: London, United Kingdom, 4-6 October 2010. 2010. Available at: http://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010/en/ (Accessed: July 21, 2014);

4. Federal Trade Commission. A Review of Food Marketing to Children and Adolescents - Follow-Up Report. 2012. Available at: http://www.ftc.gov/reports/review-food-marketing-children-adolescents-follow-report (Accessed: July 21, 2014).

Stage of review Ongoing

Date of registration in PROSPERO 13 August 2015

Date of publication of this revision 13 August 2015

DOI

10.15124/CRD42015024750

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

PROSPERO International prospective register of systematic reviews



The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.