

Vleesvervangers en zuivelvervangers en chronische ziekten

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1 Introduction

This background document belongs to the advisory report *Dutch dietary guidelines: dietary protein sources and dietary patterns 2025 (DDG2025)*.¹ It describes the methodology for the search, selection and evaluation of the literature regarding the effects and associations of meat and dairy substitutes with health outcomes. It also describes the scientific evidence on this topic. This background document has been prepared by the Health Council's committee on Nutrition. A list of the committee members can be found in the advisory report.¹

1.1 Definition of meat alternatives and dairy substitutes

The committee defines substitutes for meat and dairy as products that are (largely) made from plant-based proteins. These products are ready to eat or ready to prepare (such as baking), and the most common names are meat substitutes and dairy substitutes. These products are often marketed to replace meat or dairy in the diet and are often used as such by the consumer.

Fish substitutes are not part of this background document because there was too little research on the health effects of these products.

Meat and dairy substitutes are a very diverse group of products, even within the subgroups of meat substitutes and dairy substitutes. Factors causing the diversity include, for example, the main protein source used for the alternative (e.g. soy, pea, wheat or mycoprotein) and the type and extent of fortification (i.e. the addition of micronutrients to foods). As a result, the nutritional composition of meat and dairy substitutes varies greatly.²

1.2 Intake in the Netherlands

According to the most recent Dutch National Food Consumption Survey (DNFCS) of 2019-2021, less than half of the Dutch adult population aged 18 to 67 years consumes meat substitutes or milk substitutes. Also, these products are generally not consumed on a daily basis. On a day that meat or milk substitutes are consumed, the average consumption is 85 and 240 grams, respectively (Table 1). The average daily intake of meat and milk substitutes is 6 and 14 grams, respectively, when both consumption days and non-consumption days are considered.^{3,4}

Since 2007-2010, the mean consumption and number of consumption days of both meat substitutes and milk substitutes have increased, while the total consumption of meat and meat products (including meat substitutes) and dairy and dairy products (including dairy substitutes) decreased.³

Table 1 Observed consumption of meat substitutes and milk substitutes in grams per day in Dutch adults aged 18-79 years according to the Dutch National Food Consumption Survey 2019-2021⁴

	All measurement days				Consumption days ^a			
	Mean	P5	P50	P95	Mean	P5	P50	P95
Meat alternatives	6	0	0	46	84	NR	NR	NR
Milk alternatives	14	0	0	101	241	NR	NR	NR

Abbreviations: NR: not reported.

^a % consumption days = 7% for meat alternatives and 6% for milk alternatives (= approximately once every two weeks).

2 Methodology

Below, the methodology used for the evaluation of the evidence is presented. In addition, a description is given of the selection of literature on the topic of meat substitutes and dairy substitutes in relation to health outcomes.

2.1 Health outcomes

The committee focused on the health outcomes described below.

Chronic diseases:

Similar to the approach used for the Dutch dietary guidelines 2015 (DDG2015),⁵ the committee focused on the most common chronic diseases (that are potentially nutrition related) in the Netherlands.^{6,7} These include: coronary heart disease (CHD), stroke, heart failure, type 2 diabetes, cancer subtypes (colorectal cancer and breast cancer), obesity (in some evaluations combined with overweight), depression, chronic obstructive pulmonary disease (COPD) and dementia. Furthermore, evidence for total cardiovascular disease (CVD) and total cancer was included, but only in case the committee expected (based on the quick scans, described below) that such evidence would provide additional insights (on top of the evidence focused on the afore and below listed outcomes) that could be of added value for drawing up or changing a dietary guideline. The committee preferred to use evidence for CVD subtypes and cancer subtypes because these may have different aetiologic pathways related to different dietary exposures. Total CVD and total cancer comprise different subtypes and therefore provide less specific insights in the aetiology underlying the relationships between dietary factors and chronic diseases.

The committee focused on studies that addressed primary prevention of chronic diseases. This means that the relationship between a dietary factor and development of a chronic disease was investigated in people who did not have the disease at the start of the study. Moreover, in general, the committee preferred to base its evaluation on studies that addressed non-fatal events or the combined outcome of fatal and non-fatal events (thus: not solely focussed on fatal events) because the availability and quality of care may play a larger role in the outcome of fatal, compared to non-fatal events. Exceptions to this were made in case there were aetiological reasons to specifically address fatal events (e.g. for fish and fatal cardiovascular outcomes).

Causal risk factors and other short-term outcomes:

These include the following: blood pressure (systolic and diastolic), low-density lipoprotein (LDL) cholesterol, body weight, glycated haemoglobin (HbA1c) and estimated glomerular filtration rate (eGFR).

Causal risk factors are thought to capture the causal pathway that leads to the disease outcome and can be seen as replacement endpoints for the disease of interest.⁸ Because of this, the committee considers that an effect on a causal risk factor will also lead to an effect on chronic disease risk. An example is LDL cholesterol as causal risk factor for CHD and stroke. The advantage of using causal risk factors (and other short-term outcomes) in experimental studies is that they usually need considerably fewer participants and shorter study durations (usually several weeks to months) than studies investigating morbidity or mortality outcomes. For instance, dietary effects on LDL cholesterol can be identified in just a few weeks, compared to several years for CHD. Similar to the approach used in 2015, blood pressure, LDL cholesterol and body weight were selected as causal risk factors. As explained in the DDG2015 background document on methodology,⁵ these factors have been shown to have a causal relationship with at least one of the following chronic diseases: CHD, stroke, heart failure and type 2 diabetes. More recent evidence confirms the causality, presented below.

Blood pressure: A meta-analysis of 48 randomised controlled trials (RCTs) confirmed that multiple blood pressure lowering treatments, including more versus less intensive treatments, reduce the risk of cardiovascular events, including CHD and stroke. This was found in people with and without CVD.⁹ Moreover, Mendelian randomisation studies support that blood pressure is causally associated with the risk of CHD and stroke.^{10,11}

LDL cholesterol: Recent reports confirmed that numerous and different types of studies, including prospective cohort studies, RCTs and Mendelian randomisation studies, have convincingly shown that higher LDL cholesterol causes cardiovascular events, such as CHD.¹² The evidence from RCTs is based on various interventions performed among both primary and secondary prevention trials: A meta-analysis of 49 RCTs showed that the use of statin and various non-statin therapies, including diet, that reduce LDL cholesterol, reduce the risk of cardiovascular events.¹³ In line with the committee, the European Food Safety Authority (EFSA) also acknowledges that reducing blood LDL cholesterol (by dietary modification and drugs) would generally reduce the risk of development of CHD.¹⁴

Body weight: Recent reports confirmed the importance of weight loss via various interventions for the prevention of type 2 diabetes, based on RCTs.^{15,16} Moreover, the causal role of both general and central adiposity, indicated by body mass index and waist-to-hip ratio respectively, in the development of type 2 diabetes and other chronic diseases has been confirmed in Mendelian randomisation studies.¹⁷ Besides body weight, the committee also searched for literature with waist circumference as

outcome, because this may also reflect the causal pathway from adiposity to type 2 diabetes. However, very few relevant studies with this endpoint were found, and that evidence did not contribute to the guidelines.

HbA1c and eGFR: These factors were not yet included in 2015, and were added for the 2025 advisory report because these are important diagnostic indicators of chronic diseases (elevated HbA1c for type 2 diabetes and long-term decline in eGFR for chronic kidney disease).¹⁸⁻²⁰ However, in practice, insufficient research focussed on these factors was found to include in the committee's evaluations.

Other outcomes:

These include the following: all-cause mortality, quality of life, perceived health and fertility.

The committee additionally searched for evidence focused on quality of life, perceived health and fertility, which could be considered as supportive evidence for the guidelines. However, in practice, insufficient evidence on these outcomes, which fulfilled the inclusion criteria of the committee, was found.

Evidence focused on the all-cause mortality outcome was additionally evaluated, but only in case the committee expected (based on the quick scans, described below) that such evidence would provide additional insights that could be of added value for drawing up or changing a dietary guideline. The reason for this is similar to that described above, for the total CVD and total cancer outcomes.

2.2 Type of studies

The committee evaluated the state of science for each dietary factor – health outcome combination, based on meta-analyses (MAs) and pooled analyses. In MAs, reported results of multiple individual studies are combined and analysed. In pooled analyses, individual participant data of multiple studies are combined and analysed.

he committee selected MAs and pooled analyses of the following type of studies:

- Randomised controlled trials (RCTs) into effects of dietary factors on the incidence of morbidity/mortality due to a disease;
- RCTs into effects of dietary factors on causal risk factors;
- Prospective cohort studies into associations of dietary factors with morbidity or mortality due to disease.

Substitution analyses

In some of the background documents, substitution analyses were also included as a part of the evaluation. In RCTs, substitution was based on comparisons of the effects of consumption of two diets, each with another dietary protein source (keeping the rest of the diet as similar as possible). In observational cohort studies, substitution was hypothetically investigated by statistical modelling based on (baseline) dietary intake

data. Because substitution did not actually take place in observational cohort studies, the committee interpreted the evidence as associations for dietary protein source 1 versus dietary protein source 2 with disease outcomes.

Mendelian randomisation studies

The committee additionally considered evidence from Mendelian randomisation studies, to serve as potential supportive evidence for certain guidelines. In Mendelian randomisation studies, genetic variants are used to investigate causal associations between dietary intake and risk of chronic diseases.²¹ Only for the topic of dairy products, relevant Mendelian randomisation studies were found, as further explained in the background document on dairy products and chronic diseases.²²

2.3 Quick scans and consulted literature

For efficiency reasons, the committee decided to make use of recent reports of other organisations where possible. To this end, quick scans were performed at the start of the advisory trajectory (2023). These quick scans were aimed at summarising the state of science in an efficient way and to identify aspects on which the dietary guidelines may need to be updated.

To identify differences and similarities compared to the DDG2015, the guidelines for each specific dietary factor (e.g. fruits and vegetables, fats and oils or dairy products) were compared to the recent advices on these dietary factors of the *Nordic Nutrition Recommendations 2023 (NNR2023)*,²³ and the *Dietary Guidelines for Americans 2020-2025 (DGA2020)*.²⁴ Moreover, the conclusions and findings regarding the relationships of dietary factors with health outcomes reported in the DDG2015 were compared to conclusions and findings reported in the background documents of the NNR2023 and of the DGA2020. In addition, and based on the above referred documents, the committee identified topics for which there may now be sufficient evidence to draw conclusions on, where this was not yet possible in 2015. Specifically for the topic of meat substitutes and dairy substitutes, the committee also consulted the recent advisory report *A healthy protein transition (2023)* from the Health Council of the Netherlands.²⁵

Based on the quick scan, the committee noted the following:

- For the DDG2015, no studies into meat, dairy or fish substitutes were evaluated. Therefore, a comparison with the evidence from the 2015 version of the guidelines could not be made for this topic.
- The committee noted that the topics of meat, dairy and fish substitutes was not included in the NNR2023 advisory report. The NNR committee also prepared no background paper on this topic.

- The DGA2020 and underlying scientific reports contain very little information on meat, dairy and fish substitutes. However, the DGA committee did, in its scientific report, evaluate the relationships between consumption of milk substitutes with growth, body composition and risk of obesity in children and with body composition and risk of obesity in adults and older adults. Its conclusion was that no conclusion statements could be drawn about these relationships because there was not enough evidence available.
 - A literature search for the advisory report *A health protein transition* (published in 2023) yielded no studies into health effects of meat, dairy and fish substitutes.²⁵
- Overall, the committee concluded that, at the moment of the quick scan, there appeared to be very few studies available on the health effects of meat substitutes or dairy substitutes.

Considering that this group of food products is relatively new and very limited included in the above reports, the committee judged that a systematic literature search for recent studies on health effects of meat substitutes and dairy substitutes would be of additional value. The committee performed systematic literature searches in PubMed and Scopus. For this topic specifically, it searched for individual RCTs and prospective cohort studies, and not for MAs or SRs (the committee's usual approach), because the quick scans suggested that there are few studies on this subject. More details on the search can be found in Annex A.

In addition to the publications retrieved via the sources reported above, the committee was aware of, or informed via public consultation, of four recent MAs on the topic of substitutes for meat, fish and dairy through the Health Council's public consultation.²⁶⁻²⁹ that fit within the inclusion criteria of the committee. The committee took these MAs also into account for its evaluation.

2.4 Evaluation of evidence

The vast majority of studies included in the committee's evaluation addressed meat substitutes and/or dairy substitutes, and therefore the focus of this background document is on these food products. For each dietary factor-health outcome combination, an evaluation of the state of science was performed, further explained below.

2.4.1 Drawing conclusions based on a decision tree

The findings from prospective cohort studies and RCTs were separately evaluated by the committee. Per dietary factor – health outcome combination, a table summarising the main characteristics and results of the major MA(s) and/or pooled analyse(s) that contributed to the evaluation was presented. Below the summary table, the committee gave the conclusion, for which there are six fixed options:

- There is an association/effect with a strong level of evidence;
- There is an association/effect with a limited level of evidence;
- An association/effect is unlikely;
- The evidence is inconclusive;
- The evidence is contradictory;
- There is too little research.

The conclusions on (the certainty of) the evidence regarding the effect or association between consumption of meat substitutes and dairy substitutes and health outcomes were based on the number of studies, number of participants and number of cases that contributed to the evaluation. Also, the committee took the quality of the studies, in particular the risk of bias, and the heterogeneity in findings between studies, into account. The committee used the decision tree (presented in Annex B) as a guidance tool to support consistency in drawing conclusions. This decision tree was also applied by previous committees of the Health Council,³⁰⁻³² and includes elements that are also present in other evaluation methods for determining the quality and certainty of scientific evidence, such as GRADE (for example: heterogeneity and risk of bias).³³ The formulation of conclusions was different for RCTs than for cohort studies: RCTs allowed statements about effects (causality) to be made, whereas cohort studies only allowed statements about associations to be made.

The conclusion was followed by a text in which the conclusion was explained and in which the committee presented the publications assessed in connection with the conclusion. This text was accompanied by a table that showed relevant details related to the included studies.

2.4.2 Extensiveness of evaluation

Per dietary factor – health outcome combination, the committee decided on the level of detail of its evaluation. Extensive evaluations were performed for dietary factor – health outcome combinations of which conclusions could potentially be leading for drawing up a new guideline or changing an existing guideline. Remaining dietary factor – health outcome combinations, of which conclusions unlikely changed compared to 2015 or could only be supportive to a guideline, were evaluated less extensively.

The differences between conclusions that are leading and those that are supportive for drawing up a guideline are described in Chapter 2 of the advisory report.¹

In extensive evaluations, the committee drew formal conclusions based on the decision tree, and presented the evaluation according to the format described in Section 2.4.1.

In less extensive evaluations, the committee did not draw such formal conclusions.

Instead, the state of science was briefly (with less details) summarised in text with an accompanying table. Such a less extensive evaluation was in particular done to check whether potential effects or associations with remaining subtypes of exposures and

remaining health outcomes were indeed in a supportive direction, or at least not in an opposite direction as compared to the conclusions on the exposure subtypes and outcomes that were extensively evaluated.

The committee performed, in principle, only (extensive and less extensive) evaluations of dietary factor – health outcome relationships when at least 5 individual studies of a specific study type were included in the selected MAs and/or pooled analyses. This was done because at least 5 studies are needed to qualify the evidence as strong, and because only conclusions with a strong level of evidence are considered for drawing up the dietary guideline (see Chapter 2 of the advisory report¹). The committee could decide to make exceptions in this approach, based on expert judgement of the evidential value, public interest and extent of scientific discussion.

Considerations with respect to dietary guidelines

The evidence on effects and associations of meat substitutes and dairy substitutes with chronic disease risk are described in Chapter 3 of this background document.

The (methodology used for the) translation of the totality of evidence into dietary guidelines is described in the advisory report.¹

For the topic of meat substitutes and dairy substitutes, the committee concluded, based on the quick scans and selected recent literature, that there was not sufficient evidence for drawing up a dietary guideline on meat substitutes and dairy substitutes. This was particularly due to the large diversity between studies in terms of exposures, health outcomes and study designs. The committee therefore particularly described the study findings in broad terms (less extensive evaluations). There was one exception: the committee did expect sufficient research regarding the effect of soy drink versus cow's milk on LDL-cholesterol and blood pressure to formulate conclusions with strong evidence. Therefore, an extensive evaluation was carried out for this substitution. However, the committee noted that this is a very specific substitution and that soy drink is not representative for the broader food group of dairy substitutes.

3 Evaluation of the evidence

This chapter describes the evaluation of the scientific evidence on the associations or effects of consumption of meat and dairy substitutes with risks of chronic diseases or causal risk factors. Evaluations are grouped according to dietary exposure.

3.1 Meat substitutes and dairy substitutes combined

3.1.1 Multimorbidity (combination of CVD, type 2 diabetes or cancer)

The committee found one MA evaluating the association of consumption of meat substitutes and dairy substitutes with the risk of chronic disease: the MA by Cordova et al.²⁶ Specifically, Cordova et al. examined the association with the risk of multimorbidity, which they defined as the occurrence of at least two of the following chronic diseases: CVD, type 2 diabetes and cancer. Although multimorbidity is not selected as health outcome for this advisory report, the chronic diseases included in this definition are. Therefore, the committee decided to perform an evaluation based on the findings of this MA, especially since this is the only publication found on chronic disease risk. As explained in section 2.4.2, the committee performed a less extensive evaluation because it judged that, due to the large diversity between studies (and more specifically, the diversity in exposures and outcomes in the current evaluation), the evidence would unlikely contribute to a potential guideline on meat substitutes and dairy substitutes.

Based on a pooled analysis of EPIC cohorts from 7 European countries, Cordova et al.²⁶ found no association between consumption of meat and dairy substitutes with the risk of multimorbidity in men and women who were free of cancer, CVD and type 2 diabetes at baseline (Table 2). The exposure (meat and dairy substitutes) was not further specified in the publication. Median follow-up was 11.2 years. The committee judged that the interpretation of the study findings is complicated by the lack of subgroup analyses for meat substitutes and dairy substitutes separately, and for each of the three aforementioned chronic diseases. Therefore, it remains unclear to what extent these findings are representative for all exposures and outcomes included in the study.

Table 2 Characteristics and results of a pooled analysis of prospective cohort studies on the association between consumption of meat substitutes and dairy substitutes with risk of multimorbidity (combination of two of the following: cardiovascular disease, type 2 diabetes, cancer)

Author, year, study design	Exposure	n PCS; n cases	Strength of the association: HR (95%CI)	I^2
Cordova et al. 2023 ²⁶ <i>Pooled EPIC analysis</i>	Plant-based alternatives for meat and dairy	7; 4416	Per +1 SD: 0.97 (0.91, 1.02)	NA

Abbreviations: CI: confidence interval; EPIC: European Prospective Investigation into Cancer and Nutrition; HR: hazard ratio; NA: not applicable; PCS: prospective cohort studies; SD: standard deviation.

3.2 Meat substitutes

3.2.1 LDL cholesterol

The committee is aware of two MAs evaluating the effect of consumption of meat substitutes on LDL cholesterol: the MAs by Fernández-Rodríguez et al.²⁷ and Gibbs et al.²⁸ As explained in section 2.4.2, the committee performed a less extensive evaluation because it judged that, due to the large diversity between studies (particularly the diversity in exposures in the current evaluation), the evidence would unlikely contribute to a potential guideline on meat substitutes.

The MA by Fernández-Rodríguez et al. includes 7 RCTs with a total of 369 participants. The MA by Gibbs et al. includes 11 RCTs with a total of 420 participants. Most RCTs included European populations. Both MAs showed a statistically significant reducing effect of consumption of meat substitutes as compared to meat, fish, dairy or a habitual (omnivorous) diet on the LDL cholesterol (Table 3). Also, both MAs showed substantial heterogeneity between studies, in size of the effect, not in direction. In the MA by Fernández-Rodríguez et al., the committee noted some (mainly methodological) concerns. First, the duration of intervention of some RCTs was relatively short (1 week). Second, most RCTs were industry-funded. Third, it is unknown if the intervention and control diets were isocaloric. The committee furthermore noted that the control interventions were very diverse and appeared to include not only meat (but also other animal products such as fish or dairy). Regarding the MA by Gibbs et al., the committee noted that the control intervention was not specified (omnivorous diet) and may thus be very diverse. Also, Gibbs et al. reported that there was evidence of funnel plot asymmetry, and that adjustment for funnel plot asymmetry with the imputation of five studies resulted in a reduced effect size and loss of statistical significance (0.21 (-0.43; 0.01) mmol/L).

Table 3 Characteristics and results of the meta-analyses of RCTs on the effect of consumption of meat substitutes compared to various controls on the LDL cholesterol

Author, year, study design	Intervention (n); comparison (n)	n RCTs; n participants	Strength of the effect: MD (95%CI), mmol/L	I ²
Fernández-Rodríguez et al. 2025 ²⁷ MA	i: mycoprotein-based alternatives (4), PBMA (3); c: meat (3), meat or fish (1), meat, fish or dairy (1), animal-based product (1), habitual diet (1)	7; i: 174, c: 175 (total: 369)	-0.25 (-0.42, -0.08)	66% ^a
Gibbs et al. 2023 ²⁸ MA	i: mycoprotein-based alternatives (3), other PBMA (3), textured soy protein (5); c: omnivorous diet (11)	11; i: 261; c: 159 (total: 420)	-0.39 (-0.57, -0.21)	67% ^b

Abbreviations: c: control group; CI: confidence interval; i: intervention group; LDL: low-density lipoprotein; MA: meta-analysis; MD: mean difference; n: number; PMBA: plant-based meat alternative; RCT: randomised controlled trial.

^a Heterogeneity in magnitude of the effect, not in direction. Heterogeneity not explained by health status (healthy vs overweight/T2D/hypercholesterolemia) and type of intervention (mycoprotein-based or other).

^b Heterogeneity in magnitude of the effect, not in direction. Heterogeneity not explained by age, study duration, baseline BMI or sex. Sample size might be a source of heterogeneity.

3.2.2 Blood pressure

The committee is aware of two MAs evaluating the effect of consumption of meat substitutes on blood pressure: the MAs by Fernández-Rodríguez et al.²⁷ and Gibbs et al.²⁸ As explained in section 2.4.2, the committee performed a less extensive evaluation because it judged that, due to the large diversity between studies (particularly the diversity in exposures in the current evaluation), the evidence would unlikely contribute to a potential guideline on meat substitutes.

The MA by Fernández-Rodríguez et al. includes 4 RCTs with 126 participants in the intervention group and 124 participants in the control group. The MA by Gibbs et al. includes 7 RCTs with a total of 217 and 122 participants in the intervention group and control group, respectively. Both MAs showed no effect of consumption of meat substitutes as compared to meat or a habitual (omnivorous) diet on either systolic or diastolic blood pressure (Table 4). The MAs showed little to moderate heterogeneity between studies: effect estimates are both below and above 0 (based on forest plots), but in no case statistically significant.

Table 4 Characteristics and results of the meta-analyses of RCTs on the effect of consumption of plant-based meat alternatives compared to various controls on systolic and diastolic blood pressure

Author, year, study design	Intervention (n); comparison (n)	n RCTs; n participants	Strength of the effect: MD (95%CI), mmHg	I ²
Fernández-Rodríguez et al. 2025 ²⁷ MA	i: mycoprotein-based alternatives (1), other PBMSs (3);	4; i: 126, c: 124	SBP: -0.21 (-2.52, 2.11)	34%
	c: meat (2), animal-based product (1), habitual diet (1)		DBP: -0.06 (-1.63, 1.51)	32%
Gibbs et al. 2023 ²⁸ MA	i: PBMS (not mycoprotein-based; 4), textured soy protein (3); c: omnivorous diet (7)	7; i: 217, c: 122	SBP: -0.32 (-1.79, 1.14) DBP: 0.49 (-0.30, 1.28)	18% 0%

Abbreviations: c: control group; CI: confidence interval; DBP: diastolic blood pressure; i: intervention group; LDL: low-density lipoprotein; MA: meta-analysis; MD: mean difference; n: number; PMBA: plant-based meat substitute; RCT: randomised controlled trial; SBP: systolic blood pressure.

a Heterogeneity in magnitude of the effect, not in direction. Heterogeneity not explained by health status (healthy vs overweight/T2D/hypercholesterolemia) and type of intervention (mycoprotein-based or other).

b Heterogeneity in magnitude of the effect, not in direction. Heterogeneity not explained by age, study duration, baseline BMI or sex. Sample size might be a source of heterogeneity.

3.2.3 Body weight

The committee is aware of two MAs that addressed the effect of consumption of meat substitutes on body weight: the MAs by Fernández-Rodríguez et al.²⁷ and Gibbs et al.²⁸ Due to the large diversity between studies, the committee decided to perform a less extensive evaluation. As explained in section 2.4.2, the committee performed a less extensive evaluation because it judged that, due to the large diversity between studies (particularly the diversity in exposures in the current evaluation), the evidence would unlikely contribute to a potential guideline on meat substitutes.

The MA by Fernández-Rodríguez et al. includes 5 RCTs with 136 participants in the intervention group and 134 participants in the control group. The MA by Gibbs et al. includes 5 RCTs with a total of 168 and 126 participants in the intervention group and control group, respectively. A statistically significant reducing effect of consumption of meat substitutes as compared to meat, fish or a habitual (omnivorous) diet on body weight was observed in the MA by Fernández-Rodríguez et al., whereas Gibbs et al. did not find an effect (Table 5). In both MAs, there was no heterogeneity between studies observed. For the MA by Fernández-Rodríguez et al., the committee noted some (mainly methodological) concerns. First, the duration of intervention of some RCTs was relatively short (1 or 2 weeks). Second, most RCTs were industry-funded. Third, it is unknown if the intervention and control diets were isocaloric. The committee furthermore noted that the control interventions were very diverse and appeared to include not only meat (but also other animal products such as fish). Regarding the MA

by Gibbs et al., the committee noted that the control intervention was not specified (omnivorous diet) and may thus be very diverse.

Table 5 Characteristics and results of the meta-analyses of RCTs on the effect of consumption of meat substitutes compared to various controls on body weight

Author, year, study design	Intervention (n); comparison (n)	n RCTs; n participants	Strength of the effect: MD (95%CI), kg	<i>I</i> ²
Fernández-Rodríguez et al. 2025 ²⁷ MA	i: mycoprotein-based alternatives (2), other PBMSs (3); c: meat (2), meat or fish (1), animal-based product (1), habitual diet (1)	5; i: 136, c: 134	-0.72 (-1.02, -0.42)	0%
Gibbs et al. 2023 ²⁸ MA	i: PBMSs (2), textured soy protein (3); c: omnivorous diet (5)	5; i: 168; c: 126	-0.12 (-1.52, 1.27)	0%

Abbreviations: c: control group; CI: confidence interval; i: intervention group; MA: meta-analysis; MD: mean difference; n: number; PMBA: plant-based meat substitute; RCT: randomised controlled trial.

3.3 Soy drink (versus cow’s milk)

3.3.1 LDL cholesterol

The committee selected one MA on the effect of consumption of soy drink versus cow’s milk on LDL cholesterol: Erlich et al.²⁹ The MA suggests a beneficial effect on LDL cholesterol, and was extensively evaluated by the committee.

Summary of evidence for the effect of soy drink as compared to cow’s milk on LDL cholesterol

Aspect	Explanation
Available studies	1 meta-analysis including 10 RCTs ²⁹
Heterogeneity	No
Strength of the effect	Mean difference (95%CI) for consumption of soy drink versus cow’s milk: -0.19 (-0.29, -0.09) mmol/L
Consumption level examined	236 to 1000 ml/d soy drink (median 500 ml)
Study populations	Europe, United States of America, Australia, South America, Asia

Conclusion: Under isocaloric conditions, replacement of 240 to 1000 ml/d cow’s milk with 240 to 1000 ml/d soy drink decreases LDL cholesterol with 0.20 mmol/L on average

Evidence level: Strong

Explanation

The MA of Erlich et al.²⁹ was included in the committee’s evaluation of consumption of soy drink versus cow’s milk and the effects on LDL cholesterol. The MA included 10 RCTs, together including 312 participants. Participants with any health status were

included, including healthy people (n=2 RCTs), postmenopausal women (n=1 RCT), people with hypercholesterolemia (n=4 RCTs), overweight or obesity (n=1 RCT) and type 2 diabetes (n=2 RCTs). Study durations varied from 4 to 6 weeks.

The RCTs investigated energy-matched substitutions of soy drink with cow's milk. Some of the RCTs used fortified soy drinks, some used unfortified soy drinks, and for some it was unknown. Six RCTs addressed sweetened soy drink, and 4 RCTs non-sweetened. The investigated quantities of soy drink and cow's milk varied from 236 to 1000 ml/d. None of the RCTs were energy-restricted.

There was a statistically significant decrease of 0.19 mmol/L in LDL cholesterol with consumption of soy drink compared to cow's milk (Table 6). There was no heterogeneity between studies, and removal of any RCT at a time did not affect the result. There was no substantial difference in the effect of cow's milk versus sweetened and unsweetened soy drink. In addition, the authors reported there was no evidence of a dose-response relationship.

There were no statistically significant subgroup differences by health status, age, amount of milk fat, study design, follow-up time, funding of the RCT, or soy protein dose. However, there was a tendency towards stronger effects in people with a higher LDL cholesterol at baseline, in RCTs with a cross-over design, and in RCTs with higher soy protein doses.

Erlich et al. judged the risk of bias with the Cochrane RoB tool 2.0. All but one RCTs were judged as low risk of bias. One RCT was judged as moderate risk of bias.

Excluding this study did not substantially change the MA result. There was no evidence of publication bias.

Four RCTs were entirely or partly funded by industry. Results were not substantially different between agency and industry funded studies. The work for the MA was partly funded by the United Soybean Board (the United States Department of Agriculture Soybean Checkoff Program). The authors reported that the sponsors had no role in the work related to the MA. In addition, one of the MA authors reported a relationship with the Soy Nutrition Institute Global, an organisation that receives partial funding from the United Soybean Board.

Based on the above, and taking into account the decision tree, the committee concluded there is strong evidence that isocaloric replacement of 240 to 1000 ml/d cow's milk with 240 to 1000 ml/d soy drink decreases LDL cholesterol with 0.20 mmol/L. The number of studies and participants included in the evaluation is sufficient for drawing such a conclusion with strong evidence, and there were no major considerations that may downgrade the certainty of the evidence. The quantification of the conclusion is based on the observation that there was no heterogeneity between

studies and, based on the dose-response curve, there were no substantial differences in increase of LDL cholesterol with relatively higher soy drink and cow's milk consumption within the range of 236 to 1000 ml/d.

Table 6 Characteristics and results of a meta-analysis of randomised controlled trials on the effect of soy drink compared to cow's milk consumption on LDL cholesterol

Author, year, study design	n RCTs; n participants	Intervention; comparison	Strength of the effect: MD (95%CI), mmol/L	I ²	Study population (n)	Risk of bias (n)
Erlich 2024 ²⁹ MA	10; 312	i: soy drink: 236 to 1000 ml/d; c: cow's milk: 236 to 1000 ml/d. Diets were isocaloric	-0.19 (-0.29, -0.09)	0%	Europe (3), USA (2), Asia (3), South America (1), Australia (1)	Low (9) Moderate (1)

Abbreviations: c: control group; CI: confidence interval; i: intervention; MA: meta-analysis; MD: mean difference; mmol/L: millimoles per litre; RCT: randomised controlled trial; USA: United States of America.

3.3.2 Blood pressure

The committee selected one MA on the effect of consumption of soy drink versus cow's milk on blood pressure: Erlich et al.²⁹ The MA suggests a beneficial effect on blood pressure, and was extensively evaluated by the committee.

Summary of evidence for the effect of soy drink as compared to cow's milk on systolic and diastolic blood pressure

Aspect	Explanation
Available studies	1 meta-analysis including 5 RCTs ²⁹
Heterogeneity	Yes, in magnitude, not in direction
Strength of the effect	Mean difference (95%CI) for consumption of soy drink versus cow's milk: Systolic blood pressure: -8.00 (-14.89, -1.11) mmHg Diastolic blood pressure: -4.74 (-9.17, -0.31) mmHg
Consumption level examined	240 to 1000 ml/d soy drink
Study populations	Europe, Asia

Conclusion: Under isocaloric conditions, replacement of cow's milk with soy drink decreases systolic and diastolic blood pressure

Evidence level: Limited

Explanation

The MA of Erlich et al.²⁹ (2024) was included in the committee's evaluation of the consumption of soy drink versus cow's milk and the effects on systolic and diastolic blood pressure (Table 7). The MA included 5 RCTs, together including 158 participants. Participants with any health status were included, including people with

hypertension (n=1 RCT), overweight or obesity (n=2 RCTs), or type 2 diabetes (n=2 RCTs). No RCTs in healthy people were included. Study durations varied from 4 to 12 weeks. Most of the RCTs were performed in Asia (Iran).

The RCTs investigated energy-matched substitutions of cow's milk with soy drink. Some of the RCTs used fortified soy drink, some used unfortified soy drinks, and for some it was unknown whether the soy drink was fortified. The investigated quantities of soy drink and cow's milk varied from 240 to 1000 ml/d, with 4 RCTs examining 240 ml, and 1 examining 1000 ml/d. Two of the RCTs were energy-restricted, the other three were not.

The MA of Erlich et al. found a statistically significant decrease of 8.0 mmHg in systolic and 4.7 mmHg in diastolic blood pressure with consumption of soy drink compared to cow's milk. There was substantial heterogeneity between studies, that was only in magnitude, and not in directions of the effect, and not further explained by the MA authors. There were not sufficient data to perform dose-response analyses or subgroup analyses. The increasing effect seemed largely driven by 2 RCTs. Removal of each RCT at a time led, in some cases, to attenuation of the effect or loss of significance of the effect.

Erlich et al. judged the risk of bias based on the Cochrane Risk of Bias tool 2.0. All RCTs were judged as low risk of bias. There were not sufficient studies included to test for potential publication bias. Two RCTs were funded by agencies, and for the remaining three RCTs the funding sources were unknown. The work for the MA was partly funded by the United Soybean Board. The authors reported that the sponsors had no role in the work related to the MA. In addition, one of the MA authors reported relationships with the Soy Nutrition Institute Global, an organisation that receives partial funding from the United Soybean Board.

Based on the above and taking into account the decision tree, the committee concluded there is limited evidence that isocaloric replacement of cow's milk with soy drink decreases systolic and diastolic blood pressure. The number of studies and participants included in the evaluation was just sufficient for drawing a conclusion with strong evidence. However, the effect on blood pressure was heterogeneous, and largely driven by only 2 RCTs. Also, the findings were not always robust in sensitivity analyses. Therefore, the evidence was judged as limited by the committee.

Table 7 Characteristics and results of a meta-analysis of randomised controlled trials on the effect of soy drink compared to cow's milk consumption on blood pressure

Author, year, study design	n RCTs; n participants	Intervention; comparison	Strength of the effect: MD (95%CI), mmHg	I ²	Study population (n)	Risk of bias (n)
Erlich 2024 ²⁹ MA	5; 158	i: soy drink: 240 to 1000 ml/d; c: cow's milk: 240 to 1000 ml/d. Diets were isocaloric	SBP: -8.00 (-14,89, -1.11) SBP: -4.74 (-9,17, -0,31)	0% 0%	Europe (1), Asia (4)	Low (5)

Abbreviations: c: control group; CI: confidence interval; DBP: diastolic blood pressure; i: intervention group; MA: meta-analysis; MD: mean difference; mmHg: millimetres of mercury; RCT: randomised controlled trial; SBP: systolic blood pressure.

3.3.3 Body weight

The committee used the recent MA of Erlich et al.²⁹ for its evaluation of consumption of soy drink versus cow's milk and the effects on body weight, and performed a less extensive evaluation because no effect on body weight was suggested, and therefore the evidence would unlikely contribute to a potential guideline on dairy substitutes. The MA included 6 RCTs, together including 163 participants. The findings from this MA suggested that there is no effect of isocaloric replacement of soy drink with cow's milk on body weight in adults, without heterogeneity between studies (Table 8). Study durations varied from 4 to 8 weeks, and half of the RCTs were with energy restrictions.

Table 8 Characteristics and results of a meta-analysis of randomised controlled trials on the effect of soy drink compared to cow's milk on body weight

Author, year, study design	n RCTs; n participants	Intervention; comparison	Strength of the effect: MD (95% CI), kg	I ²
Erlich 2024 ²⁹ MA	6; 163	i: soy drink; c: cow's milk. Diets were isocaloric	-0.57 (-2.58, 1.44)	0%

Abbreviations: c: control group; CI: confidence interval; i: intervention group; MA: meta-analysis; MD: mean difference; kg: kilogrammes; RCT: randomised controlled trial.

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Annexes

A Literature search

Search criteria

The committee performed a literature search in PubMed and Scopus in August 2024 for recent randomised controlled trials (RCTs) and prospective cohort studies (including case-cohort and nested case-control studies) published since November 2022 into the effects or associations of plant-based substitutes for meat, fish and dairy with health outcomes. To this end, the committee used the following search terms:

- for meat substitutes: meat alternative, meat substitute, meat replacement, meat analogue, vegan meat, vegetarian meat, plant-based meat, PBMA (plant-based meat alternative), legume-based meat and soy-based meat;
- for fish substitutes: fish alternative, fish substitute, fish replacement, fish analogue, vegan fish, vegetarian fish, plant-based fish, soy-based fish, seafood alternative, seafood substitute, seafood replacement, seafood analogue, vegan seafood and vegetarian seafood;
- for dairy substitutes: plant-based foods, plant-based alternatives, plant-based dairy, dairy alternative, dairy substitute, dairy replacement, dairy analogue, dairy-like, plant-based milk, milk alternative, milk substitute, milk replacement, milk analogue, non-dairy milk, dairy-free milk, vegan milk, coconut milk, chickpea milk, oat milk, nut-based milk, plant-based yogurt, yogurt alternative, yogurt substitute, yogurt replacement, yogurt analogue, yogurt-like, non-dairy yogurt, dairy-free yogurt, vegan yogurt, coconut yogurt, chickpea yogurt, oat yogurt, nut-based yogurt, plant-based cheese, cheese alternative, cheese substitute, cheese replacement, cheese analogue, soy drink, soy yogurt, soy drink, plant-based protein and alternative proteins.

The remaining search terms, aimed at selecting RCTs or prospective cohort studies, were as follows:

- for RCTs: RCT, trial, clinical trials, randomised, controlled, placebo, intervention, cross-over studies, double-blind method, single-blind method, controlled before-after studies and historically controlled studies;
- for prospective cohort studies: cohort studies, prospective studies, longitudinal studies, follow-up studies, observational studies, nested case-control and case-cohort.

Only studies performed in humans and published in English language were selected.

Selection of articles

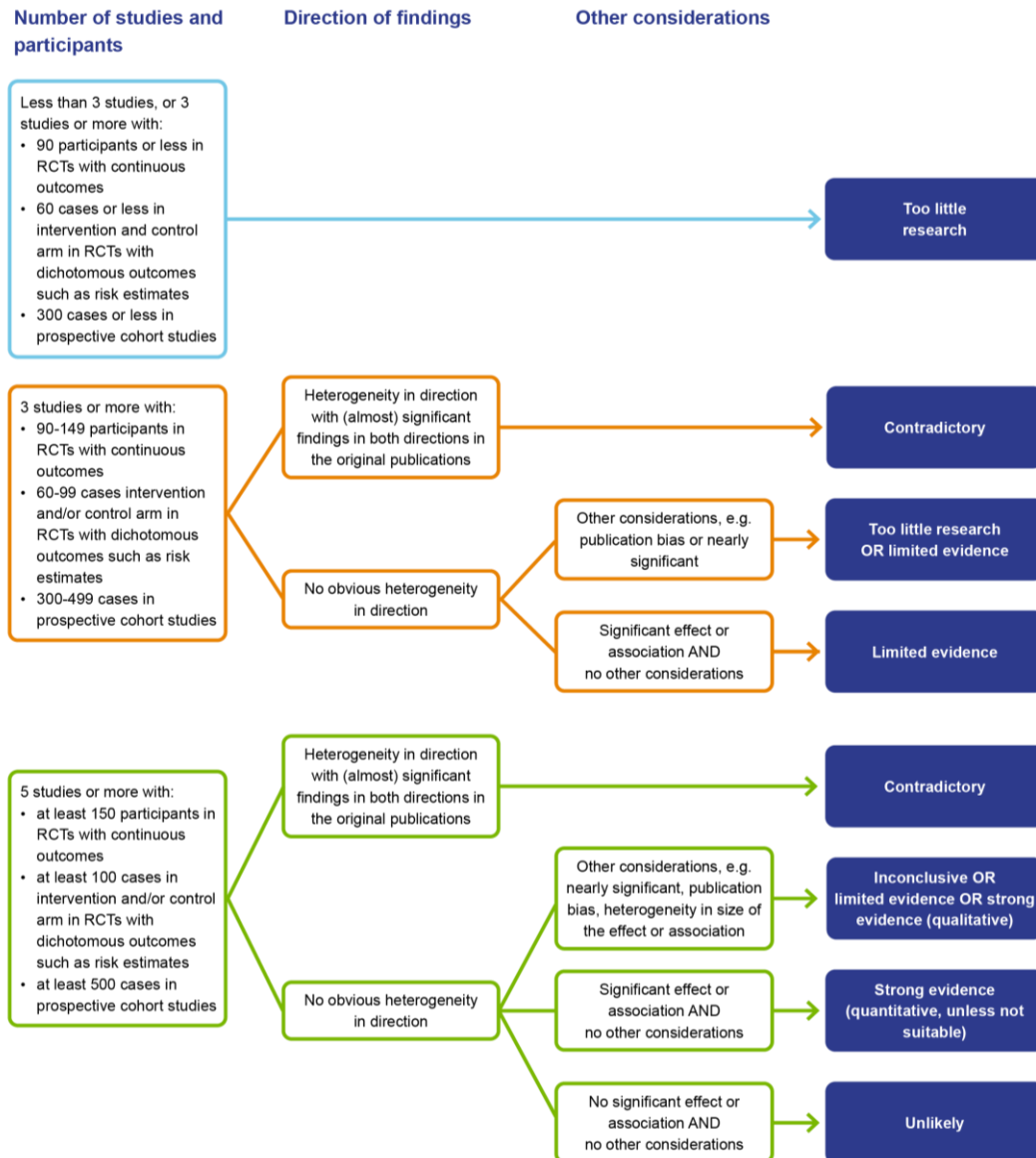
First, from the articles retrieved via PubMed and Scopus, potentially relevant articles were selected based on titles and abstracts. Second, a further selection of eligible articles was made based on full-text screening.

For plant-based alternatives for meat, fish and dairy, a total of 900 articles were screened based on title and abstract (421 found in PubMed and 711 in Scopus). Of these, 15 were selected for assessment of eligibility based on full-text screening. In total, 2 articles were found eligible.^{34,35} These are individual RCTs examining the effect of consumption of plant-based meat alternatives compared to meat on LDL cholesterol, blood pressure and body weight.

The committee noted that the 2 individual RCTs retrieved via its search are included in one of the MAs retrieved via the public consultation.²⁷ The committee used this MA for its evaluation and the individual RCTs are therefore not described separately.

B Decision tree

The decision tree below was used as a guidance tool by the committee on Nutrition for drawing conclusions based on scientific evidence from meta-analyses and pooled analyses of randomised controlled trails or prospective cohort studies.



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