

The process of setting micronutrient recommendations: a cross-European comparison of nutrition-related scientific advisory bodies

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Abstract

Objective: To examine the workings of the nutrition-related scientific advisory bodies in Europe, paying particular attention to the internal and external contexts within which they operate.

Design: Desk research based on two data collection strategies: a questionnaire completed by key informants in the field of micronutrient recommendations and a case study that focused on mandatory folic acid (FA) fortification.

Setting: Questionnaire-based data were collected across thirty-five European countries. The FA fortification case study was conducted in the UK, Norway, Denmark, Germany, Spain, Czech Republic and Hungary.

Results: Varied bodies are responsible for setting micronutrient recommendations, each with different statutory and legal models of operation. Transparency is highest where there are standing scientific advisory committees (SAC). Where the standing SAC is created, the range of expertise and the terms of reference for the SAC are determined by the government. Where there is no dedicated SAC, the impetus for the development of micronutrient recommendations and the associated policies comes from interested specialists in the area. This is typically linked with an *ad hoc* selection of a problem area to consider, lack of openness and transparency in the decisions and over-reliance on international recommendations.

Conclusions: Even when there is consensus about the science behind micronutrient recommendations, there is a range of other influences that will affect decisions about the policy approaches to nutrition-related public health. This indicates the need to document the evidence that is drawn upon in the decisions about nutrition policy related to micronutrient intake.

Keywords

Micronutrient recommendations
 Scientific advisory bodies
 Nutrition policy
 Evidence
 Food regulation

Currently, most countries in Europe establish their own nutrient recommendations, and there is large heterogeneity in the recommendations within Europe^(1–3). The European Food Safety Authority (EFSA) is in the process of reviewing and updating the last report on recommended nutrient and energy intakes for the European Union (EU) population published in 1993, prepared by the Scientific Committee on Food⁽⁴⁾. Variability is partly due to the use of different

approaches (e.g. health outcomes and methods used when data are missing for sub-populations), changes over time in the approach to establishing recommendations and/or data used⁽³⁾ and the uncertain nature of many scientific elements⁽⁵⁾. The background information provided in the recommendation reports lacks transparency as it is not possible to disentangle the relative contribution of different aspects of evidence. Because of this lack of transparency it is

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often difficult to track why there is heterogeneity in micro-nutrient recommendations. This lack of transparency then leads to perceived inconsistency, perceived lack of objectivity, complexity in presentation, lack of clarity, difficulty in implementation, decreased chances of reliability and it hides research gaps^(6,7).

Variability may also be due to the variable influence of international organisations such as the WHO, FAO or EFSA. Although the WHO and FAO are mandated by Member States to develop policy and programme guidance on health, food and agriculture-related matters, including nutrition recommendations, such guidance is freely accepted by countries. The existing significant scientific activity at the national level (e.g. Nordic countries – Denmark, Finland, Iceland, Norway and Sweden, UK, DACH countries – Germany, Austria and Switzerland) as well as the historical links that exist between some national scientific communities can explain the variability in the acceptance of the international micronutrient recommendations.

Scientific advisory bodies (SAB) are groups through which expert advice enters the political process and can establish institutions, short-term commissions, *ad hoc* and standing committees and an informal network of experts⁽⁸⁾. Their key role is to feed technical recommendations into the policy development process. Evidence suggests that SAB play a crucial role in advising government on development and implementation of nutrition policies: WHO has noted the possible link between the existence of SAB and the degree to which nutrition policies are developed and implemented⁽⁹⁾. There is, however, little research that seeks to explain why this might be the case. The way in which nutrition-related SAB operate in Europe, and how they input into public health nutrition policy related to micro-nutrient recommendations, is the focus of the current paper.

The changing policy context

Scientific expertise often underlies evidence-based policy making, as it is used to make decisions more rational, justifiable and effective. It may also facilitate greater public acceptance, and is thus a valuable tool in policy makers' efforts to manage accountability and justify value-based decisions^(9–11). Recent emphasis on evidence-based policy, the proliferation of governance bodies whose job is to monitor the evidence base (e.g. EFSA) and 'knowledge management systems' signal a shift in policy making towards greater reliance on scientific expertise⁽¹²⁾.

Although SAB play a crucial role in informing and providing a rationale for policy decisions, the recent trajectory of their involvement in government decision making has been characterised by a shift in their role and relationship with policy decision makers, from a closed, instrumental approach to policy (i.e. science-driven) to the emphasis on openness (i.e. admission into policy

considerations of different forms of evidence, including scientific) and transparency (i.e. more clarity about the way in which decisions have been achieved^(13–15)). Following a series of high-profile failures of scientific advisors and government officials to protect public interest in assessing and managing health and environmental risks (e.g. BSE), the recognition that uncertainty is inherent to scientific judgement and that subjective and objective elements of expert decision making are difficult to disentangle, there are now public and policy pressures for the democratisation of expertise^(13,16,17). Various policy documents^(12,18–20) have indicated a need for greater transparency in the workings of SAB.

In addition to transparency in the decision-making processes of SAB, there is also a call for an increased openness to the inclusion of stakeholder perspectives. Within the EU, there has been a move towards pragmatic management of multiple views and perspectives and co-production of policy decisions, so that they take into account the views of the various stakeholders^(18,21), while science itself is expected to be increasingly utilitarian in the way research questions are framed and solutions sought, with the expectations of it being informed by and responding to the views of lay citizens and society at large^(9,22). As part of the call for the democratisation of expertise, recent academic focus has been on the examination of the workings of expert advisory bodies^(9,15,23–25). The main streams of empirical work around SAB are:

- knowledge gathering/formation and expert decisions^(9,24–26); and
- knowledge transfer – the way in which expert and policy worlds meet and influence each other^(27,28).

Knowledge gathering and formation

The way in which expertise is defined and SAB are structured determine how a problem is framed, which in turn influences the decisions around the inclusion or exclusion of particular perspectives and the way in which facts are selected and interpreted and conclusions are drawn^(10,23,29,30). The nature and source of expertise may also be significant factors in whether scientific advice is taken up in the policy-making process⁽²³⁾. Traditionally, SAB-related expertise has been defined in terms of an individual expert's (i) qualifications, knowledge and experience in their chosen field; (ii) 'eminence' or 'authority' as a trusted source of science in communication with wider society; and/or (iii) their institutional affiliation^(24,30,31).

With the crisis of confidence in science, academic attention has turned towards the nature of decision making in SAB, including the way in which experts within SAB deal with scientific uncertainties, scientific controversies and pressures for consensus^(15,32) and the variety of influences on expert advice⁽¹²⁾. From a sociological perspective it is recognised that scientific decision

making is deeply intertwined with the context in which it operates^(23,32). The notion of co-production of knowledge, which is concerned with the way in which science and society shape each other, has been put forward as a useful framework for the study of decision making in SAB⁽³³⁾, leading to calls for various forms of knowledge (e.g. technical, lay) being granted equality in the formulation and deliberation around scientific issues⁽³⁴⁾. Some of the issues discussed include how to achieve engagement with the public^(34,35), the notions of ‘opening up’ of expert considerations and the questioning of the boundaries between lay and expert perspectives⁽³⁶⁾. However, many authors have recognised the inherent tension between different forms of knowledge within SAB and an unequal balance of power being assigned to representatives of lay and technical knowledge on these committees⁽³⁷⁾.

Applying these ideas to the evaluation of the existing SAB, another line of research has examined the stages of decision making and demonstrated how different types of knowledge and expertise input can inform decisions at each stage^(38–40). Typical stages include risk assessment, risk management and risk communication^(12,38). Decision making, however, is largely confined to experts and professional risk managers, with little input from other interested parties, including citizens⁽¹²⁾. In recognition of this, there have been attempts to develop a tool to guide policy makers and scientists in making decisions about when scientific decision making should be opened up and when other stakeholders should be involved^(41,42).

Knowledge transfer

Much literature examines how SAB communicate with policy decision makers^(15,23,39,43) and takes into account both the internal context in which decisions are made and the external context that shapes this^(39,43). The internal context, which can be changed and controlled from within the SAB and by their commissioners, includes the way in which expertise is defined, how representative SAB are, the degree of openness to stakeholder input in framing, analysing and formulating solutions to an issue, and transparency of the way in which decisions are made. External context amounts to the environment in which a decision is applied and cannot be easily altered or controlled. Crucially, SAB are expected to maintain independence from the bodies they advise, although in practice, this remains a challenge⁽²²⁾. Given the unique position of SAB as intermediaries between science and policy, they have been a fertile ground for the study of the boundary between politics and science, its negotiation and the degree to which the two permeate each other^(9,44). Whether scientific advice is salient, credible or legitimate is considered an important determinant of influence⁽⁴⁵⁾. However, these criteria of influence as well as SAB decision-making processes and outcomes will be

determined by the external context in which SAB operate, and include ideological, socio-political, economic and legal issues⁽⁴³⁾.

The present paper aims to examine the workings of nutrition-related SAB in the process of setting recommendations for folic acid (FA), through a comparative analysis of the process of setting micronutrient recommendations across Europe, paying particular attention to the internal and external contexts within which the SAB operate.

Methods

Questionnaire

Questionnaires were completed by key informants in thirty-five European countries/regions. The main objectives across countries were:

- to collate all the existing current micronutrient recommendations and describe the process of deriving nutrition recommendations and their use in nutrition policies; and
- for each micronutrient, to identify the policies adopted as a result of recommendations.

Data were collected on: ‘structure of the committee’ (e.g. type of expertise, selection criteria); ‘process of scientific decision making’ (for each micronutrient: nature of scientific evidence considered, type of recommendations, health endpoints, population groups, vulnerable groups, how recommendations have informed the development of food-based dietary guidelines (FBDG)); and ‘the way in which science resonates with policy’ (i.e. policy options recommended by SAB setting Nutrient Reference Values (NRV) and policy applications, i.e. actual policies adopted by governing bodies responsible for these).

Case study

An in-depth case study was conducted in seven countries varying in length of public health nutrition tradition, level of centralisation and diversity of institutions involved in the governance of nutrition, and extent of participatory democracy: Czech Republic, Denmark, England, Germany, Hungary, Norway and Spain. The main objectives were:

- to understand the process from science to policy, and the determinants of variations in this process across nations/regions, policy applications and micronutrients, with a specific focus on FA; and
- to identify the way in which scientific, policy and consumer issues interact throughout this process.

Information was obtained on: (i) the degree of transparency of decision making and its openness to public scrutiny; (ii) contextual characteristics, i.e. the institutional, administrative and political context (e.g. how food and policy were/are conceptualised, the names of key

stakeholders); (iii) the generic process of setting up micronutrient recommendations (e.g. who is in charge, triggers for the development of recommendations, who is invited to take part, what is the type of scientific data considered, the degree of scientific certainty/controversy); and (iv) the process from science to policy application for FA. An assessment was made about the public availability of literature and documentation on the workings of the institutions responsible for the development of micronutrient recommendations, public and stakeholder involvement and nutrition policy processes, indicating the degree to which participatory democracy has evolved and the level of transparency and openness in the processes of science and policy in each of the countries in question.

Results

Institutional capacity

The questionnaire data indicate that in approximately half of the countries (eighteen out of thirty-five), the final responsibility for setting micronutrient recommendations rests with government departments (Table 1). Recommendations are supported by one or a combination of scientific bodies – scientific advisory committees (often called ‘advisory councils’) or SAC (ten countries), public health institutes (fifteen countries), nutrition societies (five countries). The EU’s micronutrient recommendations were set by EFSA and supported by SAC and the WHO/FAO recommendations by a European expert consultation.

Where SAC exist, there are either standing committees providing continual advice to government, or they are formed on an *ad hoc* basis. Standing SAC often form sub-committees or working groups to deal with specific issues of importance, mainly at the request of the government, such as the need to develop recommendations for specific micronutrients (e.g. iodine) or population groups (e.g. infants).

In some countries, the decisions about recommendations and nutritional matters rest with established research centres, and sometimes with nutrition societies. Each of the three types of SAB – SAC (e.g. the UK, Nordic countries), public health institutes (e.g. Spain, Czech Republic, Hungary) and nutritional societies (e.g. DACH) – are entities that substantially differ in their statutory responsibilities and operate within diverse regulatory frameworks (e.g. funding sources). Members of the SAC are appointed by authorities (usually government departments) on the basis of their individual expertise, eminence or affiliation with an eminent institution, although potential members often have to apply to be considered for SAC. Nutrition societies are membership organisations whereby inclusion is based on self-selection and satisfaction of membership criteria, whereas research centres/institutes, like universities, are employers.

A range of criteria was mentioned within the questionnaire as the basis of the selection of members of various committees and societies (Table 1). Almost all countries, as well as the EU and WHO/FAO, mentioned individual expertise as an important criterion for the selection of persons involved in setting micronutrient recommendations, whereas institutional authority (fifteen countries), representation of a sector (e.g. industry, academia, consumer – nine countries) and forms of knowledge (six countries) were other – albeit overlapping – common criteria. Most countries based their selection of persons involved in setting micronutrient recommendations on one (typically individual expertise) or two criteria (e.g. individual expertise plus institutional authority).

The type of expertise that is selected on SAC is similar across Europe. Most countries mention at least three of the following fields of expertise: nutrition, (public) health, medicine, biochemistry, food technology, epidemiology, food hygiene and toxicology. In several countries (e.g. UK) lay or consumer representatives are included in the SAC or the working groups. The questionnaire data do not indicate that there are variations across countries in the propensity to recommend a policy option, based on the type of SAB responsible. However, it could be expected that policy recommendations (options for policy) made by each of the respective SAB (i.e. SAC, institutes and nutrition societies) would ‘resonate’ to varying degrees with the government, stakeholders and the public. The rationale for this is partly based on inferences about the independence of SAB, their eminence/credibility, their legitimacy (based on representativeness, selection criteria) and salience^(9,45). The differences might be particularly notable in the way in which recommendations for the enforcement-type policy instruments (e.g. mandatory fortification, legislation on micronutrient composition in food products and labelling) are taken up by the respective authorities. This will be explored in the case study.

A case study of mandatory folic acid fortification

Knowledge of the origins of the recommendations is important as they indicate what possible frameworks of decision making are operational within the SAB (from framing of the problem to the possible solutions). Thus, although the UK’s Scientific Advisory Committee for Nutrition (SACN), the German Nutrition Society (DGE) in DACH countries and the Nordic Nutrition Recommendations (NNR; the Nordic countries’ National Nutrition Council (NNC), now the Nordic Directorate of Health (NDH)) conduct their own systematic reviews of all the available data (in the problem area specified by their terms of reference, such as a specific micronutrient or the nutrition for a particular population group), identifying possible areas of uncertainties, the weaknesses of science and actively engaging in problem delineation, this does not seem to be the case in Czech Republic and Hungary. Hungarian recommendations are adopted from the US,

Table 1 The type and nature of the body responsible for setting micronutrient recommendations

Country/ organisation/region	Involvement in setting recommendations					
	Body responsible	Type of body	Responsible since	Persons involved	Selection criteria	Field of expertise
Albania	Ministry of Health, supported by the University Hospital, Agrofood Department of Agricultural University of Tirana and FAO local office	Governmental, scientific	No data available	Three	Individual expertise, institutional authority	Nutrition, public health, biochemistry, food technology
Belgium	National Health Council (Hoge Gezondheidsraad)	Governmental, working group	1997 (first publication)	Eight	Individual expertise	No data available
Federation of Bosnia and Herzegovina	Not defined	Most probably nutrition society or medical academic group	No data available	No data available	Individual expertise	Medical doctors, specialised in hygiene
Republika Srpska	Ministry of Health and Social Welfare, supported by the Public Health Institute and health centres	Public Health Institute: independent scientific advisory body	2003	Five	Individual expertise, institutional authority	Nutrition, public health, biochemistry, medicine, toxicology, epidemiology, food technology
Bulgaria	Ministry of Health, supported by the National Centre of Public Health Protection	Governmental	1980	Eight	Individual expertise, different forms of knowledge	Nutrition, public health, biochemistry, medicine, toxicology, epidemiology
Croatia	Ministry of Health and Social Welfare	Governmental	No data available	Eleven	Individual expertise, institutional authority, specific sector, different forms of knowledge	Nutrition, public health, biochemistry, medicine, toxicology, epidemiology
Czech Republic	Ministry of Health, Department of Public Health, supported by the Scientific Committee for Food – iodine	Governmental, working group for iodine	1995	Eight (self-selected)	Range of stakeholders included, based on individual expertise and sector	Nutrition, toxicology, chemistry, risk assessment
DACH countries	German Nutrition Society, Austrian Nutrition Society, Swiss Society for Nutrition Research and Swiss Nutrition Association	Nutrition society	1992 (previous publication)	Six (plus forty-one contributors) selected by the nutrition society	Individual expertise (experimental and scientific)	Nutrition, food, biochemistry
Estonia	Ministry of Social Affairs, supported by National Institute for Health Development	Governmental, scientific	No data available	No data available	Individual expertise (scientific), institutional authority	Nutrition, public health, biochemistry, medicine, epidemiology, food technology
France	French Food Safety Agency (Afssa), former National Centre for Studies and Recommendations on Nutrition and Diet (CNERNA)	Independent body	1999	200	Individual expertise, different forms of knowledge (from national community)	Nutrition, public health, biochemistry, medicine, epidemiology
Greece	Ministry of Health and Social Welfare, supported by Hellenic National Nutrition Policy Committee	Governmental, committee	2002	No data available	No data available	No data available
Hungary	Ministry of Health, supported by the National Institute of Food Safety and Nutrition	Governmental, working group	No data available	Twenty-five	Individual expertise	Nutrition, medicine
Ireland	Food Safety Authority of Ireland	Working group of independent and scientific body	1996	Four	Individual expertise	Clinical medicine, nutrition

Table 1 Continued

Country/ organisation/region	Involvement in setting recommendations					
	Body responsible	Type of body	Responsible since	Persons involved	Selection criteria	Field of expertise
Italy	Italian Society of Human Nutrition (SINU), supported by the National Research Institute on Food and Nutrition (INRAN)	Nutrition society (scientific with links to governmental bodies)	1977	Four working groups, each with eight to ten members	Individual expertise, institutional authority, specific sector	Nutrition, public health, biochemistry, medicine, epidemiology, food technology
Latvia	Ministry of Health, supported by the Latvian Food Centre and Nutrition Council	Governmental, probably individual experts or working group	No data available	No data available	Individual expertise, institutional authority, specific sector	Nutrition, public health, biochemistry, medicine, food technology
Lithuania	Ministry of Health, supported by Food and Nutrition Scientific Council, National Nutrition Centre and Medical Faculty of Vilnius University	Governmental, scientific	2003	Four	Individual expertise, specific sector	Nutrition, public health, biochemistry, medicine, epidemiology, food technology
Montenegro	No body responsible for setting recommendations	N/A	N/A	N/A	N/A	N/A
Netherlands	Ministry of Health, supported by The National Health Council (TNHC)	Governmental, TNHC is an independent scientific advisory body	1992	Thirty-eight	Individual expertise (independent experts)	Nutrition, public health, biochemistry, medicine, epidemiology
Nordic countries	Nordic Committee of Senior Officials on Food Issues, EK-Livs., supported by the Working Group on Diet and Nutrition (NKE)	Project group nominated by NKE	2000	Thirty (selected by government)	Individual expertise (scientific), institutional authorities	Nutrition, public health, medicine, toxicology, epidemiology (Iceland: nutrition and health)
Poland	Ministry of Health, supported by the National Food and Nutrition Institute, Warsaw	Governmental	1963	Five	Individual expertise (experience), institutional authority (long-term employment), specific sector	Nutrition, biochemistry, medicine
Portugal	No data available	No data available	No data available	No data available	No data available	No data available
Romania	Ministry of Health, supported by the Institute of Public Health Bucharest (IPH)	Governmental, National Committee of Nutrition (in 2008)	No data available	Twenty	Individual expertise, institutional authority (IPH)	Nutrition, food hygiene, public health, medicine
Russian Federation	Ministry of Health, supported by the Institute of Nutrition at the Russian Academy of Medical Sciences	Governmental, scientific	1982 (previous publication)	Three	Individual expertise (scientific), institutional authorities	Nutrition, biochemistry, medicine, toxicology, epidemiology, food technology
Serbia	Ministry of Labour and Social Policy	Governmental, expert group	1993	Four to five	Individual expertise	Nutrition, public health, hygiene, medical ecology, medicine
Slovakia	Ministry of Health	Governmental	No data available	Two	Individual expertise, institutional authority, specific sector, different forms of knowledge	Nutrition, public health, medicine, toxicology, epidemiology, food technology
Slovenia	Ministry of Health, department related to Public Health	Governmental	No data available	Two	Individual expertise, institutional authority, specific sector, different forms of knowledge	Nutrition, public health, medicine, food technology
Spain	Madrid University and Spanish Society of Community Nutrition (SENC)	Nutrition society, expert group	No data available	Three	Individual expertise, institutional authority	Nutrition

Table 1 Continued

Country/ organisation/region	Involvement in setting recommendations					
	Body responsible	Type of body	Responsible since	Persons involved	Selection criteria	Field of expertise
The former YR Macedonia	Ministry of Health, supported by Republic Institute of Health Protection (in 2001: Macedonian Association of Physicians)	Working group (2001)	No data available	Five (2001)	Individual expertise, institutional authority, specific sector, different forms of knowledge	Nutrition, public health, biochemistry, medicine, toxicology, epidemiology, food technology
UK	Department of Health and Food Standards Agency, supported by the Scientific Advisory Committee on Nutrition (SACN) (previously called Committee on Medical Aspects of Food and Nutrition Policy (COMA))	Governmental, SACN is an advisory committee of independent experts	1991 (COMA 1990)	Thirteen, including two lay representatives (plus ten observers). Members must apply and are appointed by the government	Individual expertise, specific sector, institutional authorities (COMA (appointed by ministers), the Health Education Authority and the Medical Research Council, Chief Medical Officers of England, Scotland, Wales and Northern Ireland, representatives of the Ministry of Agriculture, Fisheries and Food and the Department of Health)	Nutrition, public health, biochemistry, medicine
EC*	European Food Safety Authority, Scientific Committee for Food	Working group	No data available	Nineteen	Individual expertise, no data available on other criteria	Various
WHO/FAO*	WHO and FAO (United Nations)	Expert Consultation	1973	No data available	No data available	No data available

EC, European Commission; N/A, not applicable.

DACH countries: Germany, Austria and Switzerland.

Nordic countries: Denmark, Finland, Iceland, Norway and Sweden.

All data are based on questionnaire primarily, scientific reports on recommendations secondarily and country-specific key informants in the third place.

*Data from the scientific reports only.

EU and DACH recommendations, and some adjustments made with reference to the Hungarian population surveys. The committee was not engaged in problem framing, delineation of the criteria for systematic reviews (the type of evidence to be used) and the lengthy process of adjudging the areas of uncertainties on which recommendations are made. In Czech Republic, the few recommendations that exist are also based on international recommendations such as DACH.

Understanding how the process of setting recommendations and their translation into policies varies across types of SAB will help identify some determinants of variation in the final micronutrient-relevant policy approaches across countries. We will provide assessments of transparency of this process and describe problem formulation, evidence gathering, micronutrient recommendations achieved and policy options that are recommended, as well as how these are finally translated into policy across the seven countries in relation to FA, chosen for its salience with regard to fortification as a policy option. Options for mandatory, partly mandatory and voluntary FA fortification attract considerable debate and require considerations of both a political and a scientific nature.

Transparency of the scientific process

The UK, Norwegian, Danish and DACH SAB endeavour to provide the public with information on some aspects of their workings. The main sources of information are dedicated websites, which host information on reports, meeting minutes, the make-up of the committee and the working groups (names and affiliations), how the committee is organised, stakeholder consultation summaries and, in the UK, a document clarifying the decision-making process for evaluating scientific evidence and recommending nutrient reference values⁽⁴⁶⁾.

The main source of information about the NNR is the official publication of the Nordic Council of Ministers 2004⁽⁴⁷⁾. It lists the selection criteria for the project group, the general approach for the establishment of a recommended daily intake for certain nutrients and the methodological considerations for the evaluation of the available evidence. The evolution of nutrition-based policies in Norway is visible through policy documents (some of them published on official government websites) and the list of stakeholders involved in the process.

The main source for information about micronutrient recommendations in Germany is the official website of the DGE. Information about the composition and affiliations of the working group and of other contributors is provided, as well as press releases related to the publication of the document. Summary tables are provided and the document⁽⁴⁸⁾ is available for downloading in the English language.

In the Czech Republic and Hungary, as well as Spain, there is little documentation on the official criteria and process that are used to establish these recommendations.

In each of these countries the fragmented institutional context for the management of food and nutrition public health issues and the low priority ascribed to nutritional matters might explain this lack of transparency.

Fortification policies

The case of Norway illustrates NNC's shift from public campaign-based education to a recommendation of mandatory fortification in the space of <10 years, and a reluctance of the governing bodies to follow through the scientific advice. On two occasions, in 1996 and in 1997, the NNC was tasked with evaluating the needs for FA intake: in 1996, the terms of reference were the evaluation of the FA intake status for the general population, and in 1997, the evidence of the FA intake of women of childbearing age was examined. Committee members included researchers in the area of FA and diet, the Food Authorities, the Norwegian Medicines Agency, the Norwegian Board of Health Supervision and the NNC. The 1996 committee concluded that there was not enough evidence to change the recommendation for the general population and that the advice of the FBDG to increase fruit, vegetable, potato and dark bread intake was sufficient. The 1997 committee recommended an increase in FA intake to 0.4 mg and a recommended daily supplement and FBDG, although fortification of foods with FA was not considered a suitable option to increase intake (since the general population could be at risk of having too high an intake). A subsequent report produced in 2004 by a working group appointed by the NNC – Norwegian Directorate of Health – recommended that mandatory fortification should be considered due to the unsatisfactory results of the current preconceptional FA recommendations; but, as yet, there is no mandatory fortification policy in Norway⁽⁴⁹⁾.

A similar case is reported in Denmark. A report on FA⁽⁵⁰⁾ and neural tube defects (NTD) was prepared in 1997 by the National Food Agency in Denmark based on the work of a group of experts within the area. Enrichment as a policy option was discussed, but not recommended. Following the Danish Dietary Survey as well as the creation of a working group of experts for FA in 2003, the committee recommended to the Danish Veterinary and Food Administration policy makers a combined approach of both mandatory fortification and supplementation. Fortification levels were recommended to be low (0.1–0.2 mg) so as to minimise risk to other population groups. To date, policy makers have not introduced compulsory fortification in Denmark and, instead, as a result of foreign experience, supplementation was upheld as the only viable policy option.

To date, there is no FA food fortification policy in Germany; however, it is currently being considered. Recommendations for the prevention of NTD by FA supplementation were given for the first time in 1994 as common recommendations by five German societies (DGE, German Society of Gynaecology and Obstetrics, German

Society of Human Genetics, German Society of Paediatrics and Society of Neuropaediatrics), who recommended fortifying selected staple foods, such as bread. The fortification debate continued after the 1998 German National Health Interview and Examination Survey⁽⁵¹⁾. Two SAB worked in parallel on the issue of FA. The final recommendations included three possible policies for FA-fortified foods: mandatory fortification of wheat and rye flour all over the country; voluntary fortification of wheat and rye flour; or voluntary fortification of table and cooking salt. The DGE subsequently established an FA working group, which published a position paper in 2006⁽⁵²⁾ in which mandatory fortification of baking flours with FA was favoured.

The UK national food fortification with FA is currently being considered by Health Ministers. National FA fortification was recommended in a Committee on Medical Aspects of Food Policy (COMA) report in 2000⁽⁵³⁾; yet in 2002, the FSA decided against recommending mandatory fortification to the UK health ministers. This was largely due to stakeholder concerns over health risks in the elderly population and consumer concerns over lack of product choice. In 2007, following a review of evidence since the COMA report, the FSA received a draft report from SACN, which recommended mandatory FA food fortification (of bread and flour) in order to decrease the incidence of NTD-affected pregnancies in the UK. Recommendations also included control over industry voluntary FA fortification and the necessity of clear advice on the use of FA supplements⁽⁵⁴⁾. The SACN-updated review of FA fortification allowed stakeholders the opportunity to again discuss mandatory fortification. Following the consultation, some of the difficulties with adopting fortification were identified; however, the FSA adopted mandatory fortification of bread and flour in 2007⁽⁵⁵⁾ and presented the option to Health Ministers (who have the ultimate decision about fortification) in early 2009⁽⁵⁶⁾. In order to inform the ministers' final decision on mandatory fortification, in October 2007 the Chief Medical Officer (CMO) of England, on behalf of all the UK CMO, asked SACN to further consider two studies that suggested that FA may increase the risk of colorectal cancer^(57,58). In 2009, SACN concluded that the new evidence does not provide a substantial basis to change its previous recommendation; it was only amended to clarify the advice on supplement use. The CMO is expected to advise UK Health Ministers of SACN's recommendation shortly, and Health Ministers will then decide whether to approve mandatory FA fortification in the UK. The timing for this decision is not known.

In Spain, the recommended intake for FA was set by the Spanish Society of Community Nutrition (2005)⁽⁵⁹⁾ and included FBDG and supplementation as policy options. Industry has engaged in voluntary fortification of foods although currently there is no coherent effort to estimate the bioavailability of FA in food products, as well as population intake of FA.

In Czech Republic, nutrition recommendations issued in 1989 have been updated with the general nutrition recommendations of the Society for Nutrition of 2004 and recommendations of the Ministry of Health (MZ CR) of 2005; but these do not provide recommendations for total FA intake. Numeric recommendations for FA are defined in regulation⁽⁶⁰⁾, which deals with the requirements for food supplements and on foodstuffs fortified with food supplements. At present a proposal for recommended dietary allowances, which also includes numeric recommendations for FA, is being prepared. This proposal is based on international publications (*The Safety of Vitamins and Minerals* (2002) and *Vitamin and Mineral Supplements* (2004) by the European Responsible Nutrition Alliance) and the opinion of the Scientific Committee on Food, which proposes adopting the current EU nutrition recommendations⁽⁶¹⁾. It is not clearly defined who in the Czech Republic should be involved in establishing FA recommendations. It is thought that the initiator should be the Ministry of Health together with scientific societies and the professionals in the area of nutrition so that both state-controlled and non-governmental organisations are represented.

In Hungary, reference values have existed since 2006, based on international recommendations and adjusted for the Hungarian population, following a Hungarian Nutritional Survey in 2003–2004. Currently, in Hungary, there is no mandatory FA food fortification. An FA team was created to discuss the survey results; however, no agreement was reached, and mandatory policy is not expected to come into force in the near future. Voluntary fortification is allowed under government policy and legislation, but there is no available database showing details of the foods that are fortified. Voluntary FA bread fortification existed in Hungary, but has since disappeared due to a lack of official support and insufficient health education^(62,63). No public stakeholder consultation exercises were set up to aid final decisions on fortification. Consumer issues were considered through the adoption of voluntary fortification, which maintains that consumer choice and nutrition policies are partly visible through policy document press releases and periodical and website publications. However, micronutrient policies are exclusively discussed by scientists, medical doctors and dietitians.

Discussion and conclusions

The above analysis indicates that across Europe a variety of bodies are responsible for setting micronutrient recommendations, each with different statutory and legal models of operation. Where there are standing SAC, e.g. UK and the Nordic countries, the processes of decision making are publicly reported, and the results of at least some interactions with policy makers and stakeholders are published in the form of consultation reports, meeting minutes and final decisions. Lack of transparent and

open decision making is characteristic of those countries where there are no dedicated publicly funded and government-supported bodies dealing with nutritional issues. In the countries where there are no standing SAC or dedicated and recognised professional bodies, processes for selecting who is involved in setting recommendations, for determining which issues to focus on and how the science links with public health actions are either non-existent or non-transparent. Spain and Czech Republic are examples of countries where the links between science and regulatory realities are largely unspecified.

In the countries where a standing SAC is created, the selection of experts is carried out by the government; once selected, these committees appear to have a degree of autonomy in choosing the members who will sit on specific working groups or sub-committees. Nevertheless, the process is driven by self-selection, whereby prospective members of standing and working committees must apply to be considered. In the countries without standing committees, experts are drawn from the centres of excellence or institutes with authority and a long history of scientific work in the relevant area (as in the case of Spain, Czech Republic and Hungary), or through membership of professional organisations (e.g. DACH). The case of DACH is indicative of the important role that a strong professional corpus can play in providing vision and strategy, as well as active shaping of the public health agenda. In contrast to the UK/Nordic model, in the German case there is no clear separation between risk assessment and risk management/communication. DGE has a role both in setting NRV and in translating these into FBDG and developing communication strategies of nutritional guidelines. This may be a consequence of a specific public health and risk management context within which recommendations have evolved. Arguably, the situation in the UK has been shaped by public disquiet about the role science plays in policy decision making. The consequent separation of risk assessment from risk management has not been evident in Germany.

Where there is no dedicated SAB (Spain, Czech Republic, Hungary), the impetus for the development of micronutrient recommendations and the associated policies comes from interested specialists in the area. Typically, in these cases, we observe an *ad hoc* selection of problem areas to consider (e.g. which micronutrients or which population groups) based on specific institutional or individual interests and expertise, the lack of a coherent approach to science informing possible decisions, over-reliance on international scientific and political influences and policies that are neither informed by science nor a result of a transparent consultation process. When there is a dedicated SAB for nutrition, government sets its terms of reference. These are often to evaluate the current micronutrient status in the whole population or a population group, evaluate the existing evidence leading to setting country- and population-specific NRV and to re-evaluate

previous recommendations. However, as indicated in the analysis, their terms of reference can sometimes include a more political remit such as providing government with an assessment of feasibility of a particular policy option (although the final decision always rests with the government).

Mandatory fortification of food with FA is recommended by four (UK, Norway, Denmark, Germany) out of seven SAB studied here; however, in most cases it is rejected by governing bodies as either not feasible or too sensitive to pursue. Despite our speculation that the decision made within the dedicated SAC will 'resonate' with government bodies and be more likely to be adopted and translated into policy, we can see that this is not the case, especially in the case of mandatory fortification. The case of fortification, which necessitates considerations of wider socio-political context, illustrates the scope of political considerations performed by some SAC. The case study showed that the science behind the recommendations of mandatory FA fortification is far from conclusive – a frequently voiced concern among scientists and SAC is that excessive exposure to FA may be associated with a number of health risks, whereas ethical considerations play a part in evaluating these risks. Recent expectations to engage with stakeholders in the process of decision making (e.g. through consultations) put a further onus on these bodies to engage in a political process. Scientific uncertainties coupled with the political context in which the SAC operate indicate that the decision for mandating FA fortification is in fact subjected to multiple, often subtle influences.

Extrapolating from the case of FA we suggest that the process of setting micronutrient recommendations is political as well as scientific, and call for greater transparency in the workings of these bodies, in particular of the sources and salience of different types of evidence.

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