



Webinar 3

Navigating legal issues in policy design and implementation

16 June 2022



Summary of key points and resources

Key points

- Legal considerations will impact the success of a public health measure and must be taken into account from the early stages of research and policy design.
- Global, regional, and national legal mechanisms can help support or strengthen a legal measure or be used to challenge it once it has passed (e.g., international trade law, international or national human rights law).
- Policymakers should not be deterred by threats of legal action most laws and policies are not litigated, and governments have the sovereign right to implement legal measures necessary to protect human health. However, it is important to take appropriate steps during policy development to mitigate against legal risk.
- Enacting strong food environment measures is every government's obligation under international human rights law. Child rights should guide all policies, legal measures, and interventions that can impact children, and governments should prioritize efforts to realize children's right to health and the right to adequate, nutritious food. A human rights approach and language are important tools for policy framing and advocacy and can help overcome attempts to obstruct policy efforts.
- It is important to be prepared and seek assistance from local and international public health lawyers from the beginning stages of policy design.

"Recognizing that industry self-regulation is ineffective, Governments should impose strong regulatory systems to ensure that the food industry does not violate citizens' human rights to adequate food and nutrition."

UN Special Rapporteur on the Right to Food (Interim Report, 2016, A/71/282)

The term "**legal measure**" is used to describe a wide range of legal instruments, such as laws, regulations, executive orders, and compulsory standards, used to implement mandatory healthy food environment policies.¹

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The child's right to a healthy food environment

The Convention on the Rights of the Child (CRC) recognizes that all children up to 18 years of age are bearers of inalienable rights, including the right to the enjoyment of the highest attainable standard of health, the right to healthy food and adequate nutrition, the right to non-discrimination, and the right to consider their best interests in all matters that affect them.

"The responsibility to protect the enjoyment of the right to health warrants State intervention in situations when third parties, such as food companies, use their position to influence dietary habits by directly or indirectly encouraging unhealthy diets, which negatively affect people's health."

- UN Special Rapporteur on the right to Health (Report, 2014, <u>A/HRC/26/31</u>)

Governments are the primary duty-bearers in protecting the rights of all children. Countries that have ratified the CRC are legally bound to uphold their commitments. This includes giving special consideration to the specific needs and vulnerabilities of children, including protecting children from unhealthy food environments that undermine their right to healthy food and adequate nutrition, and ultimately their right to the highest attainable standard of health.

Rights-based policymaking highlights the obligations of governments to respect, protect and fulfil these rights for all children, which brings powerful new arguments to overcome attempts by the food industry to delay, deflect and divide effective policy efforts. Obligations include the adoption of measures to actualize child rights, such as healthy food environment regulations, and prioritizing child rights over business interests. State obligations also include non-regulatory actions such as providing and ensuring access to services necessary for children to attain the highest attainable standard of health and have access to nutritious food (e.g., provide primary health care, clean water, schooling, and assistance to parents) or ensuring functioning food supply chains.

An emphasis on children's rights is also useful when engaging with the public and government officials. A child rights based approach and language are important tools for both policy framing and advocacy.

The standards and principles of international human rights treaties, and particularly those of the CRC, should guide all policies, legal measures, and interventions that can impact children. Governments should prioritize efforts to address the root causes of poor health among children by ensuring that they have access to nutritious and affordable food. However, healthy food environments are about more than the right to health and the right to adequate, nutritious food. The indivisibility and interdependence of human rights means that in implementing healthy food environments, additional child rights are realized:

- right to life, survival, and development,
- right to education,
- right to information,
- right to rest, leisure, recreation, and cultural activities,
- right to privacy,
- right to non-discrimination,
- right to be free from all forms of exploitation.

¹ The webinar series focuses on the following four policies to support a healthy food environment, which are discussed in detail in the <u>summary sheet</u> of webinar 2: Restrict marketing of unhealthy foods and beverages; Establish interpretative front-of-pack nutrition labelling to help identify unhealthy foods; Introduce fiscal measures to encourage healthy diets (e.g., taxes on sugary drinks); Set standards for food and beverages available in and around daycare centers, preschools, and schools.

Figure 1. The rights enshrined in the CRC are interlinked and mutually supportive of children's rights to a healthy food environment.

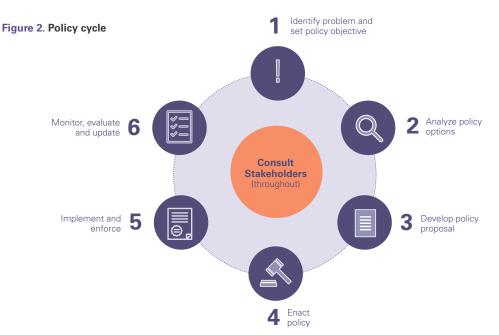


Source: Protecting Children's Right to a Healthy Food Environment, UNICEF & UNHRC, 2019.

Legal issues in the design and implementation of healthy food environment policies

When a food environment policy is first developed, legal issues are often overlooked or not recognized because policymakers, public health experts, and other stakeholders may not be aware of how decisions made through the entire policy cycle (see Figure 2) may have legal consequences or impact how well the measure will be implemented, monitored, and enforced. It is therefore important to involve a lawyer from the early stages of policy development to ensure the legal measure is effective and can withstand legal scrutiny. Below, key legal considerations along the policy cycle are summarised.²

Note that while government is the main responsible actor in policy-making, public health advocates and experts play an important role along the policy cycle. For example, they can influence agendasetting and support policy development by providing relevant evidence and technical input, help with implementation through consumer education, support enforcement with monitoring activities, and evaluate the effectiveness of a measure.



² The Global Health Advocacy Incubator has developed a <u>brief on legal issues in the design and implementation of public health</u> <u>measures</u>, consisting of seven steps and guiding questions to help identify legal issues when developing legal public health measures.

Identify problem and set policy objective

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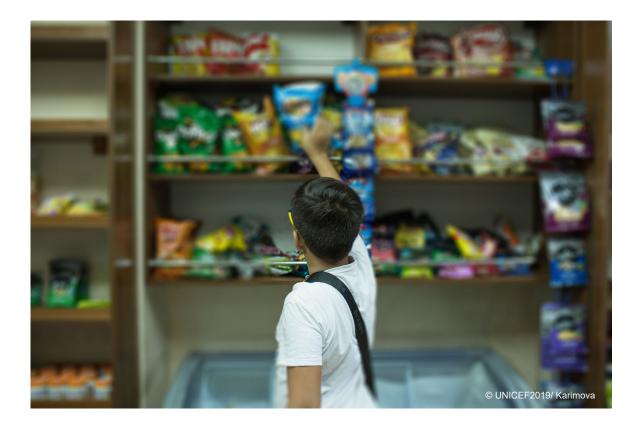
As a first step, the public health problem or risk to be addressed must be identified. Baseline data should be gathered to generate the necessary evidence to inform the choice and development of the measure (and to allow evaluation of the measure once implemented).

Based on the collected evidence, the regulatory objective(s) must be defined. It is important to articulate the relevant issues, populations, entities (e.g., food manufacturers, restaurants, school canteens), food products, behaviours, and/or activities that will be addressed in the legal measure.

Check if any dietary guidelines or priority setting documents such as a national nutrition or obesity strategy exist. While such documents are not binding, they indicate policymakers' intentions and reflect a country's nutrition or health strategy which should be considered when designing regulations.

Clearly defining the objective(s) the legal measure is trying to achieve is important for numerous reasons:

- Linking the legal measure through the objective to a clearly formulated public health goal and explaining how the measure will support achievement of this goal helps to mitigate against potential future legal challenges and weakening of the measure through industry lobbying.
- Setting a clear policy objective helps to identify challenges and barriers to achieving the objective, and to define the parameters and mechanisms to achieve them. Challenging the connection between the policy objective and measure chosen is a key tactic used in international trade law threats and challenges.
- Agreeing on the regulatory objective(s) in a transparent, consultative process supports acceptance of the healthy food environment policy, legitimises it, and enables the development of a communication strategy.
- A clear definition of the objective(s) enables monitoring and evaluation of the legal measure to determine if it was effective at reaching the policy goals.



2 Analyze policy options

In general, a range of policy options exist to address the identified public health challenge and achieve the regulatory objective(s). It is rare that a public health issue has not been addressed before, and usually legal measures exist that have been implemented elsewhere, providing insights on effective design and implementation.

The possible policy responses must be analyzed to understand the most effective and suitable options. This step might require generating local evidence to determine which policy option to choose. Local evidence will also help in the drafting stage by informing the design of the legal measure (e.g., if local evidence shows particular population groups are more vulnerable than others, or certain food groups more problematic than others, this can be addressed by the legal measure's design).

This step is also important to mitigate any challenges to the legal measure (particularly in the context of international trade) by showing that the public health problem is serious enough to warrant legal measures and that through an analysis of available policy responses the most appropriate measure was selected.³ It is equally important to document each step of the government's decision-making process, and the evidence that was relied upon to decide which option to pursue.

It is recommended to map existing policies and legal measures, responsible government bodies and their authority, and implementation and enforcement resources to inform the design of the legal measure and understand what is already working or not working well in the country. The mapping also helps identify the most appropriate way to legally mandate the chosen policy option. Often, different regulatory pathways are available (e.g., law passed by parliament, executive order issued by Ministry of Health) and both legal and political considerations influence which pathway is most suitable to pass the measure.

Develop policy proposal

Once the policy option is chosen, the legal measure must be drafted. The regulatory objective and evidence will inform the design of the legal measure. The scope should be as broad as possible, impacting the entire population and as many products as possible. For example, front-of-pack nutrition labelling should apply to all foods exceeding certain nutrient thresholds based on a nutrient profile model, and not just certain food groups and any exceptions made must have a strong public health justification to avoid the risk of international trade challenges. Restrictions on child-directed marketing should be comprehensive and not only applicable to certain marketing channels (e.g., TV or on-pack marketing).

The legal measure also needs to take account of governance and procedural parameters:

- Other existing, relevant interventions or legal measures that are in effect (or to be adopted or amended), including both domestic laws and international agreements the country is bound by. Note that relevant legal measures may exist outside health laws, e.g., in budget laws, privacy laws, procurement laws or laws governing education.
- The relevant responsible government bodies and their authority to adopt, implement, and enforce legal measures concerning health and nutrition at national and sub-national level (e.g., Ministry of Health, Ministry of Education, Food and Drug Administration). It is important to ensure that every aspect of the measure can be implemented and enforced by the appropriate agency, and that the legal measure provides the necessary powers.⁴

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³ Arguments used in (trade) litigation against food policies often include that a public health problem is not serious enough to warrant legal instead of voluntary or self-regulatory measures, or that the proposed measures do not address the public health issue. For example, arguments have been raised that marketing has no impact on food choices and behaviours, that education campaigns or recommendations for increased physical activity are best suited to address the problem, or that a proposed measure won't impact dietary choices or habits. A careful, evidence-based analysis of policy options can counter such arguments by showing why a mandatory legal measure, such as restrictions on food marketing directed at children, is necessary and the most effective approach.

⁴ For example, a measure to regulate marketing of unhealthy foods and drinks should cover all aspects of a marketing campaign - from broadcast media, print, digital channels, to outdoor advertising in urban and rural areas. In many cases, the Ministry of Health or any other one agency does not have the power to implement and enforce every aspect of that measure, so it is important to ensure the appropriate agencies are given the necessary powers from the outset.

- Existing processes and procedures the government needs to follow to enact and implement the legal measure. If the procedural requirements mandate inclusion of the food industry in the development of the measure, clear rules must be established on how policymakers and the food industry engage to ensure transparency, manage conflicts of interest, and otherwise reduce potential interference in the regulatory process. It may also be necessary to incorporate a mechanism to prevent conflicts of interest into the measure (i.e., include in the legal text). For example, a law introducing front-of-pack nutrition labelling could mandate the Ministry of Health to issue regulations detailing the parameters of mandatory labels (such as size, colour, content). To avoid any conflicts of interest in the development of the implementing regulations, the law can include a provision detailing if and how the Ministry of Health may engage with industry when developing the regulation.
- Practicalities of implementation and enforcement, available enforcement capacity and resources, and available sanctions and other enforcement measures. Implementation and enforcement are sometimes viewed as issues to consider once a legal measure has been adopted, but they should be taken into account in the drafting stage as they inform the design of the legal measure. Often, when implementation and enforcement are not accounted for at this stage, measures are passed but never implemented. To enable effective enforcement, a range of penalties, sanctions, and administrative measures should be in place that are proportionate to the violation and nuanced enough to adequately respond to the type of offender, (e.g., school canteen vs large food manufacturer), the harm caused, and whether it is the first or a repeat offence. To achieve this, a range of penalties might be considered depending on the legal measure: warnings, license suspensions or revocations, product recalls, fines, and additional testing or disclosure requirements. Imprisonment is generally not recommended as it is not commensurate with the potential harm caused. If the country's criminal law requires prison sentences, they should be reserved only for extreme violations. In countries with a large informal food sector, penalties need to be commensurate with the offender's ability to pay.



4 Enact legal measure

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Once the legal measure is drafted, it needs to be enacted and promulgated. The steps and time needed to enact the legal measure depend on the country context and type of legal instrument chosen to adopt the measure (e.g., law, regulation, executive order).

In general, a regulation goes into effect upon its publication in the Official Gazette (or equivalent public notification). For some food policies, it is appropriate to provide a transition period to allow all affected stakeholders to adjust to new requirements (e.g., reformulate recipes, update labeling, adjust procurement, use up existing stock). The length of the transition period is dependent on the complexity of implementation but generally, six months to two years is considered appropriate. It is also possible to include a staggered transition period, for example granting small- and medium-sized companies a longer transition period than large companies.

A transition period also gives government time to design an enforcement strategy, build implementation and enforcement capacity (e.g., training inspectors, update inspection procedures, set up laboratory capacity for testing of food samples), and take implementation measures such as consumer education and technical assistance to small- and medium-sized producers (e.g., help with reformulation of food products or meals).

5 Implement and enforce legal measure

To ensure successful implementation and enforcement of the legal measure, it is advisable to draw up an implementation and enforcement plan. It should consider the existing implementation and enforcement structure for food law and whether these can be used or adapted to minimize costs in implementing and enforcing the new measure. The implementation and enforcement plan should include the necessary budget to carry out the specific activities included in the plan. The allocated resources need to be realistic and sustainable over the long term. If budgetary provisions need to be included in the measure or enacted in a separate legal instrument at the same time as the measure, this needs to be considered in the drafting stage of the measure (see 'Develop policy proposal' above).

Stakeholders affected by the legal measure need to be informed about the regulatory changes and new legal requirements through outreach and education. Ideally, this happens before the new rules take effect. In some cases, capacity building of food industry actors is necessary alongside awareness campaigns or education activities. Government officials tasked with implementation and enforcement may also be trained to enable effective discharge of their duties.

Once the new requirements have come into effect, compliance needs to be monitored (label and/ or laboratory checks of food products, inspections of ports of entry and regulated entities such as food manufacturers, importers, retailers and caterers) and violators held accountable through the legal system.

In countries with a large informal sector, enforcement agencies might choose to focus on collaboration, education, and community engagement as an enforcement mechanism for this sector rather than relying too heavily on sanctioning.

In cases where enforcement agencies are unable to monitor compliance for every product, facility, or food industry actor, mechanisms can be set for members of the public, academic institutions and non-governmental organizations to help identify and report more potential violations. Enforcement agencies can set up a free, easily accessible reporting and complaints mechanism (e.g., using toll-free phone numbers or an online form) to allow reporting of suspected violations.

6 Monitor & evaluate legal measure

It is recommended to monitor and evaluate the legal measure's effectiveness. A government body may already be required to regularly monitor and evaluate its food or health related laws, such as the Ministry of Health, a food regulator, or a National Institute of Public Health. If not, it is advisable to include in the measure a provision that authorizes, requires, and empowers a government body to monitor and evaluate the measure.

Ideally, the main monitoring indicators are based on the policy objectives and defined by law. If this is not possible, they should be clearly stated in an accompanying implementation and enforcement plan or similar document which guides the responsible government bodies. The baseline assessment carried out in the policy development phase can be used to evaluate the measures' effectiveness.

The agency responsible for monitoring and evaluation should be required by law to publish its findings regularly and publicly, and actively transmit them to policymakers. Policymakers should be required to review and, if necessary, revise the legal measure and/or enforcement activities at specified intervals (for example, every five years) based on monitoring and evaluation results and the latest scientific evidence.



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Threat of legal action

It is important to note that most policy actions do not lead to litigation and when they do, most legal challenges are unsuccessful.⁵ Governments should not be deterred by the threat of food industry actors to take legal action against a food policy based on domestic or international law.

A country may be bound by numerous international commitments based on World Trade Organization (WTO) agreements, or regional or bilateral trade or investment agreements. Even though each trade or investment agreement contains unique obligations and requirements, they generally allow a government to adopt mandatory policy measures to protect human health, as long as the measures are proportionate, non-discriminatory⁶ and follow due process.

Nevertheless, legal action against public health measures does occur, and policymakers are advised to consult a public health lawyer from the beginning of the policy process, strengthen their position under international trade law, and mitigate against legal risk. Helpful steps include:

- Set a clear, valid public health objective;
- Collect and document supporting evidence and rationale for policy objective(s) and measure(s) chosen, including scientific evidence and research conducted, baseline data, international or regional standards and guidelines and an analysis of a range of available policy options;
- > Design the legal measure to apply to all domestic and imported products on the market;
- Follow and document applicable government processes and procedural requirements for regulatory action and stakeholder consultation;
- Avoid conflicts of interest in the development and implementation of the measure by setting and following clear and transparent rules of engagement with stakeholders;
- Check if and what notification requirements the measure is subject to and notify the measure to the relevant trade body or partner(s).

⁵ Most recently, Kellogg's brought a lawsuit against the UK for its regulations restricting where foods high in fat, sugar, and salt can be positioned in supermarkets and online. <u>The court dismissed Kellogg's claims and rejected its arguments on all grounds</u>.
6 Non-discriminatory means that a measure applies equally to imported and domestic products and does not discriminate against

⁶ Non-discriminatory means that a measure applies equally to imported and domestic products and does not discriminate against imported products to the advantage of domestic manufacturers.

Resources

Background information on childhood obesity and food environments

- UNICEF: Prevention of Overweight and Obesity in Children and Adolescents, Programming Guidance (2019), Prevention of Overweight and Obesity in Children and Adolescents, Advocacy Strategy and Guidance (2020).
- WHO: <u>Report of the Commission on Ending Childhood</u> <u>Obesity</u> (2016), <u>Global action plan for the prevention</u> and control of noncommunicable diseases 2013-2020 (2013), <u>Tackling NCDs: 'best buys' and other</u> recommended interventions for the prevention and control of noncommunicable diseases (2017).
- WHO, World Obesity Federation (2018). <u>Taking Action</u> on Childhood Obesity.

2 General

- <u>Legal Issues in the Design and Implementation of</u> <u>Public Health Measures</u>. Washington, D.C.: Global Health Advocacy Incubator, 2021.
- George A. (2019). Not so sweet refrain: Sugarsweetened beverage taxes, industry opposition and harnessing the lessons learned from tobacco control legal challenges. Health Econ Policy Law 14(4):509– 535. DOI:10.1017/S1744133118000178.
- Magnusson R. (2008). What's law got to do with it part 1: A framework for obesity prevention. *Aust N Z Health Policy* 5, 10. DOI: 10.1186/1743-8462-5-10.
- Magnusson R. (2008). What's law got to do with it part 2: Legal strategies for healthier nutrition and obesity prevention. *Aust N Z Health Policy* 5, 11. DOI: 10.1186/1743-8462-5-11.
- Magnusson R. & Patterson D. (2009). The role of law and governance reform in the global response to noncommunicable diseases. *Globalizatio and Health* 10, 44. DOI: 10.1186/1744-8603-10-44.
- Parent G. & Collette L. (2021). <u>Transforming agrifood systems. Legislative interventions for improved</u> <u>nutrition and sustainability. Preliminary version for</u> <u>public consultation</u>. Legal Paper 107. Rome: Food and Agriculture Organization.
- Swinburn B.A. (2009). Obesity prevention: the role of policies, laws and regulations. *Aust N Z J Public Health* 5, 12. DOI: 10.1186/1743-8462-5-12.
- Thomas B.P. & Gostin L.O. (2013). <u>Tackling the Global</u> <u>NCD Crisis: Innovations in Law and Governance</u>. *Georgetown Law Faculty Publications and Other Works*. 1205.
- Magnusson R.S. & Griffiths P.E. (2015). Who's afraid of the nanny state? Introduction to a symposium. *Public Health* 129(8):1017–1020. DOI: 10.1016/ j.puhe.2015.07.035.

3 Human rights

- Relevant treaties:
 - Convention on the Rights of the Child
 - International Covenant on Economic, Social and Cultural Rights
 - <u>Convention on the Rights of Persons with</u> <u>Disabilities</u>
- <u>Protecting Children's Right to a Healthy Food</u> <u>Environment</u>. Geneva: UNICEF & UNHRC, 2019.
- <u>A Child Rights-Based Approach to Food Marketing: a</u> <u>Guide for Policy Makers</u>. Geneva: UNICEF, 2018.
- Elver, H (2016). <u>Interim report of the Special</u> <u>Rapporteur on the right to food</u>. A/71/282, United Nations.
- General comment No. 25 (2021) on children's rights in relation to the digital environment. CRC/C/GC/25, Committee on the Rights of the Child, 2 March 2021.
- <u>General comment No. 15 (2013) on the right of the</u> <u>child to the enjoyment of the highest attainable</u>
- <u>standard of health (art. 24)</u>. CRC/C/GC/15, Committee on the Rights of the Child, 17 April 2013.
- <u>General comment No. 16 (2013) on State obligations</u> regarding the impact of the business sector on children's rights. CRC/C/GC/16, Committee on the Rights of the Child, 17 April 2013.
- Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security. Rome: Food and Agriculture Organization (FAO), 2015.
- Gostin L.O., Magnusson R.S., Krech R., et al. (2017). Advancing the Right to Health – The Vital Role of Law. *AJPH* 107(11):1755–1756. DOI: 10.2105/ AJPH.2017.304077.
- Ferguson L, Tarantola D., Hoffmann M., et al. (2016). <u>Non-communicable diseases and human rights: Global</u> <u>synergies, gaps and opportunities</u>. *Public Health* 12(10):1-28. DOI: 10.1080/17441692.2016.1158847.
- Pacific Trade and Human Rights. A joint report by UNDP, WHO and OHCHR, 2014.

4 Trade law

- Relevant treaties:
 - <u>Agreement on Technical Barriers to Trade</u> (TBT Agreement)
 - Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
- Barlow B., Sanap R., Garde A., et al. (2022). Reassessing the health impacts of trade and investment agreements: a systematic review of quantitative studies, 2016–20. *The Lancet Planetary Health* 6(5):E431–E438. DOI: 10.1016/S2542-5196(22)00047-X.
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policy in trade and investment agreements. *Bull World Health Organ* 100(4):268–275. DOI: 10.2471/ BLT.21.287395.

- Snowdon W. & Thow A.M. (2013). Trade policy and obesity prevention: challenges and innovation in the Pacific Islands. *Obesity reviews* 14(Suppl. 2):150–158. DOI: 10.1111/obr.12090150.
- Garton K, Swinburn B., Thow A.M. (2021). Implications of international trade and investment agreements on policy space for restricting marketing of unhealthy food and beverages to children: lessons from inter-disciplinary expert interviews. *Public Health Nutrition* 24(14):4750–4764. DOI: 10.1017/ S1368980021001993.