

JULY 2021

English



Introduction

The global dietary supplements industry is on track to draw USD \$295 billion in revenue by 2027. Unfortunately, weak and inconsistent regulation has created a marketplace rife with risk for consumers, particularly with supplements promising weight loss. In the United States for example, where dietary supplements do not receive rigorous prescreening from the Food and Drug Administration (FDA) before entering the market, there have been over 200 public notification reports (from 2010 till 2021) from the FDA about weight loss supplements that contain hidden active ingredients that could be harmful. The WHO global nutrition policy database does not include any policies on supplements.

About the Survey

The purpose of this survey is to identify how governments around the world regulate dietary supplements sold for weight loss. This survey was created by the <u>Strategic</u>

<u>Training Initiative for the Prevention of Eating Disorders (STRIPED)</u>, a research and training program based at the Harvard T.H. Chan School of Public Health and Boston Children's Hospital. The information collected from this survey will be used to create a database that will be an invaluable resource for researchers and community health advocates globally.

This survey takes approximately 10-15 minutes to complete. Your participation is completely voluntary. All personal information you provide in this survey will be kept confidential. Personal data provided will be anonymized, stored securely, and accessible only by the research team. Identifiable information will be utilized only to contact you about the survey.

Thank you for participating in our global policy survey about weight-loss supplements. We appreciate your input. For any questions, please contact us at striped@hsph.harvard.edu.

I understand the purpose of this survey and choose to participate voluntarily.

Yes

Contact Information

Full Name

Government	
Business/Industry	
○ Academia	
Non-governmental Organization (NGO)	
Other:	
Organization (Place of work)	
Role in the Organization	
	//

E-mail address	
Which country's policies will you be providing information on?	
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Legal Framework and Definitions

Legal Framework and Definitions

In this survey, weight-loss supplements include all dietary supplements promoted for weight loss. Weight-loss supplements may directly promise weight loss, but may also use the following phrases: "prevent weight gain," "keep weight off," "suppress/reduce appetite," "reduce fat absorption," "burn fat," "cut fat," "rev/increase metabolism," "jumpstart your diet" (often used with cleanse and detox supplements), "decrease water weight" (used with diuretic supplements), etc.

Please indicate below which government ministry/department is responsible for regulating weight-loss supplements. If there are several regulators, please indicate their respective responsibilities
Does the legislation in your country have a specific legal framework (laws or regulations) for weight-loss supplements? Yes No

Don't know
Other

Does the legislation in your country have a definition for supplements intended specifically for weight loss?

	answer is yes, please provide the definition that applies in your reweight-loss supplements
○ No	
On't know	V
Other	
Otrici	
Other	

If your country does not have a specific legal framework for weight-loss supplements, are these supplements regulated as one of the following:

Food

Medicine/Drugs

Supplements

Weight-loss supplements are not regulated in anyway

Don't know

Other (please explain):	
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For the remaining questions in this survey, please provide the relevant regulation information on the weight-loss supplements based on how they are regulated in your country (food, drug, dietary supplements, or other)

I understand

Pre-Market Regulation

Pre-Market Regulation

Pre-market regulation includes laws, rules, restrictions, or protocols that apply to a product, its manufacturer, or its importer before the product is available for purchase.

Does the regulation limit the ingredients or substances that can be used in weight-loss supplements in your country? (e.g. to limit to pre-approved ingredients or substances, etc.)?	
Yes	
○ No	
On't know	
Other (please explain)	

How does the regulator(s) in your country determine the safety of a new weight-loss supplement (a product that has not been previously registered by any regulators)?

Select all that apply

Independent evaluation of product samples

Safety information provided by the applicant

Regulator(s) does not confirm safety

Don't know

Other (please explain)	·

Does the regulator(s) in your country require that safety of a new weight-loss supplement be established through scientific criteria (e.g. scientific reference, clinical study, etc.)?

- Yes
- No
- On't know
- Other (please explain)

How does the regulator(s) in your country determine the efficacy of a new weight-loss supplement? Select all that apply

☐ Independent evaluation of product samples

<u> </u>
☐ Efficacy information provided by applicant☐ Regulator(s) does not confirm efficacy☐ Don't know
Other (please explain)
Does the regulator(s) in your country require that efficacy of a new weight-loss supplement be established through scientific criteria (e.g., scientific reference, clinical study, etc.)?
Yes

No

On't know

Other (please explain)

Are new imported weight-loss supplements subject to the same regulations in your country as new locally-produced weight-loss supplements? A new product is a product that has not been previously registered by any regulators.
Yes
○ No
On't know
Other (please explain)

Is there a registration requirement for weight-loss supplements in your country?
YesNoDon't know
Other (please explain)

Is there a licensing requirement for weight-loss supplements in your country?
○ Yes
○ No
On't know
Other (please explain)
Is there a registration requirement for producers/manufacturers of weight-loss supplements in your country?
Yes
○ No
On't know

Other (please explain)
Is there a licensing requirement for producers/manufacturers of weight-loss
supplements in your country?
Yes
○ No
On't know
Other (please explain)

Claims, Labeling and Advertisements

Claims, Labeling and Advertisements

Claims are statements made about a product's content or effects (health, nutritional or functional). These statements can be made while marketing and advertising the product, or statements can be printed on labels and marketing materials. Examples of claims include: "prevent weight gain," "keep weight off," "suppress/reduce appetite," "reduce fat absorption," "burn fat," "cut fat," "rev/increase metabolism," "jumpstart your diet", "decrease water weight", etc.

How are claims related to weight-loss supplements (e.g. weight reduction, changes to body functions, etc.) regulated in your country? Select all that apply.
Certain claims are prohibited
☐ Pre-approval of claims is required
Claims are required to have a scientific basis (e.g., scientific reference, clinical study, etc.)
☐ Claims are not regulated
☐ Don't know
Other (please explain)

Are there specific labelling requirements for weight-loss supplements (e.g, warnings, disclaimers, instruction for consumption, etc.) in your country?
Yes
○ No
On't know
Other (please explain)
Are there any regulatory limitations on advertising supplements intended for weight loss

Do limitations on advertisements apply to any of the following media outlets? Select all that apply.
□ TV and cinema □ Internet (social networks, blogs, etc) □ Billboards and banners □ Printed media (newspapers, pamphlets, magazines, etc.) □ Radio □ Don't know □ Other (please explain)
Are there any limitations on advertising weight-loss supplements to children in your country? For example, is advertising these products allowed in youth magazines or in TV programs for children, etc.?
Yes

Don't know

Qualities out vey contware
Other (please explain)
Are there any disclaimers or warnings that have to be included in advertisements for weight-loss supplements in your country?
Yes. If the answer is yes, please specify these warnings and disclaimers.

	No	
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	Other (please explain
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Availability

Availability

Are there limitations on where weight-loss supplements can be sold in your country?
Yes. If the answer is yes, please specify where these supplements CANNOT be sold.
○ No
On't know
Other (please explain)
Does the regulator(s) require that certain supplements for weight loss be sold only with a prescription in your country?
Yes
○ No
On't know
Other (please explain)

Is there a minimum legal age t	o buy supplements for weight loss in your country?
	Yes. If the answer is yes, please specify the age.
○ No	
On't know	
	Other (please explain)
Are there specific laws and reg weight-loss supplements in you	gulations regarding the online sale and purchase of ur country?
Yes	
○ No	
On't know	
	Other (please explain)

Adverse Events

Adverse Events

An adverse event is any undesirable experience associated with the use of a medical product in a patient or consumer.

Does the legal framework (laws or regulations) in your country require the manufacturer, importer or another agent (e.g. pharmacy) to report adverse events experienced by consumers related to the weight-loss supplement?	
Yes	
○ No	
On't know	
Other (please explain)	

Is there an official process in your country through which consumers can report to the regulator about adverse events experienced after consuming a weight-loss supplement?

Yes	
○ No	
On't know	
	Other (please explain)

Are the reports on adverse events related to weight-loss supplements available to the public (e.g. on the regulator's website) in your country?

Yes. If the answer is yes, please indicate where this information is available.

No
Don't know
Other (please explain)

Once an adverse event related to weight-loss supplements has been reported – does the regulator(s) in your country take steps to determine whether a recall is warranted?
YesNoDon't know
Other (please explain)
How many adverse events related to weight-loss supplements were reported in the past five years in your country?

 \bigcirc C

1-10

11-50

51-100

Over 100

On't know

How many product recalls due to adverse events related to weight-loss supplements were announced in the past five years in your country?		
01-1011-5051-100		
Over 100 On't know		

Monitoring and Enforcement

Monitoring and Enforcement

Which of the following does the regulator(s) in your country monitor regarding weightloss supplements? Select all that apply.

Presence of non-registered or non-licensed products on the market.

Compliance of registered or licensed products with regulations.

Compliance of online sales and purchases with regulations.

Regulator(s) does not mon Don't know	itor weight-loss supplements.
	Other

Does the regulator(s) in your country use penalties or other sanctions in cases where weight-loss supplements do not comply with the regulation that applies to the following (select all that apply)? Please provide information on the penalties or other sanctions for non-compliance to regulations relating to each selected option.

Pre-Market regulation
Claims
Labelling
Advertisements
Availability

	Adverse event reporting		
☐ Don't know	Other		
Are there any other relevant policy tools in your country relating to weight-loss supplements that were not covered in this survey?			
	Yes. If yes, please describe them below		
○ No			
O Don't know			

Submit

Submit

You have come to the end of this survey. You can still go back to make any changes to your responses. If you are satisfied with your responses, please select submit and click

For any questions please e-mail us at: striped@hsph.harvard.edu

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