Checklist of Key Items[a] to Include in Fortification Legislation, Standards, and Monitoring Documents

Source: Marks KJ, Luthringer CL, Ruth LJ, et al. Review of grain fortification legislation, standards, and monitoring documents. Glob Health Sci Pract. 2018;6(2). https://doi.org/10.9745/GHSP-D-17-00427

Review your national fortification documentation and note in the column at right whether it contains the key item. If the item is weak or missing, see sample language to use.

General	**Yes or No**
1. States that legislation applies to at least one food vehicle fit for human consumption (types/grades to be fortified)	
2. States the public health objective; purpose and scope of legislation	
3. References latest available science or accepted international norms and recommendations, particularly for items that may not be covered in the country's documents	
4. Provides definitions that include terms that are specific to fortification (e.g., fortified food, premix, fortificant, food vehicle)	
5. Provides repeals (if there is at least one prior document about fortification)	
6. Provides effective date or gives grace period for when fortification is to begin (e.g., effective 6 months from signing)	
Micronutrients/Premix	**Yes or No**
7. States nutrients required	
8. States fortificants (chemical compounds) to be used (including fortificants that are allowable as options)	
9. States fortification levels	
10. States consideration of bioavailability/biological activity of fortificants	
11. States consideration of nutrient stability	
Costing	**Yes or No**
12. States that the cost of fortification is regulated through cost-sharing schemes (between government, industry, consumers) or tax measures (to assist industry)	
13. States consideration of the financial responsibility (of the government) of monitoring and enforcing fortification (schedule of fees, budget)	
Labeling	**Yes or No**
14. Includes some sort of statement/label/logo that makes it clear that the product is fortified	
15. Provides guidance on health claims that can be made for this product (specific to micronutrients added through fortification)	

Internal Monitoring (Conducted by Industry)	**Yes or No**
16. States requirement for sampling as part of internal monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	
17. States that industry is required to follow quality assurance/quality control in regards to fortification	
18. States applicability of using qualitative testing (e.g., spot tests, iChecks) to determine the presence or absence of a vitamin or mineral	
External Monitoring (Conducted by Government)	**Yes or No**
19. States requirement for external monitoring at the production site to assure compliance with standards and regulations	
20. Describes protocols and systems for regulatory monitoring	
21. If there are two or more government agencies involved in external monitoring, clarifies the roles and responsibilities between different government agencies in external monitoring	
22. Allows for monitoring to be conducted often enough that problems can be identified and addressed on a timely basis; specifies a timeline for inspections (e.g., once every 6 months, increasing to once every 2 months if a discrepancy is found)	
23. States requirement for sampling as part of external monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	
24. States applicability of using qualitative testing (e.g., spot tests, iChecks) to determine the presence or absence of a vitamin or mineral	
25. States registration is required in order to use a logo/be licensed to produce fortified foods	
Commercial Monitoring (Conducted by Government)	**Yes or No**
26. Provides justification for commercial monitoring at retail stores	
27. Describes protocols and systems for commercial monitoring	
28. If there are two or more government agencies involved in commercial monitoring, clarifies the roles and responsibilities between different government agencies in commercial monitoring	
29. Allows for monitoring to be conducted often enough that problems at the production site or import companies can be identified and addressed on a timely basis; specifies a timeline for inspections (e.g., once every 6 months) or works with production companies to correct noncompliance	
30. States requirement for sampling as part of commercial monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	

Import Monitoring (Conducted by Government)	**Yes or No**
31. Provides justification for import monitoring at points of entry	
32. Describes protocols and systems for import monitoring	
33. If there are two or more government agencies involved in import monitoring, clarifies the roles and responsibilities between different government agencies in import monitoring	
34. States requirement for sampling as part of import monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	
Enforcement/Penalties	**Yes or No**
35. Indicates roles and responsibilities in enforcing the legislation	
36. States incentives to start fortification	
37. States incentives to continue fortification, including ensuring compliance	
38. States penalties to compel compliance	
39. Penalties are objectively defined (e.g., first penalty=$100, second penalty=$300)	
40. States that enforcement is required to include feedback and support to improve performance and correct noncompliance	
Laboratory	**Yes or No**
41. References required analytical assays for nutrients (e.g., liquid chromatography-mass spectrometry for folic acid, atomic absorption for iron and zinc)	
42. States recognition that laboratory results are subject to several sources of variation and do not provide conclusive evidence of compliance or noncompliance	
43. Focuses on the quantitative analysis of "marker" micronutrients such as iron	
Reporting	**Yes or No**
44. States how government monitoring results are shared with stakeholders	

[a] As identified in the literature and by content experts.