



## National and International Standards and Regulatory Issues for Biofortification

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Biofortification is a relatively new process for increasing micronutrient levels of crops through breeding. HarvestPlus is currently leading the effort to develop and introduce biofortified staple crops in 8 countries while also working with diverse partners in more than 40 countries. Currently, hundreds of thousands of households are being reached with biofortified foods, and global reach is rapidly increasing. As the effectiveness of biofortification is being demonstrated through progress of these programs, national governments are adopting biofortification into agriculture and nutrition agendas and global policies are being put into place. Internationally recognized definitions, standards, and guidelines are needed to help formulate written policies and regulatory texts referring to biofortification.

### Issues with Lack of Standards and Regulation

Without global standards, governments seeking to incorporate biofortification into national programs face significant challenges in regulation. Variation in food labelling, regulation of the safety and assessment of nutritional quality, product and crop naming issues, and guidelines for production provide barriers that complicate adoption of biofortification. This situation inevitably raises questions around what the trade challenges might be.

### Standard Setting Process and the Codex Alimentarius

In order to address the critical need for internationally accepted standards and guidelines, HarvestPlus/International Food Policy Research Institute joined The Codex Alimentarius to begin the process of introducing biofortification as a topic needing consideration by the appropriate Codex Committees. Established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in 1963, The Codex Alimentarius Commission oversees development of international standards, guidelines, and codes of practice for food to inform global and national texts.

Progress has been made in deliberating standards, though several issues have arisen in need of consensus. First introduced in 2012 by HarvestPlus to the Codex Committee on Food Labelling (CCFL), biofortification was then reviewed in 2013 through a discussion paper. CCFL referred biofortification to the Codex Committee on Nutrition and Foods of Special Dietary Use (CCNFSDU), who then requested establishment of a consensual definition of biofortification. In 2013, Zimbabwe and South Africa—supported by 31 country interventions—offered to co-lead the development of a revised discussion paper and project document to request development of a formal definition.

This complex process includes considerations on how biofortified crops are distinguished from their counterparts, potential types of organisms involved, inclusion of other attributes in addition to micronutrients (such as protein levels), and biofortification's relationship with fortification.

As this discussion continues, the next step will be to develop a Discussion Paper and Project Document by the Governments of Zimbabwe and South Africa on the need for a definition, to be presented at the next session of the CCNFSDU.

### Highlights:

- HarvestPlus gained “Member with Observer Status” in The Codex Alimentarius Commission
- The Codex Committee on Nutrition and Foods of Special Dietary Use introduced biofortification and requested the development of a formal definition for biofortification

### Challenges:

- Establishing an internationally agreed upon definition of biofortification, considering the diversity in methods and attributes
- Advising current regulation by national governments of biofortification programs without existing international standards
- Establishing how the Competent Authorities attest to the product
- Establishing whether claims can be made once there is a definition

