

# Science-based mandatory standards and the implementation gap: the case of bottled water regulations in India

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*Science-based standards and regulation-making is not a new phenomenon in India. In fact, Indian regulatory institutions have been developing standards and evolving in multiple areas over many decades. However, even mandatory standards are not easily enforceable in several cases, and often an 'implementation gap' has been reported. The present article explores this critical aspect of regulation-making exercise in India by considering the case of bottled water. The article analyses the regulatory governance of bottled water quality standards promulgated by the Bureau of Indian Standards. The findings could be useful for Indian industry, regulators, science administrators and the government.*

**Keywords:** Bottled water, implementation gap, regulation-making, science-based standards.

SCIENCE-based standards, standardization and regulation-making is at least a century-old phenomenon<sup>1</sup>. Even in India, over the last six/seven decades, standards of different kinds have been formulated by different types of institutions<sup>2</sup>. The debate for establishing the biggest and most influential standard-setting organization in the country, i.e. Bureau of Indian Standards (BIS) was initiated in the pages of *Current Science* in the 1940s (refs 3, 4). It was established in 1947 as the Indian Standards Institute (ISI)<sup>5</sup> and went through various phases of transformation over the years. So far, 21,000 standards have been formulated by BIS in different domains. As on 31 March 2013, around 18,965 standards are in force<sup>6</sup>. Of these, 90 products are under mandatory certification, in which 14 are related to food and related items (for example, milk powder, plastic feeding bottles, packaged bottled water, natural mineral water, infant milk substitute, milk protein based). The selection of such products was made keeping in mind their health and safety aspects, as these are consumed in mass scale<sup>7</sup>.

The organizational network of BIS and expertise in making regulations for products and processes in multiple areas and its reach are evidence of its functionality. The bigger question in the current scenario is how these standards are implemented or enforced. In the modern world, where life is so much dependent on consuming industrial goods produced on mass scale, standards become more important<sup>8</sup>. Standards of various kinds are used by regulatory bodies and market to govern our lives<sup>9</sup>. In 2003,

during the bottled water controversy<sup>10</sup>, the *Economic and Political Weekly (EPW)* published an editorial titled 'Drinking water: bogus standards'<sup>11</sup>. It raised questions on regulation-making and its enforcement in India as follows: 'It is surprising that the Indian Standards Institution does not have a periodic report on the monitoring of standards nor a system that periodically reviews standards as does the United States Food and Drugs Administration. So poor are the regulatory and information dissemination mechanisms that the consumer depends entirely on marketing information from the manufacturer on issues such as safety and quality standards.' The trust on standards and Government institutions, however, has not completely diminished in India. Bhaduri and Sharma<sup>12</sup> have argued that people from small towns in India have higher trust on BIS standards. On the contrary, urban people are more aware about BIS standards but they do not completely trust them<sup>12</sup>. They look for other factors (brand name, properly sealed, type of filtration) too while consuming bottled water. The major concern in India in the domain of regulatory governance is about the implementation or enforcement of standards. This view is even endorsed by the scientific community of the country, which is a major stakeholder in the regulation-making.

In this background, the present article analyses the 'implementation gap' for enforcing science-based mandatory standards in India. We take the case of bottled water quality standards for analysing this regulatory phenomenon. We draw from the field work carried out in New Delhi, Jaipur (Rajasthan), Patna (Bihar), Kolkata (West Bengal) and Bengaluru (Karnataka) during 2010–14. We interviewed around 20 scientific experts, government officials, technology suppliers; surveyed 33 bottled water

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manufacturing firms, and around 200 consumers in different parts of the country. In addition, we draw from the primary and secondary literature available on drinking water regulations in India.

### Standard-making, monitoring and enforcement

David<sup>13</sup> defined standards as ‘technical specifications that may be adhered to by a producer, either tacitly or as a result of a formal agreement’. A formal agreement or tacit understanding on the benefits of standards is crucial for enforcement of regulation. The enforcement practices become more important if the standards are made mandatory by law. In India, the bottled water standards were made mandatory under a law in 2001 (ref. 12). Leach and Scoones<sup>14</sup> provide an account of the different models of regulation enforcement employed in developing countries: ‘In the context of healthcare regulation in Tanzania, a move away from conventional but ineffective rule-based regulation has been proposed, towards a concept of “collaborative regulatory intervention”.’ It implies taking the help of other stakeholders for proper enforcement of regulation, instead of relying solely on government mechanism. In this regard, the perspective of different stakeholders helps in building trust on the overall regulatory system<sup>15</sup>. Does BIS take help of other stakeholders for implementing mandatory standards? How does BIS implement the standards? These will be analysed in the subsequent sections of the article.

One can argue, that setting standards is only one component of regulation-making; monitoring the adoption of standards and enforcement forms the other pillar of regulation-making. These concerns have been raised in the academic literature from the United States and Western Europe<sup>16,17</sup>. The existing literature on regulatory science and governance in India often does not incorporate monitoring and enforcement practices into its ambit while analysing regulation<sup>18</sup>. In other words, the analysis of the regulation-making process is not holistic; rather it considers the different components (regulation-making, monitoring, feedback loop, enforcement) as separate functions unconnected with each other.

### Disjoint between regulation-making and implementation in India

BIS promulgates the standards and monitors the certification and enforcement with the help of its offices and laboratories located in different parts of the country. The Headquarter of BIS is located in New Delhi; there are five regional offices in Kolkata (Eastern Regional Office), Chandigarh (Northern Regional Office), Mumbai (Western Regional Office), Chennai (Southern Regional Office) and New Delhi (Central Regional Office)<sup>19</sup>. In addition, 28 branch offices, 8 laboratories (central, re-

gional and branch) and training institutes are located in major Indian cities<sup>20,21</sup>. Interestingly, BIS is not the only regulatory agency for enforcing regulations, but other government agencies are also endowed with this responsibility.

The bottled water industry is monitored and regulated by different government agencies in India. The BIS certification was made mandatory under the Prevention of Food Adulteration Act, 1954 for which the Ministry of Health and Family Welfare (MOHFW), Government of India (GoI) is the nodal agency. The subject of Prevention of Food Adulteration is in the concurrent list of the Indian constitution<sup>22</sup>, and the enforcement is mainly done by the State and Union Territory governments<sup>23</sup>. Specifically, the enforcement is carried out by the State Public Health Engineering Department (PHED), which comes under MOHFW. The BIS regional branches only issue licenses to those firms whose product water adheres to standards prescribed by BIS. The BIS officials informed us that while issuing a license they do not check the raw water quality or its availability. Many districts and blocks in India are facing serious groundwater challenges in terms of pollution (high arsenic, fluoride, nitrate contaminant in groundwater) and over-extraction<sup>24</sup>. Ignoring the specific groundwater concerns (pollution and over-exploitation) in different regions by BIS while granting licenses will further aggravate the situation. In recent years, we have witnessed several controversies in different parts of the country over the extraction of groundwater by bottled water companies and other industries<sup>25,26</sup>.

There is no functional mechanism to incorporate the inputs of different stakeholders into the regulation-making process. BIS claims that it regularly engages with manufacturers. It organizes seminars and conferences, and seeks feedback from manufacturers. However, these claims were not supported by firm owners from any of the cities during field work, except in Bengaluru. It reflects the inadequacy and limitations of such activities. The BIS webpage to collect complaints regarding ISI-marked products does not work properly and provides incomplete information<sup>27</sup>. However, recently, the i-CARE Department has been created by BIS by merging its existing Consumer Affairs and Enforcement Departments<sup>28</sup>. It has provided various incentives and provisions for prompt attention and speedy redressal of consumer grievances<sup>29,30</sup>. Based on complaints registered by consumers against various firms for non-compliance of BIS standards and certification, 15 cases were dispensed by courts in India in favour of BIS in 2013–14 specifically dealing with packaged drinking water<sup>31</sup>. However, BIS enforcement activity is limited to ‘curb the use of Standard Mark or its imitation by unscrupulous traders and manufacturers not holding valid BIS licence’<sup>32</sup>. In cases where manufacturers are operating without using BIS license, other government departments (such as PHED) are responsible for curbing such activities. Such illegal (firms which are

operating without obtaining BIS license) bottled water firms are not regulated by BIS.

According to one firm owner from Jaipur, 'At least many folds more number of illegal bottled water manufacturers exist in the market than the list provided by BIS. Mostly these firms without license from BIS to do business operate in the 20-litre segment. But they never check them, it all happens under their nose. But nothing is going to change; we assume that this will continue.'

The cynicism is very much evident from this response. Contrary to this, the Director General of BIS mentions that 'the need of the hour is to review norms...promote standard quality norms in the industry; create a sense of pride in the minds of our stakeholders...'<sup>33</sup>.

Rather than trusting the BIS standards and its importance, some firm owners from Jaipur and Bengaluru reported that it is easier to operate manufacturing firms without BIS license. Indeed, numerous firms operate without the BIS license all across India. One of the small firm owners from Jaipur states that, 'The production costs of the local bottled water manufacturers are almost equal to the big players, but they do not get the same price for their products in the market. The BIS license does not have any meaning; it only acts as a hindrance. It is easier to do business without BIS certification. In that case, we will only focus on 20-litre jars. Lots of such firms are operating in the market.'

Concerns and distrust regarding the implementation of regulatory standards were also highlighted by scientific experts. According to a senior environmental scientist from Jawaharlal Nehru University, New Delhi, 'In India, the problem is with the implementation of rules and standards; we do not have the instruments and human resource to implement stringent standards. There are not enough laboratories in the country which can examine the quality of water at 10 ppb for arsenic. The main problem is with the implementation; regulation-making on paper is not going to change anything.'

Another scholar shared this concern. According to a researcher from the Indian Institute of Science (IISc), Bengaluru there are no linkages among those doing research, implementing agencies (for example, government departments), funding agencies that fund specific kinds of research work, and common public. This disjoint leads to the current situation, where regulations are being made but never implemented properly.

To tackle issues regarding implementation raised by the experts, we analyse, in the next mechanism of implementation followed by BIS and the role of supporting institutions in this light. The overlapping jurisdictions of different government bodies/departments to regulate different activities, such as regulation-making, certification process and implementation/enforcement of regulatory standards make the process more complicated. The responsibilities, duties and functioning mechanisms of the various departments and ministries, are considerably dif-

ferent from each other. There is little coordination among them. The BIS officials pass the 'blame' of non-compliance of standards and 'implementation deficits' on other departments.

### **Insufficient supporting institutions and human and technical resources**

The BIS standards specification for packaged drinking water entails divergent guidelines for different kinds of water quality tests to be performed by the firms. For some specific tests (such as, radioactive contaminants), they need to consult BIS-recognized laboratories. We found that only a small number of laboratories are licensed by BIS and the licensed ones are located mostly in the selected major metropolitan cities of India. In 2003, out of 7 laboratories of BIS, only the Central Laboratory at Sahibabad had the capability of testing for chemical and biological contaminants; however, it was unable to carry out tests on pesticide residues. At that time, BIS had recognized 13 additional laboratories (BIS-approved) for testing different water-quality parameters, out of which 10 were capable of testing pesticide residues<sup>34</sup>. BIS accepted in writing the shortage of scientific cadre required for the smooth discharge of duty<sup>35</sup>. The regulatory agency made the standards mandatory in 2001, but proper facilities to monitor and regulate the functioning of manufacturing firms for compliance with standards are not in place. Currently, the number of laboratories authorized by BIS for testing packaged drinking water is abysmally low with respect to the number of licenses issued to manufacturing firms. For instance, in May 2014, 2979 firms were licensed by BIS to manufacture bottled water, whereas only 38 laboratories are recognized to test specific parameters for packaged drinking water<sup>36</sup>. All authorized laboratories are privately owned. They are certified based on the adherence to requirements of ISO 17025 (ref. 6). Out of 38 laboratories, only 3 (SME Testing Centre, Chennai; Monarch Biotech (P) Limited, Chennai and Modern Test Centre, Ganjam, Odisha) have the capability to check radioactive residues in packaged drinking water. According to BIS guidelines, every firm needs to send samples for analysis of toxic metals once in six months, and for pesticide residues and alpha and beta emitters once in two years<sup>6,37</sup>. A very small number of laboratories are incapable of testing large number of samples per month. Moreover, there is no regulation on the number of licenses to be awarded by branch offices in a particular year. It is not linked with their capabilities to monitor the same. According to an official from BIS in Jaipur, 'we are bound to give license to anyone who applies for that and fulfils all the criteria; there is no limit on this.'

During the field work we also found that BIS is seriously struggling with shortage of human resources (trained manpower) for monitoring the licensing process.

BIS officials and firm owners from Patna, Kolkata and Bengaluru indicated the shortage of staff. Moreover, BIS has started subcontracting the inspection work to external auditors/experts<sup>38</sup>. It adopts two ways to monitor the activities of bottled water manufacturing firms. First, BIS officials do factory visits, inspect the site and collect samples for evaluation. Second, they also randomly collect samples from the market and analyse them<sup>39</sup>. It was found that information regarding the BIS monitoring scheme is not readily available in the public domain. Although this information is available on the BIS website, common public is hardly aware of such activities. The Satwant Reddy Committee report states that up to 2003, 'BIS has drawn in all 3259 samples of which 1016 samples were for testing of pesticide residue. In which, 494 samples have failed to meet one or other requirement'. The low frequency of inspection was also noted in this report<sup>40</sup>. It was found that some branch offices are struggling with the lack of human resources for carrying out such inspection.

## Conclusion

The enforcement mechanism of BIS for implementing mandatory regulatory standards for bottled water is weak. The primary reason is the disjoint between regulation-making and implementing exercise. The BIS does not see implementation as an integral part of regulation-making and this needs to be addressed. Till the regulatory agencies deal with the question of implementation while making regulations, the 'implementation gap' cannot be bridged. In this direction, the regulatory agencies should incorporate the views of diverse stakeholders, including lower-rung officials of BIS, small firm owners, technology suppliers, scientists and common consumers. They need to devise ways to engage with the stakeholder and incorporate their views in the overall process of regulation-making.

The second major challenge is the presence of several public organizations/institutions at multiple levels for implementing standards and the lack of coordination among them. There is no easy solution for this. It is a recurrent problem in the regulatory governance of environmental domain in India. There are multiple positions and views on this and we need to think along those lines to come up with a comprehensive solution. One way out is stronger self-regulation by the firms. However, this can only succeed if the appropriate regulatory environment is created, which seems quite unlikely in the present context. The third and more practical challenge is the insufficient regulatory infrastructure and human resources to enforce regulatory standards. These findings present a strong case for a rethinking on the existing regulatory governance models in India. We would like to draw attention of the scientific community, industry and government on this critical aspect of regulatory governance

in India. Hopefully, this study will be a precursor, leading to more meaningful debates on these issues in future and will help in improving the regulatory capacity of Indian regulatory institutions.

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