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Opening the 'Black Box' of Regulation-making for Bottled Water Quality Standards in India

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The paper contributes to the under-researched domain of standard setting for bottled water quality in India. The paper opens-up the 'black box' of regulation-making by analysing the mandatory bottled water quality standards set by the Bureau of Indian Standards (BIS). The regulation-making exercise is dominated by bureaucrats and technocrats representing government departments, publicly funded institutions and representatives of big industries. In the standard-setting committees, representation of NGOs, small firms, technology suppliers, independent experts, consumers and citizens are either missing or limited. The kind of experts enrolled by the technical committee and the practice and principles employed by BIS for decision-making have a strong bearing on the regulatory standards. The standard setting for bottled water was the outcome of a complex process that was significantly shaped by the views and values of the dominant regulatory actors, especially what was perceived as valid and superior 'regulatory knowledge'. Discrete actors, such as bureaucrats, technocrats, big firms and NGOs, supported the wider adoption of international standards, but they had different rationales for advocating the adoption. However, the uncritical adoption of international standards has resulted in a disregard for incorporating environmental, epidemiological, dietary and diverse socio-economic factors into setting standards. Inclusion of socio-economic and other contextual factors could increase the validity and effectiveness of regulatory standards.

Keywords: Regulation-making, science-based standards, standard-setting, bottled water, mundane technologies, India

Introduction

The Science and Technology Studies (STS) literature on regulation-making is mostly skewed toward advanced economies (Castel, 2009; Hauray, 2017; Higgins & Hallström, 2007; Levidow, 2001; Ottinger, 2010; Thevenot, 2009). In addition, it emphasises high-end technologies and emerging and controversial techno-scientific

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themes (Daemmrich & Krücken, 2000; Epstein, 1997; Hoeyer, 2015; Krimsky, 2005). The regulation-making process for science-based standards for mundane artefacts in developing countries is understudied. Even in the global north, only a few studies have examined the regulation-making process for artefacts and products used in everyday life (van Zwanenberg & Millstone, 2015; Wengle, 2015; Winickoff & Bushey, 2010). Unlike artefacts produced using high-end science, mundane artefacts rarely draw huge attention from scientists, policymakers, NGOs, or even civil society groups. Many of these products, such as drinking water, salt, sugar, cooking oil, flavour additives and the plastic used for packaging food items, are widely used and significantly shape everyday life. The safety and efficacy of such products are often debated in the public realm if controversies erupt (Bhaduri & Sharma, 2014; Lustig, et al., 2012; Pandey & Sharma, 2017; van Zwanenberg & Millstone, 2015); otherwise, they stay outside the public gaze.

The paper attempts to contribute to this less studied area of regulation-making (Koop & Lodge, 2017) by analysing the standard-setting exercises for bottled water quality standards in India.[1] During the last two decades, the bottled water industry has registered rapid growth, and India became the top ten bottled water-consuming nation (Sharma & Bhaduri, 2013; Shukla & Singh, 2016). The bottled water sector in India comprises more than 6367 manufacturers, with a market size of approximately 160 billion INR. The market is expected to reach 400 billion by 2023 (BIS, 2022; Market Research, 2022). Small manufacturing firms dominate the bottled water market in India in terms of the sheer number of manufacturers, but in terms of sales, major national (Bisleri, Bailey) and international firms (Kinley, Aquafine) dominate the market (Sharma & Bhaduri, 2013; Sharma, 2014). Besides meeting domestic needs, Indian bottled water firms cater to the international market, which has rapidly grown over the years.[2]

Bottled water has a more than 60-years history in India (Sharma & Bhaduri, 2013). The voluntary standards for packaged drinking water were published by the Bureau of Indian Standards (the National Standards Body) for the first time in 1998 and were made mandatory in 2001 (Bhaduri & Sharma, 2014). A couple of years later, a major public controversy erupted in 2003 over the issue of pesticide residue in the major bottled water brands in the country (Bhaduri & Sharma, 2014; CSE, 2003, 2004; Pandey & Sharma, 2017; Quark, 2018). This pesticide controversy in bottled water has shaken the regulatory decision-making process for setting bottled water quality standards (Bhaduri & Sharma, 2014; Pandey & Sharma, 2017; Quark, 2018). It led to the establishment of the fourth Joint Parliamentary Committee (CSE, 2003) in the history of India and the first on water; it eventually contributed to changes in the regulation-making process for bottled water (BIS, 2003; JPC, 2004).

The standard-setting process mostly remained outside the gaze of the academic community. Bhaduri and Sharma (2014) examined the public's understanding of regulation-making in the context of standard-setting for bottled water quality, and Sharma (2018) examined the monitoring and implementation gaps in regulation-making, but they did not analyse the standard-setting process of BIS

per se. The regulation-making process is still mostly perceived as a 'black box'. Rather than focussing on the consequences of the mandatory standards on the bottled water industry, public health, or the economy in general, this paper attempts to map the regulatory actors, the content of regulation making, and the influence of supranational standards on the standard-setting process for bottled water quality standards in India.

The paper is divided into five sections. Section one introduces the study; section two deals with the analytical framework; section three describes the methodology; section four presents the findings; and finally, section five concludes the study.

Standard-setting: The Site of Regulation-Making

Standard-setting has been studied as a regulatory process by many scholars over the last few decades (Bowker & Star, 1996; Bowker & Star, 1998; Brunsson & Jacobsson, 2000; Brunsson et al., 2012; Higgins & Hallstrom, 2007; Jansen, 2010; Jasanoff, 1987; Schmandt, 1984; Thevenot, 2009; Timmermans & Epstein, 2010; van Zwanenberg & Millstone, 2015; Weinberg, 1985). Over the years, standards and standardisation of different kinds created a higher level of global order, and thus standard-setting exercises emerged as a significant domain of study (Abraham, 1993; Brunsson & Jacobsson, 2000; Daemmrich & Krücken, 2000; Ottinger, 2010; Thevenot, 2009; Winickoff, 2015). Unlike other sociological studies on standards, we wish to emphasise a specific subfield, that is, the science-based standard-setting exercise employed by the BIS, a major regulatory institution in India.

STS scholars initially explored the regulation-making exercises for science-based standards by analysing the types of experts involved in the process. The regulation-making process was dominated by scientists and technical experts (Fisher, 2011; Jasanoff, 1990; Majone, 1984; Nowotny et al., 2001). The democratisation of regulation-making started as an aftermath of scientific and industrial controversies (Hagendijk, 2004; Leach & Scoones, 2006; Leach et al., 2005; Lujan & Todt, 2007; Millstone & van Zwanenberg, 2000; Pandey & Sharma, 2017). Scientific controversies led to the inclusion of other actors, such as the common public, patients' groups, civil society groups, consumer organisations and even industrial actors, in the regulatory decision-making process (Bryer, 2013; Epstein, 1996; Fisher, 2011; Hagendijk, 2004; Irwin, 2001; Pandey & Sharma, 2017; Parthasarathy, 2010).

Different regulatory actors contested the validity of scientific facts and knowledge employed during regulation-making. Regulatory actors often differ in estimating and understanding the risks and benefits derived from the standards, specifications, procedures and guidelines suggested to achieve the standards (Hagendijk, 2004; Levidow, 2001; Millstone & Zwanenberg, 2000). Scholars argue that decisions on many issues are based on the fundamental beliefs and values of experts involved in decision-making (Funtowicz & Ravetz, 1993; Levidow, 2001). In Levidow's (2001, p. 3) words, 'in seeking and organising more facts about risk, regulators implicitly make socio-political choices, for example, about what potential harms to prevent and, in so doing, about what

opportunities to forego'. Sobsey (2006) argues that while setting standards for water quality, socio-cultural beliefs, practices and perceptions should also be addressed, as human behaviour and everyday life are inextricably linked to drinking water.

The regulatory actors debate and discuss facts, values and scientific knowledge required for regulation-making by drawing from various knowledge systems (Levidow, 2001). The frames that get prominence and those that are overlooked need to be evaluated to understand the overall regulatory process. Especially in the case of drinking water, as there are numerous kinds of contaminants and a lack of studies on the health effects of different pollutants (Blette, 2008). The impacts of various contaminants on humans are often difficult to discern over short periods (Karr, 2004). Drinking water presents a unique case where scientific studies argue that the standards should take into account environmental, geographical, cultural (food habits) and demographic factors (WHO, 2004).

In cases of high uncertainty and where the scientific consensus is challenging to achieve, how are the disagreements among scientists on the permissible limits of contaminants in drinking water (Chakraborti et al., 2002; Martin, 1988; Ramachandra et al., 2010; Smith & Smith, 2004) settled during regulatory decision-making? Do the regulatory actors solely focus on 'scientific facts' produced by different scientific communities (*epidemiological studies*, *toxicological studies* and *public health studies*), or do they also rely on socio-political values, contingent choices and institutional factors while setting standards?

For instance, the assessments of 'available' technological solutions to achieve the standards significantly influence the standard-setting debate (Wallace, 1995). The scientific and technical characteristics of available purification technologies and the economic considerations of adopting such technologies have massive bearings on the regulatory standards.

Moreover, the role of supranational regulatory organisations (WHO, ISO and CODEX) in influencing standard-setting exercises has increased in the last few decades. They shape national-level standards and regulations (Quark, 2018; Thevenot, 2009), and their power has increased with trade liberalisation in developing countries (Miller, 2007; Post, 2005; Quark, 2018; Scoones, 2002; Thevenot, 2009; Winickoff & Bushey, 2010). The role of science- and technology-related factors, values and risk assessment have been identified as another major driver influencing the harmonisation of standards by STS scholars (Murphy et al., 2006; Post, 2005; Scoones, 2002). Post (2005) elucidates the background of the emergence (safety and protectionism) of Codex Standards at the global level. Winickoff and Bushey (2010, p. 357) explicitly state, 'the power of the Codex in standardising the regulation of health, trade and environment changed radically in 1994 when the WTO elevated its legal status within the global trading regime'. Miller (2007) termed supranational institutions as *international knowledge institutions*, as they shape the production and validation of knowledge at the global level.

Finally, the process of arriving at a conclusion in the regulatory decision-making process occupies a critical position in understanding the regulatory

decision-making process and overall regulatory regimes. For instance, Thevenot (2009, p. 294), while describing cancer guidelines in France, states that 'cancer guidelines called "Standards, Options and Recommendations" (SOR) are ranked according to their varying "degrees of evidence". The highest degree is evidence based on randomised clinical trials, which rests upon the solidity of statistical equipment. In contrast, "expert consensus" does not involve the same solidity: it is an evidence that is valid for communities of specialists and is based upon their embodied formatting of information, but it does not rest as strongly on equipment.' The standard-setting process often follows the evidence-based method (scientific evidence), the consensus-based method (among experts) or other methods (such as the inclusion of anecdotal evidence from laypersons) to reach consensus.

In this background, the paper explores three research questions, such as, who are the regulatory actors endowed with the authority to make regulations for bottled water quality standards in India by BIS? What kind of values and factors shape the regulation-making process? How and why do different regulatory actors enrolled by BIS in setting national standards for bottled water advocate for 'homogenising' national and 'international' standards?

The contaminants in drinking water are largely classified under four broad categories, namely, microbial, chemical, physical and radiological. We primarily focus on the chemical aspects of contaminants. We focused on select chemical contaminations in drinking water that pose the highest threat to public health. These include fluoride, arsenic and nitrate (WHO, 2008). Studies elucidated that, out of 593 districts in India for which data is available, there are problems of high fluoride in 203, nitrate in 109 districts and arsenic in 35 districts (Rahman et al., 2005; Shankar et al., 2011).

Methodology

The primary fieldwork for this study was carried out in different parts (Delhi, Kolkata, Jaipur, Patna and Bangalore) of India during multiple phases between 2011 and 2014. The data for the study were collected at two levels. First, we conducted semi-structured qualitative interviews with experts from selected universities/institutions having expertise in environmental science, water pollution, water laws and water purification technologies. In addition, we interviewed experts (at the mid and senior levels) having technical and regulatory experience in the water sector who represent government agencies (especially BIS) in different branch offices at Patna (Bihar), Kolkata (West Bengal), Jaipur (Rajasthan), Bangalore (Karnataka) and Delhi. In addition, we interviewed technology suppliers, consultants and water experts from selected NGOs (in Bangalore, Delhi and Kolkata). Furthermore, we interviewed owners, top-level and mid-level managers and technologists working in bottled water firms in different parts of India.

In total, we interviewed 53 experts working in universities, bottled water firms, government agencies, NGOs and consultancies in the water sector.

The interviews lasted from 25 to 85 minutes. Most of the interviews were recorded and transcribed. In cases when it was not possible to record the interviews, notes were taken.

In addition, we relied heavily on texts and reports produced by BIS and other government agencies, including information provided on their website and reports, standards and guidelines produced by them. We have critically analysed the annual reports (2003–2008 and 2011–2013) and standards promulgated by BIS (IS 10500, IS 13428, IS 14543 and amendments). We also analysed working reports of technical committees of BIS (Manual for Standards Formulation) and policy guidelines formulated by several other government or public agencies (Satwant Reddy Committee Report, JPC Report).

Apart from national policies and standards, we also analysed standards, guidelines and policies produced by international organisations, such as World Health Organization, the Codex Alimentarius Commission (CAC), the United States (US) Food and Drug Administration (FDA), the US Environmental Protection Agency (US EPA) and policy documents promulgated by the European Union for drinking water and packaged water. The qualitative information collected from the interviews and secondary sources was used to analyse the case using the analytical framework discussed above.

Findings and Discussion

Mapping of the Regulatory Actors and 'Democratisation' of Regulation-making Process

BIS develops and publishes Indian standards and ensures harmonious development and implementation of the standards. According to BIS, 'for formulation of Indian Standards, BIS functions through the Technical Committee structure in terms of Sectional Committees, Subcommittees and Panels set up for dealing with specific group of subjects under respective Division Councils, which includes concerned officials of BIS and representatives of various interests such as organised consumers, consumer bodies, regulatory and other government bodies, industries, scientists, technologists, testing organisations and individual experts' (BIS, 2012–2013, p. 5).

The standard-setting for packaged drinking water is formulated by the Food and Agriculture Department subcommittee number 14 (FAD 14) under the Food and Beverages Section Committee set by BIS. In principle, BIS standard-setting committees are not imagined as closed regulatory spaces and are only meant for scientific and technical experts.

BIS established two FAD 14 committees, which we examined. The highest representation in the first FAD 14 committee (BIS, 2010) was from government agencies and industries (13 representatives from each group). Apart from them, eight representatives were from publicly funded research institutes that specialise in the field of science and engineering, five consumer organisations were also represented in the committee, one representative was from an NGO, and one

Table 1

Representation of Different Stakeholders in the BIS FAD 14 Committee.

S. No.	*Kind of Organisation*	*Number of Representatives (2010)*	*Number of Representatives (2014)*
1	Government Ministries and Departments and Regulatory Agencies (Centre and State)	13	13
2	Universities and Public Funded Research Institutes	8	20
3	Industry Representatives/Trade Associations	13	10
4	Non-Governmental Organisations	1	1
5	Consumer Organisations	5	4
6	In Private Capacity	1	0
7	International Organisation	0	1
8	Total	41	49

Source: BIS, 2010, 2014.

person who participated in a personal capacity. In total, 41 representatives from different organisations participated in the committee. The second FAD 14 committee (BIS, 2014) had 20 representatives from universities and public-funded research institutions. In addition, 13 participants were from government ministries and 10 from industries. About four consumer organisations, one NGO and one international organisation were also part of the FAD 14 committee (Table 1).

Compared to the first committee, the second committee witnessed an increase in the participation of 'neutral experts', but the broad categories of the actors remained almost the same. The representation of 'neutral experts' from publicly funded research organisations has increased from 8 to 20, and they became the largest group in the second FAD 14 committee. The second FAD 14 (2014) committee included 'expertise' from an international organisation (WHO) too.

Existing studies on regulatory science in STS describe how regulatory decision-making committees are dominated mainly by scientific and technical experts (Jasanoff, 1990). Contrary to that, there is a strong presence of bureaucrats in the FAD 14 committee. Several ministries and government departments are represented by their higher officials (secretary and director level bureaucrats), whereas most public institutions are represented by their directors/heads of the institute. These committees also recognise the 'practical expertise' of industry actors. The industry actors are selected at two levels, namely, individual firms and trade associations.

BIS often categorises the stakeholders broadly as industrial and non-industrial actors. BIS has proposed that, 'in case non-industry interests are less than two third, it may be reviewed by concerned activity head to ensure that 2/3rd of the total representation on the committee is from non-industry' (BIS, n.d., p. 15). By doing this, BIS has created a binary between industry and non-industry interests, representing antagonistic positions.

Yet, for other actors, industry dominance remained a primary concern. One of the leading legal experts working on water laws and policies in India stated that 'the BIS standards are made by industry, largely for the industry' (Expert 3 – Socio-Legal Scholar from a University). Analysis of technical committees FAD (2010, 2014) reveals that mostly large domestic firms and MNCs are represented in technical committees rather than small domestic firms. However, the Indian bottled water industry is dominated by small, proprietorship-based firms (about 84%) (Sharma, 2014). In the committees, the representation of small firms is minimal compared to that of large corporate actors. We argue that industrial interests are not uniform. Different categories of firms often take conflicting positions on matters of regulation. Small firms often advocate for other priorities and concerns than large national and multinational firms.

Furthermore, BIS's current model of standard-setting is expert-centric. They rely on senior officials/scientists representing publicly funded research institutes and different ministries of government. The bias in selecting bureaucrats as experts indicates the hierarchical and bureaucratic nature of Indian regulatory and scientific institutions. Instead of finding competent experts (occupying varied levels in the academic and research hierarchy), the current regulatory regime intends to rely on top-level officials/experts, mostly from selected public institutions.

On average, BIS takes around 1 year for Priority I items and about 2 years for Priority II items for standard making (BIS, n.d.). Contrary to the way in which technical committees of BIS formulate standards in India, international regulatory agencies often take a longer period to formulate standards and draw from a broader range of expertise. For instance, the preparation of the most recent (third) edition of the Guidelines for Drinking-Water Quality by the WHO took 8 years and involved the participation of more than 490 experts from 90 countries (WHO, 2008). The FAD 14 committee has not involved environmental, economic, legal and socio-cultural experts. Moreover, in the BIS technical committee, only a single organisation from the medical field (Indian Council of Medical Research) was represented.

There are limited arrangements to include diverse public opinion.[3] The BIS does not directly and sufficiently engage with lay expertise, that is, consumers and common citizens (Bhaduri & Sharma, 2014). However, BIS claims that 'they give proportionate participation to all stakeholders, like manufactures, consumers, consumer bodies, government organisations, scientific and technical institutions/organisations, etc. while keeping the interests of the consumers paramount' (BIS, n.d., p. 6). Contrary to the BIS claim, the big manufacturers and government departments are over-represented in the BIS FAD 14 (2010, 2014) committee (Table 1), and consumers, small firms and other actors are under-represented.

Broader participation by different stakeholders may help widely discuss and negotiate the interests of different actors and the formulation of effective, transparent and legitimate standards acceptable to all stakeholders. Representations of other stakeholders and incorporation of diverse epistemic cultures are also

necessary 'to avoid the blind leading the blind' (Bhaduri & Sharma, 2014; Bowker & Star, 1996; Bryer, 2013; Hagendijk, 2004).

Regulatory Decision-making

Regulatory decisions are often posited as objective facts that result from scientific knowledge produced through validated research (Bhaduri & Sharma, 2014; Guston, 2011; Hauray, 2017; Ottinger, 2010; Thevenot, 2009). According to BIS, the thrust of the standard-setting process is to protect consumers' health and safety. In this context, it is crucial to understand what constitutes safe drinking water. According to the WHO guidelines (2006), safe drinking water implies that it 'does not represent any significant risk to health over a lifetime of consumption'. Importantly, safety does not mean risk-free (Majumder, 2007). Risk cannot be completely eliminated, and some degree of risk is always involved (ibid.).

The understanding of risk and safety also varies among different regulatory actors/groups. Standards promulgated by different regulatory organisations for several contaminants (nitrates, fluoride and arsenic) significantly vary with each other (see Table 2). The permissible limits for arsenic in drinking water have been revised several times by WHO, earlier it was 50 µg/l, then revised to 20 µg/l and currently it is 10 µg/l (Susheela, 1998, Wang & Wai, 2004; Yamamura, 2001). Smith and Smith (2004) argue that even when the arsenic concentration in drinking water is reduced to 10 µg/l as per the WHO recommendations, the potential cancer risks remain high. The risk perception of arsenic contamination in drinking water varies among different social groups (scientists, medical practitioners and lay persons) (Chakraborti et al., 2002). Several studies argue that various factors, such as nutrition, genetics and smoking, make people more susceptible to arsenic-related diseases (Chakraborti et al., 2002; Smith & Smith, 2004; Smith et al., 2000). Smith et al. (2000) argue that arsenic contamination is the largest mass poisoning of a population in history.

Yet, there are no agreements on the risks associated with it, and different standards are formulated by different regulatory agencies (Mohan & Pittman 2007; Yamamura, 2001). BIS prescribes 50 µg/l maximum permissible limits for arsenic in packaged drinking water and natural mineral water (BIS, 2004,

Table 2

Maximum Permissible Limit (MPL) for Specific Contaminants Suggested by US FDA and BIS for Packaged Drinking Water.

S. No	*Substance*	*US FDA (mg/l)*	*BIS (mg/l)*
1	Nitrates	10	45
2	Fluoride	3	1.0
3	Arsenic	0.01	0.05

Source: US FDA and BIS Standards.[1]

2005). Whereas BIS standards for public supply of drinking water are 10 µg/l, it is permissible up to 50 µg/l max in the absence of an alternate source (BIS, 2009). No relaxation in MPL is given to other toxic elements such as mercury, cadmium, chromium and lead. Scientific studies (Wang & Wai, 2004, p. 207) have reported that 'standard of 50 ppb has a substantial increased risk of cancer and is not sufficiently protective of public health'. In India, often the scientific community debates the permissible limits for arsenic in drinking water (Chakraborti et al., 2002; Robinson, 2000). A slight difference in standards can put a vast population at potential risk.

The assessment of risk of arsenic contamination becomes more complex in developing countries. A variety of geographical, socio-economic, dietary and other conditions (water intake) should be considered while setting standards (Chakraborti et al., 2002; Chowdhury et al., 2000; Milton et al., 2006). One of the leading scholars narrated that developing countries still lag behind in setting stringent standards for arsenic. In his own words,

> We do not think about standards in the same way as the developed countries. For instance, around 25 years back WHO set standards at 100 micrograms per litre for arsenic, and then they found that it is too harmful to health (based on their expertise) and reduced it to 50 micrograms, finally about three years back they reduce it to 10 micrograms. America reduces it to 10 micrograms by 2002 with the limit of 2 litres of intake of water per day. Most of the developing countries, had earlier 100 mg MPL for arsenic, and only very recently many of them changed it to 50 mg (Expert 1 – Environmental Scientist).

More importantly, the uncritical adoption of international standards would not be helpful for public health in developing countries. The scientific work (such as epidemiological and toxicology work) and socio-cultural experiences (such as drinking water habits and food choices) should be incorporated while setting standards for bottled water in India. The arsenic expert stated that

> Now it is being told by the international regulatory agencies that our recommended value is 10 mg but if you (developing countries) cannot set maximum permissible limit up to 10 mg, you can recommend it up to 50 mg of water. Such recommendations are unbelievable to a scientist. This has been recommended even after knowing fully well that if you drink 50 mg of arsenic-contaminated water per litre per day for a long time then out of 1000, 13 would become vulnerable to cancer. I voiced my opinion and argued that WHO is recommending 10 mg MPL for arsenic for people with water intake around 2 litres per day; in India, we drink 4 litres of water directly and indirectly, and additional 2 litres of water, even then why our standards will be 50 mg! I discussed it with BIS wrote them several letters in September 2003, but they remained unreachable (Expert 1 – Environmental Scientist).

Another scholar from the Indian Institute of Sciences, Bangalore, raised concern regarding the drinking water guidelines set by the WHO for developing countries. According to him,

> Most of the studies conducted by experts from WHO are from specific regions (having specific environmental conditions and demographic profile) and thus should not be adopted by developing countries in an uncritical manner (Expert 17 – Environmental Engineer from a Public University).

Countries adopting those standards should conduct their own studies to set national standards. Rather than relying on the scientific expertise and research findings of experts working in the water field, the regulatory actors often rely on the 'standards' prescribed by international organisations. A higher representation of 'neutral' scientific experts could have challenged the tendency of other stakeholders to uncritically adopt standards set by international regulatory agencies. Quark (2018) suggests that transnational firms in India tend to outsource regulatory decision-making to 'international' epistemic communities. We argue that government actors (largely bureaucrats representing different ministries) follow the same trend. Instead of relying on the scientific expertise available in the country, they advocate for the 'uncritical' adoption of international standards. In doing so, the dominant regulatory actors, that is, representatives from government agencies, even seem to overlook the environmental, social and demographic conditions of their country.

To achieve the mandatory standards, manufacturing firms must access prescribed purification technologies to purify the raw water. The JPC (2004) stated that the major stakeholders reported that the required technological solutions (water purification technologies) are easily available to achieve the standards set by BIS. However, small firms opposed such a position during the bottled water controversy in 2003. Mr. Rajendra Bhansali, President of the Karnataka Bottled Water Manufacturers Association, stated that

> Adhering to EU standards is not possible in India. It will kill the small bottled water manufacturers, as the new guidelines would require the setting up of in-house labs for the water test. This would incur huge costs, and only big players would survive such moves.[4]

The decision has led to the establishment of in-house labs for testing water quality parameters. Mandatory national standards pushed firms to upgrade their scientific and technical apparatus to build an 'efficient' monitoring system to supervise water quality at the firm level. However, it has been reported that often many small firms fail to adhere to the standards prescribed by BIS, and an 'implementation' gap has been reported (Sharma, 2018).

The big players supported introducing stringent standards and adopting advanced technologies. According to one technology consultant, 'the big firms

had better access to the international and national technology markets and also the required capital to invest in new technologies' (Expert 4 – Water Technology Consultant). The underrepresentation of small firms in standard-setting committees has restricted their power to influence the standard-setting process. Small firms' concerns regarding their limited access to technologies available in the market were overlooked and not considered while 'upgrading' the standards in 2004. Like small manufacturers, technology suppliers/manufacturers are not represented in the FAD 14 committee. One of the technology suppliers from Bangalore, Karnataka, stated that 'the technology suppliers rarely interact with the BIS. Technology suppliers act as an intermediary between technology manufacturers and users (bottled water manufacturers)'. One of the experts stated that 'presently, most of the water purification technologies (major components) are imported from outside India' (Expert 16 – Water Technology Supplier Bangalore). According to a local reverse osmosis (RO) manufacturer located at Mayapuri, Delhi, 'out of 50 components required for manufacturing RO plant, 20-30 are imported from other countries; rest is manufactured locally' (Expert 18 – Technology Supplier, Delhi). In other words, the concerns of small firms are severely under-reported during the decision-making process, as they struggle to improve their human and technical infrastructure.

National Regulations in the Era of Globalisation

The BIS draws assistance primarily from three other guidelines (BIS, 2004), which are (i) the Manual on Water Supply and Treatment prepared by the Ministry of Urban Development, New Delhi, (ii) Codex Code of Practice for collecting, processing and marketing of natural mineral waters and (iii) EEC Directive, relating to the quality of water intended for human consumption. In other words, the BIS standards for packaged drinking water draw heavily from standards and guidelines formulated by other national and international regulatory agencies.

BIS vigorously promotes the harmonisation of national standards with international standards. According to BIS, it is crucial to harmonise Indian standards as much as possible with international standards (formulated by ISO and other international regulatory agencies) to compete in the globalised market. India is a signatory to the World Trade Organization agreement on technical trade barriers; member countries must align their national and international standards. However, there is a provision to incorporate country-specific considerations based on issues related to health, environment and other concerns (BIS, 2012–2013). 'So far, BIS has harmonised 5065 Indian standards with international standards. Considering the number of standards where corresponding ISO or IEC standards exist, about 85% of Indian standards are harmonised' (BIS, 2012–2013, p. 13).

Harmonisation can lead to the upgradation of national standards if the required technologies are readily available to the manufacturers, which is not often the case, as elaborated in the previous section. Harmonisation with international standards can also lead to an implementation deficit, as discussed above. Scoones

(2002) argues that due to political and economic reasons, developing countries often adopt and upgrade their national standards in accordance with international standards, even without adequately setting up the monitoring and enforcement capabilities. We explained that even non-economic factors could lead to an uncritical adoption of international standards.

Apart from the bureaucrats and technocrats representing government departments and ministries, the civil society groups also favoured the harmonisation of standards on the grounds of achieving 'higher scientific standards'. During the pesticide controversy, the CSE claimed that the existing Indian standard does not adhere to the highest scientific quality. The Director General of Health Services explained the rationale for adoption of EU standards for pesticides residue in packaged water in front of the JPC in the following words:

> The issue before the committee was that we should have the best standards available in the whole world. We are concentrating on the issue that our people should have the best and the European norms are very high and people are paying for this bottled water. That was at the back of the mind of the experts. That is what was recommended (JPC, 2004, p. 126).[5]

BIS committees used to draw references from several other sectional committees (the Water Sectional Committee and the Pesticides Residues Sectional Committee) of BIS. This practice has changed, especially after the 2003 controversy. Over the last two decades, different regulatory actors, such as experts from government organisations, NGOs and big businesses, have advocated for the broader adoption of international standards while setting standards.

It is important to note that, often, for certain contaminants, supranational organisations prescribe less stringent standards for developing countries (refer to the WHO standards on arsenic for developing countries). Due to the uncritical adoption of 'international' standards, often environmental, economic and socio-cultural factors prevalent in different countries are overlooked, as explained by several experts in the previous section.

Moreover, the BIS adopts a 'consensus' method to take the final decision; the absence of several crucial stakeholders in the technical committee has had a bearing on the final standards in such a context.

Conclusion

The paper analysed the regulatory decision-making process employed by BIS for setting bottled water quality standards in India. The standard setting process for bottled water quality is endowed to Technical Committee No. 14 under the Food and Agriculture Division. We found that the technical committee is dominated by bureaucrats and technocrats from ministries, public research institutes and big industries, unlike high-end regulations in developed countries, which are predominantly

dominated by scientists and engineers from diverse fields (Jasanoff, 1990; Majone, 1984; Nowotny et al., 2001). The scientific controversy over pesticide residue in 2003 paved the way for the broader participation of different regulatory actors in the regulation-making process (JPC, 2004; Pandey & Sharma, 2017). After that, consumer organisations and NGOs were included as stakeholders. Yet, the democratisation of the expert committees failed to happen in an absolute sense. The FAD 14 committee has little or no representation from small firms, technology suppliers and independent experts, and it offers limited space for consumers and citizens to engage with standards. The short period in which BIS makes standards and the employment of a 'consensus' approach among limited stakeholders further create challenges in incorporating the concerns of other actors/stakeholders in the regulatory framework.

The standard-setting process for bottled water quality in India is not merely an outcome of 'regulatory objectivity', but more of the social and political choices made by the dominant regulatory actors enrolled by the regulatory body for setting standards. The standard-setting committees do not primarily rely on scientific knowledge while setting standards, but the socio-cultural contexts and other institutional factors shape the decision-making. The 'trust' in 'international' standards among the bureaucrats and technocrats representing government organisations, big firms and even NGOs played a crucial role in the uncritical adoption and homogenisation of Indian bottled water standards with international standards. They believed that 'international' standards are rigorous and scientifically superior. This view was supported not only by transnational manufacturing firms (as reported by Quark, 2018), but also by experts representing public organisations and civil society groups. For major domestic and international firms, it meant the enhanced acceptability of their products among consumers.

The paper argues that the regulation-making process is a complex process that is influenced by the kinds of expertise employed by regulatory regimes, perceptions of the 'regulatory knowledge' produced by supranational regulatory organisations, and lack of concern for 'local' environmental, epidemiological, dietary and socio-economic factors among the dominant regulatory actors. The paper would benefit regulators, industry, government organisations and academicians interested in understanding the regulation-making exercise in the global south.

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NOTES

1. In India, bottled water is classified by the Bureau of Indian Standards (BIS) into two categories, namely, normal packaged drinking water and natural mineral water. In this paper, bottled water denotes normal packaged drinking water.
2. http://164.100.24.220/loksabhaquestions/annex/175/AU412.pdf (accessed on July 20, 2022).
3. There is no mechanism to directly engage the general public. The draft standards are posted on the BIS website, and the comments are collected through the web. Due to the digital divide, the internet-based methods seriously limit the participation of marginalised social groups.
4. http://www.thehindubusinessline.in/2003/03/25/stories/2003032500441700.htm (accessed on May 24, 2014).
5. The Central Committee of Food Standards was headed by the Director General Health Services.
6. http://www.fda.gov/NewsEvents/Testimony/ucm170932.htm (accessed on May 25, 2014) and http://www.fda.gov/Food/FoodborneillnessContaminants/BuyStoreServeSafeFood/ucm077079.htm (accessed on May 25, 2014).

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