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Re: Public consultation on the Draft WHO Global Strategy for Food Safety, with particular reference to powdered infant formula[1]

Dear Dr. Branca:

I am writing on behalf of the non-profit public health organization the Centre for Health Science and Law to offer a perspective on the *Draft WHO Global Strategy on Food Safety 2022-2030.*

Unlike for any other food or period of a consumer's life, substituting (typically) milk-based infant formula for human breastmilk is a dramatic, complete, and largely irreversible change in diet until the child's diet begins to diversify with the addition of whole foods at age six months. Suboptimal breastfeeding contributes heavily to acute illness and death (especially pneumonia and severe diarrhea) as well as lifelong noncommunicable disease, especially cognitive impairment and stunting.

Properly apprising mothers and other caregivers of the benefits of breastfeeding and risks of formula feeding is also conducive fulfilling many SDG Goals, especially and namely: #1 (no poverty), #2 (zero hunger), #3 (good health and well-being), #4 (quality education), #8 (decent work and economic growth), #12 (responsible consumption and production), and #13 (climate action). Breastfeeding instead of formula feeding is also conducive to pursuing the broad food system goals of reducing irresponsible uses of antimicrobials in cattle (the source of formula's main ingredient) and reducing food waste.

The consolidation of food safety and nutrition into the same program unit at the World Health Organization will help ensure that while NCDs are estimated to cause 20 times as many deaths (8 million compared to 420,000 deaths), and nearly six times as much loss in disability adjusted life years (188 million DALYs compared to 33 million DALYs[1]) as food-borne pathogens, the harm caused by food-borne pathogens is immediate, shocking, and often strikes people in the prime of their lives.

[1] This submission is a modified version of comments submitted on June 4, 2021 to Dr. Kang Zhou of the U.N. Food and Agriculture Organization and Dr. Haruka Igarashi of the World Health Organization in connection with the public consultation on the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) Call for Data on The Safety and Quality of Water Used in the Production of Fishery and Dairy.

Also, the recently published WHO publication, *Estimating the burden of foodborne diseases: A practical handbook for countries,* underscored the importance of particularizing and quantifying the causes of food-borne illness by stating:

> *Estimating the burden of foodborne diseases is an essential component of efforts to rank risks of foodborne diseases, establish food safety priorities, and efficiently allocate resources for disease prevention.* [2]

While the report ventured (at page 21 of the handbook) that diagnosis may be biased toward more severe cases, a Public Health Agency of Canada decade-long comprehensive analysis of prevalence of illness due to food-borne pathogens found that only marginally smaller proportion of deaths attributed to food borne illness (56%) than hospitalizations (66%) were attributed to "unspecified agents."[3] Indeed, its immediately following account of country experiences (at page 22) noted that, in the Caribbean

> *Only a fraction of the cases seen by a health worker were asked for a sample or were associated with a hazard in food, and only a fraction of those were reported to the public health surveillance system.* [4]

The United States regulations on the advertising, promotion and labelling of breastmilk substitutes are among the most permissive in the world, earning it UNICEF's worst rating, an ignominious distinction shared with only 5 other OECD (i.e., rich) countries including Canada as having "no legal measures in place" to curb the advertising and promotion abuses that the WHO *International Code of Marketing of Breastmilk Substitutes* aims to prevent.[5] However, a recent Congressional report on contamination of baby food with toxins found that:

> *According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function…These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level…[And] naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.*[6]

The contamination of vitamin pre-mixes with all four investigated heavy metals—arsenic, cadmium, lead, and mercury—is especially concerning because vitamin and mineral supplements (mainly vitamin A, iron, Zinc, and iodine) are often promised to deliver IQ-boosting benefits to malnourished children in Low- and Middle-Income Countries. If vitamin pre-mixes are prone to contamination with brain-harming toxins, those benefits might be partially or even overwhelmingly counterbalanced. The Congressional Sub-Committee also expressed concern that four large companies refused to participate in the investigation.[7]

1. Human health risks of sub-optimal breastfeeding

Powdered infant formula is, by far, the most acutely dangerous food consumed by humans in the world, considering that it combines the health risks of intrinsically contaminated powdered infant formula, contaminated drinking water, errors in sterilizing bottles, and abstaining from the protective advantages of human breastfeeding. Sub-optimal breastfeeding is estimated to cause 823,000 deaths per year due to severe diarrhea and lower respiratory tract infections[8] in children under five. This is double the number of annual deaths attributed to all other contaminated foods *combined* that are consumed by people of all ages: 420,000.[9] In addition to increasing the risk of infection-related serious acute illness and death, suboptimal breastfeeding is also believed to raise the risks of permanently impaired cognitive function, overweight, type 2 diabetes, and, possibly, leukemia and type 1 diabetes in children, as well as closer birth spacing and increased incidence of breast and ovarian cancers in mothers.[10] Formula-originated invasive *Cronobacter* (a.k.a., *C. sakazakii*) infections in infants, including bloodstream infections and meningitis, can result in permanent neurologic disability.[11]

Either the risk of suboptimal breastfeeding has been underestimated by half or the success of achieving the WHO population targets is generally over-estimated two-fold. The goal of exclusive breastfeeding from birth to six months (26 weeks) appears nearly identical to a commonly cited measure of progress in achieving exclusive breastfeeding: exclusive breastfeeding among babies aged 0-5 months. However, the statistic is typically a two-fold overstatement of the extent of achieving the target because it is measured by inquiring about exclusive breastfeeding about a sample of babies ages 0-5 months old. Because exclusive breastfeeding rates often decline steadily after birth to near-zero levels at six months, the average over the first six months of life better represents the proportion of babies that are exclusively breastfed to three months.

Tables 2-5 appended to this submission depict the time-trend of exclusive breastfeeding for both 0–5-month-olds and 4-5-month-olds, the latter of which more accurately (though still imprecisely) depicts the extent to which populations achieve the WHO goal of exclusive breastfeeding for six months. The most accurate way of measuring the goal would be a survey of mothers in week 27 of their children's lives when their memories of the prior week's feeding would be reliably fresh. However, it would be challenging and expensive to locate an adequately powered sample (e.g., at least 300 respondents) born in the same week in any country. While, for example, half of African countries have insufficient recent monitoring data to illustrate this phenomenon, Kenya, Malawi, and Zimbabwe are generally indicative of trends in that region where there is good evidence. (See appended tables 3-5.)

2. Disaggregating the risks of sub-optimal breastfeeding

The WHO should take steps to better quantify population attributable risk to the foreseeable causal pathways of illness and death attributed to sub-optimal breastfeeding. Though some health risks can be attenuated by access to high quality health care and consistently safe tap water and other hygiene measures, it is possible that a large number of deaths of infants currently attributed to sub-optimal breastfeeding may actually be due to an undetected high rate of contaminated infant formula known as intrinsic contamination (and poor access to risk-compensatory health care). Unlike any other period of life, infant feeding is often entirely homogenous up to six months. Approximately a week's food supply may be unwittingly drawn from the same contaminated source: a single can of powdered infant formula. So long as doubt remains about the causal pathway of illness due to sub-optimal breastfeeding, bottle-feeding parents (or breastfeeding mothers considering a switch) may underestimate risks of doing so and marshal insufficient or misdirected mitigation measures.

Formula manufacturers and distributors benefit from this attributional ambiguity which likely aids the steady annual rise in global sales in breastmilk substitutes[12] and the paucity of class action litigation[13] to fix financial responsibility on manufacturers (which are mainly based in High-Income Countries) for harm to infant-victims (mainly living in Low- and Middle-Income Countries).

Of the aforementioned estimated 823,000 annual deaths, presumably the vast majority of deaths due to sub-optimal breastfeeding are attributable to the following more proximate causes:

i. **impaired immunity:** Under-developed immune systems in infants caused by a lack of breastfeeding increases vulnerable, but ill-health still requires exposure to a dangerous bacteria or virus, including exposure to bacteria through food and water.
ii. **contaminated formula:** It is not technologically feasible to produce sterile powdered infant formula.[14]
iii. **unhygienic preparation:** Contamination can occur by food preparation in the home or hospital environment or poorly sanitized feeding bottles, etc.
iv. **contaminated water:** Mixing powdered infant formula with contaminated water that has not been boiled can itself cause illness and death. Presumably, a small fraction of the 485,000 worldwide deaths due to contaminate drinking water among people of all ages occur in children under age five, and fewer still among children under six months of age.[15] Cleaning feeding bottles with contaminated water also contributes to risk. (Notably, impure water was not suggested as a possible vector of *Cronobacter* infection by a U.S. Centres for Disease Control team that included a lead expert on waterborne disease infection.[16])
v. **lack of refrigeration:** Poor access to refrigeration and reliable electricity can contribute to risk, especially where parents cannot afford to discard unused formula.
vi. **lack of quality healthcare:** Poor access to health care to treat infections and noncommunicable diseases can convert a dangerous infection to lethal one.

3. The magnitude of the risk of intrinsic contamination may be higher than previously assumed, especially in Low- and Middle-Income Countries.

Failure to avoid unsafe levels of *Cronobacter species*, for example, exposes infants to the possibility of an infection with a mortality rate of 40% to 80%.[17] *Cronobacter* has been linked to several cases of necrotizing enterocolitis, particularly among hospitalized infants born prematurely. Younger children and ones with co-morbidities would be more susceptible to harm, especially from higher microbiological loads. In a review of 31 cases of *Cronobacter* infections, three quarters were in infants younger than one month old, and three-quarters were premature or experienced complications of childbirth.[18] However, previously healthy full-term infants are also known to become infected. Infants born at more advanced gestational ages might even be at greater risk than early preterm infants for having *Cronobacter* meningitis, as opposed to isolated bloodstream infections.[19]

Although the Institute for Health Metrics and Evaluation's Global Burden of Disease (GBD) database estimates for disease risks do not always comport with WHO expert estimates, it reported 563,000 diarrheal disease incidents in 2019 (mainly enteric infections) among Canadian children in their first year of life—slightly more than one per infant; this could reflect multiple infections with some vulnerable infants and other infants with few or none.[20] South African babies had approximately double the incidence of diarrheal disease (reflecting an approximate two-fold higher population of infants), but a 307-fold higher risk of death due to diarrheal disease. (See Table 1.) If these numbers are accurate, the pathogen exposure may be approximately equal in the two countries, but the consequences of infection are vastly different.

The 100-page 2019 WHO/FAO meeting report entitled *Safety and Quality of Water Used in Food Production and Processing*[21] mentions death (or any of several synonyms) only once and that was in relation to the death of fish, not humans. The term illness was mentioned only four times, including three times in a single paragraph about the seasonality of risk in relation to a single pathogen. By contrast, the WHO report, *WHO Water, Sanitation and Hygiene Strategy 2018-2025* (citing a 2017 study) estimated that poor WASH (Water Sanitation and Hygiene) conditions account for 842,000 diarrhoeal deaths of humans every year. That report repeatedly quantified aspects of the human health impact of water sanitation harms and recommended targets to reduce those risks.[22]

In your work, please be mindful that standard-setting is not a trade-facilitation-harmonization end in and of itself, but a servant of the main objective: protecting human life to a quantitatively meaningful extent closer to the highest attainable standard of health.

4. Infant causes of death in High-Income Countries may underestimate the role of contaminated infant formula: The case of Canada and, indirectly, the U.S. and China.

Canada is a High-Income Country where residents enjoy near-universal access to quality health care, safe drinking water, reliable refrigeration, and reliable access to electricity or other properly ventilated sources of energy for cooking, cleaning, and food preservation. Canada also enjoys a

capable, generously resourced, and technologically well-equipped public healthcare service, by global standards.

However, the Public Health Agency of Canada's first and only comprehensive analysis of prevalence of illness due to food-borne pathogens was published only recently in 2015. It found that 66% hospitalizations and 56% of deaths due to such pathogens were attributed to "unspecified agents."[23] Even this important effort reflects a systemic failure to adequately explore sources of contamination even in the case of deaths. (Minor acute gastrointestinal illness is common in Canada; an estimated 1.3 episodes per person occur each year in Canada, which translates to more than 40 million incidents.[24])

Canada has only one infant formula manufacturing plant which is owned by a Chinese company and manufacturers food solely for export to China for consumption by Chinese babies. A recent Canadian Broadcasting Corporation investigation found numerous occupational health and safety violations at that plant[25] that could also be indicative of health risks in the powdered infant formula. However, because those products do not enter the Canadian food supply, they are not subject to many forms of product-related safety inspection. According to FAO Trade Statistics, 88% of the infant foods imported to Canada comes from the United States and another 9% comes from 6 European countries.[26] As such, the safety of Canada's infant formula supply depends heavily on the sufficiency of efforts by U.S. food manufacturers and inspectors.

Statistics Canada reports the deaths of approximately 1,700 infants (aged 0-12 months) per year, but only particularizes causes of death for approximately 1,000. Even among the purportedly specific causes, most are truly "risk factors" or "vulnerabilities" that could mask deaths due to illness caused by contaminated infant formula. For instance, Statistics Canada cites these "causes:"

- "Disorders related to short gestation and low birth weight, not elsewhere classified:" 214 deaths;
- "Congenital malformations, deformations and chromosomal abnormalities:" 345 deaths; and
- "Newborns affected by maternal complications of pregnancy:" 144 deaths.[27]

All of these causes appear to be risk factors that are consistent with vulnerability to severe consequences of infection with intrinsically contaminated of powdered infant formula. By sharp contrast, the average number of annual deaths of Canadian children aged 1-4 years old is 37. The first year of life appears both dangerous and under-examined.

5. Systematic inattention to contaminated infant formula by clinicians and food inspectors

There can be little mistake about the risk of microbiological contaminants in powdered infant formula. As long ago as 1961, reports of invasive *Cronobacter* infections were described in the scientific literature.[28] Then, 13 years ago, *Cronobacter* and *Salmonella enterica* were recognized in guidance developed by the Codex Alimentarius Commission. The 2008 Codex *Code of*

Hygienic Practice for Powdered Formulae for Infants and Young Children concluded, following negotiations by food safety officials from nearly 60 countries:

> *Two FAO/WHO meetings of experts on the microbiological safety of powdered infant formula considered cases of illnesses in infants associated with PF consumption either epidemiologically or microbiologically. They identified three categories of microorganisms based on the strength of evidence of a causal association between their presence in PF and illness in infants: A) microorganisms with a clear evidence of causality, namely, Salmonella enterica and Enterobacter sakazakii...*[29]

A 2009 study of infant formula prepared in 18 South African hospitals commissioned by UNICEF and the Ministry of Health found that 27% of sealed containers of infant formula (35 out of 130) were contaminated with clinically significant bacteria. Coincidentally, 27% of bacteria detected (45 out of 165 detected bacteria) were identified as *Klebsiella spp.* which the report described as "a serious problem for most neonatal units in South Africa and has in the past contributed to many infant deaths."[30] This also indicates that some formula samples were found to contain more than one clinically significant contaminant.

Yet, the Canadian Food Inspection Agency's annual Children's Food Project to test for pesticide, chemical, veterinary pharmaceutical residues, aflatoxin, and other contaminants in food is significantly under-powered (143 samples in 2018-2019) and does not test for bacterial contaminants.

Importantly, the Public Health Agency of Canada's first and only comprehensive study on food safety illness entitled, "Estimates of foodborne illness-related hospitalizations and deaths in Canada for 30 specified pathogens and unspecified agents" did not consider *Cronobacter*, even though Canadian outbreaks in powdered infant formula were reported in 1990, 1992, and 2007[31] and, as noted above, the estimated fatality rate for *Cronobacter* infections is 40%-80%. The Canadian report was painstakingly detailed on pathogens and infections with comparatively minor adverse health effects or rare fatalities. Only two of the 30 pathogens that were passed through food and led to more than 10 deaths per year in the period 2000—2010. Relying on the Hospital Morbidity Database (HMDB)[32] maintained by the Canadian Institute for Health Information (CIHI), researchers found that:

- *Listeria Monocytogenes* caused 100-223 hospitalizations and 23-55 deaths per year; and
- *Salmonella spp., nontyphoidal serotypes* caused 774-950 hospitalizations and 2-27 deaths per year, approximately 80% of which were related to foodborne pathogens.[33]

Doubtless *Cronobacter* infections were among the 66% of hospitalizations and 56% of deaths attributed to "unspecified agents."[34]

Likewise, the *WHO Estimates of the Global Burden of Foodborne Diseases 2007-2015*[35] did not report estimates for death or disability attributable to *Cronobacter.*

Even when a surveillance system was in place in France in 2005, it failed to detect a cluster of *Salmonella Agona* infections due to contaminated powdered infant formula because its algorithm was based on the number of cases occurring among persons of *all* ages during a five-year reference

period, rather than age-specific incidence rates.[36] Recent data from the Canadian National Studies on Acute Gastrointestinal Illness estimated that, for every patient with a verotoxigenic *E. coli*, *Salmonella* or *Campylobacter* infection detected by the national surveillance system, up to 49 people with such infections are missed in the community.[37]

Identifying a case of infection due to a food-borne pathogen in a hospitalization record, death registry or surveillance database requires that a specimen (stool, blood, or urine) be submitted and that the positive test result be recorded and reported to the proper surveillance system.[38] Digitalization of medical records even in high-income Canada with a single-payor public healthcare system (albeit administered by 13 subnational governments and, in some cases, separately governed institutions and regional health authorities), is a stubbornly slow and fragmented process that is probably hampering public health protection. Lack of digitalization of medical records makes it nearly impossible to identify such risks unless they are required to be tested and reported.

If the failure to pass all of these steps is accomplished in less than half of deaths in a clinically modern, generously well-financed hospital setting, what chance does an anemically resourced health system in a Low- or Middle-Income Country stand?

6. Challenges in detecting bacteria throughout the health and food inspection systems

The systematic lack of attention to harmful bacteria known to sometimes be present in powdered infant formula is compounded by (and likely influenced by) several analytical and detection challenges. Powdered infant formula is distinct from ready-to-feed liquid formula that has been commercially sterilized. For infants at greatest risk that are medically incapable of being breastfed, commercially sterile liquid infant formula is recommended if it is available and if an effective point-of-use decontamination procedure is used. [39]

a) Challenges for Laboratories and Food Inspection

A study of six outbreaks of *Salmonella* infection associated with powdered infant formula during the period 1985–2005 involving 287 infants found that most were identified because the *Salmonella* strains were unique in some way (e.g., the occurrence of a rare serotype or a distinguishing biochemical aberrancy). In many regions of the world, *Salmonella* serotyping is rarely performed, and surveillance networks rarely mandate reporting of *Salmonella* infection.[40] As one review concluded:

> *A common feature in the reported outbreaks of Salmonella infection was the low levels of salmonellae found in the PIF. Such levels are not easy to detect and may be missed by some of the conventional methodology or the sampling plans currently used. In most of the investigations, the epidemic strain of Salmonella species was isolated from bulk, storage, and/or retail packaged samples. This was not achieved without a great deal of effort. There are no data available to adequately describe the distribution of salmonellae in PIF, but it is considered to be sporadic or heterogeneous, leading to difficulties in detection. For example, in the investigation of the outbreak of Salmonella*

> *Ealing infection, intensive bacteriological sampling by 33 laboratories found no pathogens in 4554 samples of 658 batches of product. Finally, 1 laboratory reported the isolation of Salmonella Ealing from an opened packet of PIF taken from an infected infant's home. This facilitated targeted testing based on a specific manufacturing code, leading to the isolation of Salmonella Ealing from 4 of 267 sealed packets [19]. This highlights the difficulty for food microbiology laboratories, which could not have cultured an adequate sample of products without a targeted strategy.* [41]

The Codex-recommended test sample size is 10 grams which is equivalent to 1% of the powder in a one-kilogram container of infant formula.[42] This is, itself, a small sample within a sample of the food supply. If there is contamination, but not throughout the container, there is a risk that a 1% test-sample will produce a false negative result. The recommended Codex Committee on Food Hygiene technique for testing samples presumes a homogenous sample.[43] However, as noted above, contamination of powdered infant formula is considered to be sporadic and heterogeneous, leading to difficulties in detection.[44]

The same expert report mentioned above, including WHO and FAO food safety experts, also noted that, even using a five-fold larger sample (50 grams) which they considered to be small:

> *The other significant feature of this investigation was the very low number of salmonellae estimated to be present in the powder (1.6 organisms per 450 g); a low number of salmonellae would have been difficult to detect by the quality control sampling practiced at that time (using only 50-g samples) [citations omitted].* [45]

An outbreak of *Cronobacter* in Belgium reported that 10 infants had been fed the same formula. Initial analyses indicated that the formula powder was not contaminated so the babies resumed consuming it. It only became evident that those tests were inaccurate when one infant developed *Cronobacter*-associated necrotizing enterocolitis." [46]

According to *The Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*, the two reputedly most worrisome pathogens found in powdered infant formula are alternately difficult to detect either wet or dry processing environments, respectively, though both appear in finished products:

- *Salmonella is rarely found in dry processing areas*
- *E. sakazakii (Cronobacter species) is more frequently found than Salmonella in dry processing areas and is found regularly when using appropriate sampling and testing methods.*[47,48]

Detection challenges might have been at play in a recent Canadian Food Inspection Agency (CFIA) study of bacterial contamination in powdered infant formula which found no *Cronobacter spp.* in 997 test samples and no *Salmonella spp.* in 2,965 test samples.[49] The CFIA asserted that "very few studies similar to ours have been published." The CFIA study prevalence numbers appear to be much lower than found in any published literature. For instance, a 2004 study cited by CFIA found that 2.4% (2 of 82 samples) of packages of infant formula purchased from retailers in the UK and other European countries contained *Cronobacter spp*. (*Enterobacter sakazakii*).[50]

Importantly, at the rate of 2.4% of samples being contaminated, and considering that an infant consuming powdered infant formula exclusively for six months would consume an average of one to two containers per week (packages are typically 600-1,000 grams),[51] this would expose the majority of formula-fed babies to some *Cronobacter* at some point during the first six months of their lives (i.e., 26 x 2.4% = 62%).

Chinese studies also have reported detecting higher prevalence of contamination, possibly because Chinese researchers have been especially active in developing more reliable detection techniques.[52] The motivation to ensure the safety of infant formula there is high. An estimated 85% of Chinese babies are reputedly formula-fed.[53] Though improvements to paid maternity leave policies were promised in connection with the adoption of a three-child policy, benefits of the current three-month leave are reportedly often not honored by employers, which likely imposes high pressure on new mothers to stop breastfeeding early.[54] Likewise, China's efforts to restrict commercial advertising and promotion of breastmilk substitutes as recommended by the World Health Organization are especially weak (scoring 25 on a 100-point scale even without considering law enforcement efforts).[55]

A 2009 study on infant formula prepared in 18 South African hospitals found that 27% of formula in sealed retail packages contained clinically significant pathogens, but that the proportion had nearly doubled to 50% after the formula had been prepared for consumption.[56] While the researchers reported witnessing unhygienic conditions and practices in the hospital that could have contributed to the rise in the rate of contamination in the prepared products, they did not consider the possibility that the powdered infant formula might have had heterogenous distribution of pathogens (as presumed by other leading experts[57]) and that efforts to prepare bulk quantities for the maternity ward might have increased the likelihood of detecting pathogens. (Nor did the researchers speculate on whether preparation by trained hospital staff might have been safer than preparation by parents at home.)

According to a Standards Council of Canada accreditation directory, while 63 laboratories are accredited to test for *Salmonella*, only two are accredited to test for *Cronobacter spp*. (a.k.a., *Enterobacter sakazakii*), one in Montreal and one in Calgary.[58] The Canadian Food Inspection Agency is headquartered in Ottawa and the largest population centre, Toronto, is hub of the processed food industry, and a point of entry for most U.S. food imports.

These factors highlight the difficulty for food microbiology laboratories, which could not have cultured an adequate sample of products without a targeted, energetic, and inconvenient strategy.[59]

b) Clinics and hospitals

Cronobacter infection can be very difficult to accurately diagnose, partly because it initially presents as a minor illness with nonspecific symptoms, but becomes serious to the point of untreatable quickly as one published case report explained:

> *At 3.5 weeks, the baby was admitted to the hospital with a high temperature but was subsequently discharged without treatment [then re-admitted at 6.5*

weeks]…Cronobacter spp. were isolated from a brain abscess. At 11.5 weeks, the infant was released but had suffered severe brain damage.[60]

The hospital's 2005 investigation of the outbreak in France, noted above, revealed that the contaminated infant formula was sold under two different brand names, both of which had been manufactured on the same assembly line and initially tested negative for *Salmonella*. Subsequent tests revealed *S. Agona* contamination from one of 176 samples of formula A provided by the company, 4 of 27 packages of formula B provided by the families, and 6 of 420 environmental swabs from the production line.[61]

c) Epidemiologists and public health officials

Because reporting is not mandatory in most countries (and in most of the United States), the true incidence of invasive infant *Cronobacter* infections is unknown. Estimates from laboratory-based surveillance in the United States Center for Disease Control estimated that from 1961-2018 invasive *Cronobacter* occurred at a rate of 0.49 cases/100,000 infants.[62] In 2008, the World Health Organization (WHO) reported the yearly incidence to be at least 0.14/100,000 infants in the Philippines and 1.76/100,000 infants in England and Wales, although these are thought to be underestimates,[63] and, in light of the challenges described above, the degree of under-estimation could be very large.

Salmonella is a well-known long-standing foodborne human pathogen. The incidence of salmonellosis among infants was reported to be more than eight times greater than the incidence across all ages in the United States.[64] It is unclear whether the reportedly higher incidence of salmonellosis among infants is due to greater susceptibility, or a higher likelihood for medical care to be sought or stool cultures performed than for older people. At least 6 outbreaks of salmonellosis involving at least 287 infants have been associated with powdered infant formula between 1985 and 2005. Most of these outbreaks involved unusual *Salmonella* serotypes, which likely aided in recognition of those outbreaks. It is generally recognized that outbreaks and sporadic cases of salmonellosis due to powdered infant formula are likely to be under-reported.[65]

7. WHO's long-standing, widely disseminated guidance on preparation of powdered infant formula is incorrect, poorly actionable, and dangerously misleading.

The World Health Organization's efforts to promote breastfeeding have been laudable, particularly guidance (promoted with other UN agencies, especially UNICEF) that national governments restrict the advertising and promotion of breastmilk substitutes.[66] The International Labour Organization also urges employers to provide new mothers with paid postpartum maternity leave to help them breastfeed at home, as well as accommodations at work to facilitate daycare, breastfeeding, and expressing milk after mothers return to work.[67]

However, since 2007, WHO's model advice on the safe preparation of powdered infant formula counselled caregivers to boil water and cool it to 70°C by letting it stand at room temperature for no longer than 30 minutes. The inference is that 70°C water is hot enough to kill harmful bacteria that may be present in the powdered infant formula. However, cooling an amount of boiling water

suitable to prepare 125-250 mL of formula for 30 minutes at room temperature (approx. 20°C) reduces its temperature far below 70°C to approximately 40°C and passes the temperature of the highest risk of bacterial proliferation: 50°C some time along the way.[68] This misleading WHO guidance has been adopted extensively by national public health authorities worldwide during the past 15 years.

A half-cup of boiling water cools to 70°C at room temperature in an uncovered ceramic cup in approximately 3 minutes, and cools to 50°C in approximately 13 minutes which is the temperature most conducive to microbiological proliferation, but is still scalding hot. Though the vast majority of homes in rich and poor countries are not equipped with high temperature thermometers, but WHO food safety officials can fact-check this rate of cooling with a meat thermometer and a half-cup of coffee or tea water. Where permitted by law, Nestlé's website and label preparation instructions notoriously advise the use of water that is only 37° Celsius which is too cold to kill bacteria and was, apparently, chosen to avoid killing probiotics that are often featured in the company's health claims.[69] (Such health claims are also contrary to WHO guidance.[70]) However, the WHO's model guidance is essentially the same as Nestlé's in regard to the use of water temperature to kill bacteria.

The 2009 South African study of hospital-prepared formula noted that the U.S. Centre for Disease Control raised three concerns about using boiling water (i.e., 100° Celsius) to reconstitute powdered infant formula: speculation that it would (1) compromise vitamin content, (2) lead to clumping, and (3) activate some bacteria. All three concerns were largely dismissed by 2006 guidance from WHO/FAO.[71] The South African study actually measured the amounts of vitamins A, B1, B2, B6, C, and E when prepared with water heated to 40° and 70° Celsius. It found that the hotter water did not lead to statistically significant vitamin reductions. Although amounts of Vitamin C were substantially lower when (only) two of 10 powders were prepared with hotter water, the much bigger problem appeared to be widespread exaggeration of the amounts of Vitamin C reported on the package labels. Seven of the 10 products tested reported Vitamin C levels on labels that were two- to seven-fold higher than what was detected by the laboratory analysis regardless of water temperature.[72]

Moreover, the WHO advice sends mixed messages about scalding risk. According to Wikipedia, 60°C water can cause scalding tissue damage in three seconds and household water heaters should be set no warmer than 45°C to avoid scalding and discomfort.[73]

Please consider revising WHO's guidance to advise mixing the powder with boiling water (not [previously] "boiled" water), THEN cool the mixture long enough that it won't hurt the baby. Body temperature, obviously, is 37° Celsius and parents do not need special equipment to decide if something is close enough to body temperature to avoid scalding their babies. Consider the following revisions to the current WHO guidance:

> ***Pour the correct amount of boiling water for the corresponding number of scoops into the sterilized feeding cup containing the powdered formula. Stir the mixture with a sterilized spoon to dissolve lumps, then cool the mixture until it is near body temperature before feeding to the baby. For example, check the temperature by placing a few drops on the caregiver's wrist.*** ~~*Taking care to avoid scalds, pour the correct amount of boiled water into*~~

~~*a cleaned and sterilized feeding bottle. The water should be no cooler than 70ºC, so do not leave it for more than 30 minutes after boiling.*~~

(**Source of current guidance:** WHO. How to Prepare Formula for Bottle-Feeding at Home. Geneva: WHO, 2007 at https://www.who.int/foodsafety/publications/micro/PIF_Bottle_en.pdf **)**
Note also: The guidance URL and the guidance itself also suggest bottle-feeding rather than cup-feeding, which is contrary to WHO guidance.

8. Consequences of underreporting and next steps

Globally, infant formula is, far and above, the least safe food based on its contribution to fatal acute illness. This is especially true in Low- and Middle-Income Countries. Outbreaks and sporadic cases of infection due to *Salmonella*, *Cronobacter*, *Klebsiella*, and possibly other contaminants in powdered infant formula are likely to be under-reported.[74] Especially if this is so—but even if it is not—regulators worldwide have exhibited exceptional forbearance in restricting the marketing of breastmilk substitutes, especially powdered infant formula. It is possible that the risk is similar in similar in High-Income Countries, but children are saved by more readily available mitigation factors, especially comprehensive universal health care services.

The WHO could help quantitatively disaggregate the relative contributions of various likely causal pathways for harm caused by sub-optimal breastfeeding to help parents better assess risks and better assess their ability to apply the available, partially effective mitigation strategies. WHO's guidance for reconstituting powered infant formula is overdue for revision and vital to help curb the risk of intrinsic contamination by Powdered Infant Formula.

Respectfully submitted,

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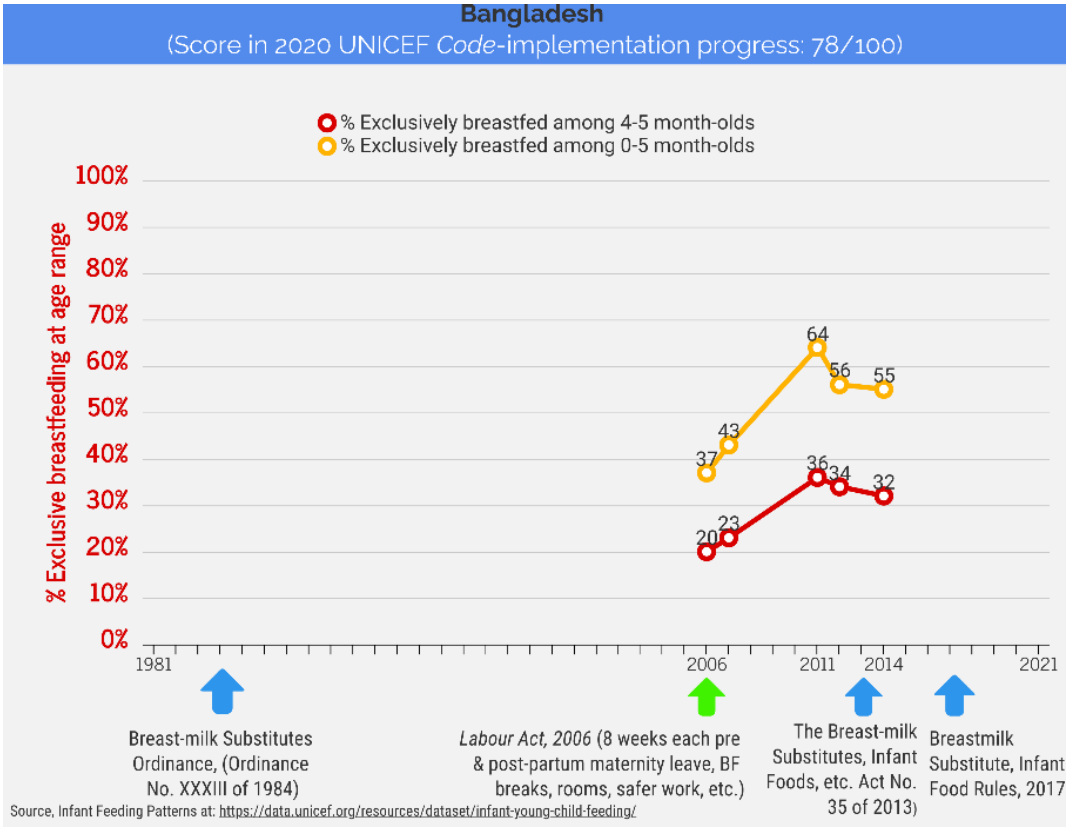
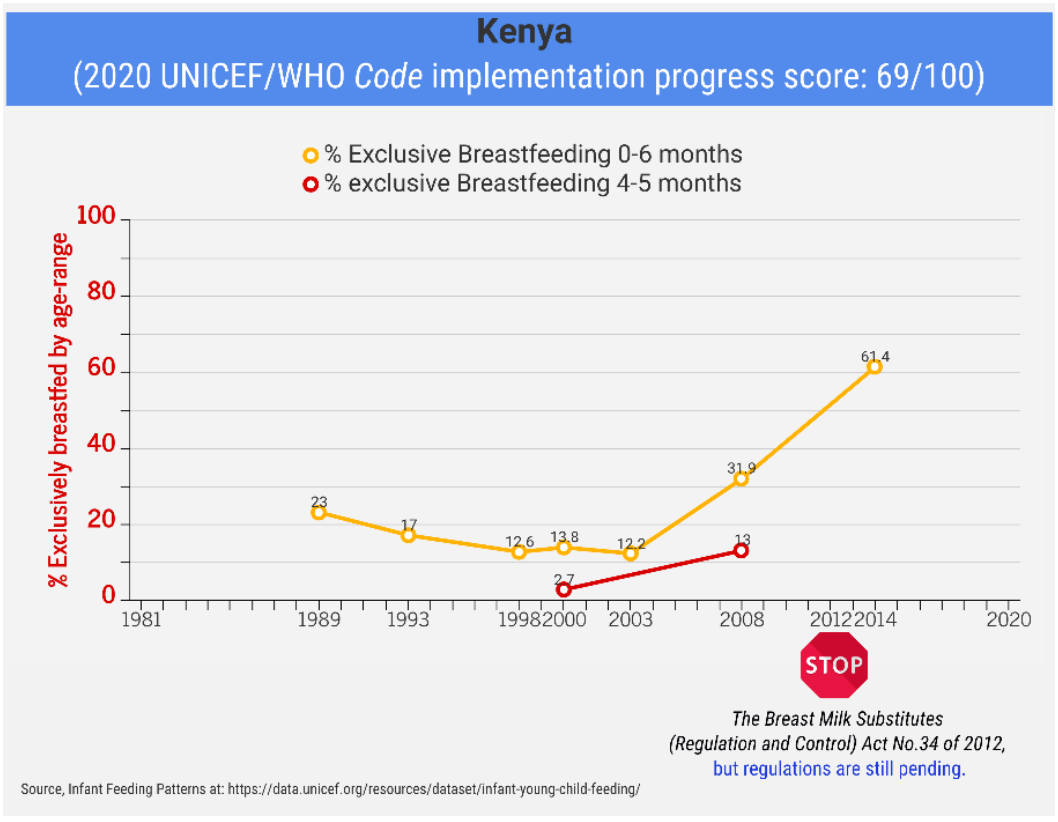
Table 1

Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) Reference Life Table. Seattle, United States of America: Institute for Health Metrics and Evaluation (IHME), 2020. Available at: http://ghdx.healthdata.org/gbd-results-tool

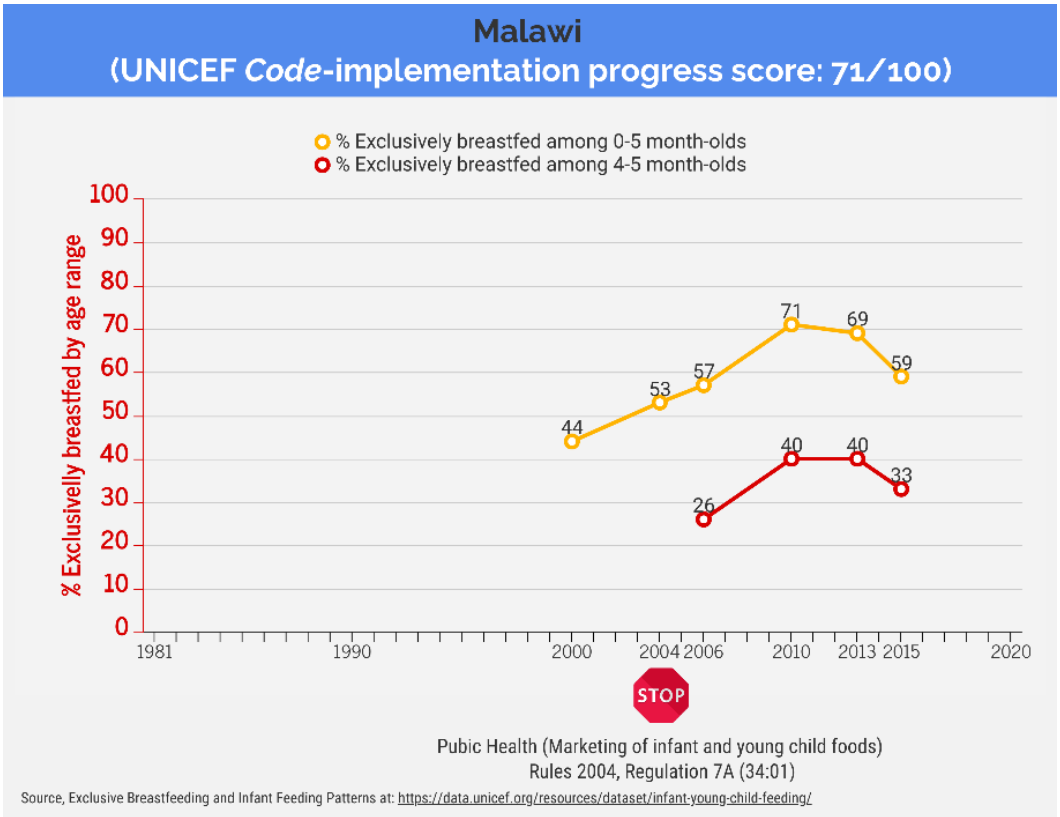
measure	location	age	cause	Deaths/cases in 2019	Ration of South African Risk to Canadian Risk
Deaths	South Africa	25 to 29	All causes	25,630	
Deaths	South Africa	All Ages	All causes	521,802	
Deaths	South Africa	<1 year	All causes	32,314	13
Deaths	South Africa	75 to 84	All causes	66,566	
Deaths	Canada	25 to 29	All causes	1,514	
Deaths	Canada	All Ages	All causes	288,193	
Deaths	Canada	<1 year	All causes	1,552	
Deaths	Canada	75 to 84	All causes	75,842	
Deaths	South Africa	25 to 29	Diarrheal diseases	418	
Deaths	South Africa	All Ages	Diarrheal diseases	13,500	
Deaths	**South Africa**	**<1 year**	**Diarrheal diseases**	**2,902**	**307**
Deaths	South Africa	75 to 84	Diarrheal diseases	2,010	
Deaths	Canada	25 to 29	Diarrheal diseases	1	
Deaths	Canada	All Ages	Diarrheal diseases	1,742	
Deaths	**Canada**	**<1 year**	**Diarrheal diseases**	**6**	
Deaths	Canada	75 to 84	Diarrheal diseases	487	
Deaths	South Africa	25 to 29	Lower respiratory infectior	821	
Deaths	South Africa	All Ages	Lower respiratory infectior	28,941	
Deaths	**South Africa**	**<1 year**	**Lower respiratory infectior**	**3,315**	**100**
Deaths	South Africa	75 to 84	Lower respiratory infectior	4,881	
Deaths	Canada	25 to 29	Lower respiratory infectior	11	
Deaths	Canada	All Ages	Lower respiratory infectior	9,125	
Deaths	Canada	<1 year	Lower respiratory infectior	21	
Deaths	Canada	75 to 84	Lower respiratory infectior	2,117	
Incidence	South Africa	25 to 29	All causes	29,142,502	
Incidence	South Africa	All Ages	All causes	309,098,307	
Incidence	South Africa	<1 year	All causes	7,455,499	2
Incidence	South Africa	75 to 84	All causes	7,870,950	
Incidence	Canada	25 to 29	All causes	12,863,608	
Incidence	Canada	All Ages	All causes	190,683,278	
Incidence	Canada	<1 year	All causes	2,849,377	
Incidence	Canada	75 to 84	All causes	9,981,840	
Incidence	South Africa	25 to 29	Diarrheal diseases	3,508,365	
Incidence	South Africa	All Ages	Diarrheal diseases	48,757,254	
Incidence	South Africa	<1 year	Diarrheal diseases	1,674,938	2
Incidence	South Africa	75 to 84	Diarrheal diseases	3,159,021	
Incidence	Canada	25 to 29	Diarrheal diseases	1,173,885	
Incidence	Canada	All Ages	Diarrheal diseases	20,732,895	
Incidence	Canada	<1 year	Diarrheal diseases	562,879	
Incidence	Canada	75 to 84	Diarrheal diseases	1,423,895	
Incidence	South Africa	25 to 29	Lower respiratory infectior	286,257	
Incidence	South Africa	All Ages	Lower respiratory infectior	4,835,818	
Incidence	South Africa	<1 year	Lower respiratory infectior	107,725	11
Incidence	South Africa	75 to 84	Lower respiratory infectior	456,342	
Incidence	Canada	25 to 29	Lower respiratory infectior	50,937	
Incidence	Canada	All Ages	Lower respiratory infectior	1,245,672	
Incidence	Canada	<1 year	Lower respiratory infectior	15,258	
Incidence	Canada	75 to 84	Lower respiratory infectior	137,370	

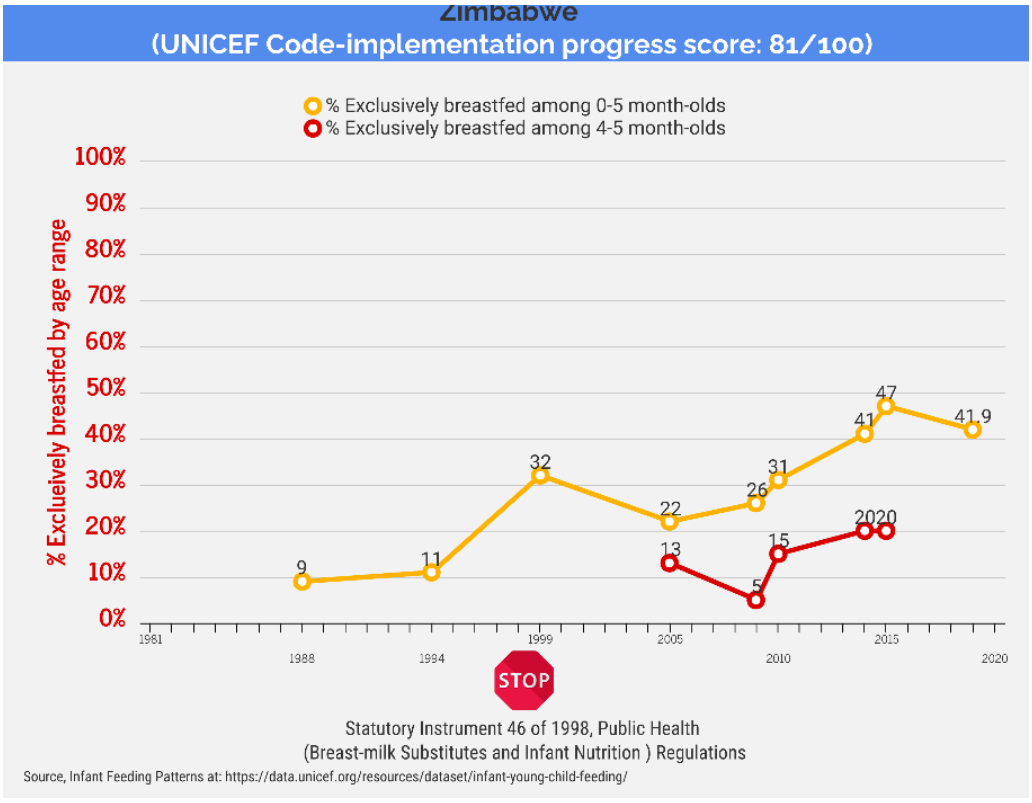
Tables 2-3


Bangladesh
(Score in 2020 UNICEF *Code*-implementation progress: 78/100)
% Exclusively breastfed among 4-5 month-olds
% Exclusively breastfed among 0-5 month-olds
% Exclusive breastfeeding at age range
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
1981
2006
2011
2014
2021
64
56
55
43
37
36
34
32
23
20
Breast-milk Substitutes Ordinance, (Ordinance No. XXXIII of 1984)
Labour Act, 2006 (8 weeks each pre & post-partum maternity leave, BF breaks, rooms, safer work, etc.)
The Breast-milk Substitutes, Infant Foods, etc. Act No. 35 of 2013)
Breastmilk Substitute, Infant Food Rules, 2017
Source, Infant Feeding Patterns at: https://data.unicef.org/resources/dataset/infant-young-child-feeding/


Kenya
(2020 UNICEF/WHO *Code* implementation progress score: 69/100)
% Exclusive Breastfeeding 0-6 months
% exclusive Breastfeeding 4-5 months
% Exclusively breastfed by age-range
100
80
60
40
20
0
1981
1989
1993
1998
2000
2003
2008
2012
2014
2020
23
17
12.6
13.8
12.2
2.7
31.9
13
61.4
STOP
The Breast Milk Substitutes (Regulation and Control) Act No.34 of 2012, but regulations are still pending.
Source, Infant Feeding Patterns at: https://data.unicef.org/resources/dataset/infant-young-child-feeding/

Tables 4-5


Malawi
(UNICEF *Code*-implementation progress score: 71/100)
% Exclusively breastfed among 0-5 month-olds
% Exclusively breastfed among 4-5 month-olds
% Exclusivelly breastfed by age range
100
90
80
70
60
50
40
30
20
10
0
1981
1990
2000
2004
2006
2010
2013
2015
2020
44
53
57
71
69
59
26
40
40
33
STOP
Pubic Health (Marketing of infant and young child foods)
Rules 2004, Regulation 7A (34:01)
Source, Exclusive Breastfeeding and Infant Feeding Patterns at: https://data.unicef.org/resources/dataset/infant-young-child-feeding/


Zimbabwe
(UNICEF Code-implementation progress score: 81/100)
% Exclusively breastfed among 0-5 month-olds
% Exclusively breastfed among 4-5 month-olds
% Excluelvely breastfed by age range
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
1981
1988
1994
1999
2005
2010
2015
2020
9
11
32
22
26
31
41
47
41.9
13
5
15
2020
STOP
Statutory Instrument 46 of 1998, Public Health
(Breast-milk Substitutes and Infant Nutrition) Regulations
Source, Infant Feeding Patterns at: https://data.unicef.org/resources/dataset/infant-young-child-feeding/

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Available at: https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf

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> *to end the inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation*.

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Public consultation on the Draft WHO Global Strategy for Food Safety

Personal Information

These comments represent input from a WHO Member State (Permanent Missions or Ministries)

No ✖

These comments represent the views of an:

Organization

Contact details:

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If your comments represent an organization, please indicate the organization type

NGOs and Civil societies

Consultation: Introduction of the strategy

The strategy described food safety as a public health and socioeconomic priority, do you agree with the statement and content within this section? Would you suggest any modifications? (p2-3)

Agree

The strategy identified 7 drivers and current trends of Food Safety; Do you agree with the identified drivers and the brief explanation under each driver? Would you suggest any modifications? (p4-6)

Interests and demands for safe food

Demographics changes

Rise of new technologies and digital transformation

Society: changing expectations and behaviour

Environmental challenges

Global changes in the economics of the food supply

Global food safety threats

yes Any Additional drivers

Access of populations to reliable sources of electricity, refrigeration, soap and clean water, and careful management of manure from domesticated food animals (esp. chickens and goats that share living and play space with families. Also, purification of municipal water supplies (with ozone or chlorine) piped directly to homes must become a priority for drinking water and sanitation. I challenge WHO to do a better job of declaring soap a global public good than it has for vaccination.

The vision of the strategy is: *"**Safe and healthy food for all; all countries are capable of promoting, supporting and protecting consumer's health by applying food safety to reduce the burden of foodborne diseases***." Do you agree with the vision of the strategy? Would you suggest an alternative or additions?

Agree

The aim of the strategy is: "***Guide and support Member States in their efforts to prioritize, plan, implement, monitor and regularly evaluate actions towards the reduction of the incidence of foodborne diseases by continuously strengthening food safety systems and promoting global cooperation***." Do you agree with the aim of the strategy? Would you suggest an alternative or additions?

Agree

Any additional comments regarding the Introduction part of the strategy?

Consultation: 5 strategic priorities (SP) and respective strategic objectives (SO)

The strategy identifies 5 strategic priorities (SP) as the scope:

- SP1: Strengthening national food controls
- SP2: Identifying and responding to food safety challenges resulting from the transformation and global changes in food systems
- SP3: Increasing the use of food chain information, scientific evidence and risk assessment in making risk management decisions
- SP4: Strengthening stakeholder engagement and risk communication
- SP5: Promoting food safety as an essential component in domestic and international trade

Are these strategic priorities clear and comprehensive as a set? (p10-11, figure3)

Agree

Under SP1: there are in total 6 strategic objectives:
SO1.1: Establish a modern, harmonized and risk-based framework of food legislation.
SO1.2: Establish an institutional framework to coordinate the work of different competent authorities within a national food control system
SO1.3: Develop and implement fit-for-purpose standards and guidelines
SO1.4: Strengthen Compliance, Verification and Enforcement
SO1.5: Strengthen food monitoring and surveillance programmes
SO1.6: Establish food safety incident and emergency response systems
Are these Strategic Objectives (SO) clear and comprehensive? Would you suggest any modifications? (p11-15)

☑ SO1.1
Replace the word modern with effective.
SO1.2
SO1.3
SO1.4
SO1.5
SO1.6

Under SP2: there are in total 2 strategic objectives:
SO2.1: Identify and evaluate food safety impacts arising from global changes and transformations in food systems and movement of food
SO2.2: Adapt risk management options to emerging foodborne risks brought about by transformation and changes in global food systems and movement of food
Are these Strategic Objectives (SO) clear and comprehensive? Would you suggest any modifications? (p15-17)

SO2.1
SO2.2

Under SP3: there are in total 4 strategic objectives:
SO3.1: Promote the use of scientific evidence and risk assessment when establishing and reviewing food control measures
SO3.2 Gather comprehensive information along and beyond food chain and utilise these data when making informed risk management decisions
SO3.3 Source food safety information and risk analysis experiences from beyond national borders to strengthen risk management decisions and technical capacity
SO3.4 Consistent and transparent risk management decisions when establishing food control measures
Are these Strategic Objectives (SO) clear and comprehensive? Would you suggest any modifications? (p17-20)

SO3.1
SO3.2
SO3.3
SO3.4

Under SP4: there are in total 5 strategic objectives:
SO4.1 Establish platforms for consultation on the national food safety agenda
SO4.2 The use of non-regulatory schemes for enhancing food safety across the food chain
SO4.3 Establish frameworks for sharing verification of compliance with food safety regulatory requirements
SO4.4 Facilitate communication and engagement with food business operators and foster a food safety culture
SO4.5 Facilitate communication, education, and engagement with consumers
Are these Strategic Objectives (SO) clear and comprehensive? Would you suggest any modifications? (p20-22)

SO4.1
☑ SO4.2
Adopting HACCP is not incompatible with regulating; processes can be mandated as easily as products.
SO4.3
SO4.4
SO4.5

Under SP5: there are in total 4 strategic objectives:
SO5.1 Strengthen food controls and capacity development in regulatory systems for the domestic market
SO5.2 Strengthen interaction between national agencies responsible for food safety and those facilitating the food trade
SO5.3 Ensure that national food safety systems facilitate and promote international trade
SO5.4 Strengthen engagements of national competent authorities with international agencies and networks that establish standards and guidelines for food in trade
Are these Strategic Objectives (SO) clear and comprehensive? Would you suggest any modifications? (p23-25)

SO5.1
☑ SO5.2
The Codex primary priority is "(a) protecting the health of the consumers and ensuring fair practices in the food trade;" which embraces the priority of fairness to consumers. Facilitating trade is a misrepresentation of that priority.
SO5.3
SO5.4

Any additional comments regarding all strategic priorities and respective strategic objectives of the strategy?

Consultation: General introduction on the Implementation of the strategy

The strategy identifies 4 fundamental steps for Member States to implement the strategy
1. Conduct a situation analysis
2. Develop a national strategy and action plan on food safety
3. Implement the strategy and national action plan
4. Conduct regular review of the implementation and adjust the plan and strategy as appropriate

Do you agree that these 4 steps and the specific contents within the strategy clearly outline a stepwise approach for Member States to implement the strategy? Would you suggest any modifications? (p25-26, figure4)

Partially agree

The strategy identifies WHO's role in supporting Member States in 4 areas:
1. Provide global leadership and foster policy dialogues
2. Synthesize evidence and generate normative guidance:
3. Enhance technical cooperation and build stronger capacity
4. Build partnership and foster global collaboration

Do you agree that these 4 areas adequately summarize WHO's role in implementing the strategy? Would you suggest any modifications? (p26-27)

Partially agree

The strategy highlights the importance of international cooperation in two broad areas:
1. Technical cooperation among countries, and
2. Participation by Member States in food safety programmes, initiatives, and networks coordinated by international organizations.

Do you agree with these two broad areas and if the respective contents illustrate well the importance of international cooperation in food safety? Would you suggest any modifications? (p28)

Any additional comments regarding the implementation chapter of the strategy?

Consultation: General introduction on the Monitoring and Evaluation

Do you agree with the general approach of the Monitoring and Evaluation of the strategy? (p29-31)

Partially agree

Currently the draft identifies 3 high-level indicators for the strategy:

1. Diarrheal diseases due to food consumption;
2. National foodborne disease surveillance in place for the detection and monitoring of foodborne disease and food contamination (currently monitored under the IHR reporting process);
3. Multisectoral collaboration mechanism for food safety events (currently monitored under the IHR reporting process).

Do you have specific comments on each indicator? Would you suggest any alternatives?

- Diarrheal diseases due to food consumption
- National foodborne disease surveillance in place for the detection and monitoring of foodborne disease and food contamination
- ☑ Multisectoral collaboration mechanism for food safety events
- Be ever mindful of conflicts of interest between public health and commercial activities.
- Alternatives

Any additional comments regarding the Monitoring and Evaluation chapter of the strategy?

See the letter to Dr. Branca concerning powdered infant formula which poses powdered infant formula as an example of an inadequately specified and quantified risk to infants and young children which resulting confusion deprives mothers, fathers, and other caregivers of guidance to best mitigate risks.

Additional comments and supplementary materials

Additional comments on the draft strategy:

If you would like to submit additional materials to support the Strategy, please do so here, please noted that maximum you can upload 5 files:

Centre for Health Science and Law focus on powdered infant formula	No comment	File type "pdf"