

2018

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Recommended Citation

Schwegel, J. (2019). Super Unleaded Malbec? A Case Study in Flawed International Standard Setting at the Codex Alimentarius. *Journal of Food Law & Policy*, 14(2). Retrieved from <https://scholarworks.uark.edu/jflp/vol14/iss2/2>

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—Journal of—
FOOD & LAW
—POLICY—

Volume Fourteen

Number Two

Fall 2018

SUPER UNLEADED MALBEC?
WHY THE CODEX ALIMENTARIUS METHODOLOGY
FOR REVISING LEAD MAXIMUM LIMITS MAY
BE FLAWED FOR ALCOHOLIC BEVERAGES

Justin Schwegel

Super Unleaded Malbec? Why the Codex Alimentarius Methodology for Revising Lead Maximum Limits May Be Flawed for Alcoholic Beverages.

Justin Schwegel*

I. Introduction

The World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) provides rules on the adoption and enforcement of SPS measures. It also presumes that food safety regulations adopted by WTO Members that conform to relevant international standards are consistent with the SPS Agreement.¹ The relevant international standard setting body for food safety is the Codex Alimentarius Commission, which conducts most of its food safety risk management work through subsidiary bodies such as the Codex Committee on Contaminants in Food (CCCF). The CCCF establishes maximum limits for food contaminants and codes of practice for reducing food contamination.² These subsidiary bodies in turn delegate risk management work to electronic working groups (EWG) that are comprised of relevant food safety authorities of Codex member states.³

One contaminant of concern is lead. Lead exposure from dietary sources is harmful to human health, and especially harmful to children.⁴ In March 2018, the *CCCF Electronic Working Group (EWG) to Revise the Maximum Levels (ML) for Lead* proposed to reduce the ML for lead in wine from .2 parts per million (ppm)⁵ to

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¹ Agreement on the Application of Sanitary and Phytosanitary Measures, art. 3.2, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 33 I.L.M. 1125, https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm [hereinafter SPS Agreement].

² Codex Alimentarius Comm'n., Procedural Manual, Twenty-Fourth Edition, at 192 (2015), <http://www.fao.org/3/a-i5079e.pdf> [hereinafter Codex Manual].

³ *Id.* at 109-111.

⁴ Joint FAO/WHO Expert Committee on Food Additives, Evaluation of Certain Food Additives and Contaminants, Seventy-Third Report, WHO Technical Report Series 960, at 176 (2010), <http://apps.who.int/iris/handle/10665/44515> [hereinafter Evaluation].

⁵ Codex Alimentarius Comm'n., Codex General Standard for Contaminants and Toxins in Food and Feed, Codex Standard 193-1995, at 46 (2018), www.fao.org/input/download/standards/17/CXS_193e_2015.pdf.

.05 ppm.⁶ The EWG ostensibly based this proposal on the “ALARA” principle, which dictates that standards for dangerous contaminants should be set at a level “as low as reasonably achievable.”⁷ The EWG applies the same methodology when establishing MLs for relatively low-value products often consumed by children, the group most vulnerable to lead exposure.⁸ Another EWG is currently charged with prioritizing commodities to establish new lead MLs in the General Standard for Contaminants and Toxins in Food and Feed.⁹ Some commodities under consideration include high value, age-restricted products like cognac and absinthe.¹⁰ Establishing MLs for alcoholic beverages using the methodology applied to products marketed for child consumption is inappropriate. It could also distract from the important work of progressively reducing lead in products commonly consumed by those most vulnerable to lead exposure, where reductions in lead provide greater public health benefit for the same economic cost.

II. The GATT, the WTO, and the Internationalization of Sanitary and Phytosanitary Standards

A. *The Need for International Standard Setting Bodies*

The WTO Members negotiated greater trade liberalization at the Uruguay Round, particularly for agricultural commodities.¹¹ The SPS Agreement was designed to help ensure this trade liberalization was not undermined by unnecessarily restrictive SPS measures.¹² An SPS measure under the terms of the SPS Agreement is any measure

⁶ Codex Alimentarius Comm’n., Proposed Draft and Draft Maximum Levels of Lead in Selected Commodities in the General Standard for Contaminants and Toxins in Food and Feed, CX/CF 18/12/5, at 5 (2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-12%252FWD%252Fcf12_05e.pdf [hereinafter Codex Draft].

⁷ *Id.* at 8.

⁸ See Codex Alimentarius Comm’n., *supra* note 6, at 8.

⁹ Codex Alimentarius Comm’n., Discussion Paper on Future Work on Maximum Levels for Lead for Inclusion in the General Standard for Contaminants and Toxins in Food and Feed, CX/CF 18/12/14 (2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-12%252FWD%252Fcf12_14e.pdf [hereinafter Codex Discussion Paper].

¹⁰ *Id.* at 29.

¹¹ See Boris Rigod, *The Purpose of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)*, 24 EUR. J. OF INT’L L. 503, 507 (2013).

¹² *Id.*; see also MARIE DENISE PRÉVOST, BALANCING TRADE AND HEALTH IN THE SPS AGREEMENT: THE DEVELOPMENT DIMENSION 481–82 (2009) (discussing the purpose behind the Uruguay Round negotiations of the SPS Agreement and trade disputes concerning market access barriers to agricultural products).

adopted to protect human, animal, or plant life or health from disease, or unsafe food and feed.¹³ While necessary to protect both human health and the security of the food supply, such measures can also be applied in such a way as to function as nontariff barriers to trade in agricultural products.¹⁴

Prior to the adoption of the SPS Agreement, sanitary and phytosanitary (SPS) measures were only subject to Article XX (b) of the General Agreement on Tariffs and Trade (GATT).¹⁵ GATT Article XX(b) provides general exceptions for the application of potentially trade-restrictive measures “necessary to protect human, animal or plant life or health.”¹⁶ This proved an ineffective regulatory structure.¹⁷ It neither effectively disciplined protectionist SPS measures nor sufficiently recognized Members’ sovereign right to adopt legitimate SPS measures.¹⁸ Additionally, under GATT Article XX, WTO Members were not obligated to avoid arbitrarily applying different levels of sanitary and phytosanitary protection in comparable situations.¹⁹

The myriad insufficiencies of the existing framework governing the application of sanitary and phytosanitary measures led GATT negotiators to begin negotiating an agreement that would explicitly articulate contracting parties’ right to adopt legitimate SPS measures and subject such measures to strict disciplines to avoid protectionism.²⁰ Namely, they must be based on a scientific assessment of risk or the relevant international standard.²¹ The SPS

¹³ SPS Agreement, *supra* note 1, at Annex A1.

¹⁴ See RENÉE JOHNSON, CONG. RESEARCH SERV., 7-5700, SANITARY AND PHYTOSANITARY (SPS) AND RELATED NON-TARIFF BARRIERS TO AGRICULTURAL TRADE 22, 33 (2014) (discussing concerns from agricultural exporters and policy makers that SPS measures act as nontariff barriers).

¹⁵ While the 1979 GATT “Standards Code” applied among states that ratified it, it was not generally applicable to all GATT members. Additionally, its substantive and procedural deficiencies rendered it ineffective even for states party to the agreement. See PRÉVOST, *supra* note 12, at 470-481 (discussing numerous shortcomings of the “Standards Code”).

¹⁶ General Agreement on Tariffs and Trade, Art. XX(b), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194, 262 [hereinafter GATT]; see also, Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶147–51, WTO Doc. WT/DS58/AB/R (adopted Oct. 12, 1998) (explaining that measures adopted under the specific exceptions enumerated under GATT Article XX must also comply with the language of the chapeau).

¹⁷ See PRÉVOST, *supra* note 12, at 474 (discussing the lack of enforceability of the Art. XX(b) exceptions).

¹⁸ *Id.*

¹⁹ *Id.*; but see SPS Agreement, Art. 5(5) (containing such an obligation).

²⁰ SPS Agreement, *supra* note 1; See also, Rigod, *supra* note 11, at 507.

²¹ SPS Agreement, *supra* note 1, at Art. 3, Art. 5.

Agreement cites three international standard setting bodies of reference, including the Codex Alimentarius mentioned above.²² The World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC) are the relevant international standard setting bodies for animal health and plant health respectively.²³

When WTO Members adopt uniform international SPS standards it reduces the cost of regulatory compliance for exporters.²⁴ This facilitates international trade.²⁵ Codex, IPPC and OIE are open to membership from WTO Members and were perceived at the time of negotiations to establish standards on a sound scientific basis by the parties negotiating the text of the SPS Agreement.²⁶ As a result, the negotiating parties supported deference to the standards promulgated by these bodies.²⁷ This deference creates a presumption that an SPS measure that complies with the relevant international standard also complies with the SPS Agreement and Article XX(b) of the GATT.²⁸ Early proposals by negotiating parties such as the United States and the Cairns group suggested that SPS measures conforming to international standards should be “deemed” consistent with WTO obligations rather than deemed necessary and “presumed” consistent.²⁹ While a presumption of consistency can be rebutted, it

²² *Id.* at Annex A(3).

²³ *Id.* at Annex A(3)(b), (c).

²⁴ See PRÉVOST, *supra* note 12, at 317.

²⁵ See *e.g.*, Codex Alimentarius Comm’n., *supra* note 2, at 21.

²⁶ See *e.g.*, Negotiating Group on Agriculture, *Communication from Israel Expressing Views on Certain Elements in the Negotiation on Agriculture*, MTN.GNG/NG5/W/153, at 5 (Feb. 13, 1990) (stressing the importance of science based standards and supporting the adoption of standards developed in the international standard setting bodies as guidelines for an effective surveillance and dispute settlement procedure in GATT), <https://docs.wto.org/gattdocs/q/.%5CUR%5CGNGNG05%5CW153.PDF>; WTO Negotiating Group on Agriculture, Supplementary Communication from the Cairns Group, at ¶19, MTN.GNG/NG5/W/164 (Apr. 18, 1990), <https://docs.google.com/document/d/1vYmqLiHdwlw2PLPWr3ZfhfCtIgc48a6ZcDsCgPX2PNo/edit>.

²⁷ *Id.*

²⁸ See SPS Agreement, *supra* note 1, at Art. 3(2) (“Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be . . . presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.”).

²⁹ Negotiating Group on Agriculture, *supra* note 26; Negotiating Group on Agriculture, *Submission of the United States on Comprehensive Long-Term Agriculture Reform*, MTN.GNG/NG5/W/118, at 12 (Oct. 25, 1989), https://www.wto.org/gatt_docs/English/SULPDF/92080128.pdf.

seems unlikely a measure “deemed” consistent with the SPS Agreement could be shown to be nonetheless inconsistent.³⁰

B. The Use of Codex Standards

WTO Members have several incentives to adopt international standards. Because many developing WTO Members lack the capacity to conduct risk assessments of their own they often defer to Codex’s food safety standards.³¹ This is often done through regulations that either explicitly defer to the Codex or mirror Codex standards.³² Additionally, because the SPS Agreement presumes measures that conform to international standards are consistent with the Agreement there is a safe harbor for regulations harmonized with the international standard.³³ WTO Members are less likely to challenge SPS measures that are consistent with international standards because of the greater burden of overcoming the presumed consistency.³⁴ Because of this safe harbor, many WTO Members either defer to the Codex when there is no domestic standard (as Morocco does for veterinary drug residues, for example)³⁵ or allow imports that comply with international standards notwithstanding a

³⁰ While beyond the scope of this article, the negotiating history eschewing an irrebuttable presumption of WTO consistency in favor of presumed consistency does not provide great clarity as to when a measure adopted by a WTO Member in accordance with an international standard can nonetheless be deemed WTO inconsistent. Likely, the adoption of international standards that fail to comply with the requirement to avoid arbitrary or unjustifiable distinctions in applying an appropriate level of sanitary or phytosanitary protection in different situations under Article 5.5 of the SPS Agreement could be considered arbitrary and unjustifiable under Articles 2.3 and 5.5 of the SPS Agreement and the chapeau of GATT Article XX.

³¹ See KIMBERLY BERRY, CODEX MRLS—USE AND TRENDS 1 (2006), https://www.globalmrl.com/downloads/whitepaper_Codex_MRLs_Use_and_Trends_globalmrl.pdf.

³² *Id.*

³³ SPS Agreement, *supra* note 1, Art. 3(2).

³⁴ See *Standards and Safety*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm (last visited Nov. 1, 2018).

³⁵ Aziz Akhannouch & Anass Doukkali, “Arrêté du ministre de la santé n°2454-17 du 3 jourmada II 1439 (20 février 2018) fixant les limites maximales autorisées de résidus des produits pharmaceutiques dans les produits primaires et les produits alimentaires,” Bulletin Officiel, 2018, no. 6666, p. 1029, http://www.sgg.gov.ma/BO/FR/2018/BO_6666_Fr.pdf?ver=2018-04-27-113812-017, translated in GLOB. AGRIC. INFO. NETWORK, U.S. DEP’T AGRIC., GAIN REP. NO. MO1826, MOROCCO, VETERINARY DRUG MRLS ESTABLISHED, 2 (2018), https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Veterinary%20Drug%20MRLs%20Established_Rabat_Morocco_6-6-2018.pdf (deferring to Codex Alimentarius maximum residue limits (MRL) for veterinary drugs when no domestic MRL has been established).

more restrictive domestic standard (as South Africa does for pesticide residues, for example).³⁶

Due to the widespread adoption of Codex standards and the deference they are given under the SPS Agreement, their importance for international trade is difficult to overstate. Consequently, the potential for negative economic impacts from overly restrictive Codex standards has been a real concern for many agricultural producers in the past.³⁷ The CCCF is the Codex committee responsible for establishing MLs for contaminants, such as lead, in food and beverages.³⁸

Several wine producing countries have likewise expressed concern about the low ML for lead in wine proposed by CCCF's EWG to revise MLs for lead.³⁹

III. The Health Concern over Lead Exposure and the Codex Response

Exposure to lead from food is harmful to everyone, but it is disproportionately harmful to children.⁴⁰ As a result of a 2010 study on lead exposure, a new Codex electronic working group was established to reconsider international standards regarding maximum levels of lead allowed in food products, especially for products

³⁶ Dep't of Nat'l Health & Population Dev., Regulations Governing the Maximum Limits for Pesticide Residues That May Be Present in Foodstuffs, GN R.246 of 11 February 1994, at 2(d) (11 Feb 1994), <https://www.nda.agric.za/docs/PlantQuality/quality%20control/MRLs%20Dept%20of%20Health%20-%20R246%20of%2011%20Feb%201994.pdf> (allowing the import of foodstuffs that comply with Codex Alimentarius standards for pesticides).

³⁷ See, e.g., Codex Alimentarius Comm'n., Proposed Draft Maximum Level for Aflatoxins in Ready-to-Eat Peanuts and Associated Sampling Plans (at Step 4), CX/CF 18/12/10-Add.1, at 2-4, (Mar. 12-16, 2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-12%252FWD%252Fcf12_10_Add1e.pdf (noting the United States and the International Council of Grocery Manufacturers Associations concerns that an overly restrictive ML for aflatoxins in ready-to-eat peanuts would cause potentially significant problems with international trade).

³⁸ Codex Manuel, *supra* note 2, at 192.

³⁹ See Codex Alimentarius Comm'n., Proposed Draft and Draft Maximum Levels of Lead in Selected Commodities in the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) (at Steps 7 and 4), CX/CF 18/12/5-Add.1, at 1-7 (March 12-16, 2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-12%252FWD%252Fcf12_05_Add1e.pdf (noting comments from Argentina, Australia, Japan, and Turkey that show such concern).

⁴⁰ Evaluation, *supra* note 4, at 176.

consumed by children.⁴¹ EWGs are subject to the Codex guidelines on risk management recommendations.⁴² These guidelines require risk management recommendations to be based on an approach that weighs the economic cost against the public health benefit.⁴³

A. The Special Vulnerability of Children to Lead Exposure

In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) held its 73rd meeting to evaluate certain food additives and contaminants.⁴⁴ The JECFA meeting report cited concerns over lead exposure and noted it was impossible to establish a tolerable weekly intake for lead that would be health protective.⁴⁵ Essentially, JECFA found that no level of lead exposure is safe. JECFA noted, “[b]ecause of the neurodevelopmental effects, fetuses, infants and children are the subgroups that are most sensitive to lead.”⁴⁶ While they are the most vulnerable, children are not the only group at risk of harmful health impacts from dietary exposure to lead. The greatest concern from lead exposure for adults is an associated risk of increased systolic blood pressure, though JECFA has found this concern is not as significant as the concern for the neurodevelopmental impact on children.⁴⁷ JECFA also noted:

[I]mpaired neurodevelopment in children is generally associated with lower blood lead concentrations than the other effects, the weight of evidence is greater for neurodevelopmental effects than for other health effects and the results across studies are more consistent than those for other effects.⁴⁸

JECFA’s case for reducing children’s dietary exposure to lead was strong. As a result of the JECFA report, the CCCF established an electronic working group to reconsider the existing

⁴¹ Codex Alimentarius Comm’n., Rep. of the Fifth Session of the Codex Committee on Contaminants in Foods, REP11/CF, at 15 (2011), www.fao.org/input/download/ereport/758/REP11_CFe.pdf.

⁴² Codex Manuel, *supra* note 2, at 129.

⁴³ *See id.* at 128 (noting that the CCCF shall consider, among other factors, protection of consumer health and the impact on international trade when preparing its priority list of substances for review).

⁴⁴ Evaluation, *supra* note 4.

⁴⁵ *Id.* at 176.

⁴⁶ *Id.* at 481.

⁴⁷ *Id.* at 480.

⁴⁸ *Id.*

lead maximum levels with a focus on reducing dietary exposure to lead, especially for infants and children.⁴⁹

The discussion paper presented at the following CCCF meeting by the EWG stressed the importance of “whether children were high consumers of the food or had significant lead exposure from the food, since lead is of particular concern for children.”⁵⁰

Concerns over the dietary exposure of children and fetuses to lead were a primary reason the EWG was established.⁵¹ The EWG’s original mandate to “focus on foods important for infants and children” reflects CCCF’s understanding of the relative risks for different population groups.⁵² By committing to prioritize lead MLs for foods consumed by the most vulnerable group in its early reconsideration of MLs in the General Standard, CCCF recognized the greater relative risk to children from dietary lead exposure identified in the JECFA report.

B. Risk Assessment, Risk Management, Codex Guidelines, and the Inherent Need for Proportionality

Under the Codex Alimentarius Working Principles, there is a clear distinction between the competences of the body charged with risk assessment, the FAO/WHO joint expert bodies, and the body charged with risk management, the Codex Alimentarius Commission and its subsidiary bodies.⁵³ For contaminants it is JECFA’s responsibility to assess risk, while the CCCF is the subsidiary Codex risk management body.⁵⁴

⁴⁹ Codex Alimentarius Comm’n, Joint FAO/WHO Food Standards Programme, REP12/CF, at ¶ 116 (Mar. 26-30, 2012), http://www.fao.org/input/download/reporth/776/REP12_CFe.pdf (stating that the EWG was established to “(i) reconsider the existing maximum levels with a focus on foods important for infants and children and also on the canned fruits and vegetables and (ii) reconsider if other existing maximum levels should be addressed”).

⁵⁰ *Id.* at ¶ 116 (stressing throughout the discussion paper the importance of the rate at which children consume various foods and the relative additional protection a lower ML would provide to children who are particularly vulnerable to lead exposure).

⁵¹ *See Report of the Fifth Session of the Codex on Contaminants in Foods*, REP11/CF, at 15, Joint FAO/WHO (2011) (stating that the EWG was established to “(i) reconsider the existing maximum levels with a focus on foods important for infants and children and also on the canned fruits and vegetables and (ii) reconsider if other existing maximum levels should be addressed.”).

⁵² *Id.*

⁵³ *See Codex Manual*, *supra* note 2, at 126–29.

⁵⁴ *See id.* at 127.

When managing risk through the propagation of international standards, Codex has the dual mandate of “protecting consumers’ health and ensuring fair practices in the food trade.”⁵⁵ The dual mandate reflects the language of the original 1961 FAO resolution calling for the establishment of the Codex Alimentarius Commission, which recognized the importance of international food standards for “protecting consumer[s] and producer[s] in all countries.”⁵⁶ The need to balance the economic costs of disrupted trade with the anticipated public health benefits of a given food safety standard is not unique to Codex; it is inherent in any food regulatory system.⁵⁷

The relevant Codex risk management body for contaminants in food is CCCF.⁵⁸ The Codex Alimentarius Commission’s Procedural Manual establishes guidelines for how CCCF is to make its risk management recommendations.⁵⁹ There are three guidelines in the Procedural Manual that are especially relevant to the consideration of MLs for lead in different commodities. The recommendations must be based on the JECFA risk assessments, they must take different consumption patterns and dietary exposures into account, and they must be based on principles established in the Codex General Standard for Contaminants and Toxins in Food and Feed.⁶⁰

With respect to the first guideline, JECFA assessed the risk posed by lead.⁶¹ It recommended that in populations with prolonged dietary exposures the relevant food safety authorities should take measures “to identify major contributing sources and foods and...to identify methods of reducing dietary exposure *commensurate with the level of risk reduction* [emphasis added].”⁶² The recommendation to pursue means of reducing dietary exposure commensurate with risk reduction reflects the balancing of economic costs and public health benefits inherent in food safety regulation. Put differently, the

⁵⁵ *Id.* at 116.

⁵⁶ See Codex Alimentarius Comm’n. Res. 12/61 (Nov. 4–24, 1961) (creating the Codex Alimentarius Commission generally, and including reasons for its creation).

⁵⁷ See generally JEAN C. BUZBY, ET AL., U.S. DEP’T AGRIC., ERS, INTERNATIONAL TRADE AND FOOD SAFETY ECONOMIC THEORY AND CASE STUDIES 828, 29 (2003) (discussing the ineluctable necessity to balance economic interests with food safety concerns).

⁵⁸ Codex Manual, *supra* note 2, at 192.

⁵⁹ *Id.* at 129–30.

⁶⁰ *Id.*

⁶¹ Evaluation, *supra* note 4, at 162–77.

⁶² *Id.* at 177.

EWG should ensure the public health benefit of the end justifies the economic cost of the means.⁶³

The Codex guideline requiring that different consumption patterns and dietary exposures be taken into account is important for determining the expected health benefit of a food safety standard.⁶⁴ If the most vulnerable populations will not ordinarily be exposed to lead from alcoholic beverages this should be taken into account when assessing the public health benefit of a new ML. Early work of the EWG seems to have taken this into account as many of the commodities reviewed by the committee in its nascence reflect a focus on infants and young children, including fruit juices, milk, and infant formula.⁶⁵

The EWG ostensibly implements the final guideline that new lead ML recommendations be based on principles established in the Codex General Standard for Contaminants and Toxins in Food and Feed. The document proposing new proposed draft MLs for lead in selected commodities prepared for CCCF's 2018 meeting specifically invoked the principle of establishing MLs based on levels that are as low as reasonably achievable (ALARA).⁶⁶ The same principle is outlined in the General Standard.⁶⁷ However, the principle that contaminants in food should be as low as reasonably achievable is itself a balancing test requiring an assessment of the economic cost and the public health benefit of further reducing MLs.⁶⁸

⁶³ See generally BUZBY ET AL., *supra* note 57 (discussing the balance of food safety and economic concerns in food safety policy making).

⁶⁴ See generally Codex Manual, *supra* note 2, at 132–35 (describing in detail the CCCF policy for conducting exposure assessments of contaminants and toxins in food or food groups).

⁶⁵ Codex Draft, *supra* note 6 (recommending stricter lead MLs for fruit juices, milk, infant formula, canned fruits and vegetables, and cereal grains).

⁶⁶ Codex Draft, *supra* note 6, at 8.

⁶⁷ Codex Alimentarius, *supra* note 5, at 3 (stating that “[c]ontaminant levels in food and feed shall be as low as reasonably achievable through best practice such as Good Agricultural Practice . . . and Good Manufacturing Practice . . .”).

⁶⁸ WHO & FAO, *Food Safety Risk Analysis: A guide for national food safety authorities*, 87 FAO FOOD AND NUTRITION PAPER, 2006, at 1, 31 (defining ALARA as an approach to risk management that aims for the lowest level of risk “technically possible and/or economically feasible under the circumstances. Some residual risk to consumer typically remains; for example for . . . environmental contaminants in otherwise wholesome foods.”); see also, FRÉDÉRIC BOUDER ET AL., THE TOLERABILITY OF RISK A NEW FRAMEWORK FOR RISK MANAGEMENT 120 (Ragnar E. Löfstedt ed., Earthscan 2007) (defining ALARA as a weighing of risk versus cost feasibility criteria); G.H. Eduljee, *Trends in Risk Assessment and Risk Management*, 249 THE SCIENCE OF THE TOTAL ENVIRONMENT 13, 19 (2000) (explaining that what

C. *The Appropriate Application of ALARA*

The correct application of ALARA means any recommended ML should be technically possible and economically feasible and should take into account the health benefit and economic impact.⁶⁹ The recommendation that measures should be commensurate with the public health benefit in the JECFA report, the obligation to take into account different consumption patterns in the Codex Procedural Manual, and the correct application of the ALARA principle identified in the General Standard all call for an approach that balances economic cost with public health benefit. For alcoholic beverages, which are age restricted, the public health benefit of stricter standards is weaker. For high value products such as wine and spirits, the economic cost is greater.

i. Expected public health benefit is reduced for lead reductions in alcoholic beverages

The most vulnerable populations are already not exposed to lead from alcoholic beverages because they are age restricted. Consequently, the methodology the EWG uses for proposing draft MLs does not clearly reflect JECFA's recommendation or the ALARA principle, and does not seem to take into account consumption patterns. The EWG has:

no specific rule to identify the appropriate cut-off value [for MLs], but in general, [its] approach has been to recommend reductions in MLs when the percentage of excluded samples was less than 5 percent.⁷⁰

constitutes "reasonableness" in an ALARA approach "necessarily accommodates a range of criteria covering human health, well being of the ecosystem, economic and social factors, as well as the concept of fairness"); Commission Regulation 2006, O.J. (L 364) ¶ 3-4 (EC) (endorsing both the ALARA principle and the principle of proportionality).

⁶⁹ WHO & FAO, *supra* note 68, at 31 (defining ALARA as an approach to risk management that aims for the lowest level of risk "technically possible and/or economically feasible under the circumstances. Some residual risk to consumer typically remains; for example for . . . environmental contaminants in otherwise wholesome foods."); G.H. Eduljee, *supra* note 68, at 19.

⁷⁰ Codex Draft, *supra* note 6, at 9.

The EWG is applying the same methodology to the review of the wine ML⁷¹ that it applied to infant formula.⁷² It is unclear how a methodology that focuses only on the percentage of trade potentially disrupted without taking into account dietary exposure or the relative economic impact can ensure that steps taken are *commensurate* with the level of risk reduction.

Alcohol has different consumption patterns than other food products.⁷³ Consumption patterns and dietary exposure should be considered when recommending maximum use levels for contaminants.⁷⁴ For adults, the greatest risk from lead exposure is elevated systolic blood pressure.⁷⁵ JECFA noted that for adults, “dietary exposure corresponding to an increase in systolic blood pressure of 1 mmHg...was estimated to be 80...µg/day, or about 1.3...µg/kg bw [body weight] per day.”⁷⁶ For children the greatest risk is neurodevelopmental and happens at much lower exposure levels than the risk for adults.⁷⁷ JECFA found that in children, “the chronic dietary exposure corresponding to a decrease of 1 IQ point was estimated to be 12 µg/day...[the] equivalent to 0.6 µg/kg bw per day.”⁷⁸ This indicates that children warrant extra protection from dietary lead exposure.

With respect to a similar contamination concern, methylmercury levels in fish, the U.S. and Japanese Codex delegations have consistently opposed maximum limits that would impact international trade flows.⁷⁹ The United States and Japan instead favor consumption guidance from national health authorities indicating the excessive consumption of fish of certain species can

⁷¹ *Id.*

⁷² Codex Draft, *supra* note 6 (stating the recommendation of the EWG for infant formula, which, one should note, was so lax that 99% of the available samples in the GEMS database would have met it).

⁷³ Priya Deshmukh-Taskar et al., *Does Food Group Consumption Vary by Differences in Socioeconomic, Demographic, and Lifestyle Factors in young Adults? The Bogalusa Heart Study*, 107(2) J. AM. DIABETIC ASSOC. 16-18 (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769987/pdf/nihms-150941.pdf>.

⁷⁴ Codex Manual, *supra* note 2, at 129–30.

⁷⁵ See Evaluation, *supra* note 4.

⁷⁶ *Id.* at 175.

⁷⁷ *Id.* at 176–77.

⁷⁸ *Id.* at 175.

⁷⁹ Codex Alimentarius Comm’n., Proposed Draft Maximum Levels for Methylmercury in Fish Including Associated Sampling Plans, CX/CF 18/12/7, at 5–6, 10, (2018) [hereinafter Codex Draft for Methylmercury in Fish]; *but see* NICHOLAS V.C. RALSTON ET AL., SELENIUM-HEALTH BENEFIT VALUES AS SEAFOOD SAFETY CRITERIA 433 (Se-Kwon Kim ed., CRC Press 2014) (discussing how an outdated understanding of the mechanisms of methylmercury toxicity leads to bad public health policy).

negatively harm infants, children, and pregnant women.⁸⁰ The risk profiles of methylmercury and lead are not identical. However, given the myriad national laws that prohibit the consumption of alcoholic beverages by minors, it is unlikely that lead exposure from alcoholic beverages presents a significant source of dietary lead exposure to infants and children.

Adults already limit alcohol consumption under the guidance of national health authorities.⁸¹ National guidelines also advise women who are pregnant or who could become pregnant not to consume alcohol.⁸² This guidance also limits dietary exposure of lead from alcoholic beverages to fetuses, which are also vulnerable. Any health benefit from reducing the ML for lead in alcoholic beverages is further reduced because the guidance already plays a significant role in reducing exposure from this source, even for adults. The same guidance warnings the U.S. and Japanese Codex delegations suggest for the most at-risk populations for methylmercury in fish are already more than accomplished with respect to alcohol. As a result, those most vulnerable to lead exposure consume a disproportionately small amount of alcohol, and those least vulnerable already limit their dietary exposure to lead from this source due to the other detrimental health impacts associated with the overconsumption of alcohol.

⁸⁰ Codex Draft for Methylmercury in Fish, *supra* note 79; *see generally Eating Fish: What Pregnant Woman and Parents Should Know*, FOOD DRUG ADMIN., <https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM537120.pdf> (last visited Oct. 14, 2018) (discussing advice on eating fish and shellfish).

⁸¹ *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., 2015-2020 DIETARY GUIDELINES FOR AMERICANS 34 (8th ed. 2015), https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf (advising adults to limit alcohol consumption to “up to one drink per day for women and up to two drinks per day for men”) [hereinafter DIETARY GUIDELINES FOR AMERICANS]; *New Alcohol Guidelines Launched*, DEP'T OF HEALTH (Jan 8, 2016), <https://www.health-ni.gov.uk/news/new-alcohol-guidelines-launched> (recommending no more than 14 units of alcohol per week); Nat'l Health & Med. Research Council, *Frequently Asked Questions*, ALCOHOL HARM REDUCTION FAQ, (last visited Oct. 15, 2018) <https://nhmrc.gov.au/file/1646/download?token=rIVX7h5N> (recommending no more than two standard drinks per day).

⁸² *See, e.g.*, DIETARY GUIDELINES FOR AMERICANS, *supra* note 81, at 103 (advising that “women who are or who may be pregnant should not drink”); *New Alcohol Guidelines Launched*, *supra* note 81 (stating that “if you are pregnant or planning a pregnancy, the safest approach is not to drink alcohol at all, to keep risks to your baby to a minimum”); Nat'l Health & Med. Research Council, *supra* note 81.

- ii. The same cut-off points for MLs would have a disproportionately large economic impact on trade vis-a-vis the relatively minor health benefit for alcoholic beverages

The relatively high unit value of alcoholic beverages, including wine, scotch, or cognac versus other products that are not age-restricted also indicates a need to exercise relatively more caution when drafting safety measures that may restrict trade. The ML currently proposed for wine is .05 ppm. This is the same ML that applied to grape juice until July 2018 when the ML was modified to .04 ppm, despite the vastly different consumer profile and consumption patterns for the two products.⁸³

The EWG's opinion is that following the same methodology for alcoholic beverages, such as wine, (i.e. recommending MLs at a level such that less than 5% of samples in the GEMS database for wine would fail to meet it) as for other products is consistent with the ALARA principle.⁸⁴ However, it is worth noting that while the percentage of wine in the sample that would fail to meet the hypothetical ML is 3.4%,⁸⁵ the percentage of GEMS samples of infant formula with a limit of quantification that would have failed to meet the hypothetical ML proposed in 2013 was only .37%, nearly one tenth as restrictive as the proposed ML for wine.⁸⁶ It is peculiar that a product that will be consumed exclusively by those least vulnerable would be subject to standards more restrictive than those for a product that is consumed exclusively by those most vulnerable. Additionally, the entire global market for infant formula, including infant formula domestically consumed, is estimated at more than \$45 billion.⁸⁷ Meanwhile, the global market for alcoholic beverages is

⁸³ FAO & WHO, Codex Alimentarius Comm'n, Rep. of the 41st Session of the Codex Alimentarius Comm'n, REP18/CAC, at 74 (2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworks.pace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-41%252FREport%252FFINAL%252FREP18_CACe.pdf (adopting maximum levels for lead in selected commodities).

⁸⁴ Codex Draft, *supra* note 6, at 13.

⁸⁵ *Id.* at 18–19 (313 out of 9342 samples).

⁸⁶ *Id.* at 9.

⁸⁷ Tage Affertsholt & Daniel Pedersen, *Infant Formula: A Young & Dynamic Market*, WORLD OF FOOD INGREDIENTS, Feb. 2017, at 32, <https://www.3abc.dk/wp-content/uploads/2017/06/Infant-Formula-A-Young-and-Dynamic-Market.pdf>.

estimated at over \$1.2 trillion.⁸⁸ If the global alcohol market contracted by 3.4%, it would equal roughly \$41 billion.

For wine there is an emerging international consensus supporting a forward-looking ML of .15 ppm for wine. In 2015, the European Union adopted an ML of .2 ppm (the current Codex ML) for wine vintages dating 2001 to 2015, and .15 ppm for wines produced in 2016 or later.⁸⁹ This is the same level the OIV (an intergovernmental wine standard organization with 46 member states) has established, though the OIV's transition year is 2007 rather than 2015.⁹⁰ Mercosur has also adopted an ML of .15 ppm, impacting Argentina, Brazil, Paraguay and Uruguay.⁹¹ Chile has likewise adopted an ML of .15 ppm.⁹² Where countries have adopted limits, these tend to be forward looking limits to avoid ex post facto regulation of a class of products with an extremely long shelf life.⁹³ An ML of .15 ppm would still provide some margin of food safety improvement (the maximum level of lead in a wine sample in the GEMS database was .584 ppm) without overly restricting international trade.⁹⁴

While the only alcoholic beverage currently under consideration for a revised lead ML is wine,⁹⁵ another EWG is currently prioritizing future work to establish lead MLs.⁹⁶ This EWG placed significant priority on the consumption patterns of children

⁸⁸ Transparency Market Research, *Global Alcoholic Beverages Market to reach US\$1,977,342.7 Million by 2025*, Globe Newswire (Sept. 21, 2017, 5:53 AM), <https://globenewswire.com/news-release/2017/09/21/1125738/0/en/Global-Alcoholic-Beverages-Market-to-reach-US-1-977-342-7-Million-by-2025-TMR.html>.

⁸⁹ Commission Regulation 2015/1005 of June 25, 2015, Amending Regulation (EC) No 1881/2006 as Regards Maximum Levels of Lead in Certain Foodstuffs, 2015 O.J. (L 161), 12 [hereinafter Maximum Levels of Lead].

⁹⁰ INTERNATIONAL CODE OF OENOLOGICAL PRACTICES, ANNEX MAXIMUM ACCEPTABLE LIMITS, at 2 (Jan. 2015), <http://www.oiv.int/public/medias/3741/e-code-annex-maximum-acceptable-limits.pdf>.

⁹¹ REGLAMENTO TECNICO MERCOSUR SOBRE LIMITES MAXIMOS DE CONTAMINANTES INORGANICOS EN ALIMENTOS 8 (2011).

⁹² Ministerio de Agricultura de Chile, Decreto N° 78, Art. 26 (1986).

⁹³ See, e.g. Maximum Levels of Lead, *supra* note 89, at 12. Note the EU Standard has markedly different standards for fruit juices and for wine, presumably based on the divergent risk profile as a result of the disparate consumption profile.

⁹⁴ Codex Draft, *supra* note 6, at 18.

⁹⁵ See FAO & WHO, Codex Alimentarius Comm'n., Rep. of the 12th Session of the Codex Committee on Contaminants in Foods, REP18/CF, at 45 (2018), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-12%252FREPORT%252520%2528FINAL%2529%252FREP18_CFe.pdf.

⁹⁶ See Codex Discussion Paper, *supra* note 9, at 126–131.

for some commodities, but ultimately concluded alcoholic beverages (other than wine) were a higher priority (intermediate priority) than non-alcoholic beverages (low priority).⁹⁷ This means there will probably be an ML established for cognac sooner than for cola. It is also likely the same methodology that is applied to Welch's concord grape juice will apply to Rémy Martin Black Pearl Louis XIII.

None of this is to say definitively that a rule based on tolerating a rejection rate of less than 5% is inappropriate for alcoholic beverages. However, there must be proportionality or else standards would be arbitrary. If the economic cost of applying this rule to alcoholic beverages is warranted based on the public health benefits, then CCCF must apply even stricter standards for lead MLs to products marketed for children and largely consumed by children. Tightening such standards would provide a far greater public health benefit for the same economic cost vis-à-vis tightening standards on alcoholic beverages.

IV. Conclusion

Reducing lead exposure from food consumption is a noble goal. It is a goal Codex, CCCF, and the EWG all take seriously. However, it is an intermediate goal. The ultimate goal is to achieve improved public health outcomes while simultaneously minimizing the negative impact on international trade. All public health regulations are designed to create public health benefits. There are also economic costs to some public health regulations, including the adoption of international standards that are often subsumed into national regulations.

It is rational that the EWG would seek to apply a heuristic method for balancing cost and benefit relying on the formulaic less than 5% rule. This approach is faster and cheaper than conducting an assessment that would truly comply with the ALARA approach. Such an assessment would require evaluating the economic impact of each proposed lead ML (due to restricted trade, or the cost to producers of modifying production methodologies to reduce contamination in the final product) weighed against a public health assessment of lead exposure with an age-specific regression analysis to ensure consistent application of a cost-benefit ratio. The former can be done with a calculator and a data set. The latter would take a team of economists and dietary experts and more rigorous dietary survey data, which in turn would entail a significant cost. However, when the very nature of the product makes it clear the most

⁹⁷ *Id.*

vulnerable would not be protected by further restriction, a different heuristic is called for.

The SPS Agreement calls for “consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection.”⁹⁸ The Codex Procedural Manual states “[u]njustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.”⁹⁹ The inherent corollary is that unjustified uniformity in the use of risk management metrics to address different risks posed by different situations should also be avoided. It would otherwise result in inconsistent levels of protection and arbitrary and unjustifiable standards.¹⁰⁰ It is not clear that the less than 5% heuristic is inappropriate when applied to alcoholic beverages. However, if this is the rule Codex will apply to alcohol, it would do well to tighten the limits on products marketed for children.

⁹⁸ SPS Agreement, *supra* note 1, at Art. 5.5.

⁹⁹ Codex Manual, *supra* note 2, at 116.

¹⁰⁰ See WTO, *United States Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, at 63–72 (Oct. 12, 1998) (stating that the United States’ application of the same environmental standard to trading partners without considering the different conditions prevalent within those trading partners constituted unjustifiable discrimination under the chapeau of GATT Article XX).