

1-1-2007

Boticas y Bodegas: The Development of Food and Drug Regulation in Peru

Alicia C. Llosa

Follow this and additional works at: <http://repository.law.miami.edu/umialr>



Part of the [Comparative and Foreign Law Commons](#), and the [International Law Commons](#)

Recommended Citation

Alicia C. Llosa, *Boticas y Bodegas: The Development of Food and Drug Regulation in Peru*, 38 U. Miami Inter-Am. L. Rev. 279 (2007)
Available at: <http://repository.law.miami.edu/umialr/vol38/iss2/2>

This Article is brought to you for free and open access by Institutional Repository. It has been accepted for inclusion in University of Miami Inter-American Law Review by an authorized administrator of Institutional Repository. For more information, please contact library@law.miami.edu.

ARTICLES

Boticas y Bodegas: The Development of Food and Drug Regulation in Peru

Alicia C. Llosa*

I.	INTRODUCTION	281
II.	FOOD AND DRUG FROM CONQUEST TO REPUBLIC	283
	A. <i>The Laws of the Indies</i>	283
	1. Cursory Spanish Regulation of Food	284
	2. Drug Regulation in Service of the Crown	284
	B. <i>A Nineteenth-Century Recompilation of the Laws of Spain</i>	286
	1. Pharmacists and Drugstores	286
	2. Food as a Component of Public Health and Some Legacies	288
III.	AN INFANT REPUBLIC'S CONCERN FOR THE PUBLIC HEALTH	289
	A. <i>Building on Colonial Foundations</i>	290
	1. The Creation of Public Health <i>Juntas</i>	291
	2. Food and Drug Regulation Under the <i>Juntas</i>	292
	3. The Public Health <i>Juntas</i> at Twenty and Beyond	295
	B. <i>Enforcement by the Police</i>	296
	1. Regulation in the Time of the <i>Caudillo</i> , 1839	297
	a. <i>Quality and Safety of Food Products</i>	298
	b. <i>Quality and Safety of Drugs</i>	299
	2. Reorganization and the <i>Reglamento</i> of 1872 .	300
	a. <i>Food and Drink</i>	301
	b. <i>Pharmacies and Drugstores</i>	301
	3. Forty Years and No Real Change	302

* J.D. (2006), Harvard Law School; A.B. (2003), Harvard University. Ms. Llosa would like to acknowledge Professor Peter Barton Hutt for his encouragement of this research and Margaret W. Elias for her sharp eyes reviewing early drafts of this manuscript. She also thanks the many family members and friends who helped keep the project moving, as well as the editors of the *Inter-American Law Review*.

C.	<i>Production and Distribution in the Nineteenth Century</i>	303
1.	Regulation Through Weights and Measures .	303
2.	Monopolies and Drug Production	304
D.	<i>Reconceptualization and a New Regime, the Last Quarter Century</i>	305
1.	The General Health Regulations at the National Level	306
2.	Municipal Regulations	307
a.	<i>Food Identities and Adulteration in Lima</i>	308
b.	<i>Public Hygiene in Arequipa</i>	310
c.	<i>Regulating the Practice of Medicine and Pharmacy</i>	311
IV.	THE ROAD TO MODERN REGULATION, THE TWENTIETH CENTURY	313
A.	<i>The Dirección General de Salubridad</i>	313
B.	<i>Modernization in the 1920s: Elaboration of Drug Regulations</i>	315
1.	Regulation of Sales and Shops: The Pharmaceutical Commission	315
2.	Regulation of Manufacturing, Importation, and Sale	318
3.	Narcotics as Controlled Substances	320
4.	Some Miscellaneous Regulations	322
a.	<i>Alternative Medicine</i>	322
b.	<i>Production and Regulation of Staple Goods</i>	323
C.	<i>The Birth of the Ministry of Health</i>	323
1.	The Need for a New Ministry	324
2.	The Work of the Ministry with Respect to Food and Drug	325
3.	A New National <i>Junta</i>	328
D.	<i>Regulation Under Military-Authoritarian Rule, 1968-1980</i>	329
V.	CURRENT REGULATION	331
A.	<i>Under the Rubric of Health</i>	332
1.	The General Law of Health	332
2.	Ministry of Health	333
2.	DIGESA	333
3.	DIGEMID	338
B.	<i>Regulation and Consumer Protection</i>	339

1. Consumer Protection Law	340
2. INDECOPI	341
VI. CONCLUDING THOUGHTS.....	344

I. INTRODUCTION

To embark on a mission to report on food and drug regulation in Peru might have been as easy as examining the online card catalogs of major universities in Peru. It might have been as easy as finding a book entitled *Food and Drug Regulation in Peru*, or even *Regulation of Food or Regulation of Drugs*—in Spanish, of course. To write about the development of this regulation would have involved, then, filling in the gaps with some information about the laws of the early Republic and drawing connections to their modern counterparts.

Instead, the Peruvian literature on the subject of food ranges from the folkloric and historical,¹ to nutrition and access,² and to production and supply,³ but apparently does not dwell on the subject of its regulation. As pertains to drug regulation, the literature on drugs includes an exploration of folk medicines, especially given Peru's rich indigenous culture.⁴ Although literature on Peru

1. See, e.g., ROSARIO OLIVAS WESTON, *LA COCINA DE LOS INCAS: COSTUMBRES GASTRONÓMICAS Y TÉCNICAS CULINARIAS* [THE KITCHEN OF THE INCAS: GASTRONOMICAL CUSTOMS AND CULINARY TECHNIQUES] (Lima, Universidad San Martín de Porres 2001) (discussing Incan food and cooking); FERNANDO CABIESES, *CIEN SIGLOS DE PAN* [A HUNDRED CENTURIES OF BREAD] (Lima, Universidad de San Martín de Porres 2d ed. 1997) (describing history of different Peruvian foods); MARIELLA BALBI, *LOS CHIFAS EN EL PERÚ: HISTORIA Y RECETAS* [THE CHIFAS IN PERU: HISTORY AND RECIPES] (Lima, Universidad San Martín de Porres 1999) (discussing the historical and social roots of Peruvian-Cantonese food).

2. See, e.g., CARLOS AMAT Y LEÓN & DANTE CURONISY, *LA ALIMENTACIÓN EN EL PERÚ* [NUTRITION IN PERU] (Lima, Universidad del Pacífico 1981) (discussing problems of malnutrition, including some analysis of nutritional content of foods); NANCY C. STEWART, *LA ALIMENTACIÓN DEL PUEBLO PERUANO* [NUTRITION OF THE PERUVIAN PEOPLE] (Lima, Gráfica Morsom 1950) (discussing general nutritional health of the population); JAVIER TANTALEÁN ARBULÚ, *PROPUESTA DE UN PLAN ALIMENTARIO NACIONAL* [NATIONAL FOOD PROPOSAL] (Lima, Instituto Nacional de Planificación 1987) (proposing national plan evaluating nutrition and cost of food).

3. See, e.g., MANUEL LAJO, *PRESENTE PASADO Y FUTURO DE LA ALIMENTACIÓN: IMPORTACIÓN DE ALIMENTOS Y DEPRESIÓN AGROPECUARIA EN EL PERÚ 1944-2007* [THE PRESENT, PAST, AND FUTURE OF NUTRITION: IMPORTATION OF FOOD AND DEPRESSION OF AGRICULTURE IN PERU] (Lima, Instituto de Desarrollo Economico 1990); JORGE FERNÁNDEZ-BACA ET AL., *AGROINDUSTRIA Y TRANSNACIONALES EN EL PERÚ* [AGRO-INDUSTRIES AND TRANSNATIONAL CORPORATIONS IN PERU] (Lima, Centro de Estudios y Promoción del Desarrollo 1983); JOSÉ MAGUÑA VILLÓN, *CONSUMO Y DEMANDA DE ALIMENTOS* [CONSUMPTION OF AND DEMAND FOR FOOD PRODUCTS] (Lima, Instituto Nacional de Planificación 1986).

4. See, e.g., HERMILIO VALDIZÁN, *LA MEDICINA POPULAR PERUANA* [PERUVIAN

also extends to the history of medicine and public health, even the works most helpful to this Article have failed to identify food or drugs as an independent heading for discussion.⁵

This story catches in its folds the first instances of food or drug regulation in the history of Peru and traces their elaboration over time. The Article begins with a glimpse into colonial Peru and looks past that into the early days of the new Peruvian Republic. Using the available relevant legislation, the Article takes the reader through the times of the *caudillo* (strong-man rule), civil war, and, finally, unification. It takes the reader to the point of a massive war between Peru and Chile and into the time of the World Wars. Drawing from decrees from the late 1960s, the Article will demonstrate the further development of legislation during the time of military dictatorship. The Article will then describe the system of food and drug regulation in place today. The development of food and drug regulation is inextricably linked to the evolution of those administrative agencies or institutions charged with that development. For that reason, this Article shifts from discussions of food or drug regulations where they are available to discussions of the public health institutions that most likely would have been promulgating (or supervising the promulgation of) these regulations where the regulations themselves could not be located. The Article takes a roughly national perspective on the development of food and drug regulation, though this is supplemented the local regulations where they have been uncovered.⁶ The story of the development of food and drug regulation in

POPULAR MEDICINE] (Lima, CISA 1985) (1922); JUAN B. LASTRES, LA MEDICINA EN LA OBRA DE GUAMAN POMA DE AYALA [MEDICINE IN THE WORK OF GUAMAN POMA DE AYALA] (Lima, Imprenta del Museo Nacional 1941) (analyzing folk medicine through the pictorial histories of an Incan artist); JORGE A. LIRA, FARMACOEPA TRADICIONAL INDÍGENA Y PRÁCTICAS RITUALES [TRADITIONAL INDIGENOUS PHARMACOPOEIA AND RITUAL PRACTICES] (Lima, El Condor 1946) (collecting various indigenous remedies and rituals).

5. See, e.g., CARLOS BUSTÍOS ROMANÍ, CUATROCIENTOS AÑOS DE LA SALUD PÚBLICA EN EL PERÚ [FOUR HUNDRED YEARS OF PUBLIC HEALTH IN PERU], 1533–1933, (Lima, Universidad Nacional Mayor de San Marcos 2004) (containing no heading in the table of contents related to food, though there are references to “drugs” in general discussions about immunizations for diseases and only fleeting references to “food”); see also 1–2 CARLOS ENRIQUE PAZ SOLDÁN, LAS BASES MÉDICO-SOCIALES DE LA LEGISLACIÓN SANITARIA DEL PERÚ [THE SOCIO-MEDICAL BASES OF PERUVIAN HEALTH LEGISLATION] (Lima, El Inca 1918) (containing no separate headings or chapters for food or drug regulation in this book).

6. Some of these were found in the 1–3 DICCIONARIO DE LA LEGISLACIÓN MUNICIPAL DEL PERÚ [DICTIONARY OF MUNICIPAL LEGISLATION OF PERU] (Juan José Calle ed., Imprenta Torres Aguirre 1906) [hereinafter 1 or 2 DICCIONARIO] in the entries for “Alimentos,” “Higiene,” and “Medicina”. Of course, these provide a

Peru rests on two pillars. First, it is a story about the persistence of old institutions and their adaptation over time—even though Peru itself underwent many regime changes in its history. The structures left by the Spanish, for example, formed the base for the regulation of the early nineteenth century and informed even later regulations. The second pillar is the development of public health. Food and drug regulations, especially early in Peru's history, grew out of concerns for public health rather than concerns about commerce.

II. FOOD AND DRUG FROM CONQUEST TO REPUBLIC

Writing the history and development of food and drug regulation requires threading together pieces of laws and policies from different sources. Presented here is the development of the law as best it can be traced chronologically. This section carries the development of food and drug law in Peru from its roots in Spanish law and the Viceroyalty of Peru until the beginning of the nineteenth century. While Peru's food regulation was scant during the colonial period, there is some information about early regulation of drugs and druggists. Furthermore, the colonial period presented a model for public administration that persisted well beyond independence.

A. *The Laws of the Indies*

The earliest regulation of food and drug in Peruvian history occurred while Peru was a colony of Spain. The Spanish arrived in Peru in 1531 and by 1542 they had established the Viceroyalty of Peru.⁷ Armed with a colonial empire in the New World, Spain set out to regulate every facet of life in its colonies. Even though the Crown lived halfway around the world, the force of its laws was felt in the every day lives of its citizens in the New World. The *Leyes de Indias* (Laws of the Indies) is one of the most comprehensive collections of regulations passed during the sixteenth century and amended over the centuries by subsequent monarchs.⁸

snapshot in the form of a dictionary of municipal legislation, and do not demonstrate any historical development. I am grateful to the Libería El Virrey in San Isidro, Lima for giving me access to this source.

7. See generally WILLIAM H. PRESCOTT, HISTORY OF THE CONQUEST OF PERU (Dover 2005) (1847).

8. See 1-3 RECOPIACIÓN DE LEYES DE LOS REYNOS DE LAS INDIAS [COMPILATION OF LAWS OF THE KINGDOM OF THE INDIES] (Madrid, Gráficas Ultra 1943) (1792) [hereinafter 1, 2, or 3 LEYES DE INDIAS].

This body of law, *inter alia*, mandated Catholicism,⁹ set the governmental structure of the colonies,¹⁰ regulated trade,¹¹ and laid out the penal code.¹²

1. Cursory Spanish Regulation of Food

Despite its breadth, the *Leyes de Indias* did not comprehensively regulate food and drug, leaving the more detailed regulations to be developed instead at local levels. However, food and drug did not escape its grasp completely. Flour and grains were regulated, at least in Mexico, as to their trade, storage, and rationing.¹³ Peruvian food products, like flour and wine, were regulated strictly in terms of trade. For example, there could be no tariffs on Peruvian flour.¹⁴ While Peruvian flour could be freely traded (though only inside the Spanish Empire), Peruvian wine was restricted. Peruvian wines could not be sold in Panama, for example.¹⁵ Furthermore, any wine that was sold had to be stored in barrels exhibiting an official seal and sold at set prices.¹⁶

2. Drug Regulation in Service of the Crown

While the regulation of food was really only incidental to the regulation of trade, there was at least one chapter in the early versions of the *Leyes de Indias* that regulated drugs with an eye to public safety. In 1570 King Felipe II amended the *Leyes de Indias* to include a chapter regulating the medical and pharmaceutical professions.¹⁷ The king decreed that doctors, herbalists, surgeons, and other specialists would travel to the colonies to set up institu-

9. See Law Nos. i–xxviii, in 1 LEYES DE INDIAS, *supra* note 8, at 1–10 (bk. 1, tit. 1, De la santa fe católica [Of the Holy Catholic Faith]).

10. See bk. 2, in 1 LEYES DE INDIAS, *supra* note 8, at 217–523 (tits. 1–34, dictating, *inter alia*, laws, ordinances, and structure of government).

11. See Law Nos. i–xxiii, in 2 LEYES DE INDIAS, *supra* note 8, at 1–108 (bk. 4, tit. 18, Del comercio, mantenimientos, y frutos de las Indias [Of the Commerce, Necessities, and Products of the Indies]).

12. See Law Nos. i–xxviii, in 2 LEYES DE INDIAS, *supra* note 8, at 343–78 (bk. 7, tit. 8, De los delitos, y penas, y su aplicación [Of Crimes, Penalties, and Their Application]).

13. See Law Nos. i–xix, in 2 LEYES DE INDIAS, *supra* note 8, at 48–53 (bk. 4, tit. 14, De las alhóndigas [Of the Granaries], pertaining specifically to Mexico).

14. See Law No. xiii, Que los corregidores del Perú no hagan estanco del trigo y harina [That the Governors of Peru Not Impede the Trade of Wheat and Flour], in 2 LEYES DE INDIAS, *supra* note 8, at 64 (bk. 4, tit. 18).

15. See Law No. xv, Que en Panamá no entre, ni se gaste vino del Perú, [That Peruvian Wines Not Enter nor Be Consumed in Panama] in 2 LEYES DE INDIAS, *supra* note 8, at 65 (bk. 4, tit. 18).

16. See *id.*

17. See Law Nos. i–vii, De los protomédicos, médicos, cirujanos y boticarios [Of the

tions and look for new kinds of medicine native to the New World. Of course, any medicinal herbs they found would be sent back to the king in Spain.¹⁸ This chapter of the laws also provided for licensing of doctors and pharmacists,¹⁹ foreshadowing provisions that the early Republic would enact after independence. These licenses would likely be issued by appeal to the Protomedical Tribunal, a council of established doctors whose responsibility it was to evaluate candidates for medicine, pharmacy, surgery, etc.²⁰ The *Leyes de Indias* also set up a blueprint for later regulations through its requirement that the Viceroy and Governors set up systems of inspections for drugstores.²¹ In 1538, the law went one step further in a provision contributed by the Emperor Carlos V demanding that these inspectors destroy any spoiled medications they found so that the public would not be harmed.²²

The real work of the colonial project in public health, encapsulated in the *Leyes de Indias*, was to be done at the local level. The *cabildos*, or town councils, were responsible for guarding and policing the public health. They were also responsible for enacting more rules if needed.²³ Perhaps this explains the dearth of food or drug regulation in the *Leyes de Indias* handed down by the Spanish monarchs. Local responsibilities included sanitation, specifically, to guarantee clean and safe water, clean streets, waste elimination, and protection of food markets.²⁴ These forms of regulation were likely highly ineffective. In his comprehensive work on the history of public health in Peru, Carlos Bustíos Romani reports that he was unable to find any information about the sanitary controls implemented for the meat markets or other food markets during the colonial period. He presumes that, even if

Chief Doctors, Doctors, Surgeons, and Druggists], in 2 LEYES DE INDIAS, *supra* note 8, at 139–41 (bk. 5, tit. 6).

18. See Law No. i, Que habiéndose de nombrar protomédicos generales, se les de esta instrucción, y ellos la guarden [That Having Named Chief Doctors, They Should Be Given and Heed This Instruction], in 2 LEYES DE INDIAS, *supra* note 8, at 139 (bk. 5, tit. 6).

19. See Law No. iv, Que ninguno cure de medicina, ni cirugía, sin grado, y licencia [That No One Cure, By Medicine or Surgery, Without Degree and License], in 2 LEYES DE INDIAS, *supra* note 8, at 141 (bk. 5, tit. 6).

20. See BUSTÍOS ROMANÍ, *supra* note 5, at 128; see also Ministerio de Salud, Reseña Histórica [Ministry of Health, Historical Description], <http://www.minsa.gob.pe/portal/00Institucional/rhistorica.asp> (last visited Dec. 28, 2006).

21. See Law No. vii, Que visiten las boticas y medicinas [That Drugstores and Drugs Be Inspected], in 2 LEYES DE INDIAS, *supra* note 8, at 141 (bk. 5, tit. 6).

22. See *id.*

23. See BUSTÍOS ROMANÍ, *supra* note 5, at 95.

24. See *id.* at 111.

they existed, they were terribly insufficient.²⁵

B. *A Nineteenth-Century Recompilation of the Laws of Spain*

A compilation of the laws of Spain from the early nineteenth century,²⁶ elaborated a more specific scheme for public health regulation, including regulation of food and drugs sold to the public and the inspection of marketplaces.²⁷ These laws were much more detailed than their earlier counterparts, laying out the development of those laws over time.²⁸ Drugs were regulated more heavily than food products, as demonstrated below. This section lays out the more intricate regime for the regulation of pharmacists and drugstores in the empire and briefly relates the regulation of food adulteration at the time.

1. Pharmacists and Drugstores

This recompilation thoroughly addressed the issue of what qualifications were necessary to be considered a candidate for pharmacy. For example, no one could seek to be admitted as a pharmacist without knowing Latin, without working for four years under licensed pharmacists, or without being at least twenty-five years old.²⁹ Furthermore, women could not own drugstores, even if they passed the necessary examination.³⁰

These laws also regulated the kinds of products that pharmacists could sell. Pharmacists could sell drugs that were opiate-, hyacinth-, or cinnamon-based provided that the containers were marked with the date that the composition was made and sealed

25. *See id.* at 116.

26. 3-4 NOVÍSIMA RECOPIACIÓN DE LAS LEYES DE ESPAÑA [LATEST COMPILATION OF THE LAWS OF SPAIN] (Madrid, Boletín Oficial del Estado 1975) (1805) [hereinafter 3 or 4 NOVÍSIMA RECOPIACIÓN].

27. *See, e.g.*, 1 PAZ SOLDÁN, *supra* note 5, at 35 (discussing the detail to be found in law no. v of bk. 7, tit. 40 of the *Novísima Recopilación*).

28. *See id.*

29. *See* Law No. i, De los boticarios, visitas de boticas, y Junta Superior Gubernativa de Farmacia [Of the Druggists, Inspections of Drugstores and Superior Governing Junta of Pharmacy], ¶ 5, *in* 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 106 (bk. 8, tit. 13).

30. *See* Law No. iii, Visitas de boticas del Reyno; y prohibición de tenerlas mujer alguna: requisitos para el examen de Boticarios; y formación de una Farmacopea general [Inspections of the Drugstores of the Kingdom and Prohibition on Ownership by Any Woman; Requisites for the Druggists' Exam; and Formation of a General Pharmacopoeia], ¶ 6, *in* 4 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 107-08 (bk. 7, tit. 8).

with the signature of the pharmacist.³¹ Importantly, in 1593, the Protomedical Tribunal was required to put together a general pharmacopoeia for purpose of creating some identity standards for the drugs the pharmacists produced.³²

The laws of Spain also expanded upon the requirements that drugstores be inspected and regulated. The head of the Protomedical Tribunal and the chief examiner were to visit all the *boticas*—pharmacies—together to assure compliance with the law.³³ Any medications or drugs found to be counterfeit, spoiled, or damaged in some way were to be burned publicly in the plaza.³⁴ By 1801, the law had developed a notice requirement. Pharmacists would be notified that their products were not in compliance with the law and if they could not remedy the situation, the products would be burned.³⁵ However, if the pharmacists were not first notified, then the inspectors should not cause a “scandal” and should instead gather the offensive drugs and submit them to the proper authorities.³⁶ Pharmacists were required to turn over any drugs requested by the inspectors and to swear that none were being hidden.³⁷ Indeed, the inspections were taken so seriously that an inspector was not permitted by law to receive any hospitality from the pharmacist whose drugstore he was going to visit.³⁸

31. See Law No. i, De los boticarios, visitas de boticas, y Junta Superior Gubernativa de Farmacia [Of the Pharmacies, Inspections of Drugstores, and the Superior Governing Junta of Pharmacy], ¶ 5, in 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 106–07 (bk. 8, tit. 12).

32. See Law No. iii, Visitas de boticas del Reyno; y prohibición de tenerlas mujer alguna: requisitos para el examen de boticarios; y formación de una farmacopea general [Inspections of the Drugstores of the Kingdom and Prohibition on Ownership by Any Woman; Requisites for the Pharmacy Exam; and Formation of a General Pharmacopoeia], ¶ 15, in 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 107–08 (bk. 8, tit. 12).

33. See Law No. i, De los exámenes de boticarios; prohibición de vender estas drogas algunas; y visitas de boticas de la Corte y cinco leguas [Of the Druggists' Exams, Prohibition on the Sale of Certain Drugs, and Drugstore Inspections], ¶ 19, in 4 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 106–07 (bk. 8, tit. 13).

34. See Law No. ii, Reconocimiento de las boticas y tiendas de especias y medicinas, para quemar las dañadas y corrompidas [Recognition of Drugstores and Spice and Medicine Shops; the Burning of the Damages and Corrupted Items], in 4 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 107 (bk. 8, tit. 13).

35. See Law No. x, Instrucción que deberán observar los visitadores de boticas [Instruction That Drugstore Inspectors Must Observe], ¶ 8, in 4 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 116 (bk. 8, tit. 13).

36. See *id.*

37. See *id.* ¶ 5, at 116.

38. See *id.* ¶ 4, at 116.

2. Food as a Component of Public Health and Some Legacies

For the first time, the ninth recompilation of the laws of Spain listed "protection of public health" as a separate title.³⁹ This Article is most interested in the provisions regarding food and drug. There appears to have been a police force whose responsibility it was to enforce the health and sanitary laws.⁴⁰ One area of public health which the law deemed "important" was the effect of food or beverages that were adulterated or of bad quality.⁴¹ Indeed, evaluating this was to be the principal responsibility of a Supreme Junta,⁴² a governmental regulatory organ similar to those that Peru established after independence. The police, under the authority of the *junta*, were to examine all slaughterhouses, ranches, farms, and markets where fish, meat, or fruit might be sold.⁴³ They were also to inspect any businesses that prepared foods or sweets.⁴⁴ They were to look for any grains or beans with defects or mixed with any harmful substances, rotten fish, or unripened fruit. They were also to examine the quality of these goods to determine whether they had been adulterated or were otherwise unsafe.⁴⁵ Ultimately, these defective foods or drinks would not be permitted to be sold to the public.⁴⁶

Many of the provisions in this chapter complemented other provisions, particularly those that regulated the pharmaceutical profession. For example, it was forbidden to sell any chemical substance intended to preserve one's health in any store that was not a drugstore, unless there was some other non-medical use for the substance.⁴⁷ The law did not use the term "drug" the way that it did in the laws regulating the pharmaceutical profession—it

39. See Law Nos. i–vii, Del resguardo de la salud pública [Of the Defense of Public Health], in 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 721 (bk. 7, tit. 40).

40. See Law No. v, Reglas sobre la policía de la salud pública, que se han de observar por la suprema Junta de gobierno de Medicina [Rules for the Police of Public Health that Should Be Observed by the Supreme Junta Governing Medicine], in 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 725–26 (bk. 7, tit. 40).

41. See *id.* ¶ 6, at 726.

42. See *id.*

43. See *id.* ¶ 7, at 726.

44. See *id.*

45. See *id.*

46. See *id.*

47. See Law No. i, Prohibición de vender en las tiendas públicas simples por menor, y todo compuesto químico para resguardo de la salud [Prohibition on Selling Chemical Compounds in Public Shops for the Defense of Health], in 3 NOVÍSIMA RECOPIACIÓN, *supra* note 26, at 721 (bk. 7, tit. 39).

used a more general concept, a chemical substance intended to preserve one's health.⁴⁸ Perhaps this was a way to define drug to make it harder to evade the regulations based on a technicality about the definition of "drug."

The *Leyes de Indias* and the laws of Spain appear to have provided a thorough regulation, at least of drugs, during the colonial era. However, very little is known about its true effects or enforcement in Peru itself. Peru was a viceroyalty of Spain, and Lima was the seat of Spanish power in South America—tending towards the conclusion that the laws were probably enforced in Lima. Certainly, a Protomedical Tribunal was created in Peru. At the very least, the Spanish code of laws provided a model of regulation that the newly-independent Peru could adopt or reject as it set out on its own mission to protect the public health.

III. AN INFANT REPUBLIC'S CONCERN FOR THE PUBLIC HEALTH

General José de San Martín declared Peruvian independence in 1821. Three years would pass until the end of the war with Spain, but Peru was finally independent from Spain in 1824.⁴⁹ Public health was a priority for the newly-independent Peru—so much so that Peru believed itself to stand out as a model for the region.⁵⁰ Despite the strong start to its public health administration, over time these institutions weakened.⁵¹ The balance of the nineteenth century could be characterized by the tension between the lofty goals set by Peruvian visionaries and the failure to breathe life into those goals.

President Andrés de Santa Cruz, one of the earliest presidents, set about formalizing the Peruvian government. This was a difficult project given the incessant civil wars and internal strife in Peru at the time. In 1826, the first year he was in office, Santa Cruz decried the lack of any health or sanitation laws in Peru.⁵²

48. *See id.*

49. For more about San Martín, see JEROME R. ADAMS, *LATIN AMERICAN HEROES* 57–73 (1991). For more on independence, see JOHN A. CROW, *THE EPIC OF LATIN AMERICA* 474 (4th ed. 1992). *See generally* MARK A. BURKHOLDER & LYMAN L. JOHNSON, *COLONIAL LATIN AMERICA* 338–48 (2004).

50. *See infra* note 57 and accompanying text.

51. *See infra* Part III.A.3.

52. *See* Decree, Sept. 1, 1826, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1826032.pdf> (creating a Supreme Commission of Charity in the capital of the republic) [hereinafter 1826 Decree]. The Peruvian congress has made most, if not all, of its laws available through a digital archive, <http://www.congreso.gob.pe/ntley/default.asp>. Various databases are available on this website, including

The man most responsible for the early development of the public health regime in Peru was Dr. Hipólito Unanue.⁵³ Unanue was among the signers of the Peruvian independence documents, and in 1825 the congress bestowed upon him the special honor of *Benemérito de la Patria en grado eminente*, a title given to heroic and outstanding citizens.⁵⁴ He was also the last *protomédico*, chief of the Protomedical Tribunal, in Peruvian history.⁵⁵ Unanue was the mastermind behind the first public hospitals, the creation of the *Dirección General de Beneficiencia* (a government agency charged with charitable works), and a regulation improving the treatment of slaves in the Republic.⁵⁶ Indeed, Unanue's brilliance prompted Carlos Enrique Paz Soldán, a prominent doctor and researcher of socio-medical policy in early twentieth-century Peru, to declare that "in that era—we can be proud about this—no other American country had reached, in medical-social matters, the advances that we had."⁵⁷ Indeed, Unanue was zealous both in trying to rid the country of charlatan doctors and in supervising the purchase and sale of medications.⁵⁸

A. *Building on Colonial Foundations*

Political scientist Howard Wiarda has argued that traditional institutions in Latin America have "remarkable persistence and staying power."⁵⁹ While he was referring to social and political institutions, his observation could rightly apply to the development of public health administration, and therefore to the development of food and drug regulation. While Peru had separated from Spain, it did not abandon certain administrative structures, like the Protomedical Tribunal and the decentralized approach to public health. Indeed, Peru's own regime sprang up around these traditional institutions.

This section will first describe the establishment of public

the *Leyes de Indias*, nineteenth-century legislation, and twentieth-century legislation. The database is keyword searchable and returns what appear to be scanned copies of the laws.

53. See BUSTÍOS ROMANÍ, *supra* note 5, at 251–52.

54. *See id.*

55. See Ministerio de Salud, *Reseña Histórica* [Ministry of Health, Historical Description], <http://www.minsa.gob.pe/porta/00Institucional/rhistorica.asp> (last visited Dec. 28, 2006).

56. See BUSTÍOS ROMANÍ, *supra* note 5, at 252.

57. 1 PAZ SOLDÁN, *supra* note 5, at 48 (translation by author).

58. *See id.* at 51.

59. HOWARD J. WIARDA, *POLITICS AND SOCIAL CHANGE IN LATIN AMERICA: STILL A DISTINCT TRADITION?* 4 (3d ed. 1992).

health *juntas* through a discussion of their enabling statute, an 1826 degree. Next, this section will elaborate on the substance of the food and drug regulations enacted by these *juntas*. Finally, the section will close with a mention of the regulation of food—of milk—in the early nineteenth century through the regulation of weights and measures.

1. The Creation of Public Health *Juntas*

In 1826, Peru enacted what is most likely the first sanitary or health code in the newly-independent Americas.⁶⁰ This decree encapsulated one solution to the public health problem, developed by Hipólito Unanue—the creation of *juntas* charged with preserving the public health under certain regulations.⁶¹ These *juntas*, like other matters of health and public safety, fell under the authority of the Ministry of Government.⁶² Through this Ministry, the police and other officials enforced the health standards.⁶³ These standards would be generated through the technical help of the Protomedical Tribunal, the Executive Junta of Medicine,⁶⁴ and of course, the public health *juntas*.⁶⁵ These public health *juntas* not only had day-to-day activities in this regard, but they also had long-term responsibilities to investigate, to develop sanitary laws, and to compare the laws of other countries.⁶⁶

Naturally these *juntas* were set up in a hierarchy. The Supreme Junta of Health was established in Lima, and a Superior Junta was set up in the capital of each department of the country.⁶⁷ Municipal *juntas* were set up in every area with a “considerable population”.⁶⁸ The *juntas* operated like commissions. The members of the Supreme Junta were to be the prefect of Lima, the head of the Protomedical Tribunal, a doctor, a chemist, and two land-owning citizens who were not merchants.⁶⁹ The Supreme

60. See 1 PAZ SOLDÁN, *supra* note 5, at 54 n.1 (citing *El primer código sanitaria en América*, EL COMERCIO, Aug. 1, 1917).

61. See 1826 Decree, *supra* note 52.

62. See BUSTÍOS ROMANÍ, *supra* note 5, at 254.

63. See *id.*

64. The Protomedical Tribunal was a relic from the days of colonial rule. In 1848 this body of doctors was renamed the Executive Junta of Medicine, a move which Paz Soldán considers a definitive break with the past and a step towards better public health administration. See 1 PAZ SOLDÁN, *supra* note 5, at 61.

65. See BUSTÍOS ROMANÍ, *supra* note 5, at 254.

66. 1826 Decree, *supra* note 52.

67. *Id.* arts. 1–2.

68. *Id.* art. 3.

69. *Id.* art. 5.

Junta was responsible for the public health at the highest level; for example, it was this *junta's* responsibility to regulate medications.⁷⁰ The Supreme Junta was in charge of naming individuals to serve on the Superior Juntas, and generally supervised all the lower *juntas*.⁷¹ The Superior Juntas were in charge of naming members to the municipal *juntas*, and they were to implement the policies handed down from the Supreme Junta.⁷² In turn, the municipal *juntas* were to report violations of that law to the Superior Junta for enforcement.⁷³ The bulk of enforcement and inspection would happen at the municipal level.

The funds to maintain the *juntas* came partly from the activities of the *juntas* themselves. The *juntas* were authorized to tax all ships entering the Peruvian harbors, which had to be inspected.⁷⁴ The *juntas* collected fines from those who violated their regulations.⁷⁵ The *juntas* also collected a fee for the registration of medicine invoices.⁷⁶ Lastly, the *juntas* would assess a fee in connection with licenses to sell medications or drugs either newly-invented or imported into the country.⁷⁷

2. Food and Drug Regulation Under the *Juntas*

The law setting out the health *juntas* does provide some substantive regulation, though the bulk of regulation came from the *juntas* themselves. Any new medications either developed in Peru or imported from abroad had to be approved by the Supreme Junta before it could be sold to the public.⁷⁸ The Supreme Junta also had to appoint accredited pharmacists to the task of registering all receipts relating to medicines being imported to the country.⁷⁹ The task of enforcement fell to the Superior Juntas. This meant they had to enforce the restriction on the sale of medications to only those drugs which had been approved by the Supreme Junta.⁸⁰ Enforcement also fell down the hierarchy to the municipal level.

The municipal *juntas* were charged with making sure that

70. *Id.* arts. 10(4), 10(5).

71. *Id.* arts. 10(1), 10(3).

72. *Id.* arts. 11(1), 11(2).

73. *Id.* art. 12(9).

74. *Id.* arts. 29–30.

75. *Id.* art. 30(2).

76. *Id.* art. 30(4).

77. *Id.*

78. *Id.* art. 10(5).

79. *Id.* art. 10(6).

80. *Id.* art. 11(4).

cafés, kitchens, *bodegas* (neighborhood grocery stores), and markets engaged in safe practices. For example, food could not be stored or cooked in copper pots or pans that had not been coated with tin, and markets could not sell unsafe fish, unripened fruits, or common meats.⁸¹ The municipal *juntas* even had a role in the regulation of drugs. In 1831, the Protopharmaceutical Tribunal split from the Protomedical Tribunal, and under the authority of the municipal *juntas* members of the Protopharmaceutical Tribunal were to inspect the various drugstores.⁸² This split between the two faculties proved to be untenable, and in 1835 they were reunited because of the failure of the Protopharmaceutical Tribunal to comply with its enabling law.⁸³ Specifically, the drugstore inspections required by the law were sorely deficient, and so they were made the responsibility of the Protomedical Tribunal.⁸⁴

Not all the regulations were found in the 1826 law establishing the *juntas*. Some additional regulations were passed by decree as needed. In 1839, for example, it became illegal for bakers to use harmful or unhealthy grains or flour either for bread, crackers, or any other food.⁸⁵ The law had created an unreasonable asymmetry—while the suppliers could be held liable for using unsafe grains, it was somehow permissible for the seller to sell bread products made with those unsafe grains. This problem was recognized in a decree dated June 25, 1839, and by July 24, 1839 the law was changed.⁸⁶ A vendor who discovered that some of his goods had been made with unsafe materials could make a claim against the supplier or he could sell the damaged goods for use as pig feed.⁸⁷ This is the kind of work that would have been done at the level of the municipal *junta*.

The municipal *juntas* had the authority to institute quarantines when necessary to protect the public health. Naturally, this involved destroying any food carried aboard a ship to be quaran-

81. *Id.* arts. 12(2), 12(3).

82. See Law, Aug. 1, 1831, arts. 9–10, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1831058.pdf> (separating the Faculty of Pharmacy from the Protomedical Tribunal).

83. See Decree, Apr. 3, 1835, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1835036.pdf> (reuniting the Faculty of Pharmacy with the Protomedical Tribunal).

84. See *id.*

85. See Decree, July 24, 1839, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1839048.pdf> (regarding vendors of wheat and flour of poor quality, and referring to a June 25, 1839 supreme order).

86. See *id.* art. 1.

87. See *id.*

tined.⁸⁸ In the 1830s Peru feared the spread of cholera, and this led to regulations requiring quarantine.⁸⁹ In 1833, a decree was handed down, noting that cholera had ravaged Europe and had made its way over to Mexico.⁹⁰ This decree empowered the government, whose responsibility it was to promote the public health and enforce health laws, to enact any measures necessary and proper to prevent the spread of cholera to Peru.⁹¹ Relying on this power, in 1837, for example, the Peruvian government decreed that any vessel proceeding from Mexico or any part of Central America would be subjected to the "most rigorous quarantine".⁹² These ships would be kept at two canon blasts' distance away from the dock for twenty days, and any person coming into contact with such ship should be fined one hundred *pesos* and put into quarantine for as long as deemed fit by a doctor.⁹³ Naturally, these quarantine regulations affected food. Flour, meats, and all edibles carried aboard a ship which had stopped in Central America were to be thrown into the ocean without opening.⁹⁴ When the cholera epidemic subsided a few months later, all the sanitation measures related to preventing its spread were repealed.⁹⁵

These two previous examples, regarding the safety of ingredients in baking and the cholera quarantines, reveal a tension underlying the public health administration at this time. On the one hand, the governing regime of the public health *juntas* would require that these two kinds of regulations be promulgated at the level of the municipal *junta*, as it was the municipal *junta* charged

88. See 1826 Decree, *supra* note 52, art. 23.

89. See Decree, July 25, 1837, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1837045.pdf> (establishing quarantine for ships coming from Mexico and Central America, citing an Oct. 22, 1833 decree) [hereinafter July 25, 1837 Decree].

90. See *id.*

91. See *id.*

92. *Id.* art. 1 (translation by author).

93. See *id.* art. 2. Please note that the *peso* and the *real* (its fraction) were originally inherited from Spain. After independence, Peru began minting its own currency, also called the *peso*. The integrity of that currency was challenged both by the existence of the Spanish currency and the existence of other currencies in present-day Bolivia. In 1863, Peru consolidated a new form of currency, the *sol*. This would remain the currency for most of its history. Today, Peru's currency is the *nuevo sol*. For a history of the Peruvian currency, see Banco Central de Reserva del Perú, Museo Numismático del Perú [Central Reserve Bank of Peru, Numismatic Museum of Peru], <http://museobcr.perucultural.org.pe/numis.htm> (last visited Dec. 29, 2006).

94. See July 25, 1837 Decree, *supra* note 89, art. 5.

95. See Decree, Jan. 3, 1838, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1838001.pdf> (revoking health measures of the July 25, 1837 Decree).

with food safety and quarantines. However, both of these examples of regulation were promulgated by decree at the national level, not the municipal level. Furthermore, neither decree makes any reference to the role of any public health *junta* in the development of the regulation. Whatever the role of these *juntas*, it appears that they did not have a monopoly over public health or food and drug regulation. This would surely affect their ability to carry out such regulations in the future, to the extent they were unable to carve out for themselves an important role in public health regulation.

3. The Public Health *Juntas* at Twenty and Beyond

There is little information about how well the *juntas* functioned during the civil wars that plagued Peru in the years after their founding. Between 1826 and the first presidency of General Ramón Castilla in 1845, a period of nineteen years, there were twelve presidents, each with an average term of a year and a half, and there were six constitutions.⁹⁶

Castilla's government found the public health *juntas* in a sorry state of disuse and set out to reorganize them, especially in the face of such health threats as yellow fever.⁹⁷ The public health *juntas* hobbled along and frequently collapsed.⁹⁸ They had to be formally reinstated in 1859 and again in 1868.⁹⁹ The institutional weakness of the *juntas* often forced government officials to bypass the *juntas* and seek assistance from the first from the Protomedical Tribunal and later from the Executive Junta of Medicine when faced with health crises.¹⁰⁰ Carlos Bustíos Romani has identified several reasons for the decline of the *juntas*. Among the external reasons, he notes the emphasis within the *juntas* on policing the public health.¹⁰¹ This distracted them from fully developing a coherent body of health law.¹⁰²

96. CARLOS CONTRERAS & MARCOS CUETO, *HISTORIA DEL PERÚ CONTEMPORÁNEO* [HISTORY OF CONTEMPORARY PERU] 103 (Lima, Pontificia Universidad Católica del Perú 1999).

97. See BUSTÍOS ROMANÍ, *supra* note 5, at 258.

98. See *id.*

99. See *id.*; see also Decree, Sept. 14, 1859, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1859062.pdf> (naming members of the Supreme Junta of Health); Decree, Feb. 19, 1868, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1868087.pdf> (reestablishing the Supreme Junta of Health and the Superior Juntas).

100. See BUSTÍOS ROMANÍ, *supra* note 5, at 259.

101. See *id.*

102. See *id.*

B. *Enforcement by the Police*

Responsibility for the quality and safety of foods and drugs in nineteenth-century Peru rested primarily with the public health *juntas*, but required enforcement by the police. While the emphasis on policing may have proved detrimental to the overall project of the *juntas*,¹⁰³ it provides an insight into some food and drug regulation, especially at the municipal level. That is, one important source of regulation of the food and drug industries comes in the form of the *Reglamento de Policía*, the police regulations. These itemize violations against food and drugs that were to be prevented or penalized by the police. At the national level, these regulations came from the president and were implemented by the Minister of State.¹⁰⁴ The first police regulation was enacted on May 21, 1825.¹⁰⁵ This section will discuss the regulations found in two important police regulations that contain food and drug provisions, one from 1839 and the other from 1872, followed by a comparison of the two.

The first regulation to provide a comprehensive template for food and drug regulation appears to have been enacted in 1839 (the "1839 Regulation").¹⁰⁶ Of course, the regulation did not solely govern the food and drug industries. The first title of the 1839 Regulation set up the hierarchy of the police force and authorized it to enforce the laws.¹⁰⁷ The second title mapped out the various police districts for Lima and its province.¹⁰⁸ The third title of the regulation laid out the problem of public safety.¹⁰⁹ This included the requirement to carry a passport for distances traveled greater than five leagues.¹¹⁰ It included provisions authorizing the police to arrest deserters, and permitted police officials to require municipalities to report on the status of their jails.¹¹¹ This document

103. See *supra* note 101 and accompanying text.

104. See Decree, Reglamento de policía para la capital de Lima y su provincia [Police Regulation for the Capital of Lima and its Province], Nov. 11, 1839, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1839096.pdf> (prologue by President Gamarra) [hereinafter 1839 Regulation].

105. See Decree, Reglamento de policía de la capital de Lima [Police Regulation of the Capital of Lima], July 20, 1826, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1826022.pdf> (referencing a May 21, 1825 police regulation) [hereinafter 1826 Regulation].

106. See 1839 Regulation, *supra* note 104.

107. See *id.* arts. 1–59.

108. See *id.* arts. 60–65.

109. See *id.* arts. 66–109.

110. *Id.* arts. 66–73.

111. *Id.* arts. 74–80.

even regulated the use of firearms.¹¹²

While this body of regulations generally provided the structure and authority of the police in the capital city, Lima, it also addressed food and drug regulation insofar as the police were required to enforce licensing and quality requirements. Despite being specific to the city of Lima and its surrounding provinces, these regulations were likely the model for regulation in the more rural areas.¹¹³ Indeed, the police regulations that were national rather than municipal in character tended not to speak to such specific issues as food or drugs.¹¹⁴

1. Regulation in the Time of the *Caudillo*, 1839

The 1839 Regulation was enacted under the second term of Agustín Gamarra, a *caudillo* and the provisional president of the republic.¹¹⁵ In his introduction to the regulation, Gamarra affirmed the responsibility of the police to protect the life and property of individuals.¹¹⁶ Through the police the government would be able to guarantee its citizens peace, health, and comfort.¹¹⁷ This police regulation was amended several times over the years, but remained in effect even as a new one came into effect in 1872; indeed, any cases not contemplated in the 1872 *Reglamento de Policía* (the “1872 Regulation”) were explicitly to be governed by the corresponding provisions of the 1839 Regulation.¹¹⁸

Before delving into greater detail about the scope of food and

112. *Id.* arts. 81–87.

113. For example, an 1887 decree regulating public morality and police only set out the infrastructure of the order of police and did not go into detail the way the 1826 Regulation, *supra* note 105, did. See Decree, Oct. 18, 1887, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1887026.pdf> (extending to all departments a regulation of public morality and police) [hereinafter 1887 Regulation].

114. See, e.g., 1887 Regulation, *supra* note 113 (referring to a regulation set up for the Department of Lima but declared effective for the whole country); Decree, Reglamento de policía de salud pública [Regulation for Public Safety Police], Mar. 20, 1866, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1866152.pdf> (laying out police procedures and hierarchy but with no reference to food or drug other than to give the police power to force pharmacies to open in case of emergency); Decree, Reglamento de Policía [Police Regulation], Nov. 30, 1869, art. 18(25), available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1869083.pdf> (referring only to food or drug in that the patrols are to notify the inspector if they find a market or other store selling damaged foods).

115. See 1839 Regulation, *supra* note 104.

116. See *id.*

117. See *id.*

118. See Decree, Reglamento de policía municipal para la ciudad de Lima [Regulation for Municipal Police of the City of Lima], July 20, 1872, art. 250 (Lima, Imprenta La Patria 1872) [hereinafter 1872 Regulation].

drug regulation enacted through this police regulation, the whole regulation should be described. Title IV of the regulation dealt with morality and public order.¹¹⁹ For example, an offense against the state religion was punishable by a fine of between four and twelve *pesos*.¹²⁰ Obscenity carried a fine of one to four *pesos* or up to four days imprisonment.¹²¹ The Peruvian government chose this space to regulate pharmacies as well as small markets and cafés.¹²² Title V sought to protect the public health and regulate sanitation partly by including penalties and restrictions on selling damaged or harmful foods.¹²³

a. Quality and Safety of Food Products

The food industry was regulated in the 1839 Regulation under the umbrella of public health.¹²⁴ Through this regulation, the government expressed its concern for the quality of food products. Vendors of food products were responsible for the quality of the products they sold to the public.¹²⁵ Anyone who tried to sell grains or flour of poor quality would be fined twenty-five *pesos* or two hundred *pesos*, depending on the quantity.¹²⁶ Furthermore, the sale of damaged fruit, meat, fish, or other foods was prohibited, subject to a fine of between two and ten *pesos*.¹²⁷ The regulation also provided that anyone who mixed harmful substances into beverages, alcoholic or otherwise, would also be fined between two and ten *pesos*.¹²⁸ In 1845, these two provisions of the 1839 Regulation were amended to increase the maximum penalty to two hundred *pesos*.¹²⁹ The government came to realize that the fines had been set too low, creating a situation where the person selling damaged or harmful goods could still profit from those sales after

119. See 1839 Regulation, *supra* note 104, art. 110.

120. *Id.*

121. *Id.* art. 112.

122. *Id.* arts. 130–36.

123. *Id.* arts 186–224.

124. Indeed, this is the title of the relevant chapter of the regulation, “De la salubridad pública” [Of the Public Health]. See *id.*, arts. 186–202.

125. *Id.* art. 186.

126. *Id.* art. 187. Whether the grains or flour are of bad quality were to be determined by two representatives, one named by the seller and another named by the Intendant of police. *Id.*

127. *Id.* art. 189.

128. *Id.* art. 190.

129. See Decree, Dec. 3, 1845, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1845155.pdf> (increasing the fine that the police regulation imposes on those who sell damaged and unhealthy foods to two hundred *pesos*).

paying the penalty.¹³⁰ Only a higher penalty would deter the bad practice. Additionally, the 1839 Regulation contemplated that for very grave infractions, the police could announce the names of violators and penalties assessed in the press.¹³¹

b. Quality and Safety of Drugs

The pharmaceutical industry in Peru fell within the scope of this code, both through its regulation of the drugs themselves and of the *botica*, the drugstore. The 1839 Regulation called for the destruction of any and all medicines sold in these *boticas* or elsewhere if they were found to be of bad quality.¹³² Additionally, the vendors would be fined between four and fifty *pesos*.¹³³ It appears that, in practice, the police tended to simply impose fines rather than take the added step of throwing out corrupted drugs.¹³⁴ In 1850, the government decreed that the police should limit their enforcement of this provision of the regulation to preventing the sale of bad drugs, leaving the vendors subject to civil liability if people were harmed by the bad drugs.¹³⁵ In 1851, this concept was further refined such that the only fines that could be imposed by the police were for fraudulent sales of drugs commonly used as spices, where these were sold either of bad quality or of doctored weights.¹³⁶ The police were to focus on destroying dangerous items.

The 1839 Regulation also determined how drugstores could operate. Each drugstore had to be licensed by the *Junta de Farmacia*, a commission set up for this purpose, and was subject to inspection by the superintendent of police.¹³⁷ These drugstores could only be operated by individuals who had been approved by the pharmaceutical profession, with a penalty of up to twenty *pesos* for failure to comply.¹³⁸ The regulation also set out permissi-

130. *See id.*

131. 1839 Regulation, *supra* note 104, art. 190.

132. *Id.* art. 194.

133. *Id.*

134. *See* Decree, Oct. 21, 1850, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1850063.pdf> (modifying the imposition of fines on drug vendors).

135. *Id.*; *see also* Decree, May 17, 1851, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1851020.pdf> (reforming police regulation for Lima and noting that it is the job of the government to assure the protection of individuals and prohibiting the police from imposing fines) [hereinafter 1851 Decree].

136. *See* 1851 Decree, *supra* note 135 (noting in the recitals that it is the job of the government to assure the protection of individuals and that excessive fines were a threat to the lower classes).

137. 1839 Regulation, *supra* note 104, art. 130.

138. *Id.* art. 131.

ble hours of operation, among other things.¹³⁹ In 1845, the regulation was amended to clarify the kinds of stores that were allowed to sell medicines.¹⁴⁰ The 1839 Regulation specified that only licensed *boticas* were permitted to sell drugs and medications.¹⁴¹ While the Peruvian government recognized the importance of such a strict regulation, it also sought to balance this need with the concern for access to medications, especially those that were in common use.¹⁴² Therefore, the government decreed that oils, ointments, syrups, and salts could be sold in establishments that were not licensed drugstores, but that no medicines more complex than those would be permitted to be sold outside of a *botica*.¹⁴³ Because these were generally used without a prescription, there was no reason not to make them widely available so long as their quality could be assured.¹⁴⁴

2. Reorganization and the *Reglamento* of 1872

The next significant iteration of food and drug law in police regulations appears in the 1872 Regulation for the City of Lima.¹⁴⁵ This regulation was passed during a tumultuous time in Peru.¹⁴⁶ That year may have also been a critical juncture in the development of public health regulation in Peru. The city of Lima was undertaking a project to put some teeth into its sanitary laws at the time,¹⁴⁷ and the 1872 Regulation probably played an important role in that project. In 1873, further regulations were passed to authorize enforcement by a police force dedicated to public health and to create a municipal health service to oversee the whole thing.¹⁴⁸ Would the 1872 Regulation live up to Peru's aspiration

139. *See id.* arts. 132–36.

140. *See* Decree, Nov. 30, 1845, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1845153.pdf> (determining what class of medicines could be sold in establishments that are not pharmacies) [hereinafter 1845 Decree].

141. *See* 1839 Regulation, *supra* note 104, art. 130.

142. *See* 1845 Decree, *supra* note 140.

143. *See id.*

144. *See id.*

145. *See* 1872 Regulation, *supra* note 118.

146. The very month this new regulation passed, July 1872, the Minister of War threw a coup, arresting the president and declaring himself head of state. When one of his supporters was killed in the ensuing turmoil, he retaliated by killing the former president. Peruvians rose up in a mob and killed the coup leader-turned-president. Manuel Pardo became president shortly after. *See* CHRISTINE HUNEFELDT, A BRIEF HISTORY OF PERU 122–23 (2004).

147. *See* BUSTÍOS ROMANÍ, *supra* note 5, at 260.

148. *See id.* While this specific municipal ordinance was unavailable through my research, a municipal ordinance of Lima from 1903, *infra* note 210, provides an example of what this might have been like.

for a better, more effective public health regime? Unfortunately, it would not.

a. Food and Drink

The 1872 Regulation is very clear and concise, reading like a set of commandments for food and drink vendors. The regulation made it illegal to sell food or beverages that were dangerous to one's health, and any dangerous foods or beverages that were found were to be destroyed by the municipality.¹⁴⁹ All vendors of food or beverages were required to make these products and their ingredients available for inspection at the request of the municipality.¹⁵⁰ The regulation also prohibited mixing harmful substances into foods, sweets, or liquors.¹⁵¹ Every seller was required to report the origin of any harmful item found to the municipality.¹⁵² Stores that sold meat or fish, for which there were special sanitation concerns, had to use special tables for these meats, presumably to avoid contamination.¹⁵³ Sick animals could not be slaughtered for sale as food.¹⁵⁴ Failure to comply with these regulations would result in a fine of between one and two hundred soles.¹⁵⁵ As pertains to the sale of food products, these statements of the law reveal that the regulation of food products stemmed primarily from a concern about health risks.

b. Pharmacies and Drugstores

This portion of the 1872 Regulation governed drugs at all levels of their distribution to the public, from regulating the drugs themselves, to regulating the stores in which they could be sold and the professionals who could dispense them. As expected, the regulation sought to assure that only good quality drugs would be sold to the public. Any medicines determined to be of bad quality would be destroyed and a fine would be levied.¹⁵⁶

The *boticas* and the drugs they sold were directly regulated by the 1872 Regulation. The general rule was that no one could sell medicinal drugs without a proper license from the municipality.¹⁵⁷

149. See 1872 Regulation, *supra* note 118, art. 1.

150. *Id.* art. 2.

151. *Id.* art. 4.

152. *Id.* art. 7.

153. See *id.* art. 5.

154. *Id.* art. 6.

155. *Id.* art. 8.

156. *Id.* art. 191.

157. *Id.* art. 186.

This license had to be obtained before the store's opening and with the consent of the Faculty of Medicine.¹⁵⁸ Establishments seeking a license would be inspected by the mayor or some other city inspector, in conjunction with a pharmacist and a doctor, to monitor the quality of the establishment and drugs sold.¹⁵⁹ However, if the Faculty of Medicine decided that some drugs could be freely and safely sold to the public, then the sale of those drugs did not require this license.¹⁶⁰ The regulations specifically discussed the sale of opiates, as well. No one could sell opiates or other dangerous drugs retail except in these licensed pharmacies and drugstores.¹⁶¹

Lastly, the pharmacists themselves were regulated. No one was permitted to mix or dispense drugs without being approved by the profession of pharmacists.¹⁶² Pharmacists were required to be on call at all times—they could be required to open at any time, by order of the police, so that a sick individual could get the medicines he or she needed.¹⁶³

3. Forty Years and No Real Change

In the 1839 Regulation, food and drug were found at the very end of the regulations, in the last title.¹⁶⁴ By contrast, in 1872, health figured very prominently in the regulations—in the very first title.¹⁶⁵ Notably, the first regulations under the heading of health were those regulating food and drink.¹⁶⁶ The 1872 Regulation was better organized, but less detailed. For example, food and drug regulations in the 1839 Regulation were combined with general sanitation provisions under the heading of public health.¹⁶⁷ By contrast, in 1872, food and drink regulations were clearly labeled in one section,¹⁶⁸ and pharmacies and drugstores were organized into another section.¹⁶⁹

Ultimately, the 1839 and 1872 Regulations were very similar in terms of content. This lack of evolution could be related to the

158. *Id.* art. 188.

159. *Id.*

160. *Id.* art. 186.

161. *Id.* art. 187.

162. *Id.* art. 189.

163. *Id.* arts. 190, 193.

164. See 1839 Regulation, *supra* note 104, arts. 186–224.

165. See 1872 Regulation, *supra* note 118, arts. 1–15.

166. See *id.*

167. See 1839 Regulation, *supra* note 104, arts. 186–202.

168. See 1872 Regulation, *supra* note 118, arts. 1–8.

169. See *id.* arts. 186–95.

weakness of the public health *juntas* and their inability to put forth comprehensive regulations. While these regulations are the most detailed encountered thus far as regards food or drugs, no data is available about the actual level of their enforcement. Bustíos Romani argues that these laws did not sufficiently protect the public health. For example, he notes that there was no institutionalized practice of inspecting food or drink, despite this requirement in the law.¹⁷⁰ Therefore, while the 1839 and 1872 Regulations represent the main work of food and drug regulation during that time, their ultimate effect on quality or safety is uncertain.

C. *Production and Distribution in the Nineteenth Century*

So far, this Article has discussed the regulation of food and drugs in connection with a deep concern for the public health. Those two industries were tangentially regulated in two other aspects described in this section. First, producers were subject to regulations on weights and measures, affecting the containers in which food or beverages were sold. Second, there was a nascent intellectual property regime in place in Peru in the nineteenth century that affected how drugs were produced and distributed.

1. Regulation Through Weights and Measures

In 1866, authorized by an 1862 law, the Peruvian government set out a regulation requiring the verification of weights and measures.¹⁷¹ While this was primarily a technical regulation that applied to the use of the metric system in manufacturing, among other things, it briefly touched on food—milk containers had to adhere to certain specifications. Milk containers had to be made of sheet iron or tin leaves, taking the form of a cylinder with a height equal to its diameter.¹⁷² The regulation laid out a chart containing the acceptable measures of milk with the corresponding heights, diameters, and margins of error.¹⁷³ These containers were to be constructed out of a single sheet, except that containers

170. See BUSTÍOS ROMANÍ, *supra* note 5, at 260.

171. See Reglamento sobre la fabricación y verificación de los pesos y medidas [Regulation of the Fabrication and Verification of Weights and Measures], Sept. 13, 1866, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1866161.pdf>.

172. *Id.* art. 50.

173. *Id.* art. 51.

for two liters of milk were permitted one well-soldered ribbon.¹⁷⁴ The bottoms of the containers also had to be a single piece.¹⁷⁵ Finally, milk containers would be considered defective if they failed to meet these specifications—if they were not made of the proper materials, if the interior dimensions were not correct, if they leaked, etc.—and would be subject to police enforcement.¹⁷⁶

2. Monopolies and Drug Production

As early as 1826, the Peruvian government was set up to provide for exclusive rights to certain individuals to sell medicines under a right.¹⁷⁷ The concept of *patente* in Peruvian law is not what we would think of as a “patent” today. Indeed, it appears to have been more like a license. Professionals paid for a patent to legally practice the craft, for example.¹⁷⁸ From time to time the Peruvian legislature would grant monopolies or exclusive privileges to individuals or businesses.¹⁷⁹ These were only to be granted where a business contributed favorably to the public utility or in cases where there had been a new discovery promoting the health and welfare of the people.¹⁸⁰

Some time in 1844 or 1845 a man by the name of Juan Moss filed a petition with the congress for an exclusive right to sell a particular medicine to fight dysentery.¹⁸¹ This exclusive privilege to sell this drug was to provide benefits to both Mr. Moss and to the congress. First, Mr. Moss benefited economically from such a monopoly, which would be protected by law. Second, the congress retained regulatory control over the drug. The law granting the privilege to Mr. Moss protected his rights to sell the drug for a period of six years.¹⁸² It provided that anyone who imitated the

174. *Id.* art. 52.

175. *Id.*

176. *Id.* art. 53.

177. See 1826 Decree, *supra* note 52, art. 30(3) (providing that the *juntas* could collect a fee for issuing the patent, though not explaining how the patents were distributed).

178. See Decree, Dec. 12, 1826, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1826073.pdf> (classifying and providing the fee schedule for various licenses).

179. See Decree, June 20, 1857, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/18571504.pdf> (denying the privileged to sell a medicine named *Pansirop*) [hereinafter *Pansirop* Decree].

180. *Id.*

181. See Law, Aug. 14, 1845, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1857154.pdf> (conceding a six-year privilege to Juan Moss to sell a medication to treat dysentery).

182. *Id.* art. 1.

drug would be fined between ten and one hundred *pesos*, to be split between the state and the person bringing the complaint.¹⁸³ Anyone who sold the drug without the authorization of Mr. Moss or his estate would be subject to the same fine.¹⁸⁴ The law also stipulated that the drug could be sold in foreign countries without being subject to Peruvian tax.¹⁸⁵

While the monopoly thus operated very much to Mr. Moss's advantage, it also worked to the benefit of the public. The congress mandated that the drug be sold in boxes containing twelve pills each.¹⁸⁶ The drug would be sold at a price of twenty *reales* to the general public, at ten *reales* to hospitals, and would be free to the poor.¹⁸⁷ Each box was also required to have had a prescription and general use instructions affixed to it.¹⁸⁸ Most importantly, at the close of six years, Mr. Moss was required to provide the Peruvian government with the specifications and formulation of the dysentery medicine.¹⁸⁹ Ownership of the drug would pass to the state at that time.¹⁹⁰

By contrast, in 1857, the congress denied a similar privilege to a company seeking to sell a medicine called *Pansirop*.¹⁹¹ The congress noted that the medicine had been freely sold in Peru for the last ten years, and so it would be inappropriate to make such a concession.¹⁹²

D. *Reconceptualization and a New Regime, the Last Quarter Century*

Between 1879 and 1883 Peru was embroiled in a bitter war with Chile, its neighbor to the south.¹⁹³ It emerged from the War of the Pacific somewhat weaker and with a new administrative agenda.

183. *Id.* art. 5.

184. *Id.*

185. *Id.* art. 6.

186. *Id.* art. 3.

187. *Id.*

188. *Id.*

189. *Id.* art. 2.

190. *Id.*

191. See *Pansirop Decree*, *supra* note 179.

192. *Id.*

193. For historical accounts of the War of the Pacific, see CLEMENTS R. MARKHAM, *THE WAR BETWEEN PERU AND CHILE, 1879-1882* (London, Sampson Low, Marston, Searle & Rivington 1882) and MARIANO FELIPE PAZ SOLDÁN, *NARRACIÓN HISTÓRICA DE LA GUERRA DE CHILE CONTRA EL PERÚ Y BOLIVIA* (Lima, Editorial Milla Batres 1979) (1884).

1. The General Health Regulations at the National Level

The year 1884 may have been the last year the public health *juntas* were even somewhat important in Peru. As discussed above, however, the *juntas* had been terribly weakened by then. In that year the government passed a new general health regulation inaugurating the first reconceptualization of the public health regime since 1826, on the grounds that the 1826 regulation which had initially set up the public health *juntas* was deficient to address current concerns.¹⁹⁴ The 1884 General Health Regulation experimented with a new administrative system: the public health service.¹⁹⁵ This General Health Regulation laid out a new structure of *juntas*, but, in effect, the former *juntas* had been completely eliminated.¹⁹⁶ This section will describe this new system.

The General Health Regulation was perhaps the country's first attempt at piecing back together its public health administration after years of war and occupation. It may have been a decent first step, but the new system of *juntas* was not as strong or as forceful as the 1826 *juntas* had been at their inception. Indeed, the Dean of the Faculty of Medicine, Dr. Ernesto Odriozola, commented in 1886 that the Supreme Junta "only shows signs of life when some epidemic threatens the capital, and even then all its influence and all the measures it dictates stumble over innumerable resistances or difficulties born of the lack of [good] organization."¹⁹⁷ That same year, José Casimiro Ulloa, the principal architect of the General Health Regulation, lamented that it had been two years since the passing of the regulation and yet nothing had been done to formally execute it.¹⁹⁸ Consequently, a new health regulation was passed in 1887, elaborating the same structure with minor modifications.¹⁹⁹

Both the 1884 and the 1887 General Health Regulations laid

194. See Decree, Reglamento General de Sanidad [General Health Regulation], Oct. 10, 1884, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1884074.pdf> (recitals) [hereinafter 1884 General Health Regulation].

195. See *id.*

196. *Id.*

197. BUSTÍOS ROMANÍ, *supra* note 5, at 449 (translation by author).

198. See 1 PAZ SOLDÁN, *supra* note 5, at 71 (citing *Informe sobre medidas que deben adoptarse para el mejor cumplimiento del nuevo Reglamento de Sanidad* [Report on Measures that Should Be Adopted to Better Comply with the New Health Regulation], EL MONITOR MÉDICO, Jan. 31, 1886).

199. See Decree, Reglamento General de Sanidad [General Health Regulation], Feb. 7, 1887, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1887102.pdf> [hereinafter 1887 General Health Regulation]. This regulation is virtually identical to its 1884 counterpart.

out a structure for the public health service that roughly paralleled the structure of the *juntas*. The public health service at each level was subject to the authority of a *junta* at that level. For example, the public health service at the national level was subject to a new Supreme or Central Junta.²⁰⁰ At the level of the provinces, the service was subject to the Departmental Junta, and at the municipal level, the service was subject to the municipality.²⁰¹ The major distinction between this new system and the old one was that the service was divided in two: the service of maritime health and the service of land health.²⁰²

The 1884 and 1887 General Health Regulations did not provide a lot of substantive regulation of food and drug. They provided, for example, that marketplaces be inspected by the municipalities under the supervision of the health *juntas*.²⁰³ They also provided that pharmaceutical establishments be inspected by the Faculty of Medicine.²⁰⁴ This paucity of regulation does not mean necessarily that food and drug were not being regulated, only that they were not regulated at the national level.²⁰⁵

2. Municipal Regulations

Much of the actual work of setting standards for the protection of foods in Peru was done at the municipal level. Guided by national decrees, the municipalities set out to regulate food safety both through specific ordinances on the topic as well as through their own police regulations—indeed, the 1872 Regulation was the police regulation for the capital of Lima.²⁰⁶ This section looks at some municipal regulations at the turn of the century. The section first describes a food safety ordinance out of Lima in 1903 and, next, a public hygiene ordinance out of Arequipa around 1906.

200. *See id.* arts. 6–11.

201. *See* 1884 General Health Regulation, *supra* note 194, art. 4; 1887 General Health Regulation, *supra* note 199, art. 4.

202. *See* 1884 General Health Regulation, *supra* note 194, art. 1; 1887 General Health Regulation, *supra* note 199, art. 1.

203. *See* 1884 General Health Regulation, *supra* note 194, art. 74; 1887 General Health Regulation, *supra* note 199, art. 74.

204. *See* 1884 General Health Regulation, *supra* note 194, art. 113; 1887 General Health Regulation, *supra* note 199, art. 113.

205. The research for this paper focused on national decrees as those were more readily available through the legislature's digital archives. *See supra* note 52.

206. *See* 1872 Regulation, *supra* note 118.

a. *Food Identities and Adulteration in Lima*

The *Diccionario de la Legislación Municipal del Peru* provides some light into the state of municipal legislation related to food and drug at the turn of the century.²⁰⁷ Particularly, the dictionary boldly states that “the policing of foods and drinks is one of the first duties of the municipal administration.”²⁰⁸ The author of the *Diccionario* recognized the need for super-vigilance over markets, spice vendors, and merchants of flour, wine, etc., because of the dangers they posed:

Wine is fabricated without a single gram of grape, and milk is made with water, flour, and some honey. Between his particular interest and the interest of public health, the merchant who sells damaged flour does not vacillate; he sells his flour without consideration for the consumption of a great city and he does not worry about the diseases that could be caused by indigestible and unhealthy breads. A confectioner wants to make his sweets look appealing, so he colors them with mineral substances which are poisonous. . . . The butchers sell inedible meats from calves that are too young, from sick cows, or from animals that died of contagious diseases. Markets sell poisonous mushrooms, unripe or rotten fruits, spoiled fish; the spice vendor sells sugar that is not sugar. . . . There is perhaps no single food or any beverage which a criminal fraud could not transform into a mechanism of death.²⁰⁹

Certainly it appears that the food supply was a great source of public health risk.

In response to this rotten state of affairs, the Municipality of Lima passed an ordinance in 1903 to more substantively regulate the food supply.²¹⁰ This regulation began by laying out general dispositions,²¹¹ proceeded to regulate specific foods,²¹² then food

207. See *Alimentos [Food]*, in 1 DICCIONARIO, *supra* note 6, at 140–48.

208. See *id.* at 140 (translation by author).

209. *Id.* (translation by author).

210. See Ordinance, Feb. 4, 1903, *reprinted in* 1 DICCIONARIO, *supra* note 6, at 140–48.

211. See *id.* arts. 1–6, at 140–41.

212. These included wines (arts. 7–18), alcoholic beverages (arts. 19–32), butter (arts. 45–48), milk and cheese (arts. 49–52), cereals (arts. 52–57), fruits and vegetables (art. 58), chocolate (arts. 60–64), coffee and tea (arts. 65–69), meats (arts. 79–85), sweets and jams (arts. 86–88), and sodas (arts. 89–91).

wrappers,²¹³ and, finally, color additives.²¹⁴ The section on general dispositions naturally prohibited the sale of foods or drugs that have been altered or adulterated.²¹⁵ The regulation recognized a difference between an altered and an adulterated product. A product was considered altered where for either natural causes or a defect, the product had been modified so it was no longer appropriate for consumption. A product was considered adulterated when the alteration was due to the addition of an inappropriate substance, or substitution of one substance for another with fraudulent intent.²¹⁶ The ordinance carved out an exception for food products or beverages that had been mixed with some additive that was not harmful or which even added nutritional value so long as the product labels clearly indicated the nature of the additives.²¹⁷

The penalty for a first violation of these provisions was a fine of between fifty and 500 *soles*.²¹⁸ The product itself could either be destroyed or be used for another, more appropriate purpose.²¹⁹ Repeat offenses could warrant closure of the offending establishment by the hygiene inspectors if necessary to protect the public health.²²⁰ Furthermore, certain toxic or fraudulent products could also be regulated through the penal code.²²¹

Next, the municipal ordinance extended to the regulation of specific food products.²²² These provisions first presented an identity standard for the product and then made specific prohibitions. For example, the entry for "Wines" indicated that natural wines are those which come exclusively from the fermentation of grapes.²²³ The ordinance prohibited the addition of water, impure alcohols, glycerin, caramel, glucose, saccharine, etc., which would alter the natural composition of the wine and render it potentially dangerous.²²⁴ The ordinance similarly regulated spirits, artificial

213. See Ordinance, Feb. 4, 1903, arts. 93-94, reprinted in 1 *DICCIONARIO*, *supra* note 6, at 147.

214. See *id.* arts. 103-04, at 148.

215. See *id.* art. 1, at 140.

216. See *id.*

217. See *id.* art. 4, at 141.

218. See *id.* art. 2, at 140.

219. See *id.*

220. See *id.* art. 3, at 140-41.

221. See *id.* art. 6, at 141.

222. See *supra* note 212.

223. See Ordinance, Feb. 3, 1903, art. 7, reprinted in 1 *DICCIONARIO*, *supra* note 6, at 141.

224. See *id.* art. 10, at 141. The ordinance contains twelve articles on wines.

liquors, beers, *chichas* (a Peruvian beer made from corn), and vinegars.²²⁵

The ordinance also regulated dairy products. Butter was defined as the grease obtained from mechanical operations, exclusively from cow's milk.²²⁶ Butter could not be sour nor have an abnormal coloring or flavor.²²⁷ It could not be artificially colored with toxic substances and could not be mixed with fats from some source other than cow's milk.²²⁸ Milk itself was rigorously regulated.²²⁹ Cheese could not be sold if it was in an advanced state of rotting.²³⁰

Indeed, the ordinance was very thorough. It regulated cereals; flour, bread, and crackers; fruits and vegetables; mushrooms; chocolate; coffee; tea; condiments and aromatic substances; preservatives; meats; sweets and candies; syrups, marmalades, etc.; carbonated sodas, lemonades, and ice cream; mineral water; candy wrappers; artificial dyes.²³¹ If one were to evaluate the development of food regulation in Peru only through the lens of national law, one would miss all of this wealth of information at the local level. While the national decrees and regulations often appeared sparse, especially at this early stage of development, it is clear that the municipalities were contributing to the regulation of food and drug in more concrete terms.

b. Public Hygiene in Arequipa

Arequipa is a city in the south of Peru famous for its alpaca wool, its facades made of a stunningly bright white volcanic rock, and Misti, its volcano. The municipal police regulation for the city of Arequipa at the beginning of the twentieth century provides an example of how police regulations at the municipal level, like their counterparts at the national level, provided a mechanism for food and drug regulation.²³² Certain activities were considered a threat to the public health, and were so banned. This regulation was not as detailed as the Lima ordinance described above, and seems

225. *See id.* arts. 19–36, at 141–43.

226. *See id.* art. 45, at 143.

227. *See id.* art. 46, at 143.

228. *See id.*

229. *See id.* arts. 49–50, at 143.

230. *See id.* art. 51, at 144.

231. *See id.* arts. 53–103, at 144–48.

232. *See* Reglamento de policía municipal de la provincia de Arequipa [Municipal Police Regulation of the Province of Arequipa], reprinted in 2 DICCIONARIO, *supra* note 6, at 363.

more in line with the 1872 Regulation in that it proscribed activities without going into great detail about standards.²³³

The police regulation of Arequipa prohibited the sale of food, beverages, or alcohols which were dangerous to one's health upon penalty of destruction.²³⁴ Producers could not use or mix adulterated or decomposing substances to make bread, foods, sweets, juice cocktails, alcohols, cigarettes, or other food products.²³⁵ Merchants who sold foods, beverages, or alcohols were obligated to submit to an inspection if the municipal authority required, and they were required to declare the origin of any unhealthy products found in their establishments.²³⁶

The municipal police regulation of Arequipa makes reference to other relevant municipal ordinances. For example, the production of bread, *chicha*, beer, and alcohols were subject to special ordinances—those ordinances were intended to address the risks of unsafe ingredients, or unsafe processes.²³⁷

c. Regulating the Practice of Medicine and Pharmacy

The municipalities in Peru similarly regulated the practice of medicine and pharmacy.²³⁸ This section will provide some examples of the regulation as it pertains to pharmacy and the dispensation of drugs. Whereas the regulation of food was primarily concerned with safety, the regulation of pharmacy and drugs was concerned both with credentialing and authorization and with safety.

The professions of medicine and pharmacy were regulated by an 1877 regulation.²³⁹ The regulation drew a sharp distinction between the practice of medicine and the practice of pharmacy—one could not practice both unless he was a doctor in a small vil-

233. Of course, it is possible that Arequipa has an ordinance similar to Lima's but that it was not included in the *Diccionario*.

234. See Reglamento de policía municipal de la provincia de Arequipa [Municipal Police Regulation of the Province of Arequipa] art. 1, reprinted in 2 DICCIONARIO, *supra* note 6, at 363.

235. See *id.* arts. 2, 4, at 363.

236. See *id.* arts. 48, 52, at 364.

237. See *id.* art. 53, at 364.

238. I cannot be sure that these are in fact municipal regulations or whether they are simply national regulations replicated at the local level. While the *Diccionario* is specifically a collection of municipal legislation, this particular entry does not specify which municipality promulgated this regulation. See *Medicina* [Medicine], in 3 DICCIONARIO, *supra* note 6, at 73 (noting that the practice of medicine is subject to an Apr. 2, 1877 Regulation).

239. See *id.*

lage that did not otherwise have a pharmacist.²⁴⁰ Pharmacists could not dispense potentially poisonous substances without a prescription signed by a known physician, and those prescriptions had to be clearly written in Spanish.²⁴¹ No establishment (presumably pharmacies or *boticas*) could purchase poisonous or toxic substances without a sworn declaration that the substances would be handled or used appropriately.²⁴² No pharmacy or *botica* could be opened without authorization and inspection by the Faculty of Medicine.²⁴³ More specifically, the regulation created a Pharmaceutical Commission that was charged with inspections of the pharmacies both insofar as they treated the public and dispensed drugs.²⁴⁴

Many of these regulations were repeated and somewhat expanded in an October 1888 law governing the exercise of medicine in Peru.²⁴⁵ There is no need to go more in-depth into a description of this regulation as it preserves the main characteristics of the prior laws: credentialing, inspection, requirement of prescriptions, etc. While there are some distinctions, they are minor.

In the eighty years after Peru became an independent nation, there was an evolution of its public health administration. Peru built on the legacies left to it by Spain—the system of public health *juntas* and a licensing scheme. The system of public health *juntas* set up by decree in 1826 were reminiscent of the colonial structures. Food was regulated by these *juntas* because spoiled or adulterated foods posed a significant health risk. Furthermore, the infant state also embraced the system of licensing pharmacists that had been set up by the Spanish. While the actual content or substance of food and drug regulations left much to be desired, the regulations were flushed out over time and through the work at the municipal levels. By the turn of the twentieth century, Peru had developed administrative structures poised to regulate food and drug, even if they were weak at times.

240. See Regulation, Apr. 2, 1877, arts. 5–7, reprinted in 3 DICCIONARIO, *supra* note 6, at 74.

241. See *id.* arts. 9–10, at 74.

242. See *id.* art. 11, at 74.

243. See *id.* art. 14, at 74.

244. See *id.* arts. 70–71, at 74.

245. See Law, Oct. 25, 1888, reprinted in 3 DICCIONARIO, *supra* note 6, at 75 (on the exercise of the medical profession in Peru).

IV. THE ROAD TO MODERN REGULATION, THE TWENTIETH CENTURY

The administrative framework and regulations discussed above lay the foundation for a more expansive apparatus to develop in the twentieth century. The first quarter of the twentieth century witnessed another reorganization of public health and it also witnessed perhaps the first rigorous attempts to study public health as a discipline—public health, but not food or drug regulation.

In 1918, Carlos Enrique Paz Soldán summarized the responsibility of the state for public health into its principal actors: the state, the municipalities, the departmental *juntas*, the Faculty of Medicine, and various social assistance organizations.²⁴⁶ More specifically, the field of public health was occupied by the *Dirección General de Salubridad*, the Superior Council of Hygiene, titular physicians, and technical-scientific establishments.²⁴⁷ He commented that the legal reality of the public health administration at this time was complicated and lacking a unifying vision.²⁴⁸ This section of the Article lays out some of the elements of that administration in the hopes that understanding this structure will provide some insight into those government organs most responsible for the development of food or drug regulation.

A. *The Dirección General de Salubridad*

At least towards the beginning of the history of food and drug regulation, responsibility for that regulation lay inside the Ministry of State, but by 1903, that responsibility had been moved to the Ministry of Development.²⁴⁹ Created in 1896, the Ministry of Development was put in charge of public works, industry, and social welfare, taking for itself what had been previously part of the Ministries of State, Housing, and Justice.²⁵⁰ This Ministry was in charge of processing and executing the work of Supreme Junta, further deprioritizing the work of those *juntas* and contributing to a lack of political capital which made it even harder for

246. See 2 PAZ SOLDÁN, *supra* note 5, at 85.

247. See *id.*

248. See *id.*

249. See Law, Nov. 6, 1903, art. 1, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1903140.pdf> (creating a public health agency in the Ministry of Development) [hereinafter Nov. 6, 1903 Law].

250. Law, Jan. 22, 1896, art. 1, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1896017.pdf> (creating the Ministry of Development to oversee public works, industries, and benefits).

the *juntas* to get any real regulatory work done.²⁵¹ It was in this new Ministry that a few years later the next important public health institution would be born: the *Dirección General de Salubridad*, the State Board of Health.²⁵²

The *Dirección General de Salubridad* was a high-level government agency whose responsibilities included ensuring that all sanitary legislation was executed and enforced, studying and proposing any necessary reforms, organizing a plan of defense against foreign pestilences, coordinating prophylactic measures against epidemics, and maintaining relevant statistics.²⁵³ The agency did so against the framework of the General Health Regulations of 1884 and 1887, which had divided the work of public health into two "services".²⁵⁴ This agency was most likely responsible for the regulation of food and drug, but the content of that regulation has not been found. What is known, however, is that one of the responsibilities of the medical officials working for the agency was to manage the execution of regulations relating to foods at the municipal level.²⁵⁵ This probably refers to the General Health Regulation of 1887, which appears to have been in effect until 1922.²⁵⁶

One of the accomplishments of the *Dirección General de Salubridad* was that it undertook what appears to be the first systematic compilation and digest of the laws related to health and sanitation in Peru. The *Prontuario de la Legislación Sanitaria del Perú* (Handbook of Health Legislation in Peru),²⁵⁷ was collected by Dr. Daniel Lavorería, sub-Director of the *Dirección*, and published by the agency in three volumes. While Dr. Lavorería does not have much more success than this Article in sifting out the substance of food or drug regulation in Peru, his compilation does reveal a couple of nuggets pertaining to potatoes and safe vegetables. In 1906, the government passed a Supreme Resolution per-

251. BUSTÍOS ROMANÍ, *supra* note 5, at 459.

252. At some point, this entity becomes the *Dirección General de Salubridad Pública* (State Board of Public Health). This probably occurs in the 1920s.

253. See Nov. 6, 1903 Law, *supra* note 249, art. 1.

254. 1884 General Health Regulation, *supra* note 194, art. 1; 1887 General Health Regulation, *supra* note 199, art. 1.

255. BUSTÍOS ROMANÍ, *supra* note 5, at 465 (citing Supreme Decree, Reglamento de Médicos Titulares [Regulation of Licensed Physicians], Oct. 15, 1915); see also Municipal Regulations, *supra* Part III.D.2.

256. See BUSTÍOS ROMANÍ, *supra* note 5, at 474-75.

257. 1-3 PRONTUARIO DE LEGISLACIÓN SANITARIA DEL PERÚ [HANDBOOK OF HEALTH LEGISLATION OF PERU] (Daniel Lavorería ed., Lima, Imp. La Equitativa 1928) [hereinafter 1 or 2 PRONTUARIO].

taining to the importation of potatoes by sea.²⁵⁸ The resolution declared that such potatoes should be stored in an area of the ship which is not disinfected with “Clayton gas”, which can cause lesions on potatoes.²⁵⁹ In 1911, fear of disease led the government to pass a Supreme Resolution prohibiting the irrigation of fruits or vegetables with dirty water.²⁶⁰

B. *Modernization in the 1920s: Elaboration of Drug Regulations*

In the realm of drug regulation, in 1906, the *Dirección General de Salubridad* was given the responsibility of overseeing the National Institute of Vaccines and Serums.²⁶¹ According to its governing regulation, the Institute was charged with managing various aspects of vaccine preparation, registration, and distribution.²⁶² Unfortunately, there is not much information about the day-to-day work of the Institute or any of its potential successes or shortcomings. This section of the Article discusses the work of the *Dirección* in regulating the sale of drugs to the public, in regulating the manufacture and development of drugs, and in regulating narcotics in particular.

1. Regulation of Sales and Shops: The Pharmaceutical Commission

Two decades after the Institute of Vaccines and Serums, another administrative body took a prominent role in drug regulation. In 1922, the Pharmaceutical Commission was created, given the responsibility of control and inspection of pharmacies, drug-

258. See Supreme Resolution, Importación de papas, deben venir en cubierta [Importation of Potatoes], Feb. 23, 1906, reprinted in 1 PRONTUARIO, *supra* note 257, at 97–98.

259. See *id.*

260. See Supreme Resolution, Frutas i legumbres, Prohibición de regar cultivos con aguas excluidas [Fruits and Vegetables, Prohibition on Watering with Excluded Waters], Aug. 18, 1911, reprinted in 1 PRONTUARIO, *supra* note 257, at 245–46.

261. In 1898, the National Institute of Vaccines was founded. See Decree, Mar. 21, 1902, art. 1, available at <http://www.congreso.gob.pe/ntley/Imagenes/LeyesXIX/1902034.pdf>. The purpose of this institute was to promote the cultivation and conservation of various therapeutic products to combat infectious disease. See *id.* (recitals). This institute was renamed the National Institute of Vaccines and Serums in 1902. *Id.* The March 21, 1902 decree contemplates that a regulation should be promulgated to govern the Institute, though I was unable to find it.

262. See Reglamento del Instituto Nacional de Vacuna i Seroterapia [Regulation of the National Institute of Vaccines and Serums], Mar. 16, 1906, reprinted in 1 PRONTUARIO, *supra* note 257, at 100–05.

stores, and the like.²⁶³ The Commission would be comprised of three members: one named by the government and two named by the Institute of Pharmacy.²⁶⁴ In addition to conducting the required inspections of drugstores, this body was responsible for maintaining records of the medications which were acceptable and which should be made available to drugstores.²⁶⁵

Within a few months of its creation, the Pharmaceutical Commission elaborated a new set of regulations governing the commercial sale of drugs and medicinal herbs.²⁶⁶ Like many of its predecessors at the national level, this regulation controlled access to the profession, the operation of the drugstore, and the sale of the drugs themselves.²⁶⁷ Unlike its predecessors, this regulation went into a fair amount of depth. The regulation itself boasted ninety-three articles.²⁶⁸ In the past, only a handful of articles in a more general regulation even applied to drugs. Interestingly, this regulation—for the first time—contemplated the creation of an official national pharmacopoeia.²⁶⁹ According to the regulation, until such a pharmacopoeia was created, drugstores were to refer to the *Codex Medicamentarius* of France.²⁷⁰

In its chapter on pharmacies and drugstores, the regulation predictably required inspection and authorization for the establishment to open.²⁷¹ It also predictably prohibited the sale of any medicines or drugs in any establishment that was not a drugstore

263. See Supreme Resolution, Comisión de Farmacia—Se crea una i se aprueba la tarifa de visitas de inspección [Pharmaceutical Commission, A Schedule of Inspections Created], Mar. 31, 1922, reprinted in 2 PRONTUARIO *supra* note 257, at 25–26. The Pharmaceutical Commission created in 1877 must have been dissolved at some point.

264. See *id.* I was unable to find any information about this entity. It is my guess that it is within the *Dirección General de Salubridad* alongside the Institute of Vaccines.

265. See Supreme Resolution, Lista de los medicamentos i útiles de que debe estar provista toda oficina de farmacia [List of Medications That Should Be Provided], June 2, 1922, reprinted in 2 PRONTUARIO, *supra* note 257, at 29–44.

266. See Regulation, Para el ejercicio de la farmacia, comercio de drogas i funcionamiento de herbolerías [Exercise of Pharmacy, Commerce of Drugs], Aug. 24, 1922, reprinted in 2 PRONTUARIO, *supra* note 257, at 57–72.

267. See *id.*

268. See *id.*

269. See *id.* at 63.

270. See *id.* The official authorization to begin work on the pharmacopoeia comes in 1924. See Supreme Resolution, Farmacopea Nacional— Se manda formular sus bases [National Pharmacopoeia, A Mandate to Formulate Its Basis], reprinted in 2 PRONTUARIO, *supra* note 257, at 256.

271. See Regulation, Para el ejercicio de la farmacia, comercio de drogas i funcionamiento de herbolerías [Exercise of Pharmacy, Commerce of Drugs], Aug. 24, 1922, reprinted in 2 PRONTUARIO, *supra* note 257, at 57–62.

and regulated as such.²⁷² Any drugstore that sold expired, altered, or fraudulent drugs was subject to fine and was subject to closure for a second offense.²⁷³ However, this regulation was also much more innovative. First, it provided definitions not previously available, distinguishing among pharmacies, drugstores, and herb shops.²⁷⁴ For example, a “pharmacy” appears to be first defined in this regulation as a shop or laboratory to be used for the preparation and sale of medications; chemical, biological, or vegetable products; and pharmaceutical preparations.²⁷⁵ Second, rather than leaving the work of more specific regulation simply to the discretion of the inspector, this regulation detailed the way the pharmacy must be maintained—lighting, ventilation, flooring, plumbing, etc.²⁷⁶

It is clear that these establishments were more in line with what we normally consider a pharmacy today. Indeed, the regulation even laid out a system of mandatory prescriptions for the dispensation of drugs.²⁷⁷ Certain drugs could only be sold with a prescription.²⁷⁸ They were to be put into a container with a label that clearly indicated the name and address of the pharmacy, the registration number, dosage instructions, and name of the prescribing physician.²⁷⁹ The prescriptions were even registered.²⁸⁰

Pharmacies did not have a monopoly on the sale of drugs. Drugstores were also authorized to sell drugs.²⁸¹ The distinction between the two appears to be that while at a pharmacy a drug might be created, at a drugstore it could only be sold. The lack of regulations regarding prescriptions at drugstores invites the conclusion that the two also sold different kinds of drugs. Nevertheless, drugstores were still regulated. Drugstores had to be licensed and inspected, and they were fined for selling products that were of bad quality, or that were somehow altered or falsified.²⁸² It is worth noting that with respect to narcotics, the government imposed strict controls. For example, it often reserved to

272. *See id.*

273. *See id.* at 63–64.

274. *See id.* at 57–72.

275. *See id.* at 62–63.

276. *See id.* at 64.

277. *See id.* at 64–65.

278. *See id.* at 66.

279. *See id.* at 65–66.

280. *Id.* at 65–66.

281. *See id.* at 69–70.

282. *See id.* at 70.

itself the power to import or export opiates and other narcotics.²⁸³

The third sorts of establishments regulated by the Pharmaceutical Commission were shops selling medicinal herbs. These tended to be run by Chinese owners.²⁸⁴ As with pharmacies and drugstores, the regulation reached every aspect of the shop itself: the kind of floor it could have and the kind of paint used on its walls.²⁸⁵ The herbs themselves were to be sold in glass containers that were clearly labeled.²⁸⁶

That 1922 regulation, while much more comprehensive than anything Peru had previously enacted, still left some open questions regarding what kinds of products were subject to control by the Pharmaceutical Commission. The following year an additional resolution was promulgated in response to some merchants who needed clarification. This resolution spelled out the kinds of products that were not subject to control: medical supplies (thermometers, stethoscopes), toiletries (Vaseline, shaving cream, perfume), soda bicarbonate, mustard, glue, sulfur, antiseptic soap, moth balls, etc.²⁸⁷ By 1926, some of these products did become regulated: dietary supplements, food products for infants, and hygiene products.²⁸⁸

2. Regulation of Manufacturing, Importation, and Sale

In 1924, just two years later, the *Dirección General de Salubridad Pública*²⁸⁹ put out a new regulation to cover issues not raised in the previous one, which had been promulgated the Pharmaceutical Commission.²⁹⁰ This set of regulations covered cura-

283. See, e.g., Supreme Resolution, Drogas tóxicas—El Gobierno se reserva el derecho exclusivo de su importación i exportación [Toxic Drugs, The Government's Exclusive Right to Import and Export], Nov. 16, 1923 reprinted in 2 PRONTUARIO, *supra* note 257, at 197.

284. See discussion of Alternative Medicine, *infra* Part IV.B.4.a.

285. See Regulation, Para el ejercicio de la farmacia, comercio de drogas i funcionamiento de herboleras [Exercise of Pharmacy, Commerce of Drugs], Aug. 24, 1922, reprinted in 2 PRONTUARIO, *supra* note 257, at 71.

286. See *id.*

287. See Artículos que pueden venderse sin control farmacéutico [Items that May Be Sold Without Pharmaceutical Control], June 1, 1923, reprinted in 2 PRONTUARIO, *supra* note 257, at 140–41.

288. Supreme Resolution, Control de productos farmacéuticos [Control of Pharmaceutical Products], Aug. 27, 1926, reprinted in 2 PRONTUARIO, *supra* note 257, at 431.

289. See *supra* note 252.

290. See Supreme Decree, Sueros, vacunas i demás productos biológicos, Reglamento para su control [Regulation for the Control of Serums, Vaccines, and Other Biological Products], Nov. 21, 1924, reprinted in 2 PRONTUARIO, *supra* note 257, at 275–88.

tive serums, vaccines against bacteria and viruses, agents for allergic reactions and the treatment of allergies, *salvarsanes*, and all similar products used in human or veterinary medicine.²⁹¹ Like the previous regulation discussed above, this regulation was modern in the sense that it sought to define specifically the category of drugs to which it applied in a manner very different from the broad regulations of the nineteenth century. This regulation, for the control and vigilance of the manufacture, importation, and sale of biological products (as they were so designated), charged the *Dirección General de Salubridad Pública* with verifying their preservation and efficacy.²⁹²

New biological products could be introduced to the country either through importation or through national development.²⁹³ If they were to be brought into the country from another, there had to be adequate guarantees that they had been produced in accordance with the regulations of the country of origin, and those regulations had to be in accord with Peru's regulations.²⁹⁴ The importer had to present authorization from the country of origin with respect to the laboratory which created the biological products and had to submit notarized documents corroborating that the product had been produced under the regulations of the country of origin.²⁹⁵ Once the biological products entered the country, the *Dirección General de Salubridad Pública* would still monitor its potency, purity, and other measures of efficacy.²⁹⁶ If for some reason the country of origin did not have adequate controls on the development of drugs, then anyone hoping to import those biological products into Peru would have had to follow procedures for verification and testing in the country—essentially, they had to follow the same regulations that pertain to drugs developed nationally.²⁹⁷ That verification and testing was the responsibility of the National Institute of Vaccines and Serums described above.²⁹⁸

While regulating the importation and customs treatment of biological products entering from other countries, this regulation also set out to regulate the production of these drugs in Peruvian

291. *See id.* at 276–77.

292. *See id.* at 277.

293. *See id.*

294. *See id.*

295. *See id.* at 278.

296. *See id.* at 277.

297. *See id.* at 278.

298. *See id.*

laboratories. While the laboratories themselves were regulated elsewhere, the regulation at hand additionally provided that the technician in charge of creating the serums, vaccines, or other biological products had to hold a special certificate granted by the *Dirección General de Salubridad Pública*.²⁹⁹ Any animals that produced serums for these laboratories had to be tested for tuberculosis and should have been immunized.³⁰⁰ The laboratories would be subject to the authority of the National Institute for Vaccines and Serums with respect to their operation, techniques, and treatment of animals.³⁰¹

The products themselves were regulated as well. This regulation provided for certain labeling requirements: product name, manufacture date, potency, proportion/concentration of antiseptic (if used), name of the manufacturer and location, and, if imported, the country of origin.³⁰² In addition, the regulation specified part of the contents of these biological products. For example, the maximum allowable amount for antiseptics was 0.5%.³⁰³ All liquid serums must have had a maximum of ten percent extract and could not contain any potentially toxic chemicals other than the permitted antiseptics.³⁰⁴ Any serums that appeared milky or otherwise tumultuous were to be discarded.³⁰⁵ Similarly detailed regulations were provided for vaccines and arsenic-based *salvarsanes*.³⁰⁶

3. Narcotics as Controlled Substances

The discussion of drug regulation at this time would not be complete without some mention of narcotics as controlled substances. In 1921 the Peruvian legislature passed and President Augusto Leguía enacted what may have been the first controlled substances act in Peru.³⁰⁷ By this law, the government sought to control opium, morphine, cocaine, heroin, and their derivatives.³⁰⁸ In 1925, however, the government clarified that novocaine was not

299. *See id.* at 281.

300. *See id.*

301. *See id.*

302. *See id.* at 282.

303. *See id.*

304. *See id.*

305. *See id.* at 283.

306. *See id.* at 282–88.

307. *See* Law No. 4428, *Opio i drogas tóxicas* [Opium and Toxic Drugs], Nov. 26, 1921, *reprinted in* 2 PRONTUARIO, *supra* note 257, at 20.

308. *See id.*

considered a controlled substance.³⁰⁹

The Port of Callao (just outside of Lima) was declared to be the only port open for the importation or exportation of these substances.³¹⁰ Any trade in these substances could happen only with the authorization of the *Dirección General de Salud Pública*.³¹¹ This meant that any merchant who hoped to import or export these controlled substances had to register with that agency and report his transactions.³¹² This registration requirement extended to any laboratory or pharmacy that purchased these substances, and no controlled substances could be sold to establishments that were not approved by the *Dirección*.³¹³ Pharmacies could only sell these substances to the public upon presentation of an original prescription made out by a doctor, dentist, or veterinarian.³¹⁴ The scripts were to be filed and stored.³¹⁵ This law and a subsequent amendment also laid out penalties for engaging in the illicit trade and recreational use of these substances.³¹⁶

It appears that authorization to engage in the trade of any controlled substances could have operated as a monopoly to the firm with the authorization. In 1925, for example, an American company, Gratry American Establishments, filed a petition with the government to take over a contract for the administration and sale of certain drugs upon the dissolution of the company which had previously owned the contract.³¹⁷ The government granted

309. Supreme Resolution, *Drogas tóxicas—La novocaína no está comprendida entre las drogas a que se refiere la ley 4428* [Novocaine Not Included Among Drugs in Law No. 4428], Sept. 25, 1925, reprinted in 2 PRONTUARIO, *supra* note 257, at 376–77.

310. See Law No. 4428, *Opio i drogas tóxicas* [Opium and Toxic Drugs], Nov. 26, 1921, reprinted in 2 PRONTUARIO, *supra* note 257, at 20.

311. See *id.*

312. See *id.*

313. See *id.* at 21.

314. See *id.*

315. See *id.* at 21; see also Supreme Resolution, *Control del comercio de narcóticos* [Control of Narcotics], July 16, 1926, reprinted in 2 PRONTUARIO, *supra* note 257, at 429 (reaffirming that pharmacies may only dispense these substances with a script and requiring physicians who may use these substances in their practices to obtain permission from the Section of Narcotics of the *Dirección de Salubridad Pública*).

316. See Law No. 4428, *Opio i drogas tóxicas* [Opium and Toxic Drugs], Nov. 26, 1921, reprinted in 2 PRONTUARIO, *supra* note 257, at 21–22; see also Supreme Resolution, *Control de drogas tóxicas—Medidas destinadas a asegurar su eficacia* [Measures To Assure Efficacy], Jan. 8, 1926, reprinted in 2 PRONTUARIO, *supra* note 257, at 392.

317. See Supreme Resolution, *Drogas tóxicas—Transferencia del contrato celebrado entre el Gobierno i la casa Ph. Ott & Co., a los Establecimientos Americanos Gratry* [Transferring Contract Between Government and Ph. Ott. & Co. to Gratry American Establishments], Sept. 11, 1925, reprinted in 2 PRONTUARIO, *supra* note 257, at 374.

the petition and ordered the *Dirección* to monitor those drugs.³¹⁸

4. Some Miscellaneous Regulations

During the first quarter of the twentieth century, food and drug were regulated under other headings as well. Two of these, alternative medicine and basic food stuffs, are presented below.

a. Alternative Medicine

In the latter half of the nineteenth century, Peru, like the United States, received waves of Chinese immigrants in the form of indentured servants to work the sugar plantations.³¹⁹ The large population stayed in Peru and apparently retained some of its medicinal practices. In 1915 the Faculty of Medicine denounced the illegal practice of medicine by Asian herbalists.³²⁰ These herbalists had been permitted to sell medicinal herbs, but they had not been authorized to practice medicine.³²¹ It seems that the normal regulations governing drugstores were a strange fit for these herbalists. In 1916, a regulation was passed specifically governing Asian herbalists.³²² This regulation declared that these stores would be considered drugstores and would only be permitted to sell medicinal herbs, examined and classified by the Pharmaceutical Commission.³²³ They would require a license from the relevant local or provincial government and would be subject to inspection.³²⁴ They were not permitted to practice medicine and they could not otherwise sell medications of any kind—these herbalists were not even permitted to advertise any potentially curative effects of their products.³²⁵ Infractions of this regulation were penalized with the closure of the store and a penalty assessed by

318. *See id.*

319. *See generally* HUMBERTO RODRÍGUEZ PASTOR, *HIJOS DEL CELESTE IMPERIO EN EL PERÚ (1850–1900): MIGRACIÓN, AGRICULTURA, MENTALIDAD Y EXPLOTACIÓN* [CHILDREN OF THE CELESTIAL EMPIRE IN PERU: MIGRATION, AGRICULTURE, MENTALITY, AND EXPLOITATION] (Lima, Instituto de Apoyo Agrario 1989) and HUMBERTO RODRÍGUEZ PASTOR, *HEREDEROS DEL DRAGÓN: HISTORIA DE LA COMUNIDAD CHINA EN EL PERÚ* [HEIRS OF THE DRAGON: HISTORY OF THE CHINESE COMMUNITY IN PERU] (Lima, Fondo Editorial del Congreso del Perú 2000).

320. *See* Supreme Resolution, *Herbolerías asiáticas* [Asian Herb Stores], Feb. 27, 1915, *reprinted in* 1 PRONTUARIO, *supra* note 257, at 272–73.

321. *See id.*

322. *See* Supreme Resolution, *Herbolerías asiáticas—Reglamento* [Regulation of Asian Herb Stores], July 7, 1916, *reprinted in* 1 PRONTUARIO, *supra* note 257, at 310–11.

323. *See id.* at 310.

324. *See id.*

325. *See id.* at 310.

the local officials.³²⁶

b. Production and Regulation of Staple Goods

Thus far, the discussion of the development of food and drug regulation in Peru has focused on the public health side. During the time of World War I, the Ministry of the Treasury set out on a legislative and regulatory project governing basic products like alcohol, sugar, guano, combustibles, and various staple food products.³²⁷ The substance of these regulations was primarily economic and tied to the production of these products and the prices at which they could be sold. Indeed, many of the laws specifically conferred certain rights to particular companies to produce and sell certain goods. However, a bit of food regulation crept in.

For example, when Santa Rosa S.A. wanted a contract with the Ministry for the sale of bread, it had to abide by certain quality standards. The bread had to contain seventy-seven parts of flour for every hundred parts of cereal. Each piece had to be 150 grams.³²⁸ Similarly, when grains were imported and found to be of bad quality, they were to be deposited with the state's warehouses and possibly sold to the public at a discount.³²⁹ While these might not be more than mere terms of a contract, spelling out the parameters for the goods to be delivered, they could also represent standards of quality that the government set for itself and by example for the country.

C. The Birth of the Ministry of Health

The provisions discussed above all brought Peru closer to the present-day system of regulation. The major milestone here, in the history of public health in Peru, and by implication for the development of food and drug regulation, is certainly the creation of the Ministry of Health. Before the 1930s, public health was administered through various other ministries. This section will discuss the inauguration of the Ministry of Health and the work undertaken there. It will end with a brief discussion of a cross-

326. *See id.* at 311.

327. *See* 2 INSPECCIÓN FISCAL DE SUBSISTENCIA, LEGISLACIÓN Y REGLAMENTACIÓN SOBRE SUBSISTENCIAS, [LEGISLATION AND REGULATION OF SUBSISTENCE ITEMS], (Lima, Imp. Torres Aguirre 1921) [hereinafter LEGISLATION AND REGULATION].

328. *See* Law of May 1, 1917, *reprinted in* LEGISLATION AND REGULATION, *supra* note 327, at 184.

329. *See* Venta en remate público de cereales en mal estado [Public Sales of Cereals of Poor Quality], Sept. 29, 1920, *reprinted in* LEGISLATION AND REGULATION, *supra* note 327, at 548.

ministry and cross-sector *junta* on food and nutrition that was both created and repealed during the 1940s.

1. The Need for a New Ministry

Ultimately, the *Dirección General de Salubridad* underwent many structural changes over the years as different governments and different regimes came to power. New services, councils, and departments were created. The power to regulate was decentralized and then recentralized, and the agency was at times powerful or weak.³³⁰ By 1935 the *Dirección* faced ever increasing and complex responsibilities. It became necessary at that point for public health to get its own ministry in the government.³³¹

The new ministry was named the Ministry of Public Health, Works, and Social Welfare.³³² The Ministry brought the *Dirección General de Salubridad* over from the Ministry of Development, along with a handful of other agencies from other ministries.³³³ In 1942, the Ministry was renamed, becoming the Ministry of Public Health and Social Assistance.³³⁴

The structure of the Ministry of Public Health appears to have been borrowed from the General Health Regulations of 1884 and 1887. The Ministry is divided into different services, but these are now more numerous and complex than the nineteenth-century division (of two services, maritime and land). The Ministry, through the *Dirección*, included a National Anti-Malaria Service³³⁵ and a National Anti-Tuberculosis Service³³⁶ among others.

330. See BUSTÍOS ROMANÍ, *supra* note 5, at 460–82.

331. See Ministerio de Salud, *Reseña Histórica* [Ministry of Health, Historical Description], <http://www.minsa.gob.pe/portal/00Institucional/rhistorica.asp> (last visited Feb. 5, 2007).

332. Like any department, the tasks of this new ministry went beyond mere regulation. Several *juntas* were set up within the ministry to handle finance, procurement, etc. For some of the resolutions and statutes setting up the structure of the Ministry of Public Health, see LEGISLACIÓN SANITARIA, LABORAL, ALIMENTICIA: LEYES, DECRETOS, REGLAMENTOS Y RESOLUCIONES DE CARÁCTER GENERAL, EXPEDIDOS POR EL MINISTERIO DE SALUD PÚBLICA, TRABAJO Y PREVISIÓN SOCIAL 3–12 (1941) (recompilation of laws, decrees, regulations, etc., pertaining to the Ministry of Public Health, 1940–1941) [hereinafter LEGISLACIÓN SANITARIA].

333. See Law No. 8124, Oct. 5, 1935, art. 3, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/08124.pdf> (creating the Ministry of Public Health, Works, and Social Welfare).

334. See Law No. 9679, Dec. 11, 1942, art. 3, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/09679.pdf>.

335. See Supreme Resolution No. 41, El servicio nacional antimalárico [National Anti-Malaria Service], Jan. 13, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 15–16 (establishing this service both at a national and rural level).

336. See Supreme Resolution No. 42, El servicio nacional antituberculoso [National

The birth of the Ministry of Health marks an important milestone in the history of public health in Peru. Starting in 1935 there would be a cabinet position dedicated to the protection and elaboration of public health. For purposes of the development of food and drug regulation in Peru this is significant in that there will be an important situs for that project. While there may be additional regulation of food or drug through other ministries (for example, the Ministry of Agriculture), the bulk of it would come through the Ministry of Health, and this is true in the present day.

2. The Work of the Ministry with Respect to Food and Drug

Naturally, the Ministry of Public Health had a prominent role in the regulation of food and drug. With respect to drugs, the Ministry of Public Health established a central laboratory.³³⁷ This laboratory was intended to be for the preparation of ampoules and other pharmaceutical formulas.³³⁸

The Ministry's regulation of food happened at many levels. Not only did the Ministry regulate such things as food safety, but it also regulated supply and prices. In 1940, another high-level agency was created inside the Ministry of Health: the *Dirección de Subsistencias*.³³⁹ This agency's mission was to secure the supply and consumption of basic food products, with an eye to thereby protect the wages and salaries of workers.³⁴⁰ This agency would be a technical one, studying the problem of supply and demand of basic food products.³⁴¹ It would include three divisions: one to study nutrition, another to study volume and quality of the production or manufacture of basic food staples, and a third to enact and coordinate the agency's functions at various levels.³⁴² It appears that this agency is replicated on more local levels by a structure of *Juntas Permanentes de Subsistencias Provisionales y*

Anti-Tuberculosis Service], Jan. 13, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 16-17.

337. See Supreme Resolution No. 821, El laboratorio central del ministerio [The Central Laboratory of the Ministry], Mar. 20, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 21.

338. See *id.*

339. Supreme Decree, Se crea la Dirección de Subsistencias [Creating State Subsistence Agency], Feb. 19, 1940, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 195-96.

340. See *id.*

341. See *id.*

342. See *id.*

Distributales (Permanent Juntas of Provisional and District Subsistence).³⁴³ It also appears that the division of nutrition may have morphed into its own agency, the *Dirección de Alimentación Nacional* (State Agency of National Nutrition), within a year.³⁴⁴

Through these responsibilities, the Ministry of Public Health, Work, and Social Planning was highly involved in the market for food items in Peru. For example, in 1941, the Ministry, through the *Dirección de Alimentación Nacional*, set out to combat food scarcity in Lima and Callao, its port cities.³⁴⁵ The scarcity was the product of several factors. First, there had been a prolonged drought in 1940. Second, there had been heavy rains which washed out or otherwise damaged major highways into the capital, making transportation of food items difficult and costly. Third, merchants and producers had engaged in illegal hoarding which was driving up the cost of these food items.³⁴⁶ The solution was for *Dirección de Alimentación Nacional* to purchase and sell the food items to be consumed in Lima and Callao. These items would be sold directly to the public and to certain small merchants, at prices set by the *Dirección*.³⁴⁷ Later that same year, the *Dirección de Alimentación Nacional* received a blanket authorization to purchase food items as necessary to fulfill its obligations.³⁴⁸ This even included superseding private contracts and purchasing basic food items that the *Dirección* found in transport on the railroads.³⁴⁹ The agency would then compensate the true owner of those food stuffs for the goods seized.³⁵⁰ The work of the Ministry on the supply side of the food industry extended to dictating what foods would be grown in each harvest cycle³⁵¹ and reg-

343. See Supreme Resolution, Guía de circulación de artículos alimenticios [Guide for Circulation of Food Products], July 6, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 197 (referring to the responsibilities of the *Juntas Permanentes de Subsistencias* [Permanent Subsistence Juntas]).

344. See *id.* (referring to the *Dirección de Alimentación Nacional* [State Board of National Nutrition], charged with maintaining information regarding the production and consumption of basic food staples).

345. See Supreme Resolution, Autorización para el establecimiento de puestos y estanquillos [Authorization for the Establishment of Markets], Mar. 6, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 203.

346. See *id.*

347. See *id.*

348. See Supreme Resolution, Aplicación de la ley no. 9047 [Application of Law No. 9047], May 3, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 214.

349. See Supreme Decree, May 21, 1941, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 215-16.

350. See *id.*

351. See Supreme Resolution, Cultivos obligatorios de artículos alimenticios

ulating (and deregulating) the cattle, meat, and fish industries.³⁵²

While the work of the Ministry of Public Health in the area of food regulation appears to have been mainly concerned with supply and production of staple goods, the Ministry was also involved with setting some food identity standards (though they were not designated as such) in the course of its regulation of food production. For example, in 1940 Peru began to import, due to a gap in domestic production, wheat for the production of bread.³⁵³ But, at the time, Peru's production of other grains, like hops (*centeno*) and quinoa, were unaffected.³⁵⁴ By law, the *Dirección de Subsistencias* stepped in to regulate the quantities of wheat, hops, and quinoa that mills could grind.³⁵⁵ The law also set maximum proportions of the domestic grains to be used in the production of bread: eighty percent imported wheat, fifteen percent hops, and five percent quinoa.³⁵⁶ The *Dirección de Subsistencias* promulgated a regulation of this law, clarifying the ingredients that could be used to make flour from hops and flour from quinoa. Furthermore, all bakeries were required to buy eighty percent wheat flour, fifteen percent hops flour, and five percent quinoa flour.³⁵⁷ It appears that despite these measures to deal with the shortage of domestically-produced wheat, a year later the situation had not improved. In May 1941, the government authorized the use of rice-based flour in the production of bread, requiring its use for ten percent of the production of bread.³⁵⁸ Outside the context of bread produc-

[Obligatory Cultivation of Food Articles], Mar. 26, 1940, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 221.

352. *See* Supreme Resolution, En favor de la industria ganadera [In Favor of the Cattle Industry], May 30, 1940, *in* LEGISLACIÓN SANITARIA, *supra* note 332, at 224–25; Ministerial Resolution, Disposiciones relacionadas con el abastecimiento de carnes y pescado [Dispositions Related to the Supply of Meat and Fish], Sept. 11, 1940, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 226–27.

353. *See* Supreme Resolution, Disposiciones relacionados con la panificación [Dispositions Related to Baking], July 8, 1940, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 231–32.

354. *See id.*

355. *See id.*

356. *See id.*

357. *See* Reglamentación de la precedente resolución [Regulation of Preceding Resolution], July 8, 1940, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 232–34.

358. *See* Supreme Resolution, Reglamentación de la venta de arroz quebrado blanco para panificación [Regulation for the Sale of White Rice for Baking], May 16, 1941, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 235–36; *see also* Ministerial Resolution, Reglamentación de la venta de arroz quebrado para la panificación [Regulation of Sale of Rice for Baking], July 9, 1941, *reprinted in* LEGISLACIÓN SANITARIA, *supra* note 332, at 251–53.

tion, rice itself was subject to regulation in 1940. This was intended both as a form of nomenclature for new varieties of rice being developed and as a way to protect and inform the consumer. That regulation set out to classify rice of different varieties into "classes" according to various factors like color, maturation, impurities, etc.³⁵⁹ Additionally, the sale of rice was also regulated. Merchants were required to have a sample of each lot of rice analyzed by the *Dirección de Subsistencias*, after which a certificate would be affixed to the lot.³⁶⁰ Furthermore, the rice was subject to price ceilings.³⁶¹

In the 1940s, the Ministry of Public Health's regulation of food seems primarily focused on the production side. The problem of scarcity of basic food items forced the Ministry and its agencies to regulate supply, prices, importation, and identities of basic food stuffs. While the regulations above purport to provide quality standards for bread and rice, it is likely that they did not result in "high quality" foods at all. Indeed, these were the product of rationing and not a desire to secure tasty bread for the people.

3. A New National *Junta*

In 1945 Peru set up a new *junta*, the National Junta of Food and Nutrition.³⁶² This *junta* would study the problem of nutrition and food production at the national level and propose solutions to the legislature and the executive.³⁶³ The members of this *junta* would come from various agencies and ministries: the legislature, some agencies within the Ministry of Agriculture, the National Institute of Nutrition within the Ministry of Public Health, and professors at the National University of San Marcos.³⁶⁴

A few years later, the military government of Manuel Odría dissolved the National Junta of Food and Nutrition.³⁶⁵ The military *junta* believed that the National Junta was incapacitated by its allegiance to too many masters.³⁶⁶ It was comprised of repre-

359. See Supreme Resolution, Reglamentación del comercio de arroces pilados [Regulation of Commerce of Rice], May 30, 1940, reprinted in LEGISLACIÓN SANITARIA, *supra* note 332, at 238-45.

360. See *id.* at 247.

361. See *id.*

362. See Law No. 10325, Dec. 17, 1945, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/10325.pdf> (creating the National Junta of Food and Nutrition).

363. See *id.* art. 2.

364. See *id.* art. 1.

365. See Decree-Law No. 10944, Jan. 17, 1949, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/10944.pdf> (repealing Law No. 10325).

366. See *id.* (recitals).

sentatives from numerous agencies both within the legislature and within the executive, making it difficult for it to accomplish its objectives.³⁶⁷ Problems of alimentation and nutrition were believed to be better dealt with by the respective agencies on their own.³⁶⁸ Unfortunately, no information regarding the projects or proposals of this National Junta was uncovered.

This short-lived and apparently ill-respected *junta* might appear to have no significance to the project of food regulation. However, it further underscores the importance of the birth of the Ministry of Health—the importance of having a central body responsible for regulation. The experiment in cross-discipline investigation and proposed legislation seemingly failed, though it would likely resurrect itself in discrete projects in the future.³⁶⁹

D. Regulation Under Military-Authoritarian Rule, 1968–1980

In 1968, a military coup led by General Juan Velasco toppled the civilian government of President Belaúnde, seeking to usher in a left-wing revolution. It is not surprising, then, that General Velasco's government would choose to re-invent Peruvian public administration (if only nominally).

In 1969, the Revolutionary Government of General Velasco enacted a new law governing the Ministry of Health.³⁷⁰ The Ministry was set up with several departments and agencies.³⁷¹ Important to the development of food and drug regulation was the creation of the National Institutes of Health under the direction of the Ministry of Health.³⁷² This institution would generally investigate problems of health and serve as a national repository for research and information.³⁷³ More specifically, the tasks of the National Institutes of Health were as follows:

- To elaborate biological products for immunization, treatment, or diagnosis;

367. *See id.*

368. *See id.*

369. One example may be the Peruvian Codex Alimentarius, which was the product of the work of various agencies including the Ministry of Health, the Ministry of Commerce, and the Ministry of Agriculture. *See* Codex Alimentarius Peru, <http://www.digesa.sld.pe/CodexPeru/index.htm> (last visited Feb. 10, 2007).

370. *See* Decree-Law No. 17523, Mar. 21, 1969, *available at* <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/17523.pdf> (law of the Ministry of Health).

371. *See id.*

372. *See id.* art. 19.

373. *See id.*

- To verify the quality of drugs, cosmetics, foods, and other biological products;
- To promote nutrition;
- To protect the health of workers by setting occupational safety standards.³⁷⁴

This institution appears to have combined the functions of the pharmaceutical commissions from the 1920s with some additional responsibilities over food and cosmetics. Before the National Institutes of Health was created, it is unclear whether there may have been some other institution administering food or cosmetics regulation, but none was identified through research. Cosmetics may have been partly regulated under the regulations for pharmacies in the 1920s.³⁷⁵

A few months after the reorganization of the Ministry of Health, the military government enacted the first law in Peru to put food adulteration front and center.³⁷⁶ Clearly, concerns about food and drug adulteration were present in earlier regulations that penalized the sale of damaged foods, but there are two distinctions. First, the term “adulteration” had not been used on a national level. Second, this law explicitly focused on food. Previous regulations often included passing references to food only as part of a more comprehensive health regulation.

This law came as part of the government’s efforts to protect the normal supply of food in Peru—the law made food adulteration, hoarding, and speculation illegal.³⁷⁷ The law defined food adulteration as the fabrication or elaboration of food products with properties that did not correspond to their stated quality or the offer or sale of these items either in a state of decomposition or with the knowledge that they are adulterated.³⁷⁸ The law defined speculation mostly in terms of sales of food items either without proper authorization or at an illegal price, but it was also considered speculation to fraudulently alter the weight of a food product.³⁷⁹ The food adulteration law did not go into details about what might constitute food adulteration or speculation. The Ministry of Agriculture and Fishing was charged with promulgating

374. *See id.*

375. *See supra* notes 287–88 and accompanying text.

376. *See* Decree-Law No. 17681, June 3, 1969, *available at* <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/17681.pdf> (penalizing the violation of rules pertaining to the sale of food products).

377. *See id.*

378. *See id.* art. 2.

379. *See id.* arts. 4(c), 4(d).

the regulations under this law, in coordination with the Ministries of the Interior, of Health, and of Industry and Commerce.³⁸⁰

The food adulteration law laid out a scheme for its enforcement. Those who violated the law would be subject to administrative sanctions, including a fine of between 1000 and 5,000,000 *soles*, forced closure of the establishment or business for at least two years, or deportation (after a fine or closure) in the case of foreigners.³⁸¹ These sanctions were not mutually exclusive.³⁸²

The enforcement of this law was not limited to penalizing offenses. The law created special administrative tribunals to mete out those penalties—Tribunals against Adulteration, Hoarding, and Speculation.³⁸³ These tribunals were to have national, departmental, and provincial jurisdictions.³⁸⁴ The national tribunals were to be headed by an official nominated by the Ministry of Agriculture and Fishing, and the rest of the tribunals would be composed of delegates from the Ministry of the Interior, Ministry of Health, and Ministry of Industry and Commerce.³⁸⁵ These would be selected by Supreme Resolution and the most senior member of the Supreme Court of Justice in Lima.³⁸⁶ The departmental tribunals were to be headed by the Prefect of the department and representatives of the various ministries as above, and the provincial tribunals were to be headed by the Sub-Prefect and representatives of the Ministries.³⁸⁷ The rest of the decree was dedicated to the specific tasks of these tribunals.³⁸⁸ Additionally, the decree anticipated the promulgation of a regulation governing the administrative procedures to be followed by these tribunals.³⁸⁹

While as before, data regarding the enforcement or prosecution of this decree is lacking, this development—under authoritarian rule—indicates a more sophisticated administrative apparatus in place to deal with issues of food safety.

V. CURRENT REGULATION

So far, this Article has traced the development of food and

380. *See id.* art. 21.

381. *See id.* art. 5.

382. *See id.* art. 6.

383. *See id.*

384. *See id.* art. 11.

385. *See id.* art. 12.

386. *See id.*

387. *See id.* arts. 13–14.

388. *See id.* arts. 16–23.

389. *See id.* art. 15. Unfortunately, this regulation was not uncovered.

drug law through a period of nearly five hundred years. This discussion would not be complete without at least an overview of the regulatory regime in place in Peru today. The regulation of food and drug falls into two categories: public health regulation and consumer protection.

A. *Under the Rubric of Health*

Like much of the history of food and drug regulation in Peru that has been covered so far, the bulk of the current regulation in Peru on this subject comes under the rubric of public health. The major regulatory bodies in this category are naturally within the Ministry of Health. This section of the Article will discuss first the General Law of Health which, along with two companion regulations, lays out the framework for food and drug regulation in Peru. Next the Article will discuss the two agencies within the Ministry of Health most active in food and drug regulation.

1. The General Law of Health

The current General Law of Health dates to 1997, during the second administration of Alberto Fujimori.³⁹⁰ This was a massive undertaking, with 137 articles in six titles.³⁹¹ Most relevant to this Article is title two, on the rights, restrictions, and responsibilities in consideration of the health of others.³⁹² Chapter three relates to pharmaceutical products, and chapter five relates to foods and beverages, cosmetic products, sanitary and hygiene products, and medical-surgical equipment.³⁹³ The main regulatory mechanism for both of these chapters is registration.³⁹⁴ Beyond registration, of course, these products are subject to certain safety standards. Interestingly, while the chapter on drug regulation simply indicates that the national health authorities are in charge of the sanitary control of pharmaceutical products,³⁹⁵ the chapter on food regulation includes a requirement that food products comply with sanitary norms and quality standards approved by the

390. See Law No. 26842, Ley General de Salud [General Law of Health], July 9, 1997, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/26842.pdf> [hereinafter General Law of Health].

391. See *id.*

392. See *id.* arts. 22–107.

393. See *id.* arts. 49–75.

394. See, e.g., *id.* arts. 50, 91 (describing registration of pharmaceutical products for manufacture, importation, or distribution and registration of food products).

395. See *id.* art. 49.

national health authorities.³⁹⁶ The regulation of potentially dangerous products, whether they be food or drug, falls into a separate chapter regulating products and substances that may be dangerous to one's health.³⁹⁷

Various regulations were promulgated to elaborate the General Law of Health. Two regulations are relevant to the administration of the provisions relating to food and drug. The Regulation on the Monitoring and Sanitary Control of Food and Beverages ("Food and Drink Regulation") seeks to "guarantee the healthy production and supply of food and beverages for human consumption, facilitate their safe commerce, and incorporate the general principles of hygiene for foods recommended by the commission of the Codex Alimentarius."³⁹⁸ Drugs and pharmaceutical products are regulated by the Regulation for the Registration, Control, and Sanitary Vigilance of Pharmaceutical Products and the Like ("Pharmaceutical Regulation").³⁹⁹ More about the content of these regulations will be discussed below with respect to the specific agencies that undertake this work.

2. Ministry of Health

Food and drug regulation falls under the more general rubric of health regulation. This is the charge of the Ministry of Health: to improve the health and quality of life of the people.⁴⁰⁰ In 1990 the Executive undertook to reorganize the Ministry of Health, relying on the power delegated to it by congress to legislate the organization and functions of the various ministries.⁴⁰¹ The resulting legislative decree gives the Ministry of Health jurisdiction over the regulation of food and drug by enumerating various

396. *See id.* art. 89.

397. *See id.* arts. 96–99.

398. Supreme Decree No. 007-98-SA, Aprueban el Reglamento sobre Vigilancia y Control Sanitario de Alimentos y Bebidas [Regulation on the Monitoring and Sanitary Control of Food and Beverages], Sept. 24, 1998, *available at* http://www.minsa.gob.pe/leyes/ds00798sa_rvcab/ds.htm (recitals) (translation by author) [hereinafter Food and Drink Regulation].

399. Supreme Decree No. 010-97-SA, Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos y Afines [Regulation for Registration and Control of Pharmaceutical Products and the Like], Dec. 23, 1997, *available at* http://www.minsa.gob.pe/leyes/DS-010-97-SA_RPF/index.htm [hereinafter Pharmaceutical Regulation].

400. *See* Legislative Decree No. 584, Aprueba Ley de Organización y Funciones del Ministerio de Salud [Organization and Functions of the Ministry of Health], Apr. 16, 1990, art. 2, *available at* <http://www.congreso.gob.pe/ntley/Imagenes/DecretosLegislativos/00584.pdf> [hereinafter Ministry of Health Decree].

401. *See id.* (recitals).

areas of responsibility. Most relevant to this Article are control over the health of the individual, family, and community;⁴⁰² environmental and occupational health;⁴⁰³ investigation and development of health technologies;⁴⁰⁴ and the production, quality, use, and sale of pharmaceutical and other medical goods.⁴⁰⁵ In 2002, during the administration of President Alejandro Toledo, the law governing the structure and function of the Ministry of Health was repealed and a more expansive one replaced it.⁴⁰⁶

The structure of the Ministry of Health reflects its responsibilities. In addition to its administration and various support and consulting organizations at various levels on the hierarchy, the Ministry of Health includes under its umbrella various agencies (*órganos de línea*).⁴⁰⁷ These are the *Dirección General de Salud de las Personas*, the *Dirección General de Salud Ambiental* (DIGESA), the *Dirección General de Medicamentos, Insumos y Drogas* (DIGEMID), and the *Dirección General de Promoción de Salud*.⁴⁰⁸ These agencies are technical and normative in nature.⁴⁰⁹ They fall under the authority of the vice minister of health and are charged with formulating, standardizing, coordinating, supervising, and evaluating various health policies at the national level.⁴¹⁰ Further, they must provide the scientific data and develop the necessary technologies to inform the policy decisions at the higher levels.⁴¹¹ The more specific jobs of regulation and enforcement of food and drugs fall to DIGESA and DIGEMID, respectively.⁴¹²

While the Ministry of Health seems the department most suited to the development of food and drug law, especially given the agencies under its umbrella, food and drug law may be developed by any of the relevant Ministries. For example, consider the Peruvian *Codex Alimentarius*.⁴¹³ This document lists all current

402. *See id.* art. 3(a).

403. *See id.* art. 3(b).

404. *See id.* art. 3(d).

405. *See id.* art. 3(i).

406. *See* Law No. 27657, Ley del Ministerio de Salud [Law of the Ministry of Health], Jan. 17, 2002, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27657> [hereinafter Ministry of Health Law].

407. *See id.* art. 6(7).

408. *See id.* The *Dirección General de Promoción de Salud* was not part of the 1990 legislation. *See also* Ministry of Health Decree, *supra* note 400, art. 5.

409. *See* Ministry of Health Law, *supra* note 406, arts. 24–27.

410. *See* Ministry of Health Decree, *supra* note 400, art. 22.

411. *See id.*

412. *See id.* arts. 24–27.

413. *See* Codex Alimentarius Peru, Normatividad Materia de Inocuidad, http://www.digesa.sld.pe/CodexPeru/normativa_digesa.asp (last visited Feb. 10, 2007).

national legislation on the subject of food regulation.⁴¹⁴ This chart reveals that regulations have been promulgated in different sectors: agriculture, fishing, industry, health, and municipalities.⁴¹⁵ At the same time, regulations have been promulgated by different government departments: Ministry of Agriculture, Ministry of State, Ministry of Fishing, Ministry of Industry, Commerce, Tourism and Integration, Ministry of Health, and the Municipality of Lima. Lastly, regulations have been promulgated at the agency level: DIGESA, INDECOPI (consumer protection), and SENASA (agriculture).⁴¹⁶

2. DIGESA

Today, DIGESA, the State Board of Environmental Health, is organized and governed by a 2002 Supreme Decree that was enacted as part of efforts to modernize the administration of the state.⁴¹⁷ Per its governing statute, DIGESA is charged with regulating basic sanitation, occupational health, food sanitation, zoonosis, and environmental protection.⁴¹⁸ DIGESA is a general agency; for each of these tasks, an executive agency has been created: Executive Board of Environmental Health, Executive Board of Food Sanitation and Zoonosis (“DEHAZ”), Executive Board of Ecology and the Environment, and Executive Board of Occupational Health.

DEHAZ is in charge of coordinating the plans and programs relating to the protection of food and drink and to the control of zoonosis, the potential for certain diseases to pass from animals to humans.⁴¹⁹ DEHAZ must also promulgate norms pertaining to the hygienic and sanitary control of consumables like food and drink.⁴²⁰ This covers a very broad spectrum of tasks. DEHAZ proposes and arranges the technical underpinnings for the development of national policies relating to the protection of food and the prevention of zoonosis.⁴²¹ At a more practical level, DEHAZ also

414. *See id.*

415. *See id.*

416. *See id.*

417. *See* Supreme Decree No. 013-2002-SA, Aprueba Reglamento de la Ley del Ministerio de Salud [Regulation of the Law of the Ministry of Health], Nov. 22, 2002 (recital, referring to Law No. 27658 for modernization of the State).

418. *See* Ministry of Health Decree, *supra* note 400, art. 24.

419. *See* DIGESA, Acerca de la Dirección Ejecutiva de Higiene Alimentaria y Zoonosis—DEHAZ, http://www.digesa.sld.pe/pw_dehaz/inicio.asp (last visited Jan. 23, 2007).

420. *See id.*

421. *See id.*

establishes technical guidelines and norms for the control of pathogens and the safety of food and beverages.⁴²² At a macro level, DEHAZ coordinates and advises the development of food sanitation and safety at the local, regional, and national levels.⁴²³ It also sets up protocols and procedures for public and private organizations involved with food safety, and it regulates manufacturers in their development, manufacturing, and sale of food and beverages to the public.⁴²⁴ Lastly, DEHAZ works to implement technical standards related to food safety and sanitation that are developed through international conventions and agreements.⁴²⁵

Most of the day to day of DIGESA's regulatory work appears to be the registration and certification of various products and producers. This is evident from the DIGESA's TUPA, the *texto único de procedimientos administrativos*.⁴²⁶ This is a detailed chart laying out the various responsibilities of the department, consolidated from the requirements and procedures laid out in various laws and degrees, the most important of which is the General Law of Health.⁴²⁷ Most pertinent to an investigation of food and drug regulation are the maintenance of the registry for health and safety of food and beverage and various certifications for imports and exports.⁴²⁸

In Peru, all food or beverage products mass-produced, whether of domestic or foreign origin, can only be sold after registration.⁴²⁹ To register, a producer must meet certain requirements.⁴³⁰ First, a producer must fill out a simple form—domestic products and foreign imports require different forms.⁴³¹ To this

422. *See id.*

423. *See id.*

424. *See id.*

425. *See id.*

426. Supreme Decree No. 001-2002-SA, Texto Único de Procedimientos Administrativos del Ministerio de Salud [Text of Administrative Procedures for the Ministry of Health], Mar. 2, 2002, available at <http://www.digesa.sld.pe/pdf/tupa.pdf> [hereinafter TUPA].

427. *See id.*

428. *See id.* No. 37.

429. *See* General Law of Health, *supra* note 390, art. 91; *see also* Food and Drink Regulation, *supra* note 398, art. 101.

430. For a list of all the requirements, see Registro Sanitario de Alimentos y Bebidas Industrializadas [Registration of Mass-Produced Food and Beverages], Instructivo para Inscripción en el Registro Sanitario [Instructions for Registration], <http://www.digesa.minsa.gob.pe/formularios/2.pdf> (last visited Jan. 27, 2007) [hereinafter Instructivo]. *See also* TUPA, *supra* note 426, No. 37; Food and Drink Regulation, *supra* note 398, arts. 101–15.

431. This form is available online. *See* Ministerio de Salud DIGESA, Registro Sanitario de Alimentos y Bebidas Industrializados, <http://www.digesa.minsa.gob.pe/>

form, the producer must attach an annex per each product being registered.⁴³² The annex requires a listing of all the ingredients of the product, including parts and additives.⁴³³ It requires the producers to identify the generic name of their product and to identify the corresponding identity under the *Codex Alimentarius*.⁴³⁴ This safeguards these foods by requiring adherence to strict food identity standards, such as those laid out by the *Codex Alimentarius*.⁴³⁵ The annex also requires information regarding the product's packaging, storage conditions, shelf life, and system of lot identification.⁴³⁶ Producers must attach to their application all laboratory reports (by accredited laboratories) of any chemical or biological analyses relevant to the product.⁴³⁷ If the product is imported, the importers must attach a copy of the product's health certification from the country of origin.⁴³⁸ Lastly, producers must supply information regarding nutritional value, be it through an example of the labeling or through a written declaration.⁴³⁹ Labels must contain the following information: commercial name and brand, ingredients and additives, name and address of the manufacturer, name and address of the importer if applicable, a code to the registry, expiration date, lot number, special storage conditions if applicable, and nutritional facts for diet foods.⁴⁴⁰

In addition, the forms must be accompanied by a sworn affidavit.⁴⁴¹ Small businesses must pay a fee of sixty-eight *soles*, while other businesses pay a fee of 238 *soles*.⁴⁴² So long as the information provided on the forms complies with the General Law

formularios/4.0_formulario.pdf (last visited Jan. 29, 2007); see also Instructivo, *supra* note 430.

432. This annex is available online. See Anexo, http://www.digesa.minsa.gob.pe/formularios/4.1_anexo.pdf (last visited Jan. 29, 2007) [hereinafter Anexo].

433. See *id.*

434. See *id.*

435. See *id.* For a listing of these standards, with corresponding hyperlinks to the standards themselves, see Normas Oficiales del Codex, Codex Alimentarius Peru, http://www.codexalimentarius.net/web/standard_list.do?lang=es (last visited Feb. 10, 2007).

436. See Anexo, *supra* note 432.

437. See *id.*

438. See Instructivo, *supra* note 430, ¶ 5.

439. For the summary of these requirements, see *id.* For a more comprehensive manual for food labeling, see the Codex Alimentarius Peru, <http://www.digesa.minsa.gob.pe/CodexPeru/bienvenidos.asp> (follow Qué es Codex, Informativos Codex, Etiquetados de los Alimentos) (last visited Feb. 10, 2007).

440. See Instructivo, *supra* note 430, ¶ 5.

441. *Id.*

442. See *id.*

of Health and the corresponding regulation,⁴⁴³ the registration becomes automatically effective.⁴⁴⁴

Besides registration, DIGESA also proposes standards to be promulgated by Ministerial Resolution. DIGESA's website provides a prominent link to the most recent laws and resolutions.⁴⁴⁵ Here are some examples:

- Directoral Resolution imposing conditions for the importation of U.S. beef with a view to guarding against Mad Cow Disease;⁴⁴⁶
- Sanitary norms governing airline food;⁴⁴⁷
- Law prohibiting the use of potassium bromide in the production of bread;⁴⁴⁸
- Sanitary norms governing restaurants;⁴⁴⁹
- Authorization of certain food additives.⁴⁵⁰

3. DIGEMID

Like DIGESA, DIGEMID was founded in 1990 as part of the renovation of the Ministry of Health.⁴⁵¹ DIGEMID is the agency charged with enforcement of the Pharmaceutical Regulation of 1997.⁴⁵² DIGEMID is in charge of formulating the national policies regarding medications and drugs, in coordination with the Ministry of Economy and Finance and the Ministry of Industry, Commerce, and Tourism.⁴⁵³ The agency should propose national

443. See Food and Drink Regulation, *supra* note 398, art. 107.

444. See General Law of Health, *supra* note 390, art. 92.

445. See DIGESA, Relación de Normas Legales del Ámbito de la DIGESA, http://www.digesa.sld.pe/normas_leg.asp (last visited Jan. 29, 2007).

446. See Directorial Resolution No. 0654/2006/DIGESA/SA, Apr. 6, 2006, available at http://www.digesa.sld.pe/normas_alimento.asp (follow R.S. 0654/2006/DIGESA/SA hyperlink).

447. See Ministerial Resolution No. 450-2005/MINSA, June 14, 2005, available at http://www.digesa.sld.pe/normas_alimento.asp (follow R.M. 450-2005 hyperlink).

448. See Reglamento de la Ley 27932 [Regulation of Law No. 29735], Feb. 10, 2003, available at http://www.digesa.sld.pe/normas_alimento.asp (follow Ley 27932 hyperlink).

449. See Ministerial Resolution No. 363-2005/MINSA, available at http://www.digesa.sld.pe/normas_alimento.asp (follow Resolución Ministerial 363-2005/MINSA hyperlink) (last visited Jan. 29, 2007).

450. See Directorial Resolution No. 0684/2003/DIGESA/SA, June 17, 2003, available at http://www.digesa.sld.pe/normas_alimento.asp (follow R.D. 0684/2003/DIGESA/SA hyperlink).

451. See Ministry of Health Decree, *supra* note 400, art. 5; see also DIGEMID, Quienes Somos, <http://www.digemid.minsa.gob.pe/digemid/Informacion02.htm> (last visited Jan. 29, 2007) [hereinafter DIGEMID, Quienes Somos].

452. See Pharmaceutical Regulation, *supra* note 399, art. 1.

453. See Ministry of Health Decree, *supra* note 400, art. 25.

standards for production, quality, use, and commercialization of these products.⁴⁵⁴ DIGEMID must also be aware of the big picture of the pharmaceutical situation in Peru, ensuring access to good quality drugs as well as the safe use of medications.⁴⁵⁵

DIGEMID accomplishes these tasks through various executive agencies under its umbrella. The first of these is the *Dirección de Autorizaciones Sanitarias*, which is an agency that regulates drug quality through an elaborate registration process.⁴⁵⁶ The next is the *Dirección de Control y Vigilancia Sanitaria*, an executive agency that seeks to regulate drug quality by inspecting manufacturers and certifying that they are adhering to best practices.⁴⁵⁷ The final executive agency, the *Dirección de Acceso y Uso de Medicamentos*, handles issues of access and consumption of drugs both by regulating prescriptions and dosages and by evaluating adverse reactions to use.⁴⁵⁸

B. Regulation and Consumer Protection

The concept of consumer protection is a modern one whose ancestry is difficult to trace back through the centuries. Prior to the birth of this precept, only merchants had protected rights as buyers under the commercial code. The commercial codes in effect between 1877 and 1884, for example, legislated all aspects of the business arena, from registration of commercial entities to bankruptcy.⁴⁵⁹ However, the rights of refusal and rescission for defective goods extended only to qualified “commercial” transactions and not to the everyday purchases of food or drugs.⁴⁶⁰ Indeed, the purchase of any good intended to be consumed by the purchaser was not a commercial transaction within the protection of the code.⁴⁶¹ Clearly throughout the development of food and drug law in Peru there had been a concern for the protection of consumers, couched in a rubric of public health. It is for that reason, for

454. *See id.*

455. *See* DIGEMID, *Quienes Somos*, *supra* note 451.

456. *See* DIGEMID, *Dirección de Autorizaciones Sanitarias*, <http://www.digemid.minsa.gob.pe/registros/index.htm> (last visited Apr. 9, 2006); *see also* *Pharmaceutical Regulation*, *supra* note 399, art. 3.

457. *See* DIGEMID, *Dirección de Control y Vigilancia Sanitaria*, <http://www.digemid.minsa.gob.pe/decvts/funciones/funcion.htm> (last visited Jan. 29, 2007).

458. *See* DIGEMED, *Dirección de Acceso y Uso de Medicamentos*, <http://www.digemid.minsa.gob.pe/daum/index.htm> (last visited Jan. 29, 2007).

459. *See* Código de Comercio arts. 18, 1053–67, *in* 1 *LEGISLACIÓN MERCANTIL DEL PERÚ [MERCANTILE LEGISLATION OF PERU]* (Miguel A. de la Lama ed., 1877), at 6.

460. *See id.* arts. 299–333, at 76–83.

461. *See id.* art. 298, at 75–76.

example, that it was illegal to add substances to food products to make them heavier.⁴⁶² In the present day there is a comprehensive administrative system in place for the protection of the consumer.

The duty of the state to provide for the protection of consumers flows from the Peruvian Constitution itself. Article 58 provides that Peru will have a market economy, fostered by private initiative.⁴⁶³ Consumer protection recognizes that the consumer plays a critical role in that market and recognizes that only through regulation will the information asymmetries of the market be overcome.⁴⁶⁴ For this reason, the Consumer Protection Law creates a presumption in favor of the consumer.⁴⁶⁵

1. Consumer Protection Law

The complete universe of food and drug regulation in Peru does not fit wholly into the jurisdiction of the Ministry of Health. The Consumer Protection Law⁴⁶⁶ supplements the health regulations with important economic ones that speak to the rights of the consumer⁴⁶⁷ and the duties of the producer.⁴⁶⁸ This law was developed by then president Alberto Fujimori through the power delegated to the executive branch by congress. Specifically, congress charged the executive branch with developing legislative decrees in various areas, including defending the rights of the consumer.⁴⁶⁹ Since its passing in 1991, the Consumer Protection Law has been modified and expanded.⁴⁷⁰ Today it constitutes a significant precedent for food and drug regulation, as food and drugs are inescap-

462. See Ordinance, Feb. 4, 1903, art. 4, reprinted in 1 DICCIONARIO, *supra* note 6, at 141.

463. See CONSTITUCIÓN POLÍTICA DEL ESTADO REPÚBLICA DEL PERÚ art. 58. This Constitution was enacted in 1993. In 1991 the relevant provision of the Peruvian Constitution would have been article 115.

464. LEY DE PROTECCIÓN AL CONSUMIDOR 23–24 (Juan Espinoza Espinoza ed., 2004) [hereinafter LEY DE PROTECCIÓN].

465. *Id.* at 24–25.

466. See Legislative Decree No. 716, July 11, 1991, available at <http://www.congreso.gob.pe/ntley/Imagenes/DecretosLegislativos/00716.pdf> (approving norms for consumer protection) [hereinafter Consumer Protection Law].

467. See *id.* art. 5 (referencing the rights of consumers).

468. See *id.* arts 6–14 (referencing the obligations of the producers).

469. See Law No. 25327, June 14, 1991, art. 1(3)(e), available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/25327.pdf> (delegating legislative power to the executive).

470. See, e.g., Law No. 27311, July 17, 2000, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27311.pdf> (bolstering the system of consumer protection); Law No. 27768, May 31, 2002, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27768.pdf> (modifying the Consumer Protection Law); Law No. 27598,

ably “products” under the law. Indeed, the most important food regulation, the Food and Drink Regulation,⁴⁷¹ promulgated certain regulations that worked within the structure laid out by the Consumer Protection Law.

At the core of the Consumer Protection Law rest the concepts of “producer” and “consumer.” A producer is a “natural or legal person that fabricates, elaborates, manipulates, conditions, mixes, bottles, stores, prepares, sells, or supplies goods or provides services to consumers.”⁴⁷² The definition of a producer is so broad so as to include distributors, merchants, manufacturers, and importers.⁴⁷³ A consumer is a “natural or legal person that acquires, utilizes, or uses a product or service for personal or family ends or social surroundings.”⁴⁷⁴ The producers are burdened by the rights of the consumers. The Consumer Protection Law requires that producers adhere to certain norms of safety and quality.⁴⁷⁵ Goods made available to the public should not carry an unjustified or undisclosed risk to the health or safety of consumers.⁴⁷⁶

The regulation extends not only to the product itself but also to its labeling and advertising. By labeling, the statute intends all information related to the product that is printed or affixed to the package or that accompanies it.⁴⁷⁷ The Consumer Protection Law specifically requires that this information include the package’s contents and the useful life of the product.⁴⁷⁸ These requirements are further elaborated in the Food and Drink Regulation described in the previous section.⁴⁷⁹

2. INDECOPI

The *Instituto Nacional de Defensa de Competencia y de la Protección de la Propiedad Intelectual* (the National Institute for the Defense of Competition and the Protection of Intellectual Property, or INDECOPI) is an independent agency founded in 1992,

Dec. 12, 2001, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27598.pdf> (modifying the Consumer Protection Law).

471. See Food and Drink Regulation, *supra* note 398.

472. See Consumer Protection Law, *supra* note 466, art. 3(b) (translation by author).

473. See *id.* arts. 3(b)(1)–3(b)(3).

474. LEY DE PROTECCIÓN, *supra* note 464, at 28 (citing Resolution No. 101-96 TDC, Dec. 18, 1996, of Defense of the Competition of Intellectual Property Tribunal).

475. See Consumer Protection Law, *supra* note 466, art. 7.

476. *Id.* art. 9.

477. LEY DE PROTECCIÓN, *supra* note 464, at 79.

478. See Consumer Protection Law, *supra* note 466, art. 8.

479. See *supra* note 398 and accompanying text.

charged with consumer protection.⁴⁸⁰ Its mission is this: "To promote and guarantee fair competition, consumer rights, and intellectual property, and to promote the well-workings of the market, through the excellence and quality of its personnel."⁴⁸¹ When it was founded, it was dependent on the Ministry of Industry, Tourism, and Commerce.⁴⁸² In 2002, that Ministry was modified, and INDECOPI became an independent agency.⁴⁸³ Because it is an independent agency, it is very different from DIGESA and DIGEMID, which depend on the Ministry of Health.

INDECOPI's regulatory power is double-sided. On the one hand, INDECOPI promulgates norms to further fair competition and consumer protection.⁴⁸⁴ On the other hand, INDECOPI is equipped with the power to adjudicate violations of its norms.⁴⁸⁵ INDECOPI is populated by various commissions who enforce compliance with the norms in their field.⁴⁸⁶ The Commission for the Protection of the Consumer, for example, is the administrative entity with jurisdiction and expertise in enforcing the Consumer Protection Law.⁴⁸⁷ This commission imposes administrative sanctions and corrective measures according to the Consumer Protection Law and other promulgated standards.⁴⁸⁸

When it comes to the substance of food and drug regulation, INDECOPI works hand in hand with DIGESA on many occasions; its jurisdiction may overlap somewhat. For example, DIGESA requires compliance with certain labeling requirements for food

480. See INDECOPI, *Quienes Somos*, <http://www.indecopi.gob.pe> (follow "Quienes Somos" hyperlink) (last visited Jan. 31, 2007) [hereinafter INDECOPI, *Quienes Somos*].

481. INDECOPI, *Misión y Objetivos*, <http://www.indecopi.gob.pe> (follow "Quienes Somos" hyperlink; then follow "Misión y Objetivos" hyperlink) (last visited Jan. 31, 2007) (translation by author) [hereinafter INDECOPI, *Misión y Objetivos*].

482. See Decree-Law No. 25868, Nov. 18, 1992, art. 1, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/25868.pdf> (organizing INDECOPI).

483. See INDECOPI, *Quienes Somos*, *supra* note 480; see also Decree-Law No. 27789, July 23, 2002, available at <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27789.pdf> (seventh final disposition of the Law of Organization and Functions of the Ministry of Production).

484. See INDECOPI, *Misión y Objetivos*, *supra* note 481.

485. See INDECOPI, *Nuestra Organización*, <http://www.indecopi.gob.pe> (follow "Quienes Somos" hyperlink; then follow "Nuestra Organización" hyperlink) (last visited Jan. 31, 2007).

486. INDECOPI, *Comisiones*, <http://www.indecopi.gob.pe> (follow "Quienes Somos" hyperlink; then follow "Nuestra Organización" and "Comisiones" hyperlinks) (last visited Jan. 31, 2007).

487. See *id.*

488. See *id.*

products for registration purposes.⁴⁸⁹ Similarly, INDECOPI approved a set of norms covering the labeling of food products in 2003.⁴⁹⁰ These norms were created by the Technical Committee for the Regulation of Packaging and Labeling of Foods (*Comité Técnico de Normalización de Alimentos Envasados y Rotulado*).⁴⁹¹ These more specific norms regarding food products were intended to dovetail with the standards set by the *Codex Alimentarius* of the Food and Agriculture Organization, especially given the increasing importance of food products in international commerce.⁴⁹² INDECOPI's more specific concern, naturally, was that consumers receive relevant information to permit them to make an informed choice when they purchase these products.⁴⁹³

The labeling requirements that INDECOPI approved above form part of the Peruvian Technical Norms. These are documents that specify the expected quality of products, processes, and services.⁴⁹⁴ They may extend to norms governing terminology, production, and packaging,⁴⁹⁵ but are not specific to food products. INDECOPI has approved several such norms related to food and drug-related products.⁴⁹⁶ These include meat standards,⁴⁹⁷ flour standards,⁴⁹⁸ alcohol (*Pisco*),⁴⁹⁹ and plastic disposable syringes.⁵⁰⁰

Thus, INDECOPI represents the efforts of Peru to address food and drug regulation from a different perspective—from the perspective of consumer protection.

489. See *supra* note 429 and accompanying text.

490. See INDECOPI, Noticias, INDECOPI Aprueba Normas Técnicas Peruanas Sobre Etiquetado de Alimentos, <http://www.indecopi.gob.pe/noticias/2003/20030923a.asp> (last visited Oct. 20, 2006) (on file with the *Inter-American Law Review*).

491. See *id.*

492. See *id.*

493. See *id.*

494. See Ministerio de Agricultura, Cómo Exportar, <http://www.minag.gob.pe/ComoExpo/ComoExpo505/shtml> (last visited Jan. 31, 2007).

495. This definition comes from the Ministry of Agriculture. See *id.*

496. See INDECOPI, Normas Técnicas Peruanas Obligatorias, <http://200.121.68.208/PortalNormalizacion/GoPortal/DesktopDefault.aspx?tabid=332> (last visited Feb. 11, 2007) (listing all the NTPs, including those related to meats and alcoholic beverages).

497. See Supreme Decree No. 019-2003-AG, Norma Técnica Peruana NTP 201.054 (2001), available at <http://www.bvindicopi.gob.pe/normas/201.054.pdf>.

498. See Ministerial Resolution No. 349-97-SA/DM, Norma Técnica Peruana NTP 205.027 (1986), available at <http://www.bvindicopi.gob.pe/normas/205.027.pdf>.

499. See Ministerial Resolution No. 316-91-ICT/IND, Norma Técnica Peruana NTP 211.001 (2002), available at <http://www.bvindicopi.gob.pe/normas/211.001.pdf>.

500. See Ministerial Resolution No. 142-86-ICT/IND, Norma Técnica Peruana NTP 311.187 (1986), available at <http://www.bvindicopi.gob.pe/normas/311187/311.187.htm>.

VI. CONCLUDING THOUGHTS

The development of food and drug regulation has spanned over 500 years in Peru—skipping, of course, any discussion of regulations that the Incas and other pre-Columbian civilizations may have put into place. This development has been traced basically through a history of the development of the administration and regulation of public health. In that vein, this Article demonstrated that institutions persist over time; structures leave imprints that affect later developments. New regulations and forms of administration were built upon the foundations laid by earlier attempts. The colonial system of *juntas* was replicated even until the brink of the nineteenth century.

Understanding the development of that law is the first step to a complete understanding of food and drug regulation as it exists in Peru, but it is not exhaustive. For the full picture of this development, a deeper investigation should be conducted into the circumstances surrounding the passing of each of these statutes or decrees.⁵⁰¹ Who were the advocates? What were the major arguments on both sides? Then, data regarding enforcement of these laws would be relevant to an understanding of how these laws and regulations affected the food and drug industries. It is likely that the bulk of this enforcement took place at the local level. While some of these local regulations were discussed, certainly others are waiting to be unearthed from municipal archives. Further research should also ask whether Peru witnessed any private regulation of food or drug, perhaps by guilds or societies of merchants or pharmacists.⁵⁰²

While the system of food and drug regulation was clearly

501. Something like a legislative history is maintained by the Peruvian legislature in memorials titled *Diarios de los Debates*. However, not all of the laws or decrees that were to be discussed here necessarily went through an elected legislative body. Some additional debates or background to the passage of certain health laws may have been published in the official newspaper, *El Peruano*, though none were uncovered during this research.

502. For example, there existed in Lima the *Sociedad Farmacéutica de Lima*, the Pharmaceutical Society of Lima. In 1871 this organization proposed a set of statutes to govern its internal structure. One of the society's objectives was to redact a codex medicamentarum or a national pharmacopoeia in collaboration with the Faculty of Medicine. The idea was to then present this to the government for its enactment against all the pharmacies in the country. SOCIEDAD FARMACÉUTICA DE LIMA, ESTATUTOS QUE LA COMISIÓN RESPECTIVA DE LA SOCIEDAD FARMACÉUTICA DE LIMA SOMETE A SU DELIBERACIÓN § 4 (May 25, 1871). I could find no information as to whether they were ever successful, but the issue of establishing a pharmacopoeia is still open and debated well into the 1920s. See *supra* notes 269–270 and accompanying text.

developed from the inside out, it would be a mistake to ignore the influence of international organizations on this development as well. From time to time these international influences have crept into the discussion. As an initial matter, Peru's original system for the administration of public health was inherited from Spanish law. The *junta* system set up by the colonial administration persisted in the first health law of 1826.⁵⁰³ Once it was codified there, it persisted even to the end of the nineteenth century.

While Peruvian politicians and lawyers adapted colonial legacies into Peruvian institutions, they were also influenced by developments in the world. Remember that in 1922, Peruvian pharmacists were to refer to the *Codex Medicamentarius* of France until a Peruvian equivalent was compiled.⁵⁰⁴ In the late 1920s, Peru participated in the eighth Pan-American Health Conference held in Washington, D.C.⁵⁰⁵ Indeed, Dr. Carlos Enrique Paz Soldán and Dr. Daniel Laverería were both representatives of Peru to that conference⁵⁰⁶ and important thinkers in the area of public health. In 1945, Peru signed the United Nations Convention founding the Food and Agriculture Organization.⁵⁰⁷ In 1952, the Peruvian Congress officially ratified the constitution of that international organization.⁵⁰⁸ Through its exports, Peruvian officials likely came into contact with the U.S. Food and Drug Administration's (FDA) own brand of food and drug regulation. Indeed, today, the Food and Drink Regulation (1998) and the Pharmaceutical Regulation (1997) both make use of FDA standards. For example, fragrant food additives are prohibited unless they are specific listed in the Peruvian *Codex Alimentarius* or listed by the FDA, the European Union, or the Flavor and Extractive Manufacturers Association.⁵⁰⁹ Additionally, DIGESA may suspend the registration of a particular product if the FDA or some other pres-

503. See *supra* Part III.A.1.

504. See *supra* note 270 and accompanying text.

505. See Supreme Resolution, VIII Conferencia Sanitaria Pan-Americana—Programa de trabajos i sesiones, Sept. 16, 1927, *reprinted in* 2 PRONTUARIO, *supra* note 257, at 509; see also VIII Conferencia Sanitaria Panamericana, celebrada en Lima del 12 al 20 de octubre de 1927—Acta final i acuerdos aprobados, *reprinted in* 2 PRONTUARIO, *supra* note 257, at 512–26 (providing the actual content of the conference and agreements contained therein).

506. See Supreme Resolution, VIII Conferencia Sanitaria Pan-Americana—Personal de la Delegación Peruana (Sept. 30, 1927), *reprinted in* 2 PRONTUARIO, *supra* note 257, at 510–11.

507. See Legislative Resolution No. 11829, Apr. 3, 1952, *available at* <http://www.congreso.gob.pe/ntley/Imagenes/Leyes/11829.pdf> (approving the FAO convention).

508. See *id.*

509. See Food and Drink Regulation, *supra* note 398, art. 62.

tigious international institution publishes information that some particular packaging poses a health hazard.⁵¹⁰ In the drug arena, products must list their ingredients to qualify for registration.⁵¹¹ Permitted ingredients include those listed by the FDA, the Cosmetics and Toiletry and Fragrance Association, and the European Union.⁵¹² Additionally, DIGEMID is required by the regulation to read reports from the World Health Organization and the FDA regarding drug safety.⁵¹³ Today, DIGESA's home page on the internet contains a prominent link to the FDA's website.⁵¹⁴

For now, the relevant agencies and institutions appear to be active. For example, in March 2006, *El Comercio*, the major daily newspaper, reported that three tons of dairy products and meat were incinerated by agents of the Economic Crimes Division of the National Police.⁵¹⁵ These damaged products were found in a state of decomposition and were going to be sold to what the newspaper reported were "unscrupulous merchants."⁵¹⁶ In May 2006, DIGESA launched a campaign to warn the public of the dangers of buying food products in pirated containers.⁵¹⁷ In Spanish these are known as *productos bamba*—pirated goods. This campaign reminded consumers to check that any product they purchased had been registered in accordance with the General Health Law.⁵¹⁸ This is surely an improvement over the situation in the 1990s, when INDECOPI was severely criticized for its inaction in the face of the threat posed by these *productos bamba*.⁵¹⁹

It would be a mistake to think that the process of the development of food and drug law in Peru has ceased simply upon the advent of modern-seeming regulations in the late 1990s and

510. See *id.* art. 110(b).

511. See Pharmaceutical Regulation, *supra* note 399, art. 102(2)(a).

512. See *id.*

513. See *id.* art. 136(a).

514. See DIGESA, <http://www.digesa.sld.pe> (look for the button on the right, halfway down the page) (last visited Feb. 4, 2007).

515. See *Notas Breves, Decomisan Carne y Leche Malogrados [Spoiled Meat and Milk Seized]*, EL COMERCIO, Mar. 15, 2006, <http://www.elcomercioperu.com.pe/EdicionImpresa/Html/2006-03-15/impLima0472602.html>.

516. See *id.*

517. See *Otros Datos, Verifique Siempre el Registro Sanitario [Always Check the Registry]*, EL COMERCIO, May 21, 2006, <http://www.elcomercioperu.com.pe/edicionimpresa/html/2006%2D05%2D21/impdefconsumidor0509323.html>.

518. See *id.*

519. See Enrique Elias Laroza, *Los "Productos Basura" Que Matan: La Teoría de la Inacción del INDECOPI y el Respeto de la Vida y la Salud de los Ciudadanos [Garbage Goods that Kill: The Theory of INDECOPI's Inaction and the Respect of the Life and Health of Citizens]*, 46 REVISTA JURÍDICA DEL PERÚ 129 (1996).

beyond. Given Peru's strong Andean culture and the social conflicts between *mestizo* and indigenous communities in the highlands on the one hand and European whites in Lima on the other hand, the issue of coca regulation is likely to be heated in the coming years. Less than two years ago, when the governor of Cuzco decided to ignore a Peruvian statute restricting the coca crop to certain quantities and locations, a political firestorm erupted pitting the coca planters (and potentially indigenous culture) against many politicians in Lima wary of opening the door to greater narco-trafficking.⁵²⁰ While coca has not been a focus of the investigation of this Article, it is an important problem that should be considered.

Even outside the environment of the coca leaf, issues of food and drug will persist. Indeed, especially given the extreme poverty and malnutrition affecting many Peruvians, the issue of nutritious foods and access to cheap medicines has been a topic for political campaigns.⁵²¹ Law and regulation are not static and will keep adapting to new situations and new problems. This Article, by laying out the development of food and drug regulation in a historical manner, has opened the door to further research and comparative studies in food and drug regulation. This is important, not just for students of Peruvian law and policy, but also for all students of food and drug law who may take the lesson that administrative schemes are not created in a sterile laboratory but can be rooted in context and history.

520. See, e.g., Rick Vecchio, *Peru's Prime Minister Resigns in Protest Over Coca Production*, THE INDEPENDENT, Aug. 13, 2005, available at http://www.findarticles.com/p/articles/mi_qn4158/is_20050813/ai_n14885442.

521. Some of the major candidates for Peru's April 2006 election included food and nutrition in their plans of government. For example, Alan García, now the president, included provisions for cheap access to quality medications and a call for greater recognition of alternative medicine in his plan of government. See PARTIDO APRISTA PERUANO, PLAN DE GOBIERNO 23 (2006), available at <http://www.apra.org.pe/neo/plan.pdf> (last visited Feb. 4, 2007); UNIDAD NACIONAL, PLAN DE GOBIERNO 11–12, 76–77, 85, available at http://www.transparencia.org.pe/documentos/plan_de_gobierno_unidad_nacional.pdf (last visited Feb. 13, 2007).