HOW AMERICAN AND EUROPEAN GOVERNMENTS COMMUNICATE ABOUT POLICY ISSUES THAT INVOLVE SCIENCE:

A COMPARATIVE CONTENT ANALYSIS OF POLICY DOCUMENTS

by

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(Under the Direction of Glen Nowak)

ABSTRACT

Guided by framing theory, this study content analyzed 108 policy documents from the European Union (EU) and the United States (U.S.) on three topics that rely on science for evidence of *risk*-related, *benefit*-related and *science*-related content. This study's topics - cyclamates, hormone-treated beef, and bisphenol A, or BPA - each present an unknown amount of risk to consumers. EU and U.S. policymakers rely on scientific evidence to evaluate the magnitude of that risk. In these circumstances, it would be expected that policy-related documents would contain statements of risk. These statements may reference risk to health, the economy, and/or the environment. This study's research questions focused on the frequency of *risk*-related, *benefits*-related and *science*-related content in policy documents involving the topics in both jurisdictions. Findings revealed that statements of *risk to health* were present 10 times more often than statements referencing *risk to economy* or *risk to environment*. Statements of *benefit* were very uncommon. Implications of these findings and their relevance for future research are discussed.

INDEX WORDS: Science communication, Science policy, Content analysis, European Union, United States, Policy documents, Cyclamate, Hormone-treated beef, Bisphenol A (BPA)

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DEDICATION

This work is dedicated to my husband Ron -- my best friend, my partner, and my person.

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CHAPTER 1

INTRODUCTION

On January 28, 2011, the European Commission issued a three-page "Directive" banning the use of Bisphenol A (BPA) in baby bottles due to concerns that ingestion of the chemical may cause negative health effects including obesity, learning disabilities, and breast cancer (Commission Directive 2011/8/EU, 2011, p. 12)[1]. On July 17, 2012, the United States Food and Drug Administration (FDA) published a three-page "Final Rule" that prohibited the use of BPA in baby bottles in response to a petition from the chemical industry that asserted that manufacturers were no longer using BPA in their products (Indirect Food Additives: Polymers, 2012). While the policy outcomes are identical, the policy discourse revealed in each of the documents is quite different, especially regarding the scientific uncertainty about the potential risks. The European text reflects caution about the possible health risks of BPA. The American text details the administrative procedures followed to justify the role of industry in bringing about the new policy. By studying and comparing the texts of the public policy documents themselves, it may be possible to identify existing or emerging points of policy divergence for the European Union (EU) and the United States (U.S.)[2]. Of specific interest is the role of scientific information in assessing the risk of a product in both jurisdictions. This is important

[1] A European "Directive" is a legally binding instrument akin to a House Bill or Senate Bill in the US. Each EU Member country must comply with the Directive, but they may do so in the manner they choose. (Europa, Directives and other acts, 2019).

[2] The European Union (EU) became the legal name for the European Economic Community in 1993 as a result of the Maastricht Treaty. The dataset for this study includes numerous documents prior to 1993. For the sake of consistency in the narrative, EU will be used regardless of the date.

because the absence of policy agreement between the EU and the U.S. could have profound ramifications on the global economy.

Background: Regulating Risk in the EU and U.S.

The EU and the U.S. are the world's largest trading partners and allies in international security (European Commission, 2018). It is in their mutual interests to enact public policies that support those strategic relationships. As the global economy continues to rely more heavily on science and technology, differences in federal-level law may create policy divergences that threaten those relationships. Over the past fifty years, the EU and the U.S. have differed in their regulatory approaches to a variety of public policy issues including growth hormones for cattle, labeling of genetically modified ingredients, and vehicle fuel efficiency (Vogel, 2012). One common attribute among these issues is that each of them presents an unknown degree of risk to the public. Another shared characteristic is that each of these issues relies on science to help assess the magnitude and certainty of that risk. In adopting policies on these issues, the EU and the U.S. have reacted with varying amount of caution, or as many scholars comparing the two polities describe it, precaution (Anker & Grossman, 2009; Dineen, 2013; Dudley & Wegrich, 2015; Dragos & Neamtu, 2008; Hammitt, Wiener, Swedlow, Kall & Zhou, 2005; Lynch & Vogel, 2001; Scott, 2005; Vogel, 2012; Wiener & Rogers, 2002; Wiener, Rogers, Hammitt, & Sand, 2011).

The precautionary principle (PP) is a legally recognized concept that governments may adopt as a measure to protect their citizens against potential and unknown harm (European Commission, 2000; Turker, 2012; Van Den Belt & Gremmen, 2002). When scientific evidence on an issue is perceived by decision-makers to be inconclusive, governments "are justified in taking action to avoid possible negative outcomes" (Runge, Bagnara, & Jackson, 2001, p. 231).

A government may require scientific evidence to ensure that the impacts or consequences of an emerging technology will not be harmful to the population (McLean and Patterson, 2006). Colloquially, the PP has come to be described as "guilty until proven innocent" (Van Den Belt & Gremmen 2002; Wiener & Rogers, 2002; Dragos & Neamtu, 2008).

The PP first emerged in the 1970s in Germany as a policy approach to managing environmental risk (Foster, Vecchia, & Repacholi, 2000; Scott, 2005; McLean and Patterson, 2006; Patterson & Gray, 2012). The PP has been formalized by its inclusion in numerous international treaties including the 1984 Ministerial Declaration of the Second International Conference on the Protection of the North Sea, 1985 Vienna Convention for the Protection of the Ozone Layer, the 1987 Montreal Protocol, the 1987 EC Treaty, the 1992 Treaty on European Union, the 1992 UN Framework Convention on Climate Change, the 1992 Rio Convention, the Maastricht Treaty of 1993 and the 2000 World Trade Organization's Sanitary and Phytosanitary Measures Agreement (Foster et al, 2000; Van Den Belt & Gremmen, 2002; Scott, 2005; Vogel, 2012; Kirilenko, 2012 EU 2011). The PP's most often cited verbiage, Principle 15 of the Rio Declaration from the 1992 United Nations Conference on Environment and Development, reads "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (United Nations, 1992, p. 3).

This language, "lack of full scientific certainty", may have contributed to the PP being cast as a non-scientific approach to policymaking. In the late 1980s and early 1990s, the E.U. banned hormone-treated beef. The U.S. accused the EU of having no scientific evidence to support their ban but rather applying the PP (Johnson & Hanrahan, 2010). However, in their 2000 Communication on the Precautionary Principle, the EU stipulates that the PP "may only be

invoked when three conditions are met: identification of potentially adverse effects; evaluation of the scientific data available; (and) the extent of scientific uncertainty" (pp. 1-2). By this definition, the PP is not only compatible with scientific evidence, but coupled with it.

Previous EU-U.S. comparative studies have examined levels of relative precaution towards science-dependent policy issues in terms of regulatory frameworks, economic impacts, legal implications, and political dynamics. The current study will contribute to the EU-U.S. comparative literature from the perspective of communication, with a focus on how government agencies communicate about public policy issues that involve science. As the world's two largest economies and one another's primary trading partners, it is imperative to understand under what circumstances they are able to achieve agreement and under what circumstances they cannot (Pollack & Shaffer, 2007).

This study used content analysis to examine policy documents and policy-related documents from the EU and U.S. on three policy topics that rely on science for evidence of *risk*-related, *benefit*-related and *science*-related content. The policy issues selected for this study were cyclamate (an artificial sweetener), hormone-treated beef, and bisphenol A, or BPA (a chemical used to strengthen plastic). BPA is a case in which the EU and the U.S. have the same policy outcome but for different reasons. In the other two cases, one jurisdiction allows the product and the other does not (see Table 1.)

Table 1: Policy Status for Cases in this Study

	EU	U.S.
Cyclamate	Permits	1970 Ban
Hormone-Treated Beef	1989 Ban	Permits
Bisphenol A (BPA)	2011 Ban	2012 Ban

This study is interested in understanding how risk, benefits, and scientific information are portrayed in the EU and U.S. policy documents on these three issues. One approach to theoretically grounding the exploration of these concepts and to guide the content analysis of policy documents is framing theory.

Framing Theory

Framing theory strives to explain how the organization and presentation of content affects message readers' perceptions, attitudes, and behaviors about a particular issue (Hallahan, 1999 p. 206; Chong and Druckman, 2007, p. 109). *Frames* are used to create meaning for audiences by selecting what to include in their message, making that information more meaningful to the audience (Gamson & Modigliani, 1989; Entman, 1993; Nisbet & Lewenstein, 2002). This information may then be used to guide opinion formation and decision-making by providing contextual cues (Hallahan,1999). When communicators use frames strategically and effectively, they may be able to persuade an audience of a particular viewpoint (National Academy of Sciences, 2017, p. 36). Framing theory has been examined in numerous disciplines including communications, psychology, history, and sociology.

Framing occurs not only for the receiver of the information, but also for the sender. The sender can decide which information to include or exclude, and which information to emphasize (Entman, 1993; Hallahan, 1999). In the case of the government as the sender, government agencies communicate on a broad array of topics including foreign relations, severe weather, trade agreements, health patterns, and emerging technologies. Many of the topics about which governments communicate include the potential for risk and/or the opportunity for benefit. To explore how *risks* and *benefits* are characterized in European and American policy documents, framing theory can be used to look for statements of *risk* and *benefit* within the document text. A

subset of framing literature examines how *risks* and *benefits* are framed in different communications media. This discussion will be developed more thoroughly in the literature review in Chapter 2.

Comparing the EU and the U.S.

There are several reasons why the EU and the U.S. are appropriate cases for this study. First, the EU and the U.S. have often differed on policy issues that involve a question of risk. One perspective argues that during the 1970s and 1980s, the U.S. tended towards stricter regulation of products where scientific evidence could not prove the product would not bring harm (Lynch & Vogel, 2001; Vogel, 2012; Wiener & Rogers, 2002; Wiener, et al. 2011). Then, in the mid-1980s and 1990s, the EU began to take on the more precautionary nature. The EU passed a series of legislative actions that banned of hormone-treated beef in spite of the lack of evidence to demonstrate harm. Another perspective agrees that the EU and U.S. have differed in their levels of precaution towards risk-based policy issues. However, this perspective rejects the idea that there was a categorical trading of places in the early 1990s, and asserts that the two polities' tolerance for risk is dependent on the circumstances (Wiener et al, 2012, p. 28). This study accepts that the EU and U.S. have traded places in terms of their general mindset towards risk-based policy issues, whether all at once, or on a case-by-case basis. Due to the nature of the inquiry, it is not imperative to understand why the attitude towards risk evolved, only that it has. The key point of interest is how the EU and the U.S. navigated the discourse in their policy documentation regarding these topics.

The second reason that the EU and the U.S. are appropriate comparators is that the governments are organized similarly. As democracies that are responsible to their citizens, government agencies publish and promote their activities in press releases, topical reports,

informational fact sheets and other document formats. These agencies generally feature an archive of their publications on their website. Additionally, because the EU conducts business in English, all the documents are published in the English language, another benefit of comparison to the U.S.

The final and most strategic reason to compare the EU and the U.S. is that they are inextricably linked as economic partners. Even though the U.S. has many economic partners, the relationship with the EU is of particular importance. The following statistics illustrate:

- The EU and the U.S. make up almost 50% of the world's gross domestic product (European Commission, 2018; Delegation of the European Union to the United States, 2016).
- Over 15 million persons are employed by the transatlantic economy (Bureau of Economic Analysis, 2017).
- In 2016, there was more than $5.5 trillion in transatlantic commercial sales (Hamilton & Quinlan, 2017).
- European Foreign Direct Investment (FDI) totaled $1.92 trillion in 2015, accounting for more than 60% of total FDI in the U.S. (Jarand, International Trade Administration blog, 2017).

These statistics quantitatively illustrate the interdependence of these two governments. Beyond being a strategic advantage to partnering, the EU and the U.S. must cooperate in order for the global economy to maintain its stability. They do this by ensuring that policies and regulations are in harmony such that commercial entities can conduct business efficiently and create jobs, thereby promoting a healthy society (Dudley & Wegrich, 2015). The goal is to align

standards and policies such that transatlantic endeavors can operate without unnecessary obstacles.

Policy Issues that Involve Science

The following sections provide background information on each of the three case topics, cyclamate, hormone-treated beef, and Bisphenol A.

Case 1: Cyclamate

In this section, cyclamate is presented as the first case study to examine language within EU and U.S. government agency documents for the presence of risk and benefit frames. The case begins with a background discussion of cyclamate followed by the policy debate. Then the respective cyclamate policies from the EU and U.S. are introduced.

Background: What is cyclamate?

Cyclamate is a synthetic chemical that tastes 30 times sweeter than sugar (Havender, 1983; National Academies of Science, 1985; Code of Federal Regulations, 1989). The artificial sweetener was discovered in 1937 by Michael Sveda when he was a doctoral student at the University of Illinois (Kaufman, 1999). First used to sweeten oral prescription drugs, its potential as a food additive was quickly recognized. As a no-calorie sugar substitute, it was marketed as an alternative to sugar for diabetics.

Cyclamate is stable at high and low temperatures which makes it a good substitute for sugar when cooking and baking (International Sweeteners Association, 2009). In addition to its chemical properties, it is also cost-effective to manufacture, making it a more economic choice for consumers (International Sweeteners Association, 2009; Bittersweet History of Sugar Substitutes, 1987). Cyclamate was commonly combined with another artificial sweetener,

saccharin. Saccharin is much sweeter than cyclamate, but cyclamate tempers saccharin's bitter aftertaste (Havendar, 1983; Taylor, 1985).

Manufactured by Abbott Laboratories, cyclamate was approved by the U.S. FDA Administration (FDA) for in 1950 for use in prescription medications for obese and diabetic persons (Mazur & Jacobson, 1999). Within ten years, it was the most popular sugar alternative in the U.S. followed by saccharin. Cyclamate has been used in soft drinks, breakfast cereals, and packaged sweet goods.

From a public policy perspective, cyclamate is referred to as a *food additive* in both the U.S. and the EU. Manufacturers may use food additives to improve food products in terms of nutritional value, color, taste, odor and/or shelf life (Council Directive 94/35/EC, 1994). Cyclamate is available in the EU, Australia, and Canada, but it is banned in the U.S. and Japan (World Market Sugar, 2004).

Debate: Is cyclamate safe for humans and the environment?

During the 1970s and 1980s, the safety of cyclamate was subject to vigorous debate. Both the EU and the U.S. have conducted multiple studies on the safety of cyclamate. In a series of periodic reviews for the FDA, the U.S. National Academy of Sciences found that cyclamate was generally safe, but expressed caution due to unknown consequences of prolonged exposure (Mazur & Jacobson, 1999). The U.S. FDA banned cyclamate from use in foods in late 1969 and expanded the ban to include prescription drugs in mid-1970. In 1985, the National Research Council released a report that found that cyclamate alone was unlikely to be a carcinogen (Boffey, 1985). However, when coupled with saccharin, another artificial sweetener, there may have been an increased risk for cancer (National Research Council, 1985).

According to news articles from the time period, the confusion around the safety of cyclamate stems from early research designs. The studies on which the FDA based their decision were conducted on rats that developed bladder tumors after being injected with a combination of cyclamate and saccharin (Boffey, 1984; Rich, 1984). As a result, scientists could not state with confidence whether the resulting bladder tumors were due to cyclamate, saccharin, the combination or potentially even spontaneous (i.e. they would have occurred without the treatment).

The manufacturer of cyclamate, Abbott Laboratories, petitioned the FDA to allow cyclamate back on the market. Despite scientific reviews demonstrating no carcinogenic harm from the chemical, the FDA denied appeals in 1973, 1980, and 1982 to allow cyclamate back on the U.S. market (Barringer, 1982; Cohn, 1979; Cyclamate, 1980). The 1982 petition filed by Abbott Laboratories, the manufacturer of cyclamate, is still technically under review.

The EU's Scientific Committee on Food evaluated cyclamate in 1984, 1988, 1991, and 1995. In each review they found that cyclamate was safe for consumption at the acceptable daily intake level (European Commission, 2007). In 2000, new epidemiological data revealed no evidence that cyclamates were harmful to humans (European Commission, 2007).

In the case of cyclamate, none of the news articles, academic literature, or policy documentation referred to any potential impact on the environment.

EU and U.S. Parent Policies on Cyclamate

The U.S. parent policy for cyclamate is entitled "Revocations Regarding Cyclamate-Containing Products Intended for Drug Use" enacted on August 27, 1970. Issued by the U.S. FDA, this policy expanded the 1969 ban on cyclamate from use as a food additive to include

prescription drugs. This policy was chosen as the parent policy because it banned cyclamate from all use in the U.S.

The EU parent policy for cyclamate is Commission Directive 2003/115/EC which amends Directive 94/35/EC on "sweeteners for use in foodstuffs" by amending the maximum usable dose from 400mg/liter to 250mg/liter (2003, p. 67). This document was chosen as the parent policy because it is the most recent action on cyclamates in the EU. Appendix B contains a list of the policy documents and policy-related documents on the topic of cyclamates.

Case 2: Hormone-Treated Beef

In this section, hormone-treated beef is presented as the second case study to examine language within EU and U.S. government agency documents for the presence of risk and benefit frames. The case begins with a background discussion of hormone-treated beef followed by the debate. Then the respective hormone-treated beef parent policies from the EU and U.S. are introduced.

Background: What is hormone-treated beef?

Hormones are chemicals that occur naturally in all animals. They support the body in normal developmental activities such as growth and reproduction (European Commission, 1999; U.S. Food and Drug Administration, 2017). Growth hormones have been approved for beef production in the U.S. since the 1950s and are used in approximately two-thirds of all cattle (Johnson & Hanrahan, 2010). There are six hormones approved by the U.S. FDA for use in food production (Balter, 1999). Estradiol, progesterone, and testosterone are naturally produced sex hormones. Zeranol, trenbolone acetate, and melengestrol acetate are synthetic hormones that promote rapid growth (Cornell University Program on Breast Cancer and Environmental Risk

Factors, 2000). These hormones are administered through an implant on the cow's ear which dissolves under the skin (U.S. FDA, 2017; American Meat Institute, 2013).

In cattle, hormones are primarily used to stimulate faster, leaner growth (Alfnes & Rickertson, 2004; American Meat Institute, 2013). It is also suggested that hormone-treated beef is more flavorful and tender (Balter, 1999). For farmers, growth promotants create an economic incentive because the animals grow faster, and they can then be slaughtered sooner than if allowed to grow at a natural rate. As a result, farmers will be able to sell more product (i.e. larger animals) more often (Program on Breast Cancer and Environmental Risk Factors, 2000). Advocates for growth promotants argue that hormones allow more efficient use of feed, land, and water, thereby minimizing the impact to the environment. For consumers, this translates into more affordable meat (American Meat Institute, 2013).

Debate: Is hormone-treated beef safe for humans and the environment?

The scientific community is divided over whether hormone-treated beef is safe or not (Johnson & Hanrahan, 2010; Meng, 1990). The main health concern is whether or not the residues from the hormones administered to animals stay in the bloodstream and have negative health impacts (Balter, 1999). Advocates for hormone-treated beef argue that the naturally occurring hormones in the human body are already higher than the levels administered to cattle and therefore the use of the hormones in animals is safe (Kolata, 1989). Opponents are concerned about the health risks that hormones may cause, in particular cancer (Alfnes & Rickertson, 2004; Balter, 1999).

A 1999 risk assessment report from the European Commission expressed several concerns about hormone-treated beef. If the hormone implant is improperly administered, it may result in higher concentrations of the hormone to a particular area of the animal (European

Commission, 1999, p. 30). In other words, the hormone is not distributed through the animal's system as intended, but to a specific location. If a consumer subsequently purchases this piece of meat, they are exposed to a higher level of hormones. The report also charged that U.S. inspectors do not check for hormones in beef. In a spot check of beef by the beef industry and the USDA, results indicated that 12% of the samples had detectable levels of hormones present (Balter, 1999). Another finding from the risk assessment was the potential for the hormone estradiol to cause cancer (Balter, 1999).

The U.S. position is that hormones approved for use in animals are not harmful to humans and the meat processed from them is safe to eat (FDA, 2017). They also argue that the EU has not conducted valid risk assessments. Therefore, there is no scientific evidence to support the EU's resistance to the meat (Carlarne, 2007; Congressional Research Service, 2017).

In contrast to the U.S., the EU does not allow the use of hormones in animals for purposes other than required for therapeutic treatments to tend to the animal's health. The resistance to hormone-treated beef in the EU derives from a previous experience when calves in Italy were given a synthetic estrogen (diethylstilbestrol, or DES) that caused abnormal development in children (Vogel, 2012, p. 54). DES had been classified as a carcinogen and had been banned in the EU and the U.S. Farmers purchased the illegal DES on the black market, treated the calves, processed the veal, where it ended up in baby food (Kolata, 1989; Vogel, 2012).

From an environmental perspective, the primary issue is whether hormones that are discharged in cattle feedlots can impact the environment. In a two-year controlled study, researchers administered steroid hormones to cattle via ear implants and food additives. They subsequently tested samples of the cattle manure and local soil. Based on their findings, they

concluded that that runoff from animal production facilities is an environmental and public health concern (Bartelt-Hunt et al, 2012).

EU and U.S. Parent Policies on Hormone-Treated Beef

The EU's parent policy for hormone-treat beef is Directive 88/146/EEC issued on March 7, 1988. This action replaced Directive 85/358/EEC from July 16, 1985 which had been ruled void by the European Court of Justice on a procedural violation. Directive 88/146/EEC went into effect January 1, 1989. There were a series of Directives regarding hormone-treated beef, but the 1988 Directive was chosen as the parent policy because it was the one that triggered the U.S. response.

On December, 24, 1987 President Ronald Reagan issued a Presidential Proclamation imposing 100% duties on European agricultural exports equating to $100 million in sanctions (Presidential Proclamation 5759). The U.S. allowed a one-year suspension of the tariffs to allow for negotiations, ultimately going into effect January 1, 1989. This action was initiated on the President's behalf by the U.S. Trade Representative, (Determination To Impose Increased Duties on Certain Products of the European Community, 1988). These tariffs remained in place until 1996 (Johnson, 2015). While the U.S. response of tariffs was technically to the 1985 policy, it was not activated until the enactment date of the 1988 policy, January 1, 1989. Appendix C contains a list of policy documents and policy-related documents on the topic of hormone-treated beef.

Case 3: Bisphenol A (BPA)

In this section, Bisphenol A (BPA) is presented as the third case study to examine language within EU and U.S. government agency documents for the presence of risk and benefit

statements. The case begins with a background discussion of BPA followed by the surrounding debate. Then the BPA parent policies from the EU and U.S. are introduced.

Background: What is BPA?

Bisphenol A, or BPA, is a synthetic chemical that is combined with other chemicals to create stronger, lighter, harder plastics (Environmental Protection Agency, 2010; Fox, Verslius, & van Asselt, 2011; Schierow & Lister, 2008; Weise & Szabo, 2007). BPA has been called an "everywhere chemical" because of its pervasive use in water bottles, baby bottles, and interior liners of canned products such as vegetables, soups, and sodas (Austen, 2008; Birnbaum, Bucher, Collman, Zeldin, Johnson, Schug, & Heindel, 2012; Fox, et al. 2011; Weise & Szabo, 2007). Over the last twenty years, the potential adverse health impacts of BPA use have become a concern for public health and the environment.

Products containing BPA have been in use since the mid-1950s, but the debate about potential health effects gained momentum towards the end of the 21st century (Environmental Protection Agency, 2010). In the late 1990s, BPA came under heightened scrutiny due to concerns that it can leach into food from the can liners or plastic containers such as storage containers, particularly when heated (Centers for Disease Control and Prevention, 2009; Derbyshire, 2008; Schierow & Lister, 2008). Due to the ubiquity of BPA in everyday products, studies have suggested that BPA may pose a potential safety risk for humans, especially infants and small children (Birnbaum et al, 2012; Fox, et al. 2011; vom Saal, et al, 2007). Consequently, most studies have focused on the acceptable level (i.e. total daily intake, or TDI) that humans can consume without harm. (vom Saal, et al, 2007). Despite studies demonstrating health concerns, the chemical industry and some government agencies maintain that BPA is safe to humans at low usage levels (American Chemistry Council, 2018).

People are exposed to BPA in three ways: food packaging (i.e. plastic wrappers, tin cans, etc.), environmental channels (i.e. air, water, soil, etc.), and consumer products (e.g. cell phones, electronics, etc.) (Environmental Protection Agency, 2010). It is believed that humans are exposed primarily to BPA through diet via food packaging and beverage containers (Birnbaum et al, 2012; Environmental Protection Agency, 2010; National Institute of Environmental Health Sciences, 2017; Schierow & Lister, 2008). While only 5% of BPA produced is used for these "food contact applications" (Environmental Protection Agency, 2010), a 2003-2004 survey by the U.S. Centers for Disease Control and Prevention (CDC) found that 92% of participants (including children under six) had BPA in their urine (CDC, 2009). The same report notes that "Finding a measureable amount of bisphenol A in the urine does not mean that the levels of bisphenol A cause an adverse health effect" (p. 31).

Debate: Is BPA safe for humans and the environment?

Research has linked BPA to various endocrine-related disorders. In studies of low doses of BPA's effects on mice and rats, the chemical has been found to mimic the sex hormone, estrogen and has been classified as an "endocrine disruptor" (Boseley, 2008; Weise & Szabo, 2007). It has been linked to urinary tract problems, early puberty, enlarged prostates, breast cancer, obesity, memory and learning problems, depression, and clogged arteries (Austen, 2008; Birnbaum et al, 2012; Schierow & Lister, 2008). The studies often examined the level of BPA in the subject. Based on the difference in academic findings, much of the debate surrounding the safety of BPA centers on the appropriate exposure level, known formally as the "total daily intake", or TDI.

In November of 2006, an international panel of 38 scientists convened in Chapel Hill, North Carolina, to review the scientific literature on BPA studies with the goal of assessing risks

to human health. The outcome of that meeting was the Chapel Hill Consensus Statement (vom Saal, et al, 2007). In their statement, the panel concluded:

> The published scientific literature on human and animal exposure to low doses of BPA … reveals that human exposure to BPA is within the range that is predicted to be biologically active in over 95% of people sampled. The wide range of adverse effects of low doses of BPA in laboratory animals exposed both during development and in adulthood is a great cause for concern with regard to the potential for similar adverse effects in humans. (vom Saal, et al, 2007, p. 12).

In 2008, the BPA debate gained heightened visibility when multiple government agencies published different positions on the safety of the chemical. The U.S. National Toxicology Program reported that rats injected with low doses of BPA developed precancerous tumors and other health problems (National Toxicology Program, 2008; Austen, 2008, Schierow & Lister, 2008). However, the American Chemistry Council maintained that there was no evidence to suggest that BPA has an adverse effect on humans (Weiss, 2005; Grossman, 2007; Austen 2008). Critics discount the studies and reports that have found harm because their experiments were conducted on mice, rats, and primates, which do not mimic the way humans ingest the chemical (Brackett, 2008).

The same week that the U.S. NTP report was issued, Canada released its own risk assessment of BPA finding that newborns and infants were at a particularly high risk to BPA (Schierow & Lister, 2008; Congressional Research Service, 2011). This prompted the Canadian government to ban polycarbonate bottles made with BPA (Schierow & Lister, 2008; Congressional Research Service, 2011). The EU followed suit in 2011 and temporarily banned BPA from baby bottles (Fox, et al. 2011). In 2012, the U.S. FDA issued a ruling to discontinue

use of BPA in baby bottles and sippy cups in response to a petition from the chemical industry (Indirect Food Additives, Polymers, 2012).

Recently, the consensus on the safety of BPA is shifting again. As of April 2018, the U.S. FDA unequivocally confirmed the safety of the chemical when used at appropriate levels. On the FDA website, a factsheet about BPA includes the question "Is BPA safe?". The response is "Yes" (FDA, 2018). In contrast, the European Chemical Agency updated BPA's status on the EU's list of chemicals that may have harmful effects on human health or the environment, "to reflect the additional intrinsic properties of concern, i.e. that BPA demonstrates probable serious effects to the environment, due to its endocrine disrupting properties" (European Chemical Agency, 2018, p. 4). Chemicals on this "Candidate List" are also known as "substances of very high concern" (European Chemical Agency website, 2018).

In addition to concern regarding BPA's impact on health, there are also questions about how BPA may affect the environment. BPA may enter air and water through industrial operations or from disposal of consumer products containing BPA (CDC, 2009, p. 30). In a brief document summarizing results from environmental studies on BPA, the Global Industry Group (2002) asserted: "The data in the validated studies and reviews…combined with current scientific understanding of BPA toxicity, indicate that the current manufacturing and use patterns of BPA pose virtually no risk to the environment" (p. 4). However, a few years later in the Environmental Protection Agency's 2010 *Bisphenol A Action Plan*, the agency identified the chemical as a potential concern because it "may present an unreasonable risk of injury to the environment on the basis of its potential for long-term adverse effects on growth, reproduction and development in aquatic species" (Environmental Protection Agency, 2010, p. 1).

EU and U.S. Parent Policies on BPA

In the case of BPA, both the EU and the U.S. have enacted bans on its use in baby bottles. In January 2011, the European Commission adopted Directive 2011/8/EU, which places a ban on the manufacture and sale of baby bottles containing BPA. This Directive was chosen as the EU's parent policy for BPA.

The U.S. parent policy is officially recognized as Docket No. FDA–2012–F–0031. In October 2011, the American Chemistry Council (ACC), an industry group representing manufacturers of BPA, submitted a petition to the U.S. FDA to ban BPA-based polycarbonate (PC) resins on the grounds that the use of BPA in baby bottles and sippy cups had been abandoned (American Chemistry Council, 2011). In other words, manufacturers had discontinued use of the chemical in these products in response to consumer preference. In July 2012, the U.S. FDA responded affirmatively to this petition and issued a regulation that banned BPA-based PC resins from baby bottles and sippy cups. Appendix D contains a list of policy documents and policy-related documents on the topic of BPA.

Policy Documents and Policy-Related Documents

Government agencies are charged with monitoring and oversight of specific public policy issues, including those that depend on science. The agencies produce documents to communicate with stakeholders about the status of their activities. In this study, the term "policy documents" refers to publicly available, written documents published by EU and U.S. government agencies (Daugbjerg, Kahlmeier, Racioppi, Martin-Diner, Martin, Oja, & Bull, 2009). Policy documents were chosen for this study because they are the official source of the policy narrative in the EU and the U.S.

At a basic level, the agencies are responsible for providing descriptive information about the issue. Sometimes called "fact sheets", these publications are usually quite brief and written in

plain language targeted at the general public. The European Commission's information page on hormones in meat is an example of a fact sheet. This page reviews the legislative history regarding hormone-treated meat as well as links to key scientific reports (European Commission, 2018).

If an agency is monitoring an issue over time, it might provide updates about the usage or prevalence of the issue in the community. This information might be communicated through press releases or summary reports. An example is the 2009 "Fourth National Report on Human Exposure to Environmental Chemicals" from the U.S. Centers for Disease Control and Prevention (CDC). This is one document in a series of assessments that monitor the prevalence of certain chemicals in the U.S. population. The reports make the results available to the public.

If the issue has been subject to disputed scientific research results, the agency might convene experts to evaluate the studies. The results of these activities are typically longer documents, with both an executive summary targeted at a lay reader and a lengthier body of the report with technical findings. One example of this type of document is the "Revised Opinion on Cyclamic Acid and Its Sodium and Calcium Salts" published by the European Commission's Scientific Committee on Food in 2000.

Press releases, referred to as policy-related documents in this study, are issued by organizations, both public and private, as a means of communicating information about their activities. They are seen as a "narrative tool for framing an organization's identity" (Graube, Clark, and Illman, 2010). Government agencies issue press releases for a variety of reasons. An example from the U.S. in the case of hormone-treated beef is entitled "Obama Administration Takes Action to Address European Union's Unfair Trade Practices against U.S. Beef Industry" (U.S. Trade Representative, 2016).

Policy documents and policy-related documents are a common unit of analysis for researchers. One reason for this is that government agencies are generally seen as trustworthy and credible (Lee & Basnyat, 2013). While politics can overshadow a government's credibility, historically, the public trusts federal agencies to execute their mission. In the U.S., nine of thirteen federal agencies were viewed favorably by over 60% of the public (Pew Research Center, 2015). A similar trend of trust in public services can be found in the EU, with over 60% of respondents saying they trust transportation, health care, law enforcement and education services (Organisation for Economic Co-operation and Development, 2015).

A second reason that government documents make an attractive dataset is that they exist without the impact or influence of the researcher (Bowen, 2009). With research methods such as experiments, surveys, and interviews, the researcher is responsible for designing the data collection instrument. While every effort is made to ensure the instrument and supporting stimuli are reliable and valid, there is a risk that the researcher's bias may inadvertently exert influence. With public documents produced by sources other than the researcher, that risk is avoided.

A third reason is that the government documents are available across a broad timeframe making comparative historical analysis a viable research path (Yin, 1994). In this proposed study, the earliest documents are from 1969 and the most recent is from 2018. This span of time allows for comparison of changes in language use both within a single case and across cases. A fourth, more practical reason is that the public documents are available online via government websites.

Significance of the Study

This research is interested in understanding how scientific information is used by the EU and U.S. in making public policy decisions by analyzing policy documents for patterns of

communication, specifically frames. This study is significant for three reasons. First, this research is significant because it extends the current framing literature by comparing *risk*, *benefit* and *science*-related frames across three topics that involve science (cyclamates, hormone-treated beef and bisphenol-A). In the majority of previous studies, the analysis considers only one topic (e.g. McComas & Shanahan, 1999; Stephens, 2005; Stewart, 2013) The current study design intentionally selected two cases in which the jurisdictions have opposite public policies on topics that involve science (i.e. cyclamates and hormone-treated beef), and one in which they share the policy outcome (i.e. bisphenol-A). This comparison of opposing policy outcomes may reveal patterns that would not otherwise be evident by only looking at one topic.

Another important contribution of this study is that it analyzes policy documents, which have not yet been studied for *risk*, *benefit,* or *science* frames. The vast literature on the use of *risk* and *benefits* in news articles has been informative in academic circles as well as for society at large. As a result of this work, some media audiences are now aware that content is intentionally framed for certain purposes. By examining policy documents for *risk*, *benefit,* and *science* frames, studies such as the current one can contribute to raising awareness in policymaking settings about how content is presented and framed.

Finally, this study explored a communications question through an interdisciplinary lens of international relations and public policy. It builds on the comparative literature examining the EU-U.S. relationship. The EU and the U.S. are not only economic and political allies, they are global leaders whose actions have international implications. If their policy goals are misaligned, the consequences may affect the stability and prosperity of dozens of countries and millions of people. Numerous studies have compared these two jurisdictions from legal, economic, and regulatory perspectives, but this current study fills a gap by complementing previous work by

approaching the comparison from a communications perspective. By analyzing the language used in public documents along with how that language is framed, it may be possible to shed light on avenues of the underlying sources of policy agreement and discord.

CHAPTER 2

LITERATURE REVIEW

The EU and the U.S. have both demonstrated various levels of risk tolerance at different times and on different policy issues. When the level of actual or potential risk is unknown, governments may invoke the precautionary principle as a safeguard against potential harm (Lin, 2001; Turker, 2012; Van Den Belt & Gremmen, 2002). Once the risk, or lack thereof, has been evaluated through scientific research, more informed policy decisions can be made. In some cases, policymakers may differ in their interpretations of the scientific evidence. This disagreement may lead to conflicting policy outcomes. For example, the EU and the U.S. have diverged in their regulation of cyclamates and hormone-treated beef based on different understandings of the risk posed by each product. In the case of bisphenol-A, while the policy outcome is currently identical, the policy justifications were based on different perceptions of the risk posed by BPA. To gain insights into these differences, this study examines the language within policy-related documents to see how risks, benefits and science-related content has been framed and presented for these three issues in the EU and the U.S.

This chapter begins with a discussion on framing theory with a focus on research that has examined policy issues that involve scientific assessments of risk. The discussion then focuses on valence framing, which includes risk framing. The literature review concludes with research that has examined framing of policy documents. Research questions and hypotheses are introduced.

Framing Theory

Frames are linguistic devices used to suggest what is important about an issue (Gamson & Modigliani, 1989; Entman, 1993). The process of framing takes place when communicators select what to include and exclude in messages to achieve the content that will resonate with their targeted audience/s (Chong & Druckman, 2007; Entman, 1993; Gamson & Modigliani, 1989). This information may then be used to guide opinion formation and decision-making by providing contextual cues (Hallahan,1999). When communicators use frames strategically and effectively, they may be able to persuade audience members to accept a particular viewpoint (National Academies of Science, 2016, p. 36).

In the case of issues that involve science, framing often influences how the public, policymakers, journalists, and other audiences think about fields such as nanotechnology, artificial intelligence, robotics, and additional issues that involve uncertainty and/or disagreement. Framing works by helping audience members understand a scientific concept in terms of previous knowledge or relevant context (Entman, 1993; Chong & Druckman, 2007; Schufele & Tewksbury, 2007; National Academies of Science, 2016). Frames leverage people's existing cognitive schemas to shape how they interpret information (Hallahan, 1999). Content creators may use frames to recast a complex issue into terms that lay audiences can understand within the time and/or space constraints present in media environments (Scheufele & Tewksbury, 2007).

Previous research that has examined message framing in the context of issues that involve science reveal two common characteristics. First, the studies typically have focused on a single science or technology issue. Topics have included nuclear energy (Gamson & Modigliani, 1989), climate change (McComas & Shanahan, 1999; Brossard, Shanahan & McComas, 2004),

nanotechnology (Anderson, Allan, Petersen & Wilkinson, 2005; Stephens 2005), biotechnology (Kim, Besley, Oh, & Kim, 2014; Marks, Kalaitzandonakes, Wilkins, & Zakharova, 2007; Nisbet & Huge, 2006;), and stem cell research (Nisbet, Brossard & Kroespch, 2003; Stewart, 2013). In these single-issue studies, findings often indicated that the issue tended to be linked with one or more specific science frames. For example, three content analyses of news articles featuring nanotechnology consistently found a dominant science frame of *scientific discovery* (Anderson, et al., 2005; Wilkinson, et al., 2007; Allan, et al, 2010). Since the data (i.e., news articles) from these studies were from the early 2000s, it might be expected that the emergence of nanotechnology into public awareness began with prominence on the frame of *scientific discovery*. The results of these studies indicate that there are consistent frames that are applied across science policy topics. Examples of these frames include *economic progress*, *social progress*, *scientific discovery, scientific background*, *political conflict*, and *Frankenstein's Monster* (also known as *Devil's Bargain* or *Runaway*).

A second common feature of studies involving science policy issues is that news articles were the most common unit of analysis (e.g. Anderson et al., 2005; Brossard et al., 2004; Kim et al., 2014; Marks et al., 2007; McComas & Shanahan, 1999; Nisbet et al., 2003; Nisbet & Lowenstein, 2002; Stephens 2005; Nisbet & Huge, 2006). News articles are attractive because generally they are addressing an issue at a specific point in time. This lends itself easily to tracking attributes of the articles over defined periods of time. Similarly, frames identified in earlier studies can be applied to later news articles to see how tone or frames shift according to topic or time.

The present study applies the preceding literature to a different unit of analysis (policy documents and policy-related documents) across three topics that utilize science (i.e. cyclamates,

hormone-treated beef, and bisphenol-A). Since policy discussions typically revolve around the levels of risk present, one would expect to find documents that support or oppose cyclamate, hormone-treated beef, and bisphenol-A to utilize different arguments. In terms of framing, these arguments would be considered to have "valence" or tone. The following discussion reviews the literature on valence framing in terms of risks and benefits.

Valence framing

Research on positive, negative, and neutral messages is called *valence framing* (Levin, Schneider & Gaeth, 1998; Schuck and DeVreese, 2006). Sometimes referred to as *tone* (Kim et al., 2014; Nisbet & Lewenstein, 2002), valence framing is used to positively or negatively influence an audience's perception of an issue. The research in valence framing uses a variety of bipolar labels to characterize tone. In addition to "positive - negative" (e.g. Gamliel, 2013; Heiman & Zilberman, 2011), other labels include "gain - loss" (e.g. Lee & Basnyat, 2013; Rothman, Bartels, Wlaschin, & Salovey, 2006; Tversky & Kahneman, 1981), "risk - benefit" (e.g. Anderson et al., 2005; Marks et al., 2007), "support - oppose" (e.g. Bizer, Larsen, & Petty, 2011; Gesser-Edelburg, Walter, Shir-Raz, & Green, 2015; Kim et al., 2014), "favorable – unfavorable" (e.g. Pollack, et al, 2017) and "risk - opportunity" (e.g. Painter, 2013; Schuck & DeVreese, 2006).

Studies on issue framing in the science domain reveal that media, for example newspapers, frequently use valence frames to describe the trade-offs associated with scientific ideas to the public, policymakers, and other lay audiences. Sometimes the research tries to measure how the issue has been described in the media, for example, more *positively* or more *negatively* (e.g. Gaskell, Bauer, Durant, & Allum, 2000; Kim et al., 2014; Marks et al., 2007; Nisbet & Lewenstein, 2002). Similarly, these analyses may characterize content in terms of *risks*

and *benefits* (e.g. Anderson et al., 2005; Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, 1995; Dusyk, Axsen & Dullemond, 2018).

Since this study is interested in how risk has been characterized in American and European policy documents, the following discussion reviews previous research that has examined *risks* and *benefits* of policy issues that utilize science in the EU or European countries, and the U.S. At present, there are no studies that analyze policy documents in terms of *risks* and *benefits*. However, there is a robust literature studying how *risks* and *benefits* are portrayed in newspaper articles. To understand what types of approaches and coding schemes have been applied, studies on newspaper articles were used. News articles are an informative proxy because they often reflect the contemporary policy debate of the jurisdiction.

Bauer, Ragnarsdottir, Rudolfsdottir, and Durant (1995) conducted a comprehensive study of science and technology in the British press from 1946 to 1990. Among their findings was that news articles tended to feature the *benefits* of science until the mid 1960s. For a brief period in the late 1960s and early 1970s, *risks* overtook *benefits*. After that, news articles tended to balance the coverage of *risks* and *benefits*. The authors provided a detailed coding scheme of *risk* and *benefit* types which informed the current study.

Research on the topic of genetically modified (GM) foods demonstrates that international press coverage varies in terms of how often the news articles feature *risks* versus *benefits*. In a comparative analysis of European and American news articles during the late 1980s and early 1990s, EU newspapers highlighted the *benefits* of GM foods much more often than they highlighted the *risks.* U.S. newspapers tended to call attention to *both risks and benefits* (Gaskell, et al., 2000). Marks, Kalaitzandonakes, Wilkins, and Zakharova (2007) conducted a comparative analysis of U.S. and UK newspapers from 1990 to 2001. The authors analyzed the news articles

for *risk-benefit* frames regarding medical and agricultural biotechnology applications. They found that international news coverage of agricultural biotechnology applications, including GM foods, has emphasized *risks* more often than *benefits* (p. 191). This finding was consistent with a study that compared news coverage of GM foods in the UK and Spain (Vilella-Vila & Costa-Font, 2008). The coverage of GM foods was much more prevalent in the UK news outlets than in Spain. However, in both countries the media emphasized *risks* while downplaying the *benefits* of GM foods. In a study of 19 newspapers worldwide from 2004 to 2014, Pollock et al. (2017) confirmed the *trend of negative* press coverage of GM foods finding that 58% of coverage was *unfavorable* (p. 587). Taken collectively over time, these studies suggest there has been a transition from highlighting the *positive* aspects to *negative* aspects in press coverage of GM products.

Framing research on nanotechnology reveals a different pattern. Stephens (2005) analyzed 350 articles from U.S. newspapers from 1999 to 2004. He found that almost 46% of the articles had "no discernable tone" (i.e. neither *risk* or *benefit*), 30% of the stories focused on *benefits over risks* and less than 10% emphasized *risks over benefits* (p. 187). Building on Stephens' study design, Anderson, Allan, Petersen & Wilkinson (2005) analyzed 344 articles from 18 daily and Sunday British newspapers in 2003-2004. They found that almost 40% of the articles emphasized *benefits over risks* while only 11% emphasized *risks over benefits*. Strekalova (2015) reviewed several U.S. newspapers between 1990 and 2013 and found that 45% featured the *benefits* of nanotechnology while 36% covered both *risks and benefits* (p. 164). Based on these studies, nanotechnology has been portrayed more often in terms of its benefits rather than potential risks.

Table 2 summarizes the framing studies previously described. Results indicate that valence often changes as a function of topic or issue, location, and time period.

Table 2: Previous Framing Studies

Issue	Time period	Geographic focus	Finding pertaining to valence
Science and Technology			
Bauer et al, 1995	1946-1990	UK	*Benefits* predominant in news articles until 1960s; late 1960s to early 1970s, *risks* predominant; mid-1970s to 1990, balance of *risks* and *benefits*
Biotechnology			
Marks, Kalaitzandonakes, Wilkins, & Zakharova, 2007	1990-2001	U.S. and UK	*Risks* predominant for agricultural biotechnology (e.g. GM foods). *Benefits* predominant for medical biotechnology (e.g. gene therapy)
GMOs			
Gaskell, Bauer, Durant & Allum (2000)	1984-1996	U.S. and EU	*Benefits* predominant in European media while *risks and benefits* predominant for U.S. media
Vilella-Vila & Costa-Font, 2008	1999-2004	UK and Spain	*Risks* predominant in both countries
Pollock et al, 2017	2004-2014	19 newspapers worldwide	*Unfavorable* coverage featured
Nanotechnology			
Stephens (2005)	1988 -2004	U.S. and non-U.S.	*Benefits* predominant in news articles
Anderson, Allan, Petersen & Wilkinson (2005)	April 2003-June 2004	UK	*Benefits* predominant in news articles
Strekalova (2014)	1990-2013	U.S.	*Benefits* predominant in news articles

Advances in science and technology offer both risks and benefits. Governments are frequently charged with weighing risks against the benefits in order to protect the rights and safety of citizens. The preceding discussion reviewed several studies of how the risks and benefits of science and technology are portrayed in the news media. Since the previous studies

analyzed news articles instead of policy and policy-related documents, the first research questions are:

RQ1: For each topic, what is the frequency of statements regarding *risks* in policy documents and policy-related documents in the EU and the U.S.?

RQ2: For each topic, what is the frequency of statements regarding *benefits* in policy documents and policy-related documents in the EU and the U.S.?

Other Frames Used on Policy Issues that Involve Science

Beyond risks and benefits, it is of value to examine whether there are specific types of content that reflect the role of scientific information in policy documents. This is important because if, for example, the scientific evidence is disputed in different jurisdictions, it may possible to identify the discrepancies.

Previous research on policy issues that involve science provides guidance for other frames used to characterize science policy topics. A common frame found in these studies was *scientific background* or *scientific information*. Described as "general scientific…background of the issue (e.g. description of previous research, recap of "known" results and findings, description of potential…uses)" (Nisbet & Huge, 2006 p. 20), it is often found in scientific reports, scientific explanations, and quotes from scientists (Mitchell & Roffey-Mitchell, 2018). For example, Nisbet, Brossard, & Kroepsch, (2003) found that *scientific background* appeared in 44% of the articles regarding the stem cell controversy between 1975 and 2001. In a content analysis of news articles related to plant biotechnology from 1978 to 2004, Nisbet and Huge (2006) found that the articles featured *scientific background* in the 1980s and early 1990s. From the mid-1990s to 2004, this frame appeared half as often. Mitchell and Roffey-Mitchell (2018) found that *scientific information* appeared in 48% of the 224 Australian online news reports

regarding the bleaching of the Great Barrier Reef (p. 12). These studies indicate that approximately half of news stories about science issues contain content that can be classified as the frame *scientific information*. These findings are relevant to the current study because scientific information such as research protocols, study data, and final results would be appropriate to support informed policy discussions. Because there are no studies of scientific frames on policy documents, the third research question is:

RQ3: For each topic, what is the frequency of statements regarding *scientific background information* in policy documents and policy-related documents in the EU and the U.S.?

An additional frame of *scientific uncertainty* is of interest to the current study as much of the policy differences for each of the three study topics stems from challenges to the scientific evidence. Nisbet, Brossard, and Kroepsch (2003) analyzed U.S. news articles regarding stem cell research from 1975 to 2001. They found that the frame of *scientific uncertainty* was the primary theme in 9% of the articles while it was the secondary theme in almost 25% of the articles (p. 58). The leading primary theme was *political strategy/conflict* occurring in over 29% of the articles. The leading secondary theme was *scientific background* occurring in 28.8% of the articles.

In their study of online media reports regarding the 2016 mass coral-bleaching of the Great Barrier Reef, Mitchell and Roffey-Mitchell (2018) identified *scientific uncertainty* with keywords such as “uncertain”, “uncertainty”, “doubt”, and “too early” (p. 9). Across 224 reports from six Australian news outlets, the frame of *scientific uncertainty* was present in 70% of the articles. It was the first framed mentioned (i.e. salience) in 25% of the articles. Finally, it was the most frequent frame (i.e. dominance) in 22% of the articles (p. 10).

For Nisbet and Huge (2006), *scientific uncertainty* "includes focus on the precautionary principle" or "criticism of scientific claims of opponents" (p. 20). It occurs when scientists studying the same product or process are not in agreement about their findings or what the findings may mean. There may be valid explanations for these disagreements (e.g. differing experimental conditions). Nisbet and Huge's definition links the frame of *scientific uncertainty* to the precautionary principle employed by the EU and the U.S. at different times.

The aforementioned studies suggest that the frame of *scientific uncertainty* occurs consistently in news articles about science-informed policy topics. The presence of this frame may be a consequence of journalists' efforts to be balanced in their coverage by presenting differing perspectives. Similarly, in public policy deliberations, policymakers try to ensure they consider all sides of an issue by inviting information from all interested parties. As it relates to the topics in the current study, the policy documents include scientific reports and opinions that may contain statements of uncertainty about results and evidence. Since the previously discussed studies analyzed news articles instead of policy documents, the next research question is

RQ4: For each topic, what is the frequency of statements regarding *scientific uncertainty* in policy documents and policy-related documents in the EU and the U.S.?

One of the motivations of this study was to discern the role of precaution in policymaking on issues that rely on science. There were no studies that examined the use of precaution as a framing or narrative tool, so the fifth research question is:

RQ5: For each topic, what is the frequency of statements regarding *precaution or the precautionary principle* in policy documents and policy-related documents in the EU and the U.S.?

Two additional frames emerged during data analysis. The two are counterparts: *science used for decision-making* and *science not used for decision-making*. Statements were coded as s*cience used for decision-making* if there was express reference to data or studies that had been used to inform the policy decision. Statements were coded as *science not used for decision-making* if there was express reference to the absence of the use of science for making the decision.

RQ6: For each topic, what is the frequency of statements regarding *science used for decision-making* in policy documents and policy-related documents in the EU and the U.S.?

RQ7: For each topic, what is the frequency of statements regarding *science not used for decision-making* in policy documents and policy-related documents in the EU and the U.S.?

Presence and prominence

The initial analysis determined which frames were present in the policy documents and their frequency. After coding was complete, an additional analysis examined where the frames appeared, and specifically whether they appeared first. A third perspective was which of the frames appeared most often. Analyzing the location and frequency of frames is of value because if a jurisdiction consistently places a particular frame first or often in their policy documents, this may signal a potential priority or value from their perspective.

Past studies have analyzed how often particular frames are present in the text, where they appear and how frequently. Mitchell & Roffey-Mitchell (2018) referred to these variables as *presence, salience and dominance* respectively. *Presence* establishes whether the frame occurs in the text or not. *Salience* describes which frame appears earliest. Because *salience* may be

interpreted in several ways, this variable will be referred to as *initial* in this study. Nisbet and Huge (2006) describe this first frame as "outstanding focus/appearing in the lead" (p. 19) while Anderson, Allan, Petersen and Wilkinson characterize it as "most significant or newsworthy" (p. 204).

Dominance is determined by the frequency of a frame in the text. Nisbet, Brossard and Kroepsch (2003) refer to this as the frequency of major and minor frames. Multiple frames can be present in a text, but the dominant one occurs most often. These concepts lead to the final set of research questions:

RQ8: For each topic, which frame appears *first* (initial) most often for the policy documents and policy-related documents?

RQ9: For each topic, which frame is the most *dominant* for the policy documents and policy-related documents?

Content Analysis Studies of Policy Documents

The current study seeks to understand policy differences between the EU and the U.S. on three topics that involve science. One approach is to content analyze policy documents on these topics, looking for frames and other patterns. Policy documents can be defined as published "documents that contain strategies and priorities, define goals and objectives, and are issued by a part of the public administration" (Daugbjerg et al., 2009, p. 806). In addition, these documents are considered decision-making tools that may define an issue, identify options, and/or make recommendations (Blumel, 2018, p. 26). Policy documents may include legislation, strategic plans, scientific reports, fact sheets, memos, and others.

As demonstrated previously, content analysis of news articles is commonly used to evaluate valence or tone towards a variety of issues. In the case of science frames, the categories

have been applied in studies since the late 1980s. For example, frames such as *scientific uncertainty* and *scientific background* have been analyzed across time periods and topics. In the case of policy documents, there is not an analogous set of frames that have been applied across studies. There are many studies on policy documents, but the frames used vary depending on the context of the study.

Stewart, Gil-Egui, Tian, and Pileggi (2006) conducted a comparative content analysis of strategic plans from the EU and the U.S. on the issue of the digital divide[3]. They sought to identify similarities and differences in the way the digital divide was framed in these documents. The dataset included five plans from the U.S. and three plans from the EU. Through a longitudinal word frequency analysis and cluster analysis, they determined that the two jurisdictions "share a converging trend towards consideration of market-based issues as key points of policies related to the digital divide" (p. 744). The primary value of the study by Stewart et al. (2006) is that it provides a scholarly precedent for the comparison between the EU and U.S. for purposes of explaining policy dis/harmony between the two jurisdictions from a communications perspective.

Steurs, Van de Pas, Delputte, & Orbie (2018) used NVivo software to analyze global health policies in the EU and five member states. Their goal was to learn whether the EU and these member states shared a "common vision" for health which would facilitate policy convergence. The member state's perspective on health would influence the overarching EU strategic plan. One main finding was that health was framed differently across the five documents. The authors discovered that '*international health*' tended to refer to assistance to developing nations while '*global health'* described a broader notion of the health impacts of

[3] The "digital divide" is a term that describes the gap between persons who have access to the Internet and those who do not.

globalization to all countries with "the shared risks and threats" (p. 437). Second, they found that different member states emphasized different health frames (e.g. *social justice, security, investment,* and *charity*). This work informs the current study by validating the importance of studying policy convergence across governments by looking at how they communicate within policy documents.

Blumel (2018) analyzed how translational research has been framed in European and American policy papers and funding programs. His analytical approach included two frames that characterized how "scientific knowledge production" is perceived: as *science as an organization* or *science as a profession*. Through a review of over 50 documents from 2003 to 2013, he determined that the American environment of translational research framed their discourse in terms of the integrity of the research endeavor and *science as a profession*. He also found the EU has a *science as an organization* conception of work which manifests as steering research needs towards societal challenges. These differences in conception of science influence how problems are framed and understood. In the case of translational research, these differences may lead to different research funding priorities. Blumel's work informs the current study by corroborating the value of analyzing divergent policy perspectives in order to identify opportunities to harmonize policy decisions for societal benefit.

The preceding studies shares several attributes with the proposed study. They share a comparative approach, use policy documents as a unit of analysis, and framing as a theoretical framework. Their primary contribution to the current study is that they have collectively demonstrated that content analyzing policy-related documents is useful in identifying points of policy divergence and convergence.

Press Releases

While press releases are a primary channel to communicate policy updates, they were not included in the policy document content analyses undertaken here because they generally do not contribute directly to the decision-making process. Rather, they are designed to promote or publicize policies, as such are better characterized as *policy-related documents*. It is worth noting that press releases have been the focus of some studies and as such, do help illustrate the value of content analyzes involving framing. For instance, one interrogative research approach is to attempt to trace the narrative used by government agencies in press releases to news articles based on the press releases. For example, Rice and Bartlett (2006) examined Australian government press releases regarding the entry into the Iraq War of 2003 and 2004. In their study, three frames were found to characterize how the government explained their position of going to war. The *talk* frame served as the matter-of-fact "reasoning for going to war…without any overt media bias" (p. 10). The *justification* frame emerged when "the government was responding to criticisms or the media was criticizing the government" (p. 10). The *crisis* frame signaled when the government was defending itself against accusations or when the media openly criticized the government. The authors found that the government's press releases were mostly written in the positive *talk* frame with a focus on positive news, while the media published articles that featured the negative *crisis* frame. Hence, they found no relationship between frames used in the government press releases and those in the related news articles. While the study design did not expressly mention the role of valence framing, their framing scheme inherently reflected positive and negative attributes. In analyzing the news articles use of crisis framing, they cited Hallahan's (1999) observation that audiences may weigh negative information more heavily than positive information (p. 208).

Murphree, Reber, and Blevens (2009) conducted an analysis of press releases from the U.S. Federal Emergency Management Agency (FEMA) during the period of Hurricanes Katrina and Rita in late summer and early fall of 2005. They found that despite public criticism of the agency's actions, or lack thereof, the agency's tone was optimistic. From a dataset of over 600 FEMA press releases, they inductively identified three main themes that reflected the role of the government agency: *instructor, superhero,* and *optimist*. The *instructor* was the most common frame. It encompassed logistical issues such as how to apply for assistance and ongoing safety guidelines (p. 281). The *superhero* frame was used in press releases highlighting funding FEMA was providing to the affected states for recovery purposes. It had a "congratulatory tone and repeatedly announced the many generous contributions of the organization" (p. 282). Finally, most of the press releases utilized an *optimist* frame, with a consistent tone of looking forward to the future. Because the frames were identified inductively, there was not a predetermination that valence would be evident. Similar to the Rice and Bartlett study of Australian press releases, the FEMA-authored press releases tended to feature a positive tone even in the face of severe crisis.

More recently, Lee and Basynat (2013) analyzed 158 press releases regarding the H1N1 influenza pandemic from the Singapore Ministry of Health (MOH) from April 2009 to August 2010. They found that 55 press releases could be linked to 57 news articles while the remaining 103 press releases did not result in media stories. They coded both the press releases and the news articles for numerous variables, including whether the texts were framed in terms of the *gains* or *losses* "that resulted from the pandemic or response efforts" (p. 124). Half of the press releases were categorized using *loss* frames, while only 15% were framed as *gain*. In addition to the gain-loss valence, the texts were also analyzed for tone in terms of feelings towards the government efforts (i.e. *positive, negative, or neutral*). Most of the MOH press releases are quite

neutral in tone (66.5%) with the remaining press releases coded as *positive*. None of the government press releases were *negative* in tone.

CHAPTER THREE

METHODS

This study uses content analysis to systematically analyze public policy documents from the EU and U.S. for *risk*-related, *benefit*-related and *science*-related content. Guided by previous studies, deductive analysis is used to code the documents. This chapter discusses the research method, the data collection process, variables, and coding procedures.

Content Analysis

The research method used for this study is content analysis, the systematic and objective review of text, images, or other media to identify trends or patterns (Bengtsson, 2016; Krippendorff, 2004; Neuendorf, 2002). While content analysis focuses on words, sentences, and passages within specific documents, the purpose of the method is to yield meaning about the dataset as a whole. The method is commonly used in the field of communication, but it has been applied to research studies in fields as diverse as nursing (Graneheim, Lindgren, & Lundman, 2017), physical fitness (Daugberg, et al), and international relations (Matthews & Callaway, 2015). Within any particular content analysis study, the researcher establishes specific procedures for collecting and analyzing the data (Stemler, 2001).

Within content analysis, there are two main types of content: manifest and latent. Manifest content takes the content at face value, looking for specific words or phrases. An advantage of manifest content is that it is observable, countable, and measurable (Riffe, Lacy, & Fico, 2014). A potential disadvantage of manifest content analysis is the context of the occurrence of the terms might be lost. Only counting instances of words without context can be

misleading and result in spurious findings. To guard against this, the complementary approach of latent content analysis can be employed (Braun & Clarke, 2006).

Latent content analysis is more subjective and seeks to analyze the underlying meaning of the passage within the document (Clarke, McLellen, & Hoffman-Goetz, 2006; Terrell, 2016). Latent content analysis is necessary for this study because the manifest terms *risk* and *benefit* are not always present in the policy documents, but it is expected that the concepts of *risk* and/or *benefit* are present. For example, the EU's *Revised Opinion on Cyclamic Acid and Its Sodium and Calcium Salts* (9 March 2000) contains this sentence: "The new epidemiological data revealed no indications of harmful effects on human reproduction parameters of either cyclamate used as food additive or of workplace exposure to cyclohexylamine" (p. 6). The word *risk* does not appear, but "no indications of harmful effects" is equivalent to stating that there is no risk.

Topic Selection

In this study, three topics that involve science were selected to analyze and compare policy documents regarding these topics. The selection process began by reviewing the comparative literature on EU-U.S. policy relations for policy issues that relied on science where the two jurisdictions differed in their policy approaches. After numerous candidate topics emerged, the researcher conducted searches on government agency websites to determine if there was a documented public policy on the topic. Upon confirming that an issue had a documented policy, the researcher than looked for additional policy documents to build the overall dataset for analysis. Over time, cyclamates, hormone-treated beef, and Bisphenol A emerged as topics with documented federal-level policies and adequate supporting documentation.

Document Selection

This study content reviewed 162 policy documents from the EU and the U.S. on the topics of cyclamate, hormone-treated beef, and bisphenol-A. After selecting the documents to be included, the resulting dataset included 108 policy documents. Using deductive analysis, the documents were analyzed for the presence of *risk*-related*, benefit*-related, *and science*-related content. NVivo, a content analysis software package, was used by the primary coder for storage of the documents and coding of the text. A second coder analyzed a subset of documents in MS Word. The data was exported from NVivo to SPSS and MS Excel for statistical analysis.

For the purposes of this study, the following terminology was chosen either to clarify the idea being discussed or to expedite workflow. The terms are specific to this study and should not be assumed to have the exact same meaning in other contexts.

Definition of terms

The following terms are specific to this research study and defined here for clarity.

- *Policy issue that involves science:* This expression is an umbrella term for the case topics being analyzed in this study. They include cyclamate, hormone-treated beef, and bisphenol A (BPA).
- *Policy documents*: These are documents issued by government organizations that record a significant development in the policy-making process. Examples of these documents include legislation, agency regulations, and scientific reports.
- *Policy-related documents*: These are press releases issued by government organizations. This term has been selected because press releases report policy activity rather than contribute to the policy-making process.

- *Parent policy*: These are the anchoring documents for each topic in each government. There is a parent policy for each topic in both jurisdictions for a total of six parent documents. The parent policy is the document that defines the current policy (e.g. ban, acceptable daily intake, etc.). These parent policies guided the selection of other case-specific policy documents.
- *DocMens*: These are documents that are mentioned within the parent policies. These documents are published before the parent policy.
- *OthGovDocs*: These are other government published documents about the topic. These documents may be published before or after the parent policy.

Step 1: Identifying parent policies

The literature on policy documents suggests that specific policy documents are identified to answer the research question/s. Stewart, Gil-Equi, Tian and Pileggi (2006) compiled a dataset of five strategic plans about the digital divide. Steurs, Van de Pas, Delputte & Orbie (2018) compared five health policies from different EU member states. Similarly for the current study, it was more appropriate to seek out specific policies than to sample from available government documents.

The first step was to identify a "parent policy" for each topic from a federal-level agency in the EU and the U.S. To do so, the researcher used the Lexis Nexis database to search for news articles for each issue. The parent policy typically revealed itself quite clearly due to the frequency of news articles around the time period of the policy's implementation. Each of the three cases will be discussed for how the parent policies were selected.

In the case of cyclamates, the U.S. FDA issued three official rules. The first action, in October 1969, banned the use of cyclamates as a food additive (Cyclamic Acid and Its Salts,

1969). An argument could be made that this document should serve as the parent policy because it mandated the ban of cyclamates as a food additive. However, it is a very brief statement with vague reference to other sources and documents:

> On the basis of animal studies recently reported to the Food and Drug Administration by Abbott Laboratories, and the review of the studies and the underlying data by experts in the National Cancer Institute, by an outside consultant, and by an ad hoc Committee of the National Academy of Sciences-National Research Council, Food Protection Committee, the Commissioner concludes that cyclamates can no longer be regarded as generally recognized as safe for use in food (Cyclamic Acid and Its Salts, 1969).

The subsequent sentences are entirely administrative, referring to other sections in the Code of Federal Regulations (i.e. the U.S. legal code) and then specify which language is to be deleted from the regulation. Because this study is interested in the narrative around cyclamates, this policy document offered little content to analyze.

The October 1969 rule banned the use of cyclamates as a food additive, but they were still allowed in prescription drugs. A second action in December 1969 clarified regulations regarding the labeling of drugs that used cyclamates (Abbreviated New-Drug Applications for Cyclamates, 1969). This action did contain more substantive narrative, but as its purpose was to provide new instructions about labeling, this rule did not seem suitable either.

A third action in 1970 extended the ban of cyclamates to prescription drug products (Revocations Regarding Cyclamate-Containing Products Intended for Drug Use, 1970). This final action was chosen because it expanded the overall ban on cyclamates and it also referred to the previous two actions within its text, allowing those documents to be included in the analysis (i.e. as DocMens).

Cyclamates are not banned in the EU, so choosing a parent policy was somewhat less clear. Among the documents found were several opinions from the EU's Scientific Committee on Food in 1988, 1991, 1995, and 2000. The most recent opinion (i.e. 2000) recommended a change in the allowable daily intake. This recommendation was included in Commission Directive 2003/115/EC. This directive was selected as the parent policy for cyclamate in the EU.

In the case of hormone-treated beef, the EU issued a series of Directives prohibiting the use of growth-promoting hormones. The documents read similarly in nature and it is difficult to distinguish their differences. To illustrate, in 1981, Council Directive 81/602/EC prohibited "certain substances having a hormonal action and of any substance having a thyrostatic action" (1981, p. 36). In 1985, Council Directive 85/358/EEC supplemented Directive 81/602/EEC concerning the prohibition of "certain substances having a hormonal action and of any substance having a thyrostatic action" (1985, p. 46). In 1988, Council Directive 88/146/EEC prohibited "the use of livestock farming of certain substances having a hormonal action" (1988, p. 16). Because all the Directives have the action of prohibiting hormones, determining how to select the parent policy was not apparent without more context. By reading the literature and news articles from the late 1980s, it was evident that a particular Directive provoked a U.S. response. The 1988 Directive (88/146/EEC) was chosen as the EU parent policy because it activated U.S. President Ronald Reagan's 1987 response of 100% tariffs on certain EU goods.

In December of 1987, President Reagan issued a proclamation increasing the tariffs on certain EU goods unless the EU permitted the importation of American beef treated with growth hormones (Proclamation No 5759, 1987). The action was suspended for negotiations, but one year later it was activated as a result of EU Council Directive 88/146/EEC through a decision by the U.S. Trade Representative. The U.S. parent policy for hormone-treated beef is the Federal

Register notice 53155 entitled "Determination To Impose Increased Duties on Certain Products of the European Community" issued on December 30, 1988.

The BPA case was straightforward as both the EU and the U.S. have bans on the use of BPA in baby bottles and sippy cups. This made selection of the parent policies apparent. Commission Directive 2011/8/EU activated the ban on BPA in the EU and FDA-2012-F-0031 did so in the U.S. These two documents are the BPA parent policies. Table 3 and 4 summarize the parent policies for all three topics in both jurisdictions.

Table 3: Parent Policies for the EU

Topic	Parent Policy	General action of the parent policy
Cyclamates	Directive 2003/115/EC (2003)	Reduce daily intake limit
Hormone-Treated Beef	Directive 88/146/EC (1988)	Ban hormone-treated beef
Bisphenol A	Directive 2011/8/EU (2011)	Ban BPA from baby bottles

Table 4: Parent Policies for the U.S.

Topic	Parent Policy	General action of the parent policy
Cyclamates	Revocations Regarding Cyclamate-Containing Products Intended for Drug Use (Aug. 27, 1970)	Ban cyclamates
Hormone-Treated Beef	Determination To Impose Increased Duties on Certain Products of the European Community (Dec. 30, 1988)	Respond to EU ban of HTB with tariffs
Bisphenol A	Indirect Food Additives: Polymers (July 17, 2002)	Ban PC resins (i.e. BPA) from baby bottles

Step 2: Documents mentioned in the Parent policies

The second strategy focused on finding documents mentioned within the parent policies. These are referred to as DocMens. By definition, all DocMens pre-date the parent policy. Examples of DocMens include previously enacted Directives and U.S. agency regulations.

Beyond the mention of the document in the parent policy, there were four additional criteria used to confirm a DocMen for inclusion in the dataset. The first was whether or not it could be located. In the case of cyclamates, the U.S. government-appointed Medical Advisory Group on Cyclamates issued two reports from 1969 and 1970 informing the decision to ban cyclamates. These could not be located.

The second criterion was whether or not the document was available in English. This criterion only affected two documents on BPA from France and Denmark. Third, because the study is interested in understanding the communications of the government, the document had to be authored by a government source. There is one exception to this criterion: The American Chemistry Council's petition to "remove the approval for polycarbonate resins in infant feeding bottles…due to the abandonment of these uses" (American Chemistry Council, 2011). It was included because without it, there would be no U.S. FDA decision and it is referred to over thirty times in the parent policy. Fourth, the DocMen needed to include the topic (i.e. cyclamates, hormone-treated beef, or BPA) expressly. It is not uncommon for policies to reference overarching legal instruments such as the Treaty on the Functioning of the European Union or the U.S. Food, Drug, and Cosmetic Act. These references are primarily procedural, and have limited practical impact for the science policy topic. Appendices C, D and E contain a full listing of all policy documents reviewed for each topic.

Step 3: Other government documents

The final category of policy documents is other government documents or "OthGovDoc". OthGovDocs are documents authored by government sources about the topic, but that are not referenced in the parent policy. Examples of OthGovDocs include scientific reports, fact sheets, press releases, and other Directives or regulations. OthGovDocs can pre-date or post-date the parent policy.

There are several strategies for identifying OthGovDocs. The first strategy was to locate documents mentioned in topic-specific academic literature and news articles. In a 1999 article in *Science* about hormone-treated beef, the author referenced "a 139-page report" issued by the European Commission that stated that the hormones used to treat cattle were potential carcinogens (Balter, 1999). While the exact title was not provided in the article, this reference led to the 1999 report from the European Commission's Scientific Committee on Veterinary Measures Relating to Public Health: *Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Animal Products*.

A second strategy was to search for the topic or parent policy on specific government agency websites (Daugbjerg et al, 2009). Once a successful hit was returned, it was not uncommon to find references to additional documents on the topic. For example, by looking for BPA on the U.S. FDA website, the first return was a factsheet. From that factsheet, numerous other documents were available including scientific safety assessments and literature reviews.

Finally, Google searches on the name of the parent policy were also used (Daugbjerg et al, 2009). These returns required careful review to confirm the documents were authored by government agencies versus non-profits or industry trade groups. In the case of cyclamate, the search returned a very informative factsheet from the International Sweeteners Association.

While not appropriate for inclusion in the dataset, this document served as informative background material.

One challenge with OthGovDocs was that it aims to collect all government documents published about a given topic. In other words, finding every government document available on the topic. Due to the number of documents potentially available, criteria were applied to constrain the final dataset. Similar to the criteria for the DocMens, OthGovDocs have to be authored by a government source, available in English, and be able to be located (i.e. finding a reference to a report but not finding the report itself would exclude it).

Another criterion was that the document needed to be about the topic in the context of the parent policy. In the case of BPA, the parent policy banned the chemical for use in baby bottles. A parallel discussion has been occurring around the safety of BPA in its use in thermal paper, more familiar as cash register receipts. These documents were omitted. This decision is appropriate because even though documents about BPA in thermal paper contain *risk* and *benefit* statements, to combine them with documents about BPA in baby bottles may result in misleading results.

In summary, of the 54 policy documents excluded, 27 were excluded because they did not mention the name of the product in the text. Eight documents could not be located. Eight documents were duplicates of documents already in the dataset. Four documents were not in English. In the case of BPA, three documents were excluded because they did not refer to baby bottles. Finally, four other documents were excluded for unique reasons (e.g. served as a test document for the coding scheme). Table 5 shows the results of the document selection process for all three topics in both jurisdictions. Appendices B, C, and D contain lists of all policy documents reviewed for each topic.

Table 5: Total No. of Policy Documents Included and Excluded by Jurisdiction and Topic

	Total number of documents identified	Documents included by meta-type			Total number of documents included	Total number of documents excluded
		Parent	*DocMens*	*OthGovDocs*		
EU	83	3	14	34	51	32
U.S.	79	3	11	43	57	22
Total	162	6	25	77	108	54

Units of Analysis and Variables

This study had two units of analysis: the policy document and the coded statements. Each policy document was classified on five independent variables. Jurisdiction was either EU or U.S. Policy topic was cyclamates, hormone-treated beef, or bisphenol A. The document types were Directive, Federal Register Rule, Federal Register, scientific/technical report, press release, fact sheet, background report, memo or other. The document meta-type was Parent, DocMen or OthGovDoc. The document's primary function was legislation, research results, dissemination of information, or other. All variables in the study are nominal.

At the statement level, this study sought to assess the presence and frequency of *risk*-related, *benefit*-related and *science*-related content that occur in American and European policy documents on cyclamates, hormone-treated beef, and bisphenol-A. Coders examined each paragraph or text section within a policy document or policy-related document. The term 'text section' was used to allow for text that may be written in another format such as legislation or some technical documents that may contain non-paragraph phrases or lists. Each paragraph or text section in the document was analyzed for the following *risk, benefit*, and *science*-related frames.

Risk or benefit type. Based on the coding scheme from Bauer, Ragnarsdottir, Rudolfsdottir, and Durant (1995), this study evaluated *risk* and *benefit* statements with the following options: *not mentioned; uncertain; possible (very unlikely, unlikely, likely, very likely)* and *certain.* Because it is difficult to measurably distinguish *unlikely* from *very unlikely* or *likely* from *very unlikely*, the current study modified this scale to four options: *uncertain*; *possible, unlikely; possible, likely;* and *certain of risk*. In addition, the option of '*none (certain of no risk*)' was added due to findings in the dataset. It was unnecessary to include Bauer et al.'s *not mentioned* because the absence of a code for a frame would indicate that it was not mentioned. Bauer et al. coded for 14 types of *risks* and *benefits*[4]. From their 14 types, the current study modified the list to include four types: *health, environmental, economic*, and *other*. Statements reflecting risks or benefits were coded as 1 for presence or 0 for absence.

These four *risk/benefit* types were recognized by explicit reference to health, environment, economy or other. Table 6 includes an example risk statement for each type. The emphasized text illustrates the coding justification.

[4] The complete list of risk and benefit categories included material, economic/financial, development; health; legal; social inequality; moral, ethical; environment, ecological; trade war; consumer rights; international status quo; loss of credibility; animal welfare; cultural, symbolic, moral; scientific; political power; other (Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, 1995). Categories were discarded primarily because they do not seem appropriate to the nature of this study. Additionally, some types seemed to overlap and there was no guidance on how to identify when a particular type occurred in the text versus another.

Table 6: Examples of Statements Coded for Risk-Related Types

	Risk to health	Risk to environment	Risk to economy	Risk to other
EU	The Committee is asked to re-evaluate *the hazards to human health arising from the migration of bisphenol A present in certain plastic materials* [emphasis added] and articles intended to come into contact with foodstuffs. (European Commission, Scientific Committee on Food Opinion on BPA, 2002)	Furthermore, the routine use of the above substances for animal growth promotion purposes *is likely to lead to increased concentration of those substances in the environment*. [emphasis added]. (Directive 2003/74/EC, 2003)	Member States shall ensure that, pending adoption of relevant Community rules, *their national provisions applying to products imported from third countries are not more favourable than those applying to intra- Community trade pursuant to this Directive* [emphasis added]. (Directive 81/602/EEC, 1981)	None
U.S.	Commissioner Kennedy found *data in the record concerning lung, liver, lymphoid tissue and mammary tumors [emphasis added]* in a number of studies which involved direct feeding of cyclamate to animals. (Fed. Reg. Vol. 45, No. 181, 1980)	In addition, *potential environmental sources of BPA contamination* [emphasis added] are due to use in dental fillings and sealants, losses at the production site, leaching from landfill, and presence in indoors air. (vom Saal et al, 2007)	The Directive, which has not yet been applied to EC meat imports, will prohibit imports into the European Community of any meat produced from animals treated with growth hormones, effective January 1,1989, *thereby severely disrupting exports of United States meat to the EC* [emphasis added]. (Fed. Reg. Vol. 53, No. 251, 1988)	The failure to disclose in advertising that cyclamate-containing artificial sweeteners as nonprescription drugs may be dangerous to health when taken in large dosages, …, *has the capacity and tendency to mislead and deceive purchasers and prospective purchasers* [emphasis added]. (Fed. Reg. Vol. 35, No. 98, 1970)

Table 7 includes an example benefit statement for each type. The emphasized text illustrates the coding justification.

Table 7: Examples of Statements Coded for Benefit-Related Types

	Benefit to health	Benefit to environment	Benefit to economy	Benefit to other
EU	None	None	None	None
U.S.	Expressed the unanimous opinion that under appropriate medical management of individuals with diabetes (particularly in the case of juvenile diabetes) and of patients in whom weight reduction and control are essential for health, *cyclamates provide medical benefits which outweigh their hazards* [emphasis added]. (Fed. Reg. Vol. 34, No. 249, 1969)	None	The agreement gives us an opportunity to add the EU to the leading export destinations for high-quality U.S. beef, *which will provide a substantial boost for U.S. ranchers and meat packers and their employees* [emphasis added]. (USTR Announces Agreement With European Union In Beef Hormones Dispute, 2009)	Since the 1950s, the Food and Drug Administration (FDA) has approved a number of steroid hormone drugs for use in beef cattle and sheep, including natural estrogen, progesterone, testosterone, and their synthetic versions. *These drugs increase the animals' growth rate and the efficiency by which they convert the feed they eat into meat.* [emphasis added]. (Steroid Hormone Implants Used for Growth in Food-Producing Animals, 2017)

After coding was completed, it was observed that most of the statements coded as *risk uncertain*. For the EU, 134 of the 164 statements coded as *risk*-related were coded as *uncertain.* For the US, 121 of the 141 statements were coded as *uncertain*. Because analysis of the remaining *risk* codes would not yield much insight, the codes of *possible, unlikely; possible, likely;* and *certain of risk* were combined with *uncertain* to become *risk*-related content. Statements of *risk-none* were counted separately. Due to the small number of statements coded as *benefit* (only 23 out of 1010 total codes), these were also combined.

Scientific background information. An additional frame of interest is *scientific information*, or *scientific background.* This frame may include an explanation of a concept,

descriptions of previous research, or summaries of results from earlier studies (Nisbet et al, 2003; Nisbet & Huge, 2006). The U.S. Congressional Research Service's report on the U.S.-EU Beef Hormone Dispute provides an example of *scientific background information*:

> Growth-promoting hormones include compounds that either naturally occur in an animal's body or mimic naturally occurring compounds. Estradiol, progesterone, and testosterone (three natural hormones), and zeranol and trenbolone acetate (two synthetic hormones), may be used as an implant on the animal's ear. (Johnson & Hanrahan, 2015, p. 1).

This frame was coded as 1 for presence or 0 for absence.

Scientific uncertainty. The frame of *scientific uncertainty* characterizes the lack of consensus among scientists of the consequences of using the substance. Words that signal this frame include "uncertain", "uncertainty", "unknown", "don't know", and "unclear" (Mitchell & Roffey-Mitchell, 2018). An example from the European Commission's Opinion of the Scientific Committee on Food on Bisphenol A (2002): "Further research is needed to resolve the uncertainties surrounding the findings in the mouse, both with respect to dose and significance of the reported effects for humans" (p. 12). This frame was coded as 1 for presence or 0 for absence.

Precautionary principle. The PP is the concept that in the absence of clear evidence of harm, governments may restrict use of a product until more proof is available. For this frame, coders looked for manifest instances of the terms *precautionary principle, precaution, caution,* and related terms. In addition, latent interpretation also helped identify the presence of PP. For example, in the 1970 U.S. Parent document for cyclamate, the following passage appears: "Based upon the new report of the Medical Advisory Group on Cyclamates, the Commissioner

concludes that in the absence of adequate evidence of safety and effectiveness continued sale of cyclamate-containing products with drug labeling cannot be permitted" (Revocations Regarding Cyclamate-Containing Products Intended for Drug Use, 1970, p. 13645). While the term *precautionary principle* does not appear, the reluctance to allow the product without evidence that it is safe upholds its spirit. This frame was coded as 1 for presence or 0 for absence.

Science used for decision-making. Statements that referred expressly to how scientific data, reports or advisors informed the policy decision (the policy decision could be to maintain the status quo or do nothing). An example of this content is from the EU's fact sheet on BPA: "Based on new data and methodologies, EFSA[5] has lowered the estimated safe level, known as the tolerable daily intake (TDI), to 4 micrograms per kilogram of body weight per day." This statement indicates that the new TDI for BPA was determined using data as obtained through scientific methods. This frame was coded as 1 for presence or 0 for absence.

Science NOT used for decision-making. Statements that referred to inputs other than science for decision-making (e.g. public opinion). This frame was often used by one jurisdiction to suggest the other had not made their decision based on science. In President Ronald Reagan's proclamation announcing increased tariffs on the European Community due to their rejection of hormone-treated beef, he stated "The need for such a prohibition is not supported by valid scientific evidence" (Proclamation 5759, 1987). This frame was coded as 1 for presence or 0 for absence.

Presence and prominence. Mitchell & Roffey-Mitchell (2018) suggest three more dependent variables. *Presence* is a binary designation of whether the frame occurs in the text or not. This value is either 1 or 0. *Salience* describes which frame is most prominent in terms of its

[5] The EFSA is the European Food Safety Authority.

location in the text. Because the word *salience* can be interpreted in several ways, the word *initial* was used in this study. The frame that appears earliest would be credited as the *initial* content. For a given document, the frame that appears first will be coded as 1 and the remaining frames will be coded as 0. *Dominance* is determined by the frequency of a frame in the text. Distinct from *presence*, multiple frames can be present in a text, but the dominant one occurs most often. This frame will be apparent from the sum of occurrences of each frame. Dominant frames will be assigned for each document, and then it will be possible to compare dominant frames by topic and jurisdiction.

Coding Procedures

The coding instrument and protocols for this study were developed over several months through extensive review of previous studies coupled with testing of the dataset of policy documents. (See Appendix A for the codebook.) Coders read each policy document, identified statements that contained relevant content, and extracted this content into an Excel file. Empirical results were recorded in an SPSS file.

The study's author used the content analysis software NVivo to store and manually code the documents. A second coder used Microsoft Word and marked statements with different colors and notations to signal his decisions about which frame/s was present. Both coders entered the text from identified statements into separate Excel spreadsheets. One tab within the spreadsheet represented a single policy document in order to facilitate reconciliation between coders. The coders had five reconciliation discussions to ensure they were interpreting the statements in the same way. During these calls, each document was reviewed code by code. The approach to reconciliation of the results also ensured that the use of different coding

platforms (NVivo vs MS Word) did not compromise the results. For statements on which the coders did not agree, results from the author's coding were used.

To strengthen the assessment of the content analysis, the author and a second person dual-coded 19 policy documents (17.5% of the dataset). The second person coded each Parent document (i.e., the anchoring policy from each jurisdiction on each topic); one DocMen from each jurisdiction on each topic (i.e., a document mentioned in the Parent); and one OthGovDoc from both jurisdictions and all three topics. One of the OthGovDocs was particularly short with few codes, so an additional document was added.

Prior to formal coding, two test documents from each jurisdiction were dual coded so that the coders could become familiar with the topical contexts and identify any points of confusion in the coding scheme. For each dual-coded document, the coders reviewed a document and reconciled any discrepancies.

Additionally, statements were allowed to be coded with more than one frame. As an example,

> Note: On the basis of animal studies disclosing the presence of malignant bladder tumors after the animals had been subjected to large dose levels of cyclamates for long periods, the Commissioner of the Food and Drug Administration, Department of Health, Education, and Welfare, concluded that cyclamates could no longer be regarded as generally recognized as safe for use in food. (Advertising of Cyclamate-Containing Artificial Sweeteners as Nonprescription Drugs, 1970, p. 7744).

This statement clearly contains the frame of *risk to health* as indicated by "the presence of malignant tumors". However, it also contains the frame of *science used for decision-making* because the decision to remove cyclamate from the GRAS (generally recognized as safe) list was

based on animal studies. Therefore, the statement was coded with both frames. Approximately 150 out of 1010 statements had two or more codes.

Intercoder Reliability

When multiple coders are used to analyze the data, it is recommended to compute how often the coders agree on their coding decisions. Scott's pi was chosen as the reliability coefficient because there were two coders and nominal data (Riffe, Lacy & Fico, 2014p. 115). A threshold of .80 indicates "adequate reliability" (Riffe, Lacy & Fico, 2014, p. 121). Table 8 shows the results of intercoder reliability for each frame.

Table 8: Results of Intercoder Reliability

Frame	**Scott's pi**
Risk	.82
Benefit	.853
Scientific uncertainty	.916
Scientific background	.928
Science used for decision-making	1
Science NOT used for decision-making	.877
Precautionary principle	.89

CHAPTER 4

RESULTS

This study content analyzed 108 policy documents from the EU and the U.S. involving three different topics to assess how they referenced *risk*-related content, *benefit*-related content and *scientific* content. The analysis focused on identifying content that made explicit reference to *risks* and *benefits* to *health*, the *economy*, and the *environment*; *scientific background information*; *scientific uncertainty*; the *precautionary principle*; *science used for decision-making;* and *science not used for decision-making*. Fifty-one EU policy documents were evaluated, with 516 statements coded. Fifty-seven U.S. policy documents were evaluated, with 494 statements coded.[6] Table 9 displays the number of policy documents analyzed from each jurisdiction by topic.

Table 9: No. of Policy Documents by Jurisdiction and Topic

Jurisdiction	Topic			Total by jurisdiction
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	12	17	22	51
U.S.	15	21	21	57
Total by topic	27	38	43	108

With respect to the research questions, the content analyses of the policy documents indicated the following:

[6] Of the dataset of 108 policy documents, 8 documents had no passages coded (2 in the EU and 6 in the U.S.). While these documents do not contribute to the framing analysis, they met the criteria for inclusion. That they did not contain any codes from this study does not suggest they are not part of the topical policy narrative. Statistical analyses were run with and without these 8 documents. The findings were statistically significant in both scenarios. For these reasons, the author decided to include them in the total document count.

Risk-Related Content

RQ1 asked "What is the frequency of statements regarding *risks* in policy documents in the EU and the U.S.?" Risk-related content involved that which explicitly referred to the frames of *risks to health*, *risks to the economy,* or *risks to the environment.* Of the EU documents that contained *risk*-related statements, *risks to health* was the most frequent with 164 coded statements. Fourteen statements were coded as mentioning *risks to the economy* and 9 were coded as referencing *risks to the environment*. In the U.S. policy documents, 141 statements were coded as having mentions related to *risks to health*, 15 as *risks to the economy*, and 4 as *risks to the environment*.

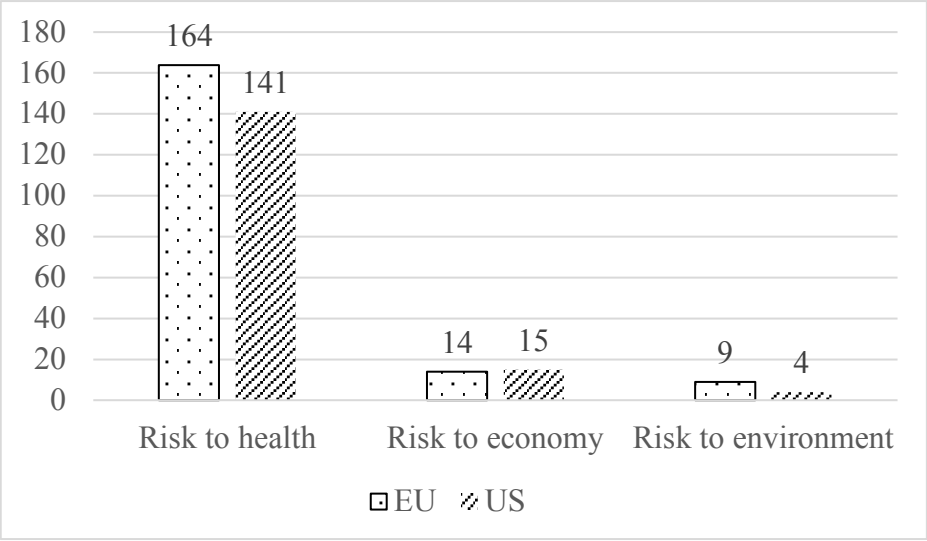

Figure 1: Statements Coded as Risk-Related Content

Cyclamate was banned in the U.S. in 1970 and remains available in the EU. In policy documents on cyclamate, there were more references to *risk* in the American policy documents than in the European policy documents. In the EU documents, 8 statements that were coded as *risk*-related while there were 58 statements were coded as such in the U.S. documents. In EU policy documents on cyclamate, the frames that were most often first were *scientific background* (5 out 12 documents) and *science used for decision-making* (5 out 12 documents). The frame that

was most often dominant in EU documents was *science used for decision-making* (6 out of 12 documents). In U.S. policy documents, *risks to health* was both the initial (8 out of 15 documents) and the dominant frame (11 out of 15 documents).

Hormone-treated beef was banned in the EU in the 1980s but remains available in the U.S. For hormone-treated beef policy documents, 83 statements in the EU documents included content coded as *risk*-related while 26 such statements were found in the U.S. documents. In EU policy documents on hormone-treated beef, the frame that was most often first was *risks to health* (11 out 17 documents) and the frame that was most often dominant was *risks to health* (10 out of 17 documents). In U.S. policy documents, *risks to economy* was the initial frame (7 out of 21 documents) and *science not used for decision-making* was the dominant frame (9 out of 21 documents).

The use of BPA in baby bottles was banned in the EU in 2011 and in the U.S. in 2012. There were 96 statements coded as mentioning *risk* in the EU policy documents compared to 76 statements mentioning *risk* in the U.S. policy documents. In EU policy documents on BPA, the frame that was most often first was *scientific background* (10 out 22 documents) and the frame that was most often dominant was *risks to health* (10 out of 22 documents). Mirroring the EU, in U.S. policy documents, *scientific background* was most of often first (13 out of 21 documents) and the dominant frame was *risks to health* (11 out of 21 documents).

Benefit-Related Content

RQ2 asked "What is the frequency of statements regarding *benefits* in policy documents in the EU and the U.S.?" *Benefit*-related content involved explicit mentions of *benefits to health, benefits to the economy, or benefits to the environment.* Overall, EU and U.S. policy documents on the three topics in this study contained few *benefit*-related statements. Out of a total of 1,010

coded statements across the 108 policy documents, only 23 (.018%) were coded as containing *benefit*-related content. There were 12 statements in the U.S. policy documents that were coded as having content mentioning *benefits to economy*, another 11 statements coded as mentioning *benefits to health*. As an example, a 2009 press release from the U.S. Trade Representative, Ambassador Ron Kirk stated "The agreement gives us an opportunity to add the EU to the leading export destinations for high-quality U.S. beef, which will provide a substantial boost for U.S. ranchers and meat packers and their employees." This statement was coded as *benefit to economy.* In a statement dual-coded as *benefit to health and benefit to economy*, the U.S. Congressional Research Service wrote:

> Cattle producers use hormones because they allow animals to grow larger and more quickly on less feed and fewer other inputs, thus reducing production costs, but also because they produce a leaner carcass more in line with consumer preferences for diets with reduced fat and cholesterol. (Johnson & Hanrahan, 2015, p. 1)

The EU had no statements coded as *benefit*-related.

Scientific Background Information

RQ3 asked: "What is the frequency of statements regarding *scientific background* in policy documents in the EU and the U.S.?" Statements were coded as containing mentions of *scientific background* if they explicitly provided information related to the technical or scientific context of the topic. Such statements contained generally accepted information about the topic, characterized a scientific process, and/or provided historical context. U.S. policy documents contained 93 statements (19% of 494 statements) that refer to *scientific background information*. Similarly, the EU policy documents contained 87 statements that had content referencing

scientific background information (almost 17% of 516 statements). Table 10 displays the frequency of statements coded for each topic for the EU and the U.S.

Table 10: No. of *Scientific Background Information* Statements by Topic and Jurisdiction

Jurisdiction	Topic			Total
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	13	18	56	87
U.S.	30	12	51	88
Total	43	30	107	180

An example of *scientific background information* comes from a U.S. document on hormone-treated beef. The statement generally defined the hormones being used:

> Within the U.S. and other countries, the hormones (three natural – estradiol, progesterone, testosterone – and three synthetic ones - melengestrol acetate, trenbolone acetate, and zeranol) have been used as implants in cattle, dating back to the years after the Second World War. The use of growth-promoting substances in raising cattle had also been legal within the countries that now comprise the EU for more than a generation, beginning in the years after World War II until their being banned in the late 1980s. (USDA Foreign Agricultural Service, 2003).

An EU document on the same topic included the following statement coded as *scientific background information*:

> Steroid hormones fulfil an important role at different stages of mammalian development comprising prenatal development, growth, reproduction and sexual and social behaviour. (Section 2.2). The importance of individual hormones varies between sexes and age and a disruption of the endocrine equilibrium may result in multiple biological effects (Section 2.2 - 2.4). (European Commission, 1999).

Scientific Uncertainty

RQ4 asked: "What is the frequency of statements regarding *scientific background* in policy documents in the EU and the U.S.?" Statements coded as mentioning *scientific uncertainty* contained information suggesting that there was not consensus on a scientific aspect of the topic. *Scientific uncertainty* also encompassed statements that expressed concern regarding a given study's research design. Of the statements from the U.S. policy documents, 64 (13% of 494 statements) referred to *scientific uncertainty*. Among the EU policy documents, 117 (23% of 516 statements) referred to *scientific uncertainty*. Table 11 displays the frequency of statements coded for each topic.

Table 11: Number of *Scientific Uncertainty* Statements by Topic and Jurisdiction

Jurisdiction	Topic			Total
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	8	34	75	117
U.S.	16	9	39	64
Total	24	43	114	181

As reflected in Table 11, content containing references to *scientific uncertainty* most frequently appeared in the BPA-related policy documents, particularly those in the EU. An example is an excerpt from a 2010 EU scientific report:

> The animal studies on developmental and reproductive toxicology reporting effects at doses lower than 5 mg/kg b.w./day have severe shortcomings and were considered to be invalid. The Panel considers that the valid studies do not raise concern regarding reproductive and developmental toxicity of BPA at doses lower than 5 mg/kg b.w./day. (European Food Safety Authority, 2010, p. 4).

From the U.S., a 2011 background report on BPA from the Congressional Research Service stated "The question remains whether those effects would adversely affect rodent health and are a useful predictor of human health impacts" (p. 2).

Precautionary Principle

RQ5 asked: "What is the frequency of statements regarding *precautionary principle* in policy documents in the EU and the U.S.?" Statements were coded as mentioning the *precautionary principle* if the text stated that guarding against unknown harm was a consideration or basis for the policy. Often, such statements also had statements that the policy may be changed if more scientific information became available regarding the safety of the product.

As measured in this study, statements that referred to *precaution* or the *precautionary principle* were not very common in the European and American policy documents involving the three topics examined. Among the EU documents, only 16 statements were found to include mentions related to the *precautionary principle*. Almost half of these statements (7) appeared in documents involving hormone-treated beef. For example, a 2002 press release from the EU Scientific Committee stated, "As regards the five other hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate), the Commission proposed to continue provisionally to apply the prohibition on these five hormones for growth promotion *until more complete scientific information is made available* [emphasis added]" (European Commission, 2002).

Among the U.S. documents, there were 12 statements coded as making references related to the *precautionary principle*. One example stated: "Based upon the new report of the Medical Advisory Group on Cyclamates, the Commissioner concludes that in the *absence of adequate*

evidence of safety and effectiveness continued sale of cyclamate-containing products with drug labeling cannot be permitted [emphasis added]." (Revocations Regarding Cyclamate-Containing Products Intended for Drug Use, 1970).

In most of coded statements, the content in the document reflected the perspective of the host jurisdiction, as in the preceding example. However, this was less common when it came to the U.S. documents involving hormone-treated beef. As noted in Table 12, six of the U.S. documents for hormone-treated beef included statements that referred to the *precautionary principle*. However, in all instances the U.S. documents mentioned the precautionary principle to characterize their perception of the EU ban on hormone-treated beef. An example is:

> In 2003, the Commission amended its policy to permanently ban one hormone—estradiol-17β—while provisionally banning the use of the five other hormones, as it continued to seek more complete scientific information. The ban reflects the EU's approach to food safety policy*, known as the precautionary principle, which supports taking protective action before there is complete scientific proof of a risk* [emphasis added]. (Johnson & Hanrahan, 2010).

Table 12: No. of *Precautionary Principle* Statements by Topic and Jurisdiction

Jurisdiction	Topic			Total
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	1	7	8	16
U.S.	5	6	1	12
Total	6	13	9	28

Science Used for Decision-Making

RQ5 asked: "What is the frequency of statements regarding *science for decision-making* in policy documents in the EU and the U.S.?" Statements were coded as mentioning that *science*

used for decision-making when they made explicit reference to how scientific data, reports or advisors informed the policy decision (including when that decision was to maintain the status quo). Table 13 shows that content that made references to *science used for decision-making* was found in policy documents from both jurisdictions and across all topics.

Table 13: No. of *Science Used for Decision-Making* Statements by Topic and Jurisdiction

Jurisdiction	Topic			Total
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	15	25	46	86
U.S.	20	11	23	54
Total	35	36	69	140

Overall, there were 86 statements in the EU policy documents that explicitly mentioned *science used for decision-making.* These statements often referred to the findings or results from specific studies that helped inform safe daily intake levels. For example, the EU's 1985 *Report of the Scientific Committee on Food* stated:

> In view of the existing areas of uncertainty relating to the relevance for man of the testicular damage found in rats fed cyclohexylamine, *the Committee decided to base its assessment on the NEL of 100 mg/kg bw in the recent extensive 90-day study* [emphasis added]. The Committee felt that there was an adequate additional safety margin in the estimation of the conversion rate of cyclamate to cyclohexylamine in man to allow for the use of the usual 100-fold safety factor and to establish a temporary ADI of 0-11 mg/kg bw, expressed as cyclamic acid, for cyclamic acid and its salts. (Commission of the European Communities, p. 10).

Similarly, many of the U.S. documents also reflected *science used for decision-making* with 54 statements coded. The following excerpt from a 1969 ruling from the FDA, described

the sources of scientific evidence that were included in the decision to remove cyclamate from the list of products safe to use in food:

> *On the basis of animal studies recently reported to the Food and Drug Administration by Abbott Laboratories, and the review of the studies and the underlying data by experts in the National Cancer Institute, by an outside consultant, and by an ad hoc Committee of the National Academy of Sciences-National Research Council, Food Protection Committee* [emphasis added], the Commissioner concludes that cyclamates can no longer be regarded as generally recognized as safe for use in food (Cyclamic Acid and Its Salts, 1969).

Science Not Used for Decision-Making

RQ6 asked: "What is the frequency of statements regarding *science for decision-making* in policy documents in the EU and the U.S.?" Statements were coded as *science not used for decision-making* if they either expressly referred to science not being used or referred to inputs other than science being the primary basis or foundation for the policy position (e.g., public opinion or media reports). In most cases, this type of content was used by one jurisdiction to suggest that the policy adopted by the other jurisdiction was not based on science. Table 14 shows the frequency of coded statements for *science not used for decision-making* in both jurisdictions and all three topics.

Table 14: No. of *Science Not Used for Decision-Making* Statements by Topic and Jurisdiction

Jurisdiction	Topic			Total
	Cyclamate	Hormone-treated beef	Bisphenol-A	
EU	0	4	0	4
U.S.	1	23	2	26
Total	1	27	2	30

Table 14 shows that explicit references to science not being used to make the policy decision appeared most often in American documents involving hormone-treated beef. In these documents, the U.S. statements referenced what was perceived to be the lack of scientific evidence for the EU's ban on hormone-treated beef. An example is the statement from the U.S. parent policy: "The need for the EC prohibition is not supported by valid scientific evidence." (Determination To Impose Increased Duties on Certain Products of the European Community, 1988).

Initial and Dominant Content

RQ8 asked "For each topic, which frame appears *first* (initial) for the policy document and policy-related documents in this study?" In EU policy documents, *risks to health* was most often first (18 of 51 documents). *Scientific background information* followed closely appearing first in 17 out 51 documents. These two frames account for 68% of the initial frames in the European documents. Among the U.S. policy documents, *scientific background information* was most often first (16 of 57 documents) with *risks to health* appearing first in 14 out of 57 documents. These two frames account for almost 53% of the initial frames in American documents.

RQ9 asked "For each topic, which frame is dominant for the policy document and policy-related documents in this study?" For both jurisdictions, the most frequently found frame was *risks to health*. Of the 51 EU policy documents, 21 documents contained *risks to health* as the dominant frame. The documents had 164 statements coded as *risks to health* (32% of 516 statements). Of the 57 US policy documents, 25 documents featured *risks to health* as the dominant content with 141 statements coded (29% of 494 statements). Table 15 summarizes the initial and dominant frames for both jurisdictions and the three topics.

Table 15: Initial and Dominant Content by Topic and Jurisdiction

	EU	U.S.
Initial Content		
Overall	*Risk to health*	*Scientific background*
Cyclamate	*Scientific background*	*Risk to health*
Hormone-treated beef	*Risk to health*	*Risk to economy*
Bisphenol-A	*Scientific background*	*Scientific background*
Dominant Content		
Overall	*Risk to health*	*Risk to health*
Cyclamate	*Science used for decision-making*	*Risk to health*
Hormone-treated beef	*Risk to health*	*Science not used for decision-making*
Bisphenol-A	*Risk to health*	*Risk to health*

As Table 15 shows, there were differences across topics and jurisdictions with respect to the content that appeared first and the content that appeared most often. In the case of cyclamate (banned in the U.S. but available in the EU), the initial statements in EU documents most often mentioned *scientific background information* while the U.S documents first mentioned *risk to health*. In terms of dominance, EU statements were most often coded as mentioning *science for decision-making* while U.S. statements were most often coded as mentioning *risk to health*.

For hormone-treated beef (banned in the EU but available in the US), the EU's initial and dominant content were *risks to health*. The U.S. initial and dominant content for hormone-treated beef was *risks to the economy*.

In the case of BPA (banned for use in baby bottles in both jurisdictions), the policy documents from the two jurisdictions mentioned *scientific background information* as the initial content and *risks to health* as the dominant content.

CHAPTER 5

DISCUSSION

The study was motivated by the desire to increase understanding of how scientific research and input are used to inform public policy on products that may involve risk or uncertainty regarding their risk. Chapter 1 discussed how the EU and the U.S. have reacted to risk over time with a particular emphasis on the use of the precautionary principle as a policy approach. Previous research suggests that both jurisdictions have exercised precaution on different products at different times. This study analyzed and compared policy documents from the EU and the U.S. to identify statements indicating *risks, benefits*, and *science*-related content that might reflect the basis for their policy decisions involving three different products: cyclamate, hormone-treated beef and Bisphenol-A use in baby bottles.

Interpretation of Findings

One particularly distinctive finding was that for both EU and U.S. policy documents involving the three products, *risks* were mentioned much more than *benefits*. In the dataset of 1,010 coded statements, 347 were coded as having *risk*-related content while only 23 statements were coded as having *benefit*-related content. This is quite unlike what has been found in content analyses news articles which have been the primary unit of analysis for evaluating valence towards policy topics that involve science. As shown in Chapter 2, content analyses of news articles have generally attempt to address both *risks* and *benefits* (e.g. Gaskell, Bauer, Durant & Allum, 2000; Marks et al., 2007; Nisbet & Lewenstein, 2002). One explanation for this difference between news articles and policy documents may be that a key tenet of journalism is

"balance," which is often defined as presenting two or more perspectives on an issue. To the extent that journalists are using this convention, their news stories on products that involve risk or uncertain risk would foster story content that encompasses two or more sides of an issues. Conversely, policymakers are usually trying to justify and/or persuade others of their policy preference. It may serve policymakers' end goals better to focus on the risks associated with a product if their policy position favors banning or heavily regulating the product. In this study, the *risks* and *benefits* component of the content analysis was part of the effort to identify points of policy divergence between the EU and the U.S. Even though the overall *risks* statements outnumbered the *benefits* statements, the nuances of the results did reveal some potentially interesting patterns.

One area of divergence between the EU and the U.S. may be their primary motivation in adopting the policy. Based on the three cases in this study, there is evidence to suggest that the U.S. may be more driven by economic factors while the EU may place a higher priority on public health. The most illustrative case is that of hormone-treated beef. The EU policy documents indicate a strong concern for *risk to health* with 67 out of 171 statements coded (39%). An example from a 1999 technical report: "Thus even exposure to residual amounts of hormonally active compounds as present in meat and meat products needs to be evaluated in terms of *potentially adverse effects to public health* [emphasis added]". (European Commission, 1999). In contrast, the U.S. appears to operate from a position of *risk to economy*. Out of 102 coded statements for hormone-treated beef, the U.S. had 27 statements related to the *economy* (26%). In contrast, the U.S. documents had 11 statements for *risk to health* and 3 statements for *benefit to health*, half of the statements related to the economy. The U.S. Parent policy document for hormone-treated beef states

> The Directive, which has not yet been applied to EC meat imports, will prohibit imports into the European Community of any meat produced from animals treated with growth hormones, effective January 1,1989, thereby *severely disrupting exports of United States meat to the EC* [emphasis added]. (Determination To Impose Increased Duties on Certain Products of the European Community, 1988).

In the case of BPA, where the EU and U.S. both banned use of the chemical for baby bottles, the EU policy documents had almost twice as many statements as the U.S. referring to *scientific uncertainty*. This difference may also reflect the primary motivations behind the respective policies. In the EU, the policy was motivated by health concerns for infants that would be potentially be exposed to small amounts of BPA. Commission Directive 2011/8/EU asserts "it is necessary and appropriate for … ensuring a high level of human health protection to obviate sources of danger to physical and mental health that may be caused to infants by BPA exposure through feeding bottle" (p. 13). In the U.S., the policy was triggered by a decline in consumer demand for products that contained BPA (American Chemical Council, 2011). BPA manufacturers requested the U.S. discontinue the use of BPA in baby bottles because "these uses have been abandoned" (Indirect Food Additives: Polymers, 2012).

Neither of these primary motivations is inherently right or wrong. Governments have a duty to foster public health as well as ensure a stable economy. However, empirical evidence of these motivations may foster better understanding of another entities differing perspective. Given the low number of codes for *risk to economy*, this finding needs to be investigated further to determine whether these motivations are unique to these three cases or whether they apply more broadly.

There may be an alternate interpretation for this distinction between the EU's and U.S.' motivation. It may be that rather than the coded statements within the documents reflecting their motivation (i.e. risk to the economy or risk to health), that their position drives the coding of the statements. For example, if the U.S.' position was that hormone-treated beef was healthy for consumers, that message would be more prominent in the coded statements. Additional research may help clarify this observation.

Another area where the two jurisdictions differ is in their use of scientific and technical reports to inform their policymaking process and decisions. Out of the 108 policy documents in this study's dataset, there were 25 scientific or technical reports. Across the three topics, the EU had three times as many scientific reports as the U.S. Table 16 displays the number of scientific or technical reports by topic and jurisdiction.

Table 16: No. of Scientific or Technical Reports by Topic and Jurisdiction

	EU	U.S.	Total
Cyclamate	6	1	7
Hormone-treated beef	4	0	4
Bisphenol A	9	5	14
Total	19	6	25

The scientific reports were of particular importance in the case of hormone-treated beef. The EU had been resisting hormone-treated beef since the early 1980s on the grounds that it was potentially harmful to human health (Council Directive 81/602/EEC). The U.S. position maintained that hormone-treated beef was safe for consumer consumption (Johnson & Hanrahan, 2010). The U.S.' main argument, potentially derivative of their underlying motivation, was that the EU has not based their ban of hormone-treated beef on science, but rather that it was a disguised protectionist tactic for European cattle farmers (Johnson & Hanrahan, 2010). While the

U.S. maintained their position regarding the EU's lack of scientific evidence demonstrating that hormone-treated beef was unsafe, the EU policy documents included four scientific/technical reports while the U.S. had none.

A third point of divergence between the EU and the U.S. has to do with their use of language in the policy documents. While it is not uncommon for policy documents on a topic to have consistent language, U.S. policy documents in all three topics were rhetorically persistent in nature. In the case of cyclamate, two statements that appeared repeatedly read "cyclamate has not been shown to be safe" and "cyclamate has not been shown not to cause cancer". In three of the fifteen U.S. policy documents on cyclamate, a version of this expression occurred over 20 times. Similarly for hormone-treated beef, the expression "not supported by science" and close permutations (e.g. "not based on sound science") appeared 16 times in 11 of the U.S.' 31 documents. Finally, in the case of BPA, the U.S. documents repeat the notion that "BPA is safe". Some version of this statement appeared six times in three of the U.S.' 21 BPA policy documents. If stated once or twice, these expressions are taken as part of the broader narrative. The persistence may signal a policy attitude. According to Pan and Kosicki (1993), these words do matter: "Choices of words and their organization…are not trivial matters. They hold great power in setting the context for debate defining issues under consideration, summoning a variety of mental representations, and providing the basic tools to discuss the issues at hand." (p. 70).

The language of "not being supported by science" led to the frame of *science not used for decision-making*. Of the 30 total statements coded for *science not used for decision-making*, 27 were in documents about hormone-treated beef. There is a subtle irony in this observation from a coding perspective: Even though the U.S. was asserting that the EU had not used scientific evidence, these statements occurred in U.S. documents and were coded as such. When analyzing

the quantitative data, the number of U.S. statements coded as *science not used for decision-making* suggests that the U.S. did not use science for this topic. Based on this dataset and the absence of any U.S. scientific or technical reports, this is an appropriate characterization. To summarize, in this research coding protocol, the U.S.' efforts to cast the EU as not using science to inform their policy decisions actually ended up reflecting more on the U.S. approach of not using science.

An observation more than a point of divergence, it may be of value to note what was not present in the policy documents. Along with *risks to health* and *risk to the economy*, the code *risks to environment* was available in the coding scheme. Across the dataset of 1,010 statements, only 13 statements were coded as *risks to the environment*. The EU had five statements coded in this frame for hormone-treated beef. The EU and U.S. both had four *risks to environment* statements for BPA. This dramatic difference in the level of coding is concerning from the perspective that health, the economy, and the environment are not isolated categories of public policy that can be legislated or regulated independently. Decisions that impact health may also affect the environment and the economy. Additional research is needed to learn more about this finding.

One of the motivating questions of this study was whether the EU was more risk averse than the U.S., leading it to apply the *precautionary principle* (PP) to products about which there remains a degree of uncertainty. With only 28 statements (out of 1,010 total) coded as PP, the results of this study did not lend support to this position. What might explain this? When reflecting on the data, the prominence of *scientific uncertainty* became apparent. In the EU, with 117 coded statements, *scientific uncertainty* was the second most coded content type after *risks to health* (164 coded statements). In the US, with 64 coded statements, *scientific uncertainty* was

the third most coded content type after *risks to health* (141 statements) and *scientific background* (93 statements).

As suggested by Nisbet and Huge (2006), *scientific uncertainty* "includes focus on the precautionary principle". Based on this characterization, it could be expected that statements coded in the current study as PP would be double-coded as *scientific uncertainty*. In fact, only one of 28 statements coded as PP was also coded as *scientific uncertainty*.

The PP reflects uncertainty about what is not yet known coupled with a reluctance to take action without additional information. *Scientific uncertainty* reflects uncertainty about the state of the science or the scientific process without a signal towards policy action or inaction. *Scientific uncertainty* appeared more often in EU documents for HTB and BPA. The U.S. has more statements about *scientific uncertainty* for cyclamate. These analyses indicate that there was more *scientific uncertainty* about the products that were banned in each jurisdiction, exactly where one would have expected the PP to appear. The results of the current study may suggest there is a transition in policy perspective from PP to *scientific uncertainty*. This may be important because unlike the PP, where there is an assumed policy direction, there is no such assumption with *scientific uncertainty*. Thus, it would be unclear how to respond in the face of scientific uncertainty. With such a small dataset, more research is needed to explore this idea.

Research Implications

There are several important implications of this research. Previous research on frames in the media reveals that news articles tend to reflect both *risk* and *benefit* frames. In contrast to this substantial body of work, the current study found that policy documents overwhelmingly featured *risk*-related content. For policymakers who have to make decisions with incomplete risk-benefit information, this emphasis could unduly influence their judgment. Awareness that

policy documents feature risks more than benefits could prime them to seek out counter-perspectives, or at least ask the question: what are the advantages or benefits of this product? Future studies could examine additional policy documents on different topics from other jurisdictions to determine whether policy documents generally can be expected to contain more *risk*-related statements.

Another implication of this research is that risks seem to be evaluated only in terms of a single dimension such as health, or environment, or economy. The results of this study, for instance, found 305 codes for *risks to health*, but only 29 for *risks to economy* and 13 for *risks to environment*. This is problematic because in fact these dimensions are interdependent. To date, the potential health risks of BPA have driven the EU policy discussion. For the U.S., the economic ramifications appeared to be prominent in their decision making. What are the environmental impacts of the chemical and how would that information influence the policy debate? Scientists and researchers contributing to policy discussions might consider enhancing their analyses to include other factors. While this approach would likely result in more complicated policy debates and more questions involving uncertainties, doing so may also lead to more informed and/or more appropriate policy outcomes.

A third implication involves the role of scientific information in the policy process. There were 25 scientific and/or technical reports in this study's dataset of 108 documents. Of those, 19 were from the EU and 7 from the U.S. Based on the three topics chosen, it appears the EU may leverage scientific information more so than the U.S. Additional studies on this specific question (i.e. how often are scientific/technical reports included in the policy debate?) would better clarify how each jurisdiction uses scientific information. If it were found that the U.S. relies less heavily on scientific and technical reports than the EU, this could indicate that scientists need to

do a better job in their public and policymaker outreach, including improving their science communication skills so that they more effectively contribute to the public policy process.

Limitations and Future Research

This study has several limitations. One is the dataset, which was limited to the use of public documents. Public policies are the product of many types of communication, including official meetings, conversations with lobbyists, public meetings, solicited public comments, unofficial in-person conversations, and emails. As a result, the content in the policy documents analyzed here represent a subset of many other communication inputs. Adding interviews with persons involved in the policymaking process for a given topic would shed additional light on these initial findings.

Another limitation of this study is the size of the dataset. Even though there were 108 policy documents, because they were divided among three topics, the resulting small sample sizes precluded additional statistical analyses. For example, one of the variables collected was document type (e.g. Directive, background report, etc.). Across the dataset there were eight distinct document types plus an "other". It would have been interesting to explore whether a particular document type was more likely to contain a particular type of content. For instance, do scientific reports contain more *scientific background information* than Directives, or do Federal Register Final Rules contain more *risk*-related statements than fact sheets or background reports? Due to the low number of cases, these analyses are not presently feasible. Future studies could increase the size of the document-related datasets in many ways, including by encompassing more types of documents, additional topics, and/or more than two jurisdictions.

Even though this study did not intentionally state that 'health' was the central focus, results indicated that the frame of *risk to health* was overwhelmingly dominant. Governments

regulate on the economy and the environment as well, but these content types did not appear as often in the policy documents in this dataset. One explanation might be that the topics chosen (cyclamate, hormone-treated beef, and BPA) primarily involved health, rather than environmental-related, content. For hormone-treated beef and BPA, the academic literature referred to concerns about *risk to environment*, yet there was very little evidence of these concerns in the policy documents themselves. This would be another potential area of further study.

Despite the limitations, this study provides insight into ideas that have not yet been explored from a communications perspective. First, by analyzing policy documents, this study contributes to the existing framing literature by illustrating how to use a new unit of analysis. In contrast to media articles, which often reflected a balance of *risk* and *benefit* statements, the results of this study indicated that policy documents may tend to have a clear valence of risk. More studies are needed to find out if these findings are unique to this study, or if policy documents can be expected to consistently reflect a tone of *risk*.

Second, this study builds on a vast body of work comparing the EU and the U.S from political, economic, and regulatory perspectives. This current study complements previous work by approaching the comparison from a communications perspective. In the cases of cyclamate, hormone-treated beef, and BPA, data suggested that the EU and the U.S. may be motivated differently as they make policy decisions. Additional research could investigate this question specifically to learn if it holds for other policy issues.

Third, the results of this study illustrate the presence of science in policymaking by examining the language in the policy documents that inform the decisions. Observing, for example, that the U.S. does not have scientific reports among their documentation for their

hormone-treated beef policy while the EU has four such reports invites new questions. Why does the U.S. not have scientific reports when their primary argument against the EU is that their ban on hormone-treated beef is not based on science? What is the role of science in the U.S. position that hormone-treated beef is safe? Including these documents in the publicly available records may help increase public trust in decision-making.

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Appendix A: Codebook

Variable	Value options	Code	Previous Literature
Document Date			
	Document	Year/month/day	
Document title			
		Text	
Document ID			
	Number between 1 and N (i.e. total number of documents in dataset).		
Document Jurisdiction			
	European Union	1	
	United States	2	
Document topic			
	Cyclamates	1	
	Hormone-Treated Beef	2	
	Bisphenol A	3	
Document meta-type			
	Parent	1	
	DocMen	2	
	OthGovDoc	3	
Document type			
	Other	0	
	Directive	1	
	Federal Register Final Rule	2	
	Federal Register Other	3	
	Technical Report or Scientific Opinion	4	
	Press Release	5	
	Fact Sheet	6	
	Background Report (e.g. CRS)	7	
	Memo	8	

Document focus	Is the document focused on the topic or does it include more than one topic?		
	Document is only about the topic	1	Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, (1995)
	Document contains more than one topic	2	
Document function	What is the primary function of the document?		
	Legislation or regulation	1	Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, (1995)
	Research results	2	
	Dissemination of information	3	
	Other	4	
Risk Type	Does the document contain a statement or statements that the use of the product poses a risk? If so, what type?	Documents may include multiple statements about one kind of risk. They may also include statements about several types of risk. For each statement found, capture the language and code it for the type of risk mentioned.	
	Not mentioned	0	Modified from Bauer, Ragnarsdottir, Rudolfsdottir, & Durant (1995); Mitchell & Roffey-Mitchell (2018); Painter (2013)
	Economic	1	
	Environmental	2	
	Health	3	
	Other	4	
Sum of Risk Statements by type	Compute the sum of statements within a single document for each risk type.		
	An integer		
Likelihood of Risk	If risk is mentioned, what is the associated level of certainty?		
	Possible/uncertain/unknown	1	Modified from Bauer, Ragnarsdottir, Rudolfsdottir, & Durant (1995); Mitchell & Roffey-Mitchell (2018); Painter (2013)
	Possible, unlikely	2	
	Possible, likely	3	
	Certain of risk	4	
	None (Certain of no risk)	5	
Benefit Type	Does the document contain a statement or statements that the use of the product offers a benefit? If so, what type?	Documents may include statements about more than one type of benefit. They may also include statements about several types of benefit. For each statement found, capture the language and code it for the type of benefit mentioned.	

	Not mentioned	0	Modified from Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, (1995)
	Economic	1	
	Environmental	2	
	Health	3	
	Other	4	
Sum of Benefit Statements by type	Compute the sum of statements within a single document for each benefit type.		
	An integer		
Likelihood of Benefit	If a benefit is mentioned, what is the associated level of certainty?		
	Possible/uncertain/unknown	1	Bauer, Ragnarsdottir, Rudolfsdottir, & Durant, (1995)
	Possible, unlikely	2	
	Possible, likely	3	
	Certain of risk	4	
	None (Certain of no benefit)	5	
SciUncertainty	Does the document contain a statement or statements that indicate scientific disagreement or uncertainty about the topic?	For each statement found, capture the language.	
	No	0	Nisbet et al (2003); Nisbet & Huge (2006); Mitchell & Roffey-Mitchell (2018); Painter (2013)
	Yes	1	
Sum SciUncertainty	Compute the sum of statements within a single document that suggest scientific uncertainty.		
	An integer		
SciBckgnd/Info	Does the document contain a statement or statements explaining technical or scientific aspects of the topic?	For each statement found, capture the language.	
	No	0	Nisbet et al (2003); Nisbet & Huge (2006); Mitchell & Roffey-Mitchell, (2018)
	Yes	1	
Sum SciBckgnd/Info	Compute the sum of statements within a single document that contain scientific background.		
	An integer		

Precautionary Principle	Does the document include the term "precautionary principle"?	For each statement found, capture the language.	
	No	0	
	Yes	1	
Science for decision-making	Does the document contain a statement or statements that suggest science is being relied upon for decision-making?	For each statement found, capture the language.	
	No	0	
	Yes	1	
Presence: *Determine after all coding is complete*	For each of the content types, determine presence or absence.		
	No	0	Mitchell & Roffey-Mitchell (2018); Painter (2013)
	Yes	1	
Initial: *Determine after all coding is complete*	Which of the frames appears first?		
	Note first frame that appears		Mitchell & Roffey-Mitchell (2018); Painter (2013)
Dominance: *Determine after all coding is complete*	Which of the frames appears most often?		
	See sums of previous frames		Mitchell & Roffey-Mitchell (2018); Painter (2013)

Appendix B: Policy Documents for Cyclamate

In the case of the cyclamate, a total of 41 policy documents were identified and 18 were excluded because 1) they did not include the term "cyclamate" or a derivative or 2) they could not be located. Exclusion justification is provided in the table.

	Total identified	**Included**			**Total included**	**Excluded**
		Parent	*DocMens*	*OthGovDocs*		
EU	21	1	6	5	12	9
U.S.	24	1	6	8	15	9
Total	45	2	12	13	23	18

Include?	**Document type**	**Document Year**	**NVivo Code or exclusion criterion**	**Document Description**
EU Documents				
Yes	Parent	2003	1120031*	Directive 2003/115/EC of the European Parliament and of the Council of 22 December 2003 amending Directive 94/35/EC on sweeteners for use in foodstuffs
DocMens listed in order of appearance in the Parent document				
No	DocMen	1957	*Excluded from dataset due to no mention of cyclamate in the text*	Treaty of Rome
Yes	DocMen	2002	1120022*	Proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs (2002/C 262 E/31) COM (2002) 375 final — 2002/0152(COD) (Submitted by the Commission on 11 July 2002)
Yes	DocMen	2003	11200321	Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs'(COM(2002) 375 final — 2002/0152 (COD)) (2003/C 85/09)

No	DocMen	1988	*Excluded from dataset due to no mention of cyclamate in the text*	Council Directive of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption
Yes	DocMen	2003	11200322	Common Position (EC) No 57/2003 adopted by the Council on 25 June 2003 with a view to the adoption of a Directive 2003/. . ./EC of the European Parliament and of the Council of . . . amending Directive 94/35/EC on sweeteners for use in foodstuffs
No	DocMen	2003	*Excluded from dataset, unable to locate*	Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal).
No	DocMen	2003	*Excluded from dataset, unable to locate*	position of the European Parliament of 22 October 2003 (not yet published in the Official Journal).
Yes	DocMen	1994	1119942	European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs
Yes	DocMen	1996	1119962	Directive 96/83/EC of the European Parliament and of the Council of 19 December 1996 amending Directive 94/35/EC on sweeteners for use in foodstuffs
Yes	DocMen	2000	1120002	Revised Opinion on Cyclamic Acid and Its Sodium and Calcium Salts
No	DocMen	2002	*Excluded from dataset due to no mention of cyclamate in the text*	Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance)
No	DocMen	1989	*Excluded from dataset due to no mention of cyclamate in the text*	Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
No	DocMen	1999	*Excluded from dataset due to no mention of cyclamate in the text*	Directive 1999/EC of the European Parliament and of the Council of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
No	DocMen	2002	*Excluded from dataset due to no mention of cyclamate in the text*	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
No	DocMen	1999	*Excluded from dataset due to no mention of cyclamate in the text*	Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (*)

Other Government Documents (OthGovDocs)				
Yes	OthGovDoc	1984	1119843	Report of Scientific Committee on Food concerning sweeteners
Yes	OthGovDoc	1988	1119883	Report of Scientific Committee on Food concerning sweeteners
Yes	OthGovDoc	1991	1119913	Report of Scientific Committee on Food concerning cyclamates
Yes	OthGovDoc	1995	1119953	Report of Scientific Committee on Food
Yes	OthGovDoc	2007	1120073*	Report from the Commission to the European Parliament and the Council on the Progress of the Re-evaluation of Food Additives
US Documents				
Yes	Parent	1970	2119701*	Part 2 – Administrative Functions, Practices, and Procedures Subpart H – Delegations of Authority Part 3 – Statements of General Policy or Interpretation Subchapter C- Drugs, Part 130 – New Drugs Subpart A— Procedural and Interpretative Regulations Revocations Regarding Cyclamate Containing Products Intended for Drug Use
DocMens listed in order of appearance in the Parent document				
Yes	DocMen	1969	21196921	Chapter I— Food and Drug Administration, Department of Health, Education, and Welfare; SUBCHAPTER B— FOOD AND FOOD PRODUCTS Part 121 - Food Additives; Subpart B -- Exemption of Certain Food Additives from the Requirement of Tolerances
No	DocMen		*Excluded from dataset, unable to locate*	21 CFR 121.101 (GRAS list)
No	DocMen		*Excluded from dataset due to no mention of cyclamate in the text*	Federal Food, Drug, and Cosmetic Act
Yes	DocMen	1969	21196922*	SUBCHAPTER C— DRUGS PART 130— NEW DRUGS; Subpart A— Procedural and Interpretative Regulations; Abbreviated New -Drug Applications For Cyclamates
No	DocMen	No date provided	*Excluded from dataset, unable to locate version from correct time period*	21 CFR 130.40
No	DocMen	1969	*Excluded from dataset, unable to locate*	Medical Advisory Group on Cyclamates established by the Assistant Secretary for Health and Scientific Affairs had reviewed all available data on cyclamates and in a December 1969 report:
No	DocMen	No date provided	*Excluded from dataset, unable to locate*	Federal Food, Drug, and Cosmetic Act (secs. 505, 701 (a/), 52 Stat. 1052-53, as amended, 1055; 21 U.S.C. 355, 371(a))

No	DocMen	No date provided	*Excluded from dataset, unable to locate*	21 CFR 2.120
Yes	DocMen	1970	21197023	Chapter I—''Food and Drug Administration, Department of Health, Education, and Welfare SUBCHAPTER A— GENERAL PART 2— ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES Subpart H— Delegations of Authority Approval of Certain New-Drug Applications and Supplements
Yes	DocMen	1970	21197021	Chapter I— Food and Drug Administration, Department of Health, Education, and Welfare SUBCHAPTER A— GENERAL PART 3— STATEMENTS OF GENERAL POLICY OR INTERPRETATION Drug Labeling for Cyclamate-Containing Artificial Sweeteners
Yes	DocMen	1970	21197022	Subpart- A-Procedural and Interpretative Regulations ABBREVIATED New-Drug APPLICATIONS FOR CYCLAMATE-CONTAINING PRODUCTS
Yes	DocMen	1970	21197024	Report to the Secretary of HEW from the Medical Advisory Group on Cyclamates
Other Government Documents (OthGovDocs)				
Yes	OthGovDoc	1969	2119693	Department of Health, Education and Welfare. Food and Drug Administration. [21 CFR Part 121] Food Additives; Cyclamic Acid and its Salts. Safe Usage.
No	OthGovDoc	1971	*Excluded from dataset because it is a record of legislative testimony.*	Hearings before Subcommittee No 2 of the Committee on the Judiciary House of Representatives Ninety-Second Congress First Session on H.R. 4264, H.R. 4180, H.R. 4870, H.R. 4912, H.R. 5862, H.R. 6155 to provide for the payment of losses incurred by growers, manufacturers, packers, and distributors as a result of the barring the use of cyclamates in food after extensive inventories of foods containing such substances had been prepared or packed or packaging, labeling, and other materials had been prepared in good faith reliance on the confirmed official listing of cyclamates as generally recognized as safe for use in food under the Federal Food, Drug and Cosmetic Act, and for other purposes September 129 and 30; October 6, 1971
No	OthGovDoc	1980	*Excluded from dataset*	By the Comptroller General Report To The Congress of the United States Need For More Effective Regulation of Direct Additives To Food

Yes	OthGovDoc	1980	2119803	Department of Health and Human Services, Food and Drug Administration [Docket No. 76F-0392] Cyclamate (Cyclamic Acid, Calcium Cyclamate, and Sodium Cyclamate), Commissioner's Decision AGENCY: Food and Drug Administration. ACTION: Final decision following a formal evidentiary public hearing.
Yes	OthGovDoc	1985	211198531*	FDA Talk Paper, NAS Report on Cyclamates
Yes	OthGovDoc	1985	21198532	Evaluation of Cyclamate for Carcinogenicity
Yes	OthGovDoc	1985	21198533	Congressional Research Service report on Artificial Sweeteners
Yes	OthGovDoc	1989	2119893	§ 189.135 Cyclamate and its derivatives.
No	OthGovDoc	1989	*Excluded from dataset, unable to locate*	FDA Talk Paper, T89-35. Cyclamate Update

Appendix C: Policy Documents for Hormone Treated Beef

In the case of hormone-treated beef, a total of 29 policy documents were identified and 11 were excluded because 1) they did not include the term "hormone-treated beef" or a derivative or 2) they could not be located. Exclusion justification is provided in the table.

	Total identified	Included			Total included	Excluded
		Parent	*DocMens*	*OthGovDocs*		
EU	25	1	4	12	17	8
U.S.	27	1	1	18	20	7
Total	52	2	5	1	37	14

Include?	Document Type	Document Year	Document Name in NVivo	Document Description
EU Documents				
Yes	Parent	1988	1219881*	Council Directive of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action
DocMens listed in order of appearance in the Parent document				
No	DocMen	1957	*Excluded from dataset due to no mention of hormone-treated meat in the text*	Treaty establishing the European Economic Community (also known as the Treaty of Rome) Article 43, dealing with agricultural policy
Yes	DocMen	1985	12198523	Resolution closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action
Yes	DocMen	1985	12198521	Opinion on the proposal for a Council Directive amending Directive 81/601/ EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action
No	DocMen	1972	*Excluded from dataset due to no mention of hormone-treated meat in the text*	Council Directive of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries

Yes	DocMen	1985	12198522*	Council Directive of 16 July 1985 supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action
Yes	DocMen	1981	1219812	Council Directive of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action
No	DocMen	1972	*Excluded because only available in French*	
No	DocMen	1985	*Excluded as duplicate of Directive 85/358/EEC*	
No	DocMen	1981	*Excluded as duplicate of Directive 81/602/EEC*	
No	DocMen	1981	*Excluded as duplicates of Directive 81/851/EEC and 81/852/EEC*	
No	DocMen	1981	*Excluded from dataset due to no mention of hormone-treated meat in the text*	Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products
No	DocMen	1981	*Excluded from dataset due to no mention of hormone-treated meat in the text*	Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products
Other Government Documents (OthGovDocs)				
Yes	OthGovDoc	1988	1219883	Council Directive of 17 May 1988 on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC
Yes	OthGovDoc	1996	1219963	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Yes	OthGovDoc	1985	1219853	Council Directive of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action
Yes	OthGovDoc	1995	1219953	Scientific Conference on the Use of Growth Promoters in Meat Production (29 November – 1 December 1995 In Brussels) press release
Yes	OthGovDoc	1999	1219993*	Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products

Yes	OthGovDoc	2000	1220003	REVIEW OF SPECIFIC DOCUMENTS RELATING TO THE SCVPH OPINION OF 30 APRIL 99 ON THE POTENTIAL RISKS TO HUMAN HEALTH FROM HORMONE RESIDUES IN BOVINE MEAT AND MEAT PRODUCTS
Yes	OthGovDoc	2002	1220023	Growth promoting hormones pose health risk to consumers, confirms EU Scientific Committee
Yes	OthGovDoc	2002	12200231	Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Review of previous SCVPH opinions of 30 April 1999 and 3 May 2000 on the potential risks to human health from hormone residues in bovine meat and meat products
Yes	OthGovDoc	20033	1220033	DIRECTIVE 2003/74/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists
Yes	OthGovDoc	2007	1220073	Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from the European Commission Related to Hormone Residues in Bovine Meat and Meat Products
Yes	OthGovDoc	2007	12200731	EFSA concludes review of new scientific data on potential risks to human health from certain hormone residues in beef (July 18, 2007. press release)
Yes	OthGovDoc	2018	12201831	Hormones in Meat (factsheet)
US Documents				
Include?	**Document Type**	**Document Year**	**Document Name in NVivo**	**Document Description**
Yes	Parent	1988	2219881*	Office of the United States Trade Representative [Docket No. 301-62] Determination To Impose Increased Duties on Certain Products of the European Community
DocMens listed in order of appearance in the Parent document				
Yes	DocMen	1987	2219872*	President Reagan's Proclamation: Increasing the Rates of Duty on Certain Products of the European Community
No	DocMen	1974	*Excluded from dataset due to no mention of hormone-treated meat in the text*	Trade Act of 1974

No. Mentioned in US doc but it is an EU doc. Included in EU.	DocMen	1985	*Excluded from US documents; included in EU*	Council Directive of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action
No	DocMen		*Excluded due to no mention of hormone-treated meat in the text*	Tariff Schedule of the United States
No	DocMen		*Excluded due to no mention of hormone-treated meat in the text*	The Harmonized Tariff Schedule of the United States (HTS) was enacted by Congress and made effective on January 1, 1989, replacing the former Tariff Schedules of the United States.
Other Government Documents (OthGovDocs)				
Yes	OthGovDoc	1989	2219893	Office of the United States Trade Representative. Further Modification to the Determination To Impose Increased Duties on Certain Products of the European Community
Yes	OthGovDoc	1999	2219993*	Office of the United States Trade Representative [Docket No. 301–62a] Implementation of WTO Recommendations Concerning EC—Measures Concerning Meat and Meat Products (Hormones)
Yes	OthGovDoc	2003	22200331	USDA Foreign Agricultural Service, GAIN Report. European Union Trade Policy Monitoring EU Presentation on Hormone Ban Directive (2003/74/EC)
No	OthGovDoc	2007	*Excluded from dataset due it being a standards and requirements document*	Food Safety and Inspection Service's Program for Certifying Non-Hormone Treated Beef to the European Union
Yes	OthGovDoc	2008	22200831	USTR Seeks Public Comments on Possible Changes to Product List in EU; Beef Hormones Dispute. Press release
Yes	OthGovDoc	2008	22200832	Office of the United States Trade Representative. Review of Action Taken in Connection With WTO Dispute Settlement Proceedings on the European Communities' Measures Concerning Meat and Meat Products
Yes	OthGovDoc	2009	22200931	USTR Announces Revised Trade Action in Beef Hormones Dispute. Press release
Yes	OthGovDoc	2009	22200933	Office of the United States Trade Representative. Additional Delay in Modification of Action Taken in Connection With WTO Dispute Settlement Proceedings on the European Communities' Ban on Imports of U.S. Beef and Beef Products
Yes	OthGovDoc	2009	22200934	Office of the United States Trade Representative. Implementation of the U.S.-EC Beef Hormones Memorandum of Understanding

Yes	OthGovDoc	2009	22200935	USTR Announces Agreement With European Union In Beef Hormones Dispute. Press release
Yes	OthGovDoc	2009	22200936	United States Trade Representative Ron Kirk Announces Delay of Trade Action in Beef Hormones Dispute. Press release.
Yes	OthGovDoc	2009	22200937	Office of the United States Trade Representative. Modification of Action Taken in Connection With WTO Dispute Settlement Proceedings on the European Communities' Ban on Imports of U.S. Beef and Beef Products
No	OthGovDoc	2009	*Excluded due to duplicate with 22200936.*	USTR Announces Delay of Trade Action in Beef Hormones Dispute.
Yes	OthGovDoc	2009	22200939	Office of the United States Trade Representative. Delay in Modification of Action Taken in Connection With WTO Dispute Settlement Proceedings on the European Communities' Ban on Imports of U.S. Beef and Beef Products. Correction
No	OthGovDoc	2017	*Excluded due to substantial overlap with 2220103.*	The U.S. - E.U. Beef Hormone Dispute. CRS Report
Yes	OthGovDoc	2010	2220103	The U.S. - E.U. Beef Hormone Dispute. CRS Report
Yes	OthGovDoc	2003	2220033	Trade Policy Monitoring: Historic Overview and Chronology of EU's Hormone Ban
Yes	OthGovDoc	2016	22201631	Office of the United States Trade Representative. Public Comments and Hearing Regarding Request To Reinstate Action Taken in Connection With the European Union's Measures Concerning Meat and Meat Products
Yes	OthGovDoc	2017	22201732	Steroid Hormone Implants Used for Growth in Food-Producing Animals
Yes	OthGovDoc	2019	2220193	Current U.S. Retaliatory Actions CHINA'S PRACTICES RELATED TO FORCED TECHNOLOGY TRANSFER, UNFAIR LICENSING, AND INTELLECTUAL PROTPERTY POLICIES (2017 to present)

Appendix D: Policy Documents for Bisphenol A

In the case of the bisphenol A, a total of 47 policy documents were identified and 13 were excluded because 1) they did not include the term "bisphenol-A", "BPA" or a derivative or 2) they could not be located. Exclusion justification is provided in the table.

	Total identified	**Included**			**Total included**	**Total Excluded**
		Parent	*DocMens*	*OthGovDocs*		
EU	37	1	4	17	22	15
U.S.	28	1	4	16	21	7
Total	65	2	8	33	43	22

Include?	**Document Type**	**Document Year**	**Document Name in NVivo**	**Document Description**
EU Documents				
Yes	Parent	2011	1320111*	Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles
DocMens listed in order of appearance in the Parent document				
No	DocMen		*Excluded from dataset due to no mention of bisphenol A in the text*	Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs
No	DocMen	1957	*Excluded from dataset due to no mention of bisphenol A in the text*	Treaty on the Functioning of the European Union
No	DocMen	2004	*Excluded from dataset due to no mention of bisphenol A in the text*	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
No	DocMen	1980	*Excluded from dataset due to no mention of bisphenol A in the text*	Commission Directive of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs. The Commission of the European Communities (80/590/EEC)
No	DocMen	1988	*Excluded from dataset due to no mention of bisphenol A in the text*	Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

Yes	DocMen	2006	1320062	Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-BIS (4-HYDROXYPHENYL) PROPANE (Bisphenol A) Question number EFSA-Q-2005-100 Adopted on 29 November 2006
Yes	DocMen	2008	1320082*	Toxicokinetics of Bisphenol A1 Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) (Question No EFSA-Q-2008-382) Adopted on 9 July 2008
No	DocMen	2010	*Excluded; not available in English*	Danish risk assessment
No	DocMen	2010	*Excluded; not available in English*	French Food Safety Authority report
No	DocMen	2010	*Excluded; not available in English*	French Food Safety Authority report
No	DocMen	2010	*Excluded; not available in English*	French National Institute of Health and Medical Research.
Yes	DocMen	2010	1320102	Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A1
No	DocMen	1997	*Excluded from dataset due to no mention of bisphenol A in the text*	Opinion of the Scientific Committee for Food on the maximum residue limit (MRL) of pesticides in foods intended for infants and young children
No	DocMen	1998	*Excluded from dataset due to no mention of bisphenol A in the text*	Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0.01 mg/Kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998)
Yes	DocMen	2002	13200221	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
No	DocMen	2006	*Excluded from dataset due to no mention of bisphenol A in the text*	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC
Other Government Documents (OthGovDocs)				

Yes	OthGovDoc	2002	*Excluded because did not address baby bottles.*	Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) Opinion on the results of the Risk Assessment of: Bisphenol A Human Health Report
Yes	OthGovDoc	2003	13200331	4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A) CAS No: 80-05-7 EINECS No: 201-245-8 Summary Risk Assessment Report
Yes	OthGovDoc	2007	13200731	EFSA re-evaluates safety of bisphenol A and sets Tolerable Daily Intake (press release, Jan 29, 2007)
Yes	OthGovDoc	2008	13200831	European Union Risk Assessment Report, Updated. April 2008
Yes	OthGovDoc	2008	13200832	STATEMENT OF EFSA on a study associating bisphenol A with medical disorders. Prepared by the Unit on food contact materials, enzymes, flavourings and processing aids (CEF) and the Unit on Assessment Methodology (AMU)
Yes	OthGovDoc	2008	13200833	EFSA updates advice on bisphenol (press release, July 23, 2008)
Yes	OthGovDoc	2010	13201031	EFSA updates advice on bisphenol A (press release, Sept 30, 2010)
Yes	OthGovDoc	2011	13201131	Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles
Yes	OthGovDoc	2011	13201132	Statement on the ANSES reports on bisphenol A1
No	*OthGovDoc*	*2011*	*Excluded because duplicate of 13201133*	Bisphenol A: EU ban on baby bottles to enter into force tomorrow
No	*OthGovDoc*	*2011*	13201133	Bisphenol A: EU ban on use in baby bottles enters into force next week
Yes	OthGovDoc	2015	13201531	Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary1 EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)2,3
Yes	OthGovDoc	2015	13201532*	EFSA explains the Safety of Bisphenol A. Scientific Opinion on bisphenol A (2015)
No	OthGovDoc	2017	*Excluded because used as test document*	Bisphenol A
Yes	OthGovDoc	2018	1320183	New rules on bisphenol A in food contact materials

Yes	OthGovDoc	2011	13201134	EFSA advises on safety of bisphenol A and confirms review of opinion in 2012 (press release, Dec. 11, 2011)
Yes	OthGovDoc	2013	13201331	Food is main source of BPA for consumers, thermal paper also potentially significant (press release, July 25, 2013)
Yes	OthGovDoc	2014	13201431	Bisphenol A: EFSA consults on assessment of risks to human health (press release, Jan 14, 2014)
Yes	OthGovDoc	2014	13201533	No consumer health risk from bisphenol A exposure (press release, Jan. 25, 2015)
Yes	OthGovDoc	2016	1201631	Bisphenol A immune system safety to be reviewed (press release, April 26, 2016)
US Documents				
Yes	Parent	2012	2320121*	Department of Health and Human Services Food and Drug Administration 21 CFR Part 177 [Docket No. FDA–2012 F–0031] Indirect Food Additives: Polymers AGENCY: Food and Drug Administration, HHS. ACTION: Final rule.
DocMens listed in order of appearance in the Parent document				
Yes	DocMen	2012	2320122	Department of Health and Human Services Food and Drug Administration 21 CFR Part 177 [Docket No. FDA–2012–F–0031] American Chemistry Council; Filing of Food Additive Petition AGENCY: Food and Drug Administration, HHS. ACTION: Notice of petition.
Yes	DocMen	2011	23201122*	Petition Seeking Amendment of Food Additive Regulation 21 C.F.R. § 177.1580 to Remove the Approval for Polycarbonate Resins in Infant Feeding Bottles and Certain Spill-Proof Cups Due to the Abandonment of these Uses.
Yes	DocMen	2011	23201121	Code of Federal Regulations Title 21 Food and Drugs Chapter 1 Subchapter B Part 177 Indirect Food Additives Subpart B Substances for Use as Basic Components of Single and Repeated Use Food Contac Surfaces §177.1580 Polycarbonate Resins.
No	DocMen	No date provided	*Excluded from dataset due to no mention of BPA in the text*	409(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(i)),
No	DocMen	No date provided.	*Excluded from dataset due to no mention of BPA in the text*	Title 21: Food and Drugs PART 171—Food Additive Petitions Subpart B—Administrative Actions on Applications §171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

Yes	DocMen	2010	2320102	Department of Health and Human Services Food and Drug Administration [Docket No. FDA–2010–N–0100] Food Additives; Bisphenol A; Availability AGENCY: Food and Drug Administration, HHS. ACTION: Notice; request for comment.
No	DocMen	1995	*Excluded from dataset due to no mention of bisphenol A in the text*	Paperwork Reduction Act of 1995
Other Government Documents (OthGovDocs)				
Yes	OthGovDoc	2001	2320013*	NTP's Report of the Endocrine Disruptors Low Dose Peer Review
Yes	OthGovDoc	2007	2320073	Chapel Hill bisphenol A expert panel consensus statement: Integration of mechanisms, effects in animals and potential to impact human health at current levels of exposure
Yes	OthGovDoc	2008	23200832	Draft Assessment of Bisphenol A for Use in Food Contact Applications
Yes	OthGovDoc	2008	23200833	NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A
Yes	OthGovDoc	2008	*Excluded due to substantial overlap with 23201131*	CRS Report Bisphenol A (BPA) in Plastics and Possible Human Health Effects
Yes	OthGovDoc	2009	2320093	CDC Fourth Report
Yes	OthGovDoc	2009	23200932	Exposure to Bisphenol A (BPA) for infants, toddlers and adults from the consumption of infant formula, toddler food and adult (canned) food.
Yes	OthGovDoc	2010	23201034	NTP Bisphenol A (factsheet)
No	OthGovDoc	2010	*Excluded because did not address baby bottles.*	Bisphenol A Action Plan
Yes	OthGovDoc	2008	23200834	FDA Response to the Scientific Peer Review of FDA's Draft Assessment of Bisphenol A for Use in Food Contact Applications
Yes	OthGovDoc	2010	*Excluded. Served as an announcement of availability of other documents.*	DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA–2010–N–0100] Food Additives; Bisphenol A; Availability
Yes	OthGovDoc	2010	23201035	Update on Bisphenol A for Use in Food Contact Applications U.S. Food and Drug Administration

Yes	OthGovDoc	2011	23201132	Updated Review of the 'Low-Dose' Literature (Data) on Bisphenol A (CAS RN 80-05-7)
Yes	OthGovDoc	2011	23201131	Bisphenol A (BPA) in Plastics and Possible Human Health Effects (CRS Report)
Yes	OthGovDoc	2014	23201431	2014 Updated safety assessment of Bisphenol A (BPA) for use in food contact applications.
Yes	OthGovDoc	2014	23201432	Update on Bisphenol A (BPA) for Use in Food Contact Applications
Yes	OthGovDoc	2014	23201433	FDA Final Report for the review of literature and data on BPA
Yes	OthGovDoc	2018	23201831	Questions & Answers on Bisphenol A (BPA) Use in Food Contact Applications
Yes	OthGovDoc	2017	*Excluded because did not address baby bottles.*	Bisphenol A Handling/Processing
Yes	OthGovDoc	2018	2320123	Food Additive Regulations Amended to No Longer Provide for the Use of BPA-Based Materials in Baby Bottles, Sippy Cups, and Infant Formula Packaging
Yes	OthGovDoc	2017	23201731	EPA, America's Children and the Environment