"SOYLENT GREEN" IS CLONES! THE GROWING EUROPEAN CONTROVERSY OVER FOOD LABELING

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I. Introduction

Modern science wields the ability to alter and to exactly replicate an organism's genetic building blocks: the organism's deoxyribonucleic acid ("DNA").[1] Genetic engineering ("GE") allows scientists to create new organisms by modifying existing DNA.[2] Cloning allows scientists to exactly duplicate existing DNA.[3] Genetically modified organisms ("GMOs") are portrayed as chimeras, fantastical creatures with juxtaposed parts.[4] In reality, GMOs are largely comprised of one organism's DNA as a base, with other foreign genes inserted in order to imbue the organism with positive qualities such as increased resistance to pesticides or infusing meat with vitamins.[5] Clones, by contrast, are exact genetic duplicates of another organism, like later-born twins.[6] While the GE process has palpable advantages in that it may introduce new, positive traits in organisms that would never appear naturally, cloning in some situations could be ideal, as with the farmer who wishes he could efficiently breed a whole herd of cattle identical to his prize-winning cow.[7]

Yet for all their advantages, GE and cloning still entail some hazards, both moral and scientific. Without proper safety precautions the processes raise ethical concerns about the treatment of sentient organisms.[8] Furthermore, genetic engineering and cloning involve relatively new technologies that, while constantly improving, are nonetheless still imperfect.[9]

In the international trade realm, biotechnology countries that accept these biotech advances—such as the United States—are pitted against skeptical nations or blocs—such

as the European Union ("EU").[10] The EU may try to stem the tide of cloned foods imported from the United States through new regulations mimicking those already covering GMOs.[11] Failing that, the EU may find itself on the receiving end of unfettered cloned food imports.[12]

This Comment will explain the history of the U.S./EU dispute regarding GMO food labeling and put it in the context of the new conflict concerning clones.[13] The Comment will then attempt to predict what, if any, EU regulation may arise or whether the current regulations covering GMOs will also apply to cloned food products.[14] If no regulation appears to be forthcoming, the Comment will propose in what direction the dispute should take the EU, and what consequences will result from going down this road.[15]

II. New Technologies and the Prelude to the Conflict

GMOs and clones are similar in the sense that they are both the products of genetic engineering.[16] GE is the manipulation of organisms on a genetic level.[17] GMOs and clones advanced by wildly different goals. GMOs are meant to be *über-organisms*, organisms with extra genetic traits inserted into their DNA in order to make the organisms something more than could be attained through natural breeding.[18] Clones already are *über-organisms*; they are the best that nature has to offer, genetically superior beings attained through natural breeding that may be duplicated *ad infinitum* so as to perpetuate the genetic perfection.[19]

Processes for cloning and the creation of GMOs are backed by the United States but are viewed with suspicion by the EU.[20] A 2006 World Trade Organization ("WTO")

decision centering on this international controversy held that the EU had improperly instituted a five-year moratorium on GMO imports.[21] What influence, if any, this decision carries is unclear.[22] The 2006 WTO decision conforms somewhat to a more expansive form of the precautionary principle, the basic philosophy followed in Europe that favors proceeding cautiously in the face of the unknown.[23] A substantial segment of the EU, however, pushes for acceptance of a more restrictive form of the precautionary principle, which drastically shifts the burden of proving safety onto those offering the scientific advancement.[24] This boils down to a basic difference in philosophy: the EU cares more about the process by which something is made, but the United States is more interested in the end product.[25]

A. *Genetically Modified Organisms v. Clones*

1. *GMOs.* - GMOs are organisms modified through invasive human intervention not using mating or natural recombination.[26] A process called transgenesis[27] allows movement of genes from one organism into another, including between different species.[28] For example, by inserting new genes into the DNA of a fertilized egg the embryo incorporates those new genes as its own, creating a transgenic animal known as a GMO.[29] Through transgenesis, scientists may make genetic modifications such as inserting jellyfish DNA into a rabbit so the rabbit can glow in the dark like the jellyfish[30] or enriching pig meat with omega-3 ("*n*-3") fatty acids.[31] Injecting cows with bovine growth hormone ("rBST") allows them to produce more milk.[32] While the most common types of GMOs currently produced are plant crops that are modified to be insect- or herbicide-resistant,[33] more exotic forms of GMOs are constantly being produced.[34]

One notable example is the use of transgenesis to increase the level of *n*-3 fatty acids in pigs.[35] In 2006, scientists responded to the demand for *n*-3 fatty acids by announcing the successful birth of transgenic pigs[36] capable of producing *n*-3 fatty acids in their meat.[37] Demand for *n*-3 fatty acids has increased in recent years because of their beneficial effects, including preventing and treating heart disease and immune-system disorder.[38] Animal meat, specifically red meat, tends to have a high amount of *n*-6 fatty acids and a low amount of *n*-3 fatty acids.[39] Fish, on the other hand, have a high amount of *n*-3 fatty acids.[40] Consumers can decrease their bad *n*-6 levels and increase their good *n*-3 levels by eating less red meat and more fish.[41] Allergies, food preferences, and declining fish populations, along with contamination of marine life from chemicals like mercury,[42] led to a recognized need for alternative means of consuming *n*-3 fatty acids.[43] Without employing transgenesis, an animal's tissues can be "enriched" with *n*-3 fatty acids only by feeding the animals a diet high in *n*-3 fatty acids, i.e., flaxseed or other fish.[44] While altering the genetic makeup of pigs in order to avoid eating fish or taking *n*-3 supplements is, arguably, tawdry and unnecessary, a counter argument is that because of the benefits of *n*-3 fatty acids, their general consumption should be promoted rather than prohibited, regardless of the source of the fatty acids.[45]

2. *Clones.* – A clone, by contrast, is a younger identical twin of another animal.[46] Cloning occurs not only in laboratories but also in nature.[47] Popular perception of cloning, however, is that it is something wholly alien to natural reproduction, as with transgenesis.[48] News accounts of cloning breakthroughs in the 1990s perpetuated this perception.[49] The cloning discussed here, however, is only "unnatural" in the sense of process, not product.[50]

Perhaps the most famous man-made clone was Dolly the sheep, who was born in 1996 and revealed to the world in early 1997.[51] Dolly was the first mammal cloned from an adult cell[52] by a process called somatic cell nuclear transfer ("SCNT").[53] This can be considered a type of synthetic fertilization, with the difference from sexual fertilization being that through SCNT the full allotment of forty-six chromosomes comes from one parent rather than half from each.[54] Thus, the donor organism supplies all of the chromosomes to the offspring.[55] Somatic cells, i.e., cells other than sperm or eggs,[56] are diploid, meaning they contain two sets of chromosomes, one from each parent.[57] Ova divide and begin the process of becoming embryos when they obtain a full complement of chromosomes, which usually occurs when ova are fertilized by sperm.[58] Through SCNT, the nucleus of an ovum is removed and replaced with the diploid nucleus of a somatic cell.[59] The ovum becomes "fertilized" because of the two sets of chromosomes from the inserted diploid nucleus, and embryo development begins.[60] The embryo then develops as a clone, an exact genetic copy, of the organism that donated the somatic cell nucleus, because only that organism's DNA is being replicated.[61] In contrast to sexual reproduction, where offspring have exactly half of the genetic material from each parent, clones replicate the entire DNA of only one parent organism.[62]

a. *Benefits of cloning*. - Cloning may be coupled with transgenesis to produce more desirable organisms and achieve other benefits.[63] For example, cloning animals without altering their genetic makeup benefits husbandry by allowing breeders to propagate animals with high-grade meat.[64] Getting the same high quality meat through natural breeding techniques, on the other hand, is slower and more imprecise.[65] Conventional breeding is more subject to mutations and imprecision, so it takes years to

reproduce animals with a desired genetic makeup.[66] While such high-grade animals may be achieved through transgenesis, the experience has been that only about five percent of livestock born carry the transgene.[67] Discovering high-grade animals and then cloning them may prove to be more efficient and less expensive than attempting to create high-grade GMOs.[68]

Cloning also benefits medical research by "dramatically" decreasing the amount of animals needed for experiments.[69] Cloning requires fewer live animals for research and permits otherwise unfeasible human studies.[70] Moreover, creating a herd of genetically identical animals benefits drug testing by assuring that any variations in responses to drugs are caused by the drugs themselves and not due to the animals' genetic differences.[71]

b. *Dangers and disadvantages of cloning*. - Despite the advantages of cloning organisms, the process raises serious moral and technological concerns.[72] Many clones have been born with side effects such as defective immune systems, cardiovascular problems, obesity, or urogenital abnormalities.[73] Additionally, many clones suffer from large offspring syndrome ("LOS"), cloned animals that are born unusually large.[74] This often leads to organ failure.[75] Dolly, for instance, was euthanized in 2003 when she was just six years old because she had progressive lung disease.[76] Dolly also suffered from arthritis,[77] which some speculate was the result of "premature aging."[78] The *n*-3 pigs had problems as well: three of them developed symptoms of heart failure shortly after birth and had to be euthanized.[79] This serves to illustrate the underlying concern about biotechnology that is reflected in the precautionary principle, a regulatory philosophy in widespread use in Europe.[80]

B. *The Precautionary Principle*

1. *Conflicting Forms*. - The precautionary principle is a philosophy that informs a mode of cautious conduct in the face of uncertainty.[81] It has two basic forms, strong and weak.[82] The weak form is widely accepted, almost to the point of being an unofficial international norm, whereas the strong form is less frequently adopted.[83] Both forms require caution in the face of uncertainty, but each carries with it a different burden of proving safety.[84]

a. *The weak form*. - Made famous by Principle 15 of the Rio Declaration on Environment and Development ("Rio Declaration"), the weak form of the precautionary principle generally is understood as "allow[ing] preventive measures to be taken in the face of uncertainty, but does not require them."[85] The Rio Declaration, enunciating the weak version, requires some evidence of the likelihood and severity of the consequences of an action before applying a precautionary approach.[86] Stated another way, the weak form presumes that something is *not* unsafe until evidence is presented that tends to show it *is* unsafe.[87] Applying the weak form of the precautionary principle would permit the introduction of GMOs and clones into the food supply in the absence of any evidence that such organisms are unsafe.[88] The FDA's analysis is that cloned animal food products are not unsafe.[89] If the FDA applies the weak form of the precautionary principle, cloned food would be introduced into the food supply.[90]

b. *The strong form*. - Generally, the difference between the weak and strong forms of the precautionary principle is the burden of proof.[91] Where the weak form permits actions in the absence of evidence of harm, the strong form demands proof

of a product's safety before releasing it to the public.[92] Products that fail to prove their safety flunk the strong form test and are not offered for public consumption.[93] Thus, in the context of GE and cloning, someone seeking to introduce GMOs or cloned animals into the food supply must show that the introduction is safe under this strong form of the precautionary principle. The European Group on Ethics in Science and New Technologies ("EGE"), which acts as an advisor to the European Community, embraces the strong form of the precautionary principle.[94] The EGE advocates that safety of cloned food products "must be guaranteed."[95] This is a much higher burden to meet than with the weak form; Europe has progressed from the weak Rio Declaration standard to something close to the strong form.[96]

C. *U.S. Regulations Regarding GMOs and Clones*

1. *Federal Regulation of GE Products*. – The United States Food and Drug Administration ("FDA") has recently proposed regulations that companies must meet before releasing onto the market products derived from GMOs.[97] The FDA proposals classify the transgenic DNA as drugs.[98] Unlike traditional drugs which go through clinical testing on humans, however, the proposed regulations would not entail human testing of the products.[99] Additionally, firms must demonstrate the safety and efficacy for the "animal drug's" intended use.[100] Moreover, shipments of the animal drug must be labeled to clearly convey that test animals are not to be used for food without prior FDA authorization.[101] Labels must also summarily describe the food product, the animal contained therein, the name of the GMO animal line, and the line's intended use.[102]

GMOs that are materially different from non-engineered organisms must also be labeled to provide the material distinction,[103] including any relevant "hazards and precautions."[104]

2. *Cloned Food Labeling Act*. – On January 26, 2007, Senator Barbara Mikulski of Maryland introduced the Cloned Food Labeling Act ("CFLA") "[t]o amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains product from a cloned animal be labeled accordingly."[105] The legislation would require food that "contains cloned product" to affix the notice, "THIS PRODUCT IS FROM A CLONED ANIMAL OR ITS PROGENY."[106] The concerns addressed by CFLA are largely echoed by organizations like the Union of Concerned Scientists, which notes that the livestock companies, which have an interest in making the numbers as favorable for cloning as possible, conduct most of the studies regarding cloning and food safety.[107] While this alleged conflict of interest is a valid concern, how a labeling system would necessarily resolve the issue is not clear. Thus far, the CFLA has not made it out of the Senate Committee on Health, Education, Labor, and Pensions, though Senators Barbara Boxer and Bernard Sanders signed on as cosponsors to the bill in late-January of 2008.[108]

D. *Europe's Response*

Directive 2001/18/EC, On the Deliberate Release Into the Environment of GMOs ("Directive"), references the strong form of the precautionary principle as the first general obligation under the directive.[109] The Directive requires food products from GMOs to carry the label, "[T]his product contains genetically modified organisms."[110]

This demonstrates the stark contrast in the regulatory approaches of the United States and the EU.

1. *Free Trade v. Precautionary Approach*. – In general, the United States and other GMO-producing countries subscribe to a philosophy of free trade with respect to GMOs.[111] This philosophy rests on the premise that the fewer restrictions placed on trade, the more efficient trade will become.[112] This *laissez-faire* philosophy results in lower government regulation of the ingredients that comprise, and the processes that produce, GMOs and clones.[113] In this setting, deregulation directly conflicts with the precautionary principle.[114] Free trade principles are irreconcilable with the philosophy that potential harms ought to be minimized through proactive government intervention.[115]

The clash between free trade and precautionary proponents led to a dispute over the EU's five-year moratorium on approving genetically modified crops.[116] The WTO adjudicated the matter and rendered a decision in 2006.[117] The decision was necessarily historical and speculative in nature, as the moratorium had voluntarily been lifted prior to adjudication.[118] Although the scope and importance of the decision is debated, it nevertheless aptly illustrates the present conflict and offers hints as to its future direction.[119]

a. *Background of the WTO dispute*. – In May 2003, a U.S.-led group of countries favoring free trade principles filed a formal complaint with the WTO against the EU alleging that the EU's five-year moratorium on approving GM crops impeded trade.[120] The complaint drew substantial attention because of the stakes involved: because in the United States a vast majority of food products now contain GE food and ingredients, halting the import of GE food from the United States would cut off most of

the United States food exports.[121] Argentina and Canada joined the United States in the complaint because those nations are among the world's leading producers of GM crops.[122]

In 2006, the WTO found that the EU's undue delays in approving GMOs for import constituted a de facto ban.[123] The finding was largely historical in nature, however, because the EU's moratorium was lifted in 2004.[124] Indeed, the decision is more interesting for its scope, or lack thereof. First it did not examine the question of biotech product safety.[125] Second, it did not examine the similarity between GMOs and their conventional counterparts.[126] Finally, it did not examine the EU's right to approve biotech products before they reach the market.[127] Most importantly, the WTO decision declared the precautionary principle to be unsettled international law, thus allowing the WTO to "refrain from expressing a view on this issue."[128]

2. *Product v. Process*. – The difference between the free trade and precautionary approaches largely comes down to an emphasis on either the process or the product.[129] Because the United States takes a free trade approach to the EU's precautionary approach, the United States tends to focus more on the end product while the EU focuses on the process by which the product is made.[130] This is reflected in the FDA's decision to not require special labeling for cloned animal food products and in the EU's reliance on the precautionary principle espoused in the Rio Declaration.[131]

a. *Product-based approach*. - The United States' product-based approach presumes that only the end product matters, not the means by which that end was achieved.[132] In the United States, the FDA concluded that there was no evidence that clones were unsafe.[133] This focus does consider the process by which something is made,

but only insofar as the process directly affects the nature of the product.[134] If the process naturally results in an unsafe product, then the process is important; if the product is safe, then the process by which it was made is deemed unimportant. An unsafe process might beget an unsafe product, but an "unnatural" process will not taint an otherwise proper product.

b. *Process-based approach*. - Underlying the process-based focus is the philosophy that the means by which something is produced is a crucial consideration.[135] This is often reflected as a "right to know."[136] In Europe, the "right to know" is backed by Regulation 1829/2003, which prohibits food from "mislead[ing] the customer."[137] This presumes that consumers would be misled into purchasing a product that they believe is repugnant by virtue of the process by which it was created.[138] Thus, in order for consumers to make an informed purchase, they have a right to know the process by which available food is made.[139] Consumers' right to know, along with the product/process distinction are critical to understanding the why cloning and GE raise substantial ethical concerns.

III. Discussion

A. *Ethical Concerns of Cloning and Genetic Engineering*

If problems such as LOS[140] are unavoidable side effects of the cloning process, that might be sufficient moral reason to halt cloning altogether.[141] This concern is mitigated, however, by the fact that the pregential defects[142] are not passed from clone to offspring when the clones mate.[143] The clones' progeny are as healthy as those born from

sexual reproduction.[144] Indeed, the disorders are more likely the result of embryo manipulation in specific cases rather than the SCNT process generally,[145] because similar disorders have been observed in situations not involving cloning that still require embryo manipulation.[146] Furthermore, scientists are focusing heavily on improving cloning technology in order to minimize side effects in animals and make the technique more efficient.[147] Until such time as scientists perfect SCNT, however, ethical debates rage between two diametrically opposed camps as to the worth of cloning.

1. *Utilitarian Balancing*. – Myriad ethical concerns inhere with animal cloning. Utilitarian philosophers raise concerns about animals being subjected to pain and suffering during the testing.[148] This theory holds that animals, as sentient creatures, have interests in avoiding pain, and that inflicting pain and suffering on animals is morally reprehensible.[149] Under this theory, current cloning techniques are at best morally questionable. LOS and other genetic disorders that are, as science currently understands it, results of imperfections in SCNT, might preclude the cloning process until it minimizes the instances of the disorders occurring.[150] Utilitarian arguments, however, require a balancing test to determine what will result in the best outcome.[151] The substantial positive uses of animal cloning likely would still outweigh pain and suffering inflicted on animals, particularly if the SCNT process continues to improve.[152]

2. *Deontological Response*. – Some other objections arise with regard to violations of animals' integrity, food safety, biodiversity, and social justice.[153] On the opposite end of the philosophical continuum from utilitarianism, deontology is concerned with one's duty to others rather than what is the best outcome.[154] This theory holds that beings have an inherent integrity and that they must therefore be treated with respect.[155]

Because animal cloning and animal experiments in general treat animals as mere means to some end, the experiments violate the animals' inherent integrity.[156] The slippery slope argument is that animal cloning will naturally lead to human cloning, which is seen by many as a more egregious example of violating a being's inherent integrity.[157] Pushback from this fear of the slippery slope, however, threatens the EU's use of the precautionary principle in regulating GE products.

B. *Prospects for the Precautionary Principle*

Although the Directive provides that the EU may consult with designated Scientific Committees "on any matter under this Directive," the scope of the Directive does not seem to cover clones.[158] The Committees' advice, then, would be limited to GMOs.[159] The Committees certainly could give advice regarding clones, but there is little bite to that bark without a new EU directive on point.[160]

1. *The Effect of the WTO Decision*. – Despite an outcry from critics, the WTO decision did not in fact eviscerate the precautionary principle.[161] Indeed, the decision highlighted the necessity for countries to follow the procedures for approving GMOs set out in the Directive.[162] That the EU failed to follow these procedures was as much the reason for the undue delays as the complex environmental and health issues involved.[163] The crux of the criticism directed at the WTO decision seems to be that the decision implicitly accepted the weak form of the precautionary principle rather than the strong form.[164] United States government and industry officials mused that the decision would require countries to base any rejections of GMOs on "sound scientific reasons" instead of political ones.[165] In a sense, this is merely reiterating Article 22 of the Directive, which

acts as a sort of supremacy clause precluding signatory countries from banning from the market GMOs that comply with the Directive.[166]

Moreover, exactly how much influence the WTO decision will ultimately have on the EU or on the development of the precautionary principle is unclear. EU officials anticipate little if any change resulting from the WTO decision.[167] Admittedly, Regulations 1829/2003 and 1830/2003 were both ratified September 22, 2003, some four months after the U.S.-led group of countries filed the WTO complaint.[168] By all appearances, the regulations were a response to the WTO complaint. In addition to promulgating a process by which a GMO becomes approved for release, the new regulations also serve to establish a 0.9 percent tolerance level of genetically modified ingredients in otherwise non-GE food.[169]

Viewed from the perspective of the biotech industry, the labeling and traceability requirements may effectively render the lifting of the de facto moratorium "utterly useless."[170] Thus, while the Regulations could be seen as something of a response to the WTO complaint, the EU appears nonplussed by the decision, as the EU continues to require companies to take certain measures to disclose any safety or health issues associated with a GMO prior to release.[171] Moreover, the WTO decision does not necessarily undermine this approach, as the decision favors something akin to the weak form of the precautionary principle.[172]

This implicit acceptance of the precautionary principle's weak form likely has little practical effect on Europe's ability to regulate GMOs.[173] Admittedly, the WTO decision does not embrace the precautionary principle exactly.[174] While the weak form permits regulations in the absence of specific scientific evidence of harm, it maintains the

burden of proof with the proposed regulators.[175] The WTO decision slightly elevates the burden of proof required so that member states "supply reasonable support for prohibition of the biotech products."[176] "Reasonable support" is, of course, a fluid concept that likely will not be hard for states to meet.[177] Moreover, given the historical nature of the decision, the WTO decision may not even hold precedential value.[178] Given the new Regulations, pro-biotech states may be faced with the prospect of either re-litigating the issue or finding an alternate solution.

2. *Free Trade v. Precaution Conflict Redux*. – The WTO decision elevates states' required burden of proving some reasonable scientific justification before they may prohibit the release of GMOs.[179] What makes the issue of cloned food products unique is that, generally speaking, states will be *unable* to show such evidence in this regard.[180] Because clones are identical to, or at least imperceptibly different from, the parent organism, there may be no way for states to show reasonable scientific evidence of harms from cloned animal products.[181] This does not mean that such products are necessarily safe; much more research needs to be done in order to ascertain the long-term effects of cloning on the cloned animals and their offspring as well as on consumers of the cloned food products.[182]

The lack of distinction between clones and their "parents" makes it difficult to pass regulations based on prospective harms associated with food derived from the organism. Clones are genetically identical to the parent organisms.[183] Assuming the cloning process did not result in any defects, attempts to ban clones created through scientific means would be impossible because no inspector would be able to tell the difference.[184] Simply put, under this WTO interpretation, states wishing to ban clones

must also ban clones' parents because parent and clone would be indistinguishable.[185] That is, to ensure that no clones enter the food supply, the parent organisms would have to be banned as well.[186] Biotech proponents will advance this argument to avoid regulation of cloned food products,[187] yet this tack too misses the point.

If cloning were a perfected process, then there would be no valid scientific argument for proscribing food derived from clones.[188] The only reason left to oppose cloned food products would be on non-scientific grounds.[189] In a sense, this would be an acceptance of the strong form of the precautionary principle: by placing the burden of proving safety on the food manufacturers, states would be accepting as valid that cloned food products could be proscribed without any evidence of harms.[190]

Any debate about hypothetical cloning using a perfected process is moot right now because cloning is *not* perfect; it is an improving process, but one that nonetheless entails many potential risks, both for the animals as well as regarding the food products.[191] In the end, it may be that the WTO decision was right on the merits. It attempted to draw a balance between scientifically unfounded fears and unregulated *laissez-faire* trade that, contrary to the weak form of the precautionary principle, requires a drawing forth of some scientific backing before prohibiting a new technology.[192] Despite the clear differences between clones and GMOs, both genetic and ethical, the issue is close enough that the WTO decision may yet apply. However, whether the WTO decision remains valid in the face of the Regulations, which were enacted shortly after the filing of the complaint, is unclear.[193] Yet, the principle derived from the WTO decision—namely that declining approval of an application to release a GMO requires some scientific assessment of risk—is nonetheless applicable in this situation.[194]

C. *Analyzing the Fungibility of the Directive*

The U.S./EU conflict regarding GMOs appears set to repeat itself with regards to cloned food products. The question whether the EU has the power or the will to enact new regulations regarding the import of cloned food products is moot if the Directive already covers clones. However, this may be too broad of a reading of the Directive. A narrower interpretation suggests that the Directive covers only GMOs, and new or amended regulations must be enacted to apply to clones.

1. *Broadly Interpreting the Directive*. – The Directive defines GMOs as organisms genetically altered in an unnatural way: methods other than mating or natural recombination[195] and transgenesis.[196] The plain language of the Directive, however, may not apply to clones.[197] By virtue of replacing the nucleus of the host cell with the nucleus of a parent cell, SCNT may "involv[e] the direct introduction into an organism of heritable material prepared outside the organism."[198] This requires a broad reading of the phrase "prepared outside the organism"—particularly the word "prepared," which implies manufacture or creation.[199] That said, "prepar[ing]" something may be as simple as making it "ready for use or consideration."[200] Under this definition, SCNT "involv[es] the direct introduction into an organism of heritable material [that is made 'ready for use or consideration'] outside the organism."[201] The nucleus of a parent cell is "prepared," and then "introduc[ed] into an organism."[202] If broadly construed, the techniques listed in the Directive would seemingly cover SCNT.[203]

The Directive defines GMOs as organisms with unnaturally altered DNA.[204] The issue here is whether clones' genetic material has in fact been altered at all. "Alter" may

be defined as "change . . . in character or composition."[205] The host cell is undeniably altered, because by removing the host cell's nucleus and replacing it with a parent cell's nucleus, the "character or composition" of the host cell is fundamentally changed.[206] Yet this belies the goal of the cloning process, which is not to alter the host cell, but rather to *replicate* the parent organism.[207] Indeed, the host cell is altered in a way, but this is unimportant because the organism that is the end product of SCNT will not be altered from the original organism.[208] The only defensible reading of the definition of a GMO in the Directive so that it covers clones requires an interpretation of "organism" to mean the *initial* organism—the host cell—instead of the *end product*.[209]

2. *A Narrower Reading*. – As discussed above, EU legislation may already cover clones.[210] Such a conclusion, however, is predicated on a broad reading of the definitions and terms in the Directive, though such a broad reading may not be justified. If the Directive contemplated including clones along with GMOs, the Directive would have been explicit.[211] This argument is strengthened by the fact that the SCNT process predates the Directive, and SCNT is a process that may be used both in cloning and transgenesis.[212] The definitions section of the Directive, though, does not list SCNT as a technique that produces GMOs.[213] This implies that there are some uses and products of SCNT that are not covered by the Directive, and cloning seems to be one.[214] Thus, the broad interpretation is likely unjustified because of the purposeful exclusion of SCNT from the definitions list.[215] New or amended legislation would therefore be required to reach past GMOs and touch clones explicitly, rather than implicitly, as the broad interpretation requires.

D. *Prospective Regulations*

As discussed above, a reasonable reading of the Directive suggests that new or amended regulations are required to cover cloned food products instead of just GMOs. Any new regulation would likely use the Directive as a template. However, the immediate necessity of any new regulation is minimal, as cloning is not currently economically feasible on a large scale.[216]

Any potential regulation would likely require labels to indicate if the food product comes from not only a clone, but also from a clone's progeny.[217] This would be consistent with the EU's process-based philosophy: it does not matter how many iterations down the line the product goes because the *initial* product was still produced by a "repugnant" process, and this taints progeny.[218] In theory, such a regulation would be fairly simple to craft, just by using the Directive as a template and substituting "clones" for "GMOs."[219] Indeed, the Directive would seem to provide many of the features necessary for regulating cloned food, particularly Regulation 1830/2003's rather robust discussion of traceability.[220] While technically such a regulation might be feasible, it seems more likely the EU will refrain from enacting another procedure.[221]

While the FDA has permitted cloned animal food products, the EU appears to be much further behind in making a decision whether to move forward with regulations.[222] The European Food Safety Authority ("EFSA"), however, has come out in cautious support of the FDA's Risk Assessment.[223] The three years of litigation in front of the WTO will likely have a strong bearing on whether the EU decides to stand athwart the coming cloned food imports.[224] Moreover, cloning is currently an expensive technology that restricts its economic application.[225] The EU may just be biding its time until the day

it becomes economically viable to clone a cow just to butcher it and send the meat to the supermarket.[226] This wait-and-see approach allows for unintended consequences, as companies scramble to take advantage of the regulation-free market.

E. *Natural v. Organic: The Coming Supermarket Labeling Wars*

Assuming that the CFLA, which seeks to curtail unfettered *laissez-faire* trading,[227] does not pass, cloned food products will likely enter the general United States food supply.[228] The EU appears to be moving toward following the United States' lead in permitting cloned food products to intermingle with the general food supply.[229] This deference to the free market will, ironically, lead to a substantial rise in the demand for both organic and natural foods, as large segments of the populations will reject foods that are not labeled as biotech-*free*.[230] The problem is that while organic certification comes with a government backing as to the ingredients and processes by which something is made, to stamp a "natural" label on a product requires little government oversight.[231] As such, companies will flock en masse to label their products "natural" in a bid to gain customers suspicious that any foods *without* an "organic" or "natural" label in fact contain cloned food.[232]

In the United States, the FDA has yet to formally define the term "natural."[233] The FDA informally considers "natural" products those that contain no "synthetic or artificial ingredients that one would not normally expect to be in the food."[234] Conversely, "organic" food must meet the standards of the USDA's National Organic Program: requiring that livestock be raised without antibiotics or synthetic hormones, that

the feed is vegetarian, pesticide- and herbicide-free, and that the livestock/meat cannot come from genetically modified sources.[235]

A question remains whether cloned animal products could be considered "organic."[236] Beef from a cloned cow that was raised without antibiotics or synthetic hormones, fed a wholly vegetarian diet, and is not the product of transgenesis seems to facially meet the requirements for "organic" certification.[237] The last requirement, of course, is the sticking point, as clones do not technically come from "genetically modified sources." Critics can argue that the initial SCNT process, which is the "source" of a clone, "genetically modifie[s]" the clone. This argument is unpersuasive because, as mentioned above, clones are genetically identical to the parent organism.[238] That is, there is no "modification" past the original process by which the nucleus of one cell is replaced with the nucleus of a parent cell.[239] This is not so much modification as it is replacement or transfer.[240] Moreover, if such a novel definition of "genetically modified sources" were valid, enacting new or changing current regulations concerning GMOs would be unnecessary.[241] That said, "organic" food clearly contemplates a kind of purity.[242]

Although clones are by definition genetically identical to their parent organisms, the public remains uneasy if not repulsed by the idea of cloning.[243] The distrust comes from feelings that clones are unnatural, implying that they are unsafe.[244] Current evidence suggests that this view is unfounded and perhaps even specious.[245]

Cloning opponents appear to be deliberately attempting to conflate the fight over the release of cloned food products with the ongoing conflict regarding the release of GM food products.[246] Framed this way, the controversy ignores the distinct differences between two issues: while GMOs are substantially different from their natural

counterparts, clones are not.[247] In fact, clones are the exact opposite because they are identical to their natural counterparts.[248] If consumers feel distrust or repulsion towards GMOs, it is likely because they think GMOs are different and alien in comparison to naturally grown and bred organisms.[249] These feelings are understandable when GMOs, by virtue of their characteristics, are distinctly unnatural. However, transferring these feelings of distrust or repulsion to clones is not understandable because clones are meant to exactly replicate something "natural."

Cloned food products therefore might also be labeled "organic" or "natural." The FDA seems immune to public unease with cloned food[250] so whether the FDA will make any move to exclude cloned food from being labeled as "organic," or to actually define "natural" at all, let alone in a way that also excludes cloned food, is unclear.[251] In this case, it may be that consumers will never be confident that their food does not contain clones.[252] At this point, however, the EU might feel confident enough to enact regulations restricting "organic" labels to only those organisms created through traditional breeding techniques.[253]

IV. Conclusion

History may be in the process of repeating itself, as the EU must decide whether or not to regulate the import of cloned food products.[254] Having come out of the WTO suit with something of a black eye, the EU likely will hold back and allow the free market to bring cloned food into Europe.[255] This same free market, however, will give rise to increased sales of organic and natural foods by companies hoping to cash in on the public's unease about biotech.[256] Eventually, cloned food will invade even the natural

and organic markets.[257] At that point, the FDA and the EU may find themselves with enough cache to answer the call of a public boiling at having lost its ability to choose not to eat cloned food, and put a lid on practices of labeling cloned foods as organic. That is, if the FDA and EU have an appetite for the fight.

[1] *See* National Institutes of Health, Cloning: Present Uses and Promises (Apr. 27, 1998), *available at* http://ospp.od.nih.gov/policy/cloning.asp [hereinafter *NIH*].

[2] Stephanie Francis Cahill, *Transgenic, Chimerical Art is What's Up, Doc*, CHI. DAILY L. BULL, at 3, Sept. 11, 2000.

[3] *NIH*, *supra* note 1.

[4] *See* Cahill, *supra* note 2, at 3. These organisms are sometimes referred to as "chimeras" because they contain the DNA of multiple organisms, much as how the Greek monster as comprised of multiple animals.

[5] *See e.g.*, Liangxue Lai et al., *Generation of Cloned Transgenic Pigs Rich in Omega-3 Fatty Acids*, 24 NATURE BIOTECHNOLOGY 435, 435 (2006) (creating genetically engineered pigs whose meat has omega-3 fatty acids, which are naturally found in fish and grains).

[6] John F. Murphy, *Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products: Mandatory Labeling of Food Made from Cloned Animals: Grappling with Moral Objections to the Production of Safe Products*, 63 FOOD & DRUG L.J. 131, 131 (2008).

[7] *See e.g.*, *id.* at 133 (describing how someone might "clone a herd of identical super-animals").

[8] *See Opinion No. 23 of the European Group on Ethics in Science and New Technologies to the European Commission on the "Ethical Aspects of Animal Cloning for Food Supply,"* at 40 (Jan. 16, 2008), *available at* http://ec.europa.eu/european_group_ethics/activities/docs/opinion23_en.pdf [hereinafter *EGE*] (concluding that animals welfare standards require five freedoms: "from hunger, thirst and malnutrition; from fear and distress; from physical and thermal discomfort; from pain, injury and disease; and to express normal patterns of behavior").

[9] *See e.g.*, CENTER FOR FOOD SAFETY, NOT READY FOR PRIME TIME: FDA'S FLAWED APPROACH TO ASSESSING THE SAFETY OF FOOD FROM ANIMAL

CLONES, 9 (2007), http://www.centerforfoodsafety.org/pubs/FINAL_FORMATTEDprime%20time.pdf [hereinafter *Prime Time*] (describing health issues in clones associated with Large Offspring Syndrome, where animals are born abnormally large). Fears of unanticipated and uncontrollable genetic mutations or side effects are not unfounded, albeit largely speculative. And there is evidence that such disorders are not inheritable; offspring of clones with the disorder are typically healthy. For an excellent discussion of these issues, *see generally* Murphy, *supra* note 6.

[10] Cinnamon Carlarne, *From the USA With Love: Sharing Home-Grown Hormones, GMOs, and Clones With a Reluctant Europe*, 37 ENVTL. L. 301, 309 (2007).

[11] *See e.g.*, Council Directive 2001/18, On the Deliberate Release Into the Environment of GMOs, 2001 O.J. (L 106) 1 (EC) [hereinafter *Directive*]; Commission Regulation 1829/2003, 2003 O.J. (L 268) 1 (EC); Commission Regulation 1830/2003, 2003 O.J. (L 268) 24 (EC).

[12] *Compare* U.S. FOOD AND DRUG ADMIN., ANIMAL CLONING: A RISK ASSESSMENT 332 (Jan. 8, 2008) [hereinafter *Risk Assessment*] (finding that meat from cloned animals' progeny is not materially different than the meat from non-clone progeny) *with Directive*, *supra* note 11, at 1 (setting forth procedures to be met before putting GMOs into the market in Europe). In finding that cloned meat is no different than non-cloned meat, the Risk Assessment clears the way for cloned food products to enter the United States market without special labeling. Because the Directive does not reach clones, *see supra*, pp. 24-27, it will not stop cloned food products from entering Europe.

[13] *See infra* pp. 14-16.

[14] *See infra* pp. 24-29.

[15] *See infra* pp. 29-32.

[16] *See* Press Release, European Union, Questions and Answers on the Regulation of GMOs in the European Union (Mar. 22, 2005), http://europa.eu/rapid/pressReleasesAction.do?reference=MEM

O/05/104 [hereinafter *Questions and Answers*]; *see NIH*, *supra* note 1.

[17] *See id.*

[18] Carlarne, *supra* note 10, at 309-10 (quoting Susana Borras, *Legitimate Governance of Risk at the EU Level? The Case of Genetically Modified Organisms*, 73 TECH. FORECASTING & SOC. CHANGE 61, 62 (2006)).

[19] *See* Murphy, *supra* note 6, at 134 (listing idealized traits of various cloned cows).

[20] *See* Carlarne, *supra* note 10, at 310 (noting that the EU's GMO regulations are based primarily on the precautionary principle, while the United States takes a more free market, *laissez-faire* approach).

[21] World Trade Organization, Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291 (Sept. 29, 2006) [hereinafter *Panel Report*].

[22] *See* Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 825 (2008) ("[T]he central questions remain unanswered.").

[23] *See* New Zealand Treasury, Environmental Risk Management in New Zealand – Is there Scope to Apply a More Generic Framework?, Policy Perspectives Paper 06/06, at 5 (Jul. 2006), *available at* http://www.treasury.govt.nz/publications/research-policy/ppp/2006/06-06/tpp06-06.pdf [hereinafter *Environmental Risk Management*] (quoting U.N. Conference on Environment and Development principle 15, June 3-14, 1992, *Rio Declaration on Environment and Development*, 31 I.L.M. 874, 879).

[24] *Id.* at 13.

[25] Carlarne, *supra* note 10, at 315.

[26] *Questions and Answers*, *supra* note 16.

[27] Glossary, NATURE, http://www.nature.com/nrg/journal/v6/n3/glossary/nrg1553_glossary.html (last visited Oct. 1, 2008) (defining transgenesis as "The process of introducing foreign DNA into a genome.").

[28] *Questions and Answers*, *supra* note 16.

[29] *See NIH*, *supra* note 1 (defining a transgenic animal as "one that is genetically altered by inserting a new gene with the desired attributes into the DNA of a fertilized egg.").

[30] Cahill, *supra* note 2, at 3.

[31] Lai et al., *supra* note 5, at 435 (stating that "[t]he total *n*-3 fatty acids . . . in skeletal muscle from the transgenic pigs were about 8% of total muscle fat on average, which is much higher than those in wild-type pigs (1–2%).").

[32] Henry I. Miller, Op-Ed, *Don't Cry Over rBST Milk*, N.Y. TIMES, Jun. 29, 2007, http://www.nytimes.com/2007/06/29/opinion/29miller.html, (stating that "[w]hen rBST is injected into cows, their digestive systems become more efficient at converting feed to milk. It induces the average cow, which produces about eight gallons of milk each day, to make nearly a gallon more."). This process does not change the organism's genetic makeup, but is still considered part of general "biotechnology" field, in which GE and cloning also reside.

[33] *See Questions and Answers*, *supra* note 16. *See also* Syngenta, Bt-11 Sweet Corn Update (Mar. 2004), *available at* http://www.syngenta.com/en/downloads/Bt_sweet_corn_update_3-04_final.pdf (explaining that Bt-11 Sweet Corn is an insect-resistant strain of corn that was recently approved in Europe); *see also* Margaret Gilhooley, *Reexamining the Labeling for Biotechnology in Foods: The Species Connection*, 82 NEB. L. REV. 1088, 1088 (2004) ("Widespread crop protection uses involve the transfer of a bacterial pesticide gene to corn and a gene to enable soybeans to survive spraying with an herbicide.").

[34] *See e.g.*, Cahill, *supra* note 2, at 3 (describing a glow-in-the-dark rabbit).

[35] Lai et al., *supra* note 5.

[36] The pigs, it should be noted, are in fact transgenic clones. *See* Lai et al., *supra* note 5, at 435.

[37] *Id.*

[38] *Id.*

[39] *Id.* This high ratio of *n*-6/*n*-3 fatty acids is thought to contribute to medical problems such as heart disease, cancer, diabetes, arthritis, and depression. *Id.*

[40] Am. Heart Ass'n, Fish and Omega-3 Fatty Acids, http://www.americanheart.org/presenter.jhtml?identifier=4632 (last visited Feb. 11, 2009).

[41] *See* Lai et al., *supra* note 5, at 435; *see also* Am. Heart Ass'n, *supra* note 40.

[42] Lai et al., *supra* note 5, at 436.

[43] *Id.*

[44] *Id.*

[45] *See id.* (discussing the health benefits stemming from increased consumption of *n*-3 fatty acids).

[46] *See* Murphy, *supra* note 6. It should be noted, "the clone will not be one hundred percent genetically identical because it will have mitochondrial DNA from the donor of the enucleated egg." Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH 643, 647 (1998). Moreover, "[o]ther research has found differences in the fatty acid and mineral content of milk from clones." Sharon Oosthoek, *I'll Have the Cloneburger and Fries*, NEW SCIENTIST, Apr. 26, 2008, at 40. However, for the purposes of this Comment the genetic difference will be considered negligible because "there [are] no obvious differences." *Id.* (quotation omitted).

[47] *EGE*, *supra* note 8, at 6 ("In more complex animals, cloning occurs when a fertilised egg splits to give identical twins.").

[48] *See* Justin Gillis, *Shoppers Uneasy About Cloning*, WASH. POST, at D01, Nov. 16, 2005, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2005/11/15/AR2005111501617.html (citing a Pew Initiative poll finding that 66% of Americans felt uncomfortable with the idea of animal cloning, and 43% thought that food from clones would be unsafe).

[49] Murphy, *supra* note 6, at 138-39.

[50] *See EGE*, *supra* note 8, at 6 ("In more complex animals, cloning occurs when a fertilised egg splits to give identical twins.").

[51] *Dolly the Sheep Clone Dies Young*, B.B.C. NEWS, Feb. 14, 2003, http://news.bbc.co.uk/2/hi/science/nature/2764039.stm [hereinafter *Dolly the Sheep*].

[52] *Id.*

[53] J. Suk et al., *Dolly for Dinner? Assessing Commercial and Regulatory Trends in Cloned Livestock*, 25 NATURE BIOTECHNOLOGY 47, 47 (2007). SCNT involves taking DNA from a somatic cell and transferring it to an unfertilized ovum whose nucleus has been removed. *See NIH*, *supra* note 1. (defining a somatic cell as "any cell of the body other than egg or sperm cells").

[54] Murphy, *supra* note 6, at 132.

[55] *See id.*

[56] *NIH*, *supra* note 1.

[57] Biology-Online.org, http://www.biology-online.org/dictionary/Diploid (last visited Feb. 11, 2009).

[58] *NIH*, *supra* note 1.

[59] *See id.*

[60] Murphy, *supra* note 6, at 132.

[61] *NIH*, *supra* note 1.

[62] *Id.*

[63] *See id.* ("Cloning the animal that incorporated the gene of interest would be much faster than selective breeding and would decrease the amount of time required to produce transgenic animals."); *see also* J. Suk et al., *supra* note 53, at 48 ("Gene targeting, which involves cloning an animal with a transgene integrated into a specific site, was first demonstrated in 2000 in sheep.").

[64] Murphy, *supra* note 6, at 133. With animal husbandry, the primary benefit of cloning is that breeders can accurately increase the quality of meat by selectively cloning high-grade meat after the animal has been slaughtered. *See also* Dept. of Agric., Food Safety of Turkey . . . From Farm to Table, http://www.fsis.usda.gov/FactSheets/Turkey_from_Farm_to_Table (last visited Feb. 11, 2009) (defining Grade A meat as meat that is "virtually free from defects").

[65] Murphy, *supra* note 6, at 133.

[66] *See NIH*, *supra* note 1. Indeed, "[t]he repeated inbreeding of animals with the best characteristics is, in a functional sense, a crude form of cloning"; *see also* Murphy, *supra* note 6, at 133. The product of cloning and traditional breeding is often the same; cloning merely seeks to artificially hasten the pace of the "repeated inbreeding." Thus, whereas breeding naturally a herd of Grade A cattle takes many years, it can be accomplished quickly by cloning one particularly worthy cow and not having to worry about genetic chance through traditional breeding.

[67] J. Suk et al., *supra* note 53, at 47.

[68] While cloning has a higher rate of success than transgenesis, the SCNT process only recently became much more viable than transgenesis. *See* Murphy, *supra* note 6, at 132 ("Efficiency rates for SCNT began around 1-5

percent, but in recent years some private entities claim to have surpassed 30 percent.").

[69] *NIH*, *supra* note 1.

[70] *Id.* Whether or not one subscribes to the view that medical research on animals is unethical, the fact of the matter is that current regulations allow experiments to be done on animals that would never be allowed to be done on humans. Cloning, combined with transgenesis, could create animals whose organs are "built" for transplanting in humans. Research on those animals would have the benefit of being medically similar to research on humans, but without the downside of actually experimenting on humans. *See* Harold Varmus, M.D., Director, National Institutes of Health, Statement for the Record on Human Cloning before the House Committee on Commerce, Subcommittee on Health and Environment (Feb. 12, 1998), *available at* http://www.hhs.gov/asl/testify/t980212b.html.

[71] Statement of Varmus, *supra* note 70.

[72] *See generally* PRIME TIME, *supra* note 9 (assessing the safety of food from cloned animals); *see also EGE*, *supra* note 8, at 32.

[73] J. Suk et al., *supra* note 53, at 49.

[74] *Id.* This may explain why clone meat often has "higher levels of fat and certain fatty acids" than the original animal. *See also* Oosthoek, *supra* note 46, at 40.

[75] J. Suk et al., *supra* note 53, at 49.

[76] *Dolly the Sheep*, *supra* note 51. Many sheep live to twelve years of age or more. Will Knight, *Dolly the Sheep Dies Young*, NEW SCIENTIST, Feb. 14, 2003, *available at* http://www.newscientist.com/article/dn3393-dolly-the-sheep-dies-young.html.

[77] *Dolly the Sheep*, *supra* note 51.

[78] Murphy, *supra* note 6, at 132.

[79] Lai et al., *supra* note 5, at 436 ("This [interatrial septal] defect has been reported in other cloned pigs and appears to be a function of the cloning process (incomplete nuclear reprogramming) rather than the . . . transgene.").

[80] *See generally Environmental Risk Management*, *supra* note 23, at 13.

[81] *Id.* at 12.

[82] *Id.*

[83] *Id.* at 13.

[84] *Id.* at 12-13.

[85] *Environmental Risk Management*, *supra* note 23, at 12. *See also* U.N. Conference on Environment and Development principle 15, June 3-14, 1992, *Rio Declaration on Environment and Development*, 31 I.L.M. 874, 879 [hereinafter *Rio Declaration*] ("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."). *See also* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, art. 1, May 15, 2000, 39 I.L.M. 1027 [hereinafter Cartagena Protocol] (affirming the weak form of the precautionary principle espoused in principle 15 of the Rio Declaration).

[86] *Environmental Risk Management*, *supra* note 23, at 12.

[87] *See id.* ("[T]he requirement to justify the need for action (the burden of proof) generally falls on those advocating precautionary action."). It should be pointed out that declaring something affirmatively safe is not the same as declaring that it is not unsafe. The former implies certainty in the continuation of that status; the latter leaves open the possibility that further testing will reveal theretofore-unknown dangers.

[88] *Id.*

[89] *See Risk Assessment*, *supra* note 12, at 332 ("[E]dible products from healthy clones that meet existing

requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals.").

[90] *Environmental Risk Management*, *supra* note 23, at 12 ("[T]he requirement to justify the need for action (the burden of proof) generally falls on those advocating precautionary action.").

[91] *See id.* at 13 (explaining that the strong form "requires those proposing an activity to prove that the product, process or technology is sufficiently "safe" before approval is granted.").

[92] *Id.*

[93] *See e.g.*, *Directive*, *supra* note 11, arts. 12-16, at 8-10 (setting the procedure for GMO products to apply for release in the EU).

[94] *See EGE*, *supra* note 8, at 45 ("The safety of food products for human consumption as a pre-condition for their marketing must be guaranteed and scientific updates and follow up research into progeny should be carried out.").

[95] *Id.*

[96] *See Environmental Risk Management*, *supra* note 23, at 13 ("[T]here has been a gradual transformation of the precautionary principle from what appears in the Rio Declaration to a stronger form that arguably acts as restraint on development in the absence of firm evidence that it will do no harm.").

[97] See FDA, Draft Guidance for Industry, *Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs*, No. 187 (Sept. 18, 2008). The proposed regulations do not, however, cover cloned animals because "[t]he FDA has already determined that clones . . . are safe." See also Karen Kaplan and Thomas H. Haugh II, *For Genetically Modified Animals, Rules Are Ready: The FDA Unveils an Approval Process that Opens a Road From Farm to Market for the Creatures*, L.A. TIMES, Sept. 19, 2008, at 24.

[98] Kaplan and Haugh, *supra* note 97, at 24.

[99] *Id.*

[100] Draft Guidance for Industry, *supra* note 97. For instance, to demonstrate effectiveness the GMO would have to in fact have the claimed GE characteristic. *Id.*

[101] *Id.* at 9.

[102] *Id.* at 13.

[103] *Id.* That is, any transgenic change in a food's composition must be put on the label. Kaplan and Haugh, *supra* note 97, at 24. However, changes that do not affect the organism's composition, e.g., allowing it to grow faster, labeling is unnecessary. *Id.*

[104] Draft Guidance for Industry, *supra* note 97, at 25. *Cf. Why Strawberry Jam is More Regulated than Cigarettes*, SCIENCE DAILY, Sept. 3, 2008, *available at* http://www.sciencedaily.com/releases/2008/09/080901090817.htm ("While jams and other consumer products are strictly regulated and are required to pass stringent tests before they can be sold, tobacco has no restrictions and manufacturers can, and do, add anything they want into the product.").

[105] Cloned Food Labeling Act, S. 414, 110th Cong. (2007) [hereinafter *CLFA*].

[106] *Id.* § 2(a).

[107] Oosthoek, *supra* note 46, at 40.

[108] Library of Congress, http://thomas.loc.gov/home/multicongress/multicongress.html (search for S. 414 under 110th Congress; click the second listing; then follow "Bill Summary & Status file" hyperlink; then follow "Cosponsors" hyperlink) (last visited Feb. 11, 2009).

[109] *Directive*, *supra* note 11, art. 4(1), at 5 ("Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to *avoid adverse effects on human health and the*

environment.") (emphasis added). The requirement that states foremost "avoid adverse effects" indicates the strong form of the precautionary principle; it presumes that GMOs will have adverse effects unless member states take measures to avoid such effects. This is echoed in the second obligation under the directive, which requires states to "carry out an environmental risk assessment" prior to releasing GMOs. *Id.*, art. 4(2), at 5.

[110] *Id.*, art. 13(2)(f), at 9.

[111] Strauss, *supra* note 22, at 811.

[112] *See* Carlarne, *supra* note 10, at 310 ("[T]he United States insists that bans, strict regulations, and labeling requirements for GMOs are unnecessary and constitute arbitrary and unjustified impediments to free trade.").

[113] *See* Foreign Agricultural Service, U.S. Mission to the European Union: Biotechnology: EU Policy, Dec. 4, 2008, *available at* http://useu.usmission.gov/agri/GMOs.html (noting that in the EU, several GM products have been under review for over six years, in comparison to about six-to-nine months in Canada, Japan, and the United States).

[114] *See* Carlarne, *supra* note 10, at 309-10 (noting that free-trade proponent WTO generally discourages regulations).

[115] *Compare* Carlarne, *supra* note 10, at 309-10 (noting that free-trade proponent WTO generally discourages regulations) *with Environmental Risk Management*, *supra* note 23, at 8 (discussing options for implementing the precautionary principle).

[116] Strauss, *supra* note 22, at 775.

[117] *Panel Report*, *supra* note 21.

[118] Strauss, *supra* note 22, at 801.

[119] *See id.* at 804, 814 (analyzing the potential scope of the ruling).

[120] *Id.* at 775.

[121] *See id.* at 778 (citing *Americans Clueless About Gene-Altered Foods* (Mar. 23, 2005), *available at* http://www.msnbc.msn.com/id/7277844/). Globally, the biotech market accounts for $5.5 billion per year. *Id.* Indeed, the United States claimed that the moratorium cost it upwards of $300 million per year in corn exports alone. *Id.* at 782 (citing Raymond J. Ahearn, Congressional Research Service, Trade Conflict and the U.S.-European Union Economic Relationship 19 (2007), *available at* http://www.nationalaglawcenter.org/assets/crs/RL30732.pdf.).

[122] *Id.* at 778 (citing Kathryn McConnell, U.S. Mission to the European Union, World Trade Agency Upholds Challenge of European Biotech Ban, Sept. 29, 2006, http://useu.usmission.gov/Article.asp?ID=BFDOD73C-E0IB-478C-A164-08F5E747FEEF).

[123] *Panel Report*, *supra* note 21, P 7.1496, at 664. What is "undue," of course, is vague. The WTO attempted to clarify the matter by emphasizing that the reason for a delay, more than its length, was crucial. *Id.*

[124] The moratorium, which was always unofficial, effectively ended in May 2004 when the EU approved a GE corn variety, Syngenta Bt-11, for human consumption. Strauss, *supra* note 22, at 808.

[125] WTO, Interim Reports of the Panel, *European Communities Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292, and WT/DS293, P 8.3 (Feb. 7, 2006) [hereinafter *Interim Report*].

[126] *Id.*

[127] *Id.*

[128] *Panel Report*, *supra* note 21, P 7.89, at 340-41.

[129] *See* Carlarne, *supra* note 10, 315 (2007) ("The EU decision to focus on analyzing the process by which GM[O]s are created, rather than focusing on the end product, will be a continuing point of contention between the EU and the United States.").

[130] *See id.* ("The U.S. regulatory process focuses on analyzing end products rather than processes. . . . The [EU] decision to emphasize process rather than product analyses reflects the EU's attempt to build precaution into its new legislation.").

[131] *See e.g.*, *Risk Assessment*, *supra* note 12, at 332 (finding that cloned food products are not materially different than non-cloned food products); *Environmental Risk Management*, *supra* note 23, at 5-6 (discussing the EU's acceptance of the precautionary principle in the Rio Declaration).

[132] Carlarne, *supra* note 10, at 315. The EU's focus on the process reflects an interest in precaution. *Id.*

[133] *Risk Assessment*, *supra* note 12, at 332. The FDA Risk Assessment was careful, however, to note that its conclusion was limited by uncertainties inherent in empirical observations of biological organisms. *Id.* This is not to suggest that the FDA was not confident in its conclusion, but, as a nod to the strong form of the precautionary principle, that in some cases it may be impossible to have complete certainty about something.

[134] *See id.* at 190 (observing that "SCNT is a relatively inefficient process"). If this seems like an understatement, recall that the primary purpose of the Risk Assessment was to determine whether the product, i.e., clones, were safe for human consumption. Had the FDA concluded that the cloned food was unsafe to eat, then the agency would have investigated whether the SCNT process tainted the food.

[135] Carlarne, *supra* note 10, at 315. A product's worth, this philosophy holds, is contingent on the process. *See e.g.*, *Directive*, *supra* note 11, art. 13(2)(f), at 9 (Notification Procedure). The emphasis on accurately labeling food products speaks to an interest in knowing where the food came from, i.e., the process by which something was made and what is in it.

[136] Murphy, *supra* note 6, at 137. Such a "right to know" presumes a belief that certain processes make foods

"repugnant." *Id.* That is, consumers have a right to know whether a given food contains clones, since those consumers may believe that the process by which the clones are created is repugnant or unnatural, and would therefore not want to purchase food made that way, even if the end product is identical to non-cloned food products.

[137] Commission Regulation 1829/2003, *supra* note 11, art. 4(1)(b), at 7.

[138] *See e.g.*, Gillis, *supra* note 48 (reporting that 35% of respondents to a poll declared they would "never buy" food made from cloned animals). Because there is a large segment of the population that will "never buy" cloned food products knowingly, they would only purchase such products if tricked or misled into purchasing them. *See also* Commission Regulation 1829/2003, *supra* note 11, art. 4(1)(b), at 7 ("Food [containing or composed of GMOs] must not mislead the consumer.").

[139] Gillis, *supra* note 48.

[140] *See* J. Suk et al., *supra* note 53, at 49.

[141] *See EGE*, *supra* note 8, at 40 (concluding that animals welfare standards require five freedoms: "from hunger, thirst and malnutrition; from fear and distress; from physical and thermal discomfort; from pain, injury and disease; and to express normal patterns of behavior").

[142] *See e.g.*, *PRIME TIME*, *supra* note 9, at 9 (describing health issues associated with Large Offspring Syndrome in clones). *But see Risk Assessment*, *supra* note 12, at 332 ("Clones exhibiting LOS may require additional supportive care at birth, but can recover and mature into normal, healthy animals. Most clones that survive the perinatal period are normal and healthy as determined by physiological measurements, behavior, and veterinary examinations. Progeny of animal clones also have been reported as normal and healthy.").

[143] J. Suk et al., *supra* note 53, at 49.

[144] Murphy, *supra* note 6, at 132. Dolly, for example, gave birth to four healthy lambs on two separate occasions. *Dolly the Sheep*, *supra* note 51.

[145] Murphy, *supra* note 6, at 132.

[146] J. Suk et al., *supra* note 53, at 49.

[147] *Id.* (offering as an example chromatin transfer, which "remodel[es] the somatic nuclei of donor genetic material before nuclear transfer."). However, scientist Rudolph Jaenisch contends, "There has been no progress – none – in the last six years in making cloning more safe." Gregory M. Lamb, *How Cloning Stacks Up*, CHRISTIAN SCIENCE MONITOR, at 11, Jul. 13, 2006.

[148] *See EGE*, *supra* note 8, at 33.

[149] *See id.* at 40 (concluding that animals welfare standards require five freedoms: "from hunger, thirst and malnutrition; from fear and distress; from physical and thermal discomfort; from pain, injury and disease; and to express normal patterns of behavior").

[150] *See Id.* That is, utilitarians might permit animal suffering in the short term on the theory that the positive benefits of cloning outweigh the animal suffering. Concordant with this view, animal suffering caused by the SCNT process is a permissible evil with the understanding that subsequent generations of animals would not also suffer in this way.

[151] *See* JOHN STUART MILL, UTILITARIANISM 24 (Mary Warnock ed., Blackwell Publishing 2003) (1871) ("By the principle of utility is meant that principle which approves or disapproves of every action whatsoever, according to the tendency which it appears to have to augment or diminish the happiness of the party whose interest is in question: or, what is the same thing in other words, to promote or to oppose that happiness.").

[152] *EGE*, *supra* note 8, at 40 (concluding that animals welfare standards require five freedoms: "from hunger, thirst and malnutrition; from fear and distress; from

physical and thermal discomfort; from pain, injury and disease; and to express normal patterns of behavior").

[153] *See id.* at 32.

[154] IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS 10 *passim* (Mary J. Gregor ed., Cambridge University Press 1999) (1785).

[155] *Id.* at 38 ("Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end.").

[156] *Id.* There is a valid argument that animals, lacking many of the higher cognitive abilities of humans, do not have an inherent integrity that can be so easily violated. However, for the purposes of this Comment this line of reasoning will be disregarded.

[157] *See* Center for Food Safety, Food Safety Fact Sheet, *Cloned Food: Coming to a Supermarket Near You?* (Jan. 2007) (observing that religious leaders oppose cloning because it "shifts authorship of life from God to scientists and lab-technicians"). Indeed, deontological arguments are closely tied to religious ones, at least insofar as humans' integrity is concerned. Religious leaders take on a more utilitarian tone when it comes to animals, which are generally seen as put on Earth for human use and enjoyment, rather than as co-equal residents. *See EGE*, *supra* note 8, at 35. Examples in popular culture of dystopian futures where cloning runs amok include *Gattaca* and *The Island*. The former speculates that cloning "perfect" people will lead to the disenfranchisement of those born through natural reproduction. The latter imagines a world where people pay to clone themselves in order to have a supply of transplant-ready organs and body parts.

[158] *Directive*, *supra* note 11, art. 28(2), at 14.

[159] *See supra* pp. 24-27 (discussing how the Directive does not cover clones).

[160] *See Directive*, *supra* note 11, art. 28(2), at 14. Because the Scientific Communities are authorized to give

advice "on any matter under this Directive," they could give advice regarding whether clones in fact fall "under this Directive," or whether a new Directive is necessary.

[161] Press Release, Inst. for Agric. and Trade Policy, WTO Ruling on Genetically Engineered Crops Would Override International, National and Local Protections: Preliminary Ruling Favors U.S. Biotech Companies Over Precautionary Regulation, at 2 (Feb. 7, 2006), *available at* http://www.iatp.org/iatp/library/admin/uploadedfiles/WTO_Ruling_on_Genetically_Engineered_Crops_Wou.pdf ("There is already a broad international consensus on how to handle GE crops at the international level established at the Cartagena Protocol. This consensus acknowledges that each country has the right to regulate GE crops based on precautionary principles, to require labeling of GE crops, and to protect farmers and others from unfair liability arising from the release of GE crops into the environment and food distribution system. Now, the WTO's unelected legal tribunal, at the request of the U.S. government, has chosen to pre-empt a strong democratic international consensus.") (last visited Jan. 28, 2009).

[162] *See supra* p. 15 (discussing what the TWO decision did not cover).

[163] Andrew Pollack, *World Trade Agency Rules for U.S. in Biotech Dispute*, N.Y. TIMES, Feb. 8, 2006, *available at* http://www.nytimes.com/2006/02/08/business/worldbusiness/08trade.html.

[164] *See* Strauss, *supra* note 22, at 805 (discussing the WTO decision's scope).

[165] Andrew Pollack, *World Trade Agency Rules for U.S. in Biotech Dispute*, N.Y. TIMES, Feb. 8, 2006, http://www.nytimes.com/2006/02/08/business/worldbusiness/08trade.html. This, of course, was interpreted as United States bullying. *See* Strauss, *supra* note 22, at 813 ("Clearly this ruling could be used to force sales of GM products to developing countries which have less political clout to stand up to pressure from the U.S. government and enact the stringent labeling and safety requirements characteristic of the European path of resistance."). Yet, fears of pressures enacted by the United States have little

bearing on whether the EU can cite legitimate scientific reasons for banning a particular GMO; the two are not mutually exclusive.

[166] *Directive*, *supra* note 11, art. 22, at 13. Before rejecting any GMOs, there must be some legitimate scientific basis for doing so, the procedure for which is spelled out in Article 6 of the Directive. *See id.*, art. 6, at 6 (requiring producers, as part of the authorization process, to notify states of various health and environmental risks associated with the GMOs).

[167] Bradley S. Klapper, *EU Broke Trade Rules by Blocking Genetically Modified Food Imports, WTO Rules*, Associated Press, May 11, 2006, *available at* http://www.tradeobservatory.org/headlines.cfm?refID=80804.

[168] Commission Regulation 1829/2003, *supra* note 11; Commission Regulation 1830/2003, *supra* note 11, at 24.

[169] Strauss, *supra* note 22, at 813.

[170] *U.S. Looking at a Special DSB Session for First Biotech Panel Request*, INSIDE U.S. TRADE, Aug. 1, 2003.

[171] *See generally Directive*, *supra* note 11. If the EU were cowed by the WTO decision, the Directive would not still be in force.

[172] *See* Strauss, *supra* note 22, at 804-5 (discussing how the WTO decision did not completely strike down the EU's regulations).

[173] *See generally Directive*, *supra* note 11. If the EU were cowed by the WTO decision, the Directive would not still be in force.

[174] *See Panel Report*, *supra* note 21, P 7.1530, at 672-73 (holding that a precautionary approach when the science was evolving did not justify the lengthy delay in approving applications).

[175] *See e.g.*, *Environmental Risk Management*, *supra* note 23, at 12 (noting that under the weak form, the party advocating precaution has the burden of proof).

[176] *See* Strauss, *supra* note 22, at 795 (citing *Panel Report*, *supra* note 21, P 8.9-10, at 1069).

[177] *See id.* at 803 (observing that "consistent with this decision members might still block GMO imports by justifying them with adequate risk assessments, by granting time-limited or conditional approvals pending further scientific assessment, or by delaying decisions in the event of new scientific evidence that conflicted with existing evidence.").

[178] *Id.* at 805.

[179] *Id.* at 795 (citing *Panel Report*, *supra* note 21, P 8.9-10, at 1069).

[180] *Cf. Directive*, *supra* note 11, art. 13, at 9 (outlining the notification procedures, including a safety assessment, before placing GMOs on the market).

[181] *Cf. id.* That is, clones and their progeny ideally should not be different from their parent organisms, so if the parent organisms are safe then so too will be the clones and their progeny. Conversely, GMOs are wholly new creatures and so their safeness cannot be compared with another organism's.

[182] *See* Alex Kirby, *U.K. Doctors Alter Tack to Back GMs*, B.B.C. NEWS, Mar. 9, 2004, *available at* http://news.bbc.co.uk/2/hi/science/nature/3545717.stm (offering the British Medical Association's stance that "huge public concern over the impact of GM foods" necessitates further research "to allay remaining concern about the potential risks to human health and the environment").

[183] Murphy, *supra* note 6, at 131.

[184] *See id.* (noting that a clone is "essentially a younger identical twin"). That is, except for the age difference, there is no way to differentiate a clone from its parent. However, after the organisms are made into food, the age difference becomes moot; at that point there is little if any way to differentiate the clone from its parent.

[185] *See id.* Parent and clone would be indistinguishable, at least, after being turned into food.

[186] *See id.* Because clones are later-born twins of parent organisms, *see* Murphy, *supra* note 6, at 131, it would be possible to tell the difference between a parent and a clone while they are alive, based on their age differences. Once the organisms are made into food, however, any chance of differentiating between a parent and a clone based on age difference is lost.

[187] After all, they will argue, a state that is so intent upon banning cloned food products will also have to ban "normal" food products, for fear that they are in fact clones. This is self-destructive. Therefore, they might argue, states should not bother to regulate cloned food products, because such regulations are pointless and self-destructive.

[188] *Cf. e.g.*, *PRIME TIME*, *supra* note 9, at 7 (describing how imperfections in the cloning process may result in defects such as Large Offspring Syndrome).

[189] *See e.g.*, *EGE*, *supra* note 8, at 32-37 (detailing various ethical objections to cloning).

[190] *See Environmental Risk Management*, *supra* note 23, at 13 (explaining that the strong form of the precautionary principle places the burden of proving product safety on the person trying to introduce the product into the market).

[191] *See e.g.*, *Risk Assessment*, *supra* note 12, at 9 (describing risks to animals involved in cloning). Risks to cloned food products appear to be back by less scientific evidence, but are should not be discounted. *See* Oosthoek, *supra* note 46, at 40 (lamenting the paucity of peer-reviewed studies concerning clones and food safety).

[192] *See Panel Report*, *supra* note 21 (finding that none of the safeguard measures at issue were based on a risk assessment).

[193] Commission Regulation 1829/2003, *supra* note 11 (enacted Sept. 22, 2003); Commission Regulation 1830/2003, *supra* note 11, 24 (enacted Sept. 22, 2003).

[194] *See Panel Report*, *supra* note 21, PP 8.9 & 8.10, at 1069 (concluding that temporary bans were improper in the absence of sufficient scientific evidence).

[195] *Directive*, *supra* note 11, art. 2(2), at 4.

[196] *Id.*, Annex I A, at 17. Additionally, the Directive provides that the methods described in the Annex are not comprehensive; there may be methods not enumerated by which an organism may be considered "genetically modified." *See id.*, art. 2(2)(a), at 5 ("[G]enetic modification occurs *at least* through the use of techniques listed in Annex I A, part 1.") (emphasis added). This leaves the door slightly ajar to make the argument that cloning is a covered technique.

[197] *See id.*, art. 1, at 4 (focusing on only GMOs).

[198] *Id.*, Annex I A, at 17.

[199] *See* THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2006), *available at* http://dictionary.reference.com/browse/prepare (second definition).

[200] NEW OXFORD AMERICAN DICTIONARY (2d ed. 2005).

[201] *See Directive*, *supra* note 11, Annex I A, at 17; NEW OXFORD AMERICAN DICTIONARY, *supra* note 200.

[202] *Directive*, *supra* note 11, Annex I A, at 17. *Accord* Carlarne, *supra* note 10, at 322 (describing the cloning process).

[203] *Compare Directive*, *supra* note 11, Annex I A, at 17 (alluding to SCNT as a "[t]echnique[] of genetic modification") *with* Carlarne, *supra* note 10, at 322 (describing the cloning process using SCNT).

[204] *Directive*, *supra* note 11, art. 2(2), at 4.

[205] NEW OXFORD AMERICAN DICTIONARY, *supra* note 200.

[206] *Id.* *Accord* Carlarne, *supra* note 10, at 322 (describing the cloning process using SCNT).

[207] *See NIH*, *supra* note 1 ("[N]ewly replicated cells are clones, or identical copies, of the original cell.").

[208] *Id.*

[209] *See id.* (noting that SCNT can be used for both cloning and transgenesis).

[210] *Compare Directive*, *supra* note 11, Annex I A, at 17 (alluding to SCNT as a "[t]echnique[] of genetic modification") *with NIH*, *supra* note 1 (noting that SCNT can be used for both cloning and transgenesis).

[211] *See e.g.*, *Directive*, *supra* note 11, Annex I A, at 17 (defining which techniques of genetic modification the Directive covers). *But see NIH*, *supra* note 1 (explaining that SCNT can be used for both cloning and transgenesis). Simply because something lists SCNT does not necessarily mean it is meant to cover both cloning and transgenesis.

[212] *NIH*, *supra* note 1.

[213] *See Directive*, *supra* note 11, Annex I A, at 17.

[214] *Cf. Id.*, Annex I A, at 17 (cloning not included).

[215] *See Id.*

[216] *See e.g.*, *Risk Assessment*, *supra* note 12, at 37 (observing that SCNT, with a success rate of less than 10%, costs approximately $20,000 to clone a live calf).

[217] *Cf. EGE*, *supra* note 8, at 22 ("Regulation (EC) No 258/97 may cover animal food products (e.g. meat, milk) produced from a clone, but not food products from offspring of clones, *since offspring are reproduced in a 'conventional' way*.") (emphasis added). That is, absent some new regulation specifically covering clones' progeny, currently food products from clones' progeny would not be required to be labeled as such. This is for a similar

reason as why the FDA in the United States may be unable to mandate such labeling; it has insufficient authority, because clones' progeny are born through conventional reproduction and are therefore not "novel." Any new EU regulations would assuredly address this.

[218] *See e.g.*, *CLFA*, *supra* note 105, § 2(a) (proposing to amend the Federal Food, Drug, and Cosmetic Act to require labeling, "THIS PRODUCT IS FROM A CLONED ANIMAL *OR ITS PROGENY*" (emphasis added)).

[219] *See Directive*, *supra* note 11, at 1 (covering, as the title suggests, only GMOs).

[220] Commission Regulation 1830/2003, *supra* note 11, arts. 4-9, at 24-27.

[221] *See supra* pp. 27-29.

[222] James Kanter, *Europe's Ethics Panel Says Cloning Harms Animals*, N.Y. TIMES, Jan. 18, 2008, *available at* http://www.nytimes.com/2008/01/18/business/worldbusiness/18clone.html.

[223] Press Release, Eur. Food Safety Auth., EFSA Adopts Final Scientific Opinion on Animal Cloning (July 24, 2008), http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902019762.htm.

[224] *See* WTO, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, Summary of the Dispute to Date, *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (establishing the start of the dispute to be May 13, 2003, and the Panel Report, *supra* note 21, circulated on Sept. 29, 2006).

[225] Kanter, *supra* note 222 ("We don't believe that someone would make a clone just to slaughter it and make it into steaks.").

[226] *See e.g.*, *Risk Assessment*, *supra* note 12, at 37 (observing that SCNT, with a success rate of less than 10%, costs approximately $20,000 to clone a live calf).

[227] *See generally CLFA*, *supra* note 105 (imposing labeling requirements on food containing clones or their progeny).

[228] *See Risk Assessment*, *supra* note 12, at 332 (finding no difference between clones, their progeny, and parent organisms in terms of risk). The Risk Assessment, in declining the impose labeling schemes on cloned food products, clears the way for cloned food products to enter the general food supply.

[229] *See id.*

[230] *See Why "Natural" Labels Don't Necessarily Mean "Healthy,"* 26 TUFTS U. HEALTH & NUTR. LETTER 4(2), (2008) [hereinafter *"Natural" Labels*].

[231] *Id.* (pointing out that "there is currently no standard definition for the term 'natural' except for meat and poultry products, and there is no organization independently certifying this claim").

[232] *See id.* With so little regulation and oversight, it is natural to assume that companies will try to jump onto the bandwagon.

[233] *Id.*

[234] *Id.*

[235] *See* Dept. of Agric., National Organic Program: Applicability Preamble, Examples of Records, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3003491&acct=noprulemaking [hereinafter *Examples of Records*].

[236] Dept. of Agric., National Organic Program, Organic Labeling and Marketing Information, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004446&acct=nopgeninfo (last visited Feb. 11, 2009) ("Agricultural products that are sold, labeled, or represented as organic must be produced and processed in accordance with the NOP standards.").

[237] *Examples of Records*, *supra* note 235.

[238] Murphy, *supra* note 6, at 131.

[239] *See Risk Assessment*, *supra* note 12, at 20 (describing the SCNT process).

[240] *See* Carlarne, *supra* note 10, at 322 ("In somatic cell nuclear transfer: the nucleus (which contains DNA) of an unfertilized egg is removed, and *replaced* with the nucleus from an adult (somatic) cell from a donor animal.").

[241] *See* discussion regarding the scope of the Directive, *supra* pp. 24-27.

[242] Such purity is, ironically, found in the colloquial definition of "natural" as "existing in or caused by nature; not made or cause by humankind." NEW OXFORD AMERICAN DICTIONARY, *supra* note 200. Similarly, Black's defines natural as being "In accord with the regular course of things in the universe and without accidental or purposeful interference." BLACK'S LAW DICTIONARY (8th ed. 2004). Under these definitions, clones would not be "natural" because they were "cause[d] by humankind" and created with "purposeful interference," respectively. Clones likewise meet the FDA's informal conception of natural above, since clones that are unaffected by transgenesis do not "contain synthetic or artificial ingredients that would not normally be expected to be in the food." *See "Natural" Labels*, *supra* note 230.

[243] Gillis, *supra* note 48 ("Two-thirds of American consumers are 'uncomfortable' with animal cloning and 43 percent believe food from clones would be unsafe to eat. . . . [In another poll,] 35 percent, the largest group, said they would 'never buy' such food."). This discomfort also, of course, extends to European citizens – thus, the dispute at issue here. The difference between Americans and Europeans in this regard is that the EU seems to be more democratically in tune with its citizenry; the FDA is by and large a political department that is governed by the popular party controlling the Executive branch.

[244] *See id.* ("If [cloned food] does get out there with no serious safety problems, unlabeled, people will eat it. . . . As long as they don't think they're eating it, they'll be fine.").

[245] *Compare* *PRIME TIME*, *supra* note 9, at 9 (describing health issues associated with Large Offspring Syndrome in clones) *with Risk Assessment*, *supra* note 12, at 332 (noting that some clones with LOS can nevertheless develop into healthy adults, and that their progeny are normal and healthy).

[246] Murphy, *supra* note 6, at 140. Ironically, the CFLA debate uses the opposite conflation, comparing clones with GMOs in a roundabout way, by focusing on an "alarmist buzzword" like cloning and minimizing the relatively benign term genetic engineering. *Id.* But the scaremongering tactic is still the same.

[247] *Compare* Cahill, *supra* note 2, at 3 (describing Alba, the glow-in-the-dark GMO rabbit) *with* Murphy, *supra* note 6, at 131 (observing that a clone is "essentially a younger identical twin" of the parent organism).

[248] Murphy, *supra* note 6, at 131.

[249] *See e.g.*, Cahill, *supra* note 2, at 3 (describing Alba, the glow-in-the-dark GMO rabbit). Alba could never have been born without the aid of transgenesis; scientists inserted the green fluorescent protein of a jellyfish into Alba during her embryonic development. *Id.*

[250] Gillis, *supra* note 48.

[251] *See "Natural" Labels*, *supra* note 230 ("[A] New Jersey judge . . . conclud[ed] that it's up to the FDA, not the courts, to define 'natural.'").

[252] *See* Gillis, *supra* note 48 (reporting that 35% of respondents to a poll would "never buy" cloned food products).

[253] *Cf. Examples of Records*, *supra* note 235 (requiring that livestock, in order to obtain "organic" certification, be raised without antibiotics or synthetic hormones, that the feed is vegetarian, pesticide- and herbicide-free, and that the livestock/meat cannot come from genetically modified sources). The Directive, like the Department of Agriculture organic certification guidelines, covers only "genetically modified" sources and organisms. *See*

Directive, *supra* note 11, art. 2, at 4. This language was not intended to reach clones. *See supra* pp. 24-27. As such, language explicitly mentioning clones is necessary to cover them. *Id.*

[254] *See generally Risk Assessment*, *supra* note 12 (finding that clones are pose no additional risk, and therefore require no special labeling); *Directive*, *supra* note 11 (establishing notification and application requirements only for GMO products). Because the Directive does not cover clones, there is no current regulation in place applying to clones. *See supra* pp. 24-27.

[255] *See generally Panel Report*, *supra* note 21 (finding that states must have some scientific basis for excluding GMO imports).

[256] *See e.g.*, *"Natural" Labels*, *supra* note 230 (observing the lack of definite FDA guidelines regarding "natural" labels); Gillis, *supra* note 48 (citing polls conducted showing widespread unease about cloned food products).

[257] *See id.* This unease will create a market in foods that the public believes do not contain GMOs or clones—namely, "natural" and "organic" foods. Without any stringent regulations of "natural" labels, companies will have no barrier against labeling cloned food products "natural," thus misleading the public.