



Synthetic Meat: An Ethical, Environmental, and Regulatory Analysis

The Harvard community has made this article openly available. [Please share](#) how this access benefits you. Your story matters

Citation	Matthew Lincicum, Synthetic Meat: An Ethical, Environmental, and Regulatory Analysis (March 2010).
Citable link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8789567
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

**SYNTHETIC MEAT:
AN ETHICAL, ENVIRONMENTAL,
AND REGULATORY ANALYSIS**

Matt Lincicum

Class of 2010

March 29, 2010

Submitted in Satisfaction of the Course Requirement

Abstract

Once relegated to the domain of science fiction, recent technological developments have rendered the production of synthetic meat—meat grown in a laboratory rather than as an animal—a real possibility. Currently available methods show promise for synthetically manufacturing processed meats, while growing fully formed, complex muscle structures—such as steaks—continues to face technical difficulties. With this strange new possibility rapidly approaching, this Paper considers two problems that the new meat may solve, and one problem that it creates. First, synthetic meat has the potential to alleviate many if not all of the moral qualms associated with eating animal meat. Second, synthetic meat could present a far more environmentally sustainable approach to supplying food than the conventional farm-based system. This new meat, however, faces an as-yet unanswered question: how will it fare in the regulatory process? The USDA and FDA have naturally not yet had occasion to address this nascent issue. This Paper seeks to present the likely response of these regulatory bodies to the introduction of synthetic meat into the marketplace. Ultimately, the budding prospect of synthetic meat carries with it the potential for vast improvements over traditional meat production, while also facing the uncertain response from the US regulatory bodies charged with ensuring food safety. Although the regulatory hurdles are very real, this Paper concludes that the significant benefits offered justify the continued pursuit of this exciting new technology.

TABLE OF CONTENTS

I. INTRODUCTION	1
II. THE TECHNOLOGY BEHIND SYNTHETIC MEAT.....	2
A. <i>Muscle Tissue and Cell Culture</i>	2
B. <i>Approaches to Producing Synthetic Meat</i>	6
1. <u>Scaffolding</u>	6
2. <u>Tissue Culture</u>	7
3. <u>Organ Printing</u>	8
III. ETHICAL ANALYSIS.....	8
A. <i>Current Meat Production Practices</i>	9
1. <u>Cows</u>	10
2. <u>Chickens</u>	11
3. <u>Pigs</u>	13
B. <i>Ethical Benefits of Synthetic Meat</i>	14
C. <i>Ethical Objections to Synthetic Meat</i>	16
1. <u>Danger to Human Health</u>	17
2. <u>Perversion of Nature</u>	17
3. <u>Harm to Food Animals</u>	20
IV. ENVIRONMENTAL ANALYSIS.....	21
A. <i>Greenhouse Gases</i>	22
B. <i>Resource Degradation, Depletion, and Pollution</i>	24
1. <u>Rangeland Degradation</u>	25
2. <u>Water Depletion and Pollution</u>	26
V. REGULATORY ANALYSIS.....	27
A. <i>Is Synthetic Meat “Meat”?</i>	28
B. <i>Is Synthetic Meat a Food Additive?</i>	30
C. <i>Labeling Requirements</i>	34
VI. CONCLUSION.....	36

I. INTRODUCTION

Since at least the appearance of the “food replicator” on *Star Trek: The Next Generation*, the tantalizing prospect of machine-fabricated foods has captured the public’s attention. While the simple push-button technology of science fiction remains a distant hope, one aspect of this technology is beginning to take shape now. Tissue engineering techniques, originally developed with an eye towards medical treatments, are now being applied to produce laboratory-grown meat. This cultured meat—which this Paper will refer to as “synthetic meat” throughout—is biologically identical to meat, but it is grown apart from any living animal. Although the technology is still in process, the feasible production of synthetic meat is approaching by the day. This approach holds promise for great improvements over current meat production, while also facing significant hurdles, both technical and regulatory.

This Paper seeks to address the issues raised by this budding technology using a multi-faceted analysis. In Part II, the technology behind synthetic meat production will be briefly explained. Currently, scientists are able to produce synthetic meat in a form similar to traditional processed meats, such as ground beef. Highly structured meats, like steak, present far greater technical challenges. Part III of this Paper discusses the significant ethical issues associated with traditional meat production, and analyzes whether and how synthetic meat ameliorates these concerns. Part IV compares the environmental impact of traditional meat production with the estimated impact of manufacturing synthetic meat, finding that significant environmental harms may be avoided to the extent that synthetic meat replaces its traditional counterparts. In Part V, the significant regulatory hurdles facing synthetic meat will be addressed. Although

neither FDA nor USDA have had occasion to address the incipient issue of synthetic meat, this Paper provide a framework for how the agencies might be expected to approach the problem. Finally, Part VI concludes, suggesting that the significant ethical and environmental advancements of synthetic meat are enough to outweigh any concerns regarding any technical or regulatory uncertainty it currently faces.

II. THE TECHNOLOGY BEHIND SYNTHETIC MEAT

The majority of edible animal meat is comprised of skeletal muscle tissue. Although the idea of engineering edible muscle tissue is not exactly new—Winston Churchill wrote about it in 1923¹—it is only in recent years that the dream of synthetic meat has begun to come within reach. This Part will explain the basics of muscle tissue and cell culture, followed by a description of three approaches to producing synthetic meat.

A. Muscle Tissue and Cell Culture

Skeletal muscles are comprised of several different elements. The actual muscle cells (the myofibers) are very long cells, each with multiple nuclei, and are unable to divide and multiply.² These myofibers grouped together form columns, which are embedded in and surrounded by fibrous connective tissue.³ In postnatal muscle tissue,

¹ Winston Churchill, *Fifty Years Hence*, in THOUGHTS AND ADVENTURES. London: Thornton Butterworth (1932), pp. 24-27 (“Fifty years hence we shall escape the absurdity of growing a whole chicken in order to eat the breast or wing by growing these parts separately under a suitable medium.”).

² See S. I. FOX, HUMAN PHYSIOLOGY. Wim. C. Brown Publishers (1996).

³ See *id.*

fully formed muscle fibers are accompanied by so-called “satellite cells” which lie between the muscle fibers, the sarcolemma, and the basal lamina.⁴ These satellite cells are the principal source for new nuclei in muscle tissue, although other sources exist.⁵ These cells facilitate growth and regeneration either by donating their DNA to existing muscle fibers or by fusing to form new fibers. These cells generally exist in stasis, and only proliferate upon stimulation by hypertrophy, increased exercise, atrophy, or other forms of injury.⁶

Muscle cells may be cultured *in vitro*, but they will not proliferate. Satellite cells, however, maintain the capacity for *in vitro* proliferation. Satellite cells are generally obtained from neonatal donors since they exist in far greater abundance in young muscles than in old.⁷ The satellite cells are isolated from the muscle, typically by mincing it entirely, digesting it enzymatically, and using one of various techniques for separating the satellite cells from the other tissue.⁸ Once separated out and placed into culture medium, these satellite cells proliferate and give rise to myoblasts. After a sufficient quantity of cells are produced, growth factors are removed from the medium, resulting in the

⁴ T. Hawke & D. Garry, *Myogenic Satellite Cells: Physiology to Molecular Biology*, 91(2) J. APPL. PHYSIOL. 434-51 (2001).

⁵ M. Grounds *et al.*, *The Role of Stem Cells in Skeletal and Cardiac Muscle Repair*, 50(5) J. HISTOCHEM CYTOCHEM 589-610 (2002).

⁶ T. Burton *et al.*, *Signalling, Cell Cycle and Pluripotency in Embryonic Stem Cells*, 12(9) TRENDS IN CELL BIOLOGY 432-8 (2000).

⁷ T. Hawke & D. Garry, *Myogenic Satellite Cells: Physiology to Molecular Biology*, 91(2) J. APPL. PHYSIOL. 434-51 (2001).

⁸ T. Burton *et al.*, *Signaling, Cell Cycle and Pluripotency in Embryonic Stem Cells*, 12(9) TRENDS IN CELL BIOLOGY 432-8 (2000).

myoblasts fusing to form myofibers. After fusion, the myofibers will start to contract randomly *in vitro*, taking on the functional characteristics of fully formed muscle tissue.⁹

Cells in culture can reproduce only up to a limited number of generations, known as the Hayflick limit.¹⁰ The shortening of telomeres—genetic sequences at the end of chromosomes that protect against rearrangement or fusion—with each cell division is responsible for this effect.¹¹ Telomere length correlates with the life span of many cell types both *in vitro* and *in vivo*.¹² Culturing skeletal muscle cells therefore requires fresh supply of satellite cells under current conditions, unless there arises a safe, feasible way to induce cellular immortality.¹³

Two technological problems arise for *in vitro* cultured meat. First, the muscle tissue may atrophy, resulting in decreased muscle mass due to lack of neuromuscular activity, denervation (the removal of the nerve supply to an organ), or disease.¹⁴ The problem of atrophy has been ameliorated in rats by exercise induced by electrical stimulation.¹⁵ It is possible that synthetic meat could be treated with electrical stimulation to force contraction of the laboratory-grown myotubes. It remains unclear whether such treatment will be necessary for synthetic meat grown according to the cell

⁹ WOLPERT *et al.*, PRINCIPLES OF DEVELOPMENT, Current Biology Oxford, 1st edition (1998).

¹⁰ *See id.*

¹¹ K. Prowse & C. Greider, *Developmental and Tissue-Specific Regulation of Mouse Telomerase and Telomere Length*, 92(11) PROC. NAT'L ACAD. SCI. USA 4818-22 (1995).

¹² *Id.*

¹³ Current methods of achieving cellular immortality rely on cancer cells. *See* F. Feng *et al.*, *The RNA Component of Human Telomerase*, 269 SCIENCE 1236 (1995).

¹⁴ S. Charge *et al.*, *Aging-Related Satellite Cell Differentiation Defect Occurs Prematurely After Sk-Induced Muscle Hypertrophy*, 283(4) AM. J. PHYSIOL. CELL. PHYSIOL. C1228-41 (2002).

¹⁵ R. Dennis *et al.*, *An Implantable Device for Stimulation of Denervated Muscles in Rats*, 25(3) MED. ENG. PHYS. 239-53 (2003).

culture technique described above. It is likely, however, that electrically induced exercise will be essential to recreate the texture and form of highly structured meats.

Another problem facing synthetic meat relates to commercial marketability. If synthetic meat is to perform well in the marketplace, it must taste and feel like traditional meat. The eating quality of meat can be characterized by the tenderness, juiciness, and flavor of the meat.¹⁶ Tenderness is often thought to be the most important of the three.¹⁷ Tenderness of skeletal muscle is determined by the protein structure of the myofibrils in the meat, along with the fat content. In dealing with conventional meat, slaughterhouses can apply chemical treatment or mechanical stress in order to offset the toughening effects of shock-freezing the carcasses.¹⁸ The flavor of traditional meat is affected by the age of the meat, the structure of carbohydrates, and by stress prior to slaughtering.¹⁹ A related consideration is the dietary value of meat, generally characterized by the high content of saturated fatty acids and low poly-unsaturated fat content. These factors must all be taken into account in developing commercially marketable synthetic meat. By adjusting the composition of the culture medium, the flavor and fatty acid composition of the synthetic meat can be influenced.²⁰ Similarly, additional factors such as vitamins can be added to the culture medium to improve the dietary value of the meat. Furthermore,

¹⁶ See J. Wood *et al.*, *Manipulating Meat Quality and Composition*, 58(2) PROC. NUTR. SOC. 363-70 (1999).

¹⁷ See *id.*

¹⁸ M. Solomon *et al.*, *The Hydrodyne: A New Process to Improve Beef Tenderness*, 75(6) J. ANIM. SCI. 1534-7 (1997).

¹⁹ J. Wood *et al.*, *Manipulating Meat Quality and Composition*, 58(2) PROC. NUTR. SOC. 363-70 (1999).

²⁰ W.F. van Eelen *et al.*, WO9931222: *Industrial Scale Production of Meat From In Vitro Cell Cultures*, Patent Description (1999).

some of the post-processing techniques used on conventional meat may be applicable to synthetic meat as well.

B. Approaches to Producing Synthetic Meat

Several different techniques for producing synthetic meat have been proposed. These techniques range from the proven to the fanciful. Three different approaches will be discussed below, in descending order from most to least technologically feasible at this point in time.

1. Scaffolding

The scaffold-based approach to producing synthetic meat adopts techniques from tissue engineering. Tissue engineering typically involves seeding a biodegradable scaffold—usually made of polyglycolic acid (PGA)—with loose cells. The scaffold is introduced into a bioreactor that provides nutrients and oxygen. As the cells grow onto the scaffold and take its shape, the desired organ is formed.²¹ Two variants of this approach have been developed for growing synthetic meat. The first approach involves growing myoblasts on collagen spheres, allowing the myoblasts to differentiate and proliferate in a bioreactor, and then harvesting the microspheres and processing them to form synthetic ground meat.²² The second approach utilizes a collagen meshwork, submerged in culture medium that is refreshed periodically. Once the myoblasts seeded onto the collagen meshwork have differentiated into myofibers, the collagen-muscle

²¹ Boland *et al.*, *Cell and Organ Printing 2: Fusion of Cell Aggregates in Three-Dimensional Gels*, 272A(2) ANAT. REC. 497-502 (2003).

²² *Id.*

mixture can be harvested and used as meat.²³ Under either of these approaches, muscle protein will be produced and harvested. The final product, however, will not be structured as meat, and is therefore suitable only for processed use such as sausage, hamburger, or chicken nuggets.

2. Tissue Culture

The tissue culture approach looks to grow synthetic meat that is structured as animal-derived skeletal muscle. This technique can involve either proliferating existing muscle tissue, or creating muscle tissue *de novo*—which is far more complicated. A significant benefit to following the former course is that muscle tissue explants already contain all the appropriate tissues in all the right proportions. One group of researchers led by Morris Benjaminson were able to successfully grow a gold fish muscle explant up to 76% greater surface area by experimenting with different types of culture media.²⁴ After a week of growth in culture, the researchers removed their newly formed tissue—which reportedly looked like fish filets—and cooked them to compare presentation. Observers stated that the fish looked and smelled no different from normal fish filets, and would have eaten them (they did not, due to the experimental nature of the process). These initial results provide some hope, but the problem of blood circulation must be solved here, as muscle explants will otherwise become necrotic. The researchers plan to use controlled angiogenesis—growing blood vessels within the explants—as a solution to this problem. Although this approach cannot yet form highly structured meats, it is likely

²³ W.F. van Eelen *et al.*, WO9931222: *Industrial Scale Production of Meat From In Vitro Cell Cultures*, Patent Description (1999).

²⁴ Benjaminson *et al.*, *In Vitro Edible Muscle Protein Production System (MPPS): Stage 1, Fish*, 51(2) ACTA ASTRONAUT 879-89 (2002).

that as our tissue engineering techniques improve, synthetic T-bone steaks will become a reality.

3. Organ Printing

Another potential solution to the problems of vascularization and incorporation of other cell types within meat culture is the so-called “organ printer.”²⁵ This technology, currently being researched for the purpose of producing organs for transplantation, may some day be applied to manufacture highly structured synthetic meat. The concept is fairly straightforward: just as with a standard printer, researchers are able to place cells or balls of cells rather than ink onto substrates acting as printing paper. These substrates are either removable or biodegradable. The printer organizes cells one layer at a time, ultimately constructing a fully formed three-dimensional organ. The shapes can include hollow tubes for vascularization, and pockets of other tissue—such as fat cells—to more closely mimic animal-based meat. This technology provides a powerful platform for engineering all kinds of meat, and theoretically allows for myriad adjustments to be made to influence look, taste, and texture. Although it remains experimental, the enormous potential advantages of organ printing may someday be brought to bear in the field of synthetic meats.

III. ETHICAL ANALYSIS

If, as seems likely, the technological hurdles to producing commercially viable synthetic meat are overcome, what might the ethical implications be? In seeking to

²⁵ V. Mironov *et al.*, *Organ Printing: Computer-Aided Jet-Based 3D Tissue Engineering*, 21(4) TRENDS IN BIOTECHNOLOGY (April 2003).

answer this question, this Part will cover three areas. First, the current meat production practices will be examined with an eye towards ethical concerns over animal suffering. Second, the benefits provided by synthetic meat over traditional meat will be discussed. Finally, ethical objections raised against synthetic meat will be considered. Ultimately, it is submitted that in the final analysis, the ethical benefits to producing synthetic meat far outweigh the ethical concerns it raises.

A. Current Meat Production Practices

Although animal cruelty statutes have long been in place in this country, many of the most important—such as the Animal Welfare Act—specifically exempt livestock from protection.²⁶ This convenient loophole gives meat producers free reign to pursue the most cost-effective way of delivering product with little or no regard for the cruelty inflicted upon the animals. Furthermore, slaughterhouses often disregard those statutes—such as the Humane Slaughtering Act (HSA)²⁷—that do apply to them, emboldened by USDA’s lax enforcement.²⁸ The result is unbelievable cruelty of the sort that would give any grocery-store shopper pause. Based on the inhumane practices that are seemingly prevalent at large factory farms, the aphorism may be true after all: if slaughterhouses had glass walls, everyone would be vegetarian.

²⁶ 7 U.S.C. §2132

²⁷ 7 U.S.C. §§1901-1906

²⁸ See GAIL EISNITZ, *SLAUGHTERHOUSE* at 18 (1997).

1. Cows

In modern factory farms, an entire cow can be processed from whole beast into prepackaged steaks in 25 minutes.²⁹ The cows are brought into the packing plant, and—as required by the HSA—rendered unconscious by an electric shock before the dismemberment and slaughter begins. The process moves so quickly, however, that the cows are not always unconscious. As one slaughterhouse worker—whose job involved cutting the legs off the supposedly unconscious cows—recalled, “They blink, they make noises . . . the head moves, the eyes are wide and looking around.”³⁰ This same worker said that on some days he would cut the legs off dozens and dozens of clearly alive and conscious animals—animals that would survive on the production line as far as the belly-ripping and hide-pulling stations. These animals were in effect killed “piece by piece.”³¹ Veterinarians confirm that this is not an unusual occurrence in slaughterhouses.³² The attitude towards slaughtering these animals is that speed and profit are so important that “[t]he line is never stopped simply because an animal is alive.”³³ USDA agents are reluctant to report violations or stop the slaughtering line for fear of rebuke by slaughterhouse owners.³⁴ Even in the instances where a USDA agent witnesses a violation and halts the production line, sanctions are reportedly rare.³⁵

²⁹ See Joby Warrick, “Modern Meat: A Brutal Harvest, ‘They die Piece by Piece’”, WASHINGTON POST, 10 April 2001.

³⁰ *Id.*

³¹ *Id.*

³² *See id.*

³³ *Id.*

³⁴ See GAIL EISNITZ, SLAUGHTERHOUSE at 18 (1997).

³⁵ Joby Warrick, “Modern Meat: A Brutal Harvest, ‘They die Piece by Piece’”, WASHINGTON POST, 10 April 2001 (Noting that, for instance, no action was taken against a Texas beef company despite 22 citations in 198 for violations including chopping the hooves off live cattle.).

Despite the gruesome process of dismembering conscious animals at blistering speed, slaughterhouses reserve a special kind of cruelty for the production of veal meat. Veal consumers have particular expectations for the meat, and slaughterhouses have apparently concluded that the most efficient way to meet these expectations is with a thorough disregard for the veal calf's welfare. Directly after birth, the young calf is separated from its mother before weaning,³⁶ and fed only powdered milk with no food or water, resulting in anemia.³⁷ The calf is chained into a crate so small that it cannot even turn around, standing for weeks in its own excrement.³⁸ The obvious harms associated with this mode of rearing results in 10% of veal calves dying before slaughter, despite being continually pumped full of antibiotics.³⁹

2. Chickens

Factory-farmed chickens are provided even less legal protection than cows, since the HSA exempts them from its purview.⁴⁰ This exemption gives chicken farmers *carte blanche* to employ whatever means they deem necessary to effect cost-savings, whatever cruelty those means inflict upon the birds. This likely explains in part why as many as 28% of chickens die on the farm, compared with only 4% of cows, and 14% of pigs.⁴¹ Chickens raised for meat—known as “broilers”—are confined to cages so small that they

³⁶ See Amy Mosel, *What About Wilbur? Proposing a Federal Statute to Provide Minimum Humane Living Conditions for Farm Animals Raised for Food Production*, 27 DAYTON L. REV. 133, 147 (2001).

³⁷ See *id.* at 148.

³⁸ See *id.*

³⁹ See *id.*

⁴⁰ See 21 U.S.C. §610.

⁴¹ See The Human Farming Association, *Factory Farming*, available at <http://www.hfa.org/factory/index.html>.

are unable even to flap their wings.⁴² The extremely close quarters drive the birds to aggression, where they begin to peck at one another. Rather than treat the cause of this behavior, chicken farmers have seen fit to instead use a hot iron to burn the beaks off chickens, disabling their ability to peck at one another.⁴³ After electric stunning is used to render the birds unconscious—a process that must be described as “an intensively painful experience”⁴⁴—birds are dipped into scalding water to soften the skin. Each year, a large number of chickens reach the scalding tanks alive, and are either boiled to death or drowned.⁴⁵

Undercover investigations by animal-rights organizations have reported even more severe instances of wanton animal cruelty. In 2007, a Mercy For Animals investigator recorded video of workers punching live animals for fun, ripping the heads off birds who had gotten their feet stuck in transport cages, and letting birds lie flapping on the floor in pain for hours on end.⁴⁶ A similar investigation by People for the Ethical Treatment of Animals (PETA) into a Tyson plant recorded video of chickens that had been mutilated by dysfunctional throat cutting machines, as well as workers ripping the

⁴² *Id.*

⁴³ *Id.*

⁴⁴ F. Boyd, *Human Slaughter of Poultry: The Case Against the Use of Electrical Stunning Devices*, 7(2) JOURNAL OF AGRICULTURE AND ENVIRONMENTAL ETHICS 221 (1994).

⁴⁵ *Cf.* USDA Food Safety and Inspection Service, *Meat and Poultry Inspection Manual*, Part 11. Under Postmortem Inspection, the term *cadaver* is defined as follows: “Poultry dead from causes other than slaughter are ‘cadavers.’ Improper slaughter cuts, inadequate bleeding time, etc., may result in birds entering the scald water with insufficient bleeding or while still breathing (drowning). Cadavers show: light red to deep cherry red skin, enlarged visceral blood vessels, congested heart, liver, and spleen. Cadavers must be condemned and recorded on Form MP 514.

⁴⁶ Video available at <http://mercyforanimals.org/hor/>.

heads off birds that had missed the machines completely.⁴⁷ Reports such as these are numerous, and should be sufficient to raise serious concerns over the inhumane conditions of current chicken farms.⁴⁸

3. Pigs

Pigs, while falling under HSA's legal protections, suffer many of the same problems as chickens. They too are held in closely confined spaces, unable even to turn around. This severe cramping causes the pigs to bite each other's tails, as they act out in aggression.⁴⁹ Again, slaughterhouse managers have decided to treat the symptom, rather than the disease, by cutting pigs' tails off and pulling their teeth out. Like cows, pigs suffer greatly when the HSA is violated in pursuit of cost-savings. The rapid pace of slaughter results in many pigs being dipped into the scalding water vat still alive and conscious.⁵⁰ Secret video from an Iowa plant reveals hogs squealing and writhing in pain as they are lowered into the scalding water.⁵¹ One author described a pig farm as "a plant where squealing hogs were left straddling the restrainer and dangling live by one leg when workers left the stick pit for their half-hour lunch breaks; where stunners were

⁴⁷ Video available at

http://www.petatv.com/tvpopup/video.asp?video=tyson_heflin&Player=qt.

⁴⁸ See, e.g., Vegan Outreach, *If Slaughterhouses Had Glass Walls*, available at <http://www.veganoutreach.org/whyvegan/slaughterhouses.html> (providing summaries and links to numerous reported instances of animal cruelty in slaughterhouses).

⁴⁹ See Betsy Tao, *A Stitch in Time: Addressing the Environmental, Health, and Animal Welfare Effects of China's Expanding Meat Industry*, 15 GEO. INT'L ENVTL. L. REV. 321, 342 (2003).

⁵⁰ See *id.* at 343.

⁵¹ See Joby Warrick, "Modern Meat: A Brutal Harvest, 'They Die Piece by Piece'", WASHINGTON POST, 10 April 2001.

shocking hogs three and four times . . . where thousands of squealing hogs were immersed in the plant's scalding tank alive."⁵²

Sows are kept in tiny crates, where they are unable to move and are continually impregnated.⁵³ They are kept in total darkness except when feeding,⁵⁴ and are killed by captive-bolt guns once they are no longer able to reproduce.⁵⁵ One author reported his observations at a Smithfield Farms gestation area in Northern California, describing abysmal conditions, including "sores, tumors, ulcers, pus pockets, lesions, cysts, bruises, torn ears, swollen legs everywhere."⁵⁶

B. Ethical Benefits of Synthetic Meat

Given the rather gruesome state of current meat production practices, it is easy to see the ethical appeal of synthetic meat. This new technology would permit the production of the food products enjoyed by so many carnivores around the globe without inflicting pain on any animals in the process.⁵⁷ Synthetic muscle contains no nervous system, and of course can feel no pain. Although there are many philosophical

⁵² J. Vorman, "USDA Inspector Claims Cattle, Pigs Often Brutalized," REUTERS, 2 April 1998.

⁵³ See Betsy Tao, *A Stitch in Time: Addressing the Environmental, Health, and Animal Welfare Effects of China's Expanding Meat Industry*, 15 GEO. INT'L ENVTL. L. REV. 321, 343 (2003).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ MATTHEW SCULLY, DOMINION 264 (2002).

⁵⁷ This assumes that donor cells can be obtained relatively harmlessly. Currently, donor cells are typically obtained by killing the animal and mincing whole muscles, but techniques that spare the animal's life have already been developed. See W.F. van Eelen *et al.*, WO9931222: *Industrial Scale Production of Meat From In Vitro Cell Cultures*, Patent Description (1999).

arguments that might be deployed in favor of animal welfare,⁵⁸ there is no need to here dive into the theoretical underpinnings of the animal rights movement. Rather, it is enough for these purposes to erect the analysis atop one simple axiom: animal suffering is bad. Although many would argue that the animal suffering incident to current meat production practices is justified by other values or ends, it is nonetheless consistent to recognize that animal suffering *per se* is an unqualified bad, and therefore any reduction is a corollary good. Only the most callous observer would argue that animal suffering is morally neutral, much less a good thing. For such a character, torturing puppies would be of no moral consequence. Society has found fit to regard such persons as morally depraved, and this Paper would not dispute the designation.

The real question is not whether animal suffering is desirable—it clearly is not. The question is whether we—as individuals or society at large—consider other values important enough to override any concern for animal welfare. Under our current system, the vast majority of Americans consume meat, despite some of the more cringe-inducing practices outlined above.⁵⁹ Some of this may be ascribed to ignorance of the animal conditions, but even without knowledge of the particulars, it is unlikely that most adults are under the illusion that animals destined for the slaughterhouse live pleasant lives.

⁵⁸ See, e.g., PETER SINGER, *ANIMAL LIBERATION: A NEW ETHIC FOR OUR TREATMENT OF ANIMALS*, Harper Perennial Modern Classics, New York (2009) (laying out utilitarian arguments for animal welfare); TOM REGEN, *THE CASE FOR ANIMAL RIGHTS*, University of California Press (2004) (adopting a rights-based approach to advocating for animal welfare).

⁵⁹ Vegetarian Resource Group, *How Many Vegetarians Are There? A 2003 National Harris Interactive Survey Question Sponsored by The Vegetarian Resource Group*, *Vegetarian Journal* May/June (2003), available at http://www.findarticles.com/p/articles/mi_m0FDE/is_3_22/ai_106422316 (finding that only 2.8% of surveyed American adults are vegetarians).

Still others may simply ignore what they know to be the case, taking advantage of sanitized supermarket displays which leave almost no visual trace as to the meat's origins as a living, breathing animal. And finally, there are those who stare the meat industry directly in the face, fully aware, and yet contend that the importance of eating meat for one reason or another outweighs any harm caused by animal suffering. Again, these arguments need not be taken up here; the point is merely raised to illustrate that countervailing concerns may outweigh our moral concern for animal suffering. The next Section therefore addresses some of the new ethical problems raised by the prospect of synthetic meat, and questions whether any of them are serious enough to counterbalance the benefit of eliminating the slaughterhouses.

C. Ethical Objections to Synthetic Meat

There are several objections that one might raise against the production and consumption of synthetic meat. Although any taxonomy of these concerns is sure to reflect arbitrariness at some level, the arguments will be grouped as follows. First, there are concerns that synthetic meat will bring with it harm to human health or the environment. Second, potential consumers may be repulsed by synthetic meat on grounds that it is unnatural, freakish, or some perversion of biology. Third is the argument that, paradoxically, food animals will be worse off under a synthetic meat system, since the life of a food animal is better than nothing. These arguments will be addressed in turn.

1. Danger to Human Health

One line of protest to the development and implementation of synthetic meat sounds in fear of dangers posed to humans or the environment. This objection is both the most and the least powerful of those discussed here. It is the most powerful because if in fact synthetic meat were to pose a serious risk of harm when ingested, either to humans or somehow to the environment at large, then of course the project ought to be abandoned. Not even the most zealous technophile would prefer to eat unhealthy synthetic meat as opposed to traditional meat, or as opposed to abstaining entirely. On the other hand, this objection is quite weak because it objects not to the morality of synthetic meat, but to the practical consequences. It is an objection raised only if the technological challenges are not met. If synthetic meat is dangerous in one way or another, the failure is ultimately technological. If, on the other hand, the technology behind synthetic meat succeeds, then the final product will be as safe and healthy—if not more so—than conventional meat. It is beyond the scope of this Paper to fully address all the possible health concerns, but it seems obvious to say that synthetic meat will not survive in the market if it is not at least as safe and healthy as traditional meat. Therefore, given that this concern is ultimately pragmatic rather than moral, alternative ethical objections to synthetic meat must be examined.

2. Perversion of Nature

In debates regarding the propriety of various new biotechnologies, one often hears the concern that the technology is unnatural, and therefore in some way bad. This argument, while inchoate as stated, is likely the most important objection to synthetic meat. This general aversion to the unnatural can be framed in three alternative forms.

First, one might simply say that the unnaturalness of synthetic meat is itself enough to eliminate it as a viable food source. Second, one might contend that eating synthetic meat further separates humanity from nature, resulting in increased alienation and other presumed harms. Third, the visceral disgust that some people feel towards synthetic meat may itself constitute a justifiable ground on which to reject it. Each of these arguments will be addressed in turn.

First is the claim that unnaturalness is *per se* bad, and synthetic meat is therefore morally suspect. There are several problems with this sort of claim. First, and most obvious, just because something is natural doesn't make it good for you. This is a formulation of the well known "naturalistic fallacy" – the tendency to erroneously equate the natural with the good.⁶⁰ There are numerous poisons that are natural in the sense of not being made by humans, and yet of course no one would suggest consuming them. Furthermore, it is difficult to articulate why the natural state ought to be preferred to all other possible states, and indeed many of our most important life-saving advances in medicine are profoundly unnatural, and yet are rightly applauded.⁶¹ Finally, this objection rests on some conception of "nature" which artificially demarcates the natural world apart from human manipulation. Yet humans are of course every bit as natural as a sunflower, and only recourse to fuzzy metaphysics would permit one to draw a distinction of kind rather than degree between humans and the rest of the animal kingdom.

⁶⁰ See generally, G.E. MOORE, *PRINCIPIA ETHICA*, Cambridge: Cambridge University Press (1903), available in electronic book form at <http://fair-use.org/g-e-moore/principia-ethica/>.

⁶¹ For instance, consider the early reaction to vaccines, which were regarded as widely unnatural and therefore (by some) improper. See, e.g., Tim Fulford & Debbie Lee, *The Jenneration of Disease*, STUDIES IN ROMANTICISM, Spring (2000).

A second form of this argument contends that eating synthetic meat will separate us from nature in some unspecified and invisible way. Again, in response one must query why remaining close to nature is morally valuable. Humans are omnivorous by nature and vegetarianism and veganism are therefore likewise unnatural. The state of nature itself can be rather brutal for animals, as they are forced to compete for survival in the wild. Staying “close to nature” therefore seems to promise enduring animal suffering, with no “natural” recourse for limiting it. As an additional critique, the current slaughterhouse practices themselves are far from “natural,” so it is not altogether clear how one would remain “close to nature”, without perhaps hunting all her own food.⁶² As the natural state is itself no particular friend to animal welfare, it is the very *unnaturalness* of synthetic meat that promises to reduce animal suffering.

The third form of argument discussed here relies on the “wisdom of repugnance”⁶³ to justify rejecting synthetic meat on the grounds that it induces disgust. Here again, it is important to ask whether and why disgust should guide moral judgments. Of course, many instances of natural disgust may be a result of evolved responses to dangerous things, such as corpses and rotting foods. Many instances of disgust, however, are culturally conditioned rather than biologically ingrained. Furthermore, throughout history people have been disgusted at practices that today we find morally unobjectionable, such as interracial marriage. The presence of disgust alone cannot therefore determine the moral status of a practice. More importantly, it is likely that the

⁶² Even this approach, however, is fraught with difficulties. What, after all, is so natural about the highly mismatched contest between a well-equipped hunter and a defenseless prey?

⁶³ This phrase is borrowed from Leon Kass’s argument that human cloning should be prohibited largely based on people’s general reaction of disgust to the technology. See L. Kass, *The Wisdom of Repugnance*, THE NEW REPUBLIC, 2 June, 17-26 (1997).

initial reaction of disgust to synthetic meat will give way to a more nuanced understanding as it becomes more commonplace and better understood. Attitudes towards new and revolutionary technologies do in fact change, as is already beginning to occur with respect to synthetic meat. As animal rights activist Rina Dreych has written, “I have come to the conclusion that it’s not about (the turning of) my stomach that’s important. It’s about the potential to spare the suffering of tens of billions of animals per year and, at the same time, to improve human health, and reduce insult to the environment.”⁶⁴ Finally, not everyone reacts to the prospect of synthetic meat with disgust. If one were to observe, from start to finish, the production process of synthetic meat (a sterilized industrial-laboratory setting) and traditional meat (with packed cages and grisly slaughterhouses), it isn’t obvious that the average observer would be more disgusted by the synthetic meat production.

3. Harm to Food Animals

The third and most counterintuitive objection is that meat-producing animals are actually better off under the current regime than in one in which synthetic meat is widespread. If the most optimistic proponents of synthetic meat turn out to be right, then the future world will be worse for meat-producing animals because they will never have been born.⁶⁵ It is better, the argument goes, to let food animals live and endure some suffering than to never have lived at all. There are at least two problems with this objection. First, it is not clear that *any* life will always be preferable over *non*-life. It

⁶⁴ R. Deych, *How Should Vegetarians See In-Vitro Meat?*, available at <http://www.animalliberationfront.com/Practical/Health/In-Vitro%20Meat.htm>.

⁶⁵ Despite any superficial parallels, nothing in this section should be considered necessarily applicable to the far more complex debate over human abortions.

seems absolutely possible that a life could be so full of suffering and pain as to be not worth living. Such may in fact be the fate of many meat-producing animals in the current system. However, this objection would run into another problem even if it were true that farm animals, on the whole, enjoyed their lives more than they suffered. In the moment before the decision is made to breed farm animals or not, the potential “beneficiaries” of that decision do not exist. Since the potential animals have yet to be born, there can be no creature that is owed any obligation by the breeder. If this objection were taken to its logical conclusion, it is *always* wrong for breeders—or parents for that matter—to limit the number of offspring produced, for the actualization of potential lives is an unmitigated good. This absurd result need not be countenanced, for the interests of non-existent animals need not enter into the moral calculus behind synthetic meat.

Given the deplorable state of current meat production practices, synthetic meat offers hope for significant reduction in animal suffering. Although the rise of synthetic meat will be met with ethical objections, these concerns are generally misplaced or overstated. Overall, the substantial ethical benefits of synthetic meat far outweigh any ethical concerns it raises.

IV. ENVIRONMENTAL ANALYSIS

In addition to its ethical benefits, synthetic meat may also provide enormous environmental benefits when compared with traditional meat production. Researchers agree that meat production poses a significant threat to our environment along several dimensions. The proliferation of meat-producing animals has contributed to increases in greenhouse gas levels, and therefore exacerbated the global warming crisis. Additionally,

factory-farming practices often introduce contaminants and toxins into the surrounding area, causing substantial resource degradation. In each of these areas, synthetic meat offers substantial improvement over traditional meat production practices.

A. Greenhouse Gases

Ask someone what the major contributors to global warming are, and the response is unlikely to include meat. Yet a 2006 report by the United Nations Food and Agriculture Organization (FAO) found that meat production contributes more greenhouses gases—such as carbon dioxide, methane, and nitrous oxide—than the either transportation or industrial sectors.⁶⁶ As has become widely known, greenhouse gases trap solar energy, thereby warming the earth’s surface. Increases in greenhouse gases and the concomitant global warming has been called “the most serious challenge facing the human race.”⁶⁷ Livestock, therefore, in fact is “one of the top two or three most significant contributors to the most serious environmental problems, at every scale from local to global.”⁶⁸ Current production levels of meat contribute between 14 to 22 percent of the 36 billion tons of “CO₂-equivalent” greenhouse gases produced each year.⁶⁹ To break this down into more readily digestible terms, producing half a pound of ground beef releases as much greenhouse gas into the atmosphere as driving a typical car nearly 10 miles.⁷⁰ Of course, all food production contributes some amount of greenhouse gas, but meat stands in a league of its own. For instance, one ecological economist has

⁶⁶ H. Steinfeld *et al.*, *Livestock’s Long Shadow: Environmental Issues and Options*, Report by the Food and Agriculture Organization of the United Nations (2006).

⁶⁷ *Id.* at xxi.

⁶⁸ *Id.*

⁶⁹ See Nathan Fiala, “The Greenhouse Hamburger,” *SCIENTIFIC AMERICAN*, February 2009.

⁷⁰ *Id.*

calculated that producing a pound of beef in a feedlot generates the equivalent of 36 times the greenhouse gas emitted by producing a pound of asparagus.⁷¹ Pork and chicken production generates less greenhouse gases, but still significantly more than vegetables.⁷²

Several factors contribute to the global warming effects of meat production. Forty percent of the overall effect comes from the production of feed crops and the forgone absorption of greenhouse gases due to the loss of CO₂-absorbing trees, plants, and grasses.⁷³ The direct emission of methane by animals and animal waste contributes 32%, with fertilizer production and general farm production contributing the remaining 28% combined.⁷⁴

Just as we are beginning to understand the tremendous damage that meat-production does to the environment, demand for meat is ever increasing, averaging about 22 pounds per person per year.⁷⁵ The rate of consumption is increasing by approximately 1 percent per year.⁷⁶ Plainly put, this rising demand is unsustainable with our current meat production systems. Many commentators advocate for people, and Americans in particular, to reduce meat consumption.⁷⁷ While this is surely a laudable goal, it isn't clear that advocacy alone will be effective. But in light of recent technological

⁷¹ Susan Subak, *Global Environmental Costs of Beef Production*, 30 *ECOLOGICAL ECONOMICS* 79-91 (1999).

⁷² See Nathan Fiala, "The Greenhouse Hamburger," *SCIENTIFIC AMERICAN*, February 2009.

⁷³ Susan Subak, *Global Environmental Costs of Beef Production*, 30 *ECOLOGICAL ECONOMICS* 79-91 (1999).

⁷⁴ *Id.*

⁷⁵ *See id.*

⁷⁶ See H. Steinfeld *et al.*, *Livestock's Long Shadow: Environmental Issues and Options*, Report by the Food and Agriculture Organization of the United Nations (2006).

⁷⁷ See, e.g., Mark Bittman, "Rethinking the Meat-Guzzler," *NEW YORK TIMES*, January 27, 2008.

developments, might synthetic meat offer a partial solution to the problems of global warming?

It is impossible at this stage to go beyond guesswork when formulating actual environmental impact of synthetic meat, as it has not yet entered commercial production. However, there is good reason to believe that it will offer vast improvements in greenhouse gas emissions over traditional meat production. The vast majority of the greenhouse gas emitted by livestock animals comes from the loss of feed crops and trees, and from the methane produced by the animals themselves. Both of these contributors will be essentially eliminated by synthetic meat. In a laboratory, the production can be scaled vertically, and can be placed anywhere, given that there is no need for expansive acres to house any animals. Furthermore, the Petri dishes and tissue cultures are obviously not producing methane the same way that feed cattle are. It is possible that the widespread production of synthetic meat will contribute greenhouse gases in its own way—such as through the increased use of electricity and laboratory waste products—but it is difficult to imagine that these effects would be anywhere near the scale of current meat production. Whatever additional environmental impact synthetic meat will have, it will almost certainly be outweighed by the reductions in greenhouse gases gained by removing the need for the feedlots of today.

B. Resource Degradation, Depletion, and Pollution

The livestock industry has been implicated in several other areas of environmental harm. These include land degradation, as well as water depletion and pollution. In each of these areas, synthetic meat offers an attractive alternative that is not shackled with the disastrous environmental effects of traditional meat production.

1. Rangeland Degradation

Land dedicated to raising livestock spans more than 3.9 billion hectares, or more than 30 percent of the world's surface land area.⁷⁸ This substantial land use has contributed to degradation along several dimensions, including prominently the desertification of pastures in Africa, Asia, and Latin America, as well as increasing deforestation in Latin America and elsewhere.⁷⁹ As the worldwide demand for meat continues to grow, crop and pasture expansion into natural ecosystems is to be expected. This practice results in the degradation of pastures from overgrazing, attributed to the mismatch between livestock density and the number of animals the pasture can sustainably support.⁸⁰ Pasture degradation is an especially prominent concern in the arid and semi-arid grazing areas of Africa and Central Asia, where it has already begun to result in soil erosion, vegetation depletion, and impaired water cycles.⁸¹

The increased global demand for meat has also driven the conversion of natural habitats, including rich forests, into pastures and cropland.⁸² This trend is increasing; in fact, more land was converted into crops between 1950 and 1980 than in the preceding 150 years.⁸³ A 2003 FAO report noted that over the previous 25 years, forests from an area the size of India had been cleared, primarily for livestock production.⁸⁴ This process has been particularly aggressive in Central and South America. The results of

⁷⁸ See H. Steinfeld *et al.*, *Livestock's Long Shadow: Environmental Issues and Options*, 74, Report by the Food and Agriculture Organization of the United Nations (2006).

⁷⁹ *Id.* at 63.

⁸⁰ *Id.* at 66.

⁸¹ *See id.*

⁸² *See id.* at 24.

⁸³ See Millennium Ecosystem Assessment, *Ecosystems and Human Well-Being: Synthesis*, Washington, DC, Island Press (2005).

⁸⁴ See *Livestock Policy Brief 03*, Report by the Food and Agriculture Organization of the United Nations.

widespread deforestation can be disastrous, including increased carbon dioxide emissions, the loss of biodiversity (in the most species-rich environments on the planet), soil degradation, and water pollution.⁸⁵ All these problems arise from the need to provide land and crops to raise livestock. Synthetic meat offers an opportunity to relieve these tremendous environmental pressures by making meat far more efficiently, and in a more controlled, environmentally responsible manner.

2. Water Depletion and Pollution

The livestock industry also contributes significantly to the depletion and pollution of water around the globe.⁸⁶ The water used by this sector accounts for more than 8% of all global human water use.⁸⁷ The FAO report found that 15 percent of the water depleted each year is attributable to the livestock industry, principally due to water evapotranspired by feed crops.⁸⁸ Water is also depleted due to the unsustainable nutrient, pesticide, and sediment loads contributed by the livestock industry.⁸⁹ Although the report was unable to determine exact figures for the water polluted by livestock, it found that the livestock sector contributed to many of the most prevalent water pollutants, including 37 percent of all pesticides and 50 percent of all antibiotics.⁹⁰ Water pollution is especially prevalent in industrial livestock production, due to high nutrient loads and increased biological contamination. This is especially important when industrial livestock production occurs near urban areas, as the contamination is more likely to affect human

⁸⁵ *See id.*

⁸⁶ *See H. Steinfeld et al., Livestock's Long Shadow: Environmental Issues and Options*, 167, Report by the Food and Agriculture Organization of the United Nations (2006).

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

health.⁹¹ The pollution process is often gradual and diffuse, only detectible once it has become quite severe and difficult to control.⁹² Several particularly disastrous occurrences have been noted in the United States. For instance, animal waste is believed to be a central contributor to the “dead zone” in the Gulf of Mexico—a region of approximately 5,000 square miles in which, due to algal blooms, there is insufficient oxygen to support aquatic life.⁹³ In a June 2001 incident, the Environmental Protection Agency found that an Oklahoma hog farm had contaminated drinking water wells, and ordered the company responsible to provide safe drinking water to area residents.⁹⁴

Needless to say, synthetic meat poses none of these water pollution and depletion problems. Whatever contaminants may be created during the process are far easier to control in the closed, laboratory setting than in the vast, open areas set for livestock production. The havoc that traditional meat production has wrought on one of the earth’s most vital and precious resources provides yet another strong reason to consider synthetic meat an especially attractive alternative.

V. REGULATORY ANALYSIS

Meat is regulated in the United States by both the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).⁹⁵ Navigating the overlapping jurisdiction of these two federal agencies is surprisingly difficult, and at least

⁹¹ *Id.*

⁹² *Id.*

⁹³ See National Resources Defense Council, *Facts About Pollution from Livestock Farms*, available at <http://www.nrdc.org/water/pollution/ffarms.asp>.

⁹⁴ *Id.*

⁹⁵ See PETER BARTON HUTT *et al.*, FOOD AND DRUG LAW, 35-36, Third edition (2007).

one USDA official has admitted that “[i]t doesn’t make any sense.”⁹⁶ The Federal Meat Inspection Act (FMIA)⁹⁷ and the Poultry Products Inspection Act (PPIA)⁹⁸ grant USDA authority to regulate these products. FDA has exclusive jurisdiction over live animals intended for food,⁹⁹ while USDA has exclusive jurisdiction over animal slaughter and the subsequent processing of meat and poultry.¹⁰⁰ The two agencies share jurisdiction over food additives in meat and poultry, as well as over distribution up to the retail store.¹⁰¹ It would be impossible to address all possible issues that might arise in the complex framework. Rather, this Part will focus on three issues of note raised by synthetic meat. First is whether the USDA will consider synthetic meat to be “meat” within the meaning of the FMIA, and therefore under its jurisdiction at all. Second is whether FDA will classify synthetic meat—somewhat counterintuitively—as a food additive in order to establish greater regulatory control. Third and finally is what labeling requirements might be imposed by FDA in light of past treatment of genetically modified organisms (GMOs) and cloned meat. Although the technology and its implications apply to both meat and poultry, this Part will restrict discussion to meat products for simplicity.

A. Is Synthetic Meat “Meat”?

One significant threshold question facing synthetic meat is whether it in fact qualifies as “meat” within the meaning of the FMIA. If it does, then USDA will exercise

⁹⁶ Carole Sugarman, “Who’s Minding the Store?; The Seemingly Senseless Division of Federal Labeling Authority,” *Washington Post*, May 11, 1988 (quoting chief of USDA’s standards branch Judy Quick).

⁹⁷ 21 U.S.C. §601.

⁹⁸ 21 U.S.C. §1301.

⁹⁹ *See United States v. Tomohara Enterprises, Ltd.* *See also* PETER BARTON HUTT *et al.*, *FOOD AND DRUG LAW*, 36, Third edition (2007).

¹⁰⁰ *See* PETER BARTON HUTT *et al.*, *FOOD AND DRUG LAW*, 36, Third edition (2007).

¹⁰¹ *Id.*

jurisdiction over its processing. If not, then synthetic meat will instead be subject to FDA regulation. The controlling definition is circuitous, and worth quoting at length:

The term “meat food product” means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.¹⁰²

Synthetic meat, as described above, is constructed by seeding a scaffold or tissue culture with cells taken from an animal, and therefore would appear to have been “made . . . in part from any meat.” However, synthetic meat, which begins with only a few original animal cells and could create millions more, certainly “contain[s] meat . . . only in a relatively small proportion,” if “meat” is understood to mean skeletal muscle directly from an animal. As a general matter, USDA has ceded authority to FDA for products that contain less than 2% meat products.¹⁰³ As proposed, synthetic meat would contain far less than 2% of original animal cells; the question then becomes whether those proliferated cells qualify as “meat.” There is little guidance to be found on this obviously novel issue, but there is reason to suspect that USDA would shy away from classifying synthetic meat as “meat”, and therefore cede authority to FDA. The technology involved in producing synthetic meat only involves actual animals at the very earliest stages, and

¹⁰² 21 U.S.C. §601(j).

¹⁰³ See PETER BARTON HUTT *et al.*, FOOD AND DRUG LAW, 35, Third edition (2007).

may not even involve killing an animal.¹⁰⁴ USDA agents are responsible for observing the slaughter of live animals, and the processing of carcasses to make meat products. These two avenues—despite producing a very similar product—are worlds apart. The institutional expertise in regulating the process of creating synthetic meat clearly lies with the FDA. After all, producing synthetic meat is, in practice, far closer to the processing of, for example, a filamentous fungus to produce mycoprotein-based meat substitute¹⁰⁵ than it is to the carving up of a dead animal. As FDA has exclusive jurisdiction over the former, it stands to reason that it ought also to assume authority for regulating synthetic meat.

B. Is Synthetic Meat a Food Additive?

Assuming that, as suggested above, USDA either is denied or perhaps cedes jurisdiction, FDA will exercise exclusive authority over synthetic meat. One of the primary questions facing FDA may seem odd to the casual observer: is synthetic meat a “food additive”? To understand why this is an intelligible—and important—question, one must consider the structure of FDA’s regulatory authority. If a substance is deemed to be a food additive, then it is presumed to be unsafe, and the producer or processor has the burden of proving that the substance is safe for human consumption.¹⁰⁶ If, on the other hand, the substance is considered food—and not a food additive—then it is presumed to be safe and the burden falls on the FDA to show that it is injurious to

¹⁰⁴ See *supra* note 57.

¹⁰⁵ See “What is Quorn?”, available at <http://www.quorn.us//cmpage.aspx?section=WhatIsQuorn>.

¹⁰⁶ See *United States v. Two Plastic Drums*, 984 F.2d 814, 816 (7th Cir. 1993).

health.¹⁰⁷ The Federal Food Drug and Cosmetic Act (FD&C Act) defines “food additive” as

. . . any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . , if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use.¹⁰⁸

Judging by the plain words, it might be hard to see how synthetic meat might qualify as a food additive. However, FDA’s strong incentive to classify certain items as food additives rather than as generic food have led it to make similarly strained arguments before. For instance, FDA once attempted to seize quantities of black currant oil, asserting that the oil was a food additive, since it would become a “component” of the food when combined with gelatin and glycerin used to make black currant oil capsules.¹⁰⁹ A similar argument might be made with respect to synthetic meat, as it likely would be produced with added spices or breading, and not merely in pure, raw form. Although FDA’s argument with respect to the black currant oil was rejected by two separate appellate courts, in both cases the opinions stressed the fact that the gelatin and glycerin were “inactive” ingredients, not affecting the characteristics of the black currant oil.¹¹⁰ The classification of synthetic meat as a food additive would therefore depend on its preparation. If the product were delivered raw, with no other ingredients, it of course

¹⁰⁷ See *id.* at 816; *United States v. An Article of Food . . . FoodScience Labs.*, 678 F.2d 735, 739 (7th Cir. 1982).

¹⁰⁸ 21 U.S.C. §321(s).

¹⁰⁹ See *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993); *United States v. 29 Cartons of An Article of Food*, 987 F.2d 33 (1st Cir. 1993).

¹¹⁰ *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993); *United States v. 29 Cartons of An Article of Food*, 987 F.2d 33 (1st Cir. 1993).

could not constitute a food additive.¹¹¹ Similarly, if producers were to add only inactive substances to the meat—such as water or glycerin—then still it would not constitute a food additive.¹¹² If, however, synthetic meat is prepared with any other active ingredients—such as spices or breaded coatings—then FDA would have a reasonable argument that synthetic meat is indeed a food additive, and therefore the burden would rest on synthetic meat producers to demonstrate to FDA’s satisfaction that the product is not injurious to health.

One caveat to this classification is the fact that a manufacturer may make a self-determination that its product is Generally Recognized as Safe (GRAS),¹¹³ and therefore is not technically a food additive within the meaning of the statute.¹¹⁴ Self-determination of GRAS would allow the manufacturer to avoid the need for a food additive petition to FDA. Given the incredibly low FDA approval rate of food additives,¹¹⁵ self-determination of GRAS status is an attractive option for food component producers. Of course, FDA might disagree with a producer’s classification of its food additive as GRAS and initiate regulatory action. The criteria for establishing GRAS status are equivalent to the “quantity and quality of scientific evidence to establish . . . the safety of a newly used

¹¹¹ Even FDA conceded that black currant oil would not be a food additive if marketed in bottles rather than pills. *See United States v. Two Plastic Drums*, 984 F.2d 814, 817 (7th Cir. 1993)

¹¹² *See id.* at 819.

¹¹³ *See* 50 Fed. Reg. 27294 (July 2, 1985); 53 Fed. Reg. 16544 (May 10, 1988); 62 Fed. Reg. 18938, 18941-18942 (Apr. 17, 1997).

¹¹⁴ *See* 21 U.S.C. §321(s).

¹¹⁵ *See* Peter Barton Hutt, *Regulation of Food Additives in the United States*, in Larry Branen et al., eds., *Food Additives*, Ch. 8 (2d ed. 2001) (noting that only eight direct human food additives were approved over a period of thirty years).

food additive.”¹¹⁶ So while self-determination of GRAS would allow synthetic meat producers to circumvent some of FDA’s bureaucratic backlog, it would not alone lessen the burden of proving that the product is safe for human consumption.

The issue presented here may, however, be moot. FDA asserts powerful influence over the regulated industries through informal as well as formal means. Particularly effective is the power of publicity. Section 705 of the FD&C Act expressly authorizes FDA to issue information to the public regarding regulated products “in situations involving . . . imminent danger to health, or gross deception of the consumer.”¹¹⁷ FDA officials, acting in this capacity, are immune from defamation claims brought by the regulated producers.¹¹⁸ For many, if not most, firms the threat of negative publicity gives FDA ample leverage to enforce compliance with agency “recommendations.” The regulated firm is at a severe disadvantage in attempting to answer FDA’s concerns in the public forum, and even serious efforts are often too little, too late. One illustrative example is the “cranberry scare” of 1959. FDA discovered that a small percentage of cranberries had been sprayed with aminothiazole—a known carcinogen—and held a press conference urging the public not to eat the contaminated berries.¹¹⁹ Despite the fact that less than 1% of cranberries were implicated, and the actual risk of harm was speculative given the low level of contamination, national

¹¹⁶ See General Recognition of Safety and Prior Sanctions for Food Ingredients, 41 Fed. Reg. 53600 (Dec. 7, 1976).

¹¹⁷ 21 U.S.C. §705(b).

¹¹⁸ See *Barr v. Mateo*, 360 U.S. 564 (1959).

¹¹⁹ See Edward L. Smith, *The Cranberry Scare and Cabinet Immunity*, 16 FOOD DRUG COSM. L. 209, 209-210 (1961).

cranberry sales fell an astonishing 67% over previous years.¹²⁰ With this mighty weapon within its complete discretion, FDA is a fearsome regulator to behold. Synthetic meat producers, therefore, are likely to do everything they can to satisfy any concerns raised by FDA, whether or not their product would properly be classified as a food additive, or whether they believed they had met the standards for establish GRAS status.

C. Labeling Requirements

An open question, which is sure to affect the marketability of synthetic meat, is what labeling requirements FDA will impose. Presumably, synthetic meat producers would prefer to not label their products as “in-vitro”, “laboratory-grown”, or anything of the kind. At least initially, one can expect consumers to shy away from products so designated.¹²¹ FDA labeling requirements could therefore cripple the industry before it ever has a chance to grow. The fate of synthetic meat in the marketplace may very well depend on FDA’s response to this issue.

FDA is charged with promoting food safety and consumer protection.¹²² In pursuit of this goal, FDA must focus not on the process by which a food was made, but

¹²⁰ See *id.*; Statement by Ambrose E. Stevens, executive vice president, National Cranberry Institute, in Washington, D.C., quoted in Associated Press dispatch, December 9, 1959.

¹²¹ By way of analogy, a 2005 survey by the International Food Information Council found that 63% of consumers would likely not purchase food from cloned animals. See Matthew R. Kain, *Throw Another Cloned Steak on the Barbie: Examining the FDA’s Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef*, 8 N. CAROLINA J. L. & TECH 303, 304 (2007).

¹²² See FDA, “What We Do”, available at <http://www.fda.gov/opacom/morechoices/mission.html>.

rather on the food itself.¹²³ Whatever the feelings of consumers, the FD&C Act “contains no general authorization to require food labels to bear whatever information some consumers might wish to know.”¹²⁴ The overriding question is whether any given food is “misleading,” including “the extent to which the labeling or advertising fails to reveal facts material . . . with respect to consequences which may result from the use of the articles.”¹²⁵ FDA has declined to require labeling of genetically modified foods¹²⁶ or cloned meat,¹²⁷ indicating that neither of those properties qualifies as “material” within the meaning of the act.

FDA’s labeling authority may be contrasted with that granted to USDA under the Organic Foods Production Act of 1990 (OFPA).¹²⁸ That act governs the labeling of foods as “organic,” and is therefore concerned almost completely with the process of food production rather than the properties of the food itself.¹²⁹ This distinction highlights two different targets of labeling: the process by which food is made, and the qualities of the

¹²³ See Matthew R. Kain, *Throw Another Cloned Steak on the Barbie: Examining the FDA’s Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef*, 8 N. CAROLINA J. L. & TECH 303, 314 (2007).

¹²⁴ Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 56 (1997).

¹²⁵ 21 U.S.C. §321(n).

¹²⁶ See Frank J. Miskiel, *Voluntary labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223, 239 (2001).

¹²⁷ See Matthew R. Kain, *Throw Another Cloned Steak on the Barbie: Examining the FDA’s Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef*, 8 N. CAROLINA J. L. & TECH 303, 314 (2007).

¹²⁸ 7 U.S.C. §§6501-6523 (2000).

¹²⁹ See USDA, *The National Organic Program, Organic Production and Handling Standards* (Oct. 2002, updated April 2008), *available at* www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3004445&acct=nopgeninf (“The national organic standards are process-based. They address the methods, practices, and substances used in producing and handling crops, livestock, and processed agricultural products. The requirements apply to the way the product is created, not to measurable properties of the product itself.”).

food itself. FDA concerns itself only with the latter. For instance, it has concluded that “[genetically modified] foods are substantially equivalent to unmodified ‘natural’ foods,” and therefore need not be labeled. However, labeling a genetically modified food would be required when its nutritional content differs significantly from its “natural” counterpart.¹³⁰ FDA has also indicated that, based on substantial scientific data, cloned beef poses no unique consumption, and is therefore not “materially different” from “natural” beef.¹³¹

Based on these precedents, the unique technology used to produce synthetic meat will not necessarily require labeling. Rather, FDA’s focus will be on the final properties of the food—and comparison to “natural” counterparts. The real hurdle with respect to this particular issue is therefore technological rather than regulatory. Time will tell just how similar synthetic meat products may be to their “natural” counterparts. But if synthetic meat producers are able to closely mimic actual meat products—whether ground beef or sirloin steak—they may escape imposition of FDA labeling requirements.

VI. CONCLUSION

This Paper has examined the potential for laboratory-grown, synthetic meat. Although the technology is still being developed, researchers seem confident that at least

¹³⁰ See FDA, FDA’s Statement of Policy; Foods Derived From New Plant Varieties (June 1992), *available at* <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm>.

¹³¹ See CENTER FOR VETERINARY MEDICINE, U.S. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANIMAL CLONING: A DRAFT RISK ASSESSMENT 308 (Dec. 28, 2006), *available at* http://www.fda.gov/cvm/Documents/Cloning_Risk_Assessment.pdf.

processed forms of synthetic meat will be brought to market before long. This budding technology offers myriad improvements over traditional meat production. The serious ethical and environmental concerns raised by the current livestock industry would be almost completely eliminated by the widespread adoption of synthetic meat. One novel consideration is how the regulatory bodies charged with overseeing food health and safety will respond to this new technology. Using past precedent as a guide, this Paper has attempted to sketch the regulatory framework and suggest FDA's likely response along three particular regulatory dimensions. Although the regulatory response remains somewhat uncertain, this Paper concludes that the significant benefits offered justify the vigorous pursuit of this exciting new technology.