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#### **Cultured Meat: A Beneficial, Crucial, and Inevitable Nutrition Technology**

Mallory E. McLaren

### Introduction

After much anticipation, on August 5, 2013 Dutch cardiologist and tissue scientist Dr. Mark Post introduced the world's first hamburger made out of beef derived from stem cells. His new food technology was presented through a well-publicized international event that took place in London. Noted British Chef Richard McGeown prepared the hamburger live on stage. Josh Schonwald, American author of *The Taste of Tomorrow*, and Hanni Rützler, a German nutrition scientist, were chosen as the first to sample Post's cultured meat. Dr. Post used the event to prove his concept and to begin opening minds to the reality of a whole new source of meat that is more efficiently sourced and ethical to produce than traditionally derived meats. While many marvel at Dr. Post's cultured meat technology, however, many others remain uneasy about the idea of consuming a piece of meat created from stem cells in a laboratory.

This paper was written in anticipation of Dr. Post introducing his important new food creation to the world and attempts to educate the reader that cultured meat products should be embraced by U.S. regulators and lawmakers as well as the American public. Cultured meat technology will provide a safe and healthy food staple that is genetically pure unlike genetically modified foods, which also originate in a laboratory. As the technology is perfected, cultured meat will also become far more efficient and environmentally friendly to produce than traditional meats.

Part One is a mildly technical overview of what cultured meat is, provides a general history surrounding the technology, explains how it is different than genetically

modified foods, and outlines the practical and social factors working both in favor and against cultured meat technology. Part Two shifts to the history of genetically modified foods in the United States and uses this technology as a base of comparison to predict how cultured meat technology will fare in U.S. courts, the U.S. legislature, and within the U.S. federal regulatory sphere. Part Three attempts to suggest a future strategy for cultured meat technology in the governance sphere by illuminating past and current political interference in the U.S. Food and Drug Administration's approval process of GMO fish. And this paper concludes in Part Four by explaining that cultured meat technology, having overcome its first hurdle of being introduced to the world, is coming ever closer to fulfilling its destiny as an inevitable piece of the long-term global nutrition puzzle. Accordingly, public discourse on cultured meat is vital to ensure that it avoids the fate of being mistakenly discarded as a folly of science.

### I. Cultured Meat: A Food Technology Just Now Emerging on the Horizon.

### A. The "What", the "Who," and the "When" of Cultured Meat.

Cultured meat technology is a cutting-edge modality of bio-agriculture that involves the cultivation of food grade animal tissues<sup>1</sup> in carefully controlled environments,<sup>2</sup> and carries with it the potential to become a viable alternative to traditional, slaughter-derived meats as well as their genetically modified (GMO) meat

<sup>&</sup>lt;sup>1</sup> Cultured Meat FAQ, NEW HARVEST, *available at* <u>http://www.new-harvest.org/cultured-meat/faq/</u> (last visited Aug. 29, 2013). <sup>2</sup> Lola Rosewig, *Humane Meat*?, UNIV. OF MICH. RISK SCI. CTR.,

Feb. 6, 2013, *available at* <u>http://www.mindthesciencegap.org/2013/02/06/humane-meat/</u> (last visited Aug. 14, 2013).

counterparts.<sup>3</sup> GMO meat technology, whose start has been with the manipulation of fish deoxyribonucleic acid (DNA) to create a new species of salmon, <sup>4</sup> has been plagued by widespread concerns over its unsuitability for human consumption<sup>5</sup> and by worries that mutated stocks might escape into the wild<sup>6</sup> and cause damage to the natural ecological balance. For those reasons, GMO meat technology has been dogged for a number of years by persistent controversy<sup>7</sup> and has faced steep resistance from the public,<sup>8</sup> some portions of the scientific community,<sup>9</sup> and, more recently, from U.S. legislators.<sup>10</sup> Cultured meat can serve as a means of sustainably increasing meat supply to support the dietary needs of a sharply increasing global population,<sup>11</sup> without the same safety concerns that surround GMO meat.<sup>12</sup>

http://www.cspinet.org/new/pdf/fda\_report\_\_final.pdf (last visited Aug. 13, 2013). <sup>10</sup> Natalia Real, *AquaBounty CEO 'Disappointed' by Another Setback*, FISH INFO. &

SERVICES, June 28, 2013, available at

http://www.fis.com/fis/worldnews/worldnews.asp?monthyear=&day=28&id=61845&l=e &special=&ndb=1%20target (last visited Aug. 12, 2013).

<sup>&</sup>lt;sup>3</sup>Makiko Kitamura, *Brin's \$332,000 Lab-grown Burger Has Cake-like Texture*, BLOOMBERG, Aug. 5., 2013, *available at* <u>http://www.bloomberg.com/news/2013-08-04/world-s-first-332-000-lab-grown-beef-burger-to-be-tasted.html</u> (last visited Sept. 7, 2013).

<sup>&</sup>lt;sup>4</sup> AquAdvantage Salmon, AQUABOUNTY TECHNOLOGIES,

http://www.aquabounty.com/products/products-295.aspx (last visited Aug. 10, 2013). <sup>5</sup> JUST LABEL IT!, Senate Committee Passes GE Salmon Labeling Amendment, available at http://justlabelit.org/senate-appropriations-committee-passes-ge-salmon-labelingamendment/ (last visited Aug. 12, 2013).

<sup>&</sup>lt;sup>6</sup> Emily Main, Are You Ready for Frankenfish?, RODALE NEWS, Jan. 9, 2013, available at <u>http://www.rodale.com/gmo-salmon</u> (last visited Aug. 11, 2013).

<sup>&</sup>lt;sup>7</sup> JUST LABEL IT!, *supra* note 5.

<sup>&</sup>lt;sup>8</sup> Id.

<sup>&</sup>lt;sup>9</sup> DOUG GURIAN-SHERMAN, CTR. FOR SCI. IN THE PUB. INT., HOLES IN THE BIOTECH SAFETY NET, at ii (creation date not disclosed), *available at* 

<sup>&</sup>lt;sup>11</sup> NEW HARVEST, *supra* note 1.

<sup>&</sup>lt;sup>12</sup> GURIAN-SHERMAN, CTR. FOR SCI. IN THE PUB. INT., *supra* note 9, at ii.

The basis of cultured meat is myosatellite adult stem cells,<sup>13</sup> whose function is to build and repair muscle tissue.<sup>14</sup> The cells are biopsied from the donor animal via a minimally invasive procedure<sup>15</sup> and isolated by using enzyme-based techniques or through pipetting, or a micro-needling process.<sup>16</sup> Once the cells are extracted, the cells are introduced to a nutrient medium, often made from fetal bovine serum <sup>17</sup> derived from fetuses taken from slaughtered cows, a similar horse fetus serum,<sup>18</sup> or fungi or algae based extract.<sup>19</sup>

Several techniques to create cultured meat products have been experimented with, some more successfully than others. The first technique, proposed by Dr. Mark Post of Eindhoven University of Technology and Maastricht University in the Netherlands,<sup>20</sup> involves stem cells being placed on a scaffold structure in a nourishing substance.<sup>21</sup> As the cells replicate and a muscle mass develops, the fibers are stimulated with electrical,

<sup>&</sup>lt;sup>13</sup> Isha Datar, *Possibilities for an In Vitro Meat Production System*, INNOVATIVE FOOD SCI. & EMERGING TECH., Nov. 2009, at 13, 14, *available at* 

http://diyhpl.us/~bryan/papers2/bio/Possibilities%20for%20an%20in%20vitro%20meat%20production%20system.pdf (last visited Aug. 17, 2013).

<sup>&</sup>lt;sup>14</sup> Z.F. Bhat & Hina Bhat, *Animal-free Meat Biofabrication*, 6 AM. J. FOOD TECH. 441, 443, *available at* <u>http://scialert.net/qredirect.php?doi=ajft.2011.441.459&linkid=pdf</u> (last visited July 17, 2013).

<sup>&</sup>lt;sup>15</sup> Nicola Jones, *Food: a Taste of Things to Come?*, 468 NATURE 752 (2010), *available at* <u>http://www.nature.com/news/2010/101208/full/468752a.html</u> (last visited July 25, 2013). <sup>16</sup> *Id.* at 752-753.

 $<sup>^{17}</sup>$  *Id*.

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> HARVARD GRADUATE SCHOOL OF THE ARTS & SCI., *Food of the Future: In Vitro Meat?* (2011), *available at* <u>https://sitn.hms.harvard.edu/sitnflash\_wp/2011/03/issue90/</u> (last visited July 25, 2013).

<sup>&</sup>lt;sup>20</sup> TEDXTALKS, *Meet the New Meat: Mark Post at TEDxHaarlem* (Jun. 23, 2013), *available at <u>http://www.youtube.com/watch?v=ZExbQ8dkJvc</u> (last visited Aug. 27, 2013).* 

<sup>&</sup>lt;sup>21</sup> Bhat & Bhat, *supra* note 14, at 443.

physical or chemical catalysts in order to "exercise" the mass<sup>22</sup> thereby promoting the development of a more muscular, structured unit. Because Post's meat-making endeavors are still largely in the experimental phase, the muscle strips produced are small: three centimeters long, one centimeter wide, and one millimeter thick.<sup>23</sup> A Russian television journalist evidenced the novelty of this new type of food in 2010 when, during an interview with Dr. Post, he grabbed and ate one of the "chewy and tasteless"<sup>24</sup> pieces of stem-cell tissue before Dr. Post had time to react.<sup>25</sup> The product of Post's cultured meat endeavors, which are financially backed by Google co-founder Sergei Brin,<sup>26</sup> were recently introduced to the world through a stream-casted event in London.<sup>27</sup>

In the second technique, Dr. Gabor Forgacs<sup>28</sup> of the United States is using a threedimensional bio-printing technology to make a biomass from livestock stem cells, the end result being an edible food product akin to a meat patty.<sup>29</sup> In 2011, Dr. Forgacs used his presentation at the annual TEDMED gathering, a prestigious medical technology and

<sup>&</sup>lt;sup>22</sup> TEDXTALKS, *supra* note 20.

<sup>&</sup>lt;sup>23</sup> Alan Boyle, *Lab-Grown Hamburger Due to Be Served Up This Year ... for \$330,000*, NBC NEWS, Feb. 19, 2012, *available at* <u>http://www.nbcnews.com/science/lab-grown-hamburger-due-be-served-year-330-000-6C10402491?franchiseSlug=sciencemain</u> (last visited July 26, 2013).

<sup>&</sup>lt;sup>24</sup> Jones, *supra* note 15, at 752-753.

<sup>&</sup>lt;sup>25</sup> Id.

<sup>&</sup>lt;sup>26</sup> BBC NEWS, *World's First Lab-Grown Burger Is Eaten in London* (Aug. 5, 2013), *available at <u>http://www.bbc.co.uk/news/science-environment-23576143</u> (last visited August 21, 2013).* 

 $<sup>^{27}</sup>$  Id.

 <sup>&</sup>lt;sup>28</sup> Stacy Lu, *Gabor Forgacs: In Vitro Meat – It's What's for Dinner!*, TEDMED BLOG,
 Feb. 23, 2012, *available at <u>http://blog.tedmed.com/?p=585</u> (last visited July 26, 2013).
 <sup>29</sup> Id.* 

healthcare conference,<sup>30</sup> to prepare and consume a small piece of his cultured meat product on stage.<sup>31</sup> Although Dr. Forgacs did not comment at length on the taste of his creation during his TEDMED presentation, he apparently had no adverse physical reaction after consuming it.<sup>32</sup>

In the third technique, Dr. Patrick Brown of Stanford University is working on cultured dairy products in addition to cultured meat.<sup>33</sup> So far, however, Dr. Brown has operated under far more secretive pretenses.<sup>34</sup> Michael Hanlon, author of a June 2012 Guardian Newspaper article on cultured meat, visited Dr. Brown's lab, and reported, "I am not allowed to say what I tried, nor which chef helped create it, and certainly not what it tasted like. But I can say this: I would have had no idea [what I tasted] wasn't "real" [meat]. Ouorn [a British line of meat substitute products] this is not."<sup>35</sup>

The fourth technique, pioneered by Dr. Morris Benjaminson of Touro College,<sup>36</sup> involved the cultivation of goldfish cells from a tissue slice which was minced, centrifuged in a Petri dish with nutrient mediums of both the mushroom and bovine variety, and left for seven days to grow into what would be a thicker<sup>37</sup> chunk of meat.<sup>38</sup>

tedmed/what-is-tedmed (last visited August 17, 2013). <sup>31</sup> Lu, *supra* note 28. <sup>32</sup> Id. <sup>30</sup> About TEDMED, TEDMED, available at http://www.tedmed.com/about-

<sup>&</sup>lt;sup>33</sup> Michael Hanlon, *Meat, the Makers: The Race to Make Fake Meat Just Got Interesting*, THE GUARDIAN, June. 22, 2012, at 24, available at

http://www.theguardian.com/science/2012/jun/22/fake-meat-scientific-breakthroughsresearch (last visited Aug. 28, 2013).

<sup>&</sup>lt;sup>34</sup> Id. <sup>35</sup> Id.

<sup>&</sup>lt;sup>36</sup> TOURO COLLEGE SCHOOL OF HEALTH SCIENCES, Growing Fish Fillets Outside the Fish (Dec. 5, 2001), available at http://legacy.touro.edu/shs/spacefish.asp (last visited July 26, 2013).

<sup>&</sup>lt;sup>37</sup> Bhat & Bhat, *supra* note 14, at 443.

 $<sup>^{38}</sup>$  Id.

The National Aeronautics and Space Administration (NASA) funded Benjaminson's efforts to develop ways to feed spacefarers on extended journeys in outer space.<sup>39</sup> Dr. Benjaminson cooked the flesh, which looked like a fish fillet in olive oil and garlic, and presented it to a panel comprised of college staff for their reactions.<sup>40</sup> Although no one was permitted to eat Benjaminson's creation, the panel commented that it smelled and looked good enough to eat.<sup>41</sup> Dr. Benjaminson's ultimate goal of making a more substantial chunk of edible flesh failed to materialize, however. Just as natural flesh depends on a vascular system to deliver nutrients and remove metabolic waste, cultured meat has a similar need.<sup>42</sup> The lack of such a mechanism in Benjaminson's experiment caused his fish tissue to become necrotic.<sup>43</sup> In the aftermath of such failure, NASA discontinued funding his research thus halting the project.<sup>44</sup>

Despite the plurality of scientists working on various techniques to make cultured meat a feasible option suitable for human nutrition, only Dr. Post has produced a hamburger patty of cultured meat for human consumption thus far.<sup>45</sup> But Dr. Post's current process remains prohibitively expensive – around \$330,000,<sup>46</sup> meaning we are still some time away from seeing cultured meat in grocery stores or restaurants.

### B. What Cultured Meat Has Going for It, and the Challenges Still to be Overcome.

<sup>&</sup>lt;sup>39</sup> TOURO COLLEGE SCHOOL OF HEALTH SCIENCES, *supra* note 22.

<sup>&</sup>lt;sup>40</sup> Jones, *supra* note 15, at 752-753.

<sup>&</sup>lt;sup>41</sup> *Id*.

<sup>&</sup>lt;sup>42</sup> Bhat & Bhat, *supra* note 14, at 443.

<sup>&</sup>lt;sup>43</sup> *Id*.

 <sup>&</sup>lt;sup>44</sup> David Cohen, *Grow Your Own Meat*, BBC NEWS, Oct. 24, 2011, *available at* <u>http://www.bbc.co.uk/news/mobile/technology-15402552</u> (last visited July 26, 2013).
 <sup>45</sup> BBC NEWS, *supra* note 26.

<sup>&</sup>lt;sup>46</sup> *Id*.

As with many technological innovations that could be interpreted as utopian miracles, many challenges remain. Socially, the most prevalent obstacle is the hesitation<sup>47</sup> that many respond with when faced with the concept of eating meat grown in a laboratory.<sup>48</sup> The status quo is also rooted more firmly by the widely held opinion that conventional meats are already appealing to the taste.<sup>49</sup>

From the practical angle, if a cultured meat hamburger was ready for production right now, animal slaughter still has not been completely subtracted from the equation. Fetal bovine serum extracted from fetuses inside of pregnant slaughtered cows remains far cheaper and more available for use as a growth medium than algae- or mushroombased formulas.<sup>50</sup> But the challenges facing cultured meat production are even more daunting. Massive labor and energy inputs are still currently required to maintain sensitive cell cultures at the right temperature, properly nourished, exercised, growing in the desired manner, and free of contamination.<sup>51</sup> This combination of engineering limitations remains the primary barrier in scaling cultured meat production up to a level that would keep pace with any level of demand, great or small.<sup>52</sup>

 <sup>&</sup>lt;sup>47</sup> Alexandre Erler, In *Vitro Meats, New Technologies, and the "Yuck" Factor*, PRAC.
 ETHICS, Mar. 5, 2012, <u>http://blog.practicalethics.ox.ac.uk/2012/03/in-vitro-meat-new-technologies-and-the-yuck-factor/</u> (last visited Aug. 10, 2013).
 <sup>48</sup> Amanda Radke, *Will Lab-Grown Meat Catch On?*, BEEF DAILY, Feb. 29, 2012,

<sup>&</sup>lt;sup>48</sup> Amanda Radke, *Will Lab-Grown Meat Catch On?*, BEEF DAILY, Feb. 29, 2012, *available at* <u>http://beefmagazine.com/blog/will-lab-grown-meat-catch</u> (last visited July 31, 2013).

<sup>&</sup>lt;sup>49</sup> Elaine Vigneault, *But Meat Tastes Good*, VEGAN SOAPBOX, June 24, 2009, *available at* <u>http://www.vegansoapbox.com/but-meat-tastes-good/</u> (last visited July 31, 2013).

<sup>&</sup>lt;sup>50</sup> HARVARD GRADUATE SCHOOL OF THE ARTS & SCI., *supra* note 19.

<sup>&</sup>lt;sup>51</sup> Christina Agapakis, *Steak of the Art: the Fatal Flaws of In Vitro Meat*, THE CRUX, Apr. 24, 2012, *available at* <u>http://blogs.discovermagazine.com/crux/2012/04/24/steak-of-the-art-the-fatal-flaws-of-in-vitro-meat/#.UWx\_a4L1vNc</u> (last visited July 31, 2013). <sup>52</sup> *Id*.

The next likely challenge for cultured meat, at least in the United States, is the federal government's system of evaluation and approval of foods.<sup>53</sup> The case of AquAdvantage salmon products, created by AquaBounty Technologies,<sup>54</sup> serves to illustrate the potential challenges that cultured meat products might experience during the regulatory review process. AquAdvantage salmon are genetically modified fish that are created to be sterile, female, and are raised on isolated farms that are kept separate from wild, non-GMO fish stocks.55

AquaBounty Technologies has met all safety benchmarks that the U.S. Food and Drug Administration (FDA) has imposed by way of its procedures throughout the company's journey to place their product into commerce.<sup>56</sup> As of August 2013, the FDA is due to make its final ruling on whether AquAdvantage salmon will be approved for sale in the United States.<sup>57</sup>

The FDA's current stall on AquAdvantage salmon is long-standing. In April 2012 a final environmental impact assessment was held up without explanation<sup>58</sup> and instead released in December 2012,<sup>59</sup> months after it was ready for release.<sup>60</sup> Then, from December 2012 to April 2013 the FDA held a public notice-and-comment period on the

<sup>&</sup>lt;sup>53</sup> Emily Anthes, Don't Be Afraid of Genetic Modification, N.Y. TIMES, Mar. 10, 2013, at 4, available at http://www.nytimes.com/2013/03/10/opinion/sunday/dont-be-afraid-ofgenetic-modification.html?pagewanted=all&\_r=0 (last visited July 31, 2013). <sup>54</sup> AQUABOUNTY TECHNOLOGIES, *supra* note 4.

<sup>&</sup>lt;sup>55</sup> *Id*.

<sup>&</sup>lt;sup>56</sup> Anthes, *supra* note 53, at 4.

<sup>&</sup>lt;sup>57</sup> Henry I. Miller, It's Not A Phony Scandal When President Obama Tramples the Constitution, FORBES MAG. Online Edition, July 31, 2013, available at http://www.forbes.com/sites/henrymiller/2013/07/31/its-not-a-phony-scandal-whenpresident-obama-tramples-the-constitution/ (last visited Aug. 12, 2013). <sup>58</sup> *Id*.

<sup>&</sup>lt;sup>59</sup> *Id*.

<sup>&</sup>lt;sup>60</sup> Id.

results of the final environmental impact assessment<sup>61</sup> for twice the normal length of time.<sup>62</sup> These multiple delays have led to suspicion that deliberate political interference slowed the process since an approval of GMO meat during President Obama's presidency could "infuriate" a portion of the Democratic Party's political base.<sup>63</sup> As and when a cultured meat product makes an application for approval in America, the hesitation that many people presently feel when faced with the idea of consuming cultured meat<sup>64</sup> mav create political and regulatory obstacles similar to those which AquaBounty Technologies has long endured.<sup>65</sup>

Despite the challenges both actual and potential currently preventing cultured meat technology from being realized, there are numerous factors that suggest its viability and possible superiority in comparison to GMO and non-GMO meat. The first advantage is that cultured meat technology is laboratory driven, and thus a very clean production process<sup>66</sup> that does not involve exposure to germs and the elements the way traditional meat cultivation entails.<sup>67</sup> By choosing cultured meat consumers will thus subject themselves to far less risk of disease than traditional meats<sup>68</sup> pose by way of contamination from feedlots and abattoirs.<sup>69</sup>

- <sup>68</sup> Id.
- <sup>69</sup> Id.

<sup>&</sup>lt;sup>61</sup> Id.

<sup>&</sup>lt;sup>62</sup> Id.

<sup>&</sup>lt;sup>63</sup> Id.

<sup>&</sup>lt;sup>64</sup> Erler, *supra* note 47.

<sup>&</sup>lt;sup>65</sup> Heidi Ledford, Transgenic Salmon Nears Approval, 497 NATURE 17 (2013), available at http://www.nature.com/news/transgenic-salmon-nears-approval-1.12903 (last visited Aug. 12, 2013). <sup>66</sup> Rosewig, *supra* note 2.

<sup>&</sup>lt;sup>67</sup> Id.

The second advantage cultured meat has on traditionally derived meats is its comparative environmental friendliness. At the current juncture, up to thirty percent of the world's ice-free land is dedicated to grazing and feeding livestock.<sup>70</sup> As cultured meat products increase market share, those vast expanses of land could be put to cleaner and more productive uses such as reforestation to help clean Earth's air and regulate climate.<sup>71</sup> Livestock agriculture presently contributes about eighteen percent to the world's anthropogenic air pollution – or air pollution caused by human activity,<sup>72</sup> by way of methane emissions from bovine digestion processes<sup>73</sup> that would also be curbed if cultured meat goes mainstream.

Third, assuming a non-meat-derived growth medium is used,<sup>74</sup> cultured meat products will also forestall objections to the purchase or consumption of meat that stem from the cruelty to animals<sup>75</sup> during the rearing and slaughter processes because no further animal input beyond a cell culture would be required.

Fourth, cultured meat also has the potential to be a purer expression of edible animal tissue than farmed meat, being comprised nearly entirely of muscle,<sup>76</sup> made without the genetic engineering modalities that cause consumers alarm in the GMO

<sup>&</sup>lt;sup>70</sup> Jeffrey Bartholet, *Inside the Meat Lab*, SCI. AM., June 1, 2011, at 64, *available at* <u>http://www.scientificamerican.com/article.cfm?id=inside-the-meat-lab</u> (last visited Aug. 10, 2013).

<sup>&</sup>lt;sup>71</sup> *Id*.

<sup>&</sup>lt;sup>72</sup> *Id*.

<sup>&</sup>lt;sup>73</sup> Id.

<sup>&</sup>lt;sup>74</sup> Jones, *supra* note 15, at 752-753.

 <sup>&</sup>lt;sup>75</sup> David J. Yount, Eight Arguments in Favor of Eating Meat and Objections Hereto (2009) (unpublished manuscript, on file with Mesa Community College), *available at* <u>http://www.mesacc.edu/~davpy35701/text/meatarg.html</u> (last visited Aug. 22, 2013).
 <sup>76</sup> Hank Hyena, *Eight Ways In-Vitro Meat Will Change Our Lives*, H PLUS MAG., Nov.

<sup>17, 2009,</sup> *available at* <u>http://hplusmagazine.com/2009/11/17/eight-ways-vitro-meat-will-change-our-lives/</u> (last visited August 11, 2013).

realm, nor antibiotics or growth hormones, <sup>77</sup> and grown in a manner that can eliminate much of the unhealthy cholesterol and fat found in traditional meat.<sup>78</sup>

Fifth, cultured meat technology has inherent potential to be more versatile in its range of application through its potential to create leather<sup>79</sup> products, milk, and other dairy products.<sup>80</sup>

Sixth, cultured meat technology opens the door to eventually make GMO products obsolete. Wittingly or unwittingly, Americans have already accepted GMO non-meat foods like GMO soy and wheat into their diets. Monsanto's GMO seeds, as of 2001, grew to take up sixty-eight percent of the U.S. soy crop and twenty-six percent of the U.S. corn crop.<sup>81</sup> Another figure from 2010 places the numbers at ninety percent for the soy crop and eighty-five percent for the corn crop.<sup>82</sup> These figures illustrate that it would be difficult for even the most vehement protester of GMO foods to currently eliminate all possibility of consuming the mutated organisms they expend so much effort resisting. Now that the United States is on the precipice of having GMO fish being introduced into commerce,<sup>83</sup> it is imaginable that at food producers and consumers alike

<sup>&</sup>lt;sup>77</sup> Cultured Meat FAQ, NEW HARVEST, available at

http://www.new-harvest.org/cultured-meat/faq/ (last visited Aug. 29, 2013).

<sup>&</sup>lt;sup>78</sup> Hyena, *supra* note 76.

<sup>&</sup>lt;sup>79</sup> Solution, MODERN MEADOW, *available at* <u>http://modernmeadow.com/about/solution/</u> (last visited Aug. 11, 2013).

<sup>&</sup>lt;sup>80</sup> Hanlon, *supra* note 33, at 24.

<sup>&</sup>lt;sup>81</sup> PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, Factsheet: Genetically Modified Crops in the United States (2004), available at

http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact\_Sheets/Food\_and\_Biote chnology/PIFB\_Genetically\_Modified\_Crops\_Factsheet0804.pdf (last visited Aug. 11, 2013).

<sup>&</sup>lt;sup>82</sup> Byron J. Richards, *Health Scandal – Monsanto's GMO Perversion of Food*, NEWS WITH VIEWS, Jan. 20, 2010, *available at* 

http://www.newswithviews.com/Richards/byron189.htm (last visited Aug. 11, 2013). <sup>83</sup> Main, *supra* note 6.

will come to view cultured meat positively -- as a technology that can help meet global demand for meat in the coming years. If such a view takes root, the technology may face less regulatory and legal hurdles than GMO foods or meats have.

### **II.** A Comparative Look at the United States Regulatory Scheme for GMO Foods.

### A. GMO Food Technology in Comparison and Contrast to Cultured Meat.

As cultured meat has yet to make its way out of the laboratory, food grade GMOs are the best analogy to examine how cultured meats could fare under the U.S. regulatory scheme and be perceived by consumers. GMOs have been defined by the World Health Organization (WHO) as "Organisms in which the genetic material ... has been altered in such a way that does not occur naturally."<sup>84</sup> A variety of molecular biology techniques are used to create these foods<sup>85</sup> for the purposes of herbicide tolerance, pesticide resistance, greater nutritional content, or increased tolerance against extreme temperatures.<sup>86</sup> GMO foods are also referred to as transgenic organisms<sup>87</sup> because their genes, having been spliced together by way of bioengineering,<sup>88</sup> come from more than one source.<sup>89</sup>

- <sup>88</sup> Id.
- <sup>89</sup> Id.

<sup>&</sup>lt;sup>84</sup> WORLD HEALTH ORG., 20 Questions on Genetically Modified Foods, available at <a href="http://www.who.int/foodsafety/publications/biotech/20questions/en/">http://www.who.int/foodsafety/publications/biotech/20questions/en/</a> (last visited Aug. 12, 2013).

 <sup>&</sup>lt;sup>85</sup> Arshad Chaudry, *Genetically Modified Foods*, SCI. CREATIVE QUARTERLY, Aug. 2004, *available at <u>http://www.scq.ubc.ca/genetically-modified-foods/</u> (last visited Aug. 12, 2013).* 

<sup>&</sup>lt;sup>86</sup> Id.

<sup>&</sup>lt;sup>87</sup> *Id*.

The deliberate combining of traits of various organisms is not new. Farmers from ancient to modern times have used the more primitive process of artificial selection to grow crops and breed animals with desired qualities.<sup>90</sup> GMO food technology speeds the process up, expands the capability to merge organisms, and is conducted in the laboratory setting.<sup>91</sup> The GMO process employs techniques that "cut" genes, which "code" for certain desired traits from one organism, and then "splice" those extracted genes into the DNA of another host organism. This splicing creates as an end result recombinant deoxyribonucleic acid (rDNA), or a helix of DNA with genetic code from more than one source. An "expression cassette" is then created,<sup>92</sup> which is a portion of an rDNA helix comprising both the spliced genes and genes from the host organism.<sup>93</sup> This cassette serves the function of making the target organism understand where the newly introduced genes are to be placed along the new rDNA strands that will be cultivated in the laboratory.<sup>94</sup> The expression cassette is then introduced to a parasitic bacterial DNA called a plasmid<sup>95</sup> and many copies are made as the spliced rDNA and plasmid merge through natural processes.<sup>96</sup> The cassette-infused plasmid is then inserted into a cell of the host organism where the plasmid "infects" it,<sup>97</sup> thus introducing the new genes into the target organism's genetic code and creating a new GMO organism.<sup>98</sup>

- <sup>90</sup> Id.
- <sup>91</sup> Id. <sup>92</sup> Id.
- $^{93}$  Id.
- $^{94}$  Id.
- $^{95}$  Id.
- $^{96}$  Id.
- <sup>97</sup> *Id*.
- <sup>98</sup> *Id*.

GMO foods and cultured meat products unfortunately share the dubious thread of eliciting an uneasy reaction for many, when they believe they have consumed or could consume such a product.<sup>99</sup> Consumers wary of GMO foods have shown dissatisfaction with the FDA's rebuttable presumption that GMO non-meat foods are to be generally recognized as safe<sup>100</sup> by suing the agency in the landmark case <u>Alliance for Bio-Integrity</u> <u>v. Shalala</u>.<sup>101</sup> The D.C. Federal Circuit, arguably the most influential court in the United States on administrative law issues, decided this case in the year 2000.<sup>102</sup> The plaintiffs, aggrieved by the notion that consumers would lack the ability to distinguish GMO from non-GMO foods if the FDA's presumption stood and continued to preclude labeling for GMO foods, alleged that the FDA's rebuttable presumption amounted to a refusal to regulate GMO technology.<sup>103</sup> A holding that the FDA had refused to regulate would result in a violation of the Food, Drug, and Cosmetics Act (FDCA), the FDA's enabling act, and force a policy change.<sup>104</sup>

The FDA's presumption that GMO foods were to be generally recognized as safe was established in a policy statement instead of through a notice-and-comment rulemaking procedure that would have allowed parties like the Alliance for Bio-Integrity greater input into the FDA's decision making process.<sup>105</sup> The FDA responded that its policy statement on GMO foods permitted it to retain all of its regulatory power over

- $^{104}$  Id.
- $^{105}$  *Id*.

<sup>&</sup>lt;sup>99</sup> Rodney August, *The Effect of Knowledge of In-vitro Meat on Attitudes Towards Science* (2013) (unpublished Masters thesis abstract, Otago University) (on file with Otago University and the author), *available at* 

http://otago.ourarchive.ac.nz/handle/10523/4062?show=full (last visited Aug. 29, 2013). <sup>100</sup> Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166, 169 (D.C. Cir. 2000). <sup>101</sup> Id. at 166.

 $<sup>^{102}</sup>$  Id.

 $<sup>^{103}</sup>$  *Id.* at 170.

GMO foods, including the ability to investigate GMO foods in cases where public safety questions created sufficient justification.<sup>106</sup> The D.C. Circuit agreed with the FDA in its opinion which explained that the agency was empowered to issue policy statements such as the one in question and that the policy statement did not foreclose the FDA from regulating this class of food products, but instead was a non-binding declaration of how it would generally treat GMO foods moving forward.<sup>107</sup>

The result of <u>Alliance for Bio-Integrity</u> is that GMO food producers are not required to label their foods. This has caused many food safety advocates to remain socially and politically active<sup>108</sup> in advocating against both the GMO foods presently on the market and GMO meat products<sup>109</sup> which are presently due for FDA approval.<sup>110</sup>

# B. After <u>Alliance for Bio-Integrity</u>: Stigmas Against GMO Meat Products and the Technology's Yet Unrealized Path to Regulatory Clearance.

In the aftermath of <u>Alliance for Bio-Integrity</u>, the path seemingly was made clear, at least for non-meat GMO food products, to permeate the American marketplace. When that case was decided, however, the technology for creating GMO meat products was still in its infancy.<sup>111</sup> AquaBounty Technologies, whose company name was AquaBounty

<sup>&</sup>lt;sup>106</sup> *Id*.

<sup>&</sup>lt;sup>107</sup> *Id.* at 175-176.

<sup>&</sup>lt;sup>108</sup> Home Page, JUST LABEL IT!, *available at* <u>http://justlabelit.org/</u> (last visited Aug. 12, 2013).

<sup>&</sup>lt;sup>109</sup> JUST LABEL IT!, We Have The Right To Know About Our Food (May 2013), available at <u>http://justlabelit.org/wp-content/uploads/2013/05/Right\_To\_Know-May-2013.pdf</u> (last visited Aug. 12, 2013).

<sup>&</sup>lt;sup>110</sup> Miller, *supra* note 57.

<sup>&</sup>lt;sup>111</sup> History, AQUABOUNTY TECHNOLOGIES, *available at* <u>http://www.aquabounty.com/company/company-history-292.aspx</u> (last visited Aug 12, 2013).

Farms before 2004,<sup>112</sup> was part of a company originally in the business of developing protein-based antifreeze technology.<sup>113</sup> The company eventually expanded its focus in the year 2000 to create a new breed of transgenic salmon.<sup>114</sup> From that time the Waltham, Massachusetts based company<sup>115</sup> began its journey to create AquAdvantage salmon, a GMO fish product that AquaBounty Technologies is still trying to convince consumers, the food service industry, and the FDA of its cost effectiveness and safety for human consumption. The AquAdvantage Atlantic salmon variant, which arrives from AquaBounty Technologies in the form of salmon eggs,<sup>116</sup> contains a growth hormone gene from the faster-growing Chinook salmon, whose growth genes are activated yearround instead of just part of the year as with Atlantic salmon.<sup>117</sup> This mutation results in accelerated growth<sup>118</sup> and a considerably larger fish<sup>119</sup> than its traditional Atlantic counterpart. AquAdvantage salmon additionally require less feed than their non-GMO Atlantic salmon counterparts, thus reducing costs for aquaculture farmers.<sup>120</sup>

After eighteen years and a sixty million dollar battle,<sup>121</sup> the FDA's final approval of the product remains the final hurdle standing in the way of AquaBounty Technologies

<sup>116</sup> Background, AQUABOUNTY TECHNOLOGIES, *available at* http://www.aquabounty.com/PressRoom/ (last visited Aug. 12, 2013).

<sup>117</sup> Elaine Watson, AquaBounty CEO: We Continue to Communicate the Reality of Our Product ... Sen[.] Murkowski Should Know Better, June 25, 2013, available at http://www.foodnavigator-usa.com/R-D/AquaBounty-CEO-We-continue-to-battle-tocommunicate-the-reality-of-our-product-Sen-Murkowski-should-know-better (last visited Aug. 13, 2013).

<sup>&</sup>lt;sup>112</sup> *Id*.

 $<sup>^{113}</sup>$  Id.

<sup>&</sup>lt;sup>114</sup> *Id*.

<sup>&</sup>lt;sup>115</sup> *Id*.

<sup>&</sup>lt;sup>118</sup> *Id.* <sup>119</sup> *Id.* 

<sup>&</sup>lt;sup>120</sup> *Id*.

<sup>&</sup>lt;sup>121</sup> Ledford, *supra* note 65, at 17-18.

putting GMO salmon in the stream of U.S. commerce<sup>122</sup> without the burden of being labeled as GMO fish.<sup>123</sup> Unfortunately for AquaBounty Technologies its AquAdvantage salmon product has made numerous new and powerful foes, including members of the U.S. Congress. Earlier this year Republican Senator Lisa Murkowski of Alaska used her position on the U.S. Senate's Appropriations Committee to repackage an Alaska state legislature resolution into a rider on the U.S. Senate's 2014 Agriculture Appropriations Bill,<sup>124</sup> which would require GMO fish to be labeled.<sup>125</sup> If enacted, this bill will use the Commerce Clause to end-run the FDCA and require labeling for GMO fish across the entire stream of U.S. commerce. Democrat Senator Mark Begich, the other senator from Alaska, co-sponsored the amendment,<sup>126</sup> which only narrowly secured the Senate Appropriations Committee's approval in a 15:14 vote.<sup>127</sup> The rider's future as part of the larger agriculture bill is uncertain.

The Alaskan legislators root their stance against GMO fish in concerns that the new transgenic species might escape into the wild and do harm to the genetic makeup of the Pacific's wild salmon populations.<sup>128</sup> But the animus behind the Alaska-based initiative to thwart AquaBounty Technologies has already been made unequivocally clear. Senator Murkowski has publicly referred to AquAdvantage salmon as "Frankenfish,"<sup>129</sup> and Representative Don Young, Alaska's only U.S. House of

<sup>122</sup> *Id.*<sup>123</sup> Real, *supra* note 10.
<sup>124</sup> *Id.*<sup>125</sup> JUST LABEL IT!, *supra* note 5.
<sup>126</sup> *Id.*<sup>127</sup> *Id.*<sup>128</sup> Main, *supra* note 6.
<sup>129</sup> Watson, *supra* note 117.

Representatives member, was quoted in regard to Murkowski's amendment as saying, "If I can keep [support for Senator Murkowski's movement against GMO fish in U.S. Congress] up long enough, I can break [AquaBounty Technologies] and I admit that's what I'm trying to do."<sup>130</sup>

AquaBounty Technologies has expressed that it is not against labeling per se,<sup>131</sup> but prefers to label on a voluntary basis<sup>132</sup> since the FDA does not require the company to label their salmon as a GMO product.<sup>133</sup> This is because the FDA has established that AquaBounty's GMO fish are nutritionally and biologically the same as Atlantic salmon.<sup>134</sup> Additional labeling is only required in cases where food product differs in nutritional value, composition, safety, or processing methods compared to its traditional counterpart.<sup>135</sup>

AquaBounty Technologies' CEO Dr. Ron Stotish has expressed disappointment in Senator Murkowski's inflammatory language in calling AquAdvantage salmon "Frankenfish"<sup>136</sup> and claims the moniker has stuck as a negative label on his company.<sup>137</sup> He furthermore blames Murkowski's stance against GMO fish products as being at least a contributing factor to major food retailers such as Target, Giant Eagle, Meijer, Trader Joe's, Aldi, Whole Foods, Marsh, and Hy-Vee refusing to carry GMO fish.<sup>138</sup> In June

<sup>131</sup> Myths and Facts, AQUABOUNTY TECHNOLOGIES, *available at* <u>http://www.aquabounty.com/PressRoom/ - 11</u> (last visited Aug. 13, 2013).
 <sup>132</sup> Id.

<sup>&</sup>lt;sup>130</sup> *Id*.

<sup>&</sup>lt;sup>133</sup> *Id*.

<sup>&</sup>lt;sup>134</sup> *Id*.

<sup>&</sup>lt;sup>135</sup> *Id*.

<sup>&</sup>lt;sup>136</sup> Watson, *supra* note 117.

<sup>&</sup>lt;sup>137</sup> *Id*.

<sup>&</sup>lt;sup>138</sup> Stephen Daniells, *GM Salmon: Target joins 58 other retailers to say no to GM fish*, May 30, 2013, FOOD NAVIGATOR USA, *available at* <u>http://www.foodnavigator-</u>

2013 Dr. Stotish was reported to claim that the recent legislative machinations to force labeling on his product is an "[A]ttempt to usurp legal authority for food labeling from the FDA where it has resided historically,"<sup>139</sup> and it was also reported that he believes Murkowski and her colleagues are trying "[T]o utilize labeling as a weapon for protection of economic interest."<sup>140</sup>

Dr. Stotish has explained his company's position that AquAdvantage salmon are not an economic threat<sup>141</sup> to Alaska's salmon industry since Alaska salmon is a branded product that is priced and distributed through entirely different channels.<sup>142</sup> The facts support Stotish's assertions: AquaBounty plans for its AquAdvantage salmon eggs to be produced in Canada<sup>143</sup> and those eggs to be farmed only in enclosed fish beds in the highlands of Panama<sup>144</sup> thus preventing exposure to wild fish. Even if an AquAdvantage salmon made its way into the wild and eventually mated, then the offspring, as Dr. Stotish explains, would be sterile and thus unable to propagate a new hybrid species in the wild.<sup>145</sup>

The Senate Appropriations Committee's resolution has not been the only political interference into AquAdvantage salmon's regulatory review process. In April 2012 the

http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/Genetic Engineering/GeneticallyEngineeredAnimals/UCM333105.pdf (last visited Aug. 14, 2013).

<sup>&</sup>lt;u>usa.com/Markets/GM-salmon-Target-joins-58-other-retailers-to-say-no-to-GM-fish</u> (last visited August 14, 2013).

<sup>&</sup>lt;sup>139</sup> Real, *supra* note 10.

 $<sup>^{140}</sup>$  *Id*.

<sup>&</sup>lt;sup>141</sup> *Id*.

<sup>&</sup>lt;sup>142</sup> *Id*.

<sup>&</sup>lt;sup>143</sup> U.S. FDA CTR. FOR VETERINARY MED., PRELIMINARY FINDING OF NO SIGNIFICANT IMPACT (2012),

 $<sup>^{144}</sup>$  Id.

<sup>&</sup>lt;sup>145</sup> Real, *supra* note 10.

White House quietly held from public disclosure a National Environmental Policy Act (NEPA) mandated environmental assessment<sup>146</sup> the FDA had previously conducted for AquAdvantage salmon.<sup>147</sup> The environmental impact assessment normally serves as the FDA's final scientific inquiry into a food product under agency review.<sup>148</sup> Slate.com reported that the delay was caused by an internal White House debate on whether an FDA approval of AquAdvantage salmon during Obama's presidency would "infuriate" a portion of the President's voting base.<sup>149</sup>

"This shouldn't be happening,"<sup>150</sup> said the Center for Science in the Public Interest's Biotechnology Director Gregory Jaffe,<sup>151</sup> who participated in a scientific review panel that unanimously endorsed the FDA's findings that GMO salmon was safe for human consumption.<sup>152</sup> Jaffe continued, "[W]e need science-based decisions made in a timely fashion. The public deserves this, and there are questions whether that is what's going on in this case."<sup>153</sup> The FDA ultimately granted a provisional approval for AquAdvantage salmon in releasing the NEPA mandated environmental assessment with a finding of "no significant environmental impact."<sup>154</sup> The public comment period ran

 $^{153}$  *Id*.

<sup>&</sup>lt;sup>146</sup> John Entine, White House Ends Its Interference in a Scientific Review, SLATE.COM, Dec. 21, 2012, available at
<u>http://www.slate.com/articles/health\_and\_science/science/2012/12/genetically\_modified\_salmon\_aquadvantage\_fda\_assessment\_is\_delayed\_possibly.html</u> (last visited Aug. 12, 2013).
<sup>147</sup> Id.
<sup>148</sup> Id.
<sup>149</sup> Id.
<sup>150</sup> Id.
<sup>151</sup> Id.
<sup>152</sup> Id.

<sup>&</sup>lt;sup>154</sup> U.S. FDA, *FDA Extends Comment Period on AquAdvantage Salmon Documents*, Feb. 13, 2013, *available at* 

until the end of April 2013,<sup>155</sup> but AquaBounty Technologies still awaits final approval or rejection to place its GMO salmon into the stream of U.S. commerce.<sup>156</sup>

A portion of the American public remains steadfast in their stance against GMO fish and voices their views through public advocacy and lobbying. American detractors of GMO fish complain that there have been no long-term safety studies on human consumption of GMO meat<sup>157</sup> and that the FDA's evaluation of the economic and environmental impact of products such as AquAdvantage is inadequate.<sup>158</sup> Advocacy group *Just Label It!* purports that polls of U.S. consumers reveal that ninety percent of American consumers desire to know more about the food they consume,<sup>159</sup> and the organization relies on those polls in imploring the United States government to give domestic consumers the ability to know which foods are genetically modified through additional labeling,<sup>160</sup> just as sixty-four other countries already do.<sup>161</sup>

### Part III: Is GMO Regulation an Accurate Predictor for Cultured Meat Regulation or Merely a "False Friend?"

### A. Cultured Meat and GMO: Marked by a Similar Firebrand.

http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm339270.htm (last visited Aug. 29, 2013).

<sup>161</sup> Labeling Around the World, JUST LABEL IT!, available at

<sup>&</sup>lt;sup>155</sup> Miller, *supra* note 57.

<sup>&</sup>lt;sup>156</sup> *Id*.

<sup>&</sup>lt;sup>157</sup> DOUG GURIAN-SHERMAN, CTR. FOR SCI. IN THE PUB. INT., *supra* note 9, at ii. <sup>158</sup>  $I_d$ 

<sup>&</sup>lt;sup>159</sup> Right to Know, JUST LABEL IT!, *available at* <u>http://justlabelit.org/right-to-know/</u> (last visited Aug. 13, 2013).

 $<sup>^{160}</sup>$  *Id*.

http://justlabelit.org/right-to-know/labeling-around-the-world/ (last visited Aug. 13, 2013).

Genetically modified foods are not a perfect analog to cultured meat technology. The first reason is technical, in that the production modalities and thinking behind the technologies diverge. The creators of GMO foods aim to re-write the genetic code of plant and animal species in order to increase food productivity of crops and livestock without fundamentally changing how the products are cultivated or reared.<sup>162</sup> Cultured meat technology, on the other hand, aims to create an entirely new, non-animal source through which meat and animal products are cultivated, shifting away from the rearing and slaughtering of an animal to growing non-transgenic food grade meat in a controlled environment.<sup>163</sup>

The technical differences between GMO foods and cultured meat products will probably result, if at all, in a divergent set of concerns raised about cultured meat by food activists as the product is rolled out to market. Critics of GMO foods are concerned about that technology's fundamental safety,<sup>164</sup> while cultured meat, technically a pure product without the genetic manipulation<sup>165</sup> distressing GMO critics,<sup>166</sup> will likely face another as yet unknown type of protest. Philosophies about how either product should be labeled differ, too, but only in principle. An often-voiced desire among those supportive of cultured meat is that they will want to know which type of meat is cultured so they can deliberately choose it in the marketplace.<sup>167</sup> This is interestingly the same thing that

<sup>&</sup>lt;sup>162</sup> Chaudry, *supra* note 85.

<sup>&</sup>lt;sup>163</sup> NEW HARVEST, *supra* note 1.

<sup>&</sup>lt;sup>164</sup> The Debate, JUST LABEL IT!, *available at* <u>http://justlabelit.org/about-ge-foods/safety/</u> (last visited Aug. 14, 2013).

<sup>&</sup>lt;sup>165</sup> NEW HARVEST, *supra* note 1.

<sup>&</sup>lt;sup>166</sup> JUST LABEL IT!, *supra* note 164.

<sup>&</sup>lt;sup>167</sup> Blog Poster (identity not disclosed), *Smart Balanced Meat: Introducing the World's First Low Fat Beef*, THE CULTURED MEAT BLOG (Mar. 12, 2010, 5:31 PM), *available at* 

critics of the FDA's handling of GMO foods want since the agency, as a general rule, does not impose additional labeling for GMO-derived food products.<sup>168</sup> Cultured meat proponents, however, are often against meat more generally, and take their position one step further by arguing that traditional meats derived from any process that involves the slaughter of an animal should carry a label similar to that of cigarettes, indicating that the product is derived from cruel, resource intensive, and ecologically damaging processes, and furthermore serves as a contributing cause to human cardiovascular disease and cancer.<sup>169</sup>

Notwithstanding, GMO foods are the closest available analog to cultured meat for two reasons. First, the FDA regulates both technologies<sup>170</sup> and it should be assumed that once cultured meat products are ready to be sold they would be subject to similar safety rigors by the government. Second, the reactions both types of food elicit among American consumers are similar on account of their novel, but unnatural, laboratory driven methods of producing meat.<sup>171</sup>

Like the Obama administration's acts to stall the FDA on account of the bulk of Democrat-leaning consumer protest against GMO fish,<sup>172</sup> it is not hard to imagine that cultured meat products may cause the same type of quandary. Certain activist groups

http://culturedmeat.blogspot.com/2010/03/smart-balanced-meat-introducing-worlds.html (last visited Aug. 14, 2013).

<sup>&</sup>lt;sup>168</sup> AQUABOUNTY TECHNOLOGIES, *supra* note 131.

<sup>&</sup>lt;sup>169</sup> Blog Poster (identity not disclosed), *supra* note 167.

<sup>&</sup>lt;sup>170</sup> Email from Andras Forgacs, CEO, Modern Meadow, to Mallory E. McLaren, Juris Dr. Candidate, Seton Hall University School of Law, Re: "Regulatory Question in Re Bioprinting & In Vitro Meats," (Mar. 19, 2013, 6:33 PM) (on file with author).

<sup>&</sup>lt;sup>171</sup> *Compare* note 159 (JustLabelIt.org's argument as to why current GMO safety review processes are inadequate in light of the organization's suspicions of the negative health ramifications of the genetic re-engineering of food) *with* note 47 (Erler's discussion of consumer hesitation in response to cultured meat products).

<sup>&</sup>lt;sup>172</sup> Miller, *supra* note 57.

might attempt to politically charge the issue of cultured meat's regulatory approval. Political interference could ensue and place undue pressure on the FDA's administrative process, thus hindering administrative autonomy and harming the guarantee of procedural due process found in a normal FDA approval or rejection. It is both hypocritical, against the interest of justice, and flatly unacceptable for our government to permit such a state of affairs in light of the rule of law being held as a core American value that we strive to adhere to.<sup>173</sup> Things must change if administrative fairness is to remain intact.

## B. The Endless (and Possibly Unconstitutional) Battle Against GMO Meat: Is It

### Worth It for Either Side?

Strong indications exist that the FDA's administrative process has been unduly interfered with on account of the Obama administration's misguided interpretation of Article II of the U.S. Constitution.<sup>174</sup> Article II requires the President to "Take care the Laws be faithfully executed,"<sup>175</sup> but also allows broad discretion in determining the method of enforcement<sup>176</sup> – including refusal to enforce a law he believes is unconstitutional.<sup>177</sup> In a recent Wall Street Journal opinion article Professor Michael W. McConnell of Stanford Law School explains that the Obama administration's current

<u>http://www.americanbar.org/content/dam/aba/migrated/publiced/features/Part1DialogueR</u> <u>OL.authcheckdam.pdf</u> (last visited Aug. 15, 2013).

<sup>&</sup>lt;sup>173</sup> AM. B. ASS'N. DIVISION FOR PUB. EDUC., *What Is the Rule of Law* (creation date not disclosed), *available at* 

<sup>&</sup>lt;sup>174</sup> U.S. CONST. ART. II, § 3.

<sup>&</sup>lt;sup>175</sup> *Id*.

<sup>&</sup>lt;sup>176</sup> Miller, *supra* note 57.

<sup>&</sup>lt;sup>177</sup> Michael W. McConnell, *Obama Suspends the Law*, WALL ST. J., July 9, 2013, at A13, *available at* 

http://online.wsj.com/article/SB10001424127887323823004578591503509555268.html (last visited Aug. 15, 2013).

position on various issues, among them GMO fish, would be strengthened if the President made a statement that he believes the FDA's administrative process for AquAdvantage salmon is unconstitutional, and then explains the grounds upon which he bases his view.<sup>178</sup> But presidential discretion, McConnell explains, does not include the right to refuse to enforce a law on the basis of policy<sup>179</sup> as President Obama seems to be doing through his administration's apparent interference in AquAdvantage salmon's FDA approval.

Henry I. Miller of Forbes Magazine referenced Professor McConnell<sup>180</sup> in a later opinion article when he pointedly accused the Obama administration of overstepping the bounds of executive discretion<sup>181</sup> by interfering in the FDA's procedures with AquAdvantage salmon in order to appease the Democratic Party's base.<sup>182</sup> Miller's conclusion is that the President's actions are ignorant, cynical, and violate due process.<sup>183</sup>

The question of what exactly will happen when the FDA is presented with an application to approve a cultured meat product is unknown because it is not possible to predict the future. But it seems reasonable to conclude, independent of political reform on the administrative front, that both the U.S. government and reasonably-minded food advocates will eventually understand that cultured meat on store shelves is a comparatively better outcome than GMO meat dominating the market, and would act accordingly.

<sup>&</sup>lt;sup>178</sup> *Id*.

<sup>&</sup>lt;sup>179</sup> *Id*.

<sup>&</sup>lt;sup>180</sup> Miller, *supra* note 57.

 $<sup>^{181}</sup>_{192}$  Id.

 $<sup>^{182}</sup>_{192}$  Id.

<sup>&</sup>lt;sup>183</sup> *Id*.

### IV. How Public Dialog about Cultured Meat Will Improve Cultured Meat Technology's Chances of Success and Promote Better Transparency in Governance.

### A. Parsing Cultured Meat Technology from GMO Technology Is a Must.

This paper admittedly takes strides to compare cultured meat to GMO foods. But this is only due to a dearth of more appropriate analogs to examine how U.S. regulatory and political processes treat cutting edge food technologies. It is indeed crucial that cultured meat be examined on its own merits and dissociated from GMO food technology because GMO foods will never possess positive attributes that cultured meat does: genetic purity,<sup>184</sup> careful manufacture<sup>185</sup> from the point of creation to the point of packaging, and a near guarantee of humane sourcing<sup>186</sup> once the technology scales up. In fact, cultured meat could even serve as a remedy to GMO meats by making them obsolete, thus eliminating fears about their future prevalence in the marketplace.

The similarities between GMO foods and cultured meat end in their shared beginnings in a laboratory. GMO foods spend far less time in the protective environment of a laboratory, unlike the more meticulous, controlled cultivation of cultured meat products. Once a GMO organism develops beyond the seed or egg phase it is usually grown in field or fishery and exposed to the elements. The organism then almost invariably becomes subjected to adulterating factors that make food unsafe for human consumption: pesticides, antibiotics, and hormones,<sup>187</sup> just to name a few.

<sup>&</sup>lt;sup>184</sup> NEW HARVEST, *supra* note 1.

<sup>&</sup>lt;sup>185</sup> Id.

<sup>&</sup>lt;sup>186</sup> Bhat & Bhat, *supra* note 14, at 451-452.

<sup>&</sup>lt;sup>187</sup> Hyena, *supra* note 76.

As yet, however, minimal public discourse has been undertaken to create awareness, neither that cultured meat is created through a completely different process that requires little to no chemical or pharmacological manipulation, nor of its origin from stem cells. The U.S. television news media has not helped the situation. Anchors frequently refer to cultured meat as "test tube hamburgers" and show a visibly negative reaction when reporting on the topic that denotes unease or disgust.<sup>188</sup> Biased television news reporting seriously and unfairly tarnishes cultured meat technology's public image and is irresponsible journalism, since so many people receive their news and formulate opinions through what they see and hear on television. Cultured meat advocates should immediately begin initiating more dialogs with the purpose of informing journalists and persuading the public if cultured meat technology is to avoid the unjust outcome of being briefly explored and unfairly discarded as a waste of scientific resources.

### B. Clarifying Cultured Meat's Eventual Necessity and Inevitability.

Cultured meat could eventually become a necessary staple to sustainably feed a global population growing at unprecedented rates. In Asia, the powerhouse economies of China<sup>189</sup> and India<sup>190</sup> are rapidly raising massive numbers of their people from poverty. As inhabitants of these densely populated regions of the world become more able to afford better nutrition, it should be inferred that these millions of increasingly affluent

<sup>189</sup> Dominic Barton, *Half a Billion: China's Middle Class Consumers*, THE DIPLOMAT, May 30, 2013, *available at* <u>http://thediplomat.com/pacific-money/2013/05/30/half-a-billion-chinas-middle-class-consumers/</u> (last visited Aug. 29, 2013).

<sup>190</sup> Eric D. Beinhocker et al., *Tracking the Growth of India's Middle Class*, THE MCKINSEY QUARTERLY, no. 3, 2007 at 54-59, *available at* http://www.genesis.iitm.ac.in/downloads/resources/startup/tracking%20the%20growth%

<sup>&</sup>lt;sup>188</sup> Jansing & Co. (MSNBC television news broadcast Aug. 22, 2013).

<sup>20</sup>of%20indian%20middle%20class.pdf (last visited Aug. 29, 2013).

consumers would create more demand for diets that include more servings of meat.<sup>191</sup> Conventional agricultural modalities will probably not be able to keep pace with need, and food shortages, hyper-inflated food prices, and irreversible damage to the environment could ultimately result.

Negative outcomes such as these can be avoided if cultured meat becomes a meaningful piece of the global nutrition puzzle. But in order to make the technology available in time to avert food or agriculture related crises, cultured meat science is going to require more aggressive development starting now.

### C. Cultured Meat: An Unlikely Vehicle to Promote Governmental Transparency?

Cultured meat advocates stand to benefit from hindsight by learning lessons from the ongoing struggle for federal approval and social acceptance that GMO food interests have endured over the last eighteen years.<sup>192</sup> Arguably the most valuable of these lessons is that the dealings of the U.S. federal legislative and executive bodies as they interact with regulatory agencies like the FDA are often opaque. As has been witnessed over the past few years in the case of AquAdvantage salmon, lack of transparency in governance can cause statutorily mandated procedures such as the FDA's review processes to take a back seat to political pressures when the President's or a politician's voting base compels action to interfere in agency workings.

It is beyond the scope of this paper to speculate on mechanisms to ensure that administrative agencies get the autonomy required for proper function in the future. But one thing is sure: any measure taken will be preceded by greater numbers of citizens and

<sup>191</sup> Id.

<sup>&</sup>lt;sup>192</sup> Ledford, *supra* note 65, at 17-18.

stakeholders becoming aware that undue political pressure could stymie American technological progress, which would hopefully inspire the action of concerned citizens to ensure that the United States remains a science-friendly nation.

### Conclusion

The idea of cultured meat seemed inevitable to Winston Churchill eighty-one years ago in his 1932 essay "Fifty Years Hence" where he wrote, "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."<sup>193</sup> Churchill certainly had vision, because this is exactly what Drs. Post, Forgacs, and Brown, among others, are doing now.

Unlike Churchill, who used his essay to make futuristic dreamers of the readers, this paper's aims are simple. The first aim is to show the reader that the intervening years since Churchill's essay have provided humans the scientific means to begin the process of making cultured meat a feasible food medium. The second aim is to make the reader understand that cultured meat will ultimately become a necessary food staple to ensure that the world's population, whose numbers are spiraling ever upward, are able to be sustainably fed. Third is to call attention to the unnecessary cruelty and deleterious ecological effects that animal husbandry has, and that cultured meat technology provides a meaningful solution to abate the resulting evils taken out on our fellow creatures and the planet.

The last aim of this paper, and perhaps the most relevant to the immediate time frame, is to convince the reader that it is utterly irresponsible to continue wasting

<sup>&</sup>lt;sup>193</sup> Winston Churchill, Fifty Years Hence, in THOUGHTS & ADVENTURES 269, 276 (1932).

resources on further GMO development, particularly GMO meat development, when so many consumers will continue to vehemently reject it. This is particularly true when factoring in the dawn of cultured meat technology, because once it is scaled up it will serve as a disruptive innovation that will make GMO meat a relic of the past.