Genetic Engineering: How can a safe application be ensured while leaving no one behind?

Abstract:

Genetic engineering is a technology which has the potential to revolutionize a plethora of characteristics that distinguish our society. Of all issues of concern, the focus was set on political and moral aspects and closes with the limits of this innovation. This threefold structure accompanies the readers on their way to gain a further insight into the keenly emotionally, but also very scientifically discussed topic. In the first part, the politics will be discussed with the example of agricultural implications and the enacted limitations by public policy set to organize research activity. The moral conclusions and proposals for ethical restrictions of a human application of bioengineering follow. Lastly, the limits of genetic engineering are summarized taking into account the previous arguments. On the basis of these aspects, a closer look on the most challenging implications leads to an overview of emerging arguments. In conclusion, the representation of different viewpoints will be evaluated. Prerequisites needed for a reliable, safe use finish this essay.

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Introduction

Many of the past perceptions of the future have been rather inaccurate, at least to a degree that can be judged today. Especially the media has had a crave for stories of the future ever since. Alien-admirers, astronaut-addicts and star-seekers are no novelty. Luckily, we have saved a media record of anything published on the future through our 21st century all-rounder, the Internet. After thorough analysis, the past perceptions of the future show:

1.) What earlier humans strived for in the future,

2.) How these aims were altered throughout the years and

3.) That the extolled „future“ has shown to be not as terrible as some representatives of the prepper-community feared but, on the other hand, did not keep up with the gloomy dreams of ancient ambitionists.

To be fair, some of the predictions were aimed at a far more distant future, which is not reached at the current state of time, and which therefore should not be judged upon, as stated above.

The future seems to be interesting not only for the general population: There are entire research professions specializing in everything yet-to-come. To cover every research distinction connected to genetic engineering on the future would imply a table of contents which would not even fit into a book the size of the Bibel. Therefore, this essay limits itself on the topic of „genetic engineering“, using the example of GMO foods for the political aspects and human genome alterations for the discussion of the moral implications.

Genetic engineering is the „direct manipulation of DNA to alter characteristics (phenotype) of an organism in a particular way“[1] or „the group of applied techniques of genetics and biotechnology used to cut up and join together genetic material and especially DNA from one or more species of organism and to introduce the result into an organism in order to change one or more of its characteristics“[2].

To use the promising techniques apparently implies to alter DNA, which could be further classified into genomic DNA (gDNA), extrachromosomal DNA, copyDNA (cDNA) or the like. Possible is the alteration of existing genes, introduction of new genes or gene deletion. We discern somatic and germline DNA manipulation. Possibly, not only DNA but also RNA could be edited, which is significant especially in proteins or the regulation of DNA. (Hier die Epigenetics Revolution-Anekdote einfügen!!!)

We will now begin to evaluate the politics, morals and limits of genetic engineering.

Politics

The political body should provide the framework for the introduction of any technique introduced to the human society. In particular, especially for the implementation of those with the potential to impact the rights of others. Although there are forms of societies which would place the emphasis on the total autonomy of the consumers without any government, it is clear to see that enforcement of rights is, in those cases, for the government hardly possible and the discussion of GMO-policies would vaporize. We will therefore concentrate on political issues in societies, where the government has the right to provide rules.

Let us assume that we now have a government which is in the position to decide whether genetic engineering should be legalized: Let us take a look at a first case.

CRISPRD

Methods such as CRISPR-Cas9 or Zinc Finger Proteins are common methods of genetic engineering. For the production of genetically modified food, CRISPR-Cas9 can be used to introduce more efficient genes into the plant genome which could result in greater harvests, flourishing crops and even better tastes.

Formerly, plant breeders used to invest years in traditional breeding, by e.g. mating female and male plants to create a more potent offspring. With modern technologies, changes in the genome which farmers in Mendel's tradition waited years for can be introduced almost instantly. Formerly, there was no guaranty in the random mating process for the desired sequence to be passed on and the chances for this to happen remained pitiful in most cases.

How should authorities handle this situation, in which a bare acceleration of natural processes occurs and no further introductions are performed? The USDA ruled in March 2018[3] that these cases of natural processes, which could happen anyway, don't require any regulation. With it's recent step, the USDA pioneers the way for improved crops. On the other hand, the EU still embraces the precautionary principle, which should work against policy proposals that lack proper scientific evidence for harmlessness. This is a noble premise to pursue, when there is no sufficient research basis. But, the Europeans even took a step back with the ruling that „Gene-edited crops should be subject to the same stringent regulations as conventional genetically modified (GM) organisms"[4].

Might the European skepticism be appropriate or did questionable critics just play out their misinformation well?

Certainly, CRISPR-Cas9 is disputable as it can induce damages very far from the target region and therefore can possibly miss specificity.[5] Some scientists would counter that gene-editing with CRISPR-Cas9 does not involve only one experiment, which, if successful, leads to a new, widespread plant species. Often times, it involves hundreds of attempts and approaches.

Those cases, in which unintended mutations occur, would just not be developed. Although, as we realize, there should not be any paranoia or even anxiety, some NGO's do a fairly great job at their promotion.

Changes in agriculture

Greenpeace talks of a „threat of GE [genetic engineering, e.n.]“[6] and a missing „adequate scientific understanding of their impact on the environment and human health.“[6]

It is a true argument that we do not have a complete overview of what happens through cross-pollination. This argument is especially relevant for corn, as other crops such as wheat, barley and rice self-pollinate while maize has separate female and male plants. Science declares that „most of pollen settles within 20 to 50 feet (6 to 15 m) of the donor plant“[7] and their pollen „is only viable for 18 to 24 hours“[7]. As it becomes clear, the chance for cross-pollination is low, but not insignificant. Phrases by protesters such as "without corn, there is no country"[8] even suggest a state-threatening curse in genetically engineered crops. In corn crops, we can distinguish super-sweet corn from regular corn. Although they are harvested from different fields, some pollen could travel from one field to the other and introduce different traits to the plant. The occasional super-sweet butter-corn in a steakhouse has never been completely evitable for decades of ancient, conventional farming and can remain a surprising culinary conincidence, but only for a low decimal of our society. From a medical perspective, there is „little documented evidence that GM crops are potentially toxic“[9]. The allergenic potential, in contrast, has been shown to be evident when crops are genetically modified. Still, these cases, in which allergens are incorporated into the pollen, will be sorted before being placed on the market. Furthermore, genetic engineering can be used to „*decrease* the levels of allergens present in plants by reducing expression levels of the relevant genes.“[10]

GMO foods have been released to the environment already years ago, which has denoted a cesura for our world as we will be incapable of entirely eliminating the implemented genes from our nature again. Unfortunately, „clean“ foods with practically only one ingredient have been rare all the way. Even EU officials acknowledged: „This is something that is not particular to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure.“[9] In Europe, it was set „a threshold of no higher than 0,9%“[11] GMO traces in organic equivalents, while e.g. in Japan it’s a 5% limit.[12]

Novel foods will have to undergo authorisation processes before being introduced to a certain market. Every food authorisation in Europe will have undergone a consultation by the European Food Safety Authority (EFSA). Interestingly, a new regulation allows market placement of a third country product if a „history of consumption“[13] can provide evidence of safety. Many GMO foods from other countries do have those „histories of consumption“ and safety. However, the EFSA can still raise concerns if applicable.

Food safety does not end at EFSA vetting, but also includes adequate labeling, which has often been discussed. When do genetically modified foods need particular identification?

In my opinion, GMO foods should always be labeled, if bioengineering has been used for their creation. This certainly imposes some issues: As discussed earlier, it’s possible to introduce new genes to a plant without using genetic engineering, but instead hoping to irradiate the desired genes or hoping for „accidental“ mutations. Furthermore, it is almost impossible to specify what is natural to a plant: Many introduced genes will just be moved from related organic plant genomes by methods similar to „copy & paste“. Would the new plant still be described „unnatural“?

Experience shows that waiting for the sequence to be implemented just by measures of chance is expensive and time-consuming. This method will, in a free market, only be used for products of promising sales and revenue prospects. This technology will have difficulties to receive widespread use, because many foods of less margins with room for improvement could only edited through genetic engineering (GE) and only through GE use less scarce agriculture fields and be resistent against pests. Genetic engineering therefore could help to equate big agriculture firms with their smaller, less prosperous competitors which then receive a chance to play in the upper league.

The consumer should be permitted to decide whether his food does include GMO's.

In the U.S., „a new rule […] would require food manufacturers and other entities that label foods for retail sale to disclose information about BE [bioengineered, e.n.] food and BE food ingredient content."[14] The new system was meant to cover more ingredients and provide clear information.

Doubts and outlook

Some opponents try to mix up inherent, implemented herbicides in the plant genome with the usage of controversial plant protection tools such as glyphosate to synthesize a pamphlet connecting two major opponents, GMOs and Glyphosate, convoyed in a menacing brigade by obscure scientists and big pharma, threatening European agriculture.

Doubts are important. It is surely crucial to be wakeful when it comes to modified organisms in our nature. Nobody will eyelessly agree on releasing untested engineered plants and organisms into our world. Since this forms an overshadowing idea above all arguments, we should not give any room to those participants of the discussion conveying arguments based on misinformation and false claims. This addresses both NGO's, which in many cases embrace complete rejections of any genetic engineering in agriculture without recognizing possible advantages especially for those most in need, and agricultural companies or advisors speaking of gene movement from „conventional to organic crops"[15], thereby insinuating that genetically engineered crops as the regular method of farming vs. the „odd", organic farming (For maize, this may be true, but the semantics still seems manipulative).

Genetic engineering could ease the burden of political leaders and agricultural companies to provide seeds with the potential to the feed the world in times where growing figures of the world's inhabitants, which are expected to hit the mark of 10 billion people in 2055[16], show future challenges to prevent mass starvings and deaths. By pursuing this path, years of research and tens of millions of dollars[17] can be saved.

Public policy should therefore allow genetic engineering in foods but exclude genetically modified products for human or animal consumption if the observed genetic changes could involve

1.) genetic instability or further, unexpected changes in the plant DNA,

2.) induction of genome changes in the respective organism or

3.) other alterations of the human genome, including possible transformations causing cancer, harming the individual.

Morals

„A child of Socrates, says Aristotle, is apt to have the characteristics as Socrates.“[18]

Even the ancient Greeks had a grasp that the phenotype relates to the genotype, which is a reallocated composition of the parental genome. Although we now distinguish that it's not characteristics that are inherited but the genes, the relation between inherited alleles and certain expressed traits is clear. As this connection exists and has been shown to be a significant factor when it comes to pathogenesis in many cases, why does hesitation and anxiety remain in the way of possible improvements through bioengineering? We will try to split the topic into its fractions and examine, whether the expressed fears do have any justified reason.

Before discussing the morals, we should make ourselves aware of possible biases affecting our thinking, such as the status quo bias: Nick Bostrom from Oxford's Future of Humanity Institute describes the status quo bias as „the preference for the status quo just because it's the status quo“.[19] Cognitive psychologists have shown this effect in various experiments. The effect seems „irrational“[2] and „inappropriate“[2].

In order to defend themselves, some people argue that the decision to stick with a preference is „just“ a preference for the status quo. But, this effect has also been explained away by means as changing the wording of the alternatives to a, for most participants, more convincing prose and thereby improving their admirance for the alternative.

How does the status quo bias affect genetic engineering? In a way, it could nudge us to think that our current aversion to the new possibilities is a mere cognitive error: If there was a medically safe potion, created by genetic engineering, which could improve average human intelligence, this could likely be ruled inappropriate due to status quo biased arguments. But, in contrast, if the pill would force stupidity on the society, this pill would be banned. As it becomes clear, stupidity is no overall ideal for the society, so why should we defend it?

Opposition to policies regarding positively the further use of genetic enhancement techniques might be severely impaired by biases of any stripe. But geneticists do not end arguments at biases. To gain a further insight into which morals have to be applied when assessing genetic engineering, we need to take a closer look.

Australian philosopher Peter Singer argues in his book „Practical Ethics“ (1980, 1993, 2011) for the „equal consideration of interests“ as a „minimal principle of equality“. This is different to the common concept that „treating everyone equally“ would mean to give „everybody the same amount of a scarce resource“. He is a pluralist about the Good.

Two persons, of which one suffers ginormous pain while the other only experiences little, would be treated according to the common concept of egality (monism about the Good) if everyone received one syringe of a bioengineered painkiller. This would still end up in one person, the more severely impaired, not receiving any improvement of the pain, while the pain of the other fades slightly. The overall pain is therefore only slightly reduced.

Singer argues the more fatally struck person should receive both syringes, as the overall pain of the considered group would be reduced to a greater amount compared to the option of equal treatment.[20] For Peter Singer, this concept corresponds to a „higher degree“ of egality.

The unborn life

Bioengineered painkillers are surely important, but may not be the reason why opponents of genetic engineering mount the barricades. Some of the most arousing opinions can be shown in the field of the unborn life.

Babies with severe conditions such as spina bifida used to die shortly after birth. With preimplantation genetic diagnosis, it has become possible to profile embryos and to detect diseases in the embryo before implantation. Along with the development of genetic engineering, the discussion of designer babies arose.

In theory, just like in plants, a human genome could be edited with tools of bioengineering. Some genes, such as HBB, which stands for the haemoglobin subunit beta[21], could be manipulated to be more efficient in the transport of oxygen. In professional sports competitions, the gap between the first and latter places is often explained by differences in their haemoglobin levels, which in top athletes tend to be greater and more efficient.

Once the responsible genes for certain traits are exactly allocated, critics fear that traits such as eye color or intelligence could be available for tiger-moms just like at a self-service buffet; in short: a configurator-like dystopia of the modern world could evolve.

Therapeutic benefits

Let's begin at the possible, therapeutic benefits: Genome editing could help curing formerly incurable diseases. We can not only edit genes which are naturally inherited but could make „genetic changes that cannot be inherited."[22]

Patients with β-thalassemia remain transfusion-dependent for their whole life due to incorrect production of haemoglobin. To heal the disease, allogenic hematopoietic stem cell transplantation of HLA-matched donors could be performed, but unfortunately, we lack enough donors for every patient to be treated. With the technologies of genetic engineering, it is now possible to heal affected persons via lentiviral vectors, which introduce the correct genes ex vivo into the patient's own, autogenic stem cells. After the procedure, the stem cells are returned into the patient's body and will start producing the correct haemoglobin protein.

Why can't we forestall the complex and expensive procedure, by including the correct haemoglobin-connected genes into the embryo's genome before development?

CRIPSR-Cas9 co-inventor Jennifer Doudna fears that „CRISPR will be used to create designer people"[23] as germline-alterations „would be passed down to children and subsequent generations, with unpredictable consequences."[24] We do have to acknowledge that at the current time, we are unable to foresee the entire set of implications that accompany possible germline-manipulations. After the 2015 Napa meeting, Doudna discussed the ethics of CRISPR on a global summit „attended by 500 scientists, ethicists, and others from 20 countries in Washington, D.C."[25] It ended up in a declaration[26] which „strongly discourage[s] […] any attempts at germline genome modification […] while […] ethical implications of such activity are discussed"[27].

It is accurate that we first need to discuss the implications before using that technology. I still believe that germline modifications could prove to be an inimitable way to cure diseases before

symptoms start. In diseases with clearly identified genes, not only somatic gene therapy, but also germline gene therapy could help healthcare rid some of the most cruel illnesses.

Borders of morality

Sheldon Krimsky from Tufts University argues that one would only use genetic engineering for two reasons: disease prevention and „enhancement“ of the genome to implement certain traits. In his opinion, the first argument is insufficient as „prenatal screening or preimplantation embryo diagnosis will suffice in most cases to prevent the birth“[28]. He then declares that the only remaining reason for germline genetic engineering would be embryonic gene improvement.

True is that the concerns over gene improvement will always persist when discussing genetic engineering. […] I would doubt that parents would just as well eliminate their offspring compared to healing them by bioengineering treatments. It might be true for especially severe diseases, but is dubious when thinking about the many different, comparably moderate illnesses such as asthma or diabetes. Many parents would prefer their children not to be born with coughing and shortness of breath or life-long dependency on substitutes when a cure is possible.

Second, he states that human traits are „complex and not only involve dozens if not hundreds of genes, but are the result of a complex mix of determinants, including nutrition, social and environmental factors, gene-to-gene interactions and epigenetic switches that are outside of the reductive chemistry of the DNA code.“[29] No scientist in favor of genetic engineering supposed that DNA will be 100% sufficient to fully bring about certain character traits. This argument is an example for a perfect solution fallacy. Just because the solution will not fully suffice to exactly steer human development away from the destinations „disease“ and „pain“, we should not simply abolish it.

Krimsky’s last argument focuses on the overall morality of the applied techniques. He see’s the possible genetic enhancement as grown out of „eugenics ideology that human perfection can be directed by genetics.“[30] Eugenics is „the science of improving the human species“[31] and „to reduce human suffering by “breeding out” disease, disabilities and so-called undesirable characteristics from the human population.“[32] The definition itself has a noble objective: Eradicating awful diseases. Though, after the high-jack by totalitarian regimes and agonizing outcomes, the once philanthropist thought left the limelight for outright detesting light.

Rejecting the use of technology just because it can be linked to a certain ideology is in my opinion scientifically arguable. Scientists regularly experience accusations claiming the immorality of research and their incoherency with specific sets of values. As researchers, we should not reject the use of genetic engineering just because an ideology also used it for it’s own purposes.

Still, we should question whether genetic engineering is morally acceptable and pay attention to previous misuse.

As we have seen before, we should not think that once the germline use of genetic engineering is enacted, we are free to manipulate wildly in the human genome. No doctor either would do this when treating a patient using the conventional methods of medicine. Clinical practice guidelines have been established[33] to be used in many countries not least to prevent mistreatments.

To sum this up, morals will always play a huge role when discussing genetic engineering. During evaluation, one should be aware of possible biases affecting our thinking. For a patient's well-being, these treatments should be legalized as they prevent pain, agony and early deaths. However, in our society, we furthermore evaluate other consequences such as potential effects on the society as a whole and the cooperation within. In conclusion, germline modifications of the human genome remain arguable, but considering their humongous potential for the prevention of diseases, we should be open to discover morally safe strategies for their implementation.

Limits

By now, we have seen that there exists a difference when we discuss somatic compared to germline DNA manipulation carried out by genetic engineering. In agriculture, CRISPR-Cas9 could bring about many changes needed to be introduced if the human population continues to grow at the same rate. The E.U. and the U.S. pursue different policy paths to gain control over genetic engineering. Distribution of engineered treatments could impose another difficulty. Formerly, patients with diseases of unfavourable prognoses had no chances to be treated. Early clinical studies can already show the humongous potential of gene therapies made possible by genetic engineering.

The difficulties in defining the limits of genetic engineering became apparent at the 2015 Napa meeting and the declaration afterwards. Although germline genome modifications were discouraged, it was acknowledged that the inofficial prohibition will prevail as long as „responsible uses of this technology, if any, [remain, e.n.] to be identified."[34] This does, in my opinion, represent a responsible self-regulation of the scientific community facing such a far-reaching technology. Key to all discussion and future research is making a clear distinction between genome editing in somatic cells and in germ cells. A voluntary moratorium seems to be an effective measure for researchers to define their own moral borders and should work, as long as every signatory stays loyal. Otherwise, state-wide legal prohibition has to follow.

For bioengineering in foods, the existing food safety authorities should acknowledge the possible prospects of genetic engineering not only for their particular nations or unions, but also for the worldwide supply of enough nutriments globally. An ease of regulation of genetically modified foods could, as long as extensive labeling and rigorous testing of newly developed foods are ensured, make improved and resistant foods possible which can positively affect human health. Although the limits might be less clear, they still exist. Food that harms or manipulates the human genome, even if only somatic cells, should not be made available. The way, whether by genetic engineering or organic farming, it is produced should not be limited by public policy. For livestock, food authorities might request further restrictions as animal ethics still apply.

Overall, genetic engineering remains a topic which has to be discussed not only in high-level meetings and secret gatherings, but recquires an inclusive approach to embed everyone in the argument. As the topic has already reached public attention, we have seen multiple protagonists taking a stand and arguing for their specific agenda. Some of them benefit from distributing false facts and claims, which occasionally have not been spreaded with intent, but just occured by relying on incorrectly evaluated data. For the use of genetic engineering in the health sector,

doctors will not least evaluate the eventual use according to guidelines such as Tomorrow's Doctors[35], following a holistic approach. Genetic engineering has the opportunity to promote improvement of crops, heal painful and incurable diseases and accelerate research in a wide range of fields, which can result in a prosperous, well-positioned global community of people, as long as we take care of everybody and leave no one behind.

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