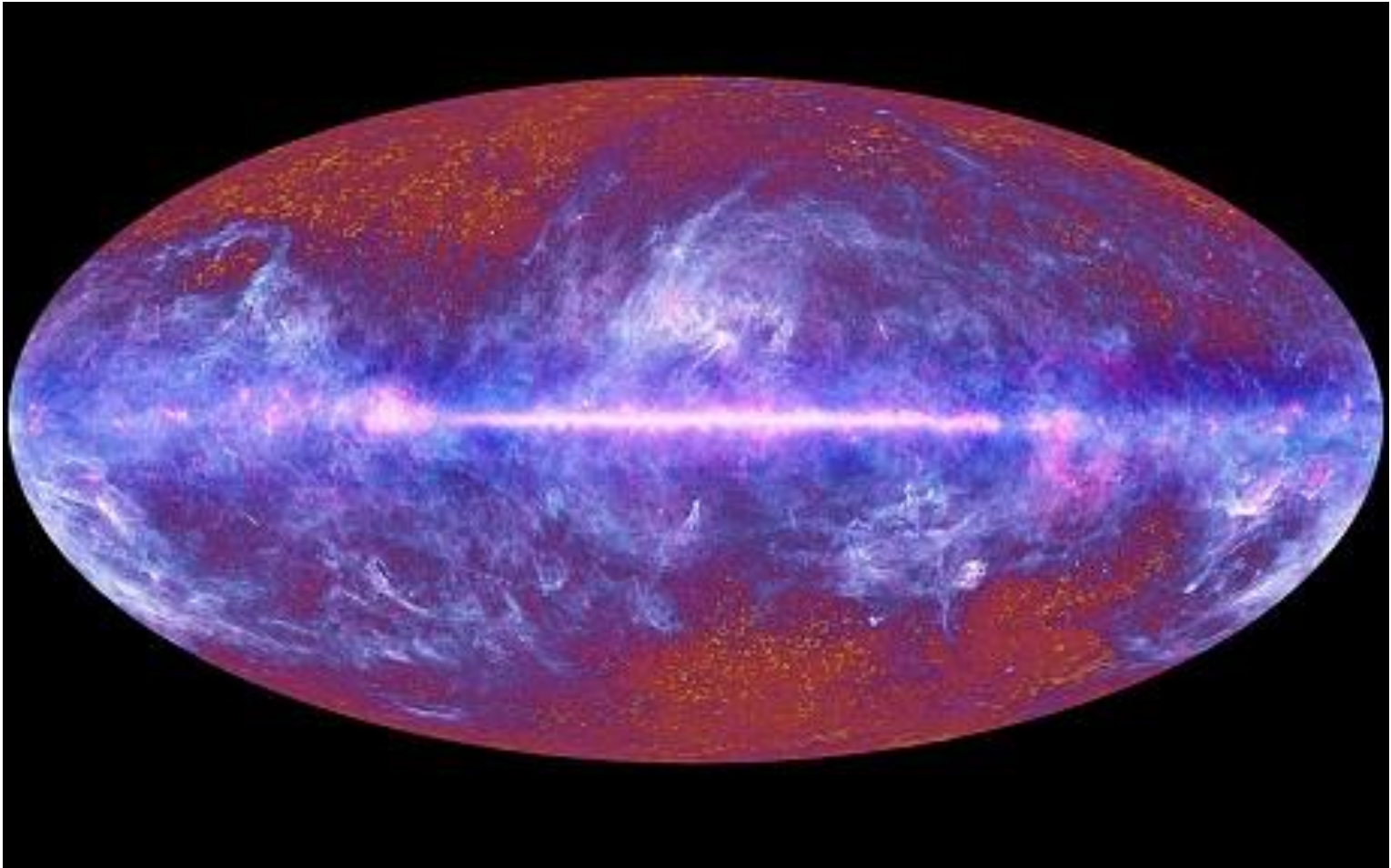


Genetic Engineering

A concept in need of environmental
assessment?

Kathryn Marsh – Sonairte, Organic Trust and the Irish
Environmental Network

In the beginning







Rising oxygen in the atmosphere, from cyanobacteria and algae, a warming climate and rising sea levels provided ideal conditions for new life-forms

Evolution happens

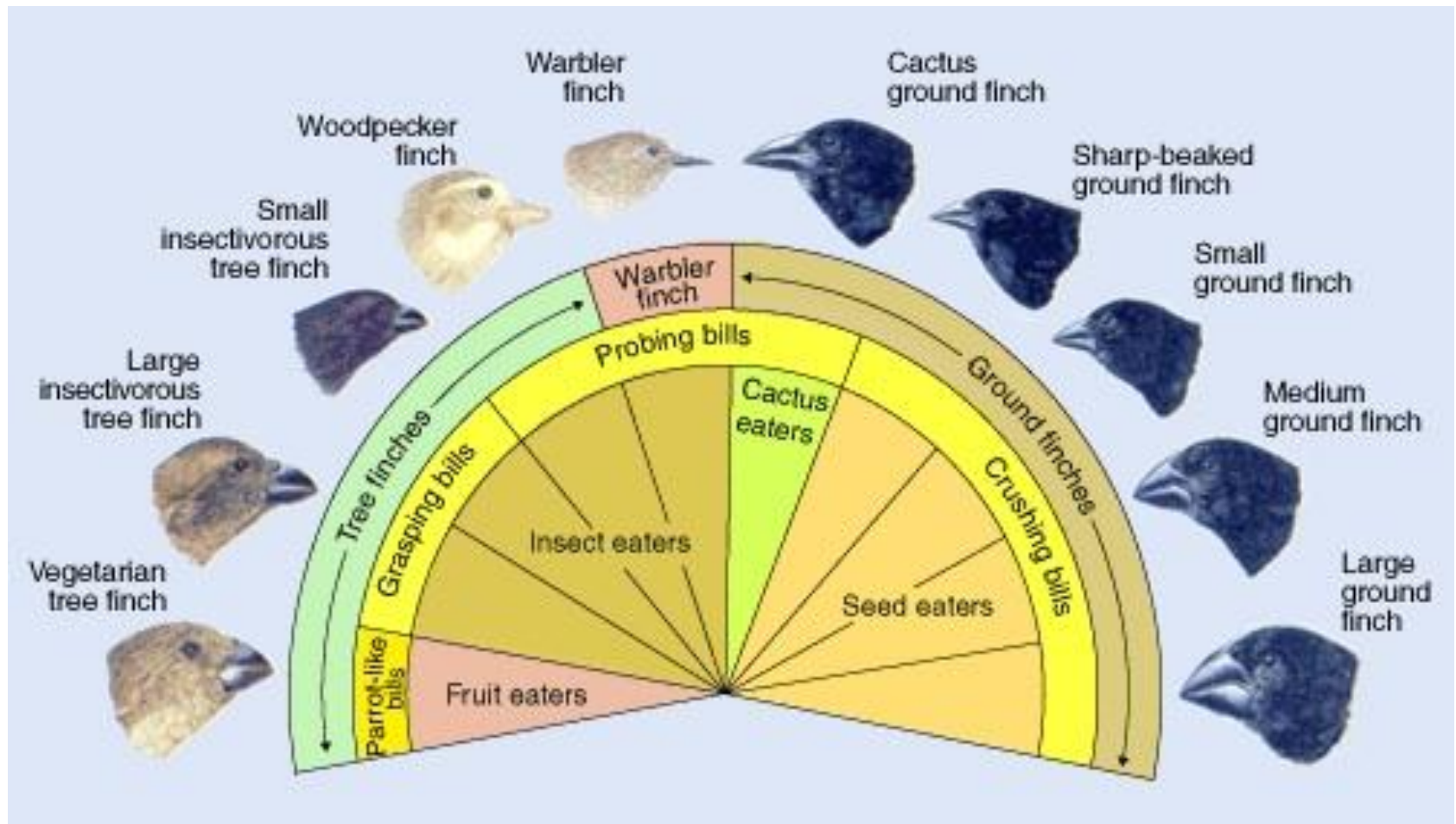
Natural selection

- Our environment shaped our evolution
- Organisms whose genetic make-up resulted in improved fitness prospered in their specific environment

G



Darwin's finches



And an insignificant hominid takes
200,000 years to dominate the
planet



Inventing agriculture
and intentionally modifying the
ecosystem it lives in

...with Genetic Engineering as one,
among many, of its tools

A genetically modified organism
has been “altered in a way that
does not occur naturally by mating
or recombination”

Normal reproduction

In normal reproduction, the chromosome rearrangements are precisely guided. The process works against defects occurring by using cellular mechanisms that have evolved over hundreds of thousands of years to preserve the order and information content of the genome of the species.

In contrast.....

Genetic engineering is devised by humans to meet their specific needs



The process of genetic engineering in plants

- Tissue from the plant to be genetically modified is placed in culture
- The new gene is inserted by either by a gene gun, which shoots the GM gene into the cells, or the GM gene is linked to a special piece of DNA present in the soil bacterium, *Agrobacterium tumefaciens*, which, when it infects a plant, carries the GM gene into the cells and can insert into the plant cell's DNA
- The culture is treated with chemicals to eliminate all the cells that have not incorporated the GM gene into their own DNA.
- The cells that survive this treatment are treated with plant hormones which stimulate them to proliferate and differentiate into small GM plants that can be transferred to soil.
- The GM plants which grow well are selected and those that express the new genes at high levels are selected as candidates for commercialisation..

An overly simplistic model

There is not one gene for one trait

On the contrary, each gene can be used in a variety of different ways depending on how it is regulated, the big thing is regulation.

Dr Tim Hubbard, Human Genetics group at the Sanger Institute in Cambridge, UK.

It is not more precise

- Genetic engineering forcibly introduces foreign DNA into the cells of a plant in an imprecise and uncontrolled process.
- The impact of other mutations that cause genes to produce harmful substances or lack important nutrients may not be visible because they may only occur at a subtle biochemical level or only under certain circumstances
- The role of bacteria and viruses used in the transfer mechanism should not be ignored

Gene transfer

- DNA uptake by bacteria
- DNA uptake during digestion
- Horizontal gene transfer by *A. tumefaciens*
- Gene transfer by viruses

“it can be argued that gene transfer via current GM techniques resembles the process of viral infection far more closely than it resembles traditional breeding”

Professor P Brown, College of Agriculture &
Environmental Science University of California Davis

In the 1980s public anxiety over the “new” technology (which had been around for quite a while), largely based on the “Yuk” factor, led to agitation for regulation within the European Union.

In Ireland this led to the setting up of the EPA’s GMO Advisory Committee

The new EU regulations were based on the Precautionary Principle

“If an action might cause severe or irreversible harm, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action.”

“Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible. Assuring its safety is the FDA’s job.”

Philip Angell, Monsanto’s director of corporate communications

“It is not foreseen that EFSA carry out such [safety] studies as the onus is on the [GM industry] applicant to demonstrate the safety of the GM product in question.”

European Food Safety Authority
(EFSA).

We are confronted with the most powerful technology the world has ever known, and it is being rapidly deployed with almost no thought whatsoever to its consequences.”

Dr Suzanne Wuerthele, US Environmental Protection Agency (EPA) toxicologist

Substantial equivalence

- first put forward by the Organisation for Economic Cooperation and Development (OECD)
- assumes that if a GMO contains similar amounts of a few basic components such as protein, fat, and carbohydrate as its non-GM counterpart, then the GMO is substantially equivalent to the non-GMO and no compulsory safety testing is required.

Biological relevance/normal variation

- In any population of a given species there will be a range of variation around the mean and some outliers
- If one re-defines the outliers as “normal”, then the concept can be used to mask statistical significance

Just how equivalent?

- In soils that reached only 25 °C during the day, genetically modified Monsanto beans grew just as well as conventional beans. But as the soil became warmer, the Monsanto plants appeared stunted. And in soils reaching 45 °C, the differences were marked.
- Plants carrying these genetic alterations have been shown to produce up to 20 per cent more lignin, the tough, woody form of cellulose: "We think it might make the plants more brittle,"

NK 603 maize (1)

- The new protein was not actually tested; instead, testing was undertaken on '*a similar protein*' as this was '*easier to obtain*'.

This approach was taken as a result of '*difficulties experienced in extracting the new genetically engineered protein*'.

It is difficult to justify such a methodology and no robust conclusions on toxicological issues can be made from such an experiment.

Furthermore, serious issues are raised, should the need arise to obtain further samples of the protein for toxicological analysis

NK 603 maize (2)

- When the whole plant is fed to laboratory animals, *statistically significant differences in average corpuscular volume and average corpuscular haemoglobin* was found in the blood of female rats given the higher dose. The EFSA accept the explanation by Monsanto that these statistical differences were ‘*artefacts*’. The EFSA also state that ‘*it was pointed out that the observed differences ... had no biological relevance*’.
- Changes in corpuscular volume can indicate incipient megaloblastic anaemia, and changes in haemoglobin may indicate problems with oxygen levels in the blood. It is not clear who suggested that this fact had no relevance, these findings, at the very least, merit further investigation. The study lasted 90 days and the life span of a rat is between 2 to 3 years.

NK 603 maize (3)

- A statistically significant difference in the weight of the fat pad between chicken fed NK 603 and chickens fed conventional maize was noted.
- This difference was not considered to have any 'biological relevance'.
- *It is difficult to have confidence in this statement as this was made after only 42 days testing.*
- Such testing must be repeated over longer time periods before any assumption of safety can be made.

Independent testing –worrying findings



A pseudo-scientific concept?

- *Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests.”*

Millstone E, Brunner E, Mayer S. Beyond “substantial equivalence”. *Nature*. 1999; 401(6753): 525–526.16

What independent testing?

No long-term rigorous safety testing of GMOs is required and regulatory assessments are based on data provided by the company that is applying to commercialise the crop.

Misreporting?

- In order to check data independent researchers have had to go through the courts to access it
- Re-analysis has often showed causes for concern

Research restrictions

- industry uses patent-based control of GM crops to restrict independent research.
- The GM industry restricts access to its products by independent researchers, so effects on health and the environment cannot be properly investigated.
- Research that has been suppressed includes assessments of health and environmental safety and agronomic performance of GM crops.
- Permission to study GM crops is withheld or made so difficult to obtain that research is effectively blocked. Researchers are often denied access to commercialised GM seed and the non-GM isogenic lines.

Attacks on Independent Researchers

Independent researchers who have published papers containing data that is not supportive of GMOs have been attacked by pro-GM industry groups and individuals.

The basis of these attacks has frequently been spurious.

Regulators and long term testing

- we don't know if changes commonly reported in short- and medium-term studies develop into serious disease.
- Such studies are not required by regulators.
- What is needed are long-term and multi-generational studies not only on Genetically Engineered Organisms but on other novel foods.

Stacked-trait crops are less rigorously tested than single-trait crops

- The assumption is made that if the traits are safe individually they will be safe in combination – no evidence for this
- The same assumption is made for agricultural chemicals
- The same is often made for medicines
- It is only when dangerous impacts are accidentally found and reported that action is taken to improve safety

What should be regulated?

- Products not processes
- Any novel food
- Genetically engineered – cisgenic as well as transgenic
- Mutagenes – however triggered
- Nanotechnology

How should it be regulated and at what stage?

- Regulatory Impact Assessments should be undertaken at the policy level
- Environmental Impact at the policy level
- User friendly application procedures
- User friendly and flexible testing
- Post approval and release monitoring

- The introduction of GM crops and their man-made genetic material into the wild leaves the door open for these genes to spread into the natural environment.
- This can happen by pollen and seed dispersal, and/or by interactions with other organisms sharing that environment.
- This has different impacts to those of the gene spread of local wild plants

Equivalence again – *Bacillus thuringiensis*

- Natural Bt toxin is different from the Bt toxin produced in GM plants. Natural Bt breaks down rapidly in daylight and only becomes toxic in the gut of the insect that eats it. It does not persist in the environment and is unlikely to find its way into animals or people that eat the crop.
- The GM plant is engineered to express Bt toxin protein in active form in every cell. The plant itself becomes a pesticide, and people and animals that eat the plant are eating a pesticide
- Increased exposure is leading to resistance

Glyphosate resistance

- Massive increase worldwide in the use of glyphosate. This crosses the placental barrier and increased birth defects have been found in areas with aerial spraying
- animal studies and test-tube studies on human cells show cell death and damage, damage to DNA, disruption of hormones, birth defects, and cancer.
- Increased glyphosate use leads to resistant weeds and more toxic herbicides being used. In the US 200 million acres of land are sprayed with Round Up every year. Giant Ragweed has developed which can survive 24 times the recommended dose of Round Up



Farm impacts

- Increased pesticide use
- Increased herbicide use
- Damage to non-target species
- Increased plant diseases – especially fusarium
- Horizontal gene transfer
- Glyphosate persists in the environment and is toxic to wildlife
- Glyphosate inhibits nutrient uptake and nitrogen fixation
- Economic impacts are variable
- Contamination of non-GM and organic crops

Fusarium in wheat after RoundUp



Mutations happen all the time in nature

- Mutations do happen all the time in nature
- Most of them are non-viable – they die
- Some are beneficial – they survive and widen the basis of the gene pool
- We do not modify the environment to ensure the survival of the non-viable mutations

Detecting harmful mutation

- It is not always possible to tell whether a GMO contains harmful mutations
- Selection is on the basis of the desired trait and undesirable traits may be (and have been) missed

Is Cisgenic safer?

- Cisgenic/intragenic foods are just as risky as any other GM food
- Inevitably, “intragenic” gene transfer uses sequences from viruses and bacteria

There are dangers in traditionally bred plants

Of course there are – there are dangers in wild plants.

If any plant is moved to a situation that suits it and where it has no naturally evolved controls it can become a problem.

Good examples in Ireland are rhododendrum ponticum and gunnera tinctoria.

(Japanese knotweed is at least edible)

And we all know many poisonous wild plants – but not on our dinner plates

Why do studies show GMOs are safe?

- Reviews of the scientific literature on the health risks of GM foods demonstrate that the studies that show safety are more likely to be industry-linked
- Re-analysis of data often shows that such studies do not demonstrate safety
- Limited human feeding studies showed unexpected outcomes

Why genetic engineering?

- GM crops are high yielding to feed the world's growing population.
- GM crops offer the best solution to problems of malnutrition
- GM crops offer the best protection against climate change

Feeding the world

- “If anyone tells you that GM is going to feed the world, tell them that it is not... To feed the world takes political and financial will.” – Steve Smith, head of GM company Novartis Seeds UK (now Syngenta)
- “Traditional breeding out-performs genetic engineering hands down. -Former US EPA and US FDA biotech specialist Dr Douglas Gurian-Sherman
- Agro-ecological farming makes better use of scarce land resources
- Small farms produce higher yields/hectare
- Existing landraces provide a wider range of adapted, nutritionally superior, higher yielding crops at a lower price
- Conventional breeding is quicker and cheaper than GM

The International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) 2009 report, a three-year collaborative study initiated by the World Bank, FAO, UNDP, WHO and signed by almost 60 countries (including Ireland) rejected the role of GM technologies in resolving hunger in the world.

Approximately 1,500,000,000 people are starving because of unjust economic policies and unfair trading, not because they lack genetically engineered food.

Real solutions to malnutrition

- Adequate incomes to buy food
- Access to land
- Peacekeeping and other political solutions
- Availability of a balanced diet - Vitamin A cannot be absorbed without fats
- Conventional breeding of locally adapted varieties and imports of suitable varieties from similar climates in other regions

Tackling micronutrient loss

- The developed world has for a long time taken micronutrients from the soil, processed them through the human gut and then dumped them into the rivers and oceans
- Efficient agriculture recycles nutrients

The role of evolution and traditional breeding

- Throughout the world wild species evolve to create a wide diversity within a single species or closely related species
- Traditional breeding creates a multitude of landraces adapted to local microclimates and soils. These give a huge reservoir of existing variability that can be translated to other situations affected by disease and climate change.



Why the emphasis on novel foods?

- Why is there not more emphasis on utilising existing landraces?
- Why is more money spent on producing novel foods than on traditional breeding

Who owns food? The patent issue

- Farmers who use GM crops find themselves dependent on the corporations supplying the seed and weed control.
- Many GM crops produce non-viable seeds thereby forcing farmers to buy new seed each year from the supply corporation.
- This leads to indebtedness for small farmers.
- The same applies to mutagenic crops

Is GM the best solution to climate change?

- One size fits all mind set
- Existence of huge range of climate adapted plants – there are 2000 indigenous rice varieties adapted to local microclimates
- Need for flexibility – GM limited by dependence on herbicides, fossil fuels, nitrogen, water
- Multiple traits needed for climate change resistance

Does Ireland need GM crops?

- What are the risks regarding the introduction of GM material into the wild?
- Who would benefit from the introduction of GM crops?
- Do consumers want food produced from GM crops?
- What will the implications be for Ireland's "green" image if GM crops are introduced into Ireland.

A broken Irish regulatory system

- Fragmentation of responsibility between departments
- Constraints on actions
- Lack of coordination
- Non-industry stakeholder input limited to GMOAC

The Science Deficit

- Environmental NGOs have played a leading role in forcing the Dept of Education to include science teaching in primary schools
- Why do our children have to take three language subjects at Leaving Cert and no science?
- It is essential that the population is trained to evaluate information and reject dogma, whether it comes from the “Yuk” faction, the Daily Mail Health Supplements or the GM industry

The statistics deficit

- We need to teach scientists to better evaluate statistics
- We need to teach doctors how to better evaluate statistics
- We need to teach the general population how to evaluate statistics

Blue Skies Research

- Industry can only afford to support short to medium impact research
- It is therefore essential that governments support long term research, regardless of short term impact

Nanotechnology

- The concept is so little understood that it is hard to find two nanotechnologists who define it in the same way
- Lack of understanding of the quantum realm
- Completely unregulated

Long term systemic problems

- Substantial equivalence
- No independent testing required
- Independent testing shows worrying findings
- Suppression of research
- No ongoing surveillance mechanisms
- Financial pressure by US government and biotechnology companies

The complex relationships between plants and animals must be protected in order to maintain and enhance the stability of our life support system – Irish Environmental Pillar policy statement

*"only a small portion of the
world is known with accuracy."*

Charles Darwin



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