Response to the Commission Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16

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1. Amending the GMO Directive

The Commission consultation on novel genomic technique is a response to the CJEU's ruling in C-528/16 - *Confédération paysanne and Other*[1] In this judgement the CJEU concluded that novel genomic techniques (NGT) could and should be defined as genetically modified organisms (GMOs). As such NGTs, like GMO's are subject to environmental risk assessment and authorisation requirements.[2] The European Commission's scientific advisers point out that applied gene editing technologies have evolved rapidly in the past two decades[3] and definitions dating to 2001 are no longer appropriate to 2021.[4] The speed with which this particular technology has and continues to advance, however, makes regulatory attempts to control it comparable to "trying to hit a moving target."[5] The challenge for the EU, therefore is to enact regulatory reform that is "resilient, future-proof and capable of being uniformly applied whilst contributing to a sustainable agri-food system."[6]

1.1 Why definitions are critical to a successful reform

Whilst the ruling in *Confédération* is clear – applied NGTs fall under existing GMO legislation - a number of important gaps in the CJEU's legal reasoning nevertheless remain. Chief amongst them definitions relating *inter alia*, to "novel gene technologies" "conventional use" "long safety record" "traditional use", "natural processes" "organic" and "sustainable agriculture".[7] The concern is that a failure to find adequate, long-lasting definitions today will result in unstable and inconsistent legislation tomorrow. To avoid existing pitfalls and repeating past mistakes the EU, I propose, should rely on *legal* not *technocratic* and *scientific* definitions. Not only will this approach create settled, consistently applied law it will assist the EU establish how, when and where the precautionary principle is triggered in GMO environmental risk regulation.

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2. The limits of technological and scientific definition in environmental risk regulation

2.1 Limits to relying on technological definitions of novel gene technologies

Ever since the EU chose to establish institutions resembling a US-style administrative state at the turn of the millennium EU secondary legislation has sought to base environmental and public health risk regulation on scientific, technocratic definitions. We see this approach in Directive 2001/18/EC where GMO's are defined technocratically.[8] The challenge with the existing technocratic definition, however, is that it is static bounded by a technology frozen in time and space. The commercialisation of gene technology, as the Commission acknowledges is a "fast moving target" constantly evolving and mutating in unexpected ways. Strengthening the GMO Directive should therefore avoid trying to set rigid technocratic definitions that are incapable of evolving alongside technological innovations.

2.2 Limits to relying on a scientific definitions of living organisms

Nor should the Commission be tempted to define applied, novel gene technologies scientifically. Natural and environmental scientists are still in the process of expanding mankind's knowledge about the billions of species existing in the natural biosphere.[9] Knowledge acquisition on how exactly living organisms interact with each other, with us and with the environment they live in is evolving and changing as swiftly as gene editing technology is advancing. So too is scientific knowledge with regard to how species are related to and inter-act with each other in the natural world. Although there appears to be a general consensus within the scientific community about how to identify, classify and name living organisms above the species level, below the species level the naming of living organisms are inconsistent.[10] Scientific definitions below the species level varies and includes words such as sub-species, varieties, sub-varieties, forma, sub-forma, and cultivars.

The International **Botanical** Congress (IBC)[11] is responsible for updating the 'Nomenclature for algae, fungi and plants (ICN)'. The ICN list all known and newly discovered varieties found in the wild which have evolved through natural mutation. Botanical varieties discovered by natural scientists working out in the field are distinct from plants bred by commercial plant breeders in controlled conditions.

The International Society for Horticultural Science (ISHS) defines cultivars as plants that have been developed[†] by plant breeders[‡] for the purposes of agriculture, forestry, and horticulture[§].[12] Unlike a botanical variety which has evolved naturally a cultivar, therefore, are defined by scientists as a "taxa of plants whose origin or selection is primarily due to intentional human activity."[13] Horticultural scientists recognise that the botanical definition of *varietas* (var) and *forma* (f.) is separate to and distinct from the ISHS definition of a 'cultivar.'[14]

Yet, somewhat confusingly both international, EU and national legislation looking to protect plant breeders' intellectual rights refer to commercial 'cultivars' as 'varieties.[15] For this reason, scientists at the ISHS point out that what legislation calls a variety is to all intents and purposes a cultivar:

> "…in certain national and international legislation or other legal conventions the word "variety" or its equivalent in other languages is a statutory or otherwise legal term used to denominate a proven variant that is distinct, uniform, and stable and is exactly equivalent to the word "cultivar" as defined in this *Code*."[16]

Scientific and legal confusions surrounding the naming and nomenclature of living organisms aside how mankind chooses to classify and describe living biological organisms is a further area which remains scientifically and legally malleable.[17] The primary criteria of classifying plants and varieties within the IBC is to describe the physical differences of newly discovered wild species and varieties in order to distinguish newly discovered varieties from known and existing botanical varieties.[18] The same is true of the UPOV Convention and EU Regulation on CPVR where new cultivars developed by plant breeders are distinguished by their morphological appearances. There are calls within some sectors of the scientific community, however, that genotype traits are a more appropriate method of taxonomizing, identifying, distinguishing, and classifying plants. Newness and distinction should, they argue, rely on genetic markers rather than visual characterization. There is by no means, however, universal consensus on this approach.[19]

To sum up, mankind's knowledge of the living world is expanding and as a result there is still no scientific consensus on how exactly to taxonomize the biosphere through identification,

[†] Not evolved.

[‡] Not botanists.

[§] Not for the purpose of expanding mankind's knowledge of the living environment

classification, and nomenclature. Were the EU to rely on scientific definitions alone to classify living organisms within the context of applied, novel gene editing techniques in food and agriculture a reformed Directive will soon run into very similar challenges the GMO Directive is currently facing namely a static, scientific definition incapable of evolving alongside evolving scientific knowledge. When all is said and done the objective of EU environmental risk regulation is (i) to maintain a rules-based internal market for food, feed and agricultural products[20] and (ii) to protect EU citizens and the European environment from unforeseen and unappreciated dangers posed by novel technologies.[21] The objective of environmental risk regulation is not to arbitrate and smooth out differences in how to define and taxonomise living organisms.

3. Risk Regulation and Precautionary requirements in an amended GMO Directive

3.1 Use of the precautionary principle in the GMO Directive

The 2001 GMO Directive forms part of the EU's environmental risk regulations.[22] The main objective of environmental risk regulation – and therefore by extension the GMO Directive - is to protect the public interest from any unforeseen risk posed by radically new and untested applied gene technologies.[23] Under the existing GMO Directive safety is assessed by technical experts based on quantifiable risk analysis and management.[24] The risk assessment, however, is qualified by the precautionary principle (PP) included not only in the GMO Directive but also in the primary Treaties of the EU.[25] Since the PP is enshrined in the EU's primary treaties its role in managing novel gene technologies must be considered and cannot be ignored in any reform of the existing legislation. It would, therefore, be prudent to strengthen the meaning and understanding of the PP within EU gene technology legislation.

3.2 The radical novelty of NGTs

Applied NGT's, as the Commission report points out, are highly novel, innovative technologies with CRISPR Cas-9 not even a decade old.[26] According to the JRC novel gene technologies are evolving fast with CRISPR Cas-9 the most prominent of all these technologies. This technology alone has, "… seen an almost exponential increase" in new applications since 2012.[27] The radical novelty of this technology has implications on risk management and knowledge.

3.3 Risk in cases of absolute novelty

It is self-evidently true and deductively logical that in cases of radically new technologies there is an initial lack of data with regard to cause-and-effect relationships. The lack of available data results in scientific experts being unable to predict what exact effect the novel technology will have on the environment, on biodiversity, on public health and wider society once in wide-spread commercial use. New products, processes and applications relating to applied gene technologies need to be tested before they can be certified as safe. Given the number of variables which need to be considered when testing for environmental cause-and-effect relationships and the dearth of initial data on which to base any analysis it becomes challenging if not impossible for experts to determine safety standards to a high level of scientific certainty.

Scientific experts working for organisations such as SAM and the JRC are highly capable of describing gene technologies with precision and accuracy. What technical experts working at the EFSA, are unable to do with precision and accuracy is make sound scientific claims of either safety or harm to a high degree of scientific certainty due to an initial lack of available data on which to base an assessment. In light of the absolute novelty of gene technologies and the expectation that this area of radical innovation will continue to grow in future it is inevitable and unfortunately unavoidable that ***significant scientific doubt*** with regard to scientific assertion of either safety or harm will remain.

4. Legal Definitions of NGTs

In view of the challenges involved in defining NGTs either technocratically or scientifically and in view of the important role the PP plays in risk regulation the EU should strengthen the existing GMO Directive by drawing a direct link between the technical criteria applied in technological intellectual property rights (TIPR) and definitions in GMO risk regulation. The TIPR criteria have the force of law behind them. They are well established and illicit a high level of both political and legal support. The legal definitions of novel, inventive (anthropogenic), industrial and non-natural are clearly understood, highly regarded, and consistently applied in this branch of the law. As such they offer EU environmental risk regulation an objective and useful way to create sound, objective definitions when looking to strengthen the GMO Directive and protect the public interest from unforeseen harm.

5. Technological Intellectual Property Rights (TIPR)

For the purpose of this consultation two technological rights, in particular, need to be considered: biotechnological patents[28] and Community Plant Variety Rights (CPVR).[29] Obtaining patents and new CPVR is a key objective of the life sciences.[30] A study published by Nature Biotechnology[31] noted that as of 31 May 2017, 352 patents had been filed for CRISPR Cas-9 gene editing of plants and animals – and these did not include patents which have broadly been described as 'technological improvements' but which relate to gene editing agricultural species – predominantly pigs, cows, buffalo, goats, sheep, chicken, birds and fish and rice for plants but also other plant species. The "CRISPR Cas-9" Pioneers have all been granted technological patents on their novel technology including Jennifer Doudna and Emanuelle Charpentier, joint winners of the 2019 Nobel Prize for Chemistry. All have created numerous companies designed to licence their patented technology.[32]

5.1 The role of Technological Intellectual Property Rights

TIPR are an exception to the general rule of open, free, and fair competition. Since TIPRs are a monopoly and an exception to the general rule strict criteria have been developed by public authorities to prevent unjustified and anti-competitive monopolies from emerging. Nowhere more than in biotechnological IPRs that monopolise the living world. Although the criteria varies between patents and CPVRs both technological IPRs share a number of common characteristics that reflect the fact they are and remain an exception to the free, fair, and open market. The most important criteria are novelty,[33] inventiveness,[34] industrialisation,[35] distinctive, stable and uniform.[36] All of which link up with the undefined aspects in GMO risk regulation concerning "novel gene technologies" "conventional use" "long safety record" "traditional use", "natural processes" "organic" and "sustainable agriculture".[37] Let us examine each criterion in turn to see how this applies in practice.

5.2 Criteria for protection

5.2.1 Absolute Novelty and Newness and Distinctiveness

The absolute novelty requirements in both patent law and CPVR rights are essential to prevent the creation of unjustifiable monopolies. The purpose of intellectual rights is to incentivise

innovation not to rob existing traders of their legitimate income. Thus, (i) if the invention is not novel it is not innovative and does not qualify for a state-sponsored monopoly and (ii) if it is not novel someone, somewhere might already be trading in the monopolised product and could be unfairly ejected from the open market.

Existing knowledge and State of the Art

To qualify for the novelty criterion the patent holder must prove that there is no existing knowledge (state of the art) of their technology.[38] If there is existing knowledge it cannot be described as novel and it fails, the absolute novelty criteria of patent law. To prove novelty the holder of a CPVR must prove that their new cultivar is distinctive from an existing cultivar, and distinctive from botanical plants around which common knowledge exists.[39] If it can be proven that the application for a CPVR is based on an existing cultivar or botanical plant with common knowledge it is not new and therefor fails, the newness criteria.

Applying TIPR Novelty in GMO Risk Regulation

The strict novelty and newness criteria applied to both TIPRs serve as a useful trigger for the application of precautionary measures. As noted above to qualify for a patent or CPVR the biotechnology and or cultivar must be novel. Strictly applied state of the art requirements confirm that both technological rights are either linked to an absolute lack of prior knowledge (in the case of patents) or a lack of common knowledge (in the case of CPVR). The novelty-state of the art criteria tell the risk regulator that there is a lack of available data on which to make a sound, scientific assessment with regard to causal relationships. Where there is scientific uncertainty due to a lack of available data the PP demands, cautionary measures are taken to protect the public and environment from unforeseen harm. At the very minimum this includes a robust and rigorous risk analysis to try and mitigate any unforeseeable harm. An amended GMO Directive, therefore, is beholden under EU law to maintain its existing risk measures and not dilute them.

Defining novel NGTs in GMO Risk Regulation

In view of the absolute novelty-state of the art requirement relating to both patents and CPVR, amendments to the GMO directive should define NGTs seeking or already subject to a TIPR as:

- untested,
- unknown,
- non-conventional,
- non-traditional.

They cannot, in law, be defined, described, or labelled as:

- conventional,
- traditional,
- having a history of safe use,
- heritage,
- landraces,
- artisanal.

5.2.2 Inventiveness, Technology, and the Anthropocene Criteria

The inventiveness criteria require the biotechnological invention to be an engineered human creation "isolated" from nature to qualify for patent protection.[40] It must have "technical" effect for it to be described as an invention. It cannot be the scientific discovery of a natural creation such a newly discovered gene – or a newly discovered botanical variety listed by the IBC on the ICN.[41] The importance of the inventiveness qualification links into (i) the novelty criteria described above (ii) the absolute need to avoid one person monopolising the existing, natural biosphere and (iii) the requirement of rewarding *applied human agency, ingenuity and creation* to distinguish it from natural creation. Per legal definition, therefore, patented gene technologies are engineered, manmade, anthropogenic, artificial, and isolated from nature. If they are natural or are created by nature, they do not qualify for a patent monopoly – unless and until a technical effect of that discovery can be applied. This criterion is reconfirmed in the EU Biotechnology Directive which states that a patent cannot be granted to products, processes or techniques that are the result of a "natural phenomenon" described as an "essentially biological crossing."[42] Similarly, plant breeders in possession of a CPVR have to

prove the new cultivar is "bred, discovered and developed" not through natural evolution but through human, anthropogenic intervention.[43] A cultivar, to recall, is defined by the ISHS as a "taxa of plants whose origin or selection is primarily due to intentional human activity."[44]

Applying TIPR inventiveness criteria in GMO Risk Regulation

The inventiveness and distinctive criteria in applied gene technologies and which qualify for either a biotechnological patent or CPVR - be it a process, product or technique - are artificial, anthropogenic, manmade constructs based on applied engineering principles and/or created under unnatural conditions.

Defining TIPRs in GMO Risk Regulation

In view of the inventiveness criteria in TIPR and requirements in the EU's Biotechnology Directive, amendments to the GMO directive should define applied NGTs seeking or already subject to a TIPR as:

- anthropogenic,
- synthetic,
- manmade,
- artificial,
- unnatural.

Applied NGTs seeking or already subject to a TIPR cannot be defined, described, or labelled as:

- natural, or
- organic.

5.2.3 Industrialisation, Stable and Uniformity Criteria

The final criteria for a biological TIPR is that the patent must be capable of industrialisation which includes food and agriculture.[45] In the case of CPVR the new plant cultivar must be stable and uniform.[46] The industrialisation criteria requires the novel, anthropogenic invention

to be *applied* and *utilised* for commercial purposes in some form or another.[47] The Biotechnology Directive states that full or partial gene sequences with no known function are not patentable.[48] From an environmental point of view these TIPR criteria pose problems particularly with regard to the suggestion that applied, novel gene editing technique are green, sustainable, pastoral, regenerative, agroecological and or conventional. The industrialisation criteria demands of patent holders to apply an industrial approach to agriculture leading to the rise in mono-crop agriculture heavily dependent on synthetic pesticides to function. Environmental scientists are warning about a steep decline in biodiversity due in large part to industrial, uniform and monocrop agriculture uniquely reliant on synthetic, artificial industrial chemicals to function as intended. Similarly, the stable and uniformity criteria in CPVR requires plant breeders to develop cultivars that are homogenised and uniform – sometimes infertile and therefor uninteresting to wild pollinators - at a time when a lack of natural genetic diversity from wild plants evolving through natural means is a matter of great concern to plant biologists.[49]

Applying TIPR industrialisation and standardisation criteria in GMO risk regulation

The strict industrialisation, uniformity, and standardisation criteria in both biotechnology patents as well as CPVR can be linked to the indirect risk of a rapid and irreversible decline in biodiversity and genetic diversity from wild, botanical species essential to a sustainable agricultural and food system.

Defining TIPRs in GMO risk regulation

In view of the strict industrialisation, standardisation, and uniformity criteria in TIPR linked to novel gene technologies in food and agriculture, amendments to the GMO directive should define applied NGTs seeking or already subject to a TIPR as forming part of:

- industrial agriculture,
- intensive monocrop agriculture,
- uniform and standardised agriculture,

Applied NGTs seeking or already subject to a TIPR cannot be defined, described, or labelled in law as:

- sustainable,
- agroecological,
- traditional,
- regenerative,
- pastoral,
- green,
- stewarded.

To sum up, all **biotechnology patents** (including those awarded to the CRISPR Cas-9 pioneers) should be legally defined, described and labelled in an amended GMO Directive as:

> untested, unknown, non-conventional, non-traditional, anthropogenic, synthetic, manmade, artificial, unnatural, industrial, uniform, and standardised.

They cannot legally be defined, described, or labelled as:

> natural, organic, conventional, traditional, having a history of safe use, heritage, landraces, artisanal, sustainable, agroecological, regenerative, pastoral, green or stewarded.

The absolute novelty and lack of existing knowledge require a strict application of the precautionary principle and precautionary measures.

Cultivars linked to a **CPVR** should be legally defined, described and labelled as:

> commercial cultivars, anthropogenic, commercially bred, non-conventional, non-traditional.

They cannot legally be defined, described, or labelled as:

> botanical varieties, natural, organic, conventional, traditional, heritage plants, landraces, artisanal, sustainable, agroecological, regenerative, pastoral, green or stewarded.

Conclusion

Based on the above legal analysis the European Commission, acting in good faith and in the interest of the wider European community, has little choice but to amend the existing GMO Directive to reflect these legally sound definitions. This approach is resilient, future-proof, and capable of being uniformly applied whilst contributing to a sustainable agri-food system. Reformed definitions linked to technical criteria in biotechnological innovations and plant variety/cultivar rights:

- allows the EU to keep the fast-moving target of applied and commercialised novel gene technologies firmly within the crosshairs of regulatory control in a fair and legally balanced manner,

- is compatible with the EU's objective of creating a sustainable, green EU within the parameters of its Green New Deal and its Farm to Fork ambitions,

- offers small European family run farms, who steward their agricultural land in accordance with knowledge accumulated over generations and unique to the varied EU's geographical topography, the chance to sell highly competitive organic, food and produce to a global market,

- acts as a useful model within environmental and public health risk regulation on when to trigger the precautionary principle and precautionary measures,

- offers EU citizens and our unique European environment protection from unforeseeable direct and indirect harm arising out of untested and radically novel gene technologies,

- eradicates legal complexities linked to evolving technocratic developments and scientific uncertainties,

- offers the EU a simplified regulatory approach in environmental risk regulation – a key objective of the EU's REFIT and Better Regulation Agenda.

Finally, it offers the EU an opportunity to align its legal commitments to intellectual rights with those of its legal commitment to offering EU citizens a high level of public health and environmental protections.

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[1] Case C-528/16, *Confédération Paysanne & Others (Confédération*), ECLI:EU:C:2018:583 2018.

[2] For an analysis of the CJEU's findings see K. Garnett 'Hold your pipettes: The European Court of Justice's findings in Confédération Paysanne & Others stirs GMOtions', *RECIEL* 2019;00:1–7.

[3] W. Broothaerts, et al, 'New Genomic Techniques: State-of-the-Art Review', (2021, Office of the European Union, Luxembourg, 2021, Joint Research Centre (JRC).

[4] Commission (EU), 'Statement by the Group of Chief Scientific Advisors: A Scientific Perspective on the Regulatory Status of Products derived from Gene Editing and the Implications for the GMO Directive' (2018).

[5] SWD(2001),92, 51.

[6] *ibid* 2, 5 & 60.

[7] *ibid* 20-21.

[8] Directive 2001/18/EC, on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 12 March 2001 (The GMO Directive), Article 2, Part 1 & 2, Annex 1 A.

[9] M. Llewelyn & M. Adcock, *European Intellectual Property*, (2006, Hart Publishing), who discuss for example. the challenge of trying to define micro-organisms scientifically. Is algae part of the plant kingdom or are they to be defined as micro-organisms? Fungi can be as small as a micro-organism, but many are too large to be considered microscopic, 119-120.

[10] B. Sherman, 'Taxonomic Property' Cambridge Law Journal, 67/3 2008, 567.

[11] Which last met in Shenzen, China in 2017.

[12] International Society for Horticultural Science, (ISHS) International Code of Nomenclature for Cultivated Plants, 9th ed., Principle 1.

[13] *ibid*, Preamble, 8.

[14] *ibid*, Article 2 'Definitions', Note 1.

[15] International Convention for the Protection of new Varieties of Plants (UPOV Convention) Article 1 (iv); Regulation 2100/94/EC on Community Plant Variety Rights, 27 July 1994. (CPVR Regulation), Article 5; Directive 98/44/EC on the legal protection of biotechnological inventions (Biotechnology Directive), Article 2 (3). Plant and animal varieties are excluded subjects from patent protection and are not defined in the European Patent Convention (EPC). Yet a number of biotechnological patents have been given to both plants and animals. See below for further details.

[16] *supra* n 12, Article 2, Definitions, Note 4.

[17] The UPOV Convention and CPVR Regulation identify, describe, and distinguish distinctive new cultivars by phenotypic traits. This includes morphological and physiological traits which seek to characterise visual difference amongst plants.

[18] Whilst the classification and taxonomizing of new, botanical plants discovered in the wild has a long and complex history there appears to be a general scientific consensus within the botanical, scientific community to rely on phenotypic rather than genotype traits. This may, of course, change in the years to come.

[19] J. Anderson *Plants, People and Practices*, (2017 CUP), 162-182 and 217 on the problem of "Essentially Derived" plants seeking description under the UPOV Convention and CPVR.

[20] GMO Directive, Article 1.

[21] *ibid*.

[22] GMO Directive, Article 4.

[23] *ibid*, Article 1.

[24] *ibid*, Article 4 Part B & C, Annex III.

[25] Article 191 (2) TFEU.

[26] 'New Genomic Techniques: State-of-the-Art Review', (JRC), 4.

[27] *ibid*, 30.

[28] Patents on living organisms through novel gene technology has been available in Europe since the early 1990's. For an evolution of European case law on the patenting of living organisms see M. Llewelyn & M. Adcock above, 247-286.

[29] Council Regulation 2100/94 on Community Plant Variety Rights, 27 July 1994. (CPVR Regulation).

[30] SWD(2021)92, 29 April 2021, 43.

[31] J. Martin-Laffon et al, 'CRISPR patent landscape shows strong geographical biases' *Nat Biotechnol* **37,** 613–620 (2019).

[32] J. Cohen 'The birth of CRISPR' *Science Magazine*, 17 February 2017; J. Cohen, 'How the battlelines over CRISPR were drawn' *Science Magazine*, 17 February 2017.

[33] European Patent Convention, 2000 (EPC), Article 54.

[34] EPC, Article 56.

[35] EPC, Article 57.

[36] CPVR, Article 6.

[37] *ibid* 20-21.

[38] EPC, Article 54 (1) & (2)

[39] CPVR, Article 7.

[40] EPO Guidelines, Part G-II, 5.2 (i).

[41] EPO Guidelines, Part G-II, 3.1 Discoveries.

[42] Biotechnology Directive, Article 2 (2) and Article 4 (1) (b), "essentially biological processes" for the production of plants and animals.

[43] CPVR, Article 11 closely linked to the distinctive criteria of Article 7.

[44] *supra*, n 12.

[45] EPC, Article 57.

[46] CPVR, Article 8 & 9.

[47] EPO Guidelines, Part G-II, 5.2 (i) "The industrial application of a sequence or partial sequence must be disclosed in the patent application as filed."

[48] Biotechnology Directive, Article 5 (3)

[49] C.Fowler & P.Mooney *Shattering: Food, Politics and the Loss of Diversity*, (1990, University of Arizona Press), Part One, Legacy of Diversity, 3-54. See also C. Fowler, *Unnatural Selection: Technology, Politics and Plant Evolution*, (1993 Gordon and Breach).