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Submission to the GTR
On DIR 108, 18/10/11

Executive Summary

Gene Ethics and other supporters of this submission ask you to reject Bayer Cropscience's application DIR 108 for unrestricted and unlimited commercial dealings with hybrid genetically manipulated (GM) canola, stacked with Glyphosate and Liberty tolerance traits on the following grounds:

- Bayer Cropscience is unsuitable to hold licence DIR 108;
- Bayer and the GTR base their case for issuing a licence on evidence that is selective, partial and out of date;
- Environmental data has not been collected on the extensive spread of GM canola in Australia's environment since the unconditional, unrestricted and unmonitored commercial release of Monsanto's GM canola began in two states three years ago so could not be assessed or managed;
- The available environmental and public health data on GM crop plants is incomplete as independent researchers cannot access the GM varieties for needed for research and GM companies also censor any negative results;
- The so-called RARMP prepared and published by the OGTR does not fulfill the statutory requirement to fully assess the real risks of GMO release and make risk management plans.

Bayer Unsuitable

Bayer Cropscience is unsuitable to hold licence DIR 108, within the meaning of Sections 57 and 58 of the Gene Technology Act 2000. The Act requires the GTR to have regard to the company's history of law-breaking and non-compliance around the world over the past ten years, as it applies to human health, safety and the environment. The company's activities have had unacceptable impacts on human health and the environment for Bayer's 125 year history and its behaviour has not improved in the past decade.

The GTR's discretion under Section 54 (2) (b) of the Act was exercised in Bayer's favour so that Bayer's own documents on its suitability to be licensed were hidden from the public. In light of Bayer's egregious record of law-breaking and non-compliance we ask you not to issue licence DIR108. Gene Ethics submits that the Bayer application for DIR108 is in direct, serious and extensive breach of legal requirement in Sections 57 and 58 of the *Gene Technology Act 2000*. Sections 57(2) and 58(2) of the *Gene Technology Act 2000* require the OGTR to be satisfied of the applicants' suitability to hold licences. Licence holders are required to meet contemporary community standards of probity, good standing and ethical behaviour but by even the most lenient standards. the vast body of examples of criminal convictions listed below show unequivocally that Bayer is neither a good corporate citizen, nor does it comply with standards of propriety required to be a fit applicant to hold license. Given that this is a public interest requirement, we submit that Bayer's commercial-in-confidence case should be transparent and open to public scrutiny.

Further, given the magnitude, grave seriousness and omission of the vast record of

criminal convictions, examples below including repeated convictions for killing, defrauding the public health system, risking public health and devastating the livelihood of farmers, we ask the GTR to comply with the requirements of the *Gene Technology Act 2000*, which states that the Regulator **must have regard** to this and other evidence in its applicant assessment.

Moreover, we alert the OGTR to Bayer's basing its application case for DIR108 on old and outdated evidence used in applications a decade ago, not on current evidence. We ask that the company be required to update the evidence supporting its application to include recent commercial experience and critical scientific research published in the past decade.

The Act states:

> **57(2) Other circumstances in which Regulator must not issue the license**
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> *The Regulator must not issue the license unless the Regulator is satisfied that the applicant is a suitable person to hold the license.*
>
> **58 (2) Matters to be taken into account in deciding whether a person is suitable to hold a license**
> *Without limiting the matters to which the Regulator may have regard in deciding whether a body corporate is a suitable person to hold a license,* ***the Regulator must have regard to the following:***
> *(a) any relevant conviction of the body corporate; and*
> *(b) if there is a relevant conviction of the body corporate:*
> *(i) whether the offence concerned was committed at a time when any person who is presently a director of the body corporate was a director; and*
> *(ii) whether that offence was committed at a time when any officer or shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such an officer or shareholder;*
> *and (c) any revocation or suspension of a license or permit (however described) held by the body corporate under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment;*
> *and*
> *(d) the capacity of the body corporate to meet the conditions of the license.*
>
> **(3) In this section: relevant conviction means a conviction for an offence against a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment, if: (a) the offence was committed within the period of 10 years immediately before the making of the application for the license; and**

(b) the offence was punishable on conviction by a fine of $5,000 or more, or by a term of imprisonment of one year or more.

and also conditions outlined in the applicant license regulations, being:

Applicant to notify of circumstances that might affect suitability
11. The license holder must immediately, by notice in writing, inform the Regulator of:
a. any relevant conviction of the license holder occurring after the commencement of this license;
b. any revocation or suspension of a license or permit held by the license holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment; or
c. any event or circumstances occurring after the commencement of this license that would affect the capacity of the license holder to meet the conditions in it.
Additional information to be given to the Regulator
12. The license holder must inform the Regulator if he or she:
a. becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the license; or
b. becomes aware of any contraventions of the license by a person covered by the license; or
c. becomes aware of any unintended effects of the dealings authorised by the license.

Gene Ethics submits that Bayer has neglected to comply with conditions outlined in the Act and OGTR regulations by (1) repeated criminal convictions and breaches of law in cases of public health and safety, environment and commercial grounds in the past ten years to the present; and (2) failing to disclose a substantial body of recent legal convictions and public health and environmental risks as required by a license-holder. A substantial body of criminal convictions and public health breaches on public record include — but are not limited to — the following:

2006-2011 Lawsuit: Bayer to pay farmers, exporters, distributors $750 million damages for contamination from unapproved Liberty Link Rice
In August 2006, Bayer's Liberty Link rice, which was not approved for human consumption, was found in the US long grain rice supply, causing devastation for farmers, distributors and suppliers. A federal multi-district litigation involving more than 11,000 rice farmers, exporters, importers, mills, and dealers was launched from five southern states: Arkansas, Louisiana, Mississippi, Missouri, and Texas. The farmers have won six jury trial verdicts against Bayer and have been awarded $750 million in compensatory and punitive damages. Attorneys Adam Levitt of Wolf Haldenstein Adler Freeman & Herz in Chicago and Don Downing of Gray, Ritter & Graham in St. Louis — the court-appointed plaintiffs' Co-Lead Counsel — negotiated the settlement which

covers all U.S. long grain rice producers who planted rice between 2006 and 2010.[1]

2011: Bayer among four fined $49 million for artificial price inflation: poor denied access to medicine
$45 million in fines from Aventis, Bayer, Schering and Pfizer were ordered to reimburse the Pennsylvania Department of Public Welfare, the state's Pharmaceutical Assistance Contract for the Elderly, known as PACE, and the Pennsylvania Employees Benefit Trust Fund, which allegedly were forced to pay higher prices for drugs.[2]

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2011: Bayer ruled in breach of several pharmaceutical codes of practice
UK Code regulator the PMCPA ruled Bayer breaches of clauses 22.1 (which bans advertising prescription-only medicines to the public) and 22.2 (which says information for the public must be factual and presented in a balanced way). Finally the Panel also considered high standards had not been maintained and ruled a breach of clause 9.1.UK Twitter account did promote prescription-only medicines to the public when it sent two product-related tweets.[4]

2010: Bayer fined $3.3 million for false health claims, FDA declares Bayer makes claims with "no credible evidence"
Bayer agreed to pay Illinois and two other states $3.3 million for using misleading promotions when claiming one of its supplements reduced the risk of developing prostate cancer. "In fact, a lawsuit filed Tuesday by Illinois Attorney General Lisa Madigan notes that the active ingredient in the supplements could actually increase the risk of the cancer," reported *The Chicago Sun-Times*.[5]

2009: Bayer among 3 fined $5.7 million for price-fixing: poor denied access to drugs
Pfizer Inc., Eli Lilly & Co. and Bayer AG were fined a total of 5.7 million francs ($5.7 million) by the Swiss Competition Commission on Tuesday for alleged price fixing of drugs.[6]

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[1] In addition to Co-Lead Counsel Levitt and Downing, other attorneys who were involved in the settlement negotiations for the plaintiffs include: Richard Arsenault of the Neblett, Beard & Arsenault law firm, William Chaney of the Looper, Reed & McGraw law firm, Scott Powell of the Hare, Wynn, Newell & Newton law firm, and Grant Davis of the Davis, Bethune & Jones law firm. See: http://www.bayerricelitigation.com/
[2] See, for example, http://www.phillyburbs.com/news/local/business/drug-companies-to-pay-million-for-inflating-drug-prices/article_e7355855-4c70-5746-9a92-46f5b9008353.html
[3] See, for example, http://www.phillyburbs.com/news/local/business/drug-companies-to-pay-million-for-inflating-drug-prices/article_e7355855-4c70-5746-9a92-46f5b9008353.html
[4] http://www.inpharm.com/news/161645/digital-pharma-bayer-uk-twitter-breaches-abpi-code
[5] See http://www.suntimes.com/news/metro/2256273-418/bayer-cancer-risk-prostate-supplements.html
[6] See http://health.gaeatimes.com/2009/12/01/swiss-fine-pfizer-eli-lilly-bayer-57m-for-price-fixing-of-erectile-dysfunction-drugs-16494/

2009: Bayer glufosinate used on GM crops poses public health risk: European Safety Authority

Alongside Japanese studies indicating that glufosinate, widely used as a "super herbicide" for GM crops, can affect the development and activity of the human brain, a European Food Safety Authority (EFSA) evaluation states that glufosinate poses a high risk to mammals. The substance is classified as reprotoxic, with laboratory experiments showing premature birth, intra-uterine death and abortions in rats. The new EU regulation declares a ban on all CRM (carcinogenic, reprotoxic and mutagenic) pesticides from categories I and II. Glufosinate is classified as falling in reprotoxic category II. Already in 2006 Swedish authorities demanded an EU-wide ban.[7]

2009: Bayer fined $143,000 for CropScience workplace fatalities: 2 killed

Bayer was reportedly fined $143,000 as a result of the August, 2008 explosion at the Bayer CropScience plant in Institute, West Virginia. The report states that "poorly planned operating procedures, flawed emergency systems and faulty employee training" led to a chemical reaction that killed two workers.[8]

2009: $2 million verdict against Bayer CropScience for experimental rice variety contaminating crops

The *St. Louis Post-Dispatch* reported that "Bayer CropScience LP must pay about $2 million for losses sustained by two Missouri farmers when an experimental variety of rice the company was testing cross-bred with their crops, a federal jury ruled.[9]

2009: Court finds Bayer liable for GM Rice Contamination: $2 million damages in first of a series of cases by farmers

A verdict was passed on 4 December by a US federal court which found Bayer Cropscience guilty of contaminating farmers' rice crops with its GM rice, LL 601 LibertyLink rice. The company was ordered to pay US$2 million to two farmers who were affected by the contamination. The two trials are said to be the first of a series of such cases filed by farmers against Bayer. LL 601 LibertyLink rice was found in US rice stocks back in 2006 and subsequently found its way into farmers' fields.[10]

2008: Bayer to pay $97.5 million to settle kickbacks case: false claims defraud Medicare

Bayer agreed to pay $97.5 million plus interest to settle allegations that it paid kickbacks to a number of diabetic suppliers and caused them to submit false claims to Medicare, according to the Department of Justice. The settlement resolves claims submitted to Medicare by the 11 suppliers for Bayer supplies from 1998 through 2007. Under the terms of the settlement, Bayer will also enter into a corporate integrity agreement with the Office of The Inspector General for the Department of Health and Human Services.[11]

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[7] For details, see http://www.cbgnetwork.org/2785.html
[8] http://www.wvgazette.com/News/Bayerexplosion
[9] See, for example, http://www.cbgnetwork.org/3169.html
[10] http://more.stltoday.com/stltoday/business/stories.nsf/0/5075056db7f3020186257683000bd26f?OpenDocument
[11] See http://www.healthcarefinancenews.com/news/bayer-healthcare-pay-975m-settle-kickbacks-case

2008: FDA orders Bayer to correct false claims and "deceptive practices" that put public health at risk

The FDA and 27 state attorneys general ordered Bayer to produce a six-month, $20 million corrective-advertising campaign for Yaz, the German pharma company's birth-control pill. The FDA ruled that Bayer's marketing and advertising for Yaz was deceptive and made false claims regarding its efficacy for acne and premenstrual syndrome. In a statement, Illinois Attorney General Lisa Madigan, who crafted the terms of the agreement with two other attorneys general and the FDA, said, "This settlement reflects the continual monitoring my office performs to ensure the pharmaceutical industry is not using deceptive marketing and advertising practices."[12]

2008: Bayer fined $16 million for price-fixing: aspirin denied to poor

The Associated Press reported that Bayer was fined for fixing the price of aspirin and other over-the-counter medications in Germany, the Associated Press. Bayer Vital, a subsidiary, made illegal deals with more than half of Germany's 21,000 pharmacies, according to Germany's cartel office.[13]

2008: FDA issues warning to Bayer to "take prompt action to correct the violations" in health labels that risk public health

The FDA issues a letter pointing out more than six violations in a single Bayer drug label, stating that "The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations."[14]

2007: US Federal Trade Commission fines Bayer "largest ever civil penalty" for "bogus" health claims

The Federal Trade Commission fined four makers of over-the-counter weight-loss products more than $25 million for false advertising, including a $3.2 million civil penalty against Bayer for claims made for One-A-Day Weight Smart. FTC chairman Deborah Platt Majoras said the Bayer fine was the largest civil penalty ever levied by the agency. The Bayer settlement, filed in the US Court in the District of New Jersey, came after Bayer had violated an earlier FTC order directing it to cease what Majoras said were bogus weight loss claims for its Weight Smart product, which added green tea extract to a standard multivitamin compound.[15]

2006-7: Bayer's unapproved LL Rice 601 found in food supplies across the world: largest GM contamination, billions in losses for farmers and exporters

The incident had a major impact on US rice exports, with US rice being pulled from shelves worldwide. Many countries including the European Union, Japan, South Korea and the Philippines imposed a strict certification and testing regime on all rice imports,

[12] See http://adage.com/article/news/bayer-campaign-means-pharma-ads/134624/
[13] http://www.pharmalot.com/2008/05/bayer-fined-16m-for-aspirin-price-fixing/
[14] See http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048456.htm
[15] See, for example, http://www.cbgnetwork.org/1749.html

with Russia and Bulgaria imposing bans on US rice. By contrast other rice exporting countries saw an increase in trade. The contamination episode also affected seed producers; an entire non-GM rice variety Clearfield 131 was banned by US regulators in early 2007 when it was found to be contaminated, costing producer BASF billions of dollars in losses.[16]

2005: Bayer Executives indicted by Grand Jury for price-fixing: denying access to pharmaceuticals to the poor

In separate indictments, filed in U.S. District Court in San Francisco, grand juries charged Jurgen Ick and Gunter Monn with conspiring with other corporate and individual co-conspirators to suppress competition by fixing the prices of rubber chemicals sold in the United States and elsewhere. Ick, former head of Bayer's Rubber Business Group, was charged with participating in the conspiracy from 1995 to 2001. Monn, former head of marketing of Bayer's Rubber Business Group, was charged with joining the conspiracy in or about January 1997. The Department of Justice issued a statement saying: “more than $200 million in criminal fines have resulted from the Antitrust Division's ongoing investigations of price fixing of various rubber-related products. Over the past 18 months the Division has obtained guilty pleas from five companies--Bayer AG, Syndial S.p.A., Crompton Corporation, DuPont Dow Elastomers, Zeon Chemicals--and including today's charges, a total of six executives.”[17]

2005: Bayer fined for cartel offences, violation of EC Treaty: €75.86 million

Bayer was among four companies (Bayer, Crompton Europe, Flexsys and General Quimica) collectively fined €75.86 million by the European Commission in what the Commission described as “clear violation of EC Treaty competition rules which forbid cartels and other restrictive business practices (Article 81). Flexsys, Bayer and Crompton (now Chemtura) (including Crompton Europe and Uniroyal Chemical Company) agreed to exchange information about prices and/or raise prices of certain rubber chemicals (antioxidants, antiozonants and primary accelerators) in the EEA and world-wide markets at least from 1996 to 2001.”[18]

2004: Bayer pleads guilty and ordered to pay $66 million for price-fixing: poor denied access to medicine

The guilty plea by Bayer Corporation is reportedly the first in a US government investigation into price fixing for the chemical additive used in a variety of products, the Justice Department said in Washington. In July, Bayer AG, based in Germany, agreed to pay a $66 million fine to settle a US charge of conspiring to fix the price of chemicals used to make rubber products.[19]

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[16] See, for example, http://www.gmcontaminationregister.org/index.php?content=nw_detail2

[17] US Department of Justice Media Release, 10 August 2005, available at http://www.justice.gov/atr/public/press_releases/2005/210540.htm

[18] See Competition Commission fines four firms €75.86 million for rubber chemical cartel available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1656&guiLanguage=de

[19] See Justice Department Media release at http://www.justice.gov/atr/public/press_releases/2004/204602.htm and also http://www.cbgnetwork.org/296.html

2003: Medicaid fraud: Bayer pays $5.5 million criminal fines; $251 million to settle civil case

In one of the largest Medicaid fraud cases in US history, Bayer was charged with knowingly providing Medicaid incorrect data regarding pricing of prescription drugs, preventing Medicaid from receiving discounts to which it was entitled. Bayer pled guilty to one federal criminal count and agreed to pay a $5.5 million criminal fine. The company also agreed to pay $251 million to settle a civil False Claims Act case.[20]

2001: 52 people killed in unsubstantiated Bayer 'experiment' with phoney cancer vaccine

In August 2001 Bayer was forced to withdraw its anti-cholesterol drug Baycol, admitting it might have killed 52 people world-wide with another 1,100 potentially crippled. Germany's Health Minister Ulla Schmidt accused Bayer of sitting on research documenting Baycol's lethal side effects for nearly two months before informing the government. Bayer, through a subsidiary, also conducted human experiments with a fraudulent 'cancer vaccine'. German scientist Alexander Kegler published a paper purporting to show that his 'fused cells' had defeated kidney cancer in the test tube. The claim depicted in a photograph portraying vanishing cancer cells, was not substantiated. On the contrary, Professor Urlich Zimmerman of Wurzburg University a leading authority in this field found "accumulated experimental errors" and "alarming misinterpretations" in the paper. Despite this, experiments were carried out within months of the claim on more than 200 humans, many of whom are now dead. A loophole in the regulatory scheme had been used to obtain authorisation for the human experimentation. An investigation begun following Prof Zimmermann's warnings found that Dr Kugler had simply taken the "conclusive" photographic evidence from the website of the USA company Molecular Probes.[21]

2000: Bayer fined $1 million for "irresponsible" aspirin claims: healthy people put at risk

The US Department of Justice charged that Bayer's aggressive aspirin marketing campaigns are misleading and may lead to medical complications in uneducated consumers. Under the settlement, Bayer was reportedly ordered spend an estimated $1 million in a public education campaign that will warn consumers of aspirin risks. The Federal Trade Commission is requiring Bayer to distribute educational brochures on the matter, available as reprints in doctors' offices and in full page print advertisements in major magazines.[22]

2000: Bayer fined $200,000 for unlicensed exports: possible use for chemical weapons

Bayer reportedly received a $200,000 fine for exporting U.S-origin glucose and other reagents to seven destinations, without obtaining the required validated export licenses. The Secretary of Commerce for Export Enforcement announced a $200,000 civil penalty on Bayer Corporation to settle allegations that the company's Diagnostics Division

[20] For details, see, for example, http://www.cbgnetwork.org/382.html
[21] http://www.independent.co.uk/uk/health/story.jsp?story=90700
[22] See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1070790/

exported U.S.-origin glucose and other reagents to several destinations. The Department alleged that on 57 occasions between October 1994 and January 1997, Bayer Corporation exported glucose and other reagents from the United States to Hong Kong, Malaysia, Mexico, Singapore, South Africa, South Korea, and Taiwan, without obtaining the required validated export licenses. The U.S. government controls glucose and other reagents because of concerns that they may be used for chemical or biological weapons.[23]

It must be emphasised that these examples comprise but a sample of Bayer convictions and health violations on public record, and that it is likely many more not on public record have been settled with non-disclosure orders.

Bayer was granted its license in DIR 021 in 2002, so during this time it has been required to regularly disclose its criminal convictions and breaches to the OGTR as it is obliged to as it "becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the license" under the license regulations. We ask for evidence that Bayer has complied with this requirement as a licence holder. We can only surmise, given that the OGTR has not revoked this license, that Bayer has not disclosed the above and other convictions. We trust that killing people, defrauding the public purse, risking the health and safety of people who buy pharmaceuticals, devastating the livelihoods of farmers and denying access to healthcare to the poor by price-fixing, are all crimes the OGTR would consider "worthy of consideration" under the Act.

Evidence selective, partial and out of date

Bayer and the GTR base their case for issuing licence DIR108 on evidence from out-dated, selected and partial sources. The evidence has not been updated as a result of commercial experience here and in other countries. Many recently published peer-reviewed scientific reports from critical research into the environmental and public health and safety of GM crops is also ignored.

For instance, no evidence from current research on the weediness of GM herbicide tolerant canola in Australia was required of the applicant despite extensive commercial plantings over the past three years. The last evidence on canola weediness cited is from 2002, six years before GM canola was first grown here. The GTR's RARMP claims: "canola is not considered a significant weed, nor invasive of natural undisturbed habitats in Australia (Dignam 2001), Canada (Canadian Food Inspection Agency 1994; Warwick et al. 1999; Beckie et al. 2001) or the UK (Crawley et al. 2001a).

This can be no more than an assumption since no new evidence on the environmental impacts of GM canola in Australia appears to have been collected. Nor does the document reference or discuss recent and relevant scientific and other literature, such as the paper by Schafer et al[24] on the spread of feral canola to diverse environments

[23] See http://www.corporatewatch.org/?lid=320
[24] Schafer, MG et al, The Establishment of Genetically Engineered Canola Populations in the U.S., Plos One, October

throughout North Dakota, USA, nor Brimner et al[25] on the influence of herbicide-resistant canola on the environmental impact of weed management.

The public health and safety risks are also downplayed, yet new evidence is emerging. For instance, Zhang L, et al[26] conclude that their: "findings demonstrate that exogenous plant miRNAs in food can regulate the expression of target genes in mammals."

Aziz Arisa, et al.[27] who found Bt insect toxin residues from GM foods in the blood of pregnant women and their fetuses report: "CryAb1 toxin were detected in PW (pregnant women), their fetuses and NPW (non-pregnant women). This is the first study to reveal the presence of circulating PAGMF in women with and without pregnancy, paving the way for a new field in reproductive toxicology including nutrition and utero-placental toxicities." Certainly more evidence is needed before we allow more GM crops into our food supply.

Concerns about the role of canola in macular degeneration raised by the ABC Radio National Health Report[28] have also never been resolved.

Other scientists who have extensively authored peer-reviewed published papers on GM crops and their products are not cited by the RARMP or the GTR document The Biology and Ecology of Canola 2011. These reputable scientists include for example:

> Entomologist Prof. Bruce Tabashnick and colleagues at the University of Arizona, USA; Prof. Gilles-Eric Seralini and colleagues at the University of Caen, France; Prof. Jack Heinemann of INBI at the University of Canterbury, New Zealand; Dr David Schubert of the Salk Institute of Biological Studies in San Diego, California, USA; Dr Rene Van Acker of the University of Guelph, Canada; Prof. Terje Traavik, Departments of Virology and Medical Microbiology, University of Tromsø, Norway; Dr Ignacio Chapela, microbial ecologist at the University of California, Berkeley; Dr Michael Antoniou, Senior Lecturer in Molecular Genetics, GKT Medical School, Guy's Hospital, London, UK; and many more.

In contrast to this unexplained neglect of critical scientific advice, OGTR cites and extensively relies on unpublished reports from Bayer and others such as Dr Ian Heap who has BASF logos emblazoned on the pages of his papers cited by the GTR.

> The International Survey of Herbicide Resistant Weeds is managed by Dr. Ian Heap, from WeedSmart LLC, Organizer of the International Survey of Herbicide

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[25] Brimner TA, et al Influence of herbicide-resistant canola on the environmental impact of weed management, Pest Management Science, DOI: 10.1002/ps.967

[26] Zhang L, et al. Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA, Published online 20 September 2011 at http://www.nature.com/cr/journal/vaop/ncurrent/full/cr2011158a.html

[27] Aziz Arisa, et al.[27], Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada, Reproductive Toxicology, 2011 Gynecology, University of Sherbrooke Hospital Centre, Sherbrooke, Quebec, Canada, at www.somloquesembrem.files.wordpress.com/2010/07/arisleblanc2011.pdf

[28] ABC Radio National Health Report, 1/11/2004 http://www.abc.net.au/rn/talks/8.30/helthrpt/stories/s1232820.htm

Resistant Weeds. Heap's co-directors are: Dr. Harvey Glick, Chair of the Herbicide Resistance Action Committee, Monsanto Global Product Stewardship. Dr. Les Glasgow, Chair of the North American Herbicide Resistance Action Committee, Syngenta. And Dr. William Vencill, Chair of the Herbicide Resistant Plants Committee for the "Weed Science Society of America, University of Georgia, Crop and Soil Sciences Department.

Section 15 of the Gene Technology Act 2000 - Relationship to other Commonwealth laws - also says: "The provisions of this Act are in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether passed or made before or after the commencement of this section)." The OGTR should therefore apply the Precautionary Principle, as enunciated in the Environment Protection and Biodiversity Conservation Act and in section 4 of its own Act, to all deliberations and decisions on applications for the release of GM organisms into the environment. Any doubts and uncertainties over environmental or public health impacts should lead the OGTR to reject the applications as violating the Precautionary Principle. But the OGTR has no benchmarks, standards or other objective criteria, set and agreed beforehand, by which to objectively assess the evidence presented by applicants or other parties. Thus, objective, science-based decisions are impossible under the OGTR system as it now exists and every decision is ad hoc.

Australian environmental data incomplete

The out-datedness of the environmental information in the RARMP is shown, for instance, by the referencing of Monsanto Report 0118/1, a 2001 physical survey of representative Australian roadside vegetation to evaluate the incidence and distribution of canola and key Brassicaceae weeds. In the absence of required follow up research after the introduction of GM canola, it is apparent that the OGTR merely assumes that extensive plantings of GM canola create no new issues when grown and transported through the Australian countryside where it is frequently spilled on roadsides and into other disturbed environments.

The OGTR has not requested or required any systematic collection of environmental data since the unconditional, unrestricted and unmonitored commercial release of GM canola in Australia over the past three years. Yet Monsanto's GM canola has created extensive contamination of roadsides, non-GM farms and other disturbed environments. The OGTR assumes that GM canola will not outcross to related weedy and native relatives so required no further research to validate its earlier assumptions.

Yet the OGTR concedes that canola is already a category 2 environmental weed. The OGTR report "The Biology and Ecology of Canola, 2002" concluded that: "In Australia and Canada, canola is a problem weed in agricultural areas due to high seed losses and a persistent seedbank. Canola is also a plant which occurs in disturbed habitats such as roadsides, railway verges and field margins in areas where canola is grown." And "Seeds can persist in undisturbed soils for up to 10 years or more, and up to five years in disturbed." And "... canola outcrossing rates between 12 - 47% can also occur. Canola pollen can be dispersed by both wind and insects."

But in its 2011 version of the same report the OGTR writes: “There are limited data on outcrossing rates under Australian conditions (Rieger et al. 2002).” Yet also: “The maximum outcrossing rate of 0.197% was measured at 1.5km.” The GTR had a responsibility to ensure that all data was available or decline to accept Bayer’s DIR108 application.

When referenced material is out of date, the GTR should require applicants to submit current research findings and contemporary data from experimental and commercial experience to support their application. Without it, applications should be rejected.

Stacked GM canola tolerant of both Liberty and Roundup herbicides may be a far greater problem weed than either conventional or one gene GM canola, further degrading town and country environments.

Data censored

The OGTR ignores the impediments to extensive contemporary research posed by GM industry prohibitions on access to GM varieties for research purposes and its censoring of any negative results from approved research, as disclosed in Nature Biotechnology ‘Under Wraps’[29], and Scientific American ‘A Seedy Practice’[30]. To address this systematic undermining of the evidence-base for the safety of GM crops, the GTR should require key additional scientific data before it accepts applications. To merely assess the impacts of proposals on the basis of available evidence is irresponsible when it is clear that negative evidence is withheld and critical research cannot be done.

OGTR’s RARMP incomplete and unsatisfactory

The GTR claims to administer a 'science-based' and 'case-by-case' regulatory regime. But there are no assessments of DIR108 that comply with the core tenets of the scientific method and sound scientific inquiry. They are, instead, based on a set of prejudiced assumptions. To be scientific, the GTR would need to apply benchmarks and standards set a priori for the quality, duration, scale and scope of the scientific evidence required for the assessment of new GMOs.

The so-called RARMP provides only a gloss of objectivity. GM crops are declared to be safe through assumption-based mind games that are not logical or transparent. These assumptions are rarely testable, verifiable or refutable by reference to objective scientific data as they should be. Yet this is mainly how the OGTR concludes that GM crops and their products are safe.

For example, the RARMP document uses the word ‘significant’ on fifty-five occasions but fifty of these are merely statements of the GTR’s pre-conceived opinion that risks are not significant or can be managed e.g.: “The Regulator considers that the dealings

[29] ‘Under Wraps’, Nature Biotechnology, Vol 27, 10, Oct 2009
[30] ‘A Seedy Practice’, Scientific American, August 2009, P 22

involved in this proposed release do not pose a significant risk to either people or the environment," repeated several times without supporting evidence.

On just five occasions the term make claims of statistical significance or objective measurement related to the results of experimentation, the actual state of affairs or the risks that GMOs pose. This makes it clear that the RARMP is not a scientific document, nor a science-based one. The RARMP does not quantify the risks that it dismisses as negligible. Yet these claims of negligible risk are the basis for the OGTR's decision to recommend grant of licence DIR108 without restrictions, limits or conditions. That is negligent!

The GTR fails to comply with the requirements of Section 50 of the Gene Technology Act 2000, to prepare a Risk Assessment and Risk Management Plan (RARMP). Instead of scientific assessment this so-called RARMP proposes and dismisses the GTR's five 'straw man' scenarios on the flimsiest of rationales. None of the scenarios envisages or analyses the worst case. The GTR takes the easy option of framing the simplified scenarios then dismissing them as not credible. That is neither an objective process nor even an objective preliminary assessment. Yet the GTR then declines to fulfill the statutory responsibility to do a comprehensive risk assessment and risk management plan to satisfy Section 50, on the flimsy grounds that its own concocted scenarios were not credible.

OGTR assumes but does not show that there are negligible risks from dealings with the two varieties of GM canola that Bayer combined in one plant through conventional breeding. Separate assessments and licenses were issued as DIR 020 and DIR 021 in 2002 but the OGTR now assumes that combining the three traits in one crop poses no additional risks or hazards. The OGTR relies on the questionable assumption that as individual genetic events now stacked in the one plant were individually assessed as safe and licensed in 2002, that further assessment is unnecessary. We disagree.

The OGTR concludes that there are negligible risks associated with commercial release of this GM canola and the regulators opinion is stated unequivocally and absolutely, but an objective review of the science behind GM canola shows much of it is contested and there is contrary evidence, much uncertainty and many unknowns.

Conclusion

This submission has shown that:

- Bayer Cropscience is unsuitable to hold licence DIR 108;
- Bayer and the GTR base their case on selective, partial and out of date evidence;
- The Australian data on the threat of GM canola are incomplete and are compelling grounds for refusing the licence;
- Other environmental and public health is incomplete because of Bayer and other GM companies' policies that thwart independent research and publication;
- The GTR's so-called RARMP and its 'straw man' scenario strategy do not meet the requirements of Section 50 of the Act, to fully assess the real risks of GMO release and make risk management plans.

We there ask you to reject application DIR108.