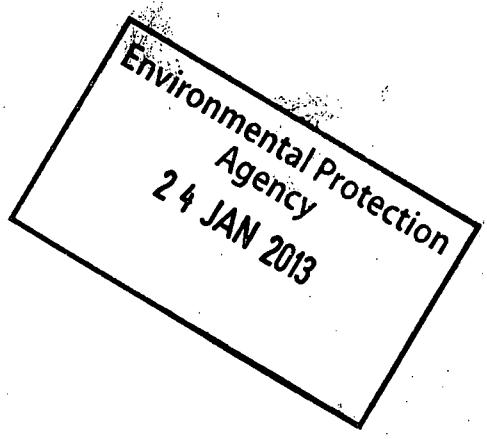
No.1

Stiofan Schmeitz

Phone: +353 61 924848
Fax: +353 1696 1079
Email: info@triscle.com



The EPA
P.O. Box 3000
Johnstown Castle Estate
Co Wexford

22.01.2013

PROPOSED DELIBERATE RELEASE OF A GENETICALLY MODIFIED ORGANISM BY ADMINISTRATION OF A NEW VACCINE TO FOALS

A Chara,

First of all I wish to complain about EPA's policy of deliberately withholding any information regarding genetically modified experiments in this country. Searching the EPA website for "GM" brings back only one single result, which is the BASF potato field trial of 2006. Neither the current Teagasc potato trial nor the above planned GM vaccine trial come up and no details whatsoever about any of the other 500 approved GM releases.

Bernadette Murray confirmed in a phone conversation on January 21st 2013 that the weekly published Farmers Journal was the only publication used for the notification and that there was currently no information available online whatsoever. She admitted that this was a shortcoming and promised to have it rectified immediately. Because of the insufficient information I request to withdraw the notification and start a new process including proper notifications and invitation to the public to participate.

This failure to properly publish the above planned trial is in itself in breach of the obligations under the Aarhus convention. It suggests that EPA is trying to deliberately keep the public uninformed about GM issues.

I wish to express my deep concerns about plans to release GM vaccine into the environment because:

- **Insufficient research regarding the effect of GM vaccines:** The only research available at present originates from companies developing GM vaccines. These can hardly be called independent. The effect on the environment is potentially lethal and surely irreversible. The applicant admits in many paragraphs of their public information that very little research has been carried out so far: see 1.1.2.A.9.:[...] "very little work is done on the transfer of the *R. equi* plasmids"

- **No specific information available regarding GM R equi vaccine:** What are the results of contained trials of this particular vaccine or any other GM vaccine?

- **What are the potential effects on human health, direct and indirect?**

Triscle Tower • Glendree Upper • Feakle • Co. Clare • Ireland

- **What are the potential effects on soil-dwelling R equi in Offaly? Intervet state that** "The organism has a long survival period in manure and soil". They also state that "The sensitivity in soil was not tested but since 1 mg soil contains much less bacteria compared to faeces, it can be assumed that sensitivity of the test for detection of *Rhodococcus equi* in soil is <1.5 CFU/mg." Where is the scientific evidence that soil contains less bacteria? A teaspoon of productive soil generally contains between 100 million and 1 billion bacteria. (see http://soils.usda.gov/sqi/concepts/soil_biology/bacteria.html)

- **Will GM R equi end up in the Brosna and the Shannon? And what effect will this have on those rivers' ecosystems?** Intervet state: "*R. equi* belongs to a genus of aerobic, non-sporulating, non-motile gram-positive bacteria closely related to Mycobacteria and Corynebacteria that have been found to thrive in a broad range of environments, including soil, manure and water."

I please ask you not to grant permission to Intervet International to proceed with the planned trial. The potential damage to the environment is irreversable. A lot of independent research is required before GM organisms or vaccine shoul be released.

Mise le meas

Stiofán Schmeitz

Cheque for 10 EUR enclosed

No. 2

EPA Headquarters
Johnstown Castle Estate
Co. Wexford

Date; 21.1.13

Dear Sirs,

Deliberate Release Notification for a GMO Rhodococcus equi vaccine.

I wish to strongly object to the forthcoming 'notification', namely the above Vaccine trial on the Belmont Stud in Co. Offaly.

Introducing any form of bacteria to an open environment which is free to be populated by any number of creatures and birds all of whom can roam to the hinterland. There is also the risk of leeching into rivers and water systems.
We do not have knowledge of the effects and impact of bacterial release. This is in breach of the Aarhus Convention (article 6) under veterinary products.
EU and Irish Law state that a GM vaccine trial can only go ahead with an Environmental Risk Assessment. Please indicate where this is in place.

I may also point out that you have failed to adequately announce this forthcoming trial in the State's major publications.

I call for this notification to be stopped immediately before damage is done that only our children may discover, too late. €10 enclosed.

Yours,

Arthur Magan
4 Lodge Court
Borris,
Co. Carlow.

• DELIBERATE RELEASE NOTIFICATION FOR A GMO Rot. EQUI VACCINE

BRACKNAGH, RATHANGAN Co. KILDARE

No. 3

MONDAY 21st JANUARY 2013,

Environmental Protection Agency
29 JAN 2013

RE: GM VACCINE TRIALS ON FOALS AT OFFALY STUD.

A CHARA,

I WISH TO MAKE A REPRESENTATION ON THE ABOVE (+ €100 FEE)

1. SHOW ME A VALID OPERATING LICENCE SHOWING WHERE YOU GOT YOUR AUTHORITY FROM + THAT TO SHOW YOU HAVE AUTHORITY TO ACCEPT FEES (AS IN €10 ABOVE)
2. WE HAVE BEEN KEPT IN THE DARK ⇒ NOT IN COMPLIANCE WITH AARHUS CONVENTION (ARTICLE 6) OBLIGATIONS
3. WHAT ARE THE ASSOCIATED HAZARDS INVOLVED

Is mise,

Tadhg Ó Criadáin

CC TO :-

(31) re No 3.

BRACKNAGH,
RATHANGAN,
Co KILDARE

Environmental Licensing Programme,

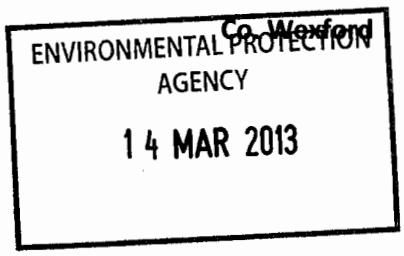
Office of climate, Licensing and Resource Use,

Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle Estate,

Co. Wexford



12 March 2013

A Chara,

I wish to refer to a letter signed by Bea Claydon, Programme Officer, acknowledging my submission of 29th January last. It pertains to GM Equine experiments on foals at Belmont Stud, Belmont, Co. Offaly. My submission was accompanied by a €10 fee.

I seek clarification on the following:

1. Show me a valid operating licence where you get your authority and forward same to me by post to the above address.
2. Shoe me a valid operating licence that you are given authority to accept finances (in this instance €10 submission fee) and forward it to my home address above.
3. Show me a Valid Tax Clearance Certificate.
4. If you are registered as a company and commercial entity operating for profit, show me company name and address of same and also enclose full details of whom your company is registered to.
5. Send me Proof and full details of exactly where all money and finances will be going if paid.

I await a reply at your nearest convenience.

Signed by Tadhg Ó Cruadhlaoich

Tadhg Ó Cruadhlaoich

2248 MARYVILLE
KILCOCK TOWN,
KILDARE

MON 28/1/2013

No. 4

RE: GM VACCINE TRIALS ON FOALS IN OFFALY.

- DO YOU HAVE A LICENCE TO CARRY OUT GM VACCINE TRIALS (AS ABOVE)? IF SO, PLEASE FORWARD A COPY OF LICENCE.
- WHERE IS THIS MONEY (€10) GOING AND HOW IS IT TO BE USED. AND DO YOU HAVE A LICENCE TO COLLECT THIS MONEY
- WHAT ARE THE POTENTIAL EFFECTS ON HUMAN HEALTH - DIRECT AND INDIRECT?
- GM VETERINARY PRODUCTS MUST COMPLY WITH CARTAGENA PROTOCOL AND THE PRECAUTIONARY PRINCIPLE MUST APPLY.

YOURS
Bríd Ní Murchú
[BRÍD NÍ MURCHÚ]

(32) re No 4.

Environmental Licensing Programme,

Office of climate, Licensing and Resource Use,

Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle Estate,

Co. Wexford

15 March 2013

A Chara,

I received an acknowledgement to my registered complaint in relation to GM Equine experiments on foals at Belmont Stud, Belmont, Co. Offaly. My handwritten submission was accompanied by a €10 fee.

I request a reply and full information to my questions on the following:

1. Show me a valid operating licence where you get your authority and forward same to me by post to the above address.
2. Shoe me a valid operating licence that you are given authority to accept finances (in this instance €10 submission fee) and forward it to my home address above.
3. Show me a Valid Tax Clearance Certificate.
4. If you are registered as a company and commercial entity operating for profit, show me company name and address of same and also enclose full details of whom your company is registered to.
5. Send me Proof and full details of exactly where all money and finances will be going if paid.

Yours sincerely,

Bríd Ní Mhurchú

Bríd Ní Mhurchú

ENVIRONMENTAL PROTECTION AGENCY

19 MAR 2013

No. 5

Ard Cullenagh,
Graigue
KILDORRERY,

Co Cork.

tele: 022 40913

January 19th 2013

The EPA
Dear Sir / Madam

I wish to make formal representation objecting to the use of GM R equi being trialled on foals in Co. Offaly.

There are many points I would wish to raise with a sense of frustration as until of now I have been unable to find any information about the GM trial on the EPA website, or anywhere else apart from the brief notification in the Farmers Journal, not every person has access to the internet and Ireland is notoriously badly served by Broadband. I would be very interested to learn of any other media used to inform the public of the trial. I have a very strong feeling of being kept 'in the dark' and that January 5th may have been chosen as a time when people are not at their most observant with just coming out of Christmas and New Year Holidays.

Questions;

- What will be the impact on the ecosystem of land being grazed by these foals, risk of vermin, bird contamination of surounding areas?
- What are the risks to human health, direct or indirect?
- Will GMR equi filter into the water courses and what effect will this have on humans , wildlife and the ecosytem?
- Will there be security in place around the Stud Farm in Offaly?
- Are the selected animals euthanased at the end of the trials.?
- What are the potential adverse effects of GM R likely to be and what measures are being taken should any of these become reality?
- What is the likelihood of culmulative effects after release?
- What is the likelihood of unanticipated effects?

I believe that all, or most of the above have implications under Aarhus Convention Article 6 obligation.

- While GM medical products are exempt from the legal obligations of the Cartagena Protocol, GM veterinary products are not. Therefore Ireland's obligations under the Cartagena Protocol remain intact, and must use the precautionary principle in its decision about whether the GM vaccine trial can proceed.

- Research relevant to GM vaccines is almost non-existent. What is, is done almost exclusively by the companies developing the vaccines, and as such is not 'independent' research as specified in EU law. Virtually no GM vaccine research is carried out regarding environmental impacts. Claims made about minimal environmental impacts cannot be true as the research on which these claims are based is non-existent.

- No information is provided (so far) regarding the results of earlier phases of the GM R equi vaccine – it impossible to make a fully-informed assessment of the notification.

I am asking you to think very carefully, to consider the points that I have raised in objecting to this GM trial being undertaken and to reject the application.

More questions ! Does the EPA publish numbers of objections to such notifications and how is the €10.00 fee used?

Yours Sincerely

Ruth Bray (Mrs)

Encl. choque; €10·00

The EPA

P.O Box 3000

Johnstown Castle Estate

Co. Wexford

No: 6

REPRESENTATION CONCERNING DELIBERATE RELEASE NOTIFICATION FOR A GMO RHODOCOCCUS EQUI VACCINE

28th January 2013

Tony Adams
Teeraveen
Lissarda
County Cork

I request that the E.P.A. consider the concerns raised in this representation before making a decision on this application.

Environmental and Health Concerns

I think it is fair to assume that under the conditions of a field trial there would be an inevitable escape of GM Rhodococcus equi into the environment through excretion by the treated animals. It would not be realistic to assume that such excrement might be entirely contained using a "foal-nappy", if such a provision were to be considered. So this proposed field trial would lead to the escape of the genetically modified bacteria into the soil and from there one must assume into the wider environment. I think it is also reasonable to assume that the modified gene would become incorperated into the natural population of Rhodococcus equi bacteria both at the trial site and then further afield, and that further mutation will subsequently take place in the natural environment.

With these considerations in mind, I find it alarming that, to the best of my knowledge, there has been virtually no research undertaken to objectively look into the potential impacts of GM vaccines on the soil ecology or on wider health concerns than the immediate efficacy of the vaccine on this particular bacterial infection in horses. The subsequent evolution of antibiotic/vaccine-resistant strains of this or closely-related bacteria might only be the most obvious risk. What about the possible effects on the bacteria in the guts of the horse, for example? Recent scandal makes it clear we can't assume that horse will never enter the human food chain, that being only one potential pathway for this GM bacteria to enter the human body as this bacteria naturally occurs in the soil throughout the country, and its potential effects inside us are unknown.

Legal Concerns

There are a number of legal concerns which lead on from these environmental and health concerns. The first of these would be the question of liability. In the event that problems arise which could be shown to result from the release of this GM bacteria, who would be legally accountable? It would surprise me greatly if the company proposing to run the trial have neglected to protect themselves from any law-suit which might subsequently result. Would it be correct to assume that in this event the E.P.A. would be held legally responsible, meaning that compensation and legal costs would fall to the taxpayer to bear? Any reasonable person would surely consider that the same company expecting to profit from this trial should also be obliged to bear the costs associated with any unforeseen consequences of the trial, though in practice there are many ways that this liability might be avoided.

There is also the question of ownership. I assume that the company applying to run this trial, or a parent company, has a patent taken out on this GM rhodococcus equi gene. As I outlined in the section above, I think it is reasonable to assume that, once released into the trial site, the GM bacteria will find its way into the wider environment. There are numerous documented cases in other countries where genetically modified seed has found its way onto lands not licensed for the growing of that patented seed, for example through spillage from a passing grain truck, and the unsuspecting land-owner has subsequently been threatened with legal action by the patent-holder unless a substantial fine for "theft of patented material" was paid and a secrecy contract signed. Historical precedents have shown that the multinational pharmaceutical companies developing these GM products are not above taking such action, morally repugnant as it may be. What is there to stop a similar abuse happening here in Ireland with this, or any other, genetically modified material? Again, it is not reasonable that the E.P.A, (ie. the taxpayer), take on this liability; less still for this risk to be left for the land-owners of Ireland to bear.

There are also various concerns regarding procedure. The Aarhus Convention states that people are entitled to have access to information about proposed actions which may affect their environment. Notification in this instance seems to amount to an advertisement in the Farmers' Journal. How a non-farmer is expected to come across this "notification" is questionable. Even today I have searched the E.P.A.'s own website and can find no notification there, though it is possible that there may be something hidden away which I failed to come across. As usual, one must depend solely upon a network of similarly concerned citizens to spread the word. In these circumstances, how are we to have faith in the E.P.A. as the body appointed to decide on important matters such as these to give thorough and impartial scrutiny of the associated risks using the Precautionary Principle, as the Cartagena Protocol legally obliges it to do for veterinary products, and to come to an appropriate decision? Can the E.P.A. even give an assurance that their person or people ultimately making this decision have no past or present business or social connections with the applicant company, its parent companies, individuals within either; or stand to gain in any way by a "favourable" decision? The evident lack of openness regarding notification of this trial gives cause for concern.

Conclusion

Bearing in mind these concerns, along with other representations received, I request that the E.P.A. refuse permission for this trial to proceed.

I request that when the E.P.A grants permission for this trial to proceed that I am sent a letter clearly explaining how the substantive legal concerns detailed here are to be dealt with.

Tony Adams

No. 7

Bea Claydon

From: Charlene aka Cinderella <moonpromo@hotmail.com>
Sent: 29 January 2013 22:21
To: Licensing Staff
Subject: Deliberate Release Notification for a GMO Rhodococcus equi vaccine - GMO Register No G0493-01

To Whom It May Concern,

Please see below representation for the Deliberate Release Notification for GMO R Equi Vaccine.

I spoke to Bernie Murray at the EPA office today who said she would contact me by phone to arrange the fee payment. Can you please by return let me know if this representation is valid for submission once the fee has been paid.

Regards,
Charlene Delaney

Charlene Delaney
37 Ard na Greine
Tullamore
Co Offaly
28/01/2013

The EPA
PO Box 3000
Johnstown Castle Estate
Wexford

Formal representation in regards to the Deliberate Release Notification for a GMO Rhodococcus equi vaccine

The proposed GM Vaccine trials areset to take place on the 13th of March in my home county, not far from where I live. I have some very serious considerations in regards to the deliberate release of this GMO vaccine, including but not limited to the following. This list is not exhaustive as I had very limited access to information.

- I am extremely upset that I have only just heard about this trial. This has given me absolutely no time to investigate the vaccine itself and the obvious short and long term enviromental and health effects. I heard about this on a Facebook page on the 23rd of January. I was provided with very little information and I was unable to find any information on the EPA website. I contacted the EPA on the 24th of January but I have not recieved a response. With little or no information available I contacted the Minister for the Environment on the 25th of January to which I recieved the link to the EPA information on their website.

- As a direct consequence of the lack of information I have not been able to research this particular vaccine in particular the health and enviromental implications on Offaly and the surrounding areas. I spent quite some time looking for information on this trial and felt let down at the lack of resources and information available to me. I draw your attention to the Aarhus Convention, in particular, obligations under Articles 3.2 and 3.9 and Articles 4.1 - This is not exhaustive and not limited to these Articles.

3.2. *Each Party shall endeavour to ensure that officials and authorities assist and provide guidance to the public in seeking access to information, in facilitating participation in decision-making and in seeking access to justice in environmental matters*

3.9. *Within the scope of the relevant provisions of this Convention, the public shall have access to information, have the possibility to participatein decision-making and have access to justice in environmental matters without discrimination as to citizenship, nationality or domicile and, in the case of a legal person, without discrimination as to where it has its registered seat or an effective centre of its activities.*

4.1 1. *Each Party shall ensure that, subject to the following paragraphs of this article, public authorities, in response to a request for environmental information, make such information available to the public, within the framework of national legislation, including, where requested and subject to subparagraph (b) below, copies of the actual documentation containing or*
comprising such information:

- I also wish to draw your attention to Article 6 of the Aarhus Convention - PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES - The lack of information provided is in direct contradiction to the above mentioned Artilce. I have no knowledge of any public participation save the representation process.

- I wish to draw your attention to the Cartagena Protocol on Biosafety. It is my understanding that GM veterinary products are not exempt from the legal obligations of the CP. In this effect when determining whether the vaccine trial can proceed the precautionary priniciple must be applied.

- There is a considerable lack of relevant research on GM Vaccines. In the limited timeframe required to make a representation I was unsucessful in finding any such research, in particular any independent research as specified in EU Law. I was unable to source any information in regards to the enviromental impacts long term or short term. I was also unable to source any information in regards to earlier phases of the GM vaccine. This makes it virtually impossible to make a fully informed assesment of this notification.

- I have many other serious concerns and valid questions to the legality and safety of this trial including but not limited to the following:

What are the potential effects on human health, direct and indirect, long term and short term?

What are the potential effects on soil dwelling R equi in Offaly?

Will GM R equi end up in the Brosna and the Shannon? What effect will this have on those rivers' ecosystems, direct and indirect, long term and short term?

Will GM R equi end up in the systems of the flora and fauna and in particular pollinating insects and thereby contaminating food products?

What are the potential adverse effects of a GM R equi release to the environment, eco systems, insects, animals and humans?

What is severity of potential adverse affects likely to be?

What are the unanticipated effects and what is the likelihood of unanticipated effects?

What is the likelihood of cumulative effects after release?

Regarding the state of GM technology and science, what is its ability to estimate uncertainty, and to reduce or avoid adverse effects?

Will procedure be put in place to avoid or reduce adverse effects on the environment, the animals and humans? If so, what are these procedures?

Sources: http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf
http://bch.cbd.int/protocol/text/
http://www.epa.ie/whatwedo/licensing/gmo/vettrial/

Charlene Delaney

(No. 8) 1

Rathvale Organic Farm

* Representation on release of GMO Rhodococcus equi vaccine.

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725
Vat No.: 6888028G
Licence No.: 5620

Date: 27.1.13

To whom it may Concern,

This is a submission in regard to the proposed deliberate release of GM Organisms by way of administration of a new GM vaccine to foals. To approve of such a trial in my option would be a drastic mistake. This would quiet simply be a licence to genetically pollute. Our soil, made up of millions of parts of bacterium including R-equi bacterium has been formed over hundred's of thousands of years, through evolutionary time with all aspects of its existence through to the foarm as nature intended. And We "Man" come along and forcefully

Rathvale Organic Farm

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725
Vat No.: 6888028G
Licence No.: 5620

Date: 27.1.13

attack the extremly complex Unit of heredity in the chromosome we call genes, to viruses, and blast them at species which have absolutly no common characteristics, in order to change the very complex, unique evolutionary gene make up of one species and create a mutant, patented life form. The very frighting part of this is the ignorance & irresponsibility On behalf of the bio-tech companyes. the agencies responsible for protecting the enviorment and the politicians For granting permission and forcing these new life forms out into a enviorment which has taken billions

Rathvale Organic Farm

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725
Vat No.: 6888028G
Licence No.: 5620

Date: 27.1.13

of years to harmonise and expect true nature to accept these new GM like forms without consquence. We have the arrogance and greed to ignore our ignorance and destroy our planet through genetic pollution. This manipulation of our foods and medicine is purely a System by which big bussness can patent the multi trillion dollor industry that is our foods and medicines. They do this with absolutly no regard for our eco-systems and all that live within. We here in Ireland are a small country with a reputation of being a green pure food island. We all still have connections to the land. We have to ask ourselves do we want this land contaminated by

Rathvale Organic Farm

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725

Date: 27.1.13

Vat No.: 6888028G
Licence No.: 5620

Unretractable GM bacterium. Do we want our plants and food contaminated by GMO's, just to make certain companies more wealthy. Are we completly mad, we have a perfect opportunity as an island to keep our green image and say no. to genetic pollution Please do as your title suggests and protect our enviorment From genetic pollution. Its not too late for Ireland to stop trials and stop the importation of maize and Soya which has been genetically modified. This is a science in its complete infancy, its your responsibility as members of the EPA to apply the precautionary principle Science its self has admitted complete ignorance as to how these new life

Rathvale Organic Farm

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725
Vat No.: 6888028G
Licence No.: 5620

Date: 27.1.13

forms react with its new enviorment and the long term effects. The negitive effects of genetic manipulation on our food, medicines and enviorment as a whole is very well documented as well as the ugly link to big buissness and thegreed of a small number of very wealthy companies.
You are in a very unique position as members of the Enviormental portection Agency to look at the evidence, look what the GM industry has created and achieved in countries like Argentina, mexico etc etc, look what its done to farmers in India, North America etc etc, look what its doing to the enviorment. Please dont grant licence to exploit our soils and food, Keep Ireland GM Free, lets Keep

6

Rathvale Organic Farm

Eddie and Swantje Kiernan
Rathvale Organic Farm
Rath
Swords
Co. Dublin
Tel.: 01- 8957725
Vat No.: 6888028G
Licence No.: 5620

Date: 27. 1. 13

the green, clean image of our food industry alive. From a marketing perspective this is of great importance If we could just see the big picture of a small GM free Island with a implicit reputation for clean GM free food of the highest quality, this would make Ireland stand out from the rest with regard to the tourist industry not the mention the healt of the people of Ireland and our children. The Fact that Seventy percent of EU citizens say they dont want GM in their food should be a huge insentive For Ireland and its politicians to do everything in their power to make Ireland a GM free Country

With the Kindest regards

Yours Sincerely

Eddie Kiernan

No. 9

28th January 2013

Isobel Baldwin
The farmhouse
Sleaveen East
Macroom
Co Cork

Representation regarding Deliberate release Notification for a GMO Rhodococcus equi vaccine

I request that the EPA consider the following concerns outlined below in this representation before coming to a decision on the above notification.

Legal issues

I had not heard about the trial until very recently from another concerned individual and understand that the deadline for submitting objections is Feb 1st. Also I was unable to find any information regarding the GM Vaccine trial on the EPA website and prior to seeing this notification was unaware that open trials of GM bacterial vaccines *could* take place with public participation in the decision process.
As I'm sure you are aware the lack of publicising the proposed trial outside of The Farmer's Journal (what of the non-farming community?) has implications under the Aarhus Convention Articles 3, 4 & 6 obligations as the Convention states that people are entitled to have access to information about proposed actions that may affect their environment and can make representations to such bodies as the EPA.
Given that the multinational company wanting to run the GM Vaccine trial in Co.Offaly has a known history of using undesirable practices namely distorting evidence used to make decisions on releasing GM medicines, why should the people of Ireland expect the vaccine trial to escape contamination when the lack of proper conduct within the pharmaceutical industry is almost common knowledge?
The EPA as the appointed body must give thorough and impartial scrutiny of the associated risks using the Precautionary Principle, as the Cartagena Protocol legally obliges it to do for veterinary products but with the lack of openess shown by the EPA in notification of this trial, there is cause for concern. Can we be assured that the EPA has no past or present social or business connections with the applicant company for instance and can come to an independent decision? Who will be shown to be responsible should there be contamination resulting from the trial?

Environmental & Health Concerns

Soil and water are our most valued resources. One doesn't need to be a scientist to appreciate their complexity and importance to life on earth and our human dependence on an abundant supply of clean water and a soil in good 'heart'. We also do not need to be scientists to assume that a vaccine given to the foals used in this trial will be excreted and GM Rhodococcus Equi released into the fields in Offaly and henceforth into the water table and eventually into the wider environment. The concern is that the modified organisms present in the vaccine will combine with the naturally present R.Equi bacterial population in the soil and further mutate causing widespread contamination. It is reasonable to assume such a high risk trial could have adverse effects in the long term, mutated GM bacteria finding its way into the human gut and the use of 'foal nappies' is a very inadequate measure to contain or control such a risk.
The greatest concern for this eventuality should be raised given that there is virtually no research or developed theories about GM Vaccine effects in existence and our health and safety from soil bacteria to human well- being is constantly under threat through trials such as these.

Conclusion

With the concerns I've outlined above and the other representations received I request the EPA refuse permission for this trial to proceed.

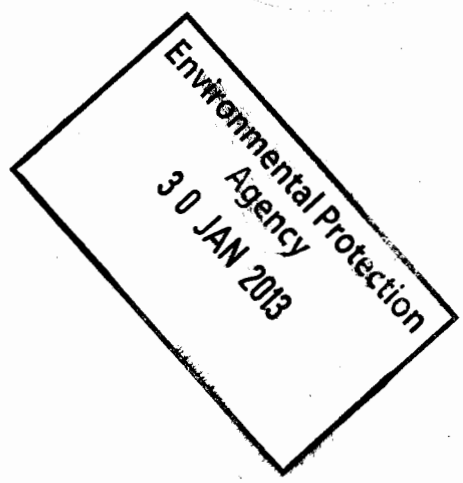
Isobel Baldwin

No. 10

Sladagh

Fethard

Co Tipperary



EPA Headquarters

Johnstown Castle

Co Wexford

Re Rhodococcus Equi Vaccine Trial

28th January 2013

Dear EPA,

I enclose a money order to the value of 10 euro in respect to my objection to the proposed trial of the GM vaccine as outlined below. I would be grateful if you could kindly acknowledge receipt of this communication which is being sent to you by registered post, as soon as possible.

Introduction:

Although I am writing to you in my capacity as a private citizen, I am also a qualified medical practitioner. My concerns about the proposed trial relate to both environmental and direct human safety.

Specific objections:

1/ Firstly, I did not become aware of this proposed trial until 20th January 2013, but understand that the closing date for objections is set for 1st February 2013. This does not allow for adequate answers to be provided to key questions about this trial. I have set in place a number of inquiries to experts in the field of soil biology and genetics, but it will not be possible to get the information I need in the time frame allowed. In addition, the initial information available on the EPA website was in summary form only, and it is my understanding that the longer document only became available at an even later date, on or about 22.01.13

2/ It is my understanding that the difficulties that I have suffered a breach of my rights as a citizen under the **Aarhus Convention** (Articles 3 and 4 in particular) in relation to access to detailed information on this trial, given that I was initially unable to find such information on the EPA website on this proposed trial (searches on 20th and 21st January 2013).

3/ It is also my understanding that there is limited research into the area of GM vaccines and in particular the fate of live bacteria GM organisms which are released into the soil. Furthermore, such research as has taken place is not independent having been carried out by, or under the auspices of commercially interested parties. Proper research is subject to rigorous peer review. Such critical appraisal is the cornerstone of Scientific Method, without which the validity and reliability of findings must be open to question. In addition, declarations of interest must be declared with any such published material.

4/There are many unknowns in this matter given the high rates of reproduction of soil based organisms and the potential for interaction with existing microorganisms, including genetic transfer and exchange. A live vaccine is capable of reproduction with horizontal transfer of genetic material. In relation to this, I would like to know the details of the Risk Assessment carried out with especial reference to the fate of release of Rhodococcus Equi live bacterium GM organisms into the Co Offaly soil and waterway systems.

In this regard I am very concerned by the number of deleted items in the proposal document which are denoted by **"INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES"** . Where such information is given in the document, assertions of low risk are unsubstantiated. For example Secton 1.1.2.C.3(e) "Other product hazards", it is claimed that " because the vaccine strain has a reduced capability to survive in macrophages, the consequence of a hazard occurring in negligible." The scientific basis for this significant assertion is not provided , and I contend that the trial as proposed is in breach of the precautionary principles enshrined in the **Cartagena Protocol on Biosafety**, to which Ireland is subject.

5/ If there are no risks or negligible risks caused by this trial why then is there a need for post release treatment of the site as outlined in 1.1.3. A 9. ? Furthermore, if there is indeed a risk of shed organisms contaminating adjacent waterways via groundwater escape from the Belmont site, then how can the removal of straw and faeces be seen as an effective post release treatment when contaminated liquids are able to reach the surrounding drainage systems?

6/ To understand the risks entailed in this trial would require access to all the previous relevant research carried out in relation to the vaccine to date, and also access to the details of the Risk Assessment for this proposed trial based on this research. This information is not available to me at present.

7/On a point of detail, it is asserted in the proposal document in 1.1.5.D that "To our knowledge, Rhodococcus has only been isolated from diseased immunocompromised people (especially AIDS patients) and never from healthy persons". This statement is factually inaccurate: a healthy 31 year old female developed R Equi infection nine weeks after a breast reduction operation in a case reported in 2011 (Sandkovsky et al (1)). This report raises the question of the greater susceptibility of those humans with relatively reduced immune status such as the very young and the elderly , not just those with known immune compromise .

In summary, I am unable to make an informed decision about the safety of the proposed trial on the basis of the information provided to date.

Based on the data available, I would conclude that further closed trials should be conducted and that the results be made available before any further consideration of trials involving the release of live attenuated vaccine strains of Rhodococcus equi into the Irish environment.

I therefore object to the trial.

Yours faithfully,

Dr Alan Moore MB, Bch, BAO, MRCGP, MRCPsych

Reference:

1. Rhodococcus infection after reduction mammaplasty in an immunocompetent patient. Uriel U Sandkovsky et al Rev Inst Med Trop Sao Paolo 53 (5): 291-4 (2011), PMID 22012456

No. 11

Sian Cowman
12 Roseville
Douglas Road
Cork.

Kirsten Walker
The Cottage
Borrowaddy Road
Skyrne
Co Meath.

30 January 2013

The EPA
P.O. Box 3000,
Johnstown Castle Estate
Co Wexford.

Deliberate Release Notification for a GMO Rhodococcus equi vaccine

Dear Sir/Madam,

In the last week, we heard about the trial of the GMO Rhodococcus equi vaccine. As you will be aware, the deadline for submitting a representation is February 1st. Unfortunately such short notice has not given us much time for informing ourselves on the implications of this trial. We are aware that the trial applicant published an advertisement in the Farmer's Journal, alerting readers to the trial and the possibility of submitting a representation to the EPA. However, we do not read that publication.

We believe that there are many people in Ireland who would like to contribute to this decision, but are unlikely to see one advertisement in a specialist publication. We also feel that the €10 fee is undemocratic, prohibiting people from participating because of the cost. We feel that the EPA is not encouraging public participation, but hindering it. This has implications under Aarhus Convention Article 6 obligations.

Regarding the vaccine itself, research relevant to GM vaccines is not very common. The research that is done is almost exclusively by **the companies developing the vaccines**. This does not qualify as 'independent' research as specified in EU law. We would also like to point out that claims made about minimal environmental impacts are based on very minimal research, and therefore are

unlikely to be true. We would like to see independent research carried out on the potential environmental and health effects of the R.equi vaccine.

In the document called 'Non-confidential application documentation for Merck Sharp and Dohme application on behalf of Intervet International BV for consent to carry out a clinical study with a GM vaccine' on the EPA website, it says 'the organism has a long survival period in manure and soil.' (Page 4) Inevitably, the GM R.equi will end up in the soil of Offaly. What effects could this have? What *cumulative* effects could this have? And what are the possibilities of transferral to water systems? What effects could *this* have? What is the likelihood of these effects? What are the capacities of the companies involved to estimate uncertainty, and to reduce or avoid adverse effects? And if there were adverse effects, what responsibilities would the companies involved have? These questions must be answered to the satisfaction of the public before this trial can proceed.

We would like to remind the EPA that while GM medical products are exempt from the legal obligations of the Cartagena Protocol, GM veterinary products are not. Therefore Ireland's obligations under the Cartagena Protocol remain intact, and Ireland and the EPA must use the precautionary principle in its decision about whether the GM vaccine trial can proceed.

Kind regards,

Sian Cowman

and

Kirsten Walker

No. 12

The Cottage
Tierhogar
Killenard
County Laois

EPA Headquarters
Johnstown Castle Estate,
Co Wexford.

Objection to deliberate release of Genetically Modified Rhodococcus equi (R. equi)

A chara,

I wish to register my objection to the proposed deliberate release of a genetically modified organism in the Irish environment by administration of a new vaccine to foals.

Firstly i did not hear about the GMO vaccine trials until the 23rd of January 2013 because it was poorly advertised and feel a large number of people who would potentially object to these trials are unaware of the proposed GM vaccine trials.

Left with such a short time to the date stipulated for objections to be received by EPA, it is difficult to properly research the implications of releasing these genetically modified organisms to the Irish environment and the effects they may have on animal, and potentially human health.

When the Environment Protection Agencies website www.epa.ie website was researched there was no information on the proposed release. This included inputting the words **Rhodococcus equi (R. equi)** and **Genetically Modified Rhodococcus equi (R. Equi)** on your websites 'Search' facility. So it was impossible to find out further information on the vaccine or potential side effects associated with such a vaccine. This lack of information has implications under Aarhus Convention Articles 3 & 4 obligations.

Recent research projects are showing the negative health implications of GMOs globally. A recent study revealing that rats fed Monsanto's GM corn showed increased incidences of cancers in comparison to the controls that were used, has sparked a wave of concern in Ireland and Europe over the health implications of GMOs. An online petition in recent months has over 18,000 people asking for the banning of GM corn/maize in Europe. (http://www.thepetitionsite.com/869/338/912/ban-dangerous-gm-corn-in-the-european-union/)
Professor Gilles-Eric Séralini, professor of molecular biology at Caen university in France in September 2012 in a peer-reviewed US journal, Food and Chemical Toxicology, reported the results of a €3.2m study. Fed a diet of Monsanto's Roundup-tolerant GM maize NK603 for two years, or exposed to Roundup over the same period, rats developed higher levels of cancers and died earlier than controls. Séralini suggested that the results could be explained by the endocrine-disrupting effects of Roundup, and overexpression of the transgene in the GMO. (Source: Guardian Newspaper, Sept 28th 2012)

Also Monsantos GM maize/corn has recently led to a mutant superworm (root worm) developing in reaction to GM corn in America and this superworm is currently spreading in the soil of the American mid west which raises grave concerns about the threat to soil ecosystems.

I am aware that open trials of GM bacterial vaccines can not take place without proper public participation in the decision making process.This has implications under Aarhus Convention Article 6 obligations.

As a concerned citizen I am objecting to the rushed manner in which these proposed trials of a genetically modified strain of a bacteria in the Irish environment and calling on you the EPA, the body charged with protecting the Irish environment on behalf of the Irish people, act in a legally responsible manner and ensure proper public involvement and debate on the issue takes place under the Aarhus Convention.

The following are a list of additional concerns I have:

- What are the potential effects on human health, direct and indirect?
- What are potential effects on soil-dwelling R equi in Offaly and the local environment where these GMOs would be released?
- Will GM R equi end up in the Brosna and Shannon rivers and what effect would this have on the river ecosystems?
- What are the potential adverse effects of a GM R equi release on farming in the area and farm income should there be adverse effects?

I am calling for a fully informed and open public debate on the issue before these GMO vaccines are released to the Irish environment, to protect human and animal health. Your 50 page 'notification' was made public on the 22nd of January 10 days before the date set for objections of February 1st 2013. This leaves inadequate time for the document to be studied properly and reviewed with independent scientific professionals.

Looking forward to your response.

Mise le meas,

Micheál Ó'Loinsigh, founder
www.EcoHomesandGardens.ie
www.IrelandEcotourism.ie (co-founder)

No. 13

Richard Auler
Ballybrado
Cahir Co.Tipperary
28.01.2013

EPA Headquarter
Johnstown Castle
Co. Wexford

Re: Proposed Rhodococcus equi vaccine trial January 2013

To whom it may concern

I saw this trial being publicised in the second week of January 2013 in *Farmers Journal.* The advert said "*..further information ...may be obtained from the EPA....*I went straight to the EPA website. There was no information there.

As far as I'm concerned my rights to access information on this environmental matter, guaranteed by the Aarhus Convention, have been violated. It is only proper that the application is re-advertised in a manner that does not violate my Aarhus-access-to-information rights.

The EPA put the notification up on its website on January 24th, i.e. **seven** days short of the deadline. This is clearly contravening the law, S.I. 500/2003 and the EU directive 2001/18.

The explanation given for this "delay" namely negotiating confidentiality issues with the applicant is not an acceptable; my rights to have access to the notification, under the S.I.500/2003, have been severely infringed. Therefore it is only proper that the application is re-advertised in a manner that does not violate my S.I. 500/2003-access-to-the-notification rights.

When I was eventually able to access the notification on the website I found that wherever specific questions occurred to me **INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES** appeared. I was shocked to find this limiting statement over 40 times in the notification.

I strongly protest that the the names, qualifications and experience of the responsible scientist (s) are deleted
What have these people to hide? Is it so damaging that it might endanger this application? Or will details come to light which might question their experience, their scientific standing or worse?

What are the EPA's reasons for agreeing to these names being deleted? I cannot accept that there is a reasonable excuse which also complies with the EPA's obligation to protect people's health and the environment in terms of approving a field trial of GM microbes, as is the issue in this case. It seems to me that the EPA has in this instance impinged on people's right to crucial information relevant to the notification, information which should not be protected by confidentiality. I put it to you that the deletion of these particular details makes the notification with its current deletions incapable of complying with my rights under Aarhus or the S.I.500/2003.
As the notification did not provide answers for many of my questions I had to seek information elsewhere.

I found that there seems to very limited research done in the field of GM vaccines and what happens to them when they are released into the soil. Indeed, the research on the vaccine in this notification appears to be fully within the control of the company behind the notification. The results (or the parts the notifier decided to submit) have been conveniently blacked out (citing confidentiality) so the public cannot check out the results.While this may follow the letter of the law it certainly does not comply with the spirit of the law, especially in terms of protecting human health and environmental health.
I have a particular problem with this concealment of the research behind this notification given that many cases are coming to light involving conflict of interest and regulatory capture in the agencies which are supposed to be looking after our interests, particularly but not solely, at EU level. Unless there is total transparency involving all aspects of the research there there cannot be trust about the agency's decision making.

Due to the high rates of reproduction of soil based organisms and the potential interactions with the GM vaccine there is no guarantee possible that no negative effects of whatever kind will occur.
As I don't know what the confidential documents are saying I can only assume that they are hiding some findings the public should not know, hiding the fact that they have not looked or hiding the inadequacy of their looking....

The notification does not go into any details about the risks to human health. It is unavoidable that the GM vaccine will contaminate soil and water, but the risks of this happening are considered as negligible by the notifier. There is no proof whatsoever that this is the case.

Para 1.1.3.A.9 goes into great details about the post release treatment of the site.
The notifier proposes to remove the feces from the foal paddock. However, there is no provision made to deal with urine which can seep un-hindered into the ground water. Although the applicant goes into great details how the drinking water for the area will be treated there is no attention whatsoever

given to the countless points of possible interaction of the GM live bacteria from the point where it is excreted in the foal's urine until it reaches the water treatment plant.

Para 1.1.4.A.1. ends as follows: *....additional risks for humans, horses and environment are nearly zero..*
This is such a sweeping generalisation to be meaningless. This is particularly so given the serious questions raised earlier about the quality and reliability of the scientific evidence presented.

To summarise:

This notification does not comply with a number of legal requirements. Particularly regarding access to information under Aarhus and access to notification under S.I. 500/2003

I claim also that information has been deleted using confidentiality excuse improperly.

The many issues regarding concealment of research render the scientific basis of the claims of the notifier invalid. Given that these claims are the basis of the notifier's conclusions regarding the risks for human health and environmental health, these conclusions are also invalid.From the perspective of protecting human health and environmental health this trial must be **NOT** be approved.

Overall, there are too many unanswered serious questions surrounding this application, the level of information provided or accessible to adequately assess the notification, is pathetic. There is virtually no effort detectable to inform the public, but the notifier seems to have put a lot of effort into keeping us in the dark. I'm very disappointed that the EPA has not taken it on itself to inform the public about this trial, neglecting its duty to the public interest.

Therefore I object in the strongest possible way to this "trial" going ahead...

.....
Richard Auler

I have attached a cheque for €10

(No. 14)

ENVIRONMENTAL PROTECTION AGENCY
31 JAN 2013

Westmeath Environmental Group

WEG, Hightown, Coralstown, Mullingar, Co. Westmeath
Tel: 044-9374798 Fax: 044-9374798, e-mail: weg1@eircom.net www.weg.ie

We wish to make representation on the application from MERCK SHARP and DOHME acting on behalf of

INTERVET INTERNATIONAL B.V.
Wim de Körverstraat 35
NL - 5831 AN BOXMEER

who wish to carry out a Clinical Study with G.M. equine vaccine EQUILIS RhodE at Belmont Stud Farm, Belmont, Co. Offaly.

We object to the granting of this permission on the grounds that:

① E.P.A. are not releasing full details of the application.

② Insufficient notice was not made available to the public.

③ The inability of the public to make representations by e-mail for their convenience

④ The inadvisability of proceeding with G.M. experiments in any shape or form in this Republic.

R. Murphy. P.R.O.

€10 fee enclosed.

No. 15

Toarlisnamore

Kilbeggan

Co Westmeath.

30 Ean 2013

To

Hq. EPA

Johnstown Castle Estate

Co Wexford.

Re: Irish GM Vaccine Trial,(GMO Rhodococcus equi vaccine) in Co Offaly.

A Chara, I am to object to the above GMO vaccine trial on the following grounds.

1. In accordance with the first pillar of the AARHUS CONVENTION 2003/04 EC , the public should have been informed properly, which the state failed to do., and also in that the state failed in its obligation to "provide for recognition of and support to associations ,organisations or groups promoting environmental protection", such as the IFA.

2. Furthermore, in accordance with the AARHUS CONVENTION, the state failed to enable public oficials and authorities to help and advise the public on access to information in respect of the GMO vaccine trial, in that the Offaly county veterinary staff were even unaware of the aforementioned scheduled trial, as of 10 days ago, and were utterly unable to give any information or guidance as to knowledge about same.

3. The state also failed to promote environmental education and environmental awareness among the public , concerning the aforementioned GMO vaccine trial, in that not even the primary farming organisation was informed or in any manner made aware of said trial, or any aspect of same.

4. As this GMO trial has possible and likely implications for each and every citizen in this country, and even possibly for future generations of people on this island through possible and likely negative impacts upon soil bacteria, and other unpredicted and unpredictable outcomes,the state failed completely to inform the general public which, as of today, 30/01/2013 is almost totally unaware of this planned GMO vaccine trial. No public participation in the planning application process for this GMO trial has been facilitated amongst the general public: a single notice in a journal/paper can not be deemed to be

adequate facilitation of said public participation. The statuary instrument 500 of 2003 has not been complied with.

5. Furthermore, the state has completely failed to inform and/ or educate the public in any general sense, in respect of the many real and varied issues arising from GMO vaccines, GMO vaccine trials, and GMOs in general. The entire matter of all GMO activity and research etc, has enormous implications for Ireland, for Ireland's agricultural industry, for the Irish horse industry, for human and environmental health, and since the state has failed to provide adequate time for proper debate and discussion on this and on related matters, the aforementioned GMO trial must be at least postponed and readvertised properly , so as to allow full and thorough analysis of all aspects of said GMO vaccine trial and related matters.

I enclose herewith the appropriate objection fee of €10.

Is Mise

Séamas Ó Muilleaneoir

No. 16

Christopher Pettes
BLOOMVILLE
CRANNAGH, TULLAMORE
Co. OFFALY, IRELAND
Tel: [redacted]

To
EPA
Johnstown Castle
Co. Wexford

27th January 2013

re. Deliberate Release Notification: GM Rhodococcus equi vaccine

Sir/Madam,

I have recently discovered references to experimentation with this GM vaccine on your website. I am sure that this could only have been there for a few days; yet the entry suggests that any objections to this trial must be registered by February 1st: this surely is an extremely undemocratic way of doing things.

I would like to know what consideration has been given to:

a) the effects of the vaccine on soil-dwelling 'natural' R. equi;
b) the possibility of this GM product finding its way into the local river systems, and thence into the Shannon;
c) the risk-factor, even if remote, for the health of humans in this area. (I write as a resident of Co. Offaly.)

I enclose a cheque for €10 to register my complaint, though I do not understand why a change in the status quo should involve such a payment.

Yours faithfully,

No. 17

Ballinreeshig
Ballygarvan,
Cork,
28.1.13.

To whom it concerns,

I am writing to object to the proposed GMO Rhodococcus equi vaccine trial.
I feel this GMO trial will cause harm to our environment.
Lack of knowledge, experience and research in using such vaccines may have long term detrimental consequences and irreversible consequences, in my opinion.
It is important for the EPA to protect our environment. Everyone involved in this trial are obliged to comply with the Cartagena Protocal, Aarhus Convention 2001/18/EC and the Irish statutory instrument 500/2003. I would like to know and ask the EPA what are the expected outcomes of such a trial and what are the long term effects on the environment expected to be?

Kindest Regards
Margie Lynch.

P.S. I enclose my fee of €10.

Ballinreeshig Nature Farm
Ballygarvan
Co Cork

No. 18

27/1/13

Re:

Deliberate Release Notification for a GMO Rhodococcus equi vaccine

To whom it concerns.

I hereby object to the proposed GMO Rhodococcus equi vaccine trial. In my opinion I feel that this GMO trial has the potential to cause major harm to our Irish environment. Too little information and results from experience of using such vaccines are known to me and I worry about the long term consequences that may result. Protecting our environment is of paramount importance & the role of the E.P.A. should fortify this. All the parties involved in this trial should be aware that they are obliged to comply with the:- Cartagena Protocol, Aarhus Convention 2001/18/EC and the Irish Statutory instrument 500/2003. The lack of information on the EPA website is very noticable and I am very concerned that there may be collusion at foot and a deliberate policy of keeping people in the dark. Question that I would like answered are:- What is the likelihood of unanticipated effects? and what is the likelihood of cumulative effects after Release?

I enclose my fee of €10 cash.

Kind Regards & hoping you will make the correct decision

Sean O'Halloran

No. 19

Bea Claydon

From: Elizabeth Cullen
Sent: 31 January 2013 13:15
To: Licensing Staff
Subject: Submission
Attachments: GMO Equine vaccine.doc

Dear Bea
Thank you for your help today
Please find enclosed my submission
Kind regards
Liz

Dr. Elizabeth Cullen
Senior Medical Officer
Health Service Executive,
St Marys,
Craddockstown road,
Naas,
Co. Kildare.

Telephone 045-882403
Fax 045-882449
Mobile 086-0617004

e-mail elizabeth.cullen1@hse.ie
MCRN 000045

M? fuair t? an r?omhphost seo tr? dhearmad, bheadh muid bu?och d? gcuirfe? in i?il don Deasc Seirbh?s? ECT ar an nguth?n ag +353 1 6352757 n? ar an r?omhphost chuig service.desk@hse.ie agus ansin glan an r?omhphost seo ded' ch?ras."

"Information in this email (including attachments) is confidential. It is intended for receipt and consideration only by the intended recipient. If you are not an addressee or intended recipient, any use, dissemination, distribution, disclosure, publication or copying of information contained in this email is strictly prohibited. Opinions expressed in this email may be personal to the author and are not necessarily the opinions of the HSE.

If this email has been received by you in error we would be grateful if you could immediately notify the ICT Service Desk by telephone at +353 1 6352757 or by email to service.desk@hse.ie and thereafter delete this e-mail from your system"

I am concerned about the impact of this genetically engineered equine vaccine 'Equilis RhodE' which contains a GM strain of *Rhodococcus equi* on the environment. It is a matter of concern that the proposer of this trial is Intervet International B.V. A full assessment of the impacts of this vaccine on the evironment must be undertaken by an independent assessor.

Section 1.1.2.A.8. states that *R. equi* is a facultative pathogenic soil saprophyte and is found in soil, especially where domesticated livestock graze. The interaction of this new organism with soil microorganisms must be important in the assessment of it impact on biodiversity. It is therefore of concern that section 1.1.2.A. 9. which relates to the potential for genetic transfer and exchange with other organisms, acknowledges that very little work has been done on the transfer of the *R. equi* plasmids. There is no bibliography attached and the reference to personal communication as a reference in this important section is not adequate.
1.1.2.A 11(d). The fact that *R. equi* is a pulmonary pathogen of AIDS patients is very important. AIDS patients are extremely vulnerable to overwhelming infection. The large number of antibiotics to which this organism is resistant, and outlined in 1.1.2.A.11 (e) is a matter of serious concern.
1.1.2. C 3 (b) The phrase in bold font in the following excerpt is a reason for serious concern. "Since it has been demonstrated that the vaccine/mutant strain is less able to survive in human macrophages (in contrast to the parent strain), it is expected to be unable to cause disease in (immunocompromised) humans, **although a direct correlation between survival in macrophages and human pathogenicity has never been tested or demonstrated**". In this regard, the possibility of long term colonization of the gut outlined in 1.1.2 C 4 (c) is also of concern. It is unclear what the list of topics outlined at the beginning of 1.1.2. C 3 (d) relates to. The statement "However, since the mutant strain is less able to survive in human macrophages (in contrast to the parent strain) it is expected to be less able to cause disease in immunocompromised humans. The attenuation was proven in the most sensitive host, the foal." requires a reference.
1.1.3 A 8 It is not stated how immunocompromised staff working in the stables will be identified.
Section 1.1.3. A 11. states that no vaccine related abnormalities were observed during studies in the Netherlands. It is not clear what surveillance was undertaken to support this statement.

Furthermore, although section 1.1.4. B 7 states that to the applicant's knowledge, Rhodococcus has only been isolated from diseased immunocompromised people (especially AIDs patients) and never from healthy persons, it is again not clear the extent to date of the surveillance undertaken of healthy people

1.1.4.B 12 The statement that the "vaccine/mutant strain is less able to survive in human macrophages (in contrast to the parent strain) and therefore it is expected to be unable to cause disease in (immuno-compromised) humans, although a direct correlation between survival in macrophages and human pathogenicity has never been tested or demonstrated", underlies a fundamental lack of knowledge of an important determinant of human pathogenicity.

1.1.5.A. 4 Independent assessment of the possibility of adverse impacts is necessary; however, it should not be in the remit of the owner of the farm of farm staff.

Part 2 of application

Are questions 9 (a) in section B and 4 (a) in section C fully answered?

There seems to be missing answers in section D also.

It is surprising to note that the phrase **INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES** occurred 42 times in the application. This is unacceptable. We need clarification on what grounds such decisions are made. It is not possible to make a decision on the impacts of a novel organism on the environment in the absence of full information. In the absence of full information, it should not be possible to decide on this application.

We need independent and peer reviewed evidence to clearly demonstrate the issues raised in this application, including evidence from an independent microbiologist and infectious disease consultant. In the absence of this, the application to test this vaccine in Ireland must be refused.

Dr Elizabeth Cullen

Irish Doctors' Environmental Association

30 Jan 2013

No. 20

Jonathan Moore,

Four Courts,

Inns Quay,

Dublin 7,

DX 81 8177.

Licensing Department,

The Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle,

Co. Wexford.

Re: Objection to *Rhodococcus Equi* Vaccine Trial in County Offaly - Deliberate Release G0493

30 January 2013

Dear Sir / Madam,

I enclose my objection to the proposed trial of the GM vaccine Deliberate Release G0493 as outlined below and payment of euro 10. I would be grateful if you could kindly acknowledge receipt of this communication which is being sent to you by post.

Although I am writing to you in my capacity as a private citizen, I am also a qualified environmental scientist and a qualified lawyer. My concerns about the proposed trial relate to both legal and environmental issues.

The first part of my objection relates to the dissemination of information and the timeframe for making a Representation, with reference to the Aarhus Convention, ratified by Ireland on 20 June 2012 and incorporated into Irish law relating to environmental consents, as follows:-

1) The EPA website states that it was made aware of this proposed trial on 14 December 2012, however the publication in the "*Irish Horse*" section of the Farmers Journal is dated 5 January 2013, a full three weeks after that date. As this information was not transmitted to the public immediately and without delay, and given the potential threat to environmental and human health from this trial, this three week delay appears to be contrary to Article 5(c) of the Aarhus Convention, which states:

> *"In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated* ***immediately and without delay*** *to members of the public who may be affected."*

(emphasis added)

2) As it happens, I only became aware of the proposed trial on 20 January 2013, when notified by a family member. I understand that the closing date for objections is set for 1 February 2013. Even if I had been notified by the Farmers Journal publication on 5 January 2013, 27 days from public

notification until the closing date does not seem adequate time to prepare and participate effectively in the environmental decision-making involved in this trial - the complexity and technical nature of genetic engineering means that as a lay person I need to have expert opinion to fully appreciate the consequences. I believe that this is contrary to Article 6 (3) of the Aarhus Convention:

> "*3. The public participation procedures shall include* ***reasonable time-frames*** *for the different phases, allowing sufficient time for informing the public in accordance with paragraph 2 above and for the public to* ***prepare and participate effectively*** *during the environmental decision-making.*"

(emphasis added)

3) I cannot confirm the date that the initial information became available on the EPA website, however, I believe that it was in summary form only, and it is my understanding that the more comprehensive document, including the risk assessment (required by Article 10 (4) (e) of S.I. No. 500 of 2003 - Genetically Modified Organisms (Deliberate Release) Regulations 2003) only became available on or about 22 January 2013. Again, I believe this is contrary to Article 6 (3) of the Aarhus Convention.

The second part of my objection is more general and relates to the environmental risks associated with GM vaccines:

1) It is my understanding that there is limited research into the area of GM vaccines and in particular the fate of live bacteria GM organisms which are released into the soil. Furthermore, such research as has taken place is not independent having been carried out by, or under the auspices of commercially interested parties. Proper research is subject to rigorous peer review. Such critical appraisal is the cornerstone of "*Scientific Method*", without which the validity and reliability of findings must be open to question. In addition, declarations of interest must be declared with any such published material.

2) There are many unknowns in this matter given the high rates of reproduction of soil based organisms and the potential for interaction with existing microorganisms, including genetic transfer and exchange. A live vaccine may be capable of reproduction with horizontal transfer of genetic material.

3) In this regard - although I understand that this application has been granted certain confidentiality benefits under S.I. No. 500 of 2003 - I am concerned that the deleted items in the Risk Assessment that are denoted by **"INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES"** effectively render the conclusions in relation to risk to humans (at 3.1.2.3 of the document) and in relation to risk to environment (at 3.1.3.3 of the document) that the risks are "*effectively zero*" are unsubstantiated.

4) To understand the risks entailed in this trial would require access to all the previous relevant research carried out in relation to the vaccine to date, and also access to the details of the Risk Assessment for this proposed trial based on this research. This information is not available to me at present.

In summary, I am unable to effectively prepare and participate in decision-making on the basis of the short timeframe provided to make a Representation and the limitation (on the basis of confidentiality) of the the information provided to date. Based on the data available, I would conclude that further closed trials should be conducted and that the results be made available before any further consideration of trials involving the release of live attenuated vaccine strains of *Rhodococcus equi* into the Irish environment.

I therefore object to the trial for the above stated reasons.

Yours faithfully,

Jonathan Moore BA(mod) BL

No. 21

Christopher Moore,

The Coach House,

Prospect House,

Sallins,

County Kildare.

Licensing Department,

The Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle,

Co. Wexford.

Re: Objection to *Rhodococcus Equi* Vaccine Trial in County Offaly - Deliberate Release G0493

30 January 2013

Dear Sir / Madam,

I enclose my objection to the proposed trial of the GM vaccine Deliberate Release G0493 as outlined below and payment of euro 10. I would be grateful if you could kindly acknowledge receipt of this communication which is being sent to you by post/email.

I am writing to you in my capacity as a private citizen. My concerns about the proposed trial relate to both legal and environmental issues.

The first part of my objection relates to the dissemination of information and the timeframe for making a Representation, with reference to the Aarhus Convention, ratified by Ireland on 20 June 2012 and incorporated into Irish law relating to environmental consents, as follows:-

1) The EPA website states that it was made aware of this proposed trial on 14 December 2012, however the publication in the "*Irish Horse*" of the Farmers Journal is dated 5 January 2013, a full three weeks after that date. As this information was not transmitted to the public immediately and without delay, and given the potential threat to environmental and human health from this trial, this three week delay appears to be contrary to Article 5(c) of the Aarhus Convention, which states:

> *"In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated* ***immediately and without delay*** *to members of the public who may be affected."*

(emphasis added)

2) As it happens, I only became aware of the proposed trial on 20 January 2013, when notified by a family member. I understand that the closing date for objections is set for 1 February 2013. Even if I had been notified by the Farmers Journal publication on 5 January 2013, 27 days from public notification until the closing date does not seem adequate time to prepare and participate effectively in the environmental decision-making involved in this trial - the complexity and technical nature of

genetic engineering means that as a lay person I need to have expert opinion to fully appreciate the consequences. I believe that this is contrary to Article 6 (3) of the Aarhus Convention:

> *"3. The public participation procedures shall include **reasonable time-frames** for the different phases, allowing sufficient time for informing the public in accordance with paragraph 2 above and for the public to **prepare and participate effectively** during the environmental decision-making."*

(emphasis added)

3) I cannot confirm the date that the initial information became available on the EPA website, however, I believe that it was in summary form only, and it is my understanding that the more comprehensive document, including the risk assessment (required by Article 10 (4) (e) of S.I. No. 500 of 2003 - Genetically Modified Organisms (Deliberate Release) Regulations 2003) only became available on or about 22 January 2013. Again, I believe this is contrary to Article 6 (3) of the Aarhus Convention.

The second part of my objection is more general and relates to the environmental risks associated with GM vaccines:

1) It is my understanding that there is limited research into the area of GM vaccines and in particular the fate of live bacteria GM organisms which are released into the soil. Furthermore, such research as has taken place is not independent having been carried out by, or under the auspices of commercially interested parties. Proper research is subject to rigorous peer review. Such critical appraisal is the cornerstone of "*Scientific Method*", without which the validity and reliability of findings must be open to question. In addition, declarations of interest must be declared with any such published material.

2) There are many unknowns in this matter given the high rates of reproduction of soil based organisms and the potential for interaction with existing microorganisms, including genetic transfer and exchange. A live vaccine may be capable of reproduction with horizontal transfer of genetic material.

3) In this regard - although I understand that this application has been granted certain confidentiality benefits under S.I. No. 500 of 2003 - I am concerned that the deleted items in the Risk Assessment that are denoted by **"INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES"** effectively render the conclusions in relation to risk to humans (at 3.1.2.3 of the document) and in relation to risk to environment (at 3.1.3.3 of the document) that the risks are *"effectively zero"* are unsubstantiated.

4) To understand the risks entailed in this trial would require access to all the previous relevant research carried out in relation to the vaccine to date, and also access to the details of the Risk Assessment for this proposed trial based on this research. This information is not available to me at present.

In summary, I am unable to effectively prepare and participate in decision-making on the basis of the short timeframe provided to make a Representation and the limitation (on the basis of confidentiality) of the the information provided to date. Based on the data available, I would conclude that further closed trials should be conducted and that the results be made available before any further consideration of trials involving the release of live attenuated vaccine strains of *Rhodococcus equi* into the Irish environment.

I therefore object to the trial for the above stated reasons.

Yours faithfully,

Christopher Moore.

No. 22

Richard Moore,

10 Albert Place East,

Dublin 2.

Licensing Department,

The Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle,

Co. Wexford.

Re: Objection to *Rhodococcus Equi* Vaccine Trial in County Offaly - Deliberate Release G0493

30 January 2013

Dear Sir / Madam,

I enclose my objection to the proposed trial of the GM vaccine Deliberate Release G0493 as outlined below and payment of euro 10. I would be grateful if you could kindly acknowledge receipt of this communication which is being sent to you by post.

Although I am writing to you in my capacity as a private citizen, I am also a qualified doctor. My concerns about the proposed trial relate to both legal and environmental issues.

The first part of my objection relates to the dissemination of information and the timeframe for making a Representation, with reference to the Aarhus Convention, ratified by Ireland on 20 June 2012 and incorporated into Irish law relating to environmental consents, as follows:-

1) The EPA website states that it was made aware of this proposed trial on 14 December 2012, however the publication in the "*Irish Horse*" section of the Farmers Journal is dated 5 January 2013, a full three weeks after that date. As this information was not transmitted to the public immediately and without delay, and given the potential threat to environmental and human health from this trial, this three week delay appears to be contrary to Article 5(c) of the Aarhus Convention, which states:

> *"In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated* ***immediately and without delay*** *to members of the public who may be affected."*
>
> (emphasis added)

2) As it happens, I only became aware of the proposed trial on 20 January 2013, when notified by a family member. I understand that the closing date for objections is set for 1 February 2013. Even if I had been notified by the Farmers Journal publication on 5 January 2013, 27 days from public notification until the closing date does not seem adequate time to prepare and participate effectively in the environmental decision-making involved in this trial - the complexity and technical nature of genetic engineering means that as a lay person I need to have expert opinion to fully appreciate the consequences. I believe that this is contrary to Article 6 (3) of the Aarhus Convention:

*"3. The public participation procedures shall include **reasonable time-frames** for the different phases, allowing sufficient time for informing the public in accordance with paragraph 2 above and for the public to **prepare and participate effectively** during the environmental decision-making."*

(emphasis added)

3) I cannot confirm the date that the initial information became available on the EPA website, however, I believe that it was in summary form only, and it is my understanding that the more comprehensive document, including the risk assessment (required by Article 10 (4) (e) of S.I. No. 500 of 2003 - Genetically Modified Organisms (Deliberate Release) Regulations 2003) only became available on or about 22 January 2013. Again, I believe this is contrary to Article 6 (3) of the Aarhus Convention.

The second part of my objection is more general and relates to the environmental risks associated with GM vaccines:

1) It is my understanding that there is limited research into the area of GM vaccines and in particular the fate of live bacteria GM organisms which are released into the soil. Furthermore, such research as has taken place is not independent having been carried out by, or under the auspices of commercially interested parties. Proper research is subject to rigorous peer review. Such critical appraisal is the cornerstone of "*Scientific Method*", without which the validity and reliability of findings must be open to question. In addition, declarations of interest must be declared with any such published material.

2) There are many unknowns in this matter given the high rates of reproduction of soil based organisms and the potential for interaction with existing microorganisms, including genetic transfer and exchange. A live vaccine may be capable of reproduction with horizontal transfer of genetic material.

3) In this regard - although I understand that this application has been granted certain confidentiality benefits under S.I. No. 500 of 2003 - I am concerned that the deleted items in the Risk Assessment that are denoted by **"INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES"** effectively render the conclusions in relation to risk to humans (at 3.1.2.3 of the document) and in relation to risk to environment (at 3.1.3.3 of the document) that the risks are *"effectively zero"* are unsubstantiated.

4) To understand the risks entailed in this trial would require access to all the previous relevant research carried out in relation to the vaccine to date, and also access to the details of the Risk Assessment for this proposed trial based on this research. This information is not available to me at present.

In summary, I am unable to effectively prepare and participate in decision-making on the basis of the short timeframe provided to make a Representation and the limitation (on the basis of confidentiality) of the the information provided to date. Based on the data available, I would conclude that further closed trials should be conducted and that the results be made available before any further consideration of trials involving the release of live attenuated vaccine strains of *Rhodococcus equi* into the Irish environment.

I therefore object to the trial for the above stated reasons.

Yours faithfully,

Richard Moore

No. 23

Dermot Moore,

Prospect House,

Sallins,

County Kildare.

Licensing Department,

The Environmental Protection Agency,

P.O. Box 3000,

Johnstown Castle,

Co. Wexford.

Re: Objection to *Rhodococcus Equi* Vaccine Trial in County Offaly - Deliberate Release G0493

30 January 2013

Dear Sir / Madam,

I enclose my objection to the proposed trial of the GM vaccine Deliberate Release G0493 as outlined below and payment of euro 10. I would be grateful if you could kindly acknowledge receipt of this communication which is being sent to you by post.

Although I am writing to you in my capacity as a private citizen, I am also a qualified doctor. My concerns about the proposed trial relate to both legal and environmental issues.

The first part of my objection relates to the dissemination of information and the timeframe for making a Representation, with reference to the Aarhus Convention, ratified by Ireland on 20 June 2012 and incorporated into Irish law relating to environmental consents, as follows:-

1) The EPA website states that it was made aware of this proposed trial on 14 December 2012, however the publication in the "*Irish Horse*" section of the Farmers Journal is dated 5 January 2013, a full three weeks after that date. As this information was not transmitted to the public immediately and without delay, and given the potential threat to environmental and human health from this trial, this three week delay appears to be contrary to Article 5(c) of the Aarhus Convention, which states:

> *"In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated* ***immediately and without delay*** *to members of the public who may be affected."*
>
> (emphasis added)

2) As it happens, I only became aware of the proposed trial on 20 January 2013, when notified by a family member. I understand that the closing date for objections is set for 1 February 2013. Even if I had been notified by the Farmers Journal publication on 5 January 2013, 27 days from public notification until the closing date does not seem adequate time to prepare and participate effectively in the environmental decision-making involved in this trial - the complexity and technical nature of

genetic engineering means that as a lay person I need to have expert opinion to fully appreciate the consequences. I believe that this is contrary to Article 6 (3) of the Aarhus Convention:

> *"3. The public participation procedures shall include **reasonable time-frames** for the different phases, allowing sufficient time for informing the public in accordance with paragraph 2 above and for the public to **prepare and participate effectively** during the environmental decision-making."*

(emphasis added)

3) I cannot confirm the date that the initial information became available on the EPA website, however, I believe that it was in summary form only, and it is my understanding that the more comprehensive document, including the risk assessment (required by Article 10 (4) (e) of S.I. No. 500 of 2003 - Genetically Modified Organisms (Deliberate Release) Regulations 2003) only became available on or about 22 January 2013. Again, I believe this is contrary to Article 6 (3) of the Aarhus Convention.

The second part of my objection is more general and relates to the environmental risks associated with GM vaccines:

1) It is my understanding that there is limited research into the area of GM vaccines and in particular the fate of live bacteria GM organisms which are released into the soil. Furthermore, such research as has taken place is not independent having been carried out by, or under the auspices of commercially interested parties. Proper research is subject to rigorous peer review. Such critical appraisal is the cornerstone of "*Scientific Method*", without which the validity and reliability of findings must be open to question. In addition, declarations of interest must be declared with any such published material.

2) There are many unknowns in this matter given the high rates of reproduction of soil based organisms and the potential for interaction with existing microorganisms, including genetic transfer and exchange. A live vaccine may be capable of reproduction with horizontal transfer of genetic material.

3) In this regard - although I understand that this application has been granted certain confidentiality benefits under S.I. No. 500 of 2003 - I am concerned that the deleted items in the Risk Assessment that are denoted by **"INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES"** effectively render the conclusions in relation to risk to humans (at 3.1.2.3 of the document) and in relation to risk to environment (at 3.1.3.3 of the document) that the risks are *"effectively zero"* are unsubstantiated.

4) To understand the risks entailed in this trial would require access to all the previous relevant research carried out in relation to the vaccine to date, and also access to the details of the Risk Assessment for this proposed trial based on this research. This information is not available to me at present.

In summary, I am unable to effectively prepare and participate in decision-making on the basis of the short timeframe provided to make a Representation and the limitation (on the basis of confidentiality) of the the information provided to date. Based on the data available, I would conclude that further closed trials should be conducted and that the results be made available before any further consideration of trials involving the release of live attenuated vaccine strains of *Rhodococcus equi* into the Irish environment.

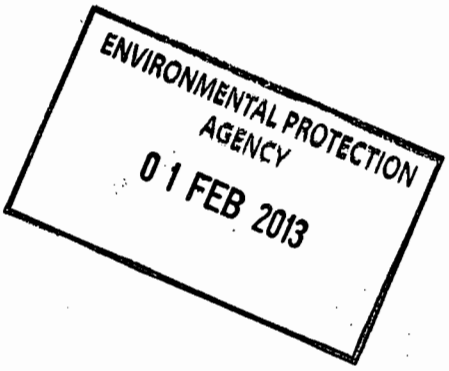
I therefore object to the trial for the above stated reasons.

Yours faithfully,

Dermot Moore.

No. 24

Sam and Anke Barker
Killemera
Glanworth
Co. Cork



The EPA
P.O. Box 3000,
Johnstown Castle Estate
Co. Wexford

30th January 2013

Deliberate Release Notification for a GMO Rhodococcus equi vaccine

To Whom It May Concern:

According to the Aarhus Convention Articles 3 & 4 it is our right to seek advice and properly inform ourselves so as to make representation to the EPA with regard the environmental implications of trials such as the Rhodococcus equi vaccine trial to be carried out in Belmont Stud, Co. Offaly. The withholding of the *GM equine vaccine Equilis RhodE* application from the EPA website until January 24, 2013 severely hampered and inhibited our ability to realise this right.

We are generally very concerned about the known and unknown effects of the release of genetically modified bacteria vaccine such as the Rhodococcus equi into our environment especially as it is not known what effect it will have on the bacteria in the soil, water, and the eco-system in general. Using genetic modification in field trials in connection with an organism that multiplies at such a high speed with the limited knowledge that we have to date on the impact of Genetically Modified Organisms (GMO) on our environment is questionable. Ireland up to now has had very little contamination through GMO in comparison to some other European countries. Ireland's great advantage is in being an island with no problems concerning cross-pollination as is the case on mainland Europe. We should embrace this chance of maintaining the country's green and clean image and its highly valuable quality food sector by holding off trials for now. We would gladly support a moratorium that would allow for more independent scientific research before a decision to introduce or ban further GMO on the island is made.

As a young family we are very concerned about the potential effects on human health both directly and indirectly linked to genetic modification. With allergies and food

intolerance on the rise we are very conscious of the importance of how we treat our environment especially our soil, water and air to ensure a livelihood for future generations.

The applicant states that:

> *"Increased incidences of R. equi pneumonia is associated with large farm size, high density and population size of foals, high numbers of airborne virulent R. equi, low soil moisture, high temperatures and a poor pasture grass cover."*[1]

i.e. good farm management has the potential to significantly lower the risk of harm by the bacteria. If there are natural ways of avoiding putting young foals at risk we do not understand the "need" for a vaccine but see it as a money making opportunity by the company/companies involved. Make your money by all means but not by introducing GM vaccines with potentially harmful outcomes into our environment, a deed that once done is irreversible.

Furthermore we feel that without further information and advice we don't share the company's confidence that the risk to humans who are immunocompromised is negligible since it appears that the effect of the modified organism on humans is unknown and the potential for mutations of the 'opportunistic' bacteria to occur seems high.[2]

Prior to reading this notification we were unaware of the possibility to participate in the decision. We greatly appreciate the public participation and would like to see in future that information was made available earlier so that the 28 days between the notice of the trial and the closing date for representations to the EPA [as in accordance with S.I. No. 500/2003 article 16(1)] can be fully used to further inform oneself on the details of the topic.

Yours sincerely,

Sam Baker

Anke Baker

---

[1] **GM equine vaccine Equilis RhodE application**
I.1.2.A.11. (d) Pathological, ecological and physiological traits. pg. 5.

[2] **GM equine vaccine Equilis RhodE application**
I.1.2.C.3. (e) Considerations for human health and animal health, as well as plant health. pg. 14.

No. 25

From

Robert Pocock
4, Royal Terrace West
Dun Laoghaire
Co Dublin
Phone 01 280 3309

30th January 2013

TO

Environmental Protection Agency,
PO Box 3000
Johnstown Castle Estate,
Co Wexford.

Representation against Deliberate Release Notification for a GMO Rhodococcus equi vaccine in proposed trial on Co Offaly.

I wish to register my strong opposition to the above proposed GM bacterial trial in the Irish state which is subject to European Union regulatory obligations in addition to S.I.500 of 2003 relating to GMO (Deliberate Release) Regulations. My reasons include:-

1. The EPA has failed to properly notify the public of the likely effects of such a trial in a clear breach of public trust, as required by the *Aarhus Convention.*

2. The possible effects on the local and national environment are enormous but the EPA has failed to even outline or communicate them to the public – another requirement of the *Aarhus Convention.*

3. The unknown risk to the local ecosystem is unacceptable particularly in light of the research evidence of 'unintended phenotypic changes' published by Podevin & Du Jardin (2012), Dasgupta et al (2001), Seralini et al (2012).

4. Since more uncertainties related to the safety of GM technology are emerging every day there is an imperative case for applying the precautionary principle to the proposed GMO Rhodococcus equi vaccine trial, as required under the *Cartagena Protocol.*

Fee of 10 Euro enclosed by cheque to accompany this representation. Cheque 000686 Robert Pocock Dun Laoghaire

Signed

Robert Pocock

Ballinreesh Nature Forum
Ballygerwin
Co Cork

No. 26

27/1/13

Re:
Deliberate Release Notification for a GMO Rhodococcus equi vaccine

To whom it concerns:

We hereby object to the proposed GMO Rhodococcus equi vaccine trial. In our opinion we feel that this GMO Trial has the potential to cause major harm to our environment many years into the future. Protecting our environment is of paramount importance. All the parties involved in this trial should be aware that they are obliged to comply with: Cartagena protocol, Aarhus Convention, 2001/18/EC and the Irish statutory instrument 500/2003.

Questions we would like answered: What is the likelihood of unanticipated effects: who benefits financially from such a approval. Why does this trial need to take place in this country. Are the instigators of such a trial willing to take responsibility for any adverse effects that may be caused to the environment.

Yours sincerely,

Liz Hopton

Niamh Traynor

Helen Alexander

Myles Berry

Daniel Benn

For and on behalf of
Ballinreesh Nature Forum

Sean O'Mellan

Peter Borton

Harwin Bogdanowitz

Ann Daly

No. 27

Bernadette Murray

From: Wexford Receptionist
Sent: 31 January 2013 09:02
To: Bernadette Murray
Subject: FW: Objection to proposed GM vaccine trial

Rec'd today at info

Ann Rochford,
Programme Officer,
Environmental Protection Agency,
P.O. Box 3000,
Johnstown Castle Estate,
Wexford.
Bosca Poist 3000,
Eastát Chaisleán Bhaile Sheáin,
Contae Loch Garman.
Tel: 00353 53 91 60600
Fax: 00353 53 91 60699
Email: info@epa.ie
web: www.epa.ie
Lo Call: 1890 33 55 99

From: alex archer [mailto:alexandraarcher@hotmail.com]
Sent: 31 January 2013 00:23
To: Wexford Receptionist
Subject: Objection to proposed GM vaccine trial

Baneshane,
Midleton
Co. Cork

EPA,
PO Box 3000
Johnstown Castle Estate,
Co. Wexford

30 January 2013

To whom it may concern:

RE Proposed GM Vaccine Trial

I am very concerned about the above, and as a consequence I wish to object to it.

As an Irish citizen, I am very worried about your allowing such a trial to take place in this country, especially without involving the public in any discussion and without presenting us with the results of research carried out elsewhere on the subject. I feel we have not been given enough notice to allow us to research the matter or give it due consideration, the notification having only recently – in the last week – been posted on your website.

The main concerns I have are for the long-term consequences of introducing a GM strain of the Equi vaccine here, and how these can be estimated if at all, given the limited state of our knowledge of these and the limited time available to apply it. I am therefore objecting on the grounds that adequate time has not been given to consider the matter, and that the information supplied by your Agency has, thus far, also been inadequate.

Because of this, I would like to think that you, as our national environmental protection body, intend to ask for further information and clarification on many fronts and have it made public, before you make your decision on this case. If you were not to do so, I fear a precedent might be set, and that other International companies, GM or not, would seek to rush through the process of obtaining permission for similarly problematical procedures in Ireland.

I await your response with anxiety and very much hope you will consider the points raised in this submission.

Alex Archer

No. 28

Bea Claydon

From: Wexford Receptionist
Sent: 01 February 2013 16:42
To: Bernadette Murray; Bea Claydon
Subject: FW: Submission to EPA re GM vaccine trial
Attachments: Stella Coffey representation EPA 1.2.13.docx

Rec'd today

Ann Rochford,
Programme Officer,
Environmental Protection Agency,
P.O. Box 3000,
Johnstown Castle Estate,
Wexford.
Bosca Poist 3000,
Eastát Chaisleán Bhaile Sheáin,
Contae Loch Garman.
Tel: 00353 53 91 60600
Fax: 00353 53 91 60699
Email: info@epa.ie
web: www.epa.ie
Lo Call: 1890 33 55 99

From: Stella Coffey
Sent: 01 February 2013 16:40
To: Licensing Staff; Wexford Receptionist
Subject: Submission to EPA re GM vaccine trial

Please find attached a representation regarding the GM vaccine trial. If you have problems opening the attachement please let me know.
The €10 fee has already been paid today by credit card in the name of Richard Auler.
Please confirm receipt of this email.
Thank you
Stella Coffey
052 7442816

Representation regarding Notification of a GM live bacteria vaccine field trial in Offaly to the EPA

Sender: Stella Coffey
Ballybrado, Cahir, Co Tipperary
stellacoffey89@gmail.com

Date: 1 February 2013
€10 paid by credit card ~3.30pm 1.2.2013 in the name of Richard Auler

---

1.A: All applicable law
Convention on Biological Diversity (CBD) and its Cartagena Protocol (CP)
Aarhus Convention
Article191(2) TFEU [1]

EC/2001/18,

SI 500 of 2003,

EC/623/2002,

EMEA/CVMP/004/04

I.B: Aarhus access to justice

In the absence of a proper accessible effective procedure to be able to review an administrative decision made (in the instant) such as per the pending instant administration decision to come, no decision ought to be made. It must follow that no decision can be made nor is permitted to be made on this notification.

I demand a finding and decision be made on this matter upfront and prior to any consideration of the instant application. Consequently, no decision and no consideration can be made on the instant application until the above procedural matter is fully determined, inter alia in the public interest and the interest of the environment and in the interest of all concerned, inclusive of the Irish Member State and the consequential financial penalty for breaches of international and EU law and our rights as EU citizens and as taxpayers and our Irish Member State character and reputation for being the worst habitual offender in Europe in this regard.

2: Access to information

2.A: Notice of the trial

[1] Previously Article 174(2)EC

2.A.1: While an advertisement in the Farmers Journal (some circulation in County Offaly) may have fulfilled some obligations under SI 500/2003, it does not fulfil the state's or its agency's obligations under other applicable law in terms of the public's right to information about matters affecting health and environment.

The deadline for objections is now[2] specified as 1 February. But the notification was not published by EPA on its website until 24 January. This is contrary to applicable law and therefore the notification must be re-advertised in order to comply with the public's right to know the details about the trial and to access the information necessary to make a decision. This is particularly relevant for people with limited or no technical knowledge as they would not have sufficient time to inform themselves and become familiar with the relevance of the notification to their health and the health of their environment within the deadline, and for those who need to consult with others in their organisations or networks. As many of these groups are voluntary and/or dispersed countrywide, consultation takes time, and 8 days is simply inadequate.

2.A.2: Timing of advertisement

According to information on the EPA website the EPA received an "application . . .seeking consent . . clinical study of GM equine vaccine" on 14 December 2012. According to SI 500/2003 article 29(3) after date of receipt by the Agency of the notification, the notifier should "cause to be published in a newspaper circulating in the State a notice of its proposal".

The notice was not published until 5 January, ie, it did not take place within the time specified in the applicable law. For this reason, the notification should be re-advertised.

2.B.1: Deprivation of access to information in the notification

The notification includes a 50-page document and a separate document titled 'Non-confidential Annex list'.

There are least 37 places in the document where the statement: INFORMATION DELETED FOR CONFIDENTIAL PURPOSES replaces deleted text.

The first instance, at 1.1.1.B, involves withholding the name, qualifications and experiences of the responsible scientist(s). It is impossible to imagine how such information can be reasonably withheld under the concept of 'sensitive commercial information' which is the legal basis for withholding information in this regulatory system. The public needs this information if only for the purposes of judging conflict of interest matters in the notification. To withhold it is depriving the public of its rights under the applicable law.

According to EPA documentation, the sections of the notification which have been replaced with INFORMATION DELETED FOR CONFIDENTIAL PURPOSES were

[2] Advertisement in Farmers Journal stated 'within the period of 28 days beginning on the day of publication of this notice'. The advertisement unhelpfully did NOT specify the date, particularly unhelpful as the paper in question is a weekly not a daily.

actually agreed between the notifier and the EPA. So the EPA had an active role in the exclusion of the public from the information about the names and qualifications of the scientists involved in this proposed trial: this action contradicts the EPA's role in protecting the public interest.

Section 1.1.5.D.5 of the notification further information is deleted regarding emergency response plans. Under the Cartagena Protocol on biosafety "any methods and plans for emergency response" shall not be considered confidential. As a party to the Protocol, this deletion is relevant to the methods and plans and does not conform with our CP obligations.

2.B.2: The non-confidential annex list

Regarding this list, I have issues with the following:
In order for people to have adequate access to information to assess the notification, copies of the papers itemised on this list must be made available – this can easily be done by having them in pdf format on the EPA website. Failing to include the approx. 36 papers online contravenes the public's right to full information. A similar recent notification in Germany is in the public domain, and included those papers.

Regarding the annexes deemed confidential by EPA, their titles and authors ought to have been included in the list. In the recent notification in Germany, details of the titles and authors of all 61 annexes were included in the annex information available to the public in a manner that did not conceal the identity of the withheld (as confidential) papers. EPA's decision to withhold this information from the public in Ireland contravenes my right to access this information.

The non-confidential annex list contains no information on Annex 6. However, this annex was not considered 'confidential' in the German notification (and given that all the journal articles in the annexes otherwise match, I am presuming that Annex 6 on the notification to EPA refers to the same paper as in Annex 6 in the notification in Germany). It is a review article described in the German notification as: Meijer WG and Prescot JF. 2004. Vet Res 35:383-396. On reading this paper, and noting that its existence as a reference was kept from the Irish public on the basis of business sensitive confidentiality, I am very concerned about the EPA's decision to agree to it being deemed confidential and its role in keeping it from the public. This exclusion by EPA is not in keeping with the public's right to information under applicable law.

3: BACTERIA: nature of & its relevance to ERA

3.A.1: Bacteria: relevant characteristics & features

"What we observe is not nature itself, but nature exposed to our method of questioning[3]" This thought ought to be borne in mind when attempting to come to terms with the astounding level of microbial diversity and the limits to what we know about bacteria and their role in the biosphere. That the GMO in this application is a bacterium deserves particular additional attention to the nature of bacteria.

The following must be kept in mind in order for meaningful assessment of this notification:
Scale: Their invisibility to the naked human eye limited man's acknowledgment of the existence of bacteria until the 19th century. The limitations of cultivation- and laboratory-based techniques throughout most of the 20th century resulted in gross under-estimation of microbial diversity levels[4] and their significance. An appreciation for the breadth and dynamics of microbial diversity in specific habitats, the spatial and temporal variability in the levels of microbial diversity, the factors driving this variability – all have resulted from new biotech tools (Fierer et al, 2011). But this new vista also shows up the huge gaps in those fields of biology that had their major growth spurts prior to the invention of genomic tools: gaps regarding bacteria and their pivotal roles in so many habitats. The specialist techniques required to work with them, and the focus limited to pathogens or those of commercial interest, has all helped to limit appropriate appreciation of bacteria.

With a lifespan of approx. twenty minutes it is virtually impossible for us to appreciate how selection pressures on bacteria can lead to development of new strains in mere hours, days or weeks of human time. Antibiotic resistance research confirms the speed of bacterial evolution. These issues are major ecological significance (including health ecology matters) and affect long term matters about the GM live bacterial vaccine in the notification.

The human microbiome was described[5] as a 'complex biological network comprising 10 microbes for each human cell (estimated 50-100 trillion cells/human) wherein the microbes have profound impacts on human health. Analysis of the microbiome led to "the discovery and characterization of a vast, human-associated network of gene exchange, large enough to directly compare the principle forces shaping HGT was described". The concepts of microbiome and ecology, and the role of HGT in bacterial genetic exchange all pinpoint aspects of bacteria that MUST be incorporated into a risk assessment of a GM bacterium

Unknown-knowns, known-unknowns, etc: In a field at such a pivotal stage of development as 'bacteria and their ecology' it is only responsible to identify the unknown knowns and the known unknowns[6] as much as possible to guide effective risk assessment and decision-making: the corollary position is to be irresponsible about risk assessment.

---

[3] Werner Heisenberg. 1962. Physics and philosophy: The revolution in modern science. Harper & Row, NY.
[4] Fierer N, Lennon JT. 2011. The generation and maintenance of diversity in microbial communities. American Journal of Botany 98(3): 439-448.
[5] Smillie CS, MB Smith, J Friedman, OX Cordero, DA Lawrence, EJ Alm 2011. Ecology drives a global network of gene exchange connecting the human microbiome. Nature. 480:8.12.2011.
[6] Late lessons from early warnings.2001. EEA report 22.

Such a list of known-unknowns must include the ecology of R equi as a soil inhabiting saprophyte. Contrast with R equi as a facultative pathogen: it is widely studied, experimented on and documented.
A recent trans-American study of soil bacterial communities[7] emphatically noted that the microbial communities differed fundamentally from the above-ground macro organisms.
Spores – Whether the state of microbial dormancy applies to R equi in the soil is relevant and must be taken into account in a manner similar to the presence of spores. A recent compilation of literature data estimated that on average, 90% of the bacteria in soils are metabolically inactive[8] and should have important implications for a variety of ecological processes that influence microbial diversity.

3.A.2: Bacteria and HGT

Humans only mix their genes when they produce offspring, but bacteria regularly exchange genes[9] throughout their lifecycles. This horizontal gene transfer (HGT) ability, is an important contributor to the rapid pace of bacterial evolution, another being changes in the bacteria's environment. When a bacterial strain develops a new way to beat antibiotics, or respond to the latest evolutionary pressure humans throw at it, the bacteria strain can share the new effect not only with its descendants but also with other bacteria.

Microbe abundance has not yet led to integrating information on distribution to ecosystem function and being on the road to increased understanding does not equate to adequate knowledge[10]. Current methodologies struggle to describe the vast microbial diversity in the soil, never mind the impact of bacterial HGT in its in vivo co-evolution.

3.A.2.1: HGT and monitoring

HGT in a major mechanism in bacterial evolution/co-evolution. Given their ubiquity and their invisibility to the naked eye, it is not reasonable to expect to be able control bacteria, never mind GM bacteria. In the origins of biotechnology GM bacteria were only ever considered in contained conditions, ie, deliberate release wasn't an option for GM bacteria.

The most obvious alternative, then, is not a technique but a decision to consider the scientific uncertainty surrounding bio-applications that introduce HGT risks and adjust the pace of releasing these products to match developments in our ability to monitor at relevant sensitivities[11]

---

[7] Fierer N, Jackson RB. 2006. The diversity and biogeography of soil bacterial communities. Proceedings of the National Academy of Sciences. 103:3.
[8] Lennon JT, SE Jones. 2011. Microbial seed banks: Ecological and evolutionary implications of dormancy. Nature Reviews Microbiology.
[9] Domingues, S et al. 2012. Natural transformation facilitates transfer of transposons, integrons and gene casettes between bacterial species. PLoS Pathogens 8(8).
[10] Kent AD, EW Triplett. 2002. Microbial communities and their interactions in soil and rhizosphere ecosystems. Annu Rev Microbiol 56:221-36.
[11] Heinemann, J.A. and Traavik, T. 2004. Problems in monitoring horizontal gene transfer in field trials of transgenic plants *Nat. Biotechnol.*

3.B: Vaccine issues

There are some fundamental issues about vaccines that need to be addressed before a GM live bacterium trial should proceed. Some need to be addressed at a global level, eg, by WHO. These include aspects of the ecological perspective of vaccines and their parent organism; co-evolution as an actor in vaccine impact; immunosystem vaccine burden; threat of and effect of vaccine escapes; the vaccine arms-race and its benefit to people.
"A major problem in developing vaccines is that microbes evolve and escape from immune responses[12]".
Genomic plasticity within lineages of recombinogenic bacteria can permit adaptation to clinical interventions over remarkably short time scales[13] (Paper title=response to clinical interventions, Streptococcus pneumonia. Vaccine-escpape serotype 19A isolates TO BE COMPLETED)
Vaccine-escapes US pneumonia vaccine[14]
One microbiology professor commented in 2011: "Our work suggests that current strategies for developing new vaccines are largely effective but may not have long-term effects that are as successful as hoped". His words about the pneumococcus vaccine make explicit the widespread unrealistic expectations for its long term effects. Moreover, many articles I surveyed about vaccines described them as 'highly effective', 'extremely effective' and other hyperbolic terms.

QUESTION: How will pathogenic strains of R equi evolve in response to the evolutionary pressure of the GM R equi vaccine? Future virulent forms of R equi and how to deal with them is part of the vaccine-development picture. The evolutionary effects of vaccines have been confirmed for mice and chickens[15] and cannot be ignored for GM R equi vaccine in terms of future virulent strains and their health impacts on humans and the environment.

The technology of GM vaccine production has developed greatly in the past 15 years. However the technology to assess the impact of GM vaccines has been virtually ignored, in other words the wherewithal to ensure the effects of GM vaccines on our environment does not exist[16]. This situation may be due to responsibility for its provision of assessment of effects on our environment lying with state, supra- and inter-national bodies. Whatever the reason, the fact is: responsibility for researching and monitoring environmental effects has been virtually ignored to date. Meanwhile the (mainly) corporate and biomedical interests involved in vaccine development and production have little incentive to change that situation. Traavik states that GM

---

[12] Iwasa Y, Michor F, Nowak MA. 2003. Evolutionary dynamics of escape from biomedical intervention. Proc R Soc London. 270, 2573-2578.
[13] Croucher NJ et al. 2011. Rapid pneumococcal evolution in response to clinical interventions. Science 331:28.1.2011.
[14] Brueggemann AB, Pai R, Crook DW, Beall B (2007) Vaccine Escape Recombinants Emerge after Pneumococcal Vaccination in the United States. PLoS Pathog 3(11): e168. doi:10.1371/journal.ppat.0030168
[15] Stearns SC. 2012. Evolutionary medicine: its scope, interest and potential. Proc R Soc B 279: 4305-4321.
[16] Traavik T. 1999. An orphan in science: Environmental Risks of Genetically Vaccines. Research Report for Directorate for Nature Management. While written in 1999, the state of development of environmental risk assessment of GM vaccines has not progressed.

vaccines constructs should be kept contained until credible ecological risk assessments are possible.

Note that a definition of vaccinology will be referred to in 5 below. Its contents have serious implications for any comprehensive overview of GM vaccines.

4. Biodiversity and biosafety rights

Life on earth is sustained by a small volume of soil surrounding roots[17], called the rhizosphere. The soil is where most of the biodiversity on earth exists and so is protected by the Biodiversity Convention. R equi is a soil-dwelling bacteria and very little is known about its role in the soil where it is presumed to have a saprophytic decomposing role.

What is the impact under contained conditions of GM R equi on the soil-inhabiting strains of R equi? And on other soil microbes? Until an appropriate response is available to these questions, on the basis of risk to the environment, approval of the field trial cannot be considered.

5: Science aspects relevant to this notification

5.A.1: Early biotechnology derived from an academic-based discipline and incorporated the more-or-less free exchange of research results "typified by openness of research and timely access to the results of research". By the late 1970s the commercial potential of genetic engineering was apparent and academic-based biotechnology developed strong corporate connections. These connections supported "the formation of a new norm of secrecy for biotechnology"[18].

Patents on GMOs became possible in 1980 following a US Supreme Court ruling. This event had further "negative impact on traditional norms of scientific enquiry". A report published in 2000 (Wright et al) concluded that "since (the biotechnology industry's) inception in the mid-1970s, this study shows that the industry has exerted considerable influence to close routes of access to knowledge concerning the nature of the organisms in use, the genes they carry, the techniques of modification, and the industry's intentions for the future of the field. Such a trend poses substantial barriers to informed public policy discussion on the advisability and safety associated with life forms that are appropriated as "intellectual property". "

While the above report was written by US-based academics, its context (the Biological Weapons Convention) is truly international; besides the involvement of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organisation (BIO), it also referred to the roles of the

---

[17] Hinsinger P, A Glyn Bengough, D Vetterlein, IM Young. 2009. Rhizosphere: biophysics, biogeochemistry and ecological relevance. Plant Soil. 321:117-152.

[18] Varieties of secrets and secret varieties: The case of biotechnology. 2000. S Wright, D Wallace. Politics and the Life Sciences. 19:1 p45-57.

European Federation of Pharmaceutical Industries and Associations (EEPIA) and the Forum for European Bioindustry Coordination (FEBC).

This information is being included to provide context for the scientific data and conclusions presented by the notifier.

The evidence to show systematic involvement of pharmaceutical interests, at national and supra-national levels, in establishing, copper-fastening and retaining legal protection for business-related science and technology data and reports is in the public domain. The practice goes way beyond the concept of 'trade secret' This practice and its spinoffs have undermined the ability of much biotechnology research to be 'independent', 'transparent[19]' or 'excellent', if only on the basis of its non-participation, or highly-selective participation, in the peer-reviewed system which is still considered to be an essential part of the 'scientific method' and a required feature of evidence-based decision-making.

Regarding the GM R equi field trial, this 'confidentiality' practice has resulted in the farcical situation where major details of research question, design, execution, results, analysis, reportage, have been fully or partly concealed from the peer review system. ALL of those details and more, have been concealed from the public in Ireland. There can be no confidence that whatever portions have gotten to the public domain in peer-reviewed journals actually reflect all relevant aspects of the research programme.

5.A.2: Business & Academia in Science

Some studies have taken place on the extent and effects of relationships between academia and industry in the life sciences. A 1994 study[20] examined the prevalence, magnitude, commercial benefits and potential risks of such relationships and reported that the relationships may pose greater threats to the openness of scientific communication that universities generally acknowledge: due attention was not being given within academia to this treat to scientific openness. This lack of attention has continued. A review[21] in 2003 reported that financial relationships among scientific investigators and academic institutions are widespread and noted how conflicts of interest[22] (CoI) arising from these ties can influence biomedical research in important ways. A later study[23] of CoI in articles published in peer-reviewed journals that report

---

[19] See Case T-13/99 Pfizer ECRII-3305 judgement summary.

[20] Blumenthal D, Causino N, E Campbell, K Seashore Louis. 1996. Relationships between academic institutions and industry in the life sciences – an industry survey. New Eng Jour Medicine. 334:6.

[21] Bekelman JE, Y Li, CP Gross. 2003. Scope and impact of financial conflicts of interest in biomedical research: A systematic review. JAMA. 289(4)p454-465.

[22] 'Conflict of interest' defined as a set of conditions in which professional judgement concerning a primary interest (eg validity of research) tends to be unduly influenced by a secondary interest (such as career or financial gain).

[23] Diels J, M Cunha, C Manaia, B Sabugosa-Madiera, M Silva. 2011. Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products. Food Policy. 36: 197-203.

on health risks or nutritional value of genetically modified food products, found the existence of either financial or professional conflict of interest was associated to study outcomes that cast genetically modified products in a favourable light, and a strong association was found between author affiliation to industry (professional conflict of interest) and study outcome. The findings likely reflect the increasing weight of corporate funding in research, publication restrictions imposed by industry funders, contractual agreements of authors with industry, industry bias favouring friendly research and researchers who are sensitive to the financial interests of their industrial sponsors or employers.

5.A.3: Corruption in Science

Another perspective on life sciences involves corruption[24], the documentation of which is reaching a mass too critical to be ignored. The following publications involve relevant research by academics of considerable :

Krimsky (a professor of urban and environmental policy and planning, and adjunct professor in the Department of Family Medicine at Tufts University) scrutinised the conditions that provide the breeding grounds for conflicts of interest in academic science and reported his findings in "Science in the private interest[25]" His information sources included appalling details of utter corruption of corporate-influenced science, details which emerged during court proceedings, ie, would otherwise otherwise have remained secret. Based on his research, Krimsky states:

> "public policies and legal decisions have created new incentives for universities, their faculty, and publicly supported non-profit research institutes to commercialize scientific and medical research and to develop partnerships with for-profit companies. The new academic-industry and non-profit-for-profit liaisons have led to changes in the ethical norms of scientific and medical researchers. The consequences are that secrecy has replaced openness; privatization of knowledge had replaced communitarian values; and commodification of discovery has replaced the idea that university-generated knowledge is a free good, a part of the social commons. The rapid growth of entrepreuneurship in universities has resulted in an unprecedented rise in conflicts of interest, specifically in areas sensitive to public concern. Conflicts of interest among scientists has been linked to research bias as well as loss of a socially valuable ethical norm – disinterestedness – among academic researchers."

The following extract by Prof Nicholas Ashford (MIT) from a letter published in the American Journal of Industrial Medicine, as noted by Krimsky, outlines the subtlety of bias that is introduced into scientific research, and more than any single study, demonstrates why total openness of research funding (and, in some cases, complete exclusion of conflict of interest is vital to the public trust of science. Ashford writes:

---

[24] Defined in Oxford online dictionary as: dishonest or fraudulent conduct by those in power.

[25] Krimsky S. 2003. Science in the private interest: Has the lure of profits corrupted biomedical research?. Rowman & Littlefield.

> "The avoidance of the appearance of conflict is every bit as important as conflicts themselves if science is to regain its proper stature in public policy debates. It is an illusion to insist that values do not shape the choices of problems addressed, data relied upon and interpreted, methodologies employed in discovery and analysis, presentations and reporting of results, and acknowledgement of contrary views and data. One does not have to manipulate data or use invalid methods tantamount to fraud to bias a scientific paper. The omission of the citation of contrary data and studies is very difficult to pick up in the process of peer review. There is considerable leeway within acceptable choices to investigate, interpret, and present data – and cite other studies . . . Intentional bias in choices of methodology, data, and styles of interpretation within well-accepted limits are well-nigh impossible to detect or prove."

Bending Science: How special interests corrupt public health research[26] *documents an* investigation of the ways science is manipulated in the process of regulatory policy- and legal decision making. Thomas McGarity and Wendy Wagner, both University of Texas law professors, present an encyclopedia of endeavors, undertaken largely by industry, to distort scientific enterprise in order to promote self-interests. Like a number of recent books on this subject . . this one presents a serious look at the mechanics of scientific manipulation[27]. McGarity's science pipeline model[28] makes it clear where benders can have effects, especially as his model extends to policy and expert panel stages. His lists science bending activities as shaping, hiding, attacking, harassing scientists, packaging, spinning. His catalogue of corruption includes vinyl chloride, silicon, tobacco, climate change, GM crops and a slew of drugs. Again and again the endangered issue was public health and environmental health.

Epidemiologist, David Michaels, is currently Assistant Secretary of Labour for Occupational Safety and Health (OSH) in the Obama administration and on leave as professor in Department of Environmental & Occupational Health in George Washington University. His 2008 book Doubt is their product: how industry's assault on science threatens your health[29] records numerous cases where industry steadily worked to subvert, corrupt or infiltrate the regulatory mechanisms in place to protect the public from health-damaging effects. A number of crucial lessons can be learned from Michaels' first person rendition of events:

> "As this story unfolded in 2004, it was hard for me to imagine that the company's scientists were deliberately promoting a drug they knew was unsafe and would result in disease and death for a considerable number of people. At first I thought their original interpretation that naproxen prevented

---

[26] McGarity T, Wagner W. 2008. Bending Science: How special interests corrupt public health research. Harvard Univ Press.

[27] Extracted from a review in the Journal of Clinical Investigation. 2009.119(1) by David Rosner, School of Public Health, Columbia University Medical Center, New York.

[28] Observation: conduct research: interpret data: journal peer review: post publish scrutiny: expert panel opinions: policy relevant information.

[29] Michael David. 2008. Doubt is their product: How industry's assault on science threatens your health. Oxford University Press.

heart attacks (rather than that Vioxx caused them) was the result of the unconscious workings of the funding effect. On the other hand, as revelation followed revelation, I found it harder and harder to believe that this was merely a case of well-meaning scientists unintentionally misinterpreting the data. It was almost painful to read the scientists' public statements suggesting that naproxen had powerful cardioprotective effect. No drug has even been shown to reduce heart attack risk by 80 percent. If the scientists honestly believed their claim, they should have lobbied the government to pour Aleve directly into the nation's water supply. Still, I had trouble believing that scientists would knowingly promote such a dangerous drug. When I presented this theory at a meeting, an editor of one of the leading US medical journals criticized me for hopeless naiveté. Industry scientists know the truth and simply lie about it, he said.

Perhaps the most outrageous part of the whole Vioxx debacle is that most of the patients who were prescribed the drug (as well as those getting Celebrex and the other COX-2 inhibitors) did not need them because they were at little or no risk for stomach bleeding. Aspirin or some of the other analgesics work just as well and at far less cost than the COX-2 drugs. For many patients, Vioxx would be more likely to cause a heart attack than to prevent a gastrointestinal event. Millions of patients were prescribed drugs they did not need; thousands had heart attacks that were 100 percent avoidable[30]."

Michaels, who has wide experience of policy development and regulatory systems, notes that regulation that protects the public's health and the environment must be based on the best available science, and the best science is science is science done by independent investigators. He notes (p255) that while drug and chemical companies companies employ the best and brightest scientists whose

"work is often of the highest quality, but for all their exceptional work we cannot assume that they provide an unbiased interpretation of the literature. The Vioxx debacle is a powerful example: Scientists working for Merck, including academic scientists who were only consultants, interpreted (or presented) the initial studies incorrectly – and helped to convince the FDA to do the same. Tens of thousands of preventable heart attacks later, the correct interpretation of the early studies is now clear."

Court-archived tobacco industry documents[31] show definitively that the industry will expend whatever effort is necessary to protect itself from public health policy that would adversely affect consumption of cigarettes and, therefore, profits. The archives contain company papers related to their advertising, manufacturing, marketing, sales, and scientific research activities, and have been accessible for just over ten years to researchers; new evidence of the depth and breadth of the corruption still emerges. One review[32] of internal company documents reveals that members of the tobacco industry and its corporate attorneys created an international scientific consultants programme to influence public opinion on environmental

---

[30] Psaty BM. Testimony before the Senate Finance Committee, USA. 18.11.2004.

[31] Muggli ME, RD Hurt, J Repace. 2004. The tobacco industry's political efforts to derail the EPA report on ETS. American Journal of Preventive Medicine. 26(2) 167-77.

[32] Muggli ME, RD Hurt RD, DD Blanke. 2003. Science for hire: a tobacco industry strategy to influence public opinion on secondhand smoke. Nicotine Tob Res. 5(3): 303-14.

tobacco smoke (ETS). The analysis shows lengths to which the tobacco industy went to battle the ETS issue worldwide by camouflaging its involvement and creating an impression of legitimate unbiased scientific research.

5.A.4: Fragmentation of Science

There is no doubt that the spinning off of specialties and sub-specialties has added to the problems of regulatory science. Not only is the effect of the fragmented reductionist framework of science as practised and taught in universities part of the problem – technical terminology alone makes some specialities unintelligible to colleagues – but the academic habit of hierarchy creation does not engender cross-discipline collaboration, concept sharing or cross-fertilisation of ideas in many cases. It is deeply ironic that the basis for systems theory was inspired by living organisms whereas many life scientists never apply systems thinking to their work perspectives.

5.A.5: Limitations of a speciality

Decribed as follows in a 2007 review[33],

> "vaccinology has become a recognised science that combines disciplines of immunology, microbiology, protein chemistry, and molecular biology with practical considerations of production costs, regulatory affairs, and commercial returns."

This definition suggests that the scientific disciplines have lost their disinterestedness (a universally-agreed requirement for valid science) under the influence of commercial returns, etc: it must be noted that commercial returns tends to block out the long-term view so necessary to accommodate biological evolutionary, co-evolution and ecological perspectives, perspectives that are crucial for protection of human health and environmental health.

5.A.6: Source of relevant evidence

Late lessons from early warnings: the precautionary principle 1896-2000[34] contains a series of case studies of harmful impacts of technical innovations, and charts the gap between the first warnings of harm to the point where political effect put a stop to the damaging activity. Some took decades, some like took over 50 years until the body count or life-less lakes forced the system into action. The cases, such as asbestos, PCBs, antimicrobials as growth promoters, lead in petrol, BSE and DES dragged out as long as they did with the collusion of scientists in industry and in academia, and regulators and with some of the corrupt practices referred to above. The evidence from these and other similar case-studies must be included in any realistic assessment of health or environmental risk.

5.A.7: Biotech's blinkers

For an outsider trying to understand how science works, the prevalence of particular blindspots is astonishing, especially when one considers the contrary evidence available. In particular I note the blinkered view of many life scientists which excludes: evolutionary perspectives, ecological perspectives and their interactions with biota and abiota, biosphere perspective. The catch-phrase of 'it's not my area of

---

[33] Meeusen ENT, J Walker, A Peters, P-P Pastoret, G Jungersen. 2007. Clinical Microbiology Reviews. 20(3) p489-510.

[34] European Environment Agency (EEA). 2001. Late lessons from early warnings: the precautionary principle 1896-2000. EEA Report 22.

expertise' is no excuse for not having at least a conceptual awareness of these core life science matters.

5.A.8: Warning for science in Ireland

A technology assessment workshop took place in TCD during Dublin's City of Science 2012. It was the Irish National Workshop of the Pacita[35] project. Titled Connecting Society and Technology the workshop report noted that 'there are real fears of the reputational and financial damage that could be caused by a 'rogue scientist' operating in Ireland. 'Bad science' is taking place in Europe and it would be naïve to believe it could not be or is not an issue in Ireland. . . Ireland lacks strong regulatory and governance structures to formally promote intergrity and tackle misconduct. . . .Closing the Irish Council for Bioethics in 2010 is viewed as a retrograde step . . . the immaturity of the Irish STI system, many elements of which emerged in the past 20 years often through 'subterfuge' – the elements were justified under the umbrella of supporting job creation. . . . many decisions involving science and technology . .continue to be justified in terms of economic impacts while largely ignoring important societal impacts."

5.B: The In vivo / in vitro issue and molecular life sciences

One of the foundational problems of the molecular life sciences is the in vivo/in vitro problem, ie, how to justify the biological relevance of in vitro experimental evidence. Roger Strand[36] in his description of the BSE crisis illustrates the limitations of in vitro evidence in terms of in vivo events involving the same organism. Strand's analysis[37] sets the object of study within ecological relationships even to a global scale and is emphatic about the uselessness of in vitro evidence for environment risk assessment and the absolute need to be responsive to the issues of ignorance, bias and uncertainty. According to Strand some things can definitely be done to articulate and manage uncertainty, bias and ignorance in molecular life sciences in a better way. However, when it comes to global problems due to non-sustainable life science technology, there are no easy answers.

5.C: ECJ & science

Aspects of science and risk assessment have been prescribed in a European Court of Justice judgement[38] as follows:

"The duty imposed on the Community institutions by the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection means that they must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research. Thus, in order to fulfil its function, scientific advice on matters relating to consumer health must, in the interests of consumers and industry, be based on the principles of excellence, independence and transparency. . . .Where experts carry out a scientific risk assessment, the competent public authority must be given sufficient reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. . . . the competent public authority must ensure that any

---

[35] Parliaments and civil society in technology assessment. www. Pacitaproject.eu

[36] Professor at Center for Science, University of Bergen, Norway.

[37] Strand R. 2000. Naivety in the molecular life sciences. Futures. 32:451-470.

[38] Case T-13/99 Pfizer ECRII-3305

measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society. That is the basis on which the authority must decide whether preventive measures are called for and, should that be the case, which measures appear to it to be appropriate and necessary to prevent the risk from materialising."
Note the ECJ's requirement for science to be excellent,independent and transparent.

5.D: EU level regulation of veterinary products
The European Medicines Agency (EMA) is the EU level body charged with regulating veterinary products. EMA uses panels and committees of experts in assessing whether products comply with the applicable regulations. In 2012 EMA was subject to an audit of the European Court of Auditors. The court concluded in its report[39] in October 2012 that EMA has not adequately managed the conflict of interest situations reviewed and its agency-specific policies and procedures and/or implementation have shortcomings. The cases noted by the Court of Auditors included: restrictions were not properly applied to EMA scientific commitees; corporate funding of a particular product was not used to exclude experts involved in assessing the funded product; restrictions on experts were not properly applied.

5:E Reputational aspects
According to current information on wwwepa.ie, the notification was presented to EPA by Merck Sharp & Dohme acting on behalf of Intervet International BV, a Netherlands-based company. It is difficult to clarify where the animal health section of Merck Sharp & Dohme ends or what or where the connection between Merck Sharp & Dohme and Intervet International BV is, particularly as Merck Sharp & Dohme in Ireland presents itself as MSD Ireland. Or indeed, which manifestation of Merck Sharp & Dohme presented the notification to the EPA. The address of the Netherlands company was provided by the EPA but not so for Merck Sharp & Dohme.

Internationally Merck Sharp & Dohme has animal health and human health divisions. Aspects of the multi-faceted Vioxx scandal have already been described in 5.A.3 above. Other shocking aspects involve research manipulation as in the ADVANTAGE[40] seeding[41] trial for Vioxx, peer-review manipulation[42], creating faux (or spurious) journals[43], and funding front organisations[44] to influence the media. In

[39] European Court of Auditors. 2012. Management of conflict of interest in selected EU agencies. Special Report No 15/2012.
[40] P213-4: Bad Pharma: How drug companies mislead doctors and harm patients. 2012. Ben Goldacre MD. Fourth Estate.
[41] Seeding trial is described by Ben Goldacre (p212) as 'viral marketing projects designed to get as many doctors as possible, with tiny numbers of participants from large numbers of clinics.
[42] P296, Bad Pharma
[43] P209, Bad Pharma
[44] P338, Bad Pharma

effect Merck has a documented reputation for spinning and distorting its research, even when the stakes involves life threatening effects.

What medical doctor and journalist Ben Goldacre describes as a 'mess hidden in plain sight' and an 'elaborate betrayal' in the biomedical field is obviously underpinned by organisational cultures that have degenerated to the stage where the incidents involved Merck referred to above took place, many within the past decade. There is nothing to suggest that the organisational culture within Merck and its many business divisions has not had an effect on how and why development of the GM equine vaccine Equilis RhodE in this notification was conceived, designed and carried out. The reputational taint regarding documented incidents of fraudulent, and corrupting behaviour with products put on the market by Merck must be taken into account when assessing the quality, transparency and independence of the scientific information in the notification.

5:F: Summary of some major science aspects of the notification
In light of all the above aspects of science, the following emerge as major issues regarding the notification and its scienctific contents as presented by the developer:
Transparency of the science is utterly lacking regarding

- The deleted information
- The withheld reference material
- The research's hypothesis, research question(s), research design, research execution, data collection, data analysis, who is directing the project, carrying out the work
- The details behind the statements in the environmental risk assessment

Independence in how the research was done is lacking regarding:
There is not enough information about the research and who is directing it. It is presumed that some if not all of the genomic work was carried out inhouse in Intervet International. (Notification does specify that testing during the trial will be done in its own laboratory.

Excellence in science cannot be determined without transparency as the concepts and data cannot be critically examined, challenged or tested by colleagues or other parties.

The field of vaccinolgy appears to be operating within a conceptual framework which excludes evolutionary and environmental perspective and is without a global perspective of immunology: as such its operations are a threat to health and the environment on a global scale, to the point where the issues needs WHO attention.

Documentary evidence of corruption of science at research, at peer review and at regulatory levels is now irrefutable. This situation has greatly contributed to the current lack of trust in corporate-run research and in regulatory science.

6. Precautionary principle and its implications
6.A: Molecular characterisation
Most details regarding the molecular characterisation of the GM bacterium have been deleted or otherwise withheld. Given the importance of this information in terms

of designing and executing a meaningful environemental risk assessment (ERA), this is unacceptable, especially in terms of being able to get 'independent' opinions on the notification claims.
The claim that the vaccine contains no foreign DNA or DNA fragments needs truly independent confirmation.

6.B: Genetic stability
Again, the argument of no additional/extra genetic material is being used to assume similarity to the wild type.
As above, the claims of genetic stability must be assessed by truly independent testing. Otherwise a meaningful ERA cannot be carried out.

6.C: Resistance issues
Resistance issues appear to have been ignored in this notification. In terms of the long-term health and environment implications of the GM vaccine, all major resistance factors, including vaccine practice, must be examined and all hazards arising be dealt with in a manner that protects human health and environmental health.

6.D: Biosafety issues
Biosafety issues appear to have been ignored in this notification. The hazards involved in releasing a live bacterium vaccine must be considered, especially as other strains of the GM bacterium are ubiquitous soil-dwellers and the similarities of the GM R equi and its wild type with Mycobacterium tuberculosis[45]. The history of M tubercul In terms of obligations under the Biodiversity Convention, this situation must be redressed.

7. Environmental Risk Assessment (ERA)
7.A: Execution of ERA
According to 2002/623/EC the ERA should be carried out in a scientifically sound and transparent manner, based on scientific and technical data. Sections 3 to 6 above contain considerable evidence regarding the questionable quality of the scientific and technical data presented, both that seen and that withheld under 'confidential' claims. Furthermore, when transparency is missing, the quality of the science is not verifiable[46].

The ECJ judgement highlighted that the science must be excellent, independent and transparent. The scientific and technical details in the notification do not comply.

The certainty claimed about the molecular characterisation details and in genetic stability is the basis for many claims in the ERA. These claims are unsupportable.

The fate of most (GM) microorganisms introduced into the soil are not very predictable since knowledge on most is scarce[47].

---

[45] Rosas-Magallanes V et al. 2006. Horizontal transfer of a virulence operon to the ancestor of Mycobacterium tuberculosis.
[46] Favre Didier, Jean-Francois Viret. 2006. Biosafety evaluation of recombinant live oral bacterial vaccines in the context of European legislation. Vaccine 24 p3856-3864.
[47] Bordogna Petriccione B. (2004) Introduction to GMO : technique and safety in Les

No independent scientific evidence available up to this point (basis for all conclusions in ERA is based on company's own data). Furthermore, testing during field trial will take place in developer's own lab.

The multi-faceted evidence above challenging the quality of the science and technical data given in the notification is at odds with the notifier's claims of "effectively zero", "nearly zero", "negligible", etc. These claims are unsupportable.

The uselessness of in vitro evidence to provide reliable information (see 5B) on in vivo behaviour of a recently-engineered bacterium strongly suggests this ERA is premature and only more independently designed and executed contained trials could determine valid and reliable information for an ERA that is capable of properly protecting human health and environmental health in terms of this GM vaccine.

The inability to monitor the actual presence of the GM R equi in the soil is acknowledged by the notifier (p39, 4a) and is presumably for technical reasons. This confirms the opinions of Heinemann and Traavik[48] who have variously described the environmental assessment technology for GMMs as being neglected and/or underdeveloped, and not in pace with GM vaccine development.

With a starting date of March 2013, there is no record in the notification regarding baseline date on the receiving environment, particularly the soil. Meaningful monitoring assessment of impact of the GM R equi should include a full annual cycle sampling, prior to the trial's commencement date, of all the soil's major components.

As monitoring is a legal requirement for a field trial/deliberate release of a GMO, then the technical inability to monitor it must lead to prohibition of the field trial. On this basis alone this field trial must not be approved as the implications for human health and environmental healths are simply hazardous.

7.B: Long-term aspects of ERA

Evolutionary biology, co-evolution aspects, evolutionary medicine, evolutionary microbiology, epidemiological knowledge related to vaccine use and pathogenic bacteria, ecology, population genetics are among the perspectives missing from the ERA. Without these perspectives it is simply not possible to fully assess the long-term human health and environmental health aspects of the GM live bacterium vaccine. Proper consideration of long-term aspects of the release is particularly specified in the applicable law.

7.C: Human health and environmental health factors on basis of 5&6 above

Given that so little is known about some aspects of Mycobacterium tuberculosis despite it having been a major cause for human and animal disease for centuries, it

---

[48] Heinemann, J.A. and Traavik, T. 2004. Problems in monitoring horizontal gene transfer in field trials of transgenic plants *Nat. Biotechnol.*

is important to note the relationship/similarities[49] of GM R equi and its wild-type to the TB-causing organism. Seeing that the contribution of interspecies HGT to the evolution and virulence of M tuberculosis has barely been investigated[50], much less understood, experimenting in uncontained conditions with a related GM bacterium would appear to be the height of irresponsibility in terms of the hazard to human health and the environment, particularly in the long-term.

Reports of R equi infection in immunocompetent humans was very underplayed in the notification. The contents of the 2011 paper[51] suggest that infection in immunocompetent people is increasing (may be due to improved indentification). The increased infection among immunocompromised people with HIV/AIDS is of concern particularly in the long term. However, the list of people at risk, eg, those receiving chemotherapy as cancer treatment, post-transplant people, is incomplete. In addition there is no information about whether the hazard for those groups – pregnant women, older people, young children and others with immune-limiting or other immune-compromising conditions, has been addressed. The unknowns are so great that this trial must not proceed.

9. Conclusion

9.1: There are short comings, legal and otherwise, regarding this notification which demand that it be re-advertised.

9.2: The science and technical information presented by the notifier are not independent and so therefore does not comply with the legal requirements for a proper ERA. On this issue alone the trial must not be allowed to proceed as the hazard for human health and environmental health is simply too great.

9.3: The implications of the history of Merck and its various corporate manifestations, and some major research/trials controversies in recent decades do not allow for the science and technical details provided by the notifier/developer to be taken at face value. On this issue alone the trial must not be allowed to proceed as the hazard for human health and environmental health is simply too great.

9:4 The state of existing knowledge, questionable reliability of data presented by the notifier, unsupportable assumptions and generalisations made in ERA by the notifier gives rise to the conclusion that: the hazard to human health and environment health is simply too great. Both these hazards demand that any further trials with this GM vaccine must take place only under contained conditions until those hazards are deemed to be addressed. Existing law demands more contained trials before deliberate release can be allowed

9.5: Apparently issues regarding the transparency, excellence and independence of the notification's science as outlined in 5 above were not taken into consideration by the German authorities when it granted approval to a similar trial in Germany, nor by the Dutch authorities when they approved trials of the same vaccine. The Irish

---

[49] Meijer WG, Prescott JF. 2004. Rhodococcus equi. Vet Res 35:383-396.

[50] Rosas-Magallanes V et al. 2006. Horizontal transfer of a virulence operon to the ancestor of Mycobacterium tuberculosis. Mol Biol Evol 23(6):1129-1135.

[51] Sandkovsky U et al. 2011. Rhodococcus equi infection after reduction mammoplasty in an immunocompetent patient. Rev Inst med Trop. 53(5):291-294.

competent authority has the obligation to include the information provided in this represention in its decision-making and so re-consider the implications of the decisions by the Dutch and German competent authorities.

29

Richard D. Barton
Kevin Street, Tinahely,
Co. Wicklow
Tel: 0402-38477

07 March 2013

EPA Headquarters
P.O.Box 3000
Johnstown Castle Estate,
Co Wexford.

Subject: Objection to yet more GM trials.

Attn. Dr. Tom McLoughlin

Dear Dr. McLoughlin,

Thank you for your registered letter.

1.. I enclose my original objection which was rejected so arrogantly and unhelpfully by Ms. Claydon. Fortunately, I did not have time to take that further before receiving your letter.

2.. I have four additional questions.

a.. I would like a clear explanation as to why I have to pay to object to something potentially dangerous being done in my country. This is supposed to be an open democracy. Or do we only vote on suits and faces but not on anything that actually happens?

b.. Why, as a voter with at least some rights left, was I not asked about this risky experiment? I only found out by complete chance. Same remarks as above about openness.

c.. Why is this experiment being carried out in Ireland? I lived in The Netherlands for over 20 years and I know that there are many horses there.

d.. Does the EPA guarantee that, if the results of this research experiment are negative, perhaps even dangerous for the horses, there will be no consequences for our environment or other animals?

3.. I also enclose, with above objections, a cheque for 10 euros.

Yours sincerely,

Richard Barton

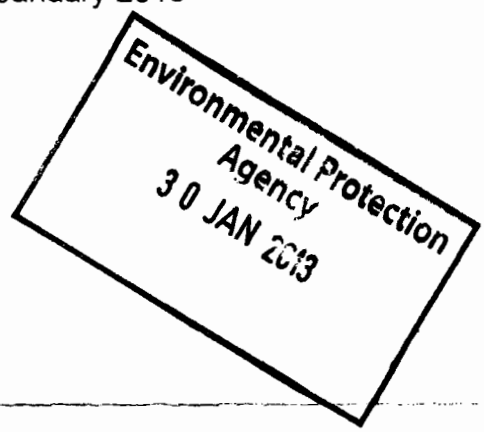
R.D.Barton (Dip Nutritional Medicine, Dip. Counselling, researcher and writer)

Invalid
No Payment
Received

Richard D. Barton
Kevin Street, Tinahely,
Co. Wicklow
Tel: 0402-38477

29 January 2013

EPA Headquarters
Johnstown Castle Estate,
Co Wexford.



Objection to yet more GM trials.

Dear Sirs,

I have only just found out about the proposed GMO vaccine trials. Seemingly, you only released the 50 pages of information on the 22 January, a mere 9 days before the deadline for objections. That in itself is an outrage in a supposedly open society. It barely gives time to send in a letter let alone actually read the information. Given the now **KNOWN**** harmful, long-term effects of almost everything connected with GM products., I would like to state my strongest objection to yet another arm of government trying to sneak yet another GM organism in the back door behind our backs.

** The results of the first long term GM trials (Scandinavia and France, for instance,) are now starting to come out into the public domain. They are ALL negative. Like so many other products of profit-oriented 'science' (asbestos, thalidomide, high-fructose corn-syrup, lead in petrol, fluoride in drinking water, mercury amalgam fillings, DDT, arsenic, mercury adjuvants in vaccines, cigarette smoking, MANY potentially lethal pharmaceutical drugs, Glyphosate, etc., etc., etc., etc.) the dangers to the public need **long-term,** VERY carefully controlled and confined studies. They do not need the usual short-term, company-oriented, sometimes even company-funded, studies.

Our government is supposed to be running the country for OUR good, for the benefit of the decent taxpayers who keep the country going, and not for large corporations !! To help convince us of this, a lot more openness would be very desirable.

Yours faithfully,

R.D.Barton (Dip Nutritional Medicine, Dip. Counselling, researcher and writer)

(30)
Additional to
No. 10

Dr Tom McLoughlin,

Senior Inspector,

Environmental Licensing Programme,

EPA

Johnstown Castle Estate,

Co Wexford

14th March 2013.

Re GM vaccine trial R.Equi

Dear Dr McLoughlin,

I am writing in response to your letter to me dated 19th February 2013 in which you extend the deadline for receipt of further representations in this matter to 19th March 2013.

In this second letter to you , I will develop further my concerns in relation to human health which were referred to in my initial submission to you dated 28th January 2013, in point 7.

In the non-confidential notification relating to the proposed GM trial, the following sections are relevant:

1.1.2.A.8 " In humans the bacterium may cause cavitary pneumonia but this is predominantly in immunocompromised individuals."

1.1.2.C.3 (c) "Since it has been demonstrated that the vaccine (mutant strain) is less able to survive in human macrophages (in contrast to the parent strain) , it is expected to be unable to cause disease in (immunocompromised) humans, although a direct correlation between survival in macrophages and human pathogenicity has never been tested or demonstrated."

1.1.2.C.3 (d) "R.Equi infections in immunocompetent humans are extremely rare."

A review of the scientific literature on R.Equi infections in human subjects demonstrates that R.Equi is regarded by the medical and scientific community as an emerging pathogen which was previously underdiagnosed, and which can cause very serious illness in both normal subjects as well as those with compromised immunity : I will make direct reference to two papers in this regard, and list a number of others.

Weinstock et al in 2002 in a peer reviewed article entitled " Rhodococcus Equi: an emerging pathogen" (1) stated that: " On the basis of available reports of cases, approximately 10%-15% of infections occur in seemingly immunocompetent hosts , with the remainder divided between patients with HIV infection and patients who are otherwise immunocompromised (either from disease, immunosuppressive medications, or both) ."

In 2007 Tuon et al while acknowledging the relative rarity of R.Equi infections in immunocompetent humans, drew attention to how it is a "commonly encountered" infection in a wide range of immunocompromised patients including HIV patients, recipients of organ transplants, patients with lymphoma, chronic renal failure, alcoholism, lung cancer, leukemia, diabetes mellitus and other states of immunodeficiency. The authors also commented on the increasing incidence of reports of this infection, noting that the bacterium can easily be mistaken for a number of other contaminants(2).

Discussion:

The current status of Rhodococcus Equi is as a rare but highly significant pathogen of both immunocompetent and immunocompromised humans. The attached extended bibliography illustrates this point clearly.

The notification document in relation to the proposed trial makes reference to this fact , but goes on to make an untested assumption about the ability of the mutant strain to cause disease in humans. Such an assumption should be the subject of further laboratory research. An open release trial is inappropriate at this stage in view of the as yet unanswered questions regarding pathogenicity in humans, both immunocompetent and immunocompromised.

Addendum:

As a final point, it is entirely unacceptable and without justification that the EPA has arbitrarily extended the deadline for further submissions on this matter to a limited group, namely those who made an initial submission. If, as your letter to me on 19th February 2013 acknowledges, the EPA "...left members of the public 11 days (instead of the required 28 days) to make represention" then the notification process was in breach of SI 500/ 2003, and the trial should have been readvertised. I am formally requesting that the rights of Irish citizens be upheld and that this is done.

Bibliography:

1. Rhodococcus Equi, an emerging pathogen, David M Weinstock and Arthur E.Brown. Clin Infect Dis. (2002) 34 (10): 1379-1385. Doi: 10. 1086/34025
2. Rhodococcus Equi Bacteremia with lung abscess misdiagnosed as corynebacterium. A report of two cases. Felipe Francisco Tuon, Rinaldo Focaccia Siciliano, et al. Clincs 2007: 62(6): 795-8

---

3. Rhodococcus equi meningitis after ventriculoperitoneal shunt insertion in a preterm infant. Strunk T, Gardiner K, et al. Pediatr Infect Dis J. 2007 Nov; 26(11):1076-7
4. Rhodococcus meningitis in an immunocompetent host. De Marais PL, Kocka FE. Clin Infect Dis. 1995 Jan: 20 (1): 167-9
5. Acute osteomyelitis caused by Rhodococcus equi in an immunocompetent child. Indian Journal of Pathology and Microbiology. 2009: 52(2) 263-264
6. Rhodococcus Equi—a newly recognized pathogen in man. Votava M, Skalka B, Tejkalova R. Epidemiol Mikrobiol Immunol. 1997 May 46 (2): 58-66
7. Rhodococcus Equi infections in immunocompetent hosts: case report and review. Kedlaya et al. Clinical Infectious Diseases 2001: 32e 39-47
8. Rhodococcus species fatal infection in an immunocompetent host. Spark Rp et al. Arch Pathol Lab Med. 1993 May 117(5): 515-20
9. Rhodococcus equi brain abscess in an immunocompetent patient. Corne P et al. Scand J Infect Dis. 2002: 34(4): 300-2
10. Rhodococcus Equi brain abscess in a patient in hemodialysis (article in Spanish) Martin MP et al. Nefrologia 2000 Jul-Aug 20(4): 387-8
11. Pyogenic liver abscess due to Rhodococcus Equi in an immunocompetent host. Napoleao F et al. J Clin Microbiol. 2005 Feb 43(2): 1002-4
12. Disseminated Rhodococcus Equi infection in a kidney transplant patient without initial pulmonary involvement. Rahamat-Langendoen JC et al. Diagn Microbiol Infect Dis. 2009 Dec: 65(4) 427-30. Doi. 10.1016/j microbio. 2009.08.004. Epub 2009 Sep 16

13. Rhodococcus Equi infection in transplant recipients: a case of mistaken identity and review of the literature. Perez MG et al. Transpl Infec Dis. 2002 Mar; 4(1); 52-6

14. Cerebral infection with Rhodococcus Equi in a heart transplant recipient. Kohl. O, Tillmanns HH. J Heart Lung Transplant 2002 Oct; 21(10): 1147-9

Bea Claydon

From: Tom McLoughlin
Sent: 19 March 2013 10:14
To: Bernadette Murray
Cc: Bea Claydon
Subject: FW: Urgent letter for Dr Tom McLoughlin re R.Equi Trial
Attachments: Dr Tom McLoughli1.docx2.docx

From: Wexford Receptionist
Sent: 19 March 2013 10:11
To: Tom McLoughlin
Subject: FW: Urgent letter for Dr Tom McLoughlin re R.Equi Trial

Rec'd for you Tom.
Thank u Ann.

Ann Rochford,
Programme Officer,
Environmental Protection Agency,
P.O. Box 3000,
Johnstown Castle Estate,
Wexford.
Bosca Poist 3000,
Eastát Chaisleán Bhaile Sheáin,
Contae Loch Garman.
Tel: 00353 53 91 60600
Fax: 00353 53 91 60699
Email: info@epa.ie
web: www.epa.ie
Lo Call: 1890 33 55 99

From: alan moore [mailto:alanomoore@gmail.com]
Sent: 18 March 2013 20:57
To: Wexford Receptionist
Subject: Urgent letter for Dr Tom McLoughlin re R.Equi Trial

Dear EPA,

I would be grateful if you could forward the attached letter to Dr Tom McLoughlin tomorrow, Tuesday 19th March, in order to meet the deadline for further submissions in relation to the proposed trial of GM Rhodococcus Equi. I should be grateful if you could also acknowledge safe receipt of this email and attachment.

Thank you,

Yours faithfully,

Alan Moore