ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

DRAFT a

Submission Form

Please feel free to write on or photocopy this form.
We have drawn it up as a guide - you do not have to use this format.

Name of person/organisation making the submission Greenpeace New Zealand, Inc.

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This submission is about - Application number: GMF07001

Application by AgResearch Limited **(applicant name)**

to To field test in containment, organisms with a range of genetic modifications and maintain these organisms in containment for research, breeding and for the production of products with potential commercial applications **(application purpose)**

Reason for submission (attach supporting information)
Our reasons are attached.

What decision do you seek (optional) Decline the application.

Do you wish to be heard in support of your submission?[1] ☑ **Yes** ☐ **No**
(at a public hearing)

Signature _____ **Date** _____

Post to: **ERMA New Zealand**
P O Box 131, Wellington

Fax to: **ERMA New Zealand**
(04) 914 0433

[1] Please note that if any submitter indicates they wish to be heard, the Authority is obliged to hold a public hearing.

Greenpeace New Zealand, Inc.
Genetically modified Cows- GMF07001
Reasons for Submission

Contents

Introduction

Greenpeace New Zealand, Inc. ('Greenpeace') opposes all four applications submitted by AgResearch for approval of activities in containment

- *GMF07001 (this application) Field test livestock in outdoor containment. Maintain those livestock for research, breeding and production.*
- *GMC07012: Import into containment livestock and laboratory animal species (live animals, sperm, embryos). Maintain animals for research, breeding and production. Import animal cell-lines (including human and monkey cell-lines), E. coli and yeast for use in the development (genetic modification) of livestock and small animals under GMD07012 and GMD07074.*
- *GMD08012: Develop livestock and laboratory animals in indoor containment. Maintain those species for research, breeding and production. Develop animal cell-lines (including human and monkey cell-lines), E. coli and yeast for use in the genetic modification of livestock and laboratory animals.*
- *GMD07074: Develop livestock species in outdoor containment. Maintain those livestock for research, breeding and production.*

For GMF07001 AgResearch wants to (page 14-15)

- *Undertake research or commercial production with transgenic livestock lines*
- *Undertake development and maintain livestock in both indoor containment and outdoor containment. For example transgenic goats are provided for in both the indoor and outdoor applications as it is possible that commercial herds will be required to be kept in-doors to meet pharmaceutical regulatory requirements but research herds maybe kept in outdoor containment.*
- *Undertake activities in outdoor containment regardless of whether they are developments or field tests.*

AgResearch is seeking an approval of **unlimited** duration (see discussion in section 5.5 A of GMD07074). Clearly this is completely unacceptable. The Applicant acknowledges "an unlimited duration adds to the uncertainties in the assessment of the effects of the organism." (page 44 of

GMD 07074). In Decision GMD02028 ERMA concluded that 7 ½ years was reasonable and 10 years was not. Obviously indefinitely is, by this standard, and almost by definition, unreasonable. "AgResearch believes that with a further six years of experience with transgenic livestock, the uncertainties associated with the transgenic livestock research have reduced." (Page 45 of 07074). The deception in this assertion, by merely cross-referencing to another application, is breathtaking. Apart from anything else, this application is for a wide range of animals, not just livestock. For another thing, simply having 'a further six years' experience does not justify an indefinite duration. Section 38E specifies the duration of conditional release approval, for example. If no date of expiry is specified, the duration is 5 years after the date on which the approval is granted. Clearly an indefinite application must not be granted.

AgResearch's application is so broad that it wishes to ensure that it can enter into development so that "ERMA can be assured that whatever the boundaries, any outdoor activity will be approved under one approval or the other. " (page 15). "Rats, mice, hamsters, guinea pigs, rabbits, possums will be used as research models for all livestock activities." (page 15). "Cell lines from livestock and small animals and from humans and monkeys will be used for evaluation of DNA construct and experimental strategies " In other words, AgResearch want to genetically engineer all these animals, anywhere they want to, using whatever gene construct they want to use, including any human and monkey genetic material they want. AgResearch also want approval for commercial release: "Approval is sought for production of biopharmaceuticals and other products with commercial applications for release." (Page 17) In so doing, AgResearch has avoided making a conditional release approval, and instead is trying to use development approval to obtain permission for commercial release of products from GM animals, such as GE milk, free of the controls, scrutiny and requirements of a conditional release application.

This dangerous application has reached the heights of absurdity. It must be rejected.

This application must be rejected *ab initio*. It should not have been notified. It is woefully and intentionally lacking in essential specific information, such as the gene constructs and the location of the activities, that it cannot be assessed. The Applicant states that "It is therefore not possible at the time of application to specify all the details of each field test which may be carried on under this approval (including the effects tested, the location or duration)" since "this application is for a generic approval (i.e. approval for any field test of organisms complying with the organism description for the purposes set out in this application) **of unlimited duration**." (page 30). Nor does the Applicant want to be constrained in the disposal of genetic material, so the location of genetic material will be unknown. (page 36, and see below).

The fourth purpose sought (page 6)[2] seeks complete *carte blanche*: to do any research for anything and then to do more research based on that research. Its breadth is an absurdity and makes a mockery of the Act.

[2] Page 6 state purpose sought: "1. Products with commercial applications: Undertake research and maintain and breed livestock for production of:
- therapeutic proteins
- proteins for use as diagnostics for human and animal disease
- other products derived from livestock with commercial applications

2. Enhancement of livestock traits: Maintain and breed livestock for research into enhancement of traits of value in livestock including productivity, welfare and sustainability

3. Animal models of human gene function and physiology: Maintain and breed livestock for use in research as models for human gene function and physiology

4. Transgenic techniques; gene function: Maintain and breed livestock for research into transgenic techniques and gene function to support the above purposes and, if discoveries of general application are made in the course of such research, for further research into such discoveries."

However there is insufficient information for ERMA to undertake an adequate risk assessment, so this application should be declined for this reason alone.

Risks

The Applicant itself acknowledges that there would be the following potential adverse effects:

"Impacts on New Zealand's clean green image and flow on impacts to sectors of the economy that utilise this marketing theme such as tourism Impacts on New Zealand's export markets for equivalent products produced using non-genetically modified or conventional animals Additional compliance costs for producers of equivalent products using conventional animals Impacts on organic production and buyer choice ***Loss of GE-free status and flow on price effects to exporters and producers relying on this status.*** *Impacts of introducing a genetically modified organism into the dairy sector."* (page 46)

In other words, if this application is approved, New Zealand will lose its GE-free status, and there will be flow-on impacts to non-GE exporters, as well as the dairy sector. This is critical. This is a severe threat to New Zealand's agricultural industry as well as to New Zealand's dairy industry in particular. The applicant acknowledges, for instance, the possibility of "[m]odification resulting in the production of ecotoxins other than those normally produced by farmed livestock." (page 42) and 'livestock infected with new pathogenic virus' (page 43). Also possible is "modification incorporating genetic elements which could increase pathogenicity or fitness of soil micro-organisms" (page 43) and new diseases in our dairy herd (page 43).

For this reason as well, this application should be declined.

Humans could also be poisoned or infected, such as by eating, intentionally or otherwise, animal products. The Applicant acknowledges this can be caused, by "modification resulting in the production of toxins other than those normally produced by farmed livestock or new pathogenic micro-organisms or prions", such as through "Livestock products transferred from containment facility and enter human food chain." (page 43). New allergic reactions may also be caused. (page 43). New diseases may be created (page 44). These risks are utterly unacceptable.

The purpose of the Act in section 4 is stated to be 'to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms." Clearly the Act does not allow an application with such serious and far ranging potential effects.

The Principles of the Act in section 5 are that:

5.• All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

(a) The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:

(b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

Accordingly, ERMA must under Clause 9 of the Methodology recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for -

(1) Their own economic, social, and cultural wellbeing and
(ii) The reasonably foreseeable needs of future generations.

By allowing the continued development of genetically modified cattle, with the attendant ethical concerns and risks to the animals, ERMA would put at risk New Zealand's economic, cultural and social wellbeing and by putting New Zealand's reputation at risk, the reasonably foreseeable needs of future generations.

When evaluating assessment of these risks, ERMA must take into account under paragraph 12 of the Methodology, the nature of the adverse effects, the probability of occurrence and the magnitude of each adverse effect the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence, the options and proposals for managing the risks identified and the uncertainty bounds on the information contained in the assessment expressed quantitatively where possible, but otherwise through narrative statements.

The Applicant acknowledges that "[a]t some point in the future, if all regulatory approvals have been obtained, milk products marketed as functional foods or nutraceuticals may legitimately be available for human consumption or as a human medicine" (page 13). Such a development would clearly threaten New Zealand's international reputation as well as other agricultural and related industries. AgResearch's application for commercial products under section 39(1)(h) of HSNO must be viewed likewise and must be denied.

While this is portrayed as a biopharming application, it is much broader. The Applicant wants to 'enhance livestock traits'. It says that "The milk produced by different dairy animals, including cattle, buffalo, goat and sheep have quite distinct characteristics and thus provide different opportunities to alter and improve milk composition." (Page 21). This intention to genetically modify, and commercially release, New Zealand milk products, is exceptionally irresponsible, given the importance of dairy products to the New Zealand economy. It must be rejected. Not satisfied with threatening our dairy herd, they also want to genetically modify sheep too. "Work may also be carried out in sheep to manipulate the characteristics of the wool fibre and in cows to improve fertility rates." (page 21). So the New Zealand wool and sheepmeat industry is also under severe threat by this application.

The Applicant has made one concession: "Developments that use DNA from Maori." (page 27). So Maori genes will not be placed into sheep, goats, cows, possums, or rabbits. But genes – any genes- from any other humans may be placed into these species.

Other risks

The Applicant acknowledges (page 12 of the Application) that the lack of specificity relating to the site raises an issue for ERMA as to whether it can properly assess effects of the activities for which we are seeking approval without knowing where the activities are carried out. This is a real problem, not least as the effects on soil, such as through horizontal gene transfer, can neither be properly assessed nor be properly monitored and controlled. The Applicant states that "[t]he impacts of the genetically modified livestock within the containment facility will be limited in scale, even if they do occur." (page 17). But we are not even told where that will be, as the locations have not been specified. Thus there can be no risk assessment or control. The Applicant acknowledges the risk: "Modification incorporating genetic elements which could increase pathogenicity or fitness of soil micro-organisms" can result from "horizontal gene transfer to micro-organisms in containment area (e.g. soil)." (page 43) as well as by transfer of micro-organisms out

of containment unit and infection of valued species or adverse effects on soil biota in farmed or natural ecosystems. This is also acknowledged on page 43.

These information deficiencies alone is a reason to deny the application. ERMA should have asked for further information under Section 52 of the Act. It has insufficient information to make a decision on this Application.

Other risks which must be assessed include whether GM animals may provide new pathways for animal or human disease. The Applicant notes that "AgResearch has endeavoured to identify those pathways and where appropriate has identified relevant controls in the assessment of the risk of adverse events required by each of the applications." (page17). Yet there is insufficient information to identify, let alone assess, these pathways, and with the lack of genetic constructs and location information, monitoring and risk assessment and control will be all but impossible.

The Applicant does not even want to be constrained in its disposal of matter which may contain genetic material. "AgResearch does not see the need to treat waste material (e.g. milk) prior to final disposal… AgResearch submits that disposal of any animals and waste may occur on site or off site in accordance with the requirements of the standard using an acceptable method agreeable with local iwi. Disposal methods may include, Incineration, burial, organic waste treatment (commercial or composting or spraying onto pasture)." (page 35). So not only will special precautions not be taken, but ERMA, and the public, will have no idea where genetically modified animals, milk, blood or other products have been landfilled, sprayed on pasture, or otherwise placed. That this is reckless and dangerous is patently obvious.

These risks are even more difficult to assess since the applicant is asking ERMA to assess the risks on a generic basis (page 16). Thus the Committee is being asked to assess an application where it does not know the host organism or the genetic modification involved.

As the Applicant itself acknowledges, "[t]he release of products derived from transgenic livestock raises risks not previously assessed by ERMA." (page 18)

The escape is also a real risk, particularly in the case of rabbits or possums. The best the Applicant can do is to state that "In case of unintended or accidental release or escape of genetically modified animals, all reasonable attempts will be made to recover the escaped animals and return them to the outdoor containment facility." (page 37). New Zealand's experience in the difficulty of controlling possums and rabbits speaks for itself. The Applicant now wishes to add the risk of genetically modified possums to the risk to our native flora and fauna. The Applicant at least acknowledges the risk: "For other species such as goats, deer and pigs where feral populations are well established, escaped transgenic animals could have a greater potential for interbreeding and establishing in these populations. The chain of events for population establishment requires first that animals escape containment and this breach remains unnoticed, evasion of capture, survival in the open environment, finding a compatible mate, successfully breeding and passing on the transgenes to successive generations. The likelihood of this chain of events occurring is possible but considered to unlikely to occur given the proposed containment measures. Should a breach of containment occur and depending on the location of the facility, the likelihood of successful establishment may be higher for animals such as goats and deer." (page 41) On page 42, the Applicant acknowledges this is a potential risk to the natural environment: and that the genetic modification causing the risk would be 'unknown'.

They also acknowledge that "[m]odification increasing ability of goats, deer or pigs to survive in the wild" is possible (page 42). This would also apply to possums. Section 37 requires ERMA to

have regard to (a) The ability of the organism to establish an undesirable self-sustaining population; and (b) The ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

The Applicant states (page 12) that "the most significant risks identified in section 6 arise from the concerns of many members of the public in New Zealand and overseas regarding the consumption of transgenic animals. No products and waste from transgenic animals containing animal tissue (including meat and products containing animal cells) may leave the containment facility other than for disposal. Disposal must also comply with any resource consent requirements under the Resource Management Act." This is disingenuous and misleading. The RMA is not designed to address genetic modification issues. Disposal is dealt with under HSNO. Secondly, release is a possibility, particularly for small animals. Thirdly, there are other pathways, such as through consumption through the food chain or horizontal gene transfer, as well as from disposed material.

Alternatives

ERMA must take into account any alternative method of achieving the research objective that has fewer adverse effects on health and safety and the environment than the field test. There are other ways to manufacture pharmaceuticals and other ethical uses of biotechnology to benefit New Zealand.

Legal Considerations

The application is lodged pursuant to section 40 of the Hazardous Substances and New Organisms Act 1996 (the "Act"), and is to be determined in accordance with matters set out in Part II of the Act (sections 5, 6, 7, 8, and 9) and in accordance with s 9, the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the *Methodology*), and with sections 44, 44A, 45 and 45A, the additional matters contained in sections 37.

Part II

ERMA must bear in mind that under section 4 of HSNO, the purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. This is an overriding purpose of the Act which colours all other provisions. Where ERMA can prevent adverse effects, in order to protect the environment, it should. The environment is best protected with this application by declining the application. This is particularly so with such a misconceived and misguided application. The adverse effects identified by Greenpeace and other submitters can and should be prevented by declining the application. This would best prevent the adverse effects of GE organisms in the New Zealand environment, as well as specific adverse effects identified in this and other submissions.

Under section 5(a) of the Act, ERMA must 'recognise and provide' for the safeguarding of the life-supporting capacity of air, water, soil and ecosystems. This is a higher duty than 'taking into account'. ERMA must provide for that safeguarding, and particular in this case the life supporting capacity of the soil and ecosystems. That includes protecting the soil from DNA from the proposed experiment and the ecosystem from adverse effects.

ERMA must also under section 5(b) of the Act recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations. This includes providing for the needs of farmers and ordinary New Zealanders to be able to grow cows

free of GE and the need to safeguard New Zealand's economic security in a world that does not want GE produce. The development of GM cows in no way meets these needs and endangers the GE-free status of New Zealand. Other methods better provide for New Zealand's economic and cultural well-being. Cultural well-being also includes local, regional and national opposition to GE cultivation.

Section 5(b) of the Act is also relevant.[3] The claimed benefits are quite simply not sustainable. GE is a highly unsustainable technology: it introduces a 'quick fix' to address problems that can be solved using sustainable methods, and introduces a whole new raft of potential problems.

Under section 6(c) of the Act, ERMA must take public health into account. There have so far been virtually no independent studies of the health effects of GM and adequate experiments have not been conducted into the effect of GM cattle or other GM produce on human health.

ERMA must under section 6(e) take into account the economic and related benefits to be derived from the use of GM cattle. This must be read in light of section 5(b) which requires ERMA to recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic well-being. Where an application such as for the GM cattle threatens people and communities to provide for their own economic well-being, in its interference with their GE-free status and the ability of New Zealanders to sell into markets which demand GE-free produce, ERMA must recognise and provide for their capacity. Comments made above about the adverse economic aspects of GE, about risks to the economy, about the lack of insurance and transfer of risk to the community and other economic matters all show this application should be declined.

Under section 6(f) ERMA must take into account New Zealand's international obligations. The Biosafety Protocol is in force. The obligations include in Article 2(2) the obligation to ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health, the provisions on risk assessment and ERMA should note the objective of the Protocol, being in accordance with the precautionary approach, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Under section 7, ERMA shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. This provision must in light of the entry into force of the Biosafety Protocol, be read in light of Principle 15 of the Rio Declaration on Environment and Development, which reads that "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

In *Bleakley v Environmental Risk Management* Authority (HC, AP177/00, 2001) ERMA had decided that the section 7 direction to "take into account the need for caution in managing adverse effects" was discharged by a cautious attitude towards containment involving strict controls. The

[3] b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations

Court considered section 7 in the context of section 45, and held that it required caution in management of effects if they occurred, a matter which went beyond mere caution over risk occurrence. The lack of knowledge about the effects of the unknown and unspecified genetic constructs in the target animals, on non-target animals and other organisms, on humans, on the economy and on the soil must be considered in this light.

Under section 44A(2)(a) of the Act, ERMA must take into account any adverse effects of field testing the organism on (i) human health and safety and (ii) the environment, in particular ecosystems and their constituent parts. The matters referred to earlier, and in particular potential effects of HGT and other effects of the field test must be taken into account under this paragraph.
Under section 44A(2)(b) of the Act, ERMA must take into account any alternative method of achieving the research objective that has fewer adverse effects on the matters referred to in paragraph (a) than the field test. These are clear. There are many other methods of producing these drugs rather than through genetically modified animals, and of enhancing milk and other dairy products.

Under section 44A(2)(c) of the Act, ERMA must take into account any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test. Any effects from HGT must be considered in this respect, as must the spread of GM material.
Under section 45 of the Act, ERMA may only approve the application if it is satisfied that the organism can be adequately contained. As discussed earlier, animals such as possums and rabbits, in particular, cannot.

Under section 45A of the Act, an approval must include controls to ensure that, after the end of the field test, the organism and any heritable material from the organism is removed or destroyed, and may include controls to ensure that, after the end of the field test and after heritable material is removed or destroyed, some or all of the genetic elements remaining from the organism are removed or destroyed. The Applicant's proposal for disposal (page 35) are in breach of this section.

Under Clause 13 of the Methodology, when evaluating the assessments of costs and benefits associated with the organism, ERMA must take into account the costs and benefits associated with the application and whether the costs and benefits are monetary or non-monetary, and the magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value, and the distributional effects of the costs and benefits over time, space and groups in the community. Clause 14 makes it clear that the costs and benefits are those that relate to New Zealand and that would arise as a result of approving the application. These matters have been referred to above under economic matters. ERMA must under Clause 15 have regard to evidence in public submissions that is relevant to the assessment of the risks, costs and benefits of introducing the substance or organism.

Production of Commercial Products for Release
The Applicant observes that section 39(1)(f) of the HSNO Act authorises ERMA to grant importation, development and field test approvals for the purpose of maintaining a new organism in containment to produce antigens, biopesticides, biopharmaceuticals, enzymes, hormones, or vaccines for release and goes on to say that section 39(1)(h) authorises ERMA to grant approvals for such other purposes as ERMA sees fit "and seeks approval for other commercial products under that section." This is a trojan horse and in the context of the breadth and lack of specificity in this application, must be declined.

Section 38(1)(a) requires that the positive effects of the organism must outweigh the adverse effects of the organism and any inseparable organism. The High Court in *GE Free NZ in Food and*

Environment Inc. v ERMA [2008] NZHC 669 (12 May 2008) placed considerable of emphasis on this requirement.

Clearly it does not. No positive effects are proven, and many adverse effects are known, such as the effect on New Zealand's GE free status, our dairy exports and our reputation.

For all these reasons, Greenpeace strongly submits that this application must be declined.