Annual Report to Environmental Protection Authority

Activities under ERMA 200223

AgResearch Ltd

For the 12 months ending 30^{th} June 2024

Submitted by Tim Hale Delegated Facility Operator / Manager AgResearch Ruakura Animal Containment Facility

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Summary of Activities for the period 1st July 2023 to 30th June 2024

This summary provides the information required by control 11 (Annual reporting) of the HSNO Act approval ERMA200223.

Outdoor Development Activities

All outdoor development activities being carried out within the Animal Containment Facility at Ruakura comply with the requirements of the ERMA200223 approval.

Cattle that were still alive at the end of the reporting period have now only been developed and maintained under the ERMA200223 approval.

Goat development and maintenance activities now only involve animals developed under the ERMA200223 approval.

Cattle, Goat and Sheep activities, other than the maintenance or growing of animals, have been flushing eggs from fertile animals, calving of recipient cattle, lambing of recipient ewes and the transfer of embryos to recipient animals. Semen has been collected from Bulls for analysis / potential export or storage for future use.

Embryo Transfer activities this year have been in cattle only.

These transferred embryos fall within the approved organism description for the ERMA200223 approval and are for the study of gene function related to animals adapting to temperature changes.

All activities have been undertaken with the approval of the Ruakura Animal Ethics Committee.

Further details on development activities are provided within the following Science, Management and Ethics reports.

Unforeseen adverse effects resulting from the genetic modifications

There have been no unforeseen adverse effects identified during this period.

Iwi liaison group relationship development and management activities

The ERMA200223 Liaison Group has still not officially met since December 2011.

As advised in previous annual reports, at the request of a group of Ngati - Wairere elders the Liaison meetings were put on hold, while representation and membership of the Liaison group was discussed within the Hapu.

Unfortunately, due to circumstances mainly outside of AgResearch influence and despite further attempts, no progress has been made in resolving this Liaison group representation directly to date.

The Facility manager is in regular contact with Tainui Group Holdings (Land owner representative) on their development activities for Ruakura and impacts for the Animal Containment Facility.

Additional Supporting Information

The following reports are supporting information provided to expand on the previous summary and provide evidence of wider compliance with ERMA200223 Controls and MAF/ERMA New Zealand Standard 'Containment Standard for Field Testing of Farm Animals'.

This additional supporting information is also provided to enable equivalence to the previous annual reporting for the inactive GMF98009 approvals.

Science Report

Cattle modified for milk composition

- Following the capture and storage of the genetics in the form of cells, semen or embryos, the last remaining cattle engineered for modified milk composition were euthanised as an endpoint of these projects.
- Tissue, DNA and milk samples provide opportunities to continue and start new research collaborations based on the unique genetics of the animals.
- No safety concerns due to the genetic modifications have emerged from maintaining the animals.

Generating cattle genome edited for adaptation to warmer temperatures

- Semen from PMEL- and SLICK-edited bulls was collected and cryopreserved.
- Oocytes from PMEL- and SLICK-edited females were used to produce and cryopreserve embryos heterozygous for both edits.
- PMEL- and SLICK-edited females were artificially inseminated to induce a natural lactation and produce next generation calves that carry the mutation in a heterozygous state.
- Detailed monitoring of behavioural and physiological characteristics under warm and cold conditions was carried out. Preliminary results have shown reduced shade use, increased grazing and lower skin temperatures for PMEL-edited cattle under warm conditions. The edits had no impact in cold conditions.
- SLICK-edited cattle continued to be monitored for behavioural and physiological traits with evaluation of data ongoing.
- SLICK-edited cattle had shorter hair in spring and autumn with only the undercoat shorter in . summer compared with unedited control cattle.
- Whole genome sequencing data is being evaluated to determine the potential for off-target mutagenesis events in any of the edited animals. This analysis is still in progress.
- We have produced seven (four female, 3 male) calves edited for the disruption of the NANOS2 gene. Once they reach sexual maturity, they will be tested for the impact of the NANOS2 disruption on female and male fertility.
- Activities and results were communicated to various stakeholders and presented at: International Embryo Technology Society, 50th Anniversary Meeting, Denver, January 2024 (invited) and American Dairy Science Association Dairy Digression Podcast, Episode Thirteen: Embryo-Mediated Gene Editing, Coat Color, and Herd Heat Absorption

(https://www.youtube.com/watch?v=cg0whwfklGs), January 2024.

Overexpression of the histone demethylase KDM4B in transgenic cattle

The project has been completed and no animals were retained and maintained.

Goats producing therapeutic proteins

- Goats were maintained to investigate longevity and potential long-term health effects.
- Several does were maintained as possible recipients for future embryo transfers.

Goats producing female-only offspring

• All remaining transgenic animals were culled.

Generating germline-complemented sheep and fertile founders for breeding sterile hosts

 One female NANOS2-/- and male NANOS2+/- cloned founder animal were bred using AI. One live F1 offspring was born, representing a heterozygous knockout genotype for future breeding and phenotype characterisation.

Generating immune-compatible sheep for xenotransplantation

• 4 female double knockout ewes (GGTA and CMAH) were used for AI, but no viable offspring were obtained.

On Farm Management Summary for year ending 30/06/2024

Animal Numbers 01/07/2023 – 30/06/2024 (Births exclude still born or animals which die soon after birth reported in Animal Ethics Reports, Aged In and Out records changes in animal age¹)

	Open		Transfer	Transfer	Aged	Aged			Closing
Stock Class	(1/07/23)	Births	In	Out	In	Out	Killed	Deaths	(30/06/24)
Casein (ERMA200223)									
Total Casein	0	0	0	0	0	0	0	0	0
MBP (ERMA200223)									
Total MPB	0	0	0	0	0	0	0	0	0
rhLF (ERMA200223)									
Total rhLF	0	0	0	0	0	0	0	0	0
BLg / hLZ KI - (ERMA200)223)								
MA Cows	13				0		13		0
Total BLg -	13	0	0	0	0	0	13	0	0
Erbitux (ERMA200223)									
Total Erbitux	0	0	0	0	0	0	0	0	0
Climate Smart (ERMA20	0223)								
R2yr Heifer	0				12				12
R1yr Heifer	12				4	12			4
Heifer Calves	0	4				4	0		0
R2yr Male	0				12				12
R1yr Male	12				3	12			3
Bull Calves	0	4				3	1	0	0
Total Climate Smart	24	8	0	0	19	31	1	0	31
Total KDM4R	0	0	0	0	0	0	0	0	0
	0	0	0	0	U	U	0	U	0
Conventional Cattle									
MA Cows	73		0	19	0		8		46
Total Conventional	73	0	0	10	0	0	8	0	46
	13	U	0	13	U	J	0	U	-+0
Cattle Total	110	8	0	19	19	31	22	0	77
Cottle alive developed			ravala (T-		Ta v r				
Cattle allve developed	unaer ERI	ма арр	rovais (1g	and non	ig pr	ogeny)		51

¹ Aligns with normal livestock reconciliation aging practice.

Stock Class	Open (1/07/23)	Births	Transfer In	Transfer Out	Aged In	Aged Out	Killed	Deaths	Closing (30/06/24)
Goats									
			F A 11 - 1 1.						
Erbitux & Enbrel (ERMA2	200223)		[All Erbit	ux line]					
	4						4		0
R1yr Doe	2				0		2		0
Kiyi Male +	1	0	0	0	0	•	1	0	0
	1	U	U	U	U	U	1	U	0
non Med inherit (ERMA2	200223)								
Total TCR	0	0	0	0	0	0	0	0	0
Conventional Goats									
MA Doe	5		29				8		26
R1yr Doe	3				0		3		0
Male R1yr +	2				0		2		0
Total Conventional	10	0	29	0	0	0	13	0	26
Goat Total	17	0	29	0	0	0	20	0	26
Goats alive developed u	under ERM	ИА аррг	rovals (Tg	and non	Tg pr	ogeny)		0
Stock Class	Open (1/07/23)	Births	Transfer In	Transfer Out	Aged In	Aged Out	Killed	Deaths	Closing (30/06/24)
Sheep									
AI on Hooves (ERMA2002	223)								
MA Ewes	9				1		0	2	8
2th Ewes	1				9	1			9
Ewe Hgts	9				1	9			1
Ewe Lamb	0	1				1	0		0
MA Ram	2				1		2		1
R1yr Ram	6				0	1	0		5
Total	27	1	0	0	12	12	2	2	24
Conventional Sheep									
MA Ewes	41				5	-	22	2	22
2th Ewes	5				0	5			0
Zth Kam	0				1		1		0
Kiyr Kam	1				0	1	0		0
Total Conventional		. O	. 0	I 0	6	6	23	- 2	22
	47	0						L	
Sheep Total	47	1	0	0	18	18	25	4	46

The preceding tables provide animal numbers by species over the reporting period in the development lines that are linked to the EPA approval. This includes transgenic and non-transgenic animals (progeny) and the conventional animals which are used to support the development lines.

For cattle there has been one movement of conventional animals out of the facility during the period. 19 conventional cattle which had never held transferred embryos.

21 MA cows (13 GM) and 1 GM bull calf have been humanely killed, all have been disposed of in offal holes on-site, as surplus or following veterinary advice during this period.

For goats there has been one movement of 29 animals on to the facility during the period.

20 (7 GM) goats of varying ages have been humanely killed and no goats died during the period; these animals have also been disposed of in offal holes on-site, as now surplus or unsuitable animals, or following veterinary advice.

For sheep there has been no movement of animals on or from the facility during the period.

23 (2 GM) sheep of varying ages have been humanely killed and 4 (2 GM) sheep died during the period; these animals have also been disposed of in offal holes on-site, as surplus or unsuitable animals, or following veterinary advice.

41 cattle recipients have been used for ET (embryo transfer). All animals are regularly monitored for live weight and health status.

For management purposes, as previously identified, the facility is treated as a separate small farm within the main Ruakura Farm. It is fully self-contained apart for some machinery requirements and specialist staffing.

Animals on the facility continue to be managed in a way which aligns with normal farming practice in New Zealand, grazing outdoors on pasture with some crops and supplementary feeding of hay, balage, silage or meal concentrates when required.

This consists of daily shifts and restricted intakes depending on the age of the animal and its feed requirements for example according to stage of pregnancy, lactating or rearing calf or kid, empty, young growing animals, etc.

Goats can at times receive a higher proportion of their daily intake as supplementary feed or concentrates, to reduce their impact on pasture availability for cattle and normally have access to covered shelter in inclement weather.

Surplus pasture is conserved when possible for use in periods of low growth, as balage, silage or hay and there was only minimal purchasing of extra supplement (meal) required this season, mainly due to lower animal numbers which enabled maintenance of an adequate annual feed supply.

Nearly 3ha within the facility was undersown with a chicory and clover mix in anticipation of a dry summer.

Mineral supplementation is carried out using a mineral dispensing system through the water troughs for assisting Facial Eczema control and other normal mineral deficiencies during identified periods of risk, as occurs on many farms.

Maintenance fertiliser was not applied this season.

Operationally we continued juggling animal movements and grazing for much of the season within the facility around construction activities to install water and waste water services for Tainui Group Holdings inland port development which is to the south east of the Animal Containment Facility.

Milk Production 23/24 season

No GM cows calved and no GM goats kidded specifically for seasonal milk production again this year. This has meant there was again no milk stored this year for surplus disposal by irrigation to pasture.

Ruakura Animal Ethics Committee Reports

The Ruakura Animal Ethics Committee (RAEC) removed the requirement for interim reporting on a quarterly basis as approvals are now normally only approved for a 12-month period with formal reporting required at the end of the approval period.

Regular updates on approved activities are provided verbally to the RAEC at scheduled fortnightly meetings during the year.

Below are the active approvals during the 12-month period of this report:

RAEC 2022-0381 – Maintenance of Cattle on the Animal Containment Facility

RAEC 2023-0685 - Climate smart cattle - production and characterisation

RAEC 2023-2024 - Maintenance breeding of different cloned sheep genotypes

RAEC 2024-2288 - Characterisation of animals produced as part of the climate-smart cattle programme

RAEC 2024-2337 - Climate-Smart cattle embryo development

RAEC 2024-2385 - Collection of cloned transgenic goat fetuses for cell line rejuvenation

Reports Received during the period: (*These reports may contain information on activity in last years EPA reporting period.*)

RAEC 2022-0381 – Maintenance of Cattle on the Animal Containment Facility – Animal Welfare and Use report at end of trial approval period.



Animal Welfare and Use Form - 0381

Nease name and contact th	e Farm/Facility manager	to comment on the	The second s	
		to contribute on the	study	
nimal use year				
our Animal Use Return	MUST be completed	for the year that	your Approval Period ended	
ear for this Return	2023	<u>.</u>		
pplicant				
irst Name				
iumame				
elephone				
imail	@agresearch.co.r	nz		
Arganisation	gResearch Ltd		3	
roject				
Project Title: Maintenance	of Cattle on the Animal Cont	ainment Eacility		1

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Summary of manipulations					
Briefly describe all the treatments/manipulations (type and frequency) each animal underwent during this application	standard husbandry 1 cow was stimulate of IVF embryos Humane killing of an	treatments d prior to ovum pick-up treatme imals no longer required or inju	nt to recover oocyte red	es and production	
Did the manipulations go according to plan	[€] Yes	C No			
Were there any adverse events during t project	he ^{(°} Yes	∩ No			
If any changes or issues outlined within this approved, ensure this is captured in your Ar	form, or adverse eve nimal Use Return belo	nts reported, require a chang ow	e in grading from t	hat previously proposed	and
Did the adverse event increase the Impa	act Grading of the a	nimals affected	G Yes	C No	
Were any animals withdrawn from the e already covered above)	xperiment or eutha	nised prematurely (if not	^C Yes	۹ No	
Do you have documents to support your report	C Yes	۳ No			
We are now required to report example:	s of the 3R's to MP	along with our animal use	statistics.		

Please briefly describe and comment on each of the approaches you outlined in your application to implement the 3R's

Did you implement them successfully?

Did additional opportunities to implement the 3R's arise during the study?

Replacement

Implementation

Presently, no alternatives exist that could replace the use of animals in this project.

Reduction

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Implementation

Only a limited number of recipients were maintained in support of a publicly funded research programme into adapting dairy cattle to warming climatic conditions. A minimum number of animals for different transgenic lines were maintain to support accumulation of data on benefits and risks of the technology.

Refinement

Implementation

The animals are well cared for by experienced and competent staff with support from a veterinarian with extensive experience in caring for the unique animals under containment conditions.

Reflecting on the study

Provide a comment on the welfare of animals during the study - e.g. general health, nutrition, shade/shelter provisions, mental state etc

animals are cared for by dedicated staff, had good general health and were well fed

What went really well in the study

access to a pool of recipient animal to support another programme

Is there anything about the study you would do differently if you had to repeat or do a similar study

not having a separate application for maintaining recipients and instead include them into a programme were they are being used

Is there any advice you would like to give others carrying out a study in a similar area or using similar techniques

this only involved standard practices		
Were there any staffing or resourcing issues that affected the study	C Yes	[℃] No
Were there any health and safety concerns or issues during the study	C Yes	⁽⁷ No

Animal use details for each species

Complete the "USED" column only

Remember to include the Impact Grading for the animals affected by the Adverse Event(s)

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ANIMAL USE RETURN

. Animal Type	Cattle			•				
. Source:								
2. Source.								
Breeding uni	t		Commercial	2	Farm			Born during project
Captured		1.	Imported		Public sources			
			Proposed		Used			
Farm		94			34	÷		
Source total		100			34	÷		
3. Status:								
		_	00510	-			_	
Normal/Conv D Protocted will	entional		SPF/Germfree		Diseased	hed		Transgenic/Chimera
Protected wi	alle	1.	Pregnant		Unborn/Prenator	lea		Other
			Proposed		Used			
			•					
						1 -1		
Normal/Conventiona	1	79	•		19	⊡		
Fransgenic/Chimera	1	19			15	-		
Status total		100			34	Э		
4. Purpose:								
Teaching		Γ	Species conservation		Environmental			Animal husbandry
Basic biologi	cal		Medical research		Veterinary resea	irch		Testing
Biological ag	ents		Offspring		Aitemativés			Uner
			Proposed		Used			
					5000			
Purpose other		100	–		34	-		
ruipose otilei		100			04			

8 August 2024

Purpose total		100			34	l.					
Details of "other" purp	pose										
Research into the app environmental and me	plication of t	transge fits.	nic and gene	ome editir	ng technology	to genetically	improve cattle fo	r animal wel	fare,		
. Re-use of anim	nals:										
No prior use		9	Previously	used							
			Propose	d		Used					
lo prior use		14		÷	0		3				
Previously used		86			34	l.	÷				
etails of how these a	animals ha	100 ave be	en used pr y used as re	eviously cipients f	34 in Research	, Testing ar	d Teaching	viously used	for genoty	ping	_
etails of how these a	animals ha	100 ave be	en used pr y used as re	eviously	34 in Research or embryo tran	, Testing ar	d Teaching	viously used	for genoty	ping	
Duestion 5 Total Details of how these a Conventional cows ha and phenotyping.	animals ha ave been pr nipulati	100 ave be reviousl ons:	en used pr y used as re	eviously cipients f	34 in Research or embryo tran	, Testing ar	d Teaching	viously used	for genoty	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. Grading of ma E A	animals ha ave been pr nipulati R	100 ave be revious! ons: B	en used pr y used as re	eviously cipients f	34 in Research or embryo tran	, Testing ar sfer. GM catt	d Teaching le have been pre	viously used	for genoty	ping	
tuestion 5 Total etails of how these a Conventional cows ha and phenotyping. Grading of ma R A	animals ha ave been pr nipulati	ave be reviousl	en used pr y used as re Propose	eviously ccipients f	34 in Research or embryo trar C	, Testing ar	d Teaching le have been pre	viously used	for genoty E	ping	
Luestion 5 Total Letails of how these a Conventional cows ha and phenotyping. . Grading of ma PA	animals ha ave been pr nipulati	ave be reviousl ons: B	en used pr y used as re Propose	eviously ccipients f	34 in Research or embryo tran	, Testing ar Isfer. GM catt IZ Used	d Teaching le have been pre	viously used	for genoty E	ping	
tuestion 5 Total letails of how these a Conventional cows ha and phenotyping. Grading of ma R A	animals ha ave been pr nipulati	100 ave be revious ons: B	en used pr y used as re Propose	eviously cipients f d	34 in Research or embryo trar C	, Testing ar	d Teaching le have been pre	viously used	for genoty E	ping	
tuestion 5 Total etails of how these a Conventional cows ha and phenotyping. Grading of ma R A Grade A Grade B	animals ha ave been pr nipulati	100 ave be reviousl ons: B 78	en used pr y used as re Propose	eviously cipients f d	34 in Research or embryo trar C	, Testing ar	d Teaching le have been pre	viously used	for genoty E	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. Standing of ma Image: A Strade A Strade B	animals ha ave been pr nipulati	100 ave be reviousi ons: B 78 21	en used pr y used as re Propose	eviously cipients f d	34 in Research or embryo tran	, Testing ar	d Teaching le have been pre	viously used	for genoty	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. Conventional complexity Grading of ma Image: A Grade A Grade B Grade C	animals ha ave been pr nipulati	100 ave be revious ons: B 78 21	en used pr y used as re Propose	eviously cipients f d	34 in Research or embryo tran	, Testing ar		viously used	for genoty	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. S. Grading of ma Image: A Srade A Grade B Grade C	animals ha ave been pr nipulati	100 ave be revious ons: B 78 21	en used pr y used as re Propose	eviously cipients f F d	34 in Research or embryo tran C	, Testing ar	d Teaching le have been pre	viously used	for genoty	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. S. Grading of ma Image: A Grade A Grade B Grade C Grade D	animals ha ave been pr nipulati ₽	100 ave be revious) 0ns: B 21 1 1	en used pr y used as re Propose	eviously cipients f d d	34 in Research or embryo tran C	, Testing ar sfer. GM cat Used	d Teaching le have been pre	viously used	for genoty	ping	
Question 5 Total Details of how these a Conventional cows ha and phenotyping. S. Grading of ma Image: A Grade A Grade B Grade C Grade D	animals ha ave been pr nipulati	100 ave be revious) 0ns: B 78 21 1 0	en used pr y used as re Propose	eviously cipients f d t t t t t t t t t t t t t t t t t t	34 in Research or embryo tran	, Testing ar	d Teaching le have been pre	viously used	for genoty	ping	

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7. Animals alive at end of	/ project:			
Retained Rehomed	Returned None alive	□ Released		Disposed of
3. Animals DEAD at end	of the project:			
Killed for Research, Test tissues	ting or Teaching on body or	Other dead	d:	
	Proposed	Used		
Other dead	0	34	-	
Dood total		24	_	
Jead total	0	34		
For the other dead numbers list	ted above, please confirm the	e breakdown of numb	ers in the follow	ing categories:
Note: When filling in PROPOSI	ED numbers: ONLY complete	e the numbers for thos	se animals plani	ned to be euthanised / killed as a
planned end to the project.				
The other categories of animals Form.	s that die during the project m	nust be reported at the	e end of the pro	ject in the Animal Welfare and Use
Euthanised / killed as a p Died - unrelated to mani	planned end to project	Died - rela	ted to manipula	tions
Dieu - unrelateu to mani	pulauons	Edulariise		150115
	Proposed	Used		
Euthanised / killed	0	30		
		4	-	
utilaniacu for wenare reasons	•	4		
Details for the animals	TG cow had acquired a hip inju	ry resulting in lameness	/2	
killed/died above	Recips for Cancer eye / 1 TG of movement	ow poor (large) udder ef	fecting	
(for Animal Use form only)	30 animals were euthanised inc	cluding maintained TG ar	nimals	
	due to end of project and old re	ecipients no longer fit foe		
	purpose.			
Where will animals be killed	Animal Containment Facility			
Method of Killing the animals	Other			
g	e a fei			
Please remember to list an SOF	P in Section 11 for your meth	od of killing such as o	Irug administrat	ion or decapitation

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Details for "Other" method of killing	pentobarbitone via intravenous injection / Disposal via Firearm	
How and where will the animal's	deep burial	
bodies be disposed of		
Q. Total number of animal		
9. Total number of animal	15.	
	Proposed Used	
Total number of animals	100 34 1	
10. Animals bred for rese	earch, testing and teaching but not used and killed:	
	de mente effet de la colorie de la dese mente effet de la della d	
were animals bred to enable the	is project to take place but not used in the project and killed	
C Yes	" No	
JSE ADD ANOTHER FOR EAC	CH ANIMAL TYPE/SPECIES	
Changes from proposed		
Were there any changes in anir	mal numbers, Impact grade or details from C Yes C No	
those Proposed and Approved?		
Please explain why the changes	s occurred	
No calves were born during the ap	ipproval period.	
Some of the recipients were no lo	onger fit for purpose, investigation of the GM lines came to an end and overall animal numbers had to	
One animal acquired a hip injury t	that changed its grading to D and was humanely killed	
One animal was humanely killed a	at the planned end of the investigation	

Roles on project

Roles on project:

Tick all the roles on the project

- Program manager
- Lead Technician / Research Associate
- Project staff
- Project staff without access to ~ Te Ara ~
- P Biometrician
- F Farm or Facility Manager
- Commercial Farmer
- ₽ Veterinarian

Program mana	ger		
Name	Select Some Options		
Program manager	Comments		
Project staff			
Project staff with a	access to ~ Te Ara ~		
First Name			
Sumame			
Email	⊉agresearch.co.	vz]	
Organisation	AgResearch Ltd	·	
Project staff with a	access to ~ Te Ara ~		
First Name			
Surname			
Email	gagresearch.co.nz		
Organisation	AgResearch Ltd	·	
Project staff with a	access to ~ Te Ara ~		
First Name			
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Sumame			
Email	§agresearch.co.nz		
Organisation	AgResearch Ltd	•	
Project staff with acc	cess to ~ Te Ara ~		
First Name			
Sumame			
Email	@agresearch.co.nz		
Organisation	AgResearch Ltd		
Project staff with acc	cess to ~ Te Ara ~		
First Name			
Sumame			
Email	Biagresearch.co.nz		
Organisation	AgResearch Ltd	3	
Name	Select Some Options		
Project Staff comme	nts		
	L		

gagresearch.co.nz		
AgResearch Ltd		
Select Some Options		
]
	Bagresearch.co.nz AgResearch Lid Select Some Options	Bagresearch.co.nz

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umame Falle umame Falle rganisation kgResearch AgResearch Ltd	ingt Magne	Tue
umame Hale mail Em.hale@agressarch.co.nz rganisation ApResearch Ltd gResearch arm Facility Research Ltd gResearch arm Facility Research Ltd acting Manager mments	rst Name	2.00
mail Sin hale@agresearch.co.nz kganisation AgResearch Ltd gResearch Ruskurs Animal Containment Facility arm/Facility Ruskurs Animal Containment Facility arm/Facility Ruskurs Animal Containment Facility arm/Facility Ruskurs Animal Containment Facility arme and contact the farm / facility manager(s) to comment here. If there is more than one manager, multiple names and comments can be added here) arme Tim - Hale X arme This approval basically covers the alive recipients and GM cattle which are not part of a comments and uneventul Use whith the CP confines. Beyond specific animals identified within the CP confines. Staff are all experienced and competent in their responsibilities. commercial farmer ame staff are all experienced and competent in their responsibilities. content specific ASC sprease Content staff are all experienced and competent in their responsibilities. content specific science content specific scien	umame	Hale
Imail Em.hale@agressearch.co.nz Agressearch Agressearch Ltd gRessearch Ruskura Animal Containment Facility artify Manager		
Organisation AgResearch Ltd AgResearch Ruskura Animal Containment Facility Facility Manager Image: State and contact the farm / facility manager(s) to comment here. If there is more than one manager, multiple names and comments can be added here) Name Image: State and comparison of the source	Email	tim.hale@agresearch.co.nz
AgResearch ramiFacility Rustura Animal Containment Facility: Facility Manager comments	Organisation	AgResearch Ltd
NgResearch Ruskum Animal Containment Facility Facility Manager		
Facility Manager comments Name and contact the farm / facility manager(s) to comment here. If there is more than one manager, multiple names and comments can be added here) Vame Tim - Hale X Facility Manager Comments This approval basically covers the alive recipients and GM cattle which are not part of a current specific AEC approved project. Beyond specific antimals identified within this report they have a well cared for environment and uneventiful life within the ACE confines. Staff are all experienced and competent in their responsibilities. Commercial farmer Vame Select Some Options Vame Select Some Options pplicant sign off	AgResearch Farm/Facility	Ruakura Animal Containment Facility
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Commercial farmer Name Select Some Options Veterinarian(s) Veterinarian Comments pplicant sign off	Facility Manager Comments	This approval basically covers the alive recipients and GM cattle which are not part of a current specific AEC approved project. Beyond specific animals identified within this report they have a well cared for environment and uneventful life within the ACF confines. Staff are all experienced and competent in their responsibilities.
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8 August 2024 Reference #: 2024-0381-AWU - 7964	8 August 20	Page 10 of 11
8 August 2024 Reference #: 2024-0381-AWU - 7964 Page 10 of 11	8 August 20.	
8 August 2024 Reference #: 2024-0381-AWU - 7964 Page 10 of 11	8 August 20.	
8 August 2024 Reference #: 2024-0381-AWU - 7964 Page 10 of 11	8 August 20	Concertain name
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8 August 2024 Reference #: 2024-0381-AWU - 7964 Page 10 of 11	8 August 20	
8 August 2024 Reference #: 2024-0381-AWU - 7964 Page 10 of 11 Signed: This form was signed by AgResearch Ltd - @agresearch.co.nz) on 22/02/2024 3:11 PM	8 August 20 Signed: This f	orm was signed by AgResearch Ltd - @agresearch.co.nz) on 22/02/2024 3:11 PM

RAEC 2023-0685 - Climate smart cattle - production and characterisation - Animal Welfare and Use report at end of trial approval period.



Animal Welfare and Use Form - 0685

vote on completing	g this form	
Please name and conta	act the Farm/Facility manager to comment on the study	
Animal use year		
Your Animal Use Re	turn MUST be completed for the year that your Approval Period ended	
Year for this Return	2023	
Applicant		
First Name		
Sumame		
Telephone		
Email	⊉agresearch.co.nz	
Organisation	AgResearch Ltd	
Project		
Project Title:		

Page 1 of 13

Summary of manipulations

Briefly describe all the	standard husbandry treatments
treatments/manipulations (type and	hair plucking
frequency) each animal underwent	shaving of small coat patch
during this application	fitted with IceQube, cow manger ear tags and implanted Star-oddi data loggers
	received SmaXtech rumen boluses
	scanning of the coat in the visible and hear infrared spectrum
	transier of embryos, edited for NANOS2 knockout, chimaenc homozygous/heterozygous NANOS2 knockout, cloned with embryonic cells
	Use of 57 recipients for ET, range of 1-3. ETs
	rectal ultrasound scanning, twice following ET around day 35 and 45 of gestation.
	around day 35 (3x20, 1x37) and 45 (3x20, 1x37). Pregnant animals of different ET
	groups were rescanned around day 80 (6), day 100 (6) and 165/187 (8) of gestation
	delivery of two calves by C-section with recipients humanely killed
	era punch biopsy
	blood samples
	behavioral observations
	semen collection
	2010012022 451412022 4714412022
	26/09/2023 15/11/2023 1//11/2023
	#6 AV v3 28 AV Electro 0 Manual 204
	#14 AV x3 0 AV x2 373
	#16 AV x3 0 AVx2 250
	#17 AV x3 0 AV x2 0
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	Synchronisation protocols
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	16 PC
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	7 ET
	day of destation treatment
	-10 CIDr In
	-3 CIDr Out & 3mL PG
	0 Heats
	7 Transfers
Did the manipulations as according to	C Van
plan manipulations go according to	tes NO
Were there any adverse events during	the CVer CNo
averse events during	
Dioject	
	6
Were any animals withdrawn from the	experiment or euthanised prematurely (if not 'Yes 'No
already covered above)	
	с. С
Do you have documents to support yo	ur yes No
report	
7 August 2024 Reference	ence #: 2024-0685-AWU - 7965

We are now required to report examples of the 3R's to MPI along with our animal use statistics.

Please briefly describe and comment on each of the approaches you outlined in your application to implement the 3R's

Did you implement them successfully?

Did additional opportunities to implement the 3R's arise during the study?

Replacement

Implementation

Presently, no alternatives exist that could replace the use of animals in this project.

Reduction

Implementation

Only a limited number of recipients are used for production of limited numbers of edited animals still predicted to meet programme objectives. We have used recipient animals multiple times for embryo transfer to minimise the number of animals.

Refinement

Implementation

All manipulations are carried out according to SOP's or contracted out to commercial service providers as technology experts which aim to minimize any pain or noxiousness by use of minimally invasive techniques, sedation, pre-emptive pain relief and gold standard nursing and husbandry. SOPs and husbandry protocols are regularly updated to ensure the best possible welfare conditions for the experimental animals.

Reflecting on the study

Provide a comment on the welfare of animals during the study - e.g. general health, nutrition, shade/shelter provisions, mental state etc

animals are well cared for by dedicated staff, had good general health and were well fed

7 August 2024

Reference #: 2024-0685-AWU - 7965

hyperspectral scanning of t	he coats					
there anything about the	e study you would do	differently i	f you had to repeat	or do a similar stud	ty	
greater focus on generating switch from embryo-mediate	embryos and animals fr ed genome edition to usi	rom OPU-deri ing cloning of	ved oocytes edited embryonic cells			ļ
s there any advice you we	ould like to give other	rs carrying o	ut a study in a simi	lar area or using si	milar techniques	
the most efficient production followed by embryonic cloni	n of genome edited clave ing with such cells.	es with define	d mutations is likely to	be achieved by editing	g embryonic stem cells	1
Were there any staffing or	resourcing issues th	nat affected	the study	^C Yes	[€] No	
Nere there any health and	d safety concerns or	issues durir	ig the study		[™] No	
nimal use details fo	r each species					
Complete the "USED" co	olumn only e Impact Grading fo	or the anima	als affected by the	Adverse Event(s)		
Complete the "USED" co Remember to include th ANIMAL USE RE	e Impact Grading fo	or the anima	als affected by the	Adverse Event(s)		
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3. St	atus:						
ы Ц	Normal/Conventional Protected wildlife	Г Я	SPF/Germfree Pregnant	Г Г	Diseased Unborn/Prehatched	ц В	Transgenic/Chimera Other
			Proposed	_	Used	_	
Norm	al/Conventional	111	3		61		
Trans	sgenic/Chimera	14	3		16		
Pregr	nant	0	<u>×</u>		6		
Statu	ıs total	125			83		
4. Pi	urpose:						
ר פ ר	Teaching Basic biological Biological agents	Г Г Г	Species conservation Medical research Compromised Offspring		Environmental Veterinary research Alternatives	с с	Animal husbandry Testing Other
_			Proposed		Used		
Basic	biological research	125			83		
Purp	ose total	125			83		
5. Re	e-use of animals: No prior use	ą	Previously used				
_			Proposed		Used		
No pr	ior use	28	ž		2		
Previ	ously used	97	÷		81		
_	tion 5 Total	Line			(ac		

7 August 2024

Reference #: 2024-0685-AWU - 7965

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Al recipients (57) were previously used for embryo transfers for the production of live edited and control calves Stick (b) and control (6) calves were previously characterized for genotype and lighter coat colour under the previous AE approval. PMEL (B) and control (6) calves were previously characterized for genotype and lighter coat colour under the previous AE approval. ANAOS2 took calves (2) were born during the project. P B Proposed Used Grade C 12 33 34 Proposed Used F Relained F Relained 110 210 Proposed Used Used C Disposed of Proposed of Relained F Rela	Details of how these animals	have been use	d previously in Re	search, Testing	and Teaching				
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	Other dead	6	3	20					

Dead total	6	20	2	
and the address of a state of the	d about allows a	m the knock town	for the follow the	a unita an aliance
or the other dead numbers liste	above, please confir	m the breakdown o	for these enimels players	g categories:
lanned end to the project.	D humbers. ONE F con	npiete the numbers	ior mose animais planne	d to be eutramised / kined as a
The other categories of animals Form.	that die during the proj	ject must be reporte	d at the end of the project	ct in the Animal Welfare and Use
E Education / 100 - document		-		
 Euthanised / killed as a p Died - unrelated to manip 	pulations	r Die ₽ Eut	a - related to manipulatio	ons
	Proposed	Us	ed	
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uthanised for welfare reasons	6	1 2		
	(<u>~</u>			
Setable for the extended	(
Details for the animals illed/died above	recipients not kept alive f calving. Recipients used	ollowing C-section birt for ET and never estal	ns for Group 91 blished a	
for Animal Lise form only)	pregnancy are deemed n	not fit for purpose and o	an be removed	
or Animar Use form only)	from the ACF (19 during are euthanised on anima	period) and any anima I welfare grounds are o	Is that die or fisposed of by	
	deep burial at the ACF as	s approved by Ngati W	airere and in	
	ERMA200223 controls. A with timing of events	gain cross over with n	umbers for 381	
Maan will apinote be billed	(
vnere will animals de killed	on ACF			
Aethod of Killing the animals	Other		1	
ice and of running the arminals	Other		l	
lease remember to list an SOP	in Section 11 for your	method of killing su	ch as drug administration	n or decapitation
Details for "Other" method of	Drug admin or using Fire	arm		
illing				
low and where will the animal's	ACF			
odies be disposed of				
. Total number of animal	s:			
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Total number of anim	als 12	5	83	3		
10. Animals bred	l for resear	ch, testing and t	eaching but no	t used and killed	:	
Were animals bred to	o enable this p	roject to take place	but not used in the	project and killed		
	Yes		@ No			
USE ADD ANOTHER	FOR EACH A	NIMAL TYPE/SPEC	CIES			
Changes from pr	oposed					
Were there any char those Proposed and	nges in animal Approved?	numbers, <mark>I</mark> mpact gr	rade or details from	۴ Yes	∩ No	
Please explain why t	he changes of	curred				
Fewer recipients wer	e used as not as	many embryo transfer	s were conducted as o	riginally planned.		
Roles on project Roles on project Tick all the roles o Program man Lead Technic Project staff Project staff Project staff Farm or Facil Commercial F Veterinarian	: in the project ager ian / Research /ithout access ity Manager Farmer	Associate to ~ Te Ara ~				
Program manage	ər					
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	Lasie or some op					
Program manager Co	omments					
Project staff						
7 August 2024	Re	ference #: 2024-06	85-AWU - 7965			

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First Name		
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Email	@agresearch.co.nz	
Organisation	AgResearch Ltd	1
Project staff with ac	cess to ~ Te Ara ~	
First Name		
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Email	@agresearch.co.nz	
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Organisation	AgResearch Ltd	×	
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Biometrician Commer	ts		

Farm or facility	manager	
First Name	Tim	
Sumame	Hale	

7 August 2024

Reference #: 2024-0685-AWU - 7965

Email	tim.hale@agresearch.co.nz
Organisation	AgResearch Ltd
AgResearch Farm/Facility	Ruakura Animal Containment Facility
Facility Manager comments	
Name and contact t	he farm / facility manager(s) to comment here.
(If there is more that	n one manager, multiple names and comments can be added here)
(If there is more that Name	n one manager, multiple names and comments can be added here)

Commercia	l farmer	
Name	Select Some Options	

Veterinarian(s)			
Veterinarian			
First Name			
Sumame			
Telephone			
Email			
Organisation	External Contractor	×	

7 August 2024

Reference #: 2024-0685-AWU - 7965

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Comment on application			
Veterinarian			
First Name			
Surname			
Telephone			
Email			
Organisation		•	
Comment on application			
Name	Select Some Options		
Veterinarian Con	nments		
Applicant sig	n off		

Applicant sign off Signed: This form was signed by AgResearch Ltd - @@agresearch.co.nz) on 22/02/2024 3:11 PM If the form is complete (use the completeness checker) it will AUTO-SUBMIT once you have signed

Reference #: 2024-0685-AWU - 7965

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RAEC 2023-2024 - Maintenance breeding of different cloned sheep genotypes – Animal Welfare and Use Report at end of trial approval period



16 September 2024 Reference #: 2024-2024-AWU - 9520

Page 1 of 10

Summary of manipulations

Briefly describe all the treatments/manipulations (type and	Overview of maintenance breeding activities for different NANOS2 and CMAH/GGTA genotypes 2023:
frequency) each animal underwent during this application	1) Natural mating - 26/05/23 a cloned NANOS2+/- ram (Howie) was mated with a cloned
	Minole) of the CMAH-/-/ GGTA-/- genotype. From these matings we obtained one lamb
	from 1927 on 30/10/23 (alive and well), but no pregnancies from the 4 other ewes.
	2) #1927 – Died twisted gut 9/11/23. As for the lamb it was brought into the PC2 room at the ACF on sawdust and feed 3 times a day and monitored until it accepted the bottle
	and came for feeding then we let it back into a paddock with shelter with youngest ewes
	(2022 brn animals) until it was big enough to go in with more sheep and weaned at recommended weigh.
	One non-experimental ewe died:
	3) #1935 - Found dead. No known cause 27/02/24
	Several non-experimental rams, which are not covered by this application, were
	euthanised on welfare grounds as part of normal farm maintenance: 4) Ram – Euthed 1/08/23
	5) Rams x2 – Tendon problems, euthanised (adverse event) 11/10/23. As stated above, these were not part of the study but covered here regardless.
	Several recipient ewes were culled as surplus:
	6) 1x 1/07/23, 12x 4/09/23, 1x 17/08/23, 2x 14/12/23
	These animals listed under 3)-6) are not listed under animal usage numbers since they
	mentioned here for completeness.
	7) mated ewes were scanned around D45 for pregnancy
	8) The born lamb was blood sampled for genotyping.
Did the manipulations go according to plan	Yes No
Describe what did not go as planned	The 4 'xeno' ewes did again not get pregnant, even though the ram was fertile with
	in a row that these ewes did not get pregnant, either by AI or mating. This is
	despite the fact that they all performed well in OPU/IVF experiments and produced normal numbers of eggs, as well as possessing an anatomically normal
	reproductive tract and organs. This is an intruiging observation, pointing at a
	development. It could be related to immune rejection. We are planning to follow up
	this observation in the future.
Were there any adverse events during project	the ^C Yes ^C No
If any changes or issues outlined within thi approved, ensure this is captured in your A	is jorm, or aaverse events reported, require a change in grading from that previously propo Animal Use Return below
Did the adverse event increase the Imp	pact Grading of the animals affected Yes C No

16 September 2024

Reference #: 2024-2024-AWU - 9520

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Were any animals withdrawn from the experiment or euthanised prematurely (if not already covered above) ∩ No

Please describe the circumstances

see above summary

We are now required to report examples of the 3R's to MPI along with our animal use statistics.

Please briefly describe and comment on each of the approaches you outlined in your application to implement the 3R's

Did you implement them successfully?

Did additional opportunities to implement the 3R's arise during the study?

Replacement

Implementation

Live animals were required as recipients since exo vivo gestation is not possible. The unexpected but reproducible 'non-pregnant' phenotype of the GGTA/CMAH ewes, is a good illustration why live animal studies are so valuable. This observation was not predictabel based on available in vitro evidence and warrants further investigation.

Reduction

Implementation

We used the minimal numbers of animals required to get at least one female NANOS2-/- (1 animal). The ram is +/- and the ewe is -/-, so the chances of getting -/- offspring is 50% and getting female -/- is 25%, so the ideal outcome is not guranteed. However, we only have one female -/- available and even generation of +/- females will increase our chances of obtaining NANOS2-/- females in future breeding.

By using one ram to simultaneously generate animals with different edits we reduced animal use. We will also did not include any wildtype animals because the resulting genotypes will not be required and have to be culled.

Refinement

Implementation

Manipulations were carried out according to SOPs to minimize any pain or noxiousness

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Reflecting on the study			
Provide a comment on the welfare of animals during the study - e.g. general etc	health, nutrition, shac	le/shelter provisions,	mental state
Animals were well looked after throughout.			
What went really well in the study			
Study went to plan and a heterozygous NANOS2 female was produced, which is value	ble for further breeding.	ä	1
Is there anything about the study you would do differently if you had to repea	t or do a similar stud	y	
no			
Is there any advice you would like to give others carrying out a study in a sim	nilar area or using sin	nilar techniques	_
no			
Were there any staffing or resourcing issues that affected the study		^G No	
Were there any health and safety concerns or issues during the study	Yes	G No	
Animal use details for each species			
Complete the "USED" column only			
Remember to include the Impact Grading for the animals affected by th	e Adverse Event(s)		

 1. Animal Type
 Sheep

 2. Source:

 Ø

 Breeding unit
 Commercial

 Ø
 Farm

 Ø
 Born during project

 Ø
 Daptured

 Ø
 Born during project

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		Proposed		Used		
	6.55	जा	1	ন		
Breeding Unit	7	Ξ		6		
orn during project	10	3	[1		
Source total	17	4	(7 4		
3. Status:						
Normal/Conventional Protected wildlife		SPF/Germfree Pregnant	Г Г	Diseased Unborn/Prehatched	р Г	Transgenic/Chimera Other
		Proposed		Used		
ransgenic/Chimera	17	×.	(7		
Status total	17		1	7		
4 Purnose:						
 ✓ Teaching ✓ Basic biological ✓ Biological agents 		Species conservation Medical research Compromised Offspring		Environmental Veterinary research Alternatives		Animal husbandry Testing Other
		Proposed		Used		
asic biological research	17	×	-	7 *		
ourpose total	17		1	7. 4	_	
5. Re-use of animals:						
R No prior use	9	Previously used				
		Proposed		Used		

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Previously used	7		6	1		
Re-use of animals total	17	÷	7			
		dama da ser la la D		and Too doloo		
Details of how these animal	is have been use	d previously in Re	esearch, Testin	g and Teaching		
The NANOS2+/- ram was us	ed for successful m	ating and AI, the 5 e	ewes were used fo	or OPU. The lambs	wiill not have beer	i used
before.						
6. Grading of manipul	lations:					
	₽ B	г с		Г D	L E	
19 1	Prop	osed	Use	d		
Grade B	17		7			
-						
Grada total	47	-	7	-		
Grade total	17		/			
7. Animals alive at en	d of project:					
7. Animals alive at en	d of project:	red	C Release	ed.		of
7. Animals alive at en Retained Rehomed	d of project:	ned alive	□ Release	ed	Disposed	of
7. Animals alive at end ☞ Retained ☞ Rehomed	d of project: ┌── Return ┌── None :	ned alive	⊏ Release	ed	□ Disposed	of
7. Animals alive at en F Retained 다 Rehomed	d of project: □ Return □ None : Prop	ned alive osed	□ Release	ed ed	☐ Disposed	of
7. Animals alive at en	d of project:	ned alive osed	r Release	ed ed	☐ Disposed	of
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7. Animals alive at end ♥ Retained □ Rehomed Retained	d of project: Return None : Prop	ned alive osed	☐ Release Use 6	ed ed	☐ Disposed	of
7. Animals alive at end ✓ Retained ← Rehomed Retained	d of project: Return None : Prop	ned alive osed	C Release	ed ed	☐ Disposed	of
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7. Animals alive at end F Retained F Rehomed Retained Alive total Who will be RETAINING th	d of project: Return None : Prop 17 17 17 17 17	ned alive osed x x x ny specific care th		ed ed ed ed ed red	☐ Disposed	of
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7. Animals alive at end F Retained Retained Alive total Who will be RETAINING th Retained at ACF, born nature	d of project:	ned alive osed	C Release Use 6 6 6 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ed ed ed ed ed end end end end end end e	□ Disposed	of
7. Animals alive at end F Retained F Rehomed Retained Alive total Who will be RETAINING th Retained at ACF, born nature 8. Animals DEAD at end	d of project: Return None : Prop 17 17 e animals and an ally nd of the proi	ned alive osed	C Release	ed ed ed	□ Disposed	of
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7. Animals alive at end F Retained C Rehomed Retained Alive total Who will be RETAINING th Retained at ACF, born natura 8. Animals DEAD at end Killed for Research, tissues	d of project:	ned alive osed	C Release	ed ed ind ind ind ind ind ind ind ind ind in	□ Disposed	of
7. Animals alive at end	d of project:	ect: ning on body or	C Release	ed	□ Disposed	of

Other dead					
	0	1	1	3	
Dead total	0	*	1		
For the other dead numbers li	isted above inleas	e confirm th	e breakdown of	numbers in the following c	ategories:
Note: When filling in PROPO	SED numbers: ON		a the numbers f	r those animals planned to	o be outbanized / killed as a
planned end to the project.	GED Humbers. OF	it i complet	e ule numbers i	n mose animais planned t	o be equilarised / killed as a
The other categories of anima Form.	als that die during	the project r	nust be reported	at the end of the project i	n the Animal Welfare and Use
E Futhanised / killed as a	a planned end to r	miect		- related to manipulations	
Died - unrelated to mar	nipulations	nojoor	E Euth	anised for welfare reasons	3
	Propose	d	Use	d	
Diad related	a		G	2	
Jieu - relateu	0 - адаада				
Details for the animals	#1025 Found	dead No kee	up cause 27/02/2		
killed/died above	tagged!	dead. No kno	will cause 21/02/2	- was prik	
(for Animal Line form only)	#1927 - Died wit	h Twisted gut	post lambing		
9. Total number of anim	als:				
	Brenner				
	Propose	a	Use	0	
	Topose				
Total number of animals	17		7	ㅋ	
Total number of animals	[17]	÷	7	ž	
Total number of animals	17 search, testing	i and teac	7 hing but not	used and killed:	
Total number of animals 10. Animals bred for res Were animals bred to enable	17 search, testing	and teac	7 hing but not ot used in the p	used and killed:	
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Total number of animals 10. Animals bred for res Were animals bred to enable ^C Yes	17 search, testing this project to take	and teac	7 hing but not ot used in the p	used and killed:	
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Total number of animals 10. Animals bred for res Were animals bred to enable ^C Yes JSE ADD ANOTHER FOR EA	17 search, testing this project to take	and teac	7 hing but not ot used in the p	used and killed:	
Total number of animals 10. Animals bred for res Were animals bred to enable C Yes USE ADD ANOTHER FOR EA Changes from proposed	17 search, testing this project to take	and teac	7 hing but not ot used in the p	used and killed: roject and killed	
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Total number of animals 10. Animals bred for res Were animals bred to enable Yes USE ADD ANOTHER FOR EA Changes from proposed Were there any changes in ar those Proposed and Approved	17 search, testing this project to take ACH ANIMAL TYP d	g and teac	7 hing but not ot used in the p	In used and killed: roject and killed	с No
Total number of animals 10. Animals bred for res Were animals bred to enable C Yes USE ADD ANOTHER FOR EA Changes from proposed Were there any changes in ar those Proposed and Approved	17 search, testing this project to take ACH ANIMAL TYP d	g and teac	7 hing but not ot used in the p	In used and killed: roject and killed	с No

Please explain why the changes occurred

4 instead of 5 GGAT/CMAH ewes were mated because one was not up for it due to health reasons.

Roles on project Roles on project: Tick all the roles on the project Program manager Lead Technician / Research Associate Project staff Project staff Project staff without access to ~ Te Ara ~ Biometrician Farm or Facility Manager Commercial Farmer Veterinarian Veterinarian

Program m	anager	
Name	Select Some Options	
Program man	ager Comments	

Project staff			
Project staff with ac	cess to ~ Te Ara ~		
First Name			
Surname			
Email	@agresearch.	co.nz	
Organisation	AgResearch Ltd	<u> </u>	
Project staff with ac	cess to ~ Te Ara ~		
First Name			
	Reference # 2024.2024	24 AWIL 0220	

Sumame			
Email	@agresearch.co.nz		
Organisation	AgResearch Ltd	÷	
Name	Select Some Options		
Project Staff comments			

Biometrician		
Name	Select Some Options	

Farm or Facility Ma	nager
First Name	Tm
Surname	Hale
Email	tim.hale@agresearch.co.nz
Organisation	AgResearch Ltd
AgResearch Farm/Facility	Ruakura Animal Containment Facility
Comment on application	
Name and contact t	the farm / facility manager to comment here
Name	Tim - Hale X
Facility Manager Comments	Beyond separation for mating and lambing these sheep run with the recipient ewes for management purposes and receive same health treatments etc. Feet management and condition require regular monitoring and frequent pedicures.

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Commercia	I farmer
Name	Select Some Options
Veterinaria	n(s)
Name	Select Some Options
Applicant s	ign off
Signed: 1	This form was signed by AgResearch Ltd - (Carter and Carter and Ca
in the form is	complete (use the completeness checker) it will AUTU-SUBMIT once you have signed

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RAEC 2024-2288 - Characterisation of animals produced as part of the climate-smart cattle programme – Interim Report



Interim Report - 2288

Project Title: Characteri	isation of animals produced as part of the climate-smart cattle programme
nterim Report Title	
Title	
include timeframe cover	red)
Title	First interim report 2288, 23 January to 30 June 2024
(include timeframe covered)	
ntorim Papart Number	
HENRI REDUITING THE	#1

Report

Instrumential proposes on the project so for, including a semicond of semicond of semicond of semicond of semicond of semicon	summaries programs on the	Internit report Leop		
projects of gr. including diversions of gr. including diversions of gr. including diversions of gr. including with a diversion of gr. with the second round of A with the diversion of gr. including with ABS to grian approval for the collection and production of semen and embryos, respectively for export to Australia. Fellowing an internal audit by ABS and an audit by ABS and and the second responses approval for makers of collection, processing and storage of books semen to ABS to processing and their return to AgResearch to graph approval for collection, processing and their return to AgResearch to graph approval for collection, processing and their return to AgResearch to graph approval for collection and empty processing and their return to AgResearch of export eligible collection and empty processing and their return to AgResearch and CSINO in Australia. The first equation approval for collection and empty processing and their return to AgResearch and CSINO in Australia. The first equation approval for collection and empty processing and their return to AgResearch and CSINO in Australia. The existing to draph approval for eligible collection and empty processing and their return to AgResearch and CSINO in Australia. The existing to draph approval for the automation with our collaborators at CSINO in Australia. The addition, we received the approval for collection and empty processing and their return to AgResearch and CSINO in Australia. The addition, we received the approval for collection and empty processing and their return to AgResearch and CSINO in Australia. The addition, we received the approval for the addition and the matter of books and the Australian to the Australian Department to Agraph and their return with warm days than for the 2022/23 aurmee. Data collected for the advariant human day and their return with a sum and to the collection of the advariant to the advariant the advariant human day that the two and their return with a sum and to the collection of the advariant to the advariant to t	summarise progress on the	Nine edited and control heifers were artificially inseminated to get them in calf and into lactation. Seven		
deference to any adverse prenents and approved mendments and approved mendments and approved for MPI to Natrials. Flobum pain Internal audit MA SBS of an audit MA SBS of approval for MPI to Natrials. Flobum and production of seme and embryos, rescience the approval for collection, processing and atorage of bovies seme to Australia. We fuely descent for atorage. The first export eligible seme collection on 22 May 2024 was observed by AssureQuality as mandatory control. The collection of exports after min mound bits in nor collub is non-complet. In addition, we received the approval for MPI to Collection and embry processing will need to be observed by AssureQuality as mandatory control. Use an in communication with our colluborators at CSIRO in Australia. The existing but expired heads of agreement between ApResearch and CSIRO in presently being renewed. Conversations with head to abserve between the service and the service service and embryos to CSIRO have been initiated. This year we had a between ApResearch and CSIRO in Australia. The existing but expired heads of agreement between ApResearch and CSIRO is presently being renewed. Conversations with head to abserve being end to the service of the transfer of bovies semen and embryos to CSIRO have been initiated. This year we had a between the same with ware and embryos to CSIRO have been initiated. This year what ad a between the addition, who have established embryon is tem cells with a bear and swithing the transfer at the transfer base in a base of a proceed from of bovies at and a write of the transperior for transfer and development to individue dates and characteristic of the injection of the transfer is undividue and that embry and a base of the development of the transperior for transfer and development that instand produce. One complete is additioned to have a homosyous NANOS2 knockout. The detailed genotype analysis using angle cell clones developed an heaterosyous NANOS2 knockout. The detailed genotype analysis using single cell clones developed in	project so far, including	heifers were pregnant after the first round of AI, with one pregnant from the second round of AI with due		
Preprint. Pre	reference to any adverse	dates of 30 November and 20 December 2024. Only one heifer, a wild type control, failed to become		
amendments In resentancy for sogiet to sustainal a Foleowing in themai used by ABS and amouth by Astronomy Chanting for solicition for collicition of concessing and starged of home seminor to Austrolia. We gained approval from MP1 to transfer seminor to ABS for processing and their rutum to ApResearch for storage. The solicities of export of systemen collection or a methy or processing and their rutum to ApResearch for storage. The solicities of export of systemen collection or a methy or processing and their rutum to ApResearch for storage. The solicities of export of the seminor balance of the backet of the Australia. The solicities of export of the seminor balance of the backet of the Australia. The solicities of experiment balance on and entry or processing will also append to the Come Technology and another the Australian Department of Agrine PAResearch and entry or busine and they append to the Come Technology and another the Australian Department of the information of the banket of the Come Technology and solicities of experiment balance on the seminor balance on the solicities of the Come Technology and the Australian Department of the information of the Solicities and the expectability of the Come Technology and the Australian Department of the information and processing and there abalance and the complex of the Australian Department of the information and processing and the expectability of the Come Technology and the Australian Department of the information and processing and the expectability of the Come Technology and the Australian Department of the information and processing and the expectability of the Come Technology and Australian Department of the information and processing and the expectability of the Come Technology and Australian Department of the information and processing and the expectability of the Societ Australian Department of the information and processing and the expectability of the Societ Australian Department of the the Australian D	events and approved	pregnant. We have been working with APS to gain approval for the collection and production of semen and embruos		
Signature (s) Signature (s)	amendments	We have been working with ABS to gain approval for the collection and production of semen and empryos, respectively for export to Australia. Following an internal audit by ABS and an audit by AssureQuality we		
Bigrowing from MPH to transfer semen to ABS for processing and their return to AqRessend rot stronger. The transfer seven religible norty 2 May 2224 was observed by AssureQuality as mandatory control. The contension of export approvales from advances of transfer seven religible norty or processing will need to be observed by AssureQuality as mandatory control. We are in communication with our collaborators all CSIRO in Australia. The resisting but expired heads of adverse and Forestry and the Office of the Genes Technology Regulator about neighbor optic processing will need to be observed by AssureQuality as mandatory control. We are in communication with our collaborators all CSIRO in Australia. The resisting but expired heads of agreement between AgResearch and CSIRO is presently being renewed. Observations and presently being renewed. Observations are presently being renewed. Conversestions with the Australian Department of Agricines and Forestry and the Office of the Genes Technology Regulator about neight and the Use as a setting of a mandatory control. We have optimized collines of bovine embryos to CSIRO have been inhibited. This asset and the observations and the vesting of injection of the transgene as genetic match, in addition, we have derived prints and the observation and the vesting of injection of the transgene embryon is tern cells into cloned NANOS2 hout embryos. And babay estimates of injection of the transgene embryon is tor ransfer and development to mid-term. Converse stand were asset and the observation and the vesting of injection of the transgene embryos. Strongels, were additional made and the formation and the observation and the vesting of injection of the transgene embryos for transfer and development in mid-term. The first severy is provide to the fermione and the rene site in the internste of injection of the transgene embryos in the math and babay as a		received the approval for collection, processing and storage of bovine semen to Australia. We gained		
If the capitch of export-approved ament from or builts in now complete. In addition, we received the approval for collection, nor collaborators at CSIRO in Australia. The existing but expired heads of approvant for collection and embryo processing will need to be observed by AssureClaulity as mandatory control. We are in communication with our collaborators at CSIRO in Australia. The existing but expired heads of approvant between AgResearch and CSIRO is presently being renewed. Conversations with the Australia of the graphical pathween AgResearch and CSIRO is presently being renewed. Conversations with the Australia of approvants of the pathween adaptes and Foresty and the Office of the Gene Technology Regulator about required approvals for the transfer of bovine semen and embryos to CSIRO have been initiated. This yeare we had a better summer with warn days than for the 202223 summer. Data collected from observations, toggers and runnen boluses, and exercise challenges under warm conditions are presently being evaluated. We have optimized culture of bovine embryosit setm cells into domor delis bor produce cloned, sterils host embryonic stem cells into domor and how togs have been developed. Final testing collection of the transfer and development to mid-tem. Outcomes is underline bated bANOS2 kindle cahes research and suitable for the produces of the transfer and how togs and one of the finandes was dentified to have a shored bate NANOS2 kindle cahes and suitable for the produces of the finandes was dentified to have a tembryos. Output have documents * Yes * No Improving the have bate MANOS2 kindle cahes renewed produces for the finandes was dentified to have a tembryos is the cale in the MANOS2 kindle cahes and availis the toproduce stentite NANOS2 kindle cahes are easily and start		approval from MPI to transfer semen to ABS for processing and their return to AgResearch for storage. The		
The collection of export-approved semen from our bulls is now complete. In addition, we received the properties of eligible occyle collection, processing and storage of in vito bovine embryos Australia. The first export eligible occyle collection, processing and storage of in vito bovine ombryos to Australia. The first export eligible occyle collection and embryo processing will need to be observed by AssureQuality as mandatory of ends to bovine semen and embryos of CSIRO in Australia. The existing bulk proteomed and the Australian Department of Agriculture, Fisheries and Forestry and the Office of the Ceren Technology Regulator about preview had a better summer with warm days than for the 202203 summer. Data collected form observations, togens and rumen boluses, and exercise challenges under warm conditions are presently and better summer with warm days than for the 202203 summer. Data collected form of botine embryosic stem cells into choice cells protection cond, steffic hold embryon. Finds tables and have established embryos. Fridocols for the transfer of and private intervent and advised preduction conduct and the density on a NANOS2 A to choose at the advised preduction of the transgence as genetic marker. In addition, we have derived privaty cells for a NANOS2 A to choose at the tot conduct and the density on a NANOS2 A tot context is the derived privaty cells for the set as tables to produce stering of injection of the transgence as genetic marker. In addition, we have derived privaty cells the advised and have established embryos. Fridocols for the transfer and development to mid-term. Context and the advised preduction of the transgence as the advised and the received preduction of the transgence as previous dark and the development on the advised and the received previous and the advised preduction of a term received the advised preduction of stering Almong advised and the received previous advised and the received preduction of a term received the advised preduction of the transgence as genetic mark		first export eligible semen collection on 22 May 2024 was observed by AssureQuality as mandatory control.		
approved the collection, and embry processing will not borne embryos to AssureQuality as mandatory control. We are in communication with our collaborators at CSIRO in Australia. The existing but expired heads of agreement between AgResearch and CSIRO is presently being renewed. Conversations with the Australia and embryos to CSIRO have been initiated. This yeare what ad beeter summer with warm days than the Office of the Gene Technology Regulator about required approvals for the transfer of borine semen and embryos to CSIRO have been initiated. This yeare what ad beeter summer with warm days than for the 202223 summer. Data collection from observations, loggers and runne boluses, and exercise challenges under warm conditions are presently being revoluted. We ware optimized culture of borine embryotic stem cells and heave established embryons. The solution is been developed. Final ethics are presently being revoluted for on consisting and transfer the source of embryone is the call in developing the interaction of the interactions to for the interactions in cells and versified these as sulfable doner cells to produce doned, stelline host embryos. The transfer of edveloping the interaction of the material interactions for the interactions for the interactions is underway. This has taken longer than initially expected. Once completed, we will produce of underse stelling of injection of the transgerine cells into advelopment to molecum. Centro advelopment to molecum and willows to Produce into AMNOS2 male host embryos. Although both females had complex on-alte advelopment to molecum and willows to produce into advelopment to molecum advelopment to advelopment to advelopment to molecum advelopment to a		The collection of export -approved semen from our bulls is now complete. In addition, we received the		
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RAEC 2024-2337 - Climate-Smart cattle embryo development – Interim Report



Interim Report - 2337

Project Title: Climate-Sm	art cattle embryo development	
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Title		
(include timeframe covere	d)	
Title	First interim report 2337, 29 March to 31 July 2024	
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Report		

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Ministry for Primary Industries Manatū Ahu Matua



Verification Report

Report ID:	PBV/2501/2023/03
Outcome:	Acceptable
Issued to:	AgResearch - Ruakura Campus
Operator ID(s):	2501
Issued by:	Crystal Lange
	Phone: 079578319 Email: crystal.lange@mpi.govt.nz
Verification Period:	2023-05-03 to 2023-08-09
Verification Date:	2023-08-08
Published:	2023-08-18 14:38
Next Due Date:	2024-02-09
Level/Step:	6.1 (started on 5.2, and ceiling is 6)
Report Type:	Scheduled
Peer Reviewed By:	Nicki Sherratt

¹ A Verification Report is a formal report issued when sufficient evidence has been assessed to arrive at an outcome for a verification period. This report may contain Technical Reviews and external audit findings completed during the period. Inadequate and/or untimely responses to deficiencies identified in this report, poor/unacceptable performance, or failure to pass subsequent audits may result in the escalating imposition of sanctions and/or interventions provided by law.

This report, including any attachments, is intended solely for the Operator of 'AgResearch - Ruskura Campus'. The information it contains is confidential and may be legally privileged. Unauthorised use of this report, or the information it contains, may be unlawful. If you have received this report by mistake please call Crystal Lange immediately on 079578319 or notify by email using crystal.lange@mpi.govt.nz and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.





1. Premises Profile

AgResearch - Ruakura Campus is, under section 39 of the Biosecurity Act 1993, approved as a Transitional and Containment Facility in accordance with the requirements of the MPI/EPA standard(s) identified. Under section 40 of the Biosecurity Act, AgResearch is approved as an operator of that facility and is primarily responsible for the facility, compliance with facility approvals and all activities involving risk goods.

The standards that the facility is approved to specify the structural and operating requirements for containment and/or transitional facilities holding regulated organisms and risk goods that are, or may contain:

- Agricultural Compounds
- Animals
- Animal Products
- · Biologicals
- Miscellaneous
- Non-risk Goods
- Plant Products

Physical Address :

10 Ruakura Campus Bisley Road, Ruakura, Hamilton

Glossary of terms :

TF	Transitional Facility
ACF	Animal Containment Farm
ACU	Animal Containment Unit
BACC	Biosecurity Authority Clearance Certificate
CAR	Corrective Action Request
CF	Containment Facility
СТО	Chief Technical Officer
	CTO decision/permission under Section 52/53 of the
CTOd	Biosecurity Act 1993
DFO	Delegated Facility Operator
EPA	Environmental Protection Authority
GH	Glasshouse
GM	Genetically Modified
HSNO	Hazardous Substances and New Organisms
MPI	Ministry for Primary Industries
NC	Non-Compliance
NZFS - VS	New Zealand Food Safety - Verification Services
PBV	Performance Based Verification
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2
PP	Plant Protection
PPE	Personal Protective Equipment
R&M	Repairs and Maintenance
SAC	Small Animal Containment

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2. Executive Summary

The objective of this PBV was to verify compliance with the facility manual, the Import Health Standards, the Standards identified in the "Biosecurity" section of this report, the HSNO Act 1996 and the facility and operator approvals as held under the Biosecurity Act 1993.

This was a scheduled and announced inspection of the AgResearch Limited transitional and containment facility at the Ruakura site in Hamilton. The outcome of the verification undertaken 8/08/2023 had an acceptable outcome. One NC has been issued for Laboratories. Nothing required follow up from the previous verification and AgResearch – Ruakura returns to a six-monthly verification frequency.

MPI is satisfied that AgResearch is operating in compliance with the requirements of the standards it is approved to. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meetings along with the reality check of the facility was carried out by Crystal Lange (MPI) with **Constant Constant Constant** (DFO) and Tim Hale (DFO). Animal records were reviewed in the SAC and ACF. Laboratory records were reviewed prior to the reality check.

The Inspectors' authority under the Biosecurity Act 1993 and HSNO Act 1996 was confirmed. Health and Safety is covered by a visitor register. No additional hazards were notified. Crystal was accompanied at all times.

The inspection process included a review of onsite records and a reality check. Records reviewed included: staff training, biological products register, new organisms' registers, animal registers and internal audits. The reality check included PC1 and PC2 laboratories in Plant Protection, Animal Physiology, animal containment in SAC and ACF and the Glasshouses.



4. Verification Completed (this period)

Biosecurity

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Plants: 2007	Acceptable
Biosecurity:Containment Facilities for Vertebrate Laboratory Animals	Acceptable
Biosecurity:Containment Standard for Field Testing of Farm Animals	Acceptable
Biosecurity:Facilities for Microorganisms and Cell Cultures: 2007a	Acceptable
Biosecurity:Transitional Facilities for Biological Products	Acceptable
Biosecurity:Transitional and Containment Facilities for Invertebrates	Acceptable

Subject: Transitional Facilities for Biological Products

Note List:

[Crystal Lange]

Management of biological products is closely aligned with that of products under the Microorganism standard.

Subject: Facilities for Microorganisms and Cell Cultures: 2007a

Note List:

[Crystal Lange]

Normal audit frequency of six monthly can now be resumed following an acceptable verification outcome. Approval of two tenant companies and independent containment facilities can be confirmed.

Updated or new CTO approvals are supplied to the verifier in a timely manner. Decontamination or structural repairs are advised as needed.

Subject: Containment Facilities for Plants: 2007

Note List:

[Crystal Lange]

PC2 rooms in use had the permissions (CTO or HSNO) noted on the door. All plants were clearly labelled. R&M, general maintenance and housekeeping was recorded in a number of logs, some entries were therefore duplicated. PC1 trial work was labelled and contained in trays to prevent loss following irrigation.

Subject: Transitional and Containment Facilities for Invertebrates

Note List:

[Crystal Lange]

Nematology work is ongoing. Nematodes are managed through multiple levels of containment.

Subject: Containment Standard for Field Testing of Farm Animals

Note List:

[Crystal Lange]

Day old lambs not yet in the site register were advised. Calves 32 and 33 were seen to be tagged in compliance with the Standard. Buck goats and sheep were

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seen during the reality check and discussed further. Cows in a selected paddock were located on the farm map (phone App) and movement history confirmed.

A perimeter breach and theft of an electric fence unit was notified to MPI. The inner fence was not breached.

Subject: Containment Facilities for Vertebrate Laboratory Animals

Note List:

[Crystal Lange]

Containment and cage card labelling was accessed. The delegated operator was knowledgeable of all strains held and future uses of each cell line. Enrichment tools were available in each rodent cage.

Room 80 (SAC) was inspected and approved for use under dual standards (154.03.03, 154.03.02/154.02.17).

Quality Assurance

Site functions with regards to research and land holdings were discussed. Landmark dates were confirmed.

The site containment manual had been updated this verification period with changes to the facility footprint following the removal of some laboratories and the resignation of the Site Maintenance Engineer.

Internal audits had been completed for all areas. The PP audit was assessed as part of the previous PBV. Training was up to date with one induction, two contractor and one cleaner being trained since the last verification

The following elements were verified in this PBV period:

Quality Assurance: Biosecurity Contingency Plans	Acceptable
Quality Assurance: Chief Technical Officer (CTO) Permissions and	
Decisions	Acceptable
Quality Assurance: Notifications to MPI/EPA	Acceptable
Quality Assurance: Operating Procedures	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance: Operator Internal Verification	Acceptable
Quality Assurance: Training and Competency of Personnel	Acceptable

Documentation and Certification

Two imports had been received over the last three months. Transfer records were maintained to a high standard and the Delegated Operator was able to advise on the status of all approved transfers.





There have been no modifications to laboratories, just removal of some from the footprint due to changes in leased space.

The following elements were verified in this PBV period:

Documentation and Certification:Biosecurity Authority Clearance Certificates (BACCs)	Acceptable
Documentation and Certification:Documentation and Record Keeping	Acceptable
Documentation and Certification:Site Plans, Specification and Modifications	Acceptable

Identification, Traceability & Management

Work underway and projects to be started were discussed. Imports and transfers were reconciled. Transfers EM2609 and EM2610 had yet to occur. Animal inventories were supplied and were up to date (7/08/2023) for the ACF and as at 26/07/2023 for SAC. Updates for the SAC were notified at the PBV. Records for PC1 plants (unwanted organisms) was not reviewed at this visit. PC2 GH register recorded work for the unwanted organism M.minor. Plant trial work is recorded in individual lab books.

The following elements were verified in this PBV period:

Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management:Product and Organism Identification	Acceptable
Identification, Traceability & Management:Segregation	Acceptable
Identification, Traceability & Management:Transfer of Goods and Organisms	Acceptable

Hygiene & Sanitation

Notification had been received of cluster files entering laboratories through light fittings recessed into the ceiling space. Replacement lights are being installed that are fully sealed units. Excessive rainfall and long term ponding has raised the duck population in areas of standing water. Farm and building vermin control continue to be managed well.

PPE was available PC1, PC2, Planthouse and Small Vertebrate facilities. Autoclave function was confirmed using dual iButtons in July (PP-PC2) and August (PP-Glasshouse and SAC). Sufficient offal holes are present on the farm to manage Large Vertebrate waste.

The following elements were verified in this PBV period:

Hygiene & Sanitation: Cleaning and Disinfection	Acceptable
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The following elements were verified in this PBV period:

Hygiene & Sanitation: Personnel Hygiene and Personal Protective	
Equipment (PPE)	Acceptable
Hygiene & Sanitation:Pest, Vermin and Weed Control	Acceptable
Hygiene & Sanitation:Waste Management	Acceptable

Design and Construction

All facilities inspected were well constructed. Minor repairs were noted for PP.

The following elements were verified in this PBV period:

Design and Construction: Access and Security	Acceptable
Design and Construction:Animal Enclosures and Facilities (inc. invertebrates)	Acceptable
Design and Construction:Laboratories	Acceptable
Design and Construction:Open Field Testing Facilities	Acceptable
Design and Construction: Physical Containment Level 1 (PC1)	Acceptable
Design and Construction: Physical Containment Level 2 (PC2)	Acceptable
Design and Construction:Plant Houses and Glasshouses	Acceptable
Design and Construction:Signage	Acceptable

Subject: Laboratories

Note List:

[Crystal Lange]

Glass flasks of water were seen to be carried into the PC2 Embryo suite in fabric bags. These bags were placed on the floor prior to being placed on the bench. Fabric bags are not impervious, they also pose a safety risk as they weaken with age.

The self closers on doors in the PC2 GH and PP-PC2 (lab) were not working properly and the doors would not close without a push. Paint work in the PP-PC2 needs to be repaired to maintain the impervious finish. A small crack in the vinyl flooring in PP-PC1 was noted along with a bench needing to be sealed.

NON-COMPLIANCE Rated: Minor

Laboratories not maintained to meet the requirements of section 4.7 of AS/NZS 2243.3:2002 as required by the Micro2007a and Biological Products standards.

Corrective Action Request

- 1. Ensure walls, floors and work surfaces are sealed and impervious.
- 2. Remedy self closing doors.
- 3. Review use of fabric bags.





To Be Completed By: 29/09/2023

Subject: Open Field Testing Facilities

Note List:

[Crystal Lange]

Notification received of breach of outer perimeter fence. Double fence line used for unlawful entry to the General farm sheds. As soon as the hole in the fence was noted an animal count was undertaken and no animals were missing. The only item found missing was an electric fence unit.

Hazardous Substances and New Organisms (HSNO) Act

Compliance with recording requirements and containment controls was verified for; ARPN013 (GMD02023, APP203832), GMC03001 (GMC001197), GMD04112 (GMD003420), GMO04/ARR005 [GMD04112] (GMD003421) and ERMA200223.

The following elements were verified in this PBV period:

Hazardous Substances and New Organisms (HSNO) Act:HSNO Act	ar 1000
Approvals for Development of New Organisms	Acceptable
Hazardous Substances and New Organisms (HSNO) Act:HSNO Act	
Approvals for New Organisms for Containment	Acceptable

Mandatory Tasks

5. Definitions

 Acceptable
 Where the Animal Products Officer (or Biosecurity Inspector) is satisfied that the operator is substantially complying with requirements; and where there have been any departures from regulatory requirements, that the operator's corrective actions have been, or are being, applied appropriately and effectively.

 Obs
 Departures from regulatory requirements, identified by the Animal Products Officer (or Biosecurity Inspector), are to be transferred to the operator's issue management system for resolution. (Key Topic / Non-compliance)

 Unacceptable
 Where the Animal Products Officer (or Biosecurity Inspector) has determined that the operator is not

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Verification Report

Report ID:	PBV/2501/2024/01
Outcome:	Acceptable
Issued to:	AgResearch - Ruakura Campus
Operator ID(s):	2501
Issued by:	Crystal Lange
0.53	Phone: 079578319 Email: crystal.lange@mpi.govt.nz
Verification Period:	2023-08-09 to 2024-02-09
Verification Date:	2024-02-13
Published:	2024-02-28 15:58
Next Due Date:	2024-08-09
Level/Step:	6.1 (started on 6.1, and ceiling is 6)
Report Type:	Scheduled
Peer Reviewed By:	Elizabeth Buckley

¹ A Verification Report is a formal report issued when sufficient evidence has been assessed to arrive at an outcome for a verification period. This report may contain Technical Reviews and external audit findings completed during the period. Inadequate and/or untimely responses to deficiencies identified in this report, poor/unacceptable performance, or failure to pass subsequent audits may result in the escalating imposition of sanctions and/or interventions provided by law.

This report, including any attachments, is intended solely for the Operator of 'AgResearch - Ruakura Campus '. The information it contains is confidential and may be legally privileged. Unauthorised use of this report, or the information it contains, may be unlawful. If you have received this report by mistake please call Crystal Lange immediately on 079578319 or notify by email using crystal.lange@mpi.govt.nz and erase the report and attachments. Thank you.

The Ministry for Primary Industries retains the 'original' of this report and accepts no responsibility for changes made to 'copies', including attachments, however they may be distributed.

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1. Premises Profile

AgResearch - Ruakura Campus is, under section 39 of the Biosecurity Act 1993, approved as a Transitional and Containment Facility in accordance with the requirements of the MPI/EPA standard(s) identified. Under section 40 of the Biosecurity Act, AgResearch is approved as an operator of that facility and is primarily responsible for the facility, compliance with facility approvals and all activities involving risk goods.

The standards that the facility is approved to specify the structural and operating requirements for containment and/or transitional facilities holding regulated organisms and risk goods that are, or may contain:

- Agricultural Compounds
- Animals
- Animal Products
- Biologicals
- Miscellaneous
- Non-risk Goods
- Plant Products

Physical Address :

10 Ruakura Campus Bisley Road, Ruakura, Hamilton

Glossary of terms :

TF	Transitional Facility
ACF	Animal Containment Farm
ACU	Animal Containment Unit
	Australian New Zealand Standard 2243.3 Microbiological
ASNZS	Safety and containment
B3	Better Border Biosecurity
BACC	Biosecurity Authority Clearance Certificate
CAR	Corrective Action Request
CF	Containment Facility
СТО	Chief Technical Officer
	CTO decision/permission under Section 52/53 of the
CTOd	Biosecurity Act 1993
DFO	Delegated Facility Operator
EPA	Environmental Protection Authority
GH	Glasshouse
GM	Genetically Modified
HSNO	Hazardous Substances and New Organisms
IHS	Import Health Standard
MPI	Ministry for Primary Industries
NC	Non-Compliance
NZFS - VS	New Zealand Food Safety - Verification Services
PBV	Performance Based Verification
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2

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PP	Plant Protection
PPE	Personal Protective Equipment
R&M	Repairs and Maintenance
SAC	Small Animal Containment

2. Executive Summary

This was a scheduled and announced inspection of the AgResearch Limited transitional and containment facility at the Ruakura site in Hamilton.

The objective of this PBV was to verify compliance with the facility manual, the Import Health Standards, the Standards identified in the "Biosecurity" section of this report, the HSNO Act 1996 and the facility and operator approvals as held under the Biosecurity Act 1993.

The outcome of the verification undertaken 13/02/2024 had an acceptable outcome. One minor NC was issued for Laboratory Hygiene. The minor NC s at the previous inspection t was closed 26/09/2023.

MPI is satisfied that AgResearch is operating in compliance with the requirements of the standards it is approved to. As such the facility and operator approvals will be continued.

3. Operator Summary

The entry and exit meetings along with the reality check of the facility was carried out by Crystal Lange (MPI) with (DFO) and Tim Hale (DFO). The Inspectors' authority under the Biosecurity Act 1993 and HSNO Act 1996 was confirmed. Health and Safety is covered by a visitor register. No additional hazards were notified.

Two key support roles for AgResearch (not affecting the transitional facility) are not being filled. Tim has added Facilities Support to his role. There is no adverse impacts between Tims' roles at present.

The inspection process included a review of onsite records and a reality check. Records reviewed included information supplied prior to the PBV by both DFOs as well as on the day. The reality check included PC1 laboratories in the South Wing, PC2 laboratories in Animal Physiology, animal containment in SAC and ACF. (Animal Technician) led the tour of SAC and was able to answer all

questions presented.



4. Verification Completed (this period)

Biosecurity

The facility demonstrated substantial compliance with the standards.

The following elements were verified in this PBV period:

Biosecurity:Containment Facilities for Vertebrate Laboratory Animals	Acceptable
Biosecurity:Containment Standard for Field Testing of Farm Animals	Acceptable
Biosecurity: Facilities for Microorganisms and Cell Cultures: 2007a	Acceptable
Biosecurity: Transitional Facilities for Biological Products	Acceptable

Quality Assurance

The facility manual was updated in December 2023 to Version 4.3. Ongoing updates were advised at the PBV. The internal audits identified minor maintenance issues. Refresher training was not yet due. Two cleaners and four summer students had been inducted along with nine contractors and two casual workers.

CTO expiry dates are regularly checked. Two approvals expire this year and the B3 project ceases June 2024. A copy of the current Velvet Leaf CTO was requested and supplied in a timely manner.

The following elements were verified in this PBV period:

Quality Assurance: Chief Technical Officer (CTO) Permissions and Decisions	Acceptable
Quality Assurance:Operator Control	Acceptable
Quality Assurance: Operator Internal Verification	Acceptable
Quality Assurance: Training and Competency of Personnel	Acceptable

Documentation and Certification

Transfer of samples for the B3 project (C2024/90933) did not occur. The BACC direction has since been rejected by MPI. Three other imports during the verification period were all released under an IHS. Registers of imports, transfers and animals were up to date.

The following elements were verified in this PBV period:

Documentation and Certification:Biosecurity Authority Clearance	
Certificates (BACCs)	Acceptable
Documentation and Certification:Documentation and Record Keeping	Acceptable





The following elements were verified in this PBV period:

Documentation and Certification:Site Plans, Specification and	
Modifications	Acceptable

Identification, Traceability & Management

Transfers were reconciled and confirmed. Four outward movements under transfer EM2609 preceded the return (EM2160) which is yet to occur. Mice registers supplied prior to the PBV were updated on the day. Calves and cows were selected for traceability. One Mob was selected for location status. Inventory matched when deaths and yet to calve cows (held in a fence break) were added in.

The following elements were verified in this PBV period:

Identification, Traceability & Management: Authorised Signatories	Acceptable
Identification, Traceability & Management:Inventory Control and Accuracy	Acceptable
Identification, Traceability & Management:Transfer of Goods and Organisms	Acceptable

Hygiene & Sanitation

Installing of sealed lights in the Animal Physiology complex has been completed and there have been no further incidences of cluster flies.

iButton records were sighted for the three waste autoclaves (SAC, PP and GH) with all hold times exceeding the minimums in the ASNZS.

The following elements were verified in this PBV period:

Hygiene & Sanitation:Cleaning and Disinfection	Acceptable
Hygiene & Sanitation: Personnel Hygiene and Personal Protective	
Equipment (PPE)	Acceptable
Hygiene & Sanitation:Waste Management	Acceptable

Subject: Cleaning and Disinfection

Note List:

[Crystal Lange]

During the South Wing reality check cardboard was noted stored under a bench in 101, cobwebs in 117, and water staining was noted on wooden clipboard in 111. A minor NC has been issued for hygiene.

Corrective Action Request



Confirmation of action take to be emailed to the Inspector.

Design and Construction

All South Wing laboratories (PC1) were visited for the reality check along the the PC2 Tissue Cultures laboratories in Animal Physiology. Identification of issues at internal audits and by other staff in between times is pleasing to see. A split floor seal in 112 was on the facility maintenance list.

The SPF room was empty with mice only held in one room of the SAC. Perimeter fencing was secure at the ACF along with internal paddock fencing.

The following elements were verified in this PBV period:

Design and Construction:Animal Enclosures and Facilities (inc. invertebrates)	Acceptable
Design and Construction:Laboratories	Acceptable
Design and Construction: Open Field Testing Facilities	Acceptable
Design and Construction: Physical Containment Level 1 (PC1)	Acceptable
Design and Construction: Physical Containment Level 2 (PC2)	Acceptable

Hazardous Substances and New Organisms (HSNO) Act

Compliance with recording requirements and containment controls was verified for; GMC03001 (GMC001197), GMD04112 (GMD003420), and ERMA200223.

The following elements were verified in this PBV period:

Hazardous Substances and New Organisms (HSNO) Act:HSNO Act	
Approvals for Development of New Organisms	Acceptable
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Mandatory Tasks

5. Definitions

Acceptable

Where the Animal Products Officer (or Biosecurity Inspector) is satisfied that the operator is substantially complying with requirements; and where there have been any departures from

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regulatory requirements, that the operator's corrective actions have been, or are being, applied appropriately and effectively.



Departures from regulatory requirements, identified by the Animal Products Officer (or Biosecurity Inspector), are to be transferred to the operator's issue management system for resolution. (Key Topic / Non-compliance)

Unacceptable Where the Animal Products Officer (or Biosecurity Inspector) has determined that the operator is not in substantial compliance with regulatory requirements; evidenced by inadequate operator controls. (Key Issue / Non-compliance)