New Zealand Food Safety
Ministry for Primary Industries
Manatū Ahu Matua

ACVM July Workshop

Wednesday 24th July 2019, 9.00am - 4.00pm

Te Papa

Wellington

(Please note there may be some minor changes to the agenda on the day)

AGENDA

8.30am - 9.00am	**Tea and coffee available**	
9.00am - 9.05am	**ACVM Welcome and housekeeping**	
9.05am – 9.25am 9.25am – 9.35am 9.35am – 9.45am 9:45am – 10.00am 10:00am – 10:15am	**ACVM Updates** 1. ACVM Manager update (staff, work programme, performance measures, fees) 2. Approvals Operations update 3. Reassessment update (process, in progress, possible future) 4. ACVMs and Biosecurity assessment/approval 5. Advertising of ACVMs	
10.15am - 10.45am	**Morning tea**	
10.45am – 11.30am 11.30am – 11:55am 11:55am – 12:00pm 12:00pm – 12:10pm	6. John Roche (Science Adviser MPI) – “Regaining Consumer Trust in a Digital Age” 7. Compliance update 8. Introducing the ACVM team and Approvals Operations team 9. Allan Kinsella, Director Assurance, New Zealand Food Safety	
12.10pm - 1.15pm	**Lunch; opportunity to network with MPI staff**	
1.15pm – 2.15pm 2:15pm – 2:45pm	**Break-out session Veterinary medicines** ▪ Chemistry & Manufacturing ▪ 2017 AB Sales Analysis Report	**Break-out session Agricultural chemicals** ▪ Dave Lunn (MPI) – “Plant Residues from an Export Perspective” ▪ VTA review update
2.45pm – 3.15pm	**Afternoon Tea**	
3:15pm – 3:45pm	**Break-out session Veterinary medicines** ▪ Bioequivalence ▪ Vet Med team: General queries	**Break-out session Agricultural chemicals** ▪ Application rates ▪ Ag Chem team: General queries
3:45pm – 4:00pm	Wrap up and close – Vet med team	Wrap up and close – Ag chem team
4.00pm	**End**	

New Zealand Food Safety
Haumaru Kai Aotearoa

ACVM Group Update

ACVM Workshop
24 July 2019
Karen Booth

ACVM Staff

Manager ACVM Programmes & Appraisals
Karen Booth

Principal Adviser ACVM
Warren Hughes

Manager Approvals
Maree Zinzley

Ag Chem & VTA Assessors
Bruce Nalder
Sarah Lester
Wayne Severn
Evan Brenton-Rule
Shixi Wu
Charmaine Rickerby

Vet Med Assessors
Alfredo Caicedo
Jenni Doyle
Sara Ashby

Regulatory Programmes
Holly Jeboult-Jones
Barry Meade
Russell Clark
Trish Whittaker
Emily Jones

Snr Adviser Food & Trade
Awilda Baoumgren

Approvals Operations Advisers
Shaleen Narayan
Teresa Robinson
Kaea Smiler
Phillippa Skeet
Jillian Edwards
Grace Aislabie
Kate Jolly

Contractors
Paul Spencer (AgChem)
Richard McKinley (Vet)
Jennie Moran (Vet)
Meg Moffat (Vet)
Suzanne Lane (Vet)
Sarah de Barr (AER Support & QMS)
Jeanne Boland (Documents)

Fees, Charges and Levies

- New fees regulations came into effect 1 July 2019
- Reduction in assessment charge by $20 ($155 to $135/hr)
- Screening now cost vs time (no flat fee)
- Registering in the register $455 per application

2019 In Progress

- Core service delivery – vet med queue
- VTA review (brodifacoum)
- Reassessments (see reassessment presentation)
- Ag Chem Chemistry & Manufacturing Guideline - in draft
- Vet Med Chemistry & Manufacturing Guideline (non-biologicals) – out for second round of consultation
- Labelling guidelines – updating and consulting
- Business analyst working on requirements for on-line system and pharmacovigilance tool
- Data assessor workshop
- If enough interest, ACVM 101 workshop

System Audits

Proposed for 2019 and in progress:

- RVM seller compliance with operating plans (compliance and information gathering)
- Manufacture and sale of fertilisers (compliance with exemption regulations and information gathering)

Completed (2018-19):

- General Oral Nutritional Compounds (focussed on pet food and Calf Milk Replacements
- Current Hemp Industry Practices In Relation to Hemp as Oral Nutritional Compounds Including Animal Feed Commodities and Hemp-Based ONC Products.
- Research, Training and Testing Operating Plans.

ACVM in Numbers – *Registrations*

ACVM receives

~ 2,600 registration applications/year

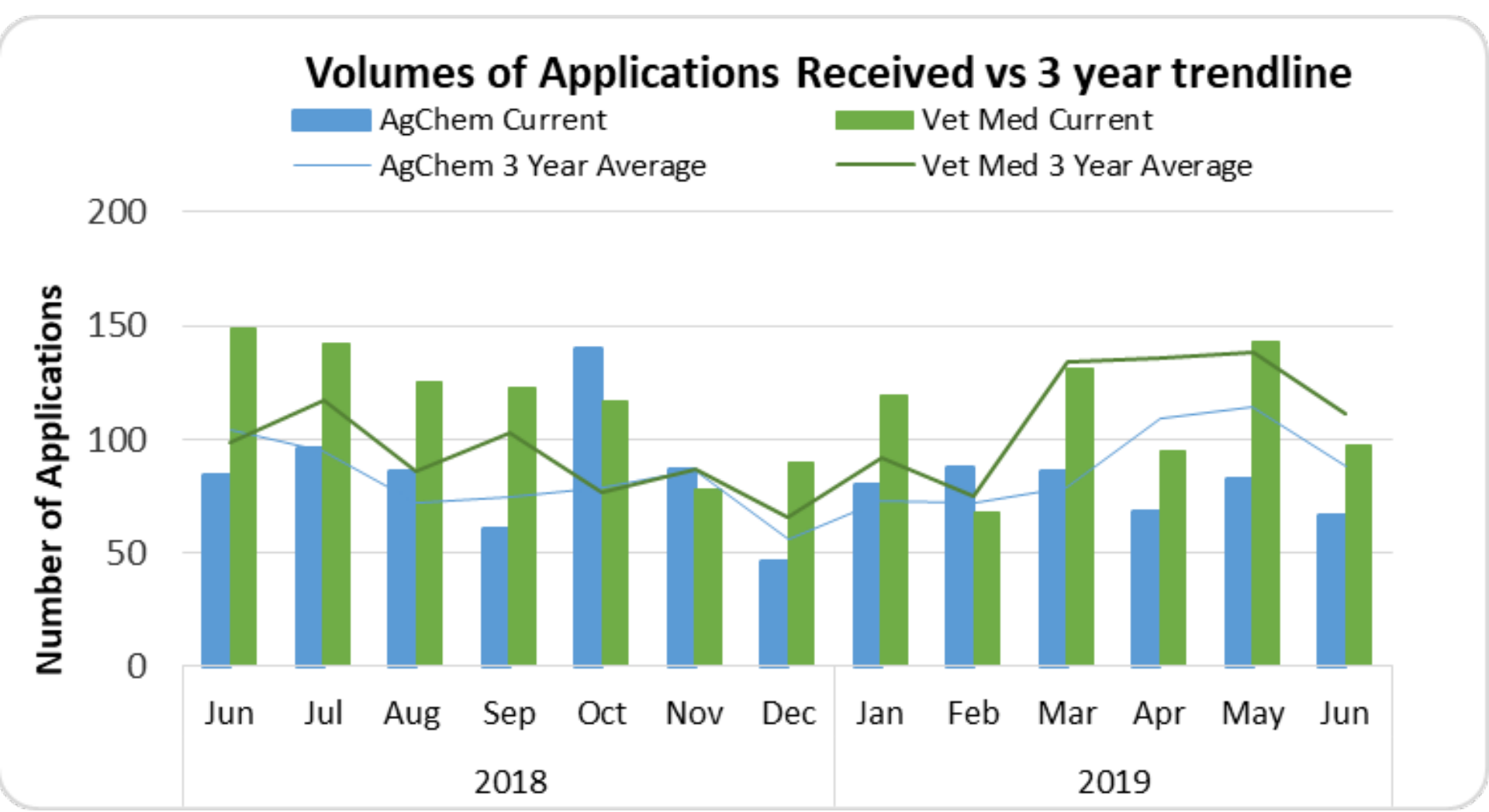
Application Type	Number (2018)	Number (2019 15 July)
New products	167	97
New uses	40	35
Chemistry & Manufacturing changes	654	565
Administrative	1247	470
Research Approvals	26	9

ACVM in Numbers – *Other Authorisations*

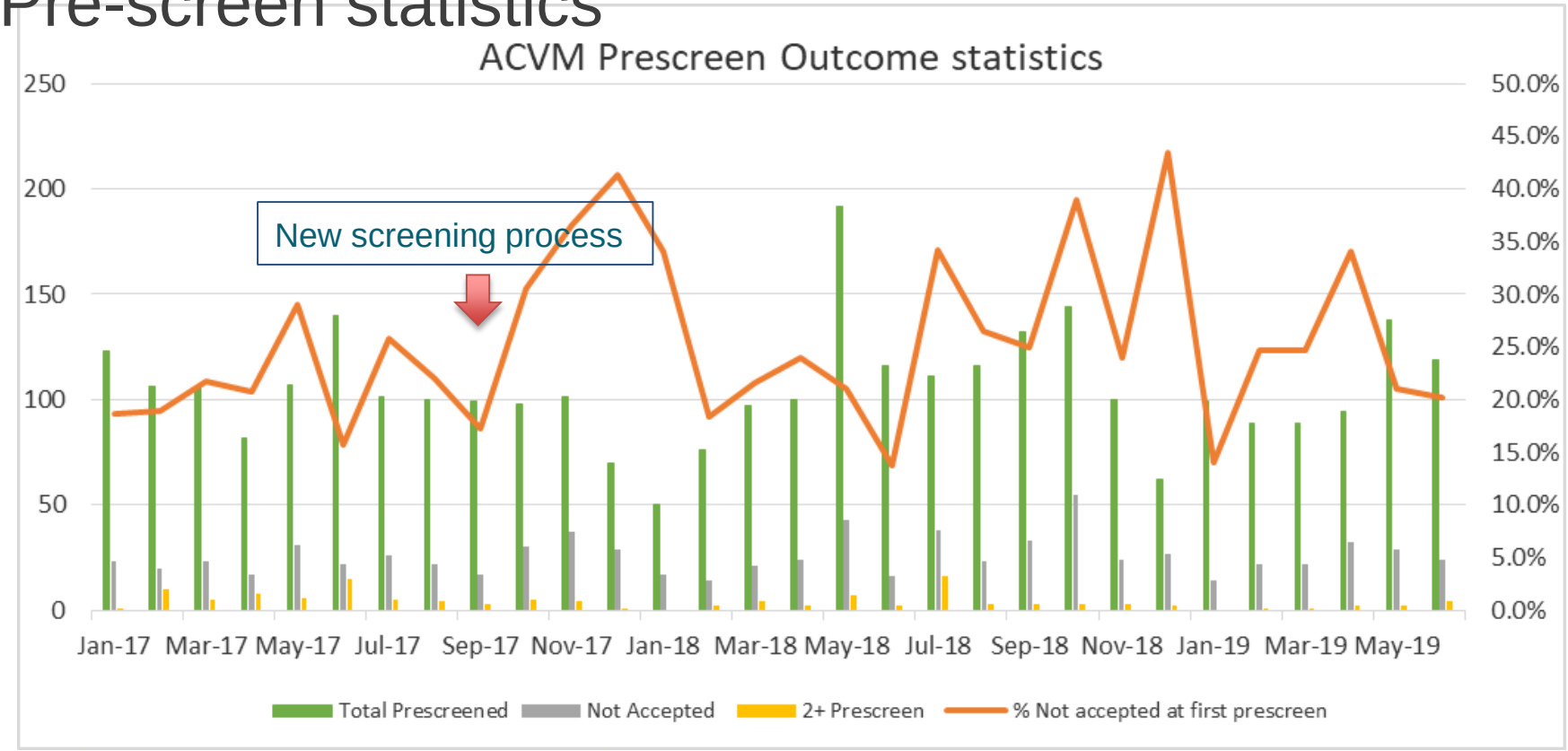
	2016	2017	2018	2019 (YTD)
Special Circumstances	138	138	141	85
Maintenance Compounds (non-dairy)	558	789	703	0
GMP Audits (site days)	21 (45)	21 (50)	25 (38)	13 (42)
PS & RTT OPs	15	12	7	4
RVM Sellers OPs	5	33	18	8
Data Assessments	28	11	33	15
Deviations	40	22	21	20

ACVM in Numbers – *Post Authorisation*

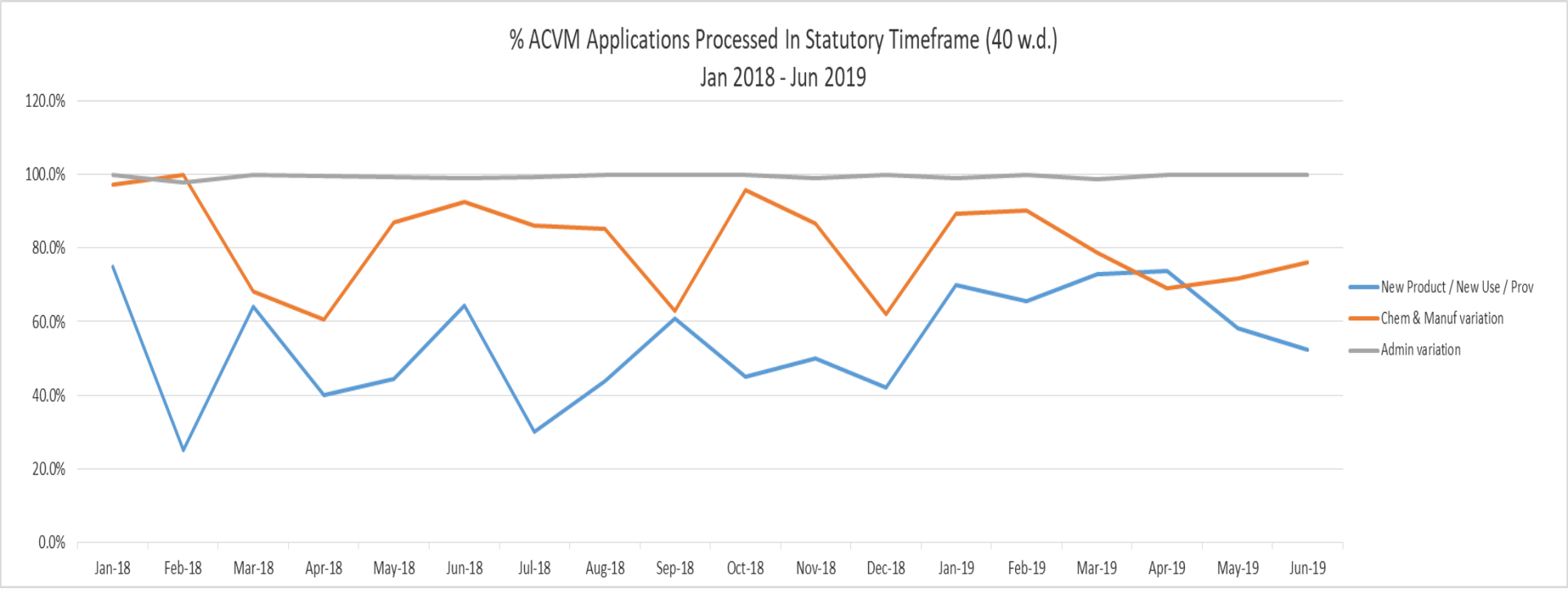
	2016	2017	2018	2019 (YTD)
Compliance Matters	50	91	115	56
- Recalls	5	8	12	6
Batch Variations	20	21	43	8
Rapid Alerts	33	15	19	10
AERs	1222	1192	1362	733
Ministerials	43	41	45	14
Residue Investigations	19	17	26	tbc


Volumes of Applications Received vs 3 year trendline
AgChem Current
Vet Med Current
AgChem 3 Year Average
Vet Med 3 Year Average
Number of Applications
200
150
100
50
0
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
2018
2019

Pre-screen statistics

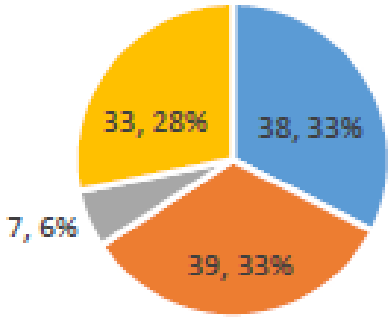


Performance for processing within 40 working days



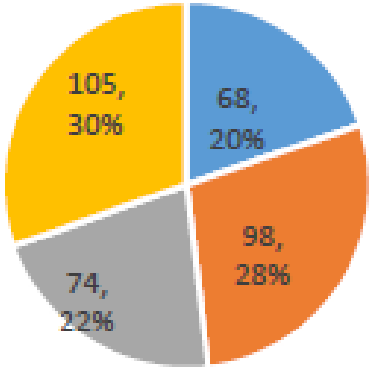
Applications in the System

AgChem/VTA Applications end June 2019 (total 117, % of total)



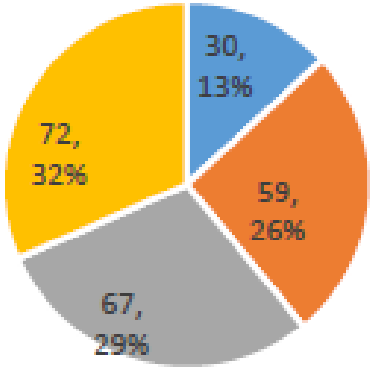
- Applications in time waiver
- Applications in appraisal
- Applications in queue
- Applications completed

ACVM Applications end June 2019 (total 345, % of total)



- Applications in time waiver
- Applications in appraisal
- Applications in queue
- Applications completed

Vet Med Applications end June 2019 (total 228, % of total)



- Applications in time waiver
- Applications in appraisal
- Applications in queue
- Applications completed

Proposal

- Publication on MPI website of:
  - Recalls (voluntary and mandatory)
  - Prohibition notices
  - Suspension of registrations
- Has been tabled with AVMAC in November 2018, and again June 2019
- Proposing similar mechanism to APVMA

How to contact ACVM

- First point of call – contact your Operations Adviser for any general application queries, meeting requests etc.

- For applications that have passed pre-screen and are in appraisal – contact the Technical Assessor

- For general queries approvals@mpi.govt.nz
- For compliance issues ACVM-recallsandcompliance@mpi.govt.nz
- For RVM Seller Ops ACVM.RVMSellers@mpi.govt.nz
- For manufacturing ACVM.manufacturingandassurance@mpi.govt.nz

- For Adverse Events ACVM-AdverseEvents@mpi.govt.nz

ACVM Website

ACVM Home page

MPI Home page


Thank you
Any questions?

New Zealand Food Safety

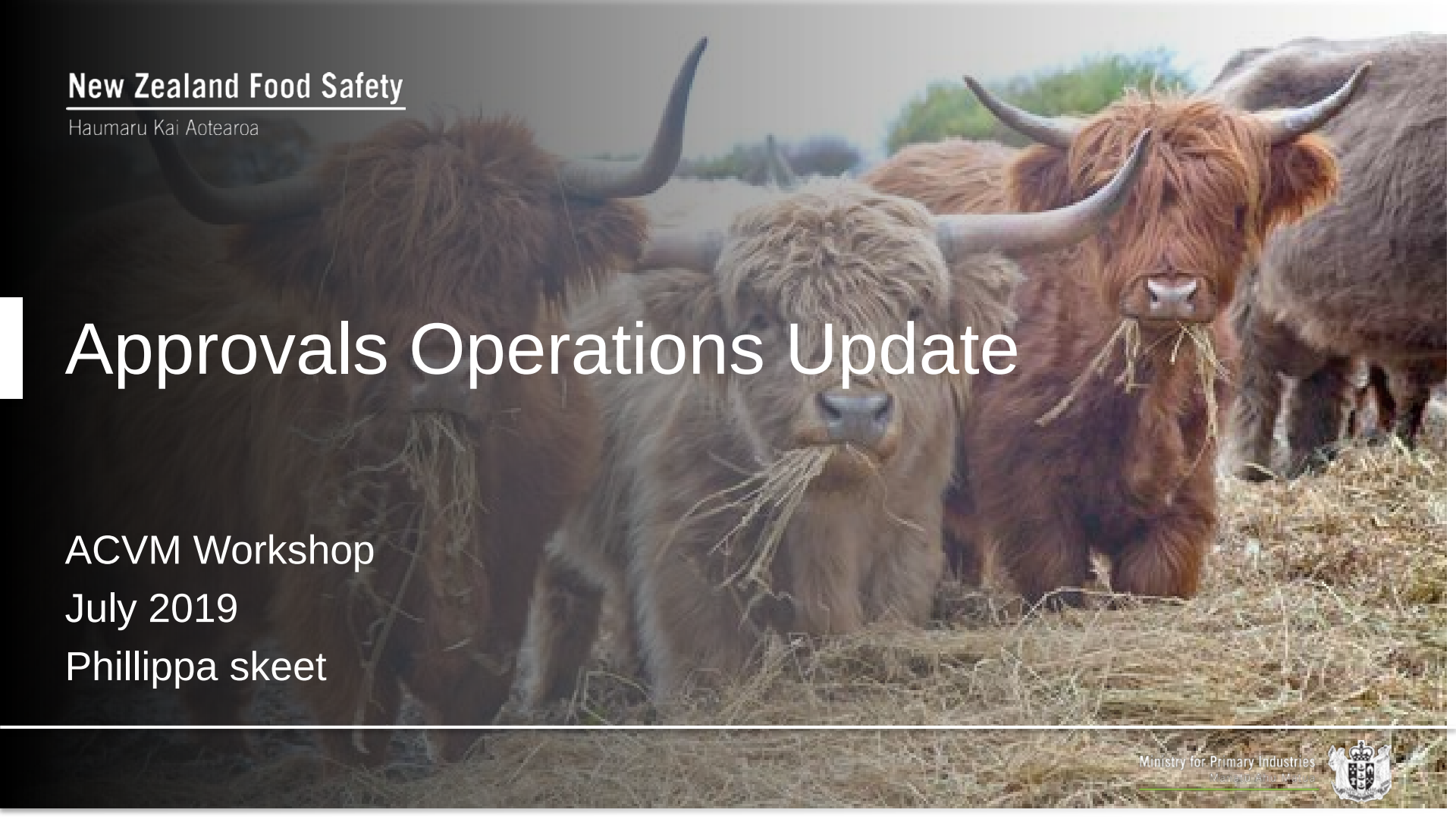
Haumaru Kai Aotearoa

Approvals Operations Update

ACVM Workshop

July 2019

Phillippa skeet



Agenda

- Approvals Team update
- Procedure Updates
- Application Feedback

  Electronic submissions

  Application forms

  PDS (incl. Confidential)

  Labels

Approvals Team Update

Grace Aislabie
Approvals Inbox/
Phones

Maree Zinzley
Manager Approvals
Operations

Shaleen Narayan
Senior Adviser
Works across all legislation

Teresa Robinson
Adviser
ACVM Act

Jillian Edwards
Adviser
Works across all Acts

Kaea Smiler
Adviser
Works across all acts

Phillippa Skeet
Adviser
Works across all acts and
Statutory Appointments

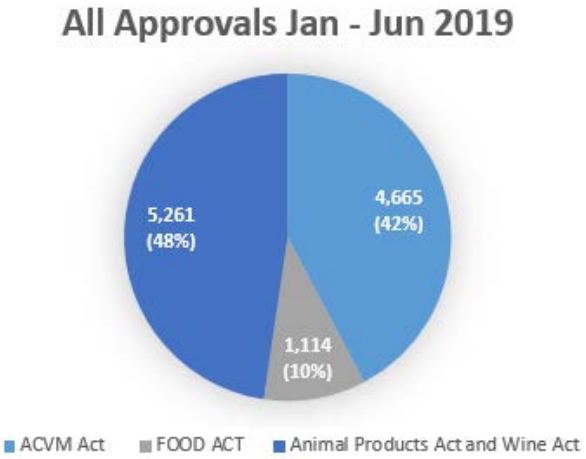
Jed Aubrey
Adviser
Works across all acts
Last day 25th July 2019

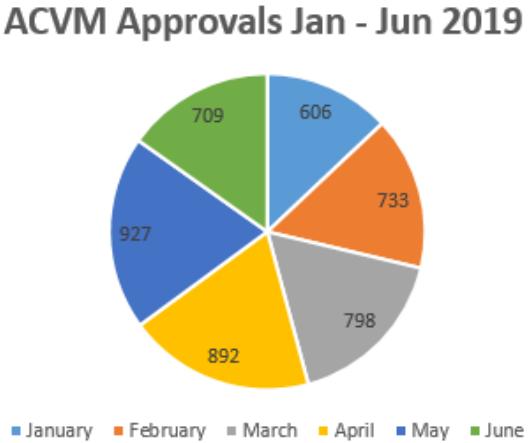
Kate Jolly
Adviser
Recently appointed as replacement
for Jed's position. All Acts

Approvals Team Update

The Four Acts we work across

- ACVM Act
- Animal Products Act
- Food Act
- Wine Act





High Workloads - Time Constraints - Communication - Urgent Requests

Procedure Updates

- Biosecurity applications
- Share-files
- Email notifications

Procedure Updates

- Biosecurity applications
  - Section of the form
  - Approval Letter with all applications
  - Expiry – 5 years

Procedure Updates

- Share-files
  - Notification of each upload
  - Email Client Manager or Approvals@MPI.govt.nz
  - 5+ documents in .zip file

Procedure Updates

- Email Notifications
  - Variations & Pre-Screen
  - Registration Renewals/C9 Variation

Application Feedback - Electronic Submissions

- Overall improvement on application submissions
- We want electronic documents
- Please do not send ‘protected’ PDF documents
- Notification is an application and is charged.
- Multiple – 10 max applications

Application Feedback – Electronic Submissions

- File names
  - Unable to upload documents with ‘special’ characters in file name:

/	\	*	&	:	?	(	)	<	>	{	}	%	#

  - Dates are always required when file naming (PDS, Label, 1V, 1R, ACVM7 etc.)
    - e.g. 20170919 P1234 PDS
  - During assessments please **re-date** files to the date the documents are signed and sent.

All covered by our guideline for E-files

Application Feedback – Application forms

- Submitting a variation application, remember to:
  - Indicate ALL variation types by highlighting in **bold**
  - Provide ALL the relevant forms
  - Use the current version of the forms – 2019
  - Fill in the biosecurity section

Application Feedback – Application forms

6. **Variation Application Type** (Indicate type by highlighting in BOLD.)	**Form to use**
C1 Change in formulation	ACVM 6
C2 Change in active ingredient manufacturer	ACVM 7
C2 Change in formulation manufacturer	ACVM 8
C2 Change in manufacturing process, including changes in AI or formulated product specifications	ACVM 9
C3 Change in packaging	ACVM 10
C3 Change in shelf life	ACVM 11
C4 Extension of use to include additional target host or species C5 Extension of use to include control of additional pests, weeds, species, diseases or conditions	ACVM 12
C6 Change in dose regime or application rate or timing C7 Change in method of administration/application	ACVM 13
C8 Change in withholding period	ACVM 14
C9 Administrative change, such as phone number, postal/email address.	Provide details in section 7 below. No additional form required.

Application Feedback - PDS

- Signature and current date on every page
- Change in method on Section B6 is a C2 not C9/notification.
- Confidential PDS must be signed and dated (current date) by the confidential person.
- Approval A, B, C should be supplied in Section B4 as well as all manufacturers in the process – further explanation in the break-out sessions.

Application Feedback - Labels

- If label has changes
  - State this on ACVM 1V form and include a clean label AND full tracked changes label
  - Should be clear what has been moved, deleted or an addition
  - Reminder that the MRL statement must say ‘FOR’ not ‘OF’
    - It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.

Appreciation

- We thank you for being patient and understanding during this busy year ☺

Any Questions?

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Update on Reassessments Under the ACVM Act

ACVM Workshop
24 July 2019

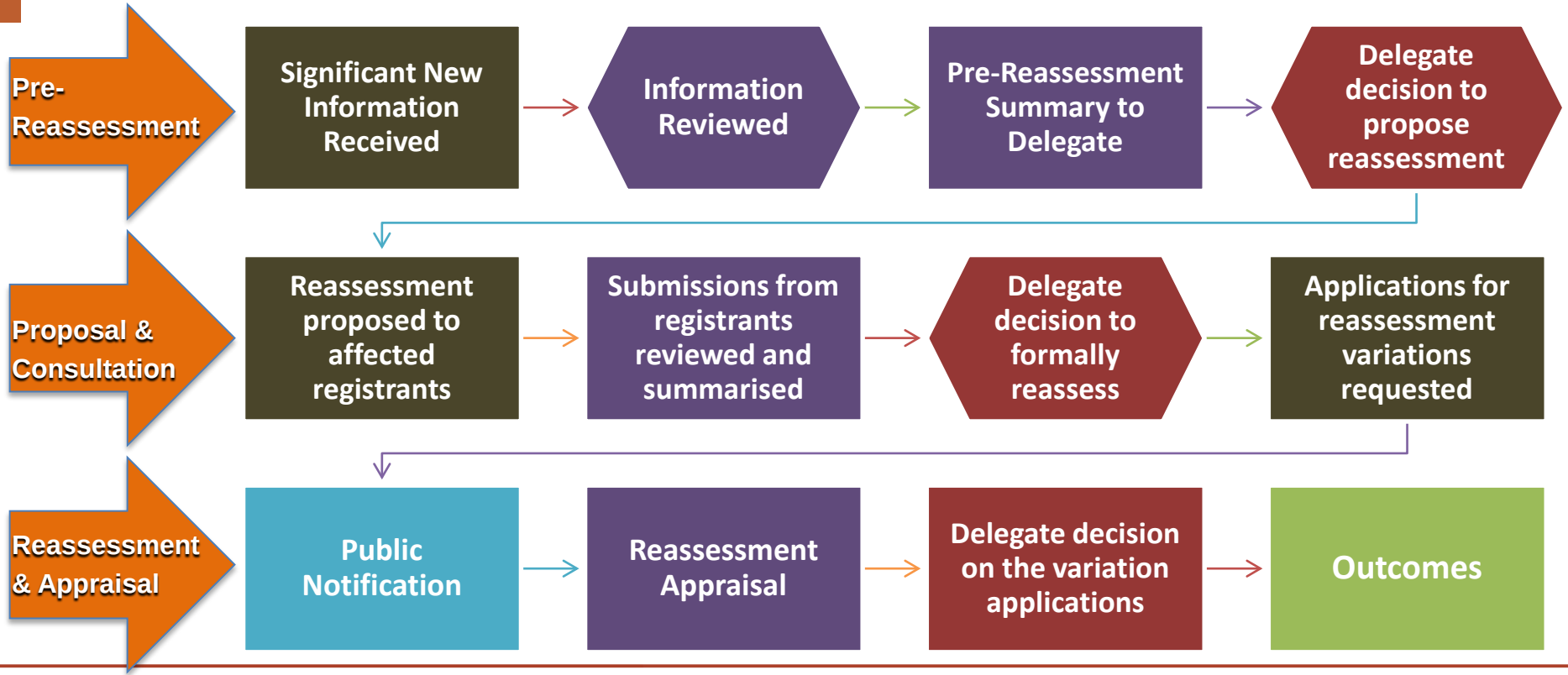
Ministry for Primary Industries
Manatū Ahu Matua

Reassessment under the ACVM Act

- Reassessment process summary
- An update on reassessments currently in progress
- Future Reassessments and Reviews

The Reassessment Process

The Reassessment Process



Pre-Reassessment and Review

- Information gathering phase:
    - Why is reassessment being considered?
    - What evidence is there to support a change to the previous risk profile?
- Can be driven by MPI monitoring findings (e.g. AERs, GMP audits, residues monitoring) or international matters (e.g. trade risks, international agreements)
- Sometimes requires in-depth review before reassessment is proposed, especially if an emerging risk

Reassessment Proposal

- If risks are significant enough to warrant reassessment, reassessment summary prepared for Delegate
- If approved for proposal, the registrants of affected products are contacted with an outline of “what,” “why,” and expected outcomes if progressed
- Registrants are asked for submissions outlining:
    - ACVM risks from their perspective
    - Other considerations associated with the issue not raised in the letter
    - Whether they support reassessment and/or voluntary change if appropriate

Reassessment Proposal Submissions

- All submissions are reviewed, and adjustments are made as needed
- Discussion with wider MPI may be needed – Market Access, Animal Welfare, Chemical and Microbiological Assurance, Animal Products, etc.
- Once determined, the final recommendations are made to Delegate on whether reassessment should progress (with scope and interim controls) or whether other options are appropriate for consideration

❖ The Delegate makes the final decision on whether to monitor, request voluntary changes, or progress to formal reassessment

- **Note: If the decision is to monitor, reassessment may go forward later once the issue is better defined and we know more**

Reassessment and Appraisal

- Treated as a variation application (C10) with public notification
- Application documents: PDS, label, data and/or information to support changes indicated by reassessment scope (DAS may be needed)
    - Historical file information may still be applicable and will be considered
- Standard application timeframes: 30 days PN + 40 working days, +/- time waiver – Note: MRL promulgation time may be required before finalisation

Reviews and Reassessments in Progress

Pre-Harvest Use of Glyphosate in Cereal Crops

- Evidence from testing under the Food Residue Surveillance Programme (FRSP) showed that the current MRL is consistently being exceeded in cereal grains, particularly wheat

- Pre-reassessment consultation concluded that all submitters agreed reassessment was appropriate

- Currently working through reassessment scope and data/information required
    - **Critical that this is done as completely as possible so the reassessment phase can remain within timeframe**

Brodifacoum-based Vertebrate Toxic Agents

- Recent issues and residue detections indicated that a review of the current controls on the anticoagulant VTAs was needed
- Currently working through data and information available, and a review of the controls
    - ➢ More detail in Wayne's presentation later today

Antibiotic Reassessment: Penicillins, 3rd & 4th Generation Cephalosporins, and Macrolides

- Staged reassessments underway as part of the New Zealand AMR Action Plan
    - First tranche: 17 antibiotic active ingredients, 115 products
- Actives classed by AMR risk and clinical importance at active ingredient level, registration changes will reflect relative risk and classification
- Future work will follow the process established in the first tranche: reassessment proposal → internal review to establish classification → summary of review and proposed product changes to registrants → applications received

First Tranche Antibiotic Reassessment Outcomes

Penicillins	3rd & 4th Gen Cephalosporins	Macrolides
• Amoxicillin • Ampicillin • Cloxacillin • Penethamate • Pen G benzathine • Pen G procaine • Penicillin procaine	• Cefovecin • Cefpodoxime • Ceftiofur • Cefquinome	• Erythromycin • Oleandomycin • Spiramycin • Tilmicosin • Tulathromycin • Tylosin
Highly Important	**Critically Important**	**Critically Important**

Other VM Reassessments

Decoquinate, Lasalocid, and Monensin in Ruminants

- Data under review for all registered products, and data and information available in the public domain, to establish a baseline for revised MRLs
- Further information will be requested from registrants if needed before PN

Carbadox

- Data provided by registrant currently under review to evaluate residue and trade risks associated with the compound

Dimetridazole

- Trade risk and potential changes to the registration being discussed internally

➢ **Completed: Reassessment of advertising controls for antibiotic vet meds**

Future Reviews and Reassessments

Future Reviews and Reassessments

Agricultural Chemicals

- **Animal Transfer Review:** Review and appraisal of all data and information related to animal feed related crops and pasture, promulgate animal MRLs, and set animal WHPs where required
- **Lime Sulphur Products:** Review of all registered products containing lime sulphur to align active ingredient product label statements
- **Varroaicides and Other Bee Products:** Review and realignment of products used on bees as treatments for food-producing animals (e.g. converting them to vet meds), use controls on varroaicides
- **Crop Groupings:** Review and apply Codex crop groupings, particularly brassicas

Future Reviews and Reassessments

Vertebrate Toxic Agents

- **Anticoagulant VTAs:** Review and reassessment of all other anticoagulants following the brodifacoum reassessment
- **Other VTA Product Controls:** Review and reassessment of other products where indicated to ensure controls are suitable to manage the associated risks

Future Reviews and Reassessments

Veterinary Medicines

- **Product Alignment Reviews:** teat sanitisers and labelling, clostridial vaccines and RVM status, altrenogest WHPs, flumethrin WHPs, benazepril product claims, copper boluses and RVM status
- **Residues and Trade Related Reviews:** residue controls on companion-only products, lignocaine MRLs and WHPs (other than velvet), clenbuterol MRLs, residues from mineral supplementation products (especially iodine parenteral products), re-evaluate historic use of nil WHPs

Future Reviews and Reassessments

Other Reviews and Reassessments

- **Remaining Antibiotic Reassessments:**
  - Tranche 2: aminoglycosides (except hort antibiotics), fluoroquinolones, polypeptides (zinc bacitracin and polymyxin), 1st and 2nd generation cephalosporins
  - Tranche 3: Fusidic acid, lincosamides, tetracyclines, sulphonamides/ diaminopyrimidines
  - Tranche 4: Amphenicols, nitrofurans, nitroimidazoles, pleuromutilins, virginiamycin
  - Tranche 5: Horticultural aminoglycosides – streptomycin and kasugamycin
- **MRL Review:** Review and promulgate MRLs for all target crops and FP species with on-label uses – will capture review of all other ag compounds not covered in other reviews/reassessments
- **Reviews/reassessments from emerging issues (e.g. EPA reassessments)**

Thank you!

Biosecurity New Zealand

Tiakitanga Pūtaiao Aotearoa

Biosecurity Assessment of Agricultural Compounds & Veterinary Medicines

Nasser Ahmed
Senior Adviser
Animal Trade Team

Ministry for Primary Industries
Manatū Ahu Matua

What's changing?

- Assessment every five years
- Assessment of locally-manufactured TNPs produced from imported biological ingredients
- Guidance for products containing ingredients for treating/preventing diseases not present in New Zealand
- Updated biosecurity advice in ACVM class determination letters
    - Semen extenders
    - Products containing viable microorganisms

Why this change?

- Emerging and re-emerging risks
    - Seneca Virus A*
    - Porcine Epidemic Disease Virus
    - *Mycoplasma bovis*
- Viral pathogens in animal feed**
- Differential biosecurity assessment
    - Lab use versus bio-production

**USDA Center for Veterinary Biologics Notice No. 18-05 - Detection of Senecavirus A in Veterinary Biological Products.* https://www.aphis.usda.gov/animal_health/vet_biologics/publications/notice_18_05.pdf

***Dee SA, Bauermann FV, Niederwerder MC, Singrey A, Clement T, de Lima M, et al. (2018). Survival of viral pathogens in animal feed ingredients under transboundary shipping models. PLoS ONE 13(3): e0194509.* https://doi.org/10.1371/journal.pone.0194509

When are these changes happening?

- Already in place within MPI
- Updated ACVM documents will be published soon


Thanks

New Zealand Food Safety
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ACVM Act - Advertising

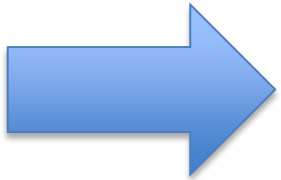
Warren Hughes
Principal Adviser ACVM
ACVM Team

Background

- Current advertising guidance now 6 years old
  - Covers only Registered Trade Name Products
- Advertising Environment has evolved
  - Social media
- Change to advertising rules for Antibiotic RVMs
  - Advertising will be no longer be allowed to general public

Advertising Guidance Refresh

- Clarification needed around
  - social media
    - Facebook
    - Twitter
    - The next social media phenomenon
  - Newsletters
    - Electronic or paper



Pre Registration Statements

Advertising Guidance Refresh

- The perennial issue of
  - Advertising versus Information Transfer
    - Particularly regarding pre registration statements
- Should there be guidance on products exempt from registration
  - Statements about its regulatory status

Advertising Guidance Refresh

- Does it need to be more prescriptive
  - Specifying wording for certain statements
- Advertising change to Antibiotic RVMs
  - What can the marketer communicate to the end user about their product

Outcome

- Minimise
  - Uncertainty
  - Greyness
- Maximise
  - Clarity
  - Consistency
  - Fairness

Timeline

- Soon
- Process and Consultation
  - May establish a working group with industry sectors
  - Consultation could be targeted such as using AVMAC

Thank you!

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Regaining consumer trust in a digital age

J. R. Roche

Chief Science Advisor

Success of Science in Food Production has been huge

Ministry for Primary Industries
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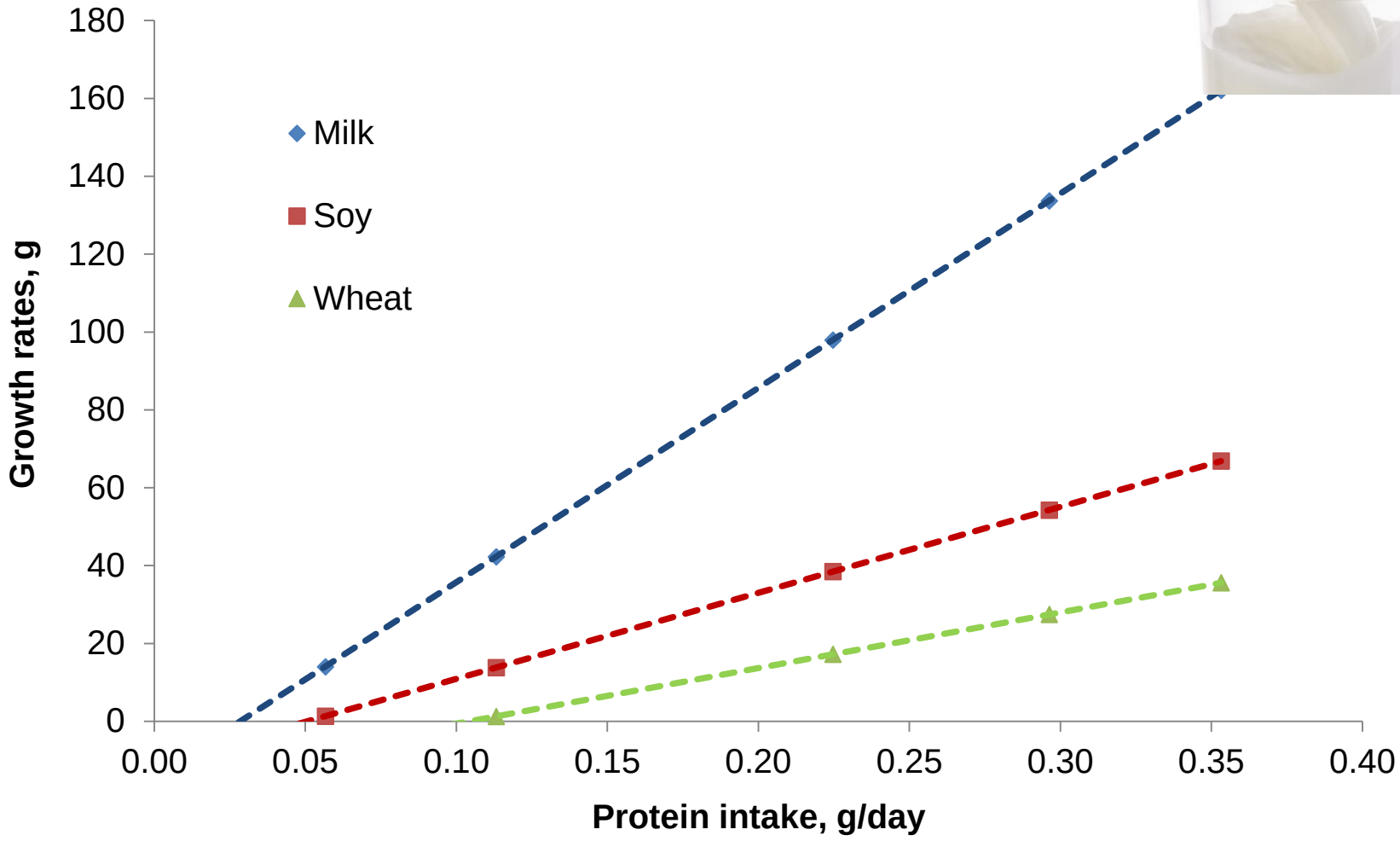
Milk – the highest quality protein on the planet!



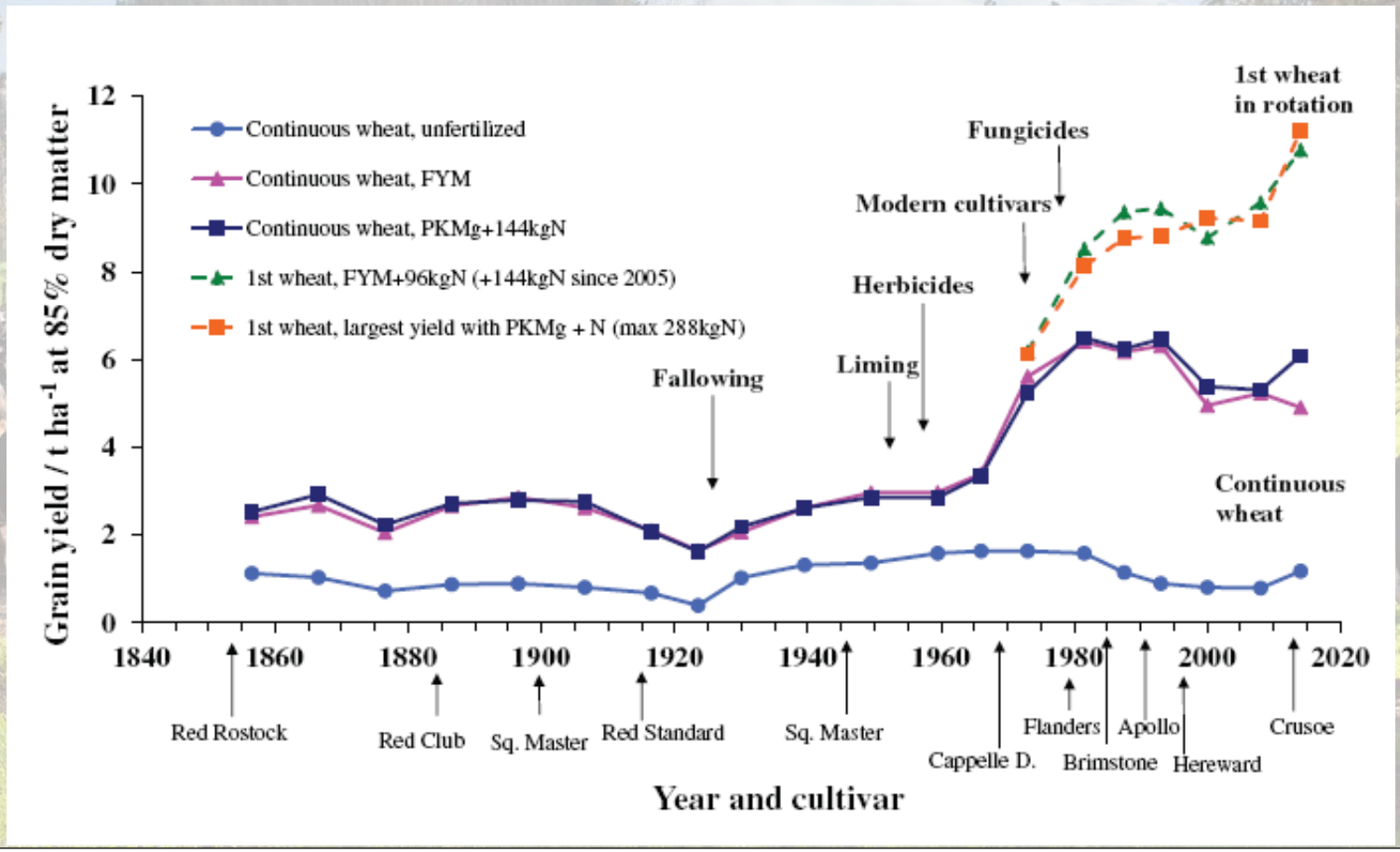
European Journal of Soil Science

European Journal of Soil Science, January 2018, 69, 113–125 doi: 10.1111/ejss.12521

The importance of long-term experiments in agriculture: their management to ensure continued crop production and soil fertility; the Rothamsted experience

A. E. Johnston & P. R. Poulton

Sustainable Agriculture Sciences Department, Rothamsted Research, West Common, Harpenden, AL5 2JQ, UK



The environmental impact of beef production in the United States: 1977 compared with 2007

J. L. Capper[1,2]

Department of Animal Sciences, Washington State University, PO Box 646310, Pullman 99164

J. Anim. Sci. 2011. 89:4249–4261
doi:10.2527/jas.2010-3784

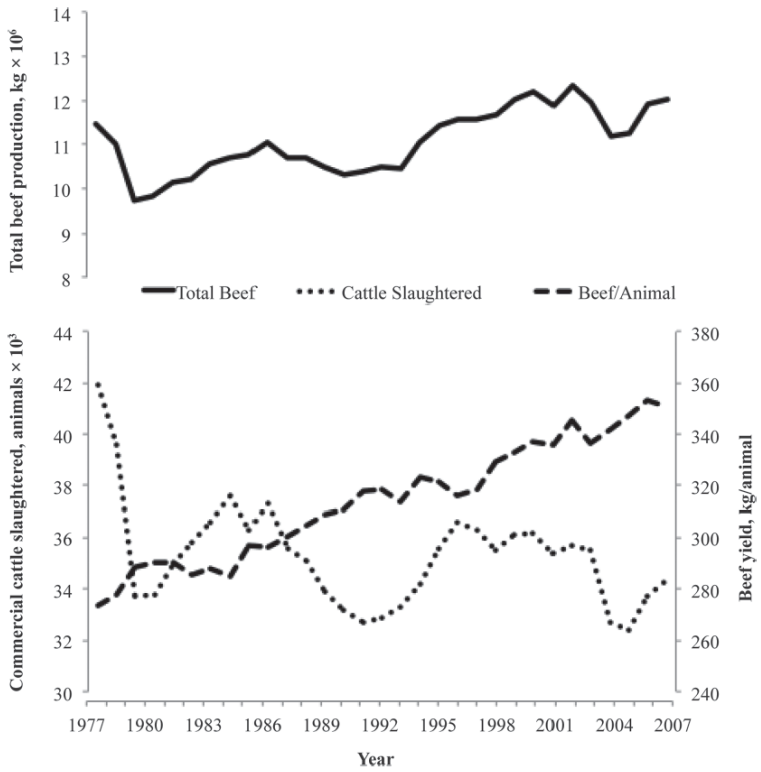


Figure 3. Changes in total US beef production, number of commercial cattle slaughtered, and beef yield per animal from 1977 to 2007.

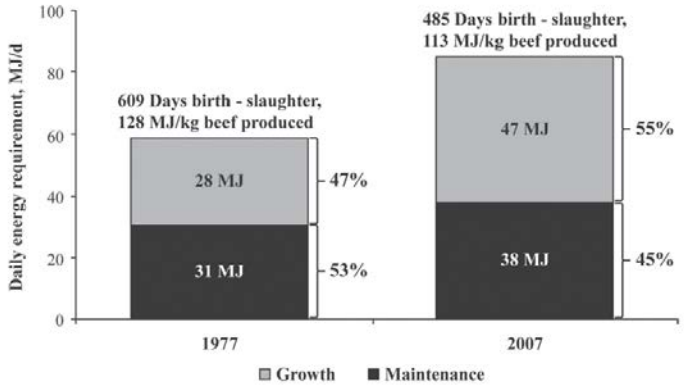


Figure 2. The "dilution of maintenance" effect conferred by increasing growth rate in steers within the 2007 US beef production system when compared with the 1977 US beef system. Energy values represent the average maintenance and growth requirements for steers destined for slaughter within the beef system. Requirements were weighted according to the number of days spent within the cow-calf, stocker, and feedlot system, and in the case of the 2007 system, to account for the proportion of yearling-fed beef, calf-fed beef, and calf-fed dairy steers within the slaughter population.

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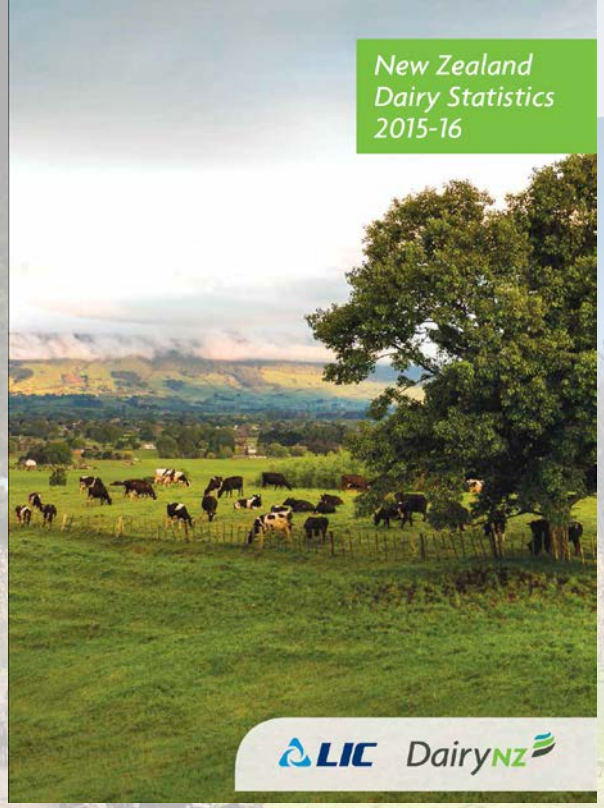
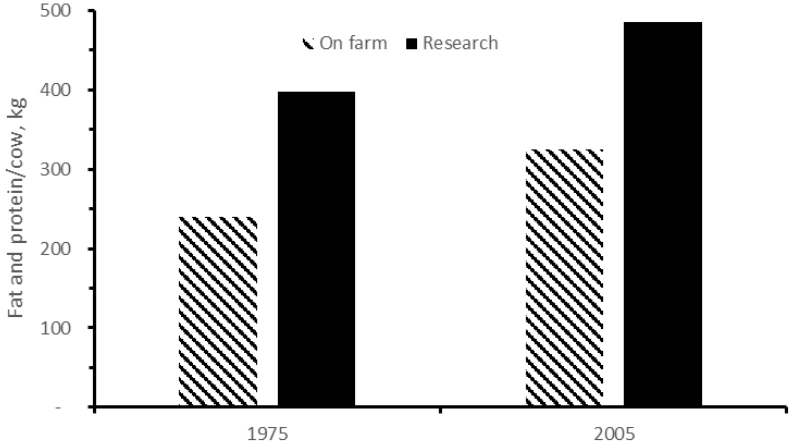


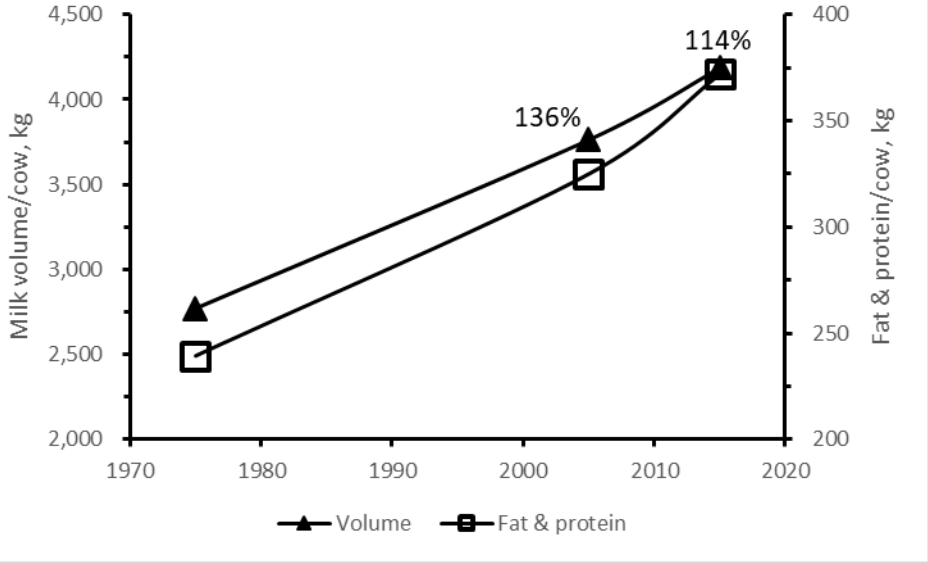
J. Dairy Sci. 91:1693–1707
doi:10.3168/jds.2007-0441

A Comparison of Three Strains of Holstein-Friesian Grazed on Pasture and Managed Under Different Feed Allowances

K. A. Macdonald,*[1] G. A. Verkerk,* B. S. Thorrold,* J. E. Pryce,† J. W. Penno,*[2] L. R. McNaughton,† L. J. Burton,† J. A. S. Lancaster,* J. H. Williamson,* and C. W. Holmes‡
*DairyNZ, Private Bag 3221, Hamilton, New Zealand 3240
†LIC, Private Bag 3123, Hamilton, New Zealand 3240
‡Institute of Veterinary, Animal and Biomedical Sciences, Massey University, Private Bag 11222, Palmerston North, New Zealand 4442



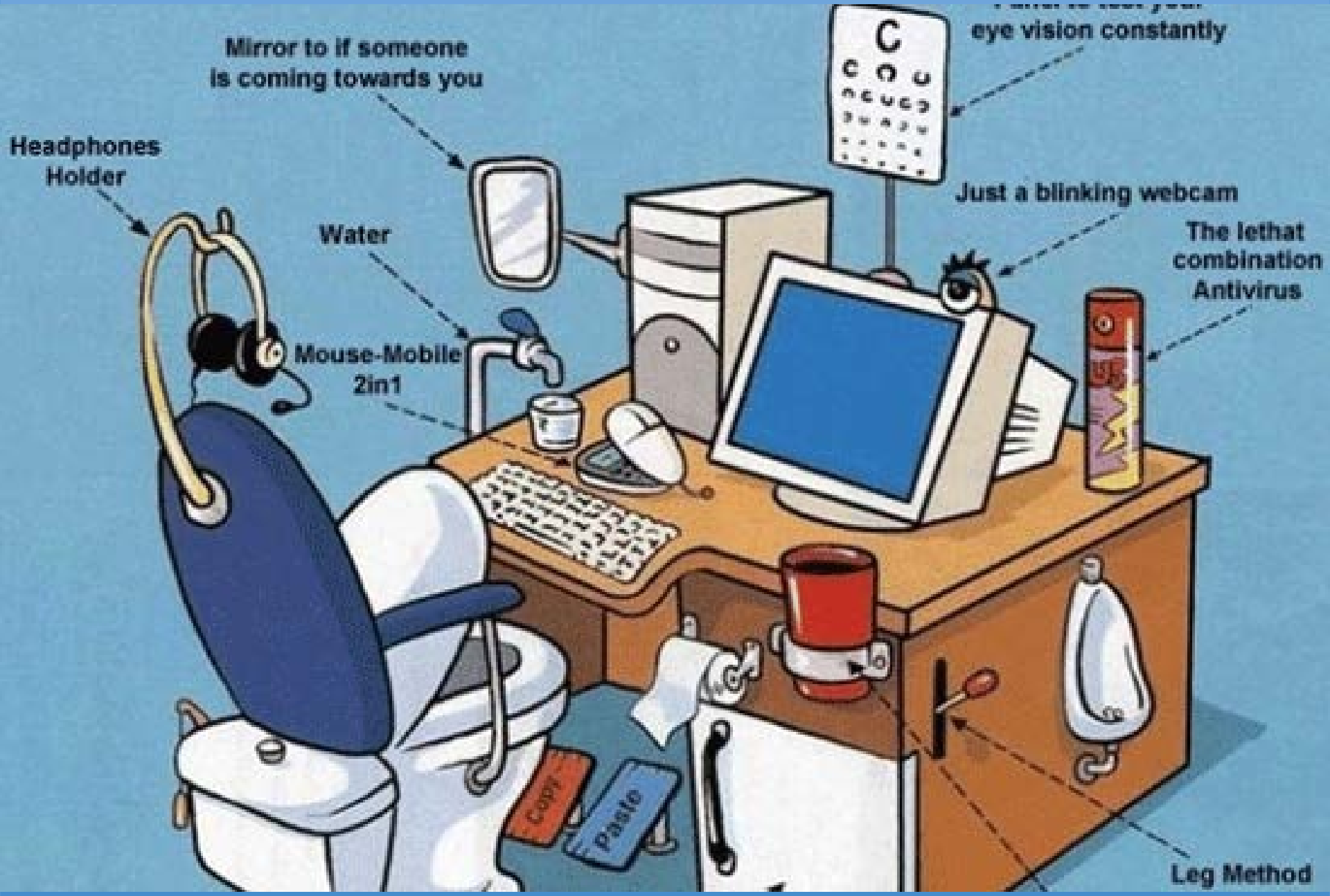
17% more fat & protein/kg BW$^{0.75}$



Ministry for Primary Industries
Manatū Ahu Matua

- 62% more milk from the same number of cows;
- 20% more from each cow in the last decade


Celebration Time


eye vision constantly
Mirror to if someone
is coming towards you
Headphones
Holder
Just a blinking webcam
Water
The lethat
combination
Antivirus
Mouse-Mobile
2in1
Copy
Paste
Leg Method

INTERNET TOUGH GUY

Because it's easy to be a 6 foot 4 Olympic powerlifter and streetfighting god,

Social media as a source of truth!!

USA: Social media acts as an echo-chamber to re-enforce views

Rabobank

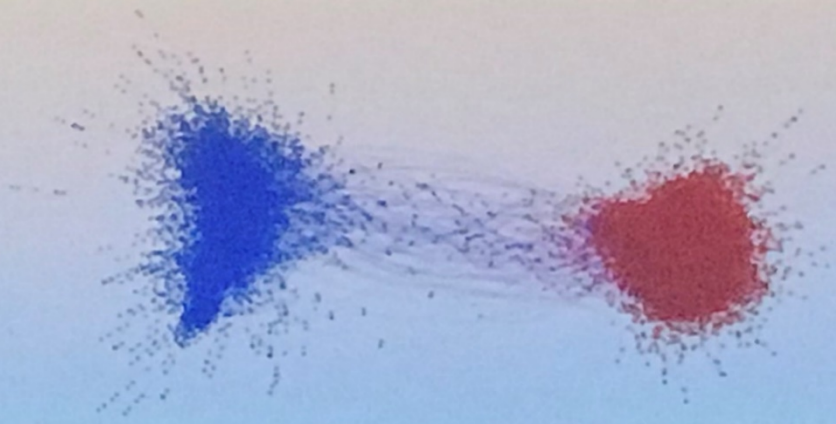
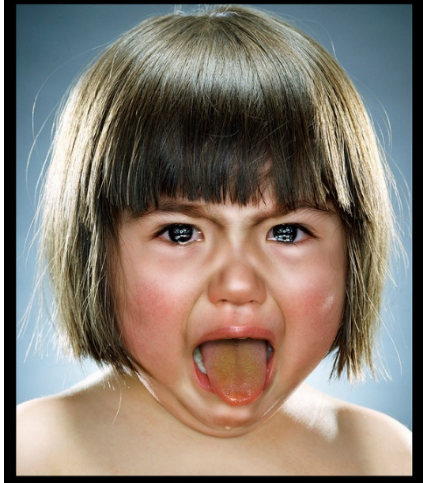
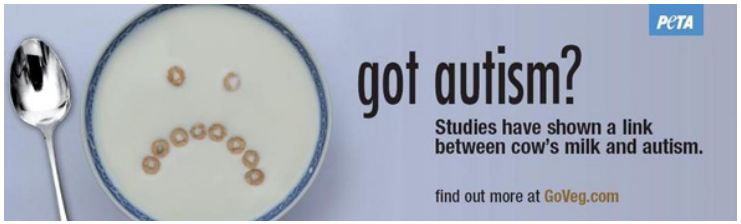


Fig. 3. Network graph of moral contagion shaded by political ideology. The graph represents a depiction of messages containing moral and emotional language, and their retweet activity, across all political topics (gun control, same-sex marriage, climate change). Nodes represent a user who sent a message, and edges (lines) represent a user retweeting another user. The two large communities were shaded based on the mean ideology of each respective community (blue represents a liberal mean, red represents a conservative mean).

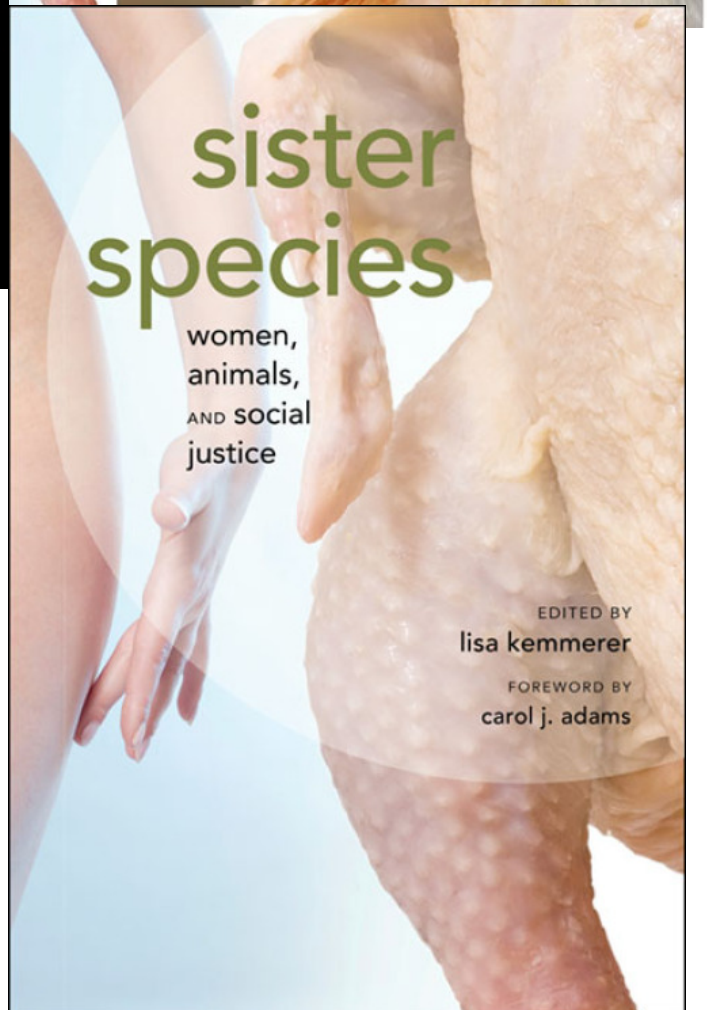

"Those who seek justice must make consumer choices that diminish cruel exploitation."

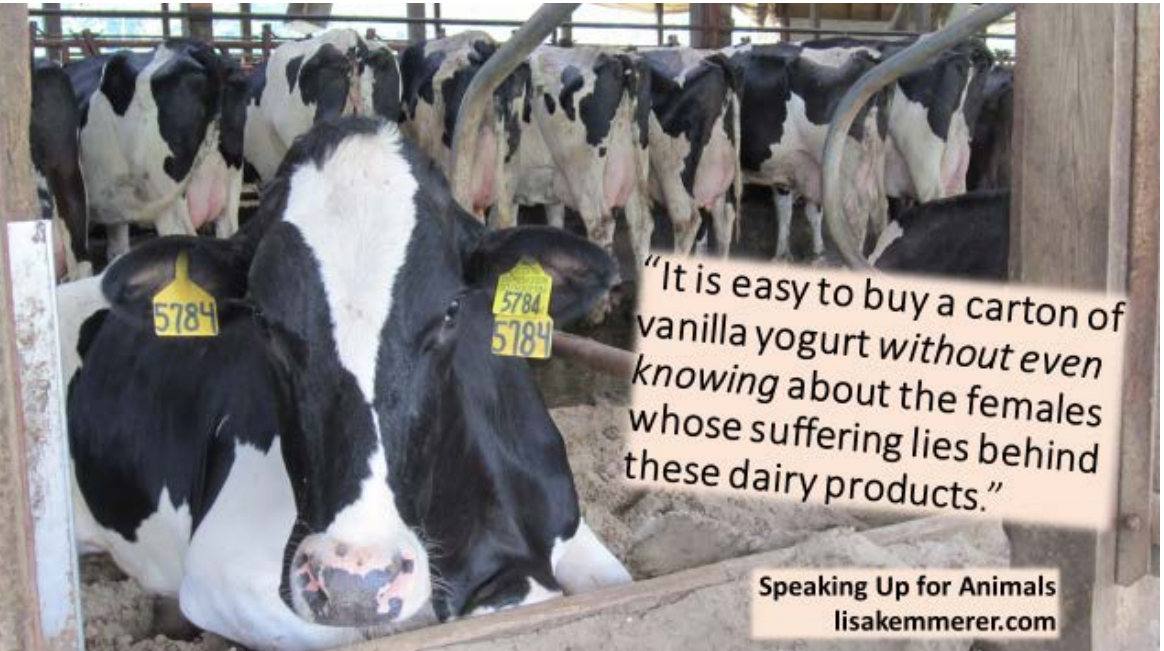



"No moral code encourages selfishness, cruelty, or exploitation"
Go Vegan
lisakemmerer.com


PETA
got autism?
Studies have shown a link between cow's milk and autism.
find out more at GoVeg.com


MUMMY, I SPAT IT OUT
i PROMISE NEVER TO
EAT MEAT AGAIN
DO YOU STILL LOVE ME


sister species
women, animals, AND social justice
EDITED BY
lisa kemmerer
FOREWORD BY
carol j. adams

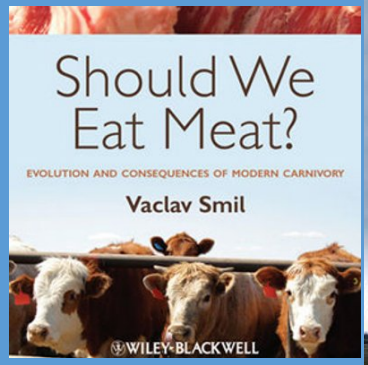

5784
5784
5784
"It is easy to buy a carton of vanilla yogurt *without* even *knowing* about the females whose suffering lies behind these dairy products."
Speaking Up for Animals
lisakemmerer.com

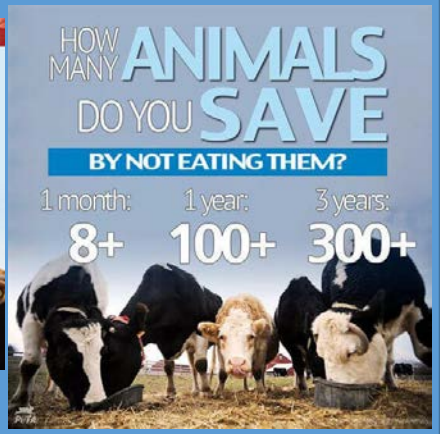
Two parts to this

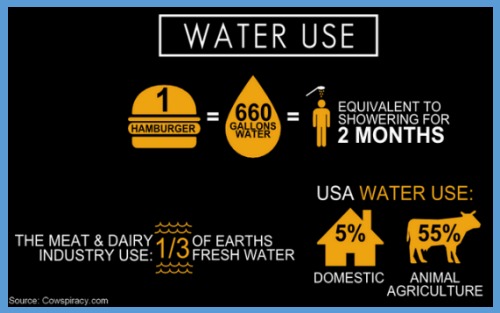
1. Consumer trust

2. Digital age


The digital age!







"information that is not objective and is used primarily to influence an audience and further an agenda, often by presenting facts <u>selectively</u> to encourage a particular synthesis or perception"

Behistun inscription (c 500 BC)


twitter
FAKE NEWS
ORLANDO MASSACRE
LIVE
PULSE
ISLAMOPHOBIA
LATUFF
2016

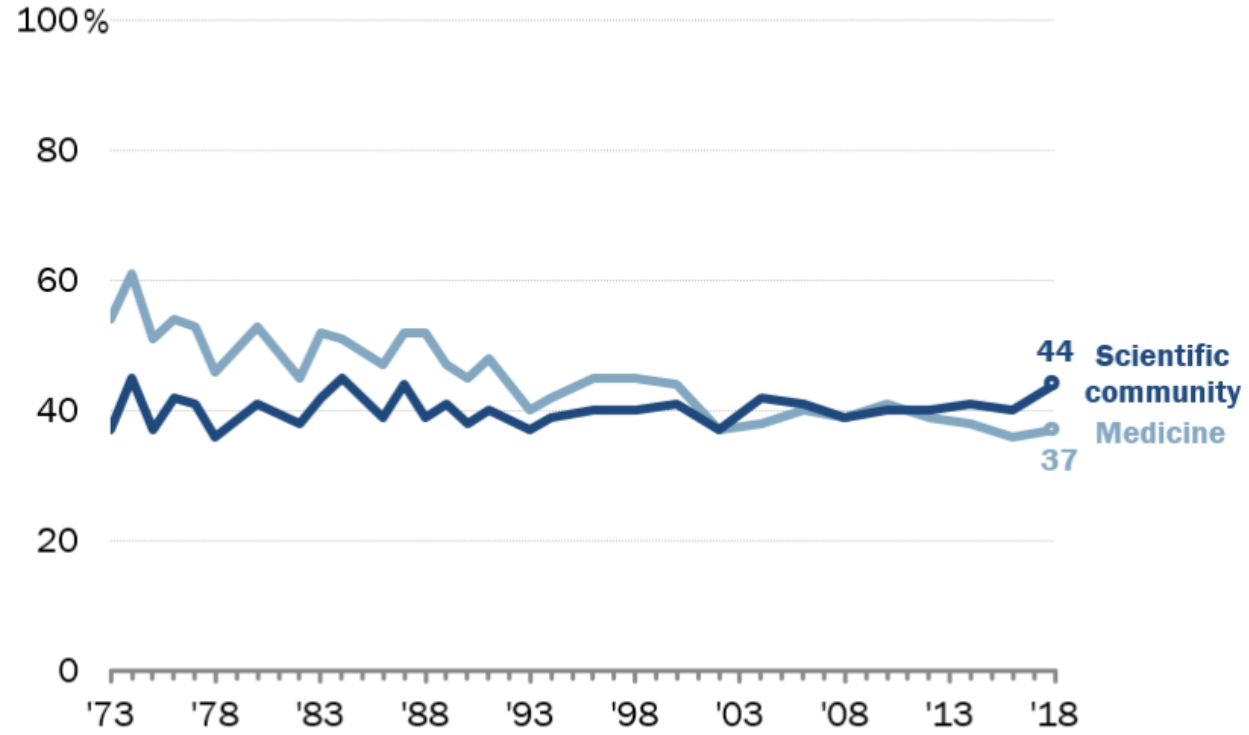

THE PEOPLE
THE PEOPLE
THE LOCOMOTIVE INN
ENGLISH DEFENCE LEAGUE
SUPPORT OUR BRITISH TROOPS
ENGLISH DEFENCE LEAGUE
IN HOC SIGNO VINCES
BAN THE BURKA
NO SHARIA LAW IN AMERICA

Confidence in the leaders of the scientific community has been stable since the 1970s

% of U.S. adults who say they have a great deal of confidence in the people running each of these institutions

Confidence in the leaders of the scientific community has been stable since the 1970s

% of U.S. adults who say they have a great deal of confidence in the people running each of these institutions



Note: Respondents who gave other responses or who did not give an answer are not shown.
Source: General Social Surveys, NORC.

PEW RESEARCH CENTER

Use of gl threat

OXFORD

JNCI J Natl Cancer Inst (2018) 110(5): djx233

doi: 10.1093/jnci/djx233
First published online November 9, 2017
Article

ARTICLE

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Gabriella Andreotti, Stella Koutros, Jonathan N. Hofmann, Dale P. Sandler, Jay H. Lubin, Charles F. Lynch, Catherine C. Lerro, Anneclaire J. De Roos, Christine G. Parks, Michael C. Alavanja, Debra T. Silverman, Laura E. Beane Freeman

Affiliations of authors: Occupational and Environmental Epidemiology Branch (GA, SK, JNH, CCL, DTS, LEBF), Biostatistics Branch (JHL), and Formerly of Occupational and Environmental Epidemiology Branch (MCA), Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, Bethesda, MD; Epidemiology Branch, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, NC (DPS, CGP); Department of Epidemiology, University of Iowa, Iowa City, IA (CFL); State Health Registry of Iowa, Iowa City, IA (CFL); Department of Environmental and Occupational Health, Drexel University Dornsife School of Public Health, Philadelphia, PA (AJDR)

Correspondence to: Laura Beane Freeman, PhD, 9609 Medical Center Drive, Rm 6E136, MSC 9771, Bethesda, MD 20892 (e-mail: freemala@mail.nih.gov).

Abstract

Background: Glyphosate is the most commonly used herbicide worldwide, with both residential and agricultural uses. In 2015, the International Agency for Research on Cancer classified glyphosate as "probably carcinogenic to humans," noting strong mechanistic evidence and positive associations for non-Hodgkin lymphoma (NHL) in some epidemiologic studies. A previous evaluation in the Agricultural Health Study (AHS) with follow-up through 2001 found no statistically significant associations with glyphosate use and cancer at any site.

Methods: The AHS is a prospective cohort of licensed pesticide applicators from North Carolina and Iowa. Here, we updated the previous evaluation of glyphosate with cancer incidence from registry linkages through 2012 (North Carolina)/2013 (Iowa). Lifetime days and intensity-weighted lifetime days of glyphosate use were based on self-reported information from enrollment (1993–1997) and follow-up questionnaires (1999–2005). We estimated incidence rate ratios (RRs) and 95% confidence intervals (CIs) using Poisson regression, controlling for potential confounders, including use of other pesticides. All statistical tests were two-sided.

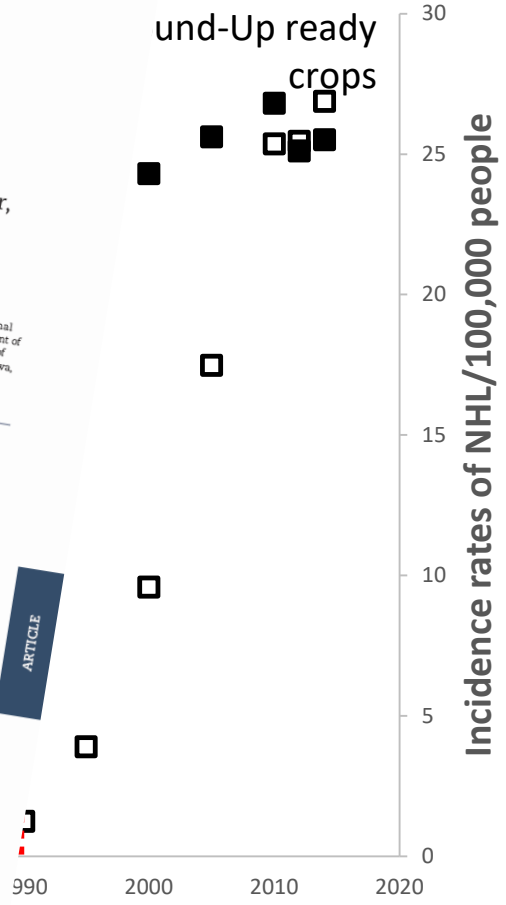
Results: Among 54 251 applicators, 44 932 (82.8%) used glyphosate, including 5779 incident cancer cases (79.3% of all cases). In unlagged analyses, glyphosate was not statistically significantly associated with cancer at any site. However, among applicators in the highest exposure quartile, there was an increased risk of acute myeloid leukemia (AML) compared with never users (RR = 2.44, 95% CI = 0.94 to 6.32, $P_{trend} = .11$), though this association was not statistically significant. Results for AML were similar with a five-year ($RR_{Quartile\ 4} = 2.32$, 95% CI = 0.98 to 5.51, $P_{trend} = .07$) and 20-year exposure lag ($RR_{Tertile\ 3} = 2.04$, 95% CI = 1.05 to 3.97, $P_{trend} = .04$).

Conclusions: In this large, prospective cohort study, no association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL and its subtypes. There was some evidence of increased risk of AML among the highest exposed group that requires confirmation.

Glyphosate was introduced as a broad-spectrum herbicide in 1974, and it quickly became one of the most heavily used herbicides worldwide. With the introduction of genetically engineered glyphosate-tolerant crops, glyphosate use increased dramatically in the late-1990s and 2000s. In addition to agricultural uses, glyphosate is one of the most common residential

Received: August 22, 2017; Revised: September 20, 2017; Accepted: October 6, 2017

und-Up ready crops



But this is not new

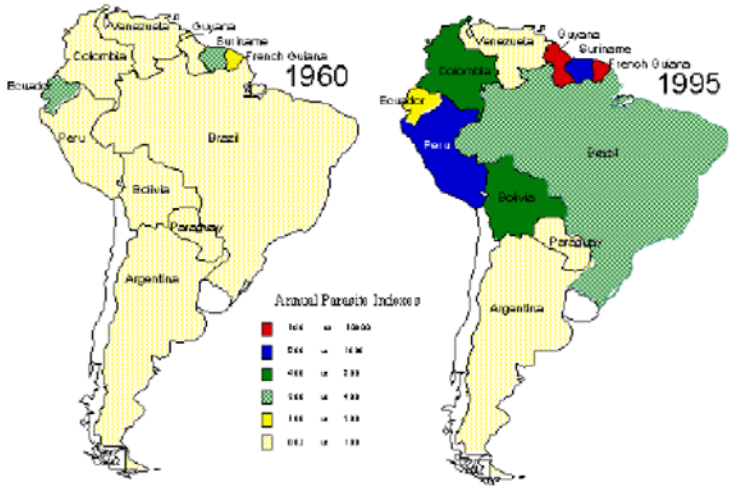
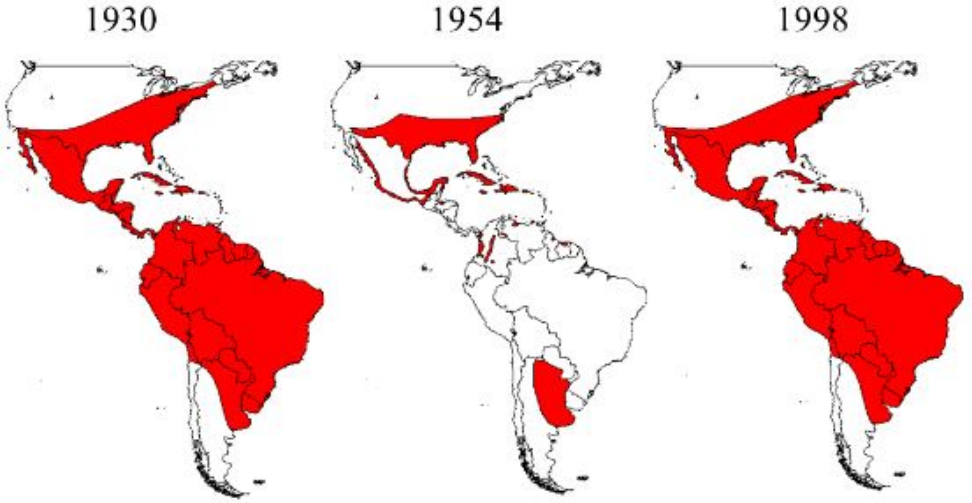
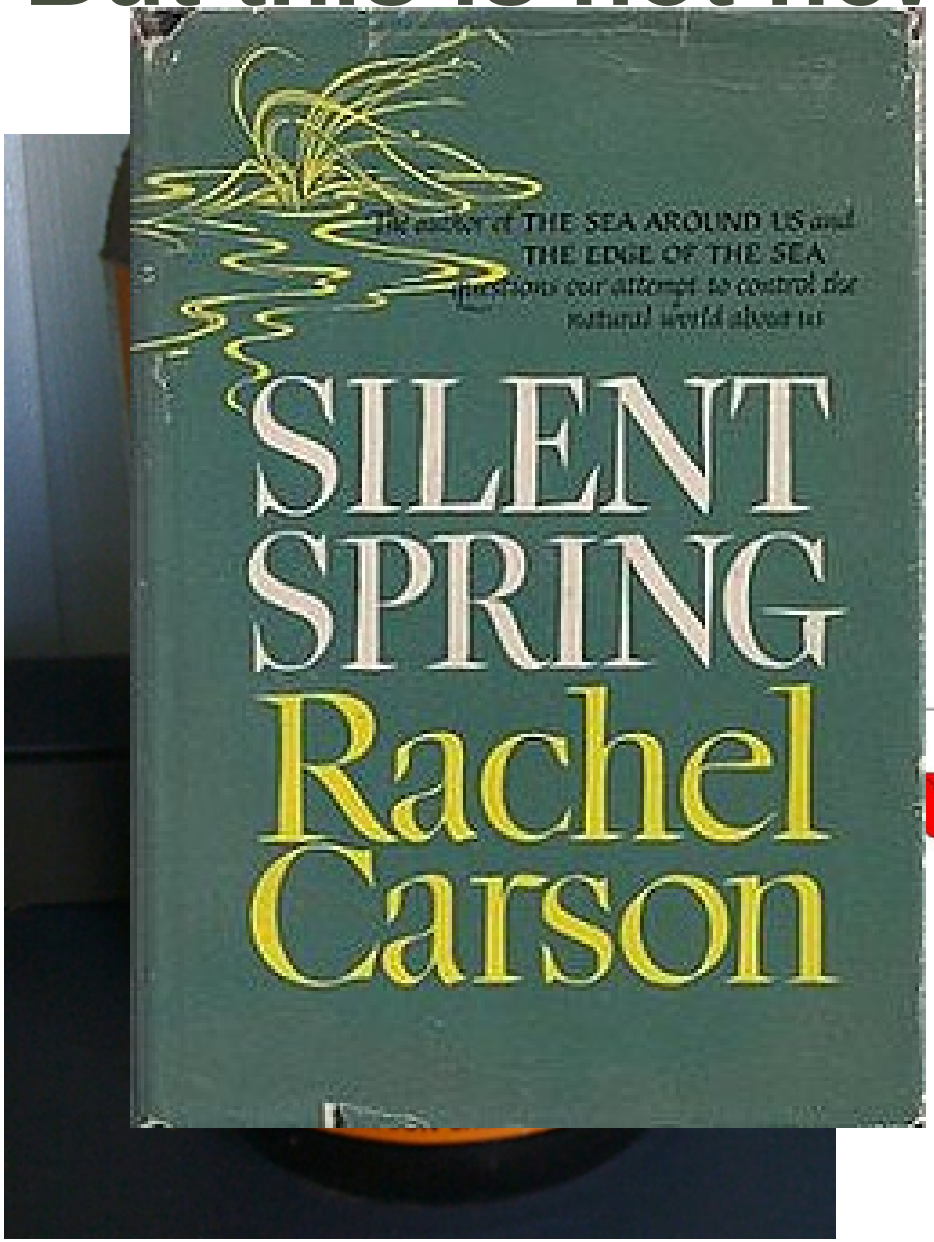


Figure 1. Distribution of malaria in South America (2-5). Color codes correspond to annual parasite indexes as reported by the Pan American Health Organization.



But this is not new



The digital era

- Propaganda is the same;
- Medium is more pervasive;
- We use the same media!

Consumer Trust!

NEW ZEALAND

Does NZ really have a science denial problem?

3 Dec, 2017 10:43am

4 minutes to read

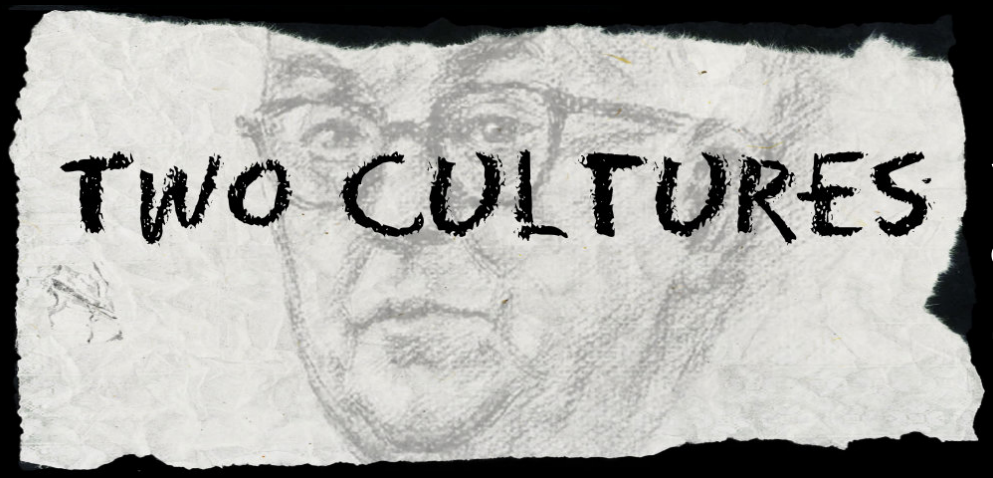
The Prime Minister's chief science advisor, Sir Peter Gluckman, has been giving talks overseas and published discussion papers about the "post-truth" issue. Photo / File

- Anti GM
- Anti 1080
- Anti fluoride
- Anti chloride
- Anti vax

What do Kiwis think about science?

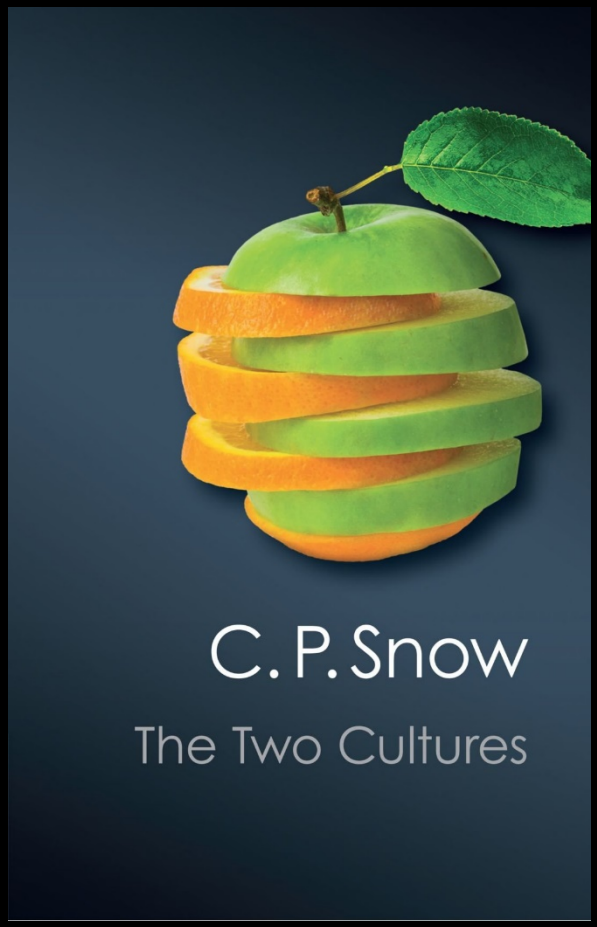
- 90% - important subject to study;
- 83% - worthwhile career to pursue;
- 59% - science important in their daily lives;
- 42% - too little information about science;
- 35% - too specialised to understand;
- 51% - too much conflicting information;
- **62% - scientists need to listen to what ordinary people think!**

Nielson survey, 2014; n = 3,000



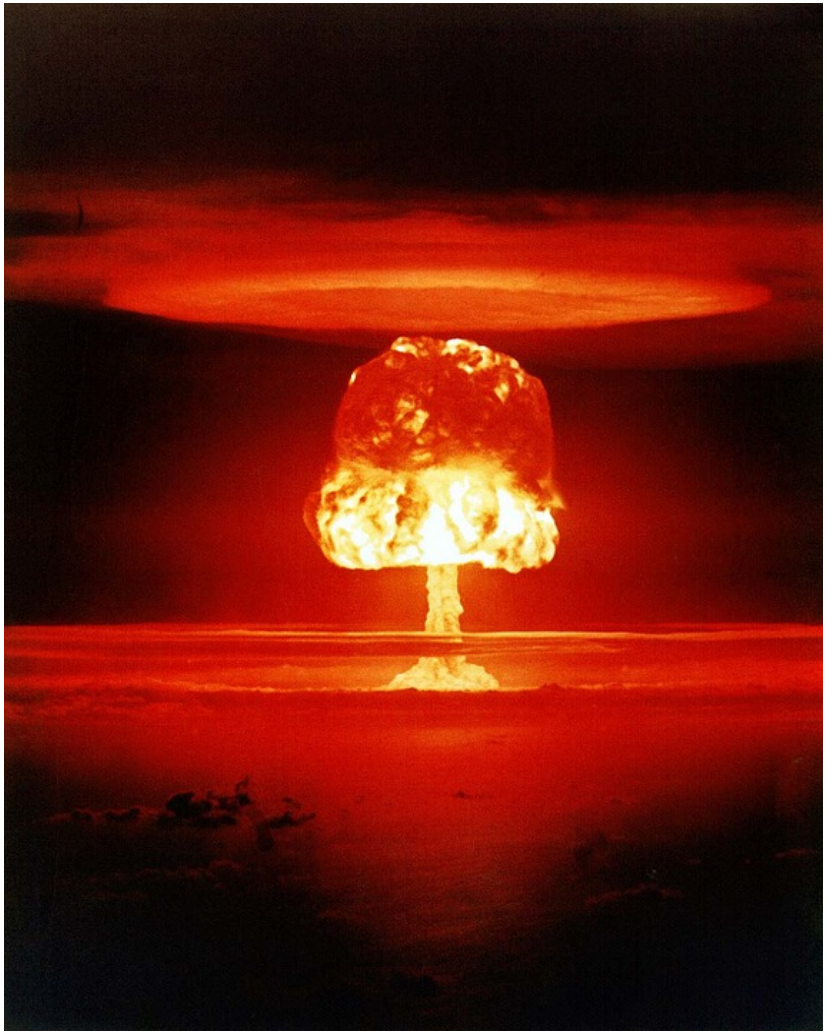
Scientists know nothing about art or culture!

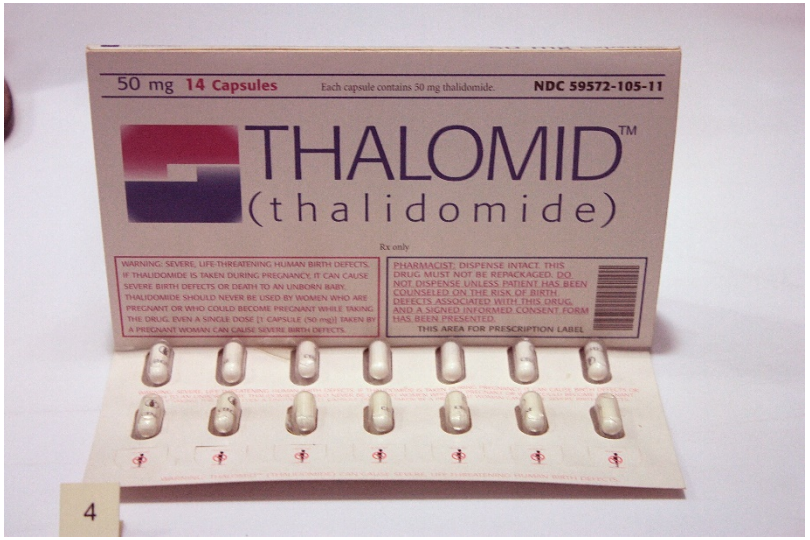
‘Literary intellectuals’ know nothing about science!



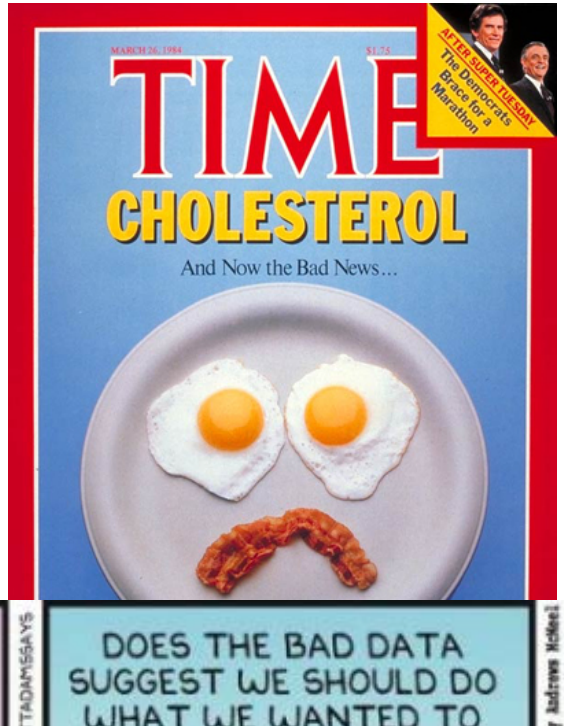
since the Victorian era, education over-rewarded the humanities (especially Latin and Greek) at the expense of scientific and engineering education

Why don’t they trust us?

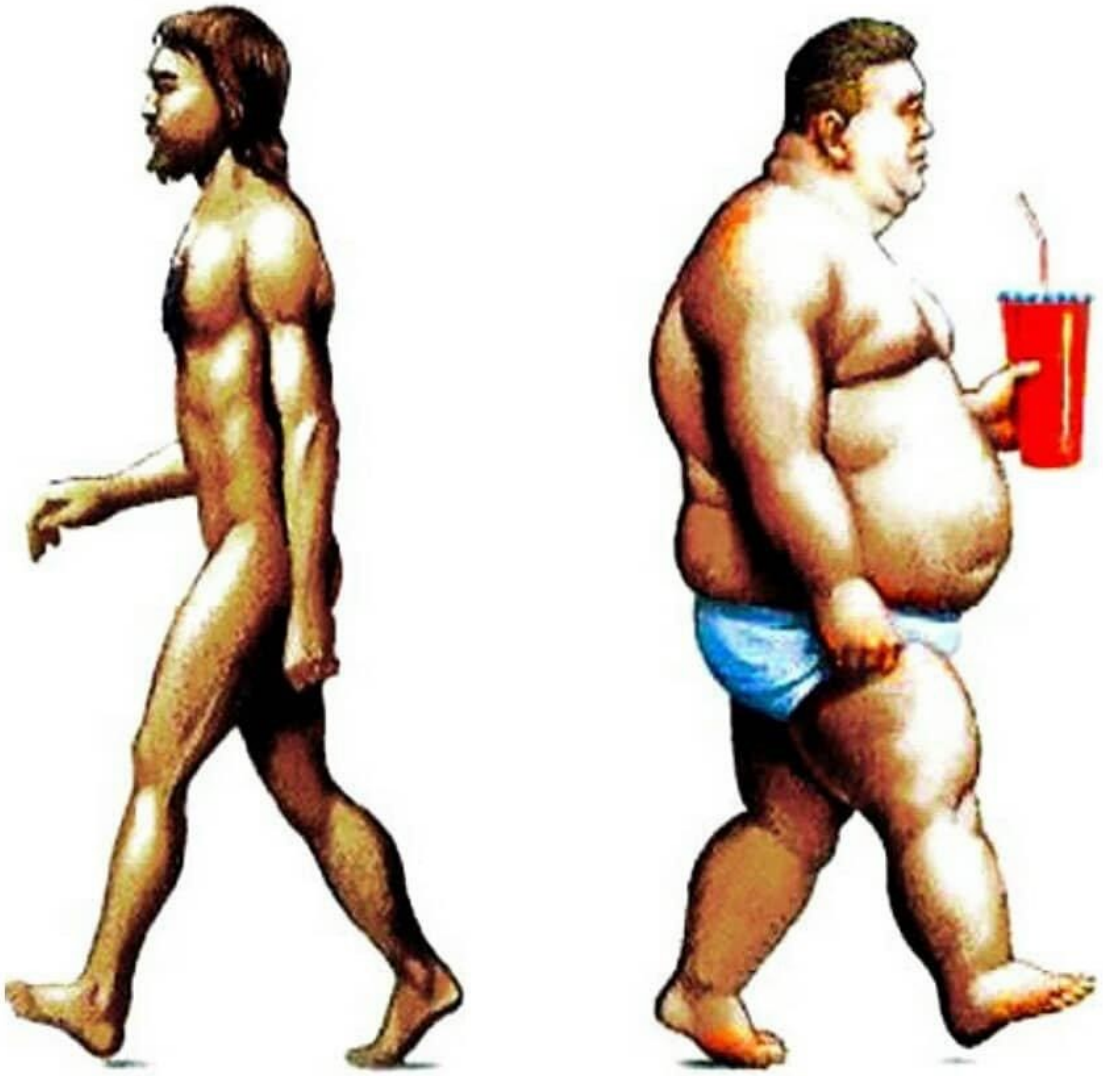




How do I know who to believe?



CARNIVORE & CARBIVORE

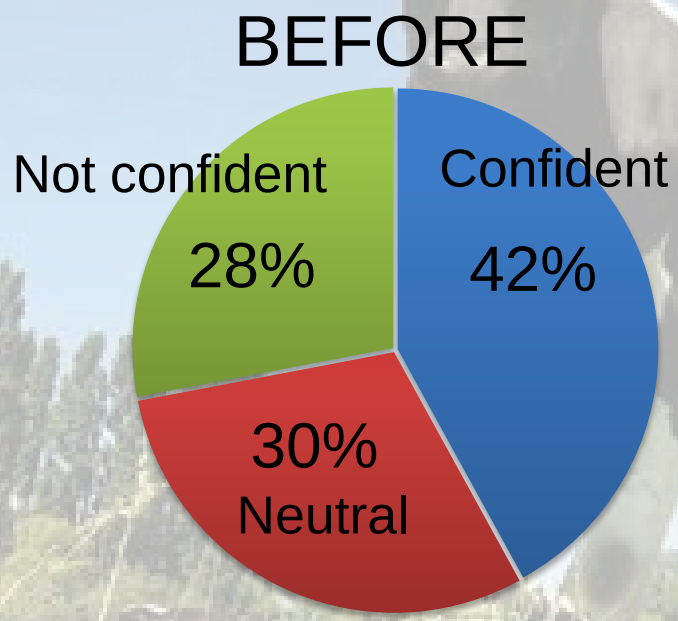


Scientists as part of the problem

"Should we force science down the throats of those that have no taste for it?
Is it our duty to drag them kicking and screaming into the twenty-first century?
I am afraid that it is."

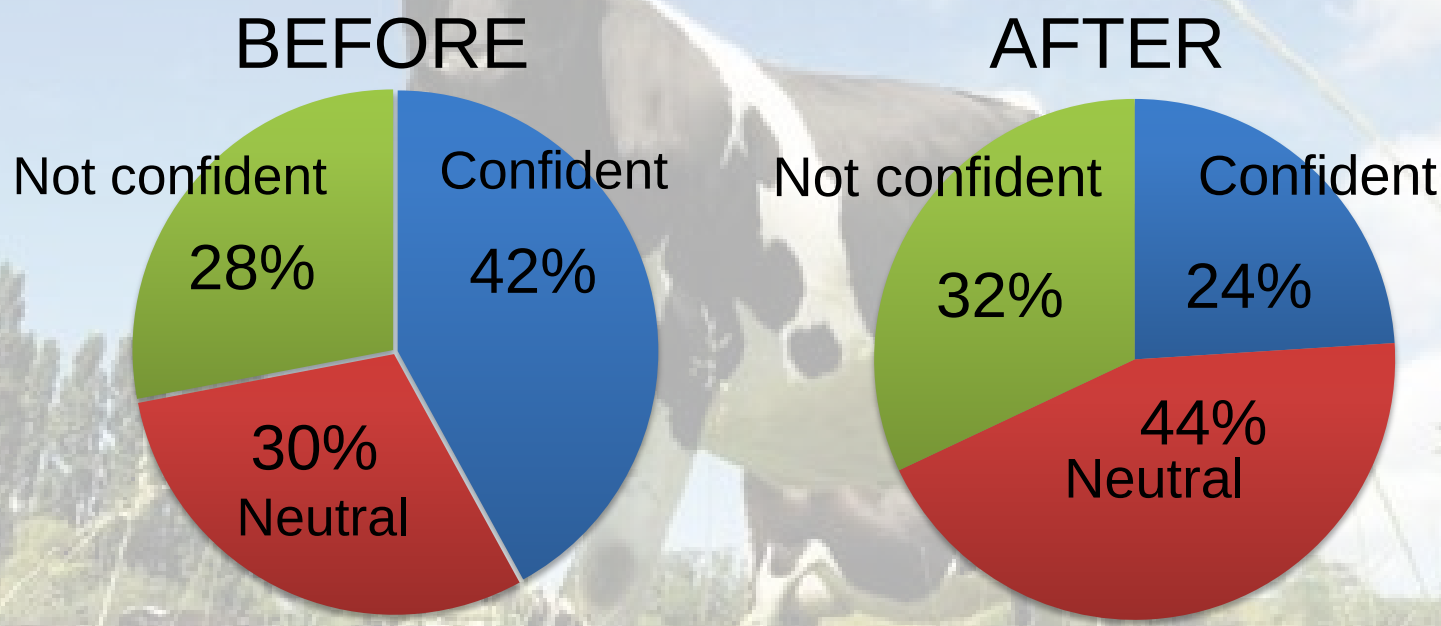
- Sir George Porter

How confident are you that dairy cattle have a good life?



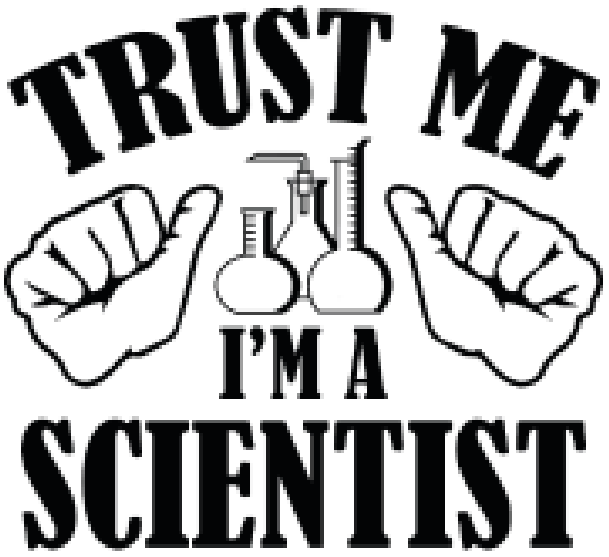
Ventura et al., 2016. PLoS ONE 11: e0154733.

How confident are you that dairy cattle have a good life?



Ventura et al., 2016. PLoS ONE 11: e0154733.


TRUST ME
I WORK
FOR THE
GOVERNMENT


TRUST ME
I'M A
SCIENTIST


KEEP
CALM
AND
Trust me
I got this


Trust Me
I'm A
Doctor


No one cares how much you know, until they know how much you care.
Theodore Roosevelt
quotefancy

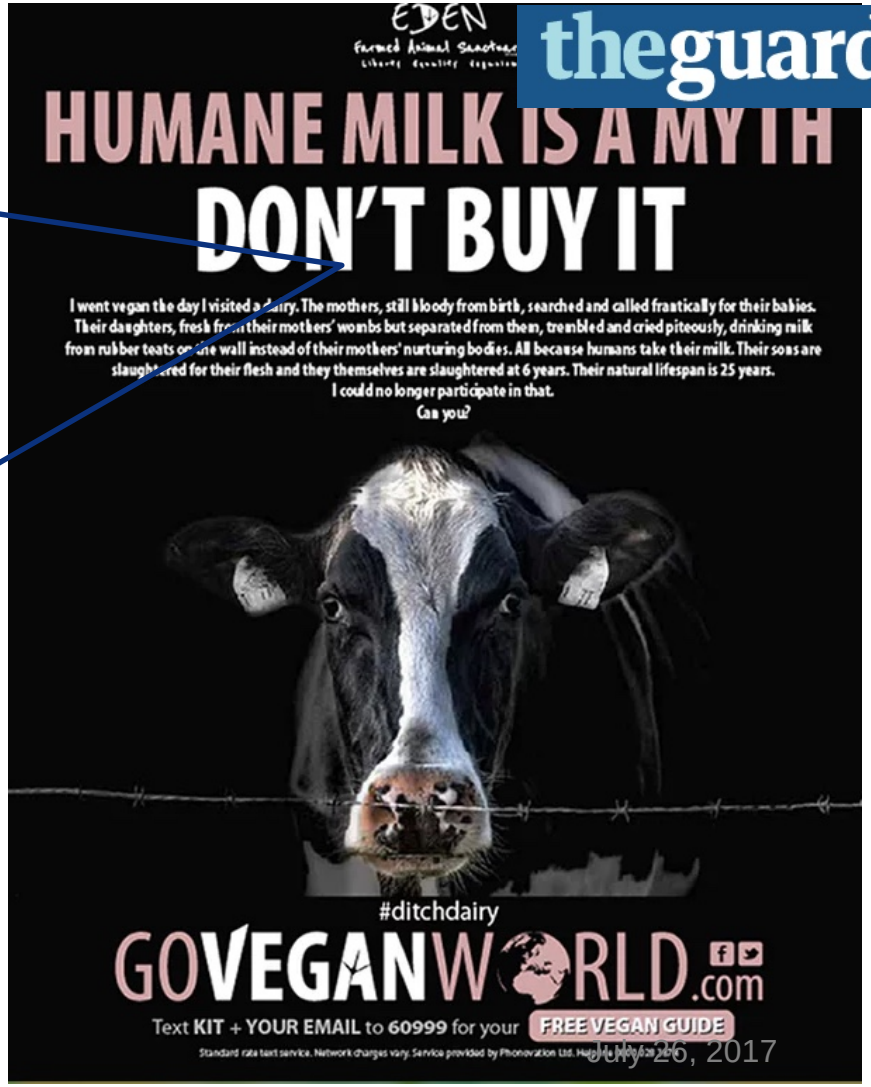
theguardian

'Humane milk is a myth': veganism advert cleared by standards body

ASA rejected claims from dairy industry that advert was 'misleading' readers into thinking farms were not complying with animal welfare standards

July 26, 2017

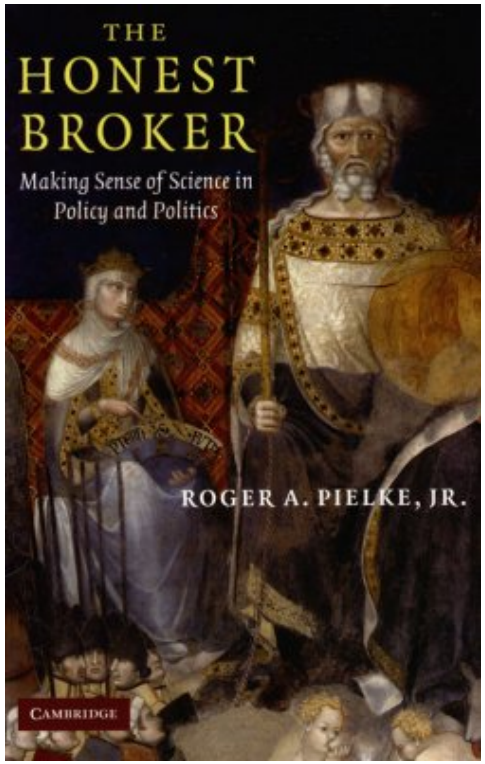
I went vegan the day I visited a dairy farm. The mothers, still bloody from birth, searched and called frantically for their babies. Their daughters, fresh from their mothers' womb but separated from them, trembled and cried piteously, drinking milk from rubber teats on the wall, instead of their mothers nurturing bodies. All because humans take their milk. Their sons are slaughtered for their flesh and they themselves are slaughtered at 6 years. Their natural lifespan is 25 years. I could no longer participate in that. Can you?



theguardian


EXCLUSIVE
GOOD NEWS!

Scientists as part of the solution



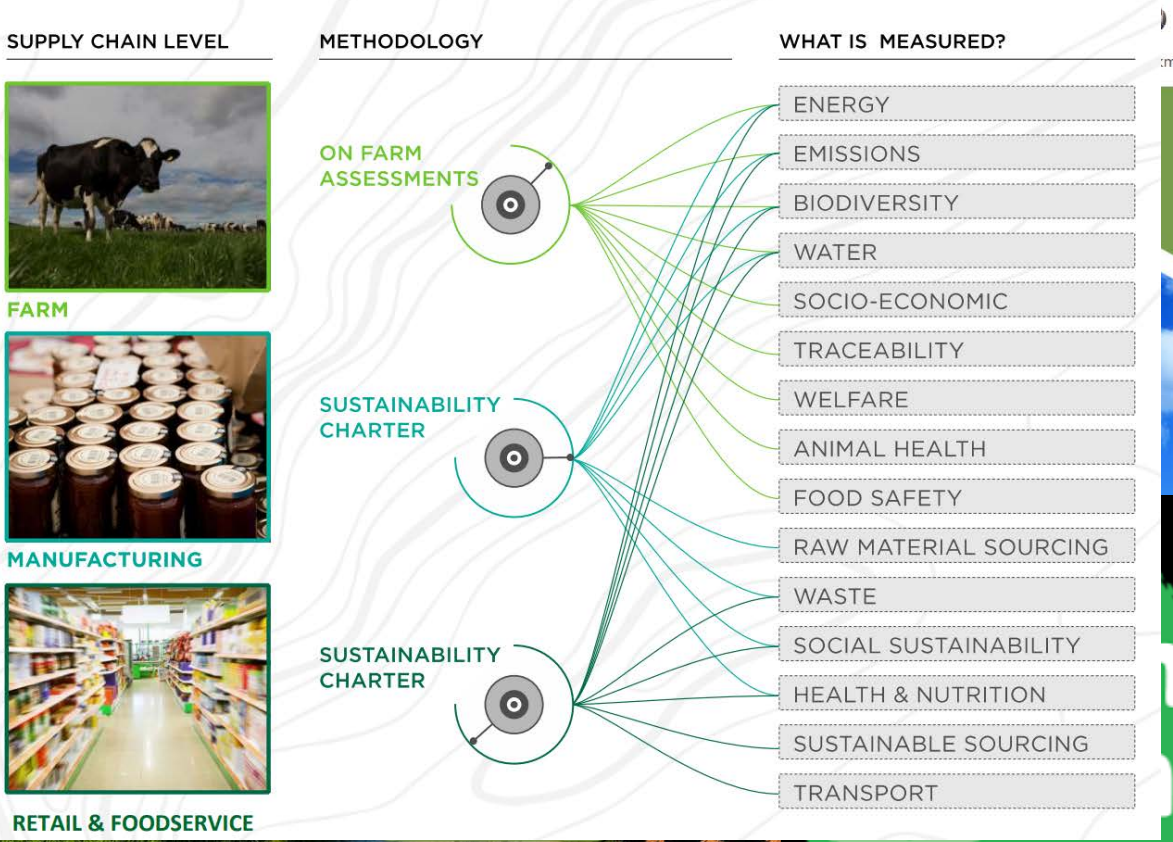
"I cannot give any scientist of any age better advice than this: the intensity of the conviction that a hypothesis is true has no bearing on whether it is true or not!"

- Peter Medewar

The way consumers interact with their food has changed!

People want the provenance story!

How does Origin Green work along the Supply Chain?




People are buying the Process
Not the Product!

Scientists as part of the solution

- We must be more humble!
- The consumers concerns are valid

  (even if YOU think they aren't)
- We must empathise;
- We must be genuine;

Summary

Summary

- Propaganda has been pervasive for millennia;
- We have lost consumer trust;
  - By not listening to their concerns with respect;
  - By not showing empathy;
- ‘Educating’ the consumer is not a solution;
- We must tell our ‘good news’ stories;
- We must engage, be humble & empathetic;
- We must acknowledge the validity of their concerns;
- **What are we going to do about it!**

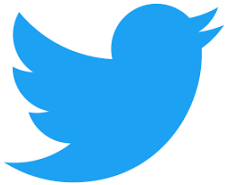
Thank you

Contact me:

john.roche@mpi.govt.nz

Follow me:

Down to Earth Advice Ltd



@down2earth_john

"***Rest satisfied with doing well, and leave others to talk of you as they please***" — Pythagoras

New Zealand Food Safety
Haumaru Kai Aotearoa

Compliance Update

Agricultural Compounds and Veterinary Medicines (ACVM) Group

Holly Jeboult-Jones – ACVM Workshop – 24 July 2019

Ministry for Primary Industries
Manatū Ahu Matua

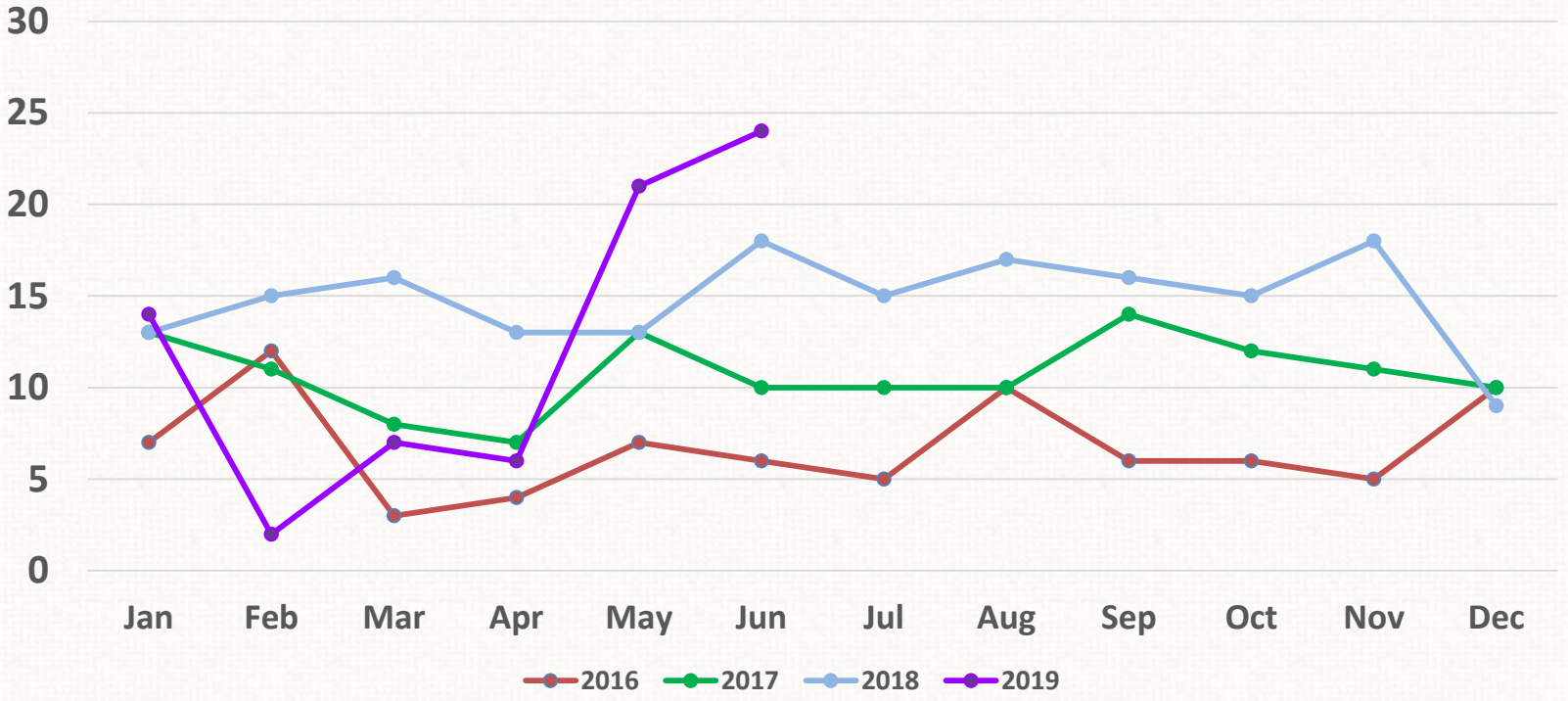
Agenda:

1. Compliance update and current stats
2. Non-compliance - common examples
3. Communication expectations for outsourced activities
4. Product Data Sheet details

Non-Compliance – Update

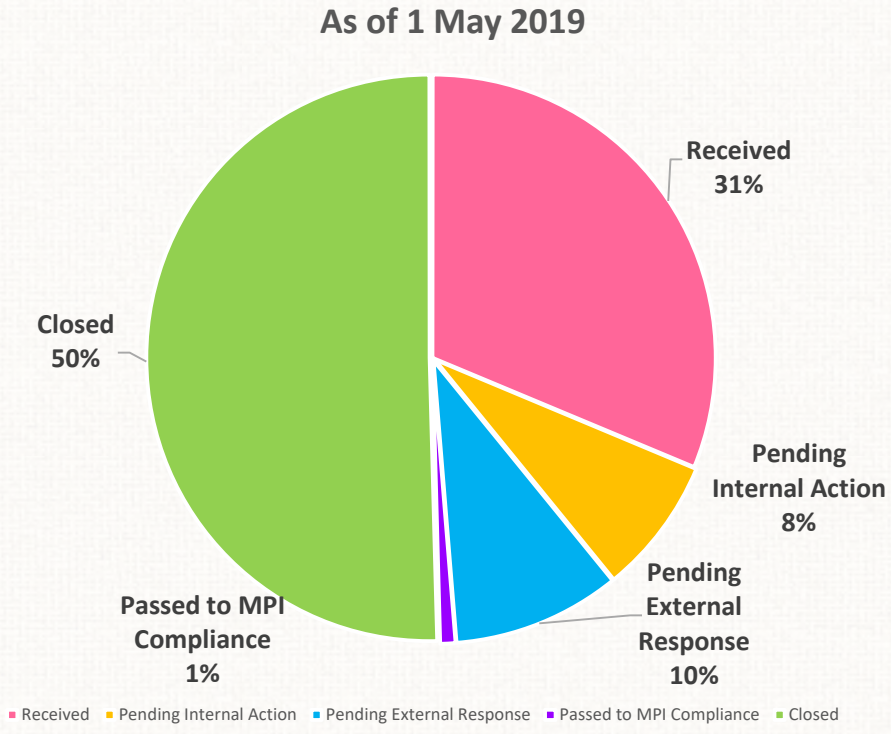
- Increasing number of non-compliance events being reported
- Increased time and focus being spent
- Temporary contractor employed
- Largely focussed on getting non-compliant product removed from websites
- Lot of time spent with exempt products or products that should be registered

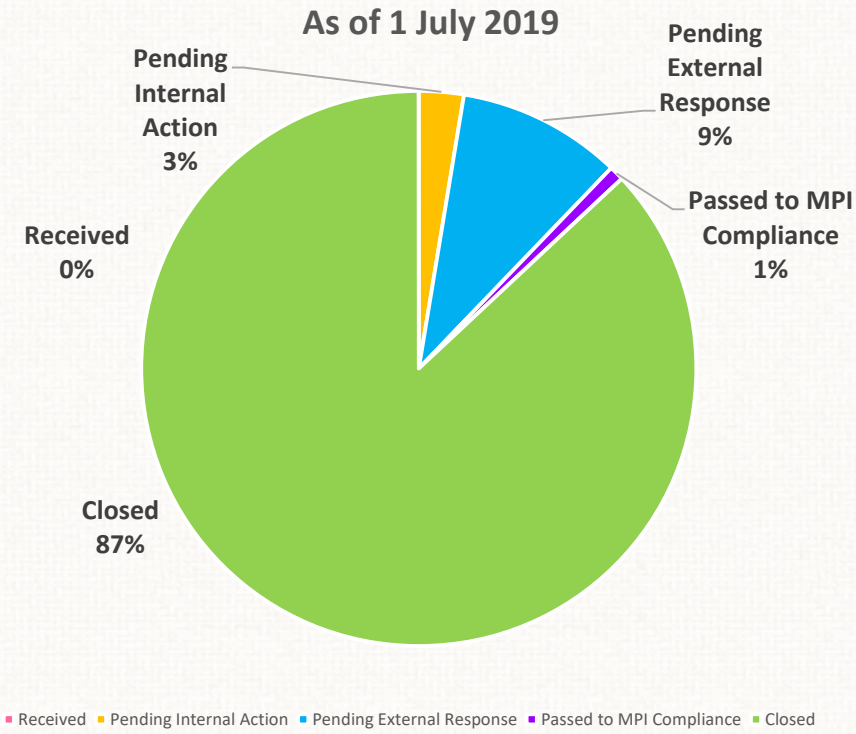
Total Compliance Activities Reported - Including reported events, BSVs and RAs



Reported Events of Non-Compliance: Jan to Dec 2018 (115)

(excl. BSVs and Rapid Alerts)



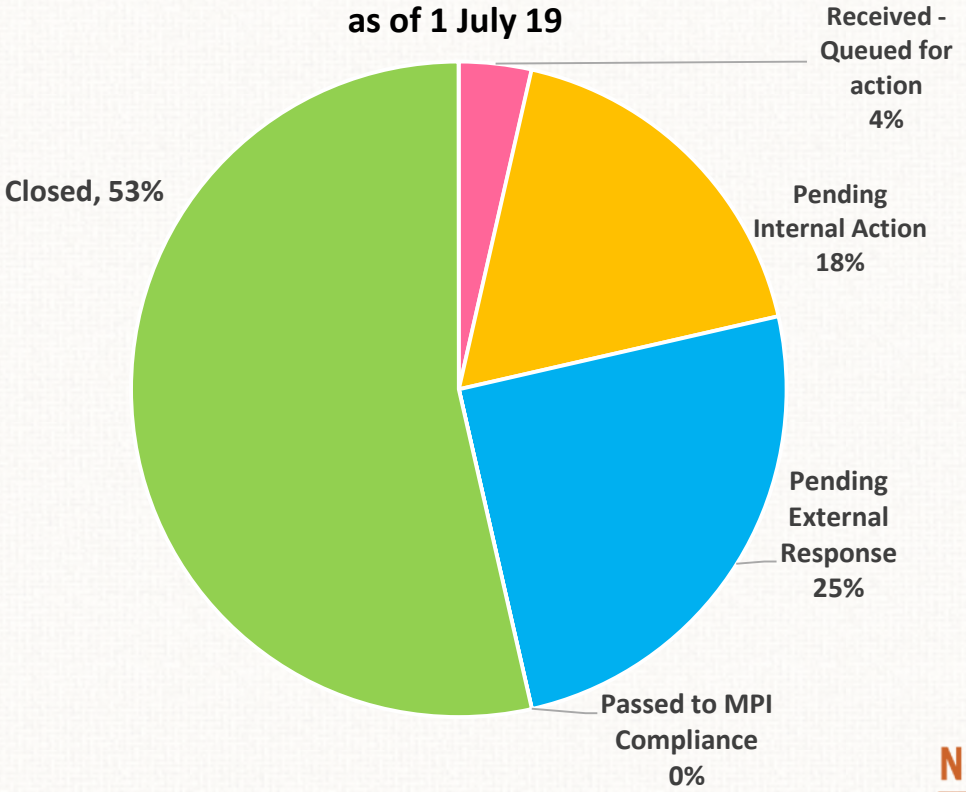


Ministry for Primary Industries
Manatū Ahu Matua

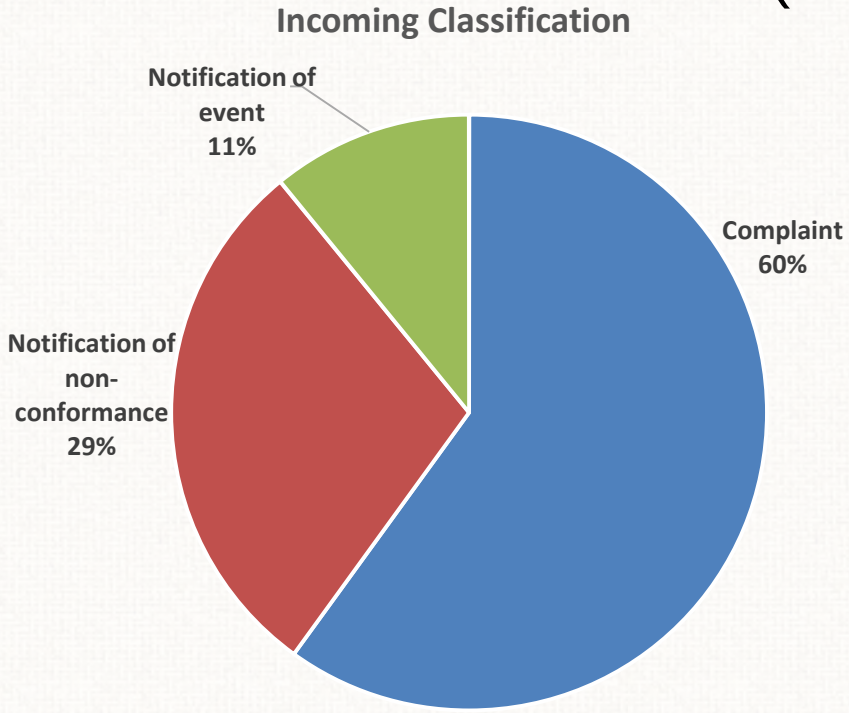
New Zealand Food Safety
Haumaru Kai Aotearoa

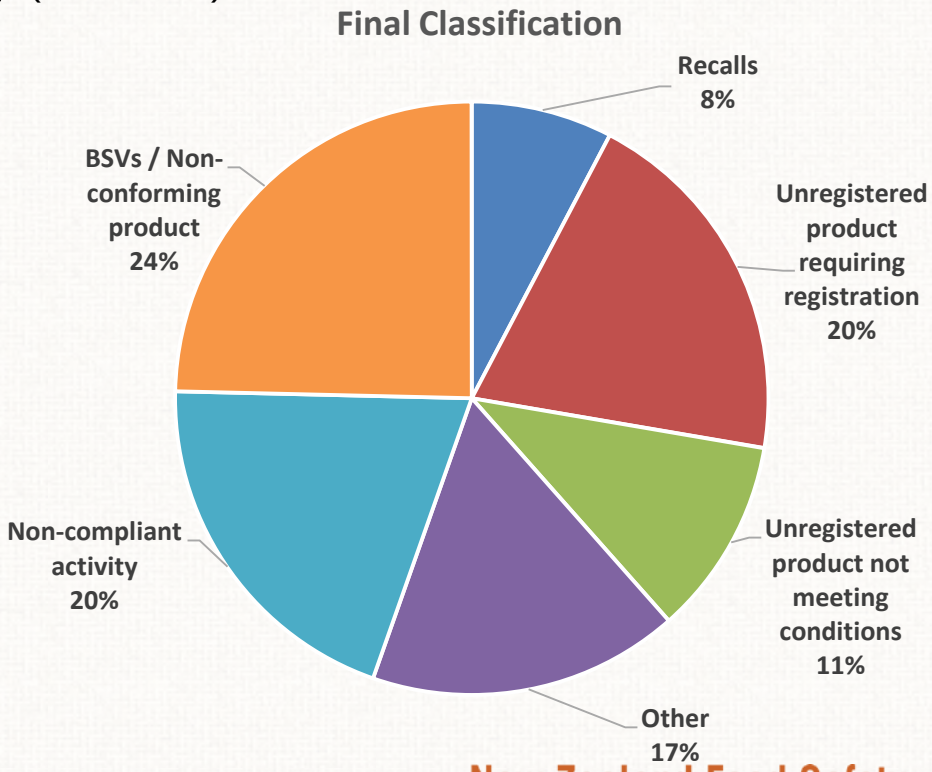
Reported Events of Non-Compliance: Jan to June 2019 (56)

(excl. BSVs and Rapid Alerts)



Classification of incoming reports of Non-Compliance (2018) (158) (incl. BSVs)





Common incidences of non-compliance - Reported to MPI

- Non-compliant labelling and advertising of exempt products
  - Incomplete labels or misleading statements
  - Statements not conforming to exemption conditions
- Unregistered product being sold
- Registered product not meeting conditions of registration
  - Product quality
  - Incomplete, inaccurate or outdated PDS

Common incidences of non-compliance
- Identified during site visits

- Testing performed by different testing laboratory than listed
- No testing laboratory listed on PDS but testing contracted to third party
- Incorrect shelf life
- Incorrect label
- Different AI manufacturer to that listed on PDS
- Different specs or incomplete parameters being tested

Non-Compliance – Plans going forward

- Increased focus on thorough investigation, appropriate corrective actions and repeat non-conformance events
- Improving the system, better reporting, recording and follow-up
  - guidance, form for reporting, regulations
- Establish FAQs for certain common non-compliance issues
- Published recalls
- Approach
  - Education
  - Opportunity to return to compliance
  - Use of Legislative tools e.g. prohibition notice, recall notice, Section 55 offences, suspension of registration

Communication expectations for outsourced activities

Responsibilities under the ACVM Act

The Registrant is **ultimately responsible** for product compliance with approved registration details

However there is generally a lot of other parties involved in the process

i.e. Outsourced activities

Outsourced Activities

Any activity in relation to manufacturing that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstanding that could result in a product (or work) that is of unsatisfactory quality.

Communication is key

Outsourced activities can include:

- Manufacturing related activities
- Down-packing/re-packing/assembly
- Re-labelling/Over-labelling
- Equipment calibrations and maintenance
- Testing/analysis
- Label printing
- Storage and warehousing
- Product Sterilisation
- Release for Supply

Registrants (and Manufacturers)

- Must carefully choose third parties
- Ensure each party's responsibilities are clearly defined, understood and agreed upon
- Ensure there is ongoing regular communication

Manufacturers who aren't the product registrant need to ensure the registrant is aware of any changes and vice-versa

Communication with third parties

Ensure the third party has applicable current approved product details

This includes:

- Active ingredient manufacturer details
- Raw material specifications
- Manufacturing methods & equipment
- Packaging Materials/Labelling
- Release and expiry specifications, QC test methods

Communication with third parties

- Clearly establish responsibilities for each party in relation to regulatory and quality requirements
- Ensure each party understands requirements and expectations and commits to these
- Establish reporting channels and timelines for communications
- Consider each party's responsibilities in relation to
  - issues management - including complaints and recalls
  - performing final checks and release for supply
- Have considerations been given to auditing your contracted party?

Why is this important?

- Establishing and maintaining clear lines of responsibility, and having regular communication is critical to good product stewardship and pharmacovigilance

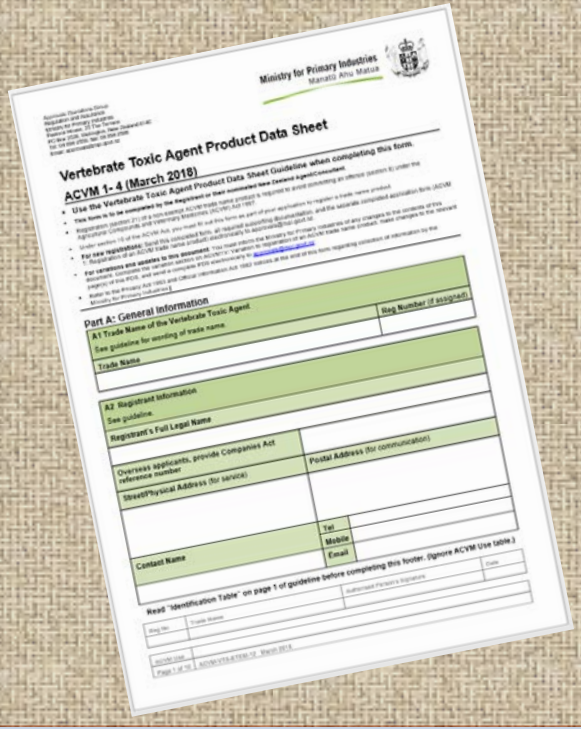
- Product complies with registration and is safe, pure and fit for purpose and associated risks are mitigated

Risks

- Wide range of products
- Wide range of manufacturing processes
- Many different companies involved
- Many different testing laboratories, test methods and specifications involved

Different level of risk for each product and each activity

Product Data Sheets


Ministry for Primary Industries
Manatū Ahu Matua

Vertebrate Toxic Agent Product Data Sheet

ACVM 1- 4 (March 2018)

- Use the Vertebrate Toxic Agent Product Data Sheet Guideline when completing this form.
- This form is to be completed by the Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your application to register a trade name product.
- **For new registrations:** Send this completed form, all required supporting documentation, and the separate completed application form (ACVM 1: Registration of an ACVM trade name product) electronically to approvals@mpi.govt.nz.
- **For variations and updates to this document:** You must inform the Ministry for Primary Industries of any changes to the contents of this document. Complete ACVM 1V: Variation to registration of an ACVM trade name product - make changes to the relevant page(s) of this PDS, and send a complete PDS electronically to approvals@mpi.govt.nz.
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

Part A: General Information

A1 Trade Name of the Vertebrate Toxic Agent
See guideline for wording of trade name.

Trade Name	Reg Number (if assigned)

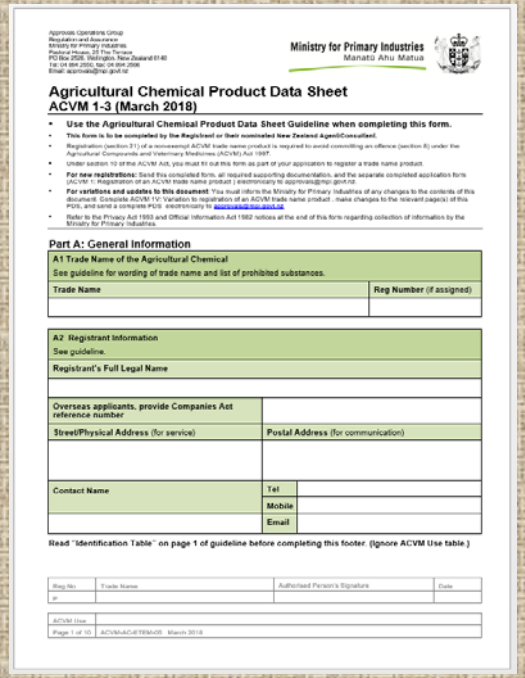
A2 Registrant Information
See guideline.

Registrant's Full Legal Name	
Overseas applicants, provide Companies Act reference number	Postal Address (for communication)
Street/Physical Address (for service)	
Contact Name	Tel
	Mobile
	Email

Read "Identification Table" on page 1 of guideline before completing this footer. (Ignore ACVM Use table.)

Reg No	Trade Name	Authorised Person's Signature	Date
IP			

ACVM Use


Approvals Operations Group
Regulation and Assurance
Ministry for Primary Industries
Pastoral House, 25 The Terrace
PO Box 2526, Wellington, New Zealand 6140
Tel: 04 894 2500, fax: 04 894 2566
Email: acvmvets@mpi.govt.nz

Ministry for Primary Industries
Manatū Ahu Matua

Agricultural Chemical Product Data Sheet

ACVM 1-3 (March 2018)

- Use the Agricultural Chemical Product Data Sheet Guideline when completing this form.
- This form is to be completed by the Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your application to register a trade name product.
- **For new registrations:** Send this completed form, all required supporting documentation, and the separate completed application form (ACVM 1: Registration of an ACVM trade name product) electronically to approvals@mpi.govt.nz.
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- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

Part A: General Information

A1 Trade Name of the Agricultural Chemical
See guideline for wording of trade name and list of prohibited substances.

Trade Name	Reg Number (if assigned)

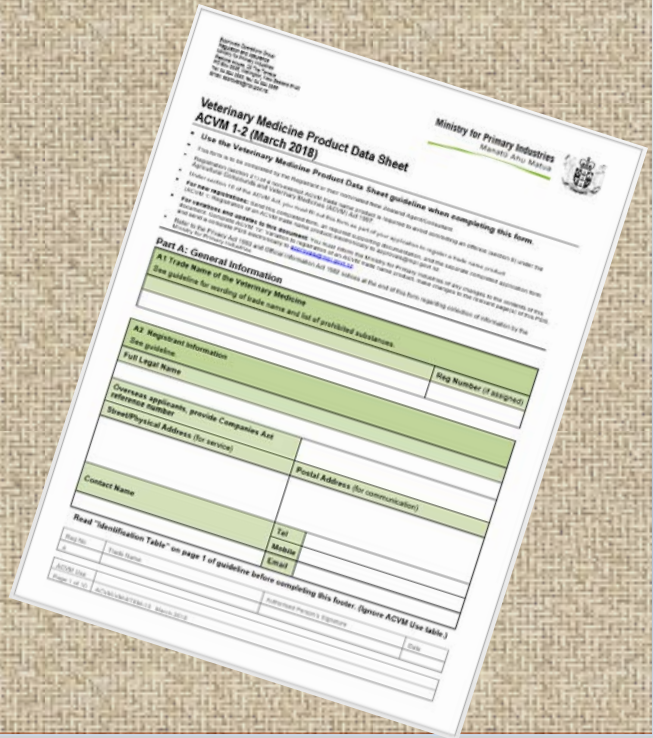
A2 Registrant Information
See guideline.

Registrant's Full Legal Name	
Overseas applicants, provide Companies Act reference number	
Street/Physical Address (for service)	Postal Address (for communication)
Contact Name	Tel
	Mobile
	Email

Read "Identification Table" on page 1 of guideline before completing this footer. (Ignore ACVM Use table.)

Reg No	Trade Name	Authorised Person's Signature	Date
IP			

ACVM Use


Ministry for Primary Industries
Manatū Ahu Matua

Veterinary Medicine Product Data Sheet

ACVM 1-2 (March 2018)

- Use the Veterinary Medicine Product Data Sheet guideline when completing this form.
- This form is to be completed by the Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your application to register a trade name product.
- **For new registrations:** Send this completed form, all required supporting documentation, and the separate completed application form (ACVM 1: Registration of an ACVM trade name product) electronically to approvals@mpi.govt.nz.
- **For variations and updates to this document:** You must inform the Ministry for Primary Industries of any changes to the contents of this document. Complete ACVM 1V: Variation to registration of an ACVM trade name product - make changes to the relevant page(s) of this PDS, and send a complete PDS electronically to approvals@mpi.govt.nz.
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

Part A: General Information

A1 Trade Name of the Veterinary Medicine
See guideline for wording of trade name and list of prohibited substances.

A2 Registrant Information
See guideline.

Full Legal Name	Reg Number (if assigned)
Overseas applicants, provide Companies Act reference number	
Street/Physical Address (for service)	Postal Address (for communication)
Contact Name	Tel
	Mobile
	Email

Read "Identification Table" on page 1 of guideline before completing this footer. (Ignore ACVM Use table.)

Reg No	Trade Name	Authorised Person's Signature	Date
IP			

ACVM Use

Each Product Data Sheet (PDS) needs to be:

- *clear and detailed*
- *accurate*
- *current*

PDS – Vet Meds, Ag Chems and VTAs

The current PDS Guideline states:

B4 Manufacturer(s) of the Formulated Product

‘Provide the name, site address and function of all facilities involved in any step of manufacture. This includes but is not limited to the following: bulk product formulation, filling, packaging and labelling, contract sterilisation, external analytical laboratory testing, re-packing/re-labelling and release for supply.

B4 Manufacturer(s)/Formulator(s) of the Formulated Product See guideline.		
Company name	**Street address of manufacturing site**	**Manufacturing step/ Function**
Micky Mouse Manufacturing Ltd	1 Levels Lane, Carterton, Germany	Formulation

Provide details of the main company responsible for 'release for supply' of this product	
Company Name	Micky Mouse Manufacturing Ltd
Site Address	1 Levels Lane, Carterton, Germany
Postal Address (if different)	N/A

B4 Manufacturer(s)/Formulator(s) of the Formulated Product See guideline.		
Company name	**Street address of manufacturing site**	**Manufacturing step/ Function**
Micky Mouse Manufacturing Ltd	1 Levels Lane, Auckland, New Zealand	Formulation
Contract Trials Ltd	876 People Drive, Auckland, New Zealand	QC
Quacky QC Services	86 Duck Lane, Tauranga, New Zealand	QC
Quirky Quality Ltd	45 Truck Street, Waimate, New Zealand	QC

Provide details of the main company responsible for 'release for supply' of this product	
Company Name	Micky Mouse Manufacturing Ltd
Site Address	1 Levels Lane, Auckland, New Zealand
Postal Address (if different)	PO Box 89 322, Levels, Auckland

B4 Manufacturer(s)/Formulator(s) of the Formulated Product See guideline.		
Company name	**Street address of manufacturing site**	**Manufacturing step/ Function**
Micky Mouse Manufacturing Ltd	1 Levels Lane, Carterton, Germany	Manufacturer/Formulator
Minty Mouse Mixing Ltd	28 Maxwell Way, Maxwell, Australia	Manufacturer/Formulator
Rupert Repacking Ltd	28 Wellington Road, Wellington, New Zealand	Re-packer/Relabeller
Lobby Logistics	594 Auckland Road, Auckland, New Zealand	Re-packer/Relabeller
Lobby Logistics	64 Hamilton Avenue, Hamilton, New Zealand	Re-packer/Relabeller

Provide details of the main company responsible for 'release for supply' of this product	
Company Name	Micky Mouse Manufacturing Ltd
Site Address	1 Levels Lane, Carterton, Germany
Postal Address (if different)	N/A

B4 Manufacturer(s)/Formulator(s) of the Formulated Product

See guideline.

Company name	Street address of manufacturing site	Manufacturing step/ Function
Micky Mouse Manufacturing Ltd	59 Manufacturing Way, Australia	All
Quacky QC Services	86 Duck Lane, Tauranga, New Zealand	External QC laboratory (Assay)

Provide details of the main company responsible for 'release for supply' of this product

Company Name	Micky Mouse Manufacturing Ltd
Site Address	59 Manufacturing Way, Australia
Postal Address (if different)	N/A

B4 Manufacturer(s)/Formulator(s) of the Formulated Product

See guideline.

Company name	Street address of manufacturing site	Manufacturing step/ Function
Micky Mouse Manufacturing Ltd	59 Manufacturing Way, Australia	Formulation of bulk product, filling, packing, chemical testing and packing
Quacky QC Services	86 Duck Lane, Tauranga, New Zealand	Sterility Testing
Repackers Anonymouse	32 Party Street, Greymouth, New Zealand	Labelling

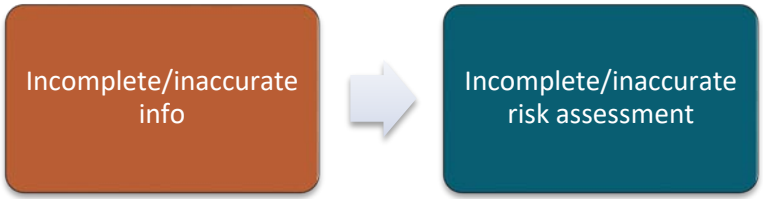
Provide details of the main company responsible for 'release for supply' of this product

Company Name	Repackers Anonymouse
Site Address	32 Party Street, Greymouth, New Zealand
Postal Address (if different)	PO Box 89 322, Greymouth, New Zealand

PDS – Vet Meds, Ag Chems and VTAs

Similar detail needs to be considered in other sections as well:

- B1: AI Manufacturer(s), B2: Active Ingredient Minimum Purity and Impurities
- B3: Formulation Details
- B5: Manufacturing Process
- B6: Specifications of the Formulated Product
- B7: Packaging Details
- B8: Distribution Process



In Summary - Key points

- Registrants, manufacturers and exempt product entities need to ensure that the relationships and responsibilities of all parties is well defined, understood and agreed upon
- Make sure the PDS is complete, detailed, and up to date
- Exempt products – make sure the regulations and conditions of exemption are complied with
- Things do go wrong - but please let us know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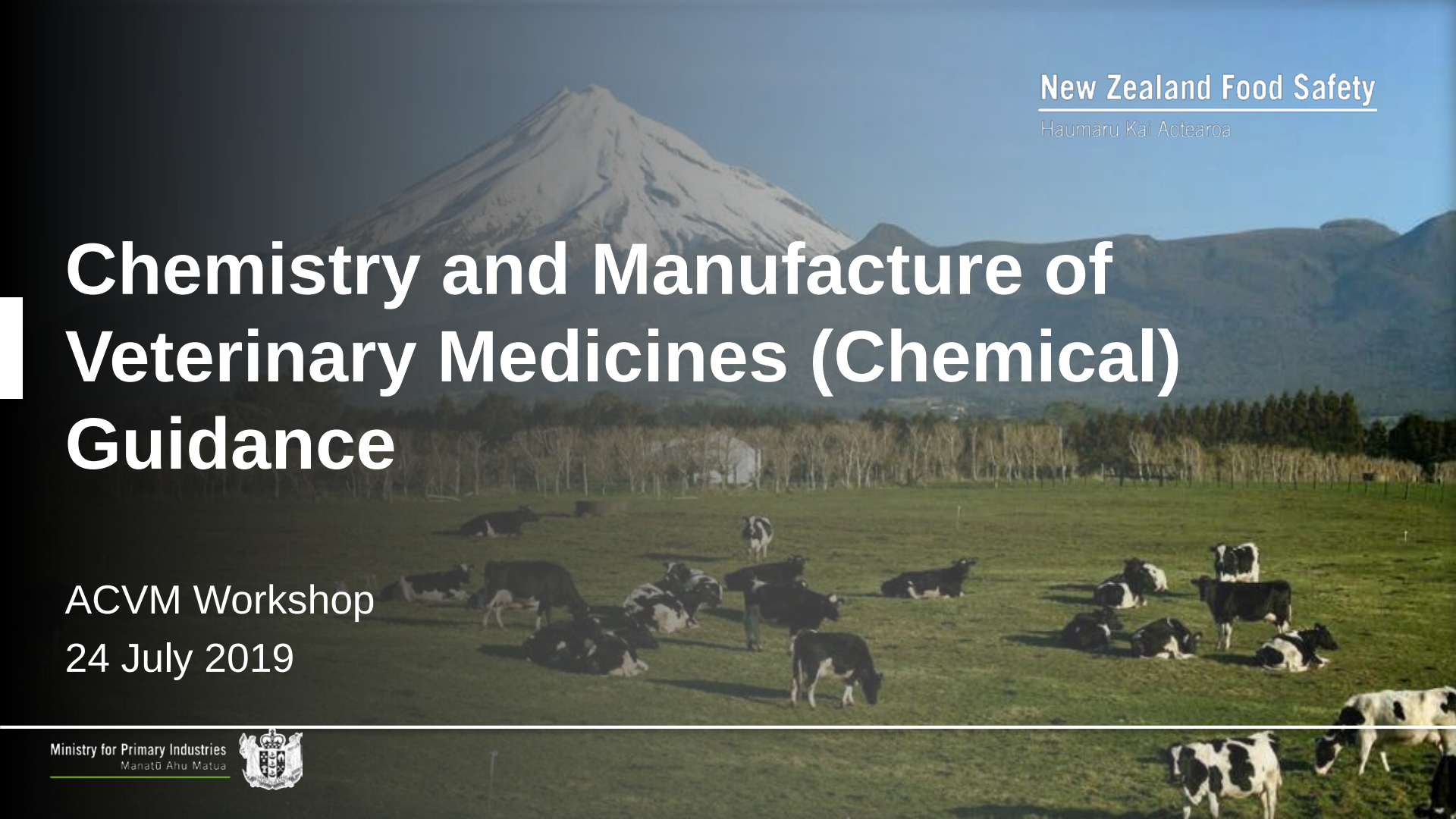
Manatū Ahu Matua



New Zealand Food Safety
Haumaru Kai Aotearoa

Chemistry and Manufacture of Veterinary Medicines (Chemical) Guidance

ACVM Workshop
24 July 2019

Ministry for Primary Industries
Manatū Ahu Matua

Chemistry and Manufacture of Veterinary Medicines (Chemical) Guidance

- Key changes in the revised Guidance
- Next steps
- Upcoming Guidance

Key Changes in the Revised Guidance

Key Changes in the Revised Guidance

- The new Guidance document is a complete overhaul compared to the current Standard – changes in all sections including appendices
    - **More detailed guidance and updates on expectations relating to:**
        - Active and excipient ingredient management
        - Manufacturing information including process validation
        - Product packaging
        - Stability studies, including in-use stability
        - Formulation types appendix updated

Key Changes in the Revised Guidance

- The new Guidance document is a complete overhaul compared to the current Standard – changes in all sections including appendices
    - **New guidance on expectations relating to:**
        - Variation applications
        - Self-assessable changes
    - **New Appendices for product types, release and expiry specifications, a checklist for new product submissions**
    - **New Appendix for guidance on recognised evidence of GMP certification (TBC)**

Key Changes in the Revised Guidance

Standard	Guidance
1 Introduction	**1 Purpose; 2 Background; 3 Definitions and Abbreviations; 4 Information Needed; 5 Additional Guidelines**

- ‘Definitions and Abbreviations’ updated and significantly expanded to include 36 new definitions
- ‘Information Needed’ added to provide general advice on deviations, technical discussions, and consultants
- Reference list revised to ‘Additional Guidelines’ and updated to include all applicable VICH guidelines and other overseas guidance

Key Changes in the Revised Guidance

Standard	Guidance
	6 Registration of a new Trade Name Product
2 Formulation and Ingredient Requirements	6.1 Product type, formulation type, and description; 6.2 Formulation of the Product; 6.3 Active ingredients; 6.4 Excipient Ingredients

- Four distinct sections created to provide more detail on product and formulation presentation, active ingredient requirements, and excipient ingredient requirements

Key Changes in the Revised Guidance

6.1 Product type, formulation type and description

- Provision of pharmaceutical development information for the product
  - Currently submitted by some registrants for certain products, has been added to the guidance to standardise submission across all products to inform the risk profile

Key Changes in the Revised Guidance

6.2 Formulation of the product

- There can only be one distinct formulation per TNP
    - ➢ TNPs are regulated by formulation, and guidance based on best practice: each product is expected to have a distinct and fixed formulation (deviations considered case by case)
- Change in the management of overages
    - ➢ Splitting out overages into stability related (in section 6.2) and manufacturing related (section 6.5) since reasons for their inclusion, risks, and management strategies are different for each kind

Key Changes in the Revised Guidance

6.3 Active Ingredients

- Introduction of JP as an MPI-recognised pharmacopoeia, provision for use of third-country pharmacopoeial monographs with additional information
    - ➢ These changes reflect VICH best practice and allow registrants greater flexibility in choosing active ingredient sources
- Introduction of the functional active ingredient category
    - ➢ Allows for better classification of ingredients and more appropriate risk management for those ingredients that are not true actives but are also not excipients

Key Changes in the Revised Guidance

6.4 Excipient Ingredients

- Introduction of the critical excipient category
  - Like the new functional active ingredient category, the critical excipient category allows for better classification and more appropriate risk management for those ingredients that are excipients (i.e. included to manage the formulation and its delivery) but have a direct impact on the risk profile of the product
    - **Example: penetrants for pour-on products**

Standard vs Guidance: Overall Structure

Standard	Guidance
	6.5 Formulated Product Manufacturing
3.1 Manufacture of the trade name product	6.5.1 Manufacturer identity and GMP
3.2 Manufacturing process	6.5.2 Manufacturer batch formula and batch formula table
3.3 Identification and management of critical manufacturing control points	6.5.3 Manufacturing process
3.4 Quality control	6.5.4 Manufacturing related overages
	6.5.5 In-process quality control testing
	6.5.6 Manufacturing process validation

Key Changes in the Revised Guidance

6.5.1 Manufacturer identity and GMP

- Introduction of GMP-specific information
  - Outlines expectations around providing evidence of GMP approval for formulated product manufacturers
- Clarification around repacker/relabeller and release for supply entities, and the activities they may undertake
  - Repackers/relabellers may only undertake activities that do not breach primary packaging
  - Release for supply entities must be able to confirm conformance to NZ approval and have direct authority over NZ distribution

Key Changes in the Revised Guidance

6.5.2 Manufacturing batch formula and batch formula table

- Will now be separating out manufacturing formulas from final product formulations
    - ➢ Allows for a full assessment of the formulation risks that may differ at different points of TNP production
    - ➢ Supports manufacturer auditing for GMP approval

- NOTE: The batch formula table will be incorporated in the upcoming revised PDS

Key Changes in the Revised Guidance

6.5.3 Manufacturing process

- Expectations around the recording and approval of manufacturing processes have been updated and more detail provided
    - Clarity around when the manufacturing process starts and ends
    - More detail of what is expected in the manufacturing process flow diagram/description
    - The potential impacts of bulk storage have been more specifically addressed
    - Guidance on how to manage ingredients that are partially or completely consumed in the manufacturing process

Key Changes in the Revised Guidance

6.5.4 Manufacturing related overages

- As per notes on the stability related overages, the two types will be managed separately going forward

6.5.5 In process quality control testing

- More detail about what qualifies as in-process quality control testing, and what information to provide

Key Changes in the Revised Guidance

6.5.6 Manufacturing process validation

- Guidance includes details of what is expected regarding manufacturing process validation
  - What should be validated
  - When a validation protocol is accepted, and what it should contain
  - What should be included in a validation report
  - Sterilisation process validation

Standard vs Guidance: Overall Structure

Standard	Guidance
	6 Registration of a new Trade Name Product (cont.)
4 Specifications	6.6 Finished product specification; 6.7 Formulated product batch analyses; 6.8 Product packaging

- More consistent application of the term “specification” to refer to the full set of testing parameters and results
- Introduction of an expectation for providing specification rationales, and what should be included in that rationale discussion
- More detail around packaging information expectations

Key Changes in the Revised Guidance

6.6 Finished product specification

- 6.6.1 Specification rationale
  - Requirement for a rationale for specification parameters and their acceptable values/ranges, to evaluate their fitness to manage product risks
- 6.6.2 Formulated product release specification and 6.6.3 Formulated product expiry specification
  - More detail on the expectations around what is expected of a specification and method validation
- 6.6.4 Formulated product specifications for functional AIs
  - Expectations for specification parameters for these ingredients

Key Changes in the Revised Guidance

6.7 Formulated product batch analyses

- Specified expectations for formulated product batch analyses regarding:
  - Number of expected batch analyses
  - Batch size, and information reported in the analysis
  - Analytical methods match those validated for the specification
  - Reporting of all results including those that do not conform to specification

Key Changes in the Revised Guidance

6.8 Product packaging

- More detailed expectations for product packaging information, including packaging materials and closure systems
- Guidance on the presentation and management of:
  - Requests for and management of pack sizes ranges
  - Additional product-specific administration devices packaged with the TNP
  - Additional commercial administration devices packaged with the TNP
  - Recycled and reused packaging of expected batch analyses

Standard vs Guidance: Overall Structure

Standard	Guidance
	6 Registration of a new Trade Name Product (cont.)
5 Stability testing of the finished product	6.9 Formulated product stability; 6.10 In-use stability

Key Changes in the Revised Guidance

6.9 Formulated product stability

- Introduction of extrapolation (as per VICH GL51)
  - Extrapolation of a longer shelf life than is evidenced in the data can be considered provided that, if approved, confirmatory data will be submitted at a later date
- Introduction of the interim shelf life option for products with limited data
  - Existing internal policy made added to the guidance
- Introduction of the expectation of a commitment to an ongoing stability programme
- Further guidance on choice of batches of product to use stability trial work throughout

Key Changes in the Revised Guidance

6.10 In-Use Stability

- Overall, expansion and more detail on existing expectations for in-use stability for multi-dose packs, in-feed products, and in-water products
- Clarity on:
  - That in-use stability is expected for all multi-dose packs, not just sterile and/or parenteral products (existing requirement)
  - Expectations around types of feed to use and timing for in-feed stability trials, and mixing/solubility for in-water stability trials
  - Expectation that the findings of the in-use stability trials are applied to product label storage and use instructions as applicable

Guidance Section 7: Variations

Guidance
7.1 Changes to approved formulation details
7.2 Changes to approved active ingredient manufacturers
7.3 Changes to approved active ingredients and functional active ingredients
7.4 Changes to approved excipient ingredients
7.5 Changes to approved formulated product manufacturers
7.6 Changes to the manufacturing process and quality control
7.7 Changes to the finished product specifications or test methods
7.8 Changes to product packaging
7.9 Changes to formulated product shelf life and storage conditions

Guidance Section 7: Self-Assessable Changes

- **Introduction of self-assessable changes**
  - Case-by-case guidance of when self-assessable changes can apply, and how to manage them
  - Overall, they are actioned based on the registrant's risk assessment and the product information is updated at the next variation or registration renewal
  - Allowable changes in certain circumstances: removal of a manufacturer, removal of a testing site, tightening of specification parameters and batch sizes within the approved range, some other changes to pharmacopoeial standards and specifications, adding pack sizes within an approved range, and shortening of a shelf life

Appendices

Standard	Guidance
Appendix: Declaration for stability exemptions	Appendix 1: Product Types
Annex 1: Definition of formulation types	Appendix 2: Formulation Types
Annex 2: Veterinary medicine ingredient specifications for cited chemicals	Appendix 1: Expected release and expiry specifications by product and formulation type
Annex 3: Shelf life exemptions for veterinary medicines	Appendix 4: Checklist for new product submissions
Annex 4: Recommended chemical and physical parameters for stability studies based on dosage form	Appendix 5: Evidence of GMP certification recognised [working title]

Appendices

- **Appendix 1: Product types**
  - Provides the MPI definitions for the different product types as requested in the PDS
  - Includes the newly agreed definitions for antibiotic, antifungal, antimicrobial, antiprotozoal, antiseptic, and antiviral
- **Appendix 2: Formulation Types**
  - Updated and expanded from Annex 1 in the current Standard
- **Appendix 3: Expected release and expiry specifications by product and formulation type**
  - Updated from Annex 4 in the Standard, and expanded to include more detailed release and expiry information

Appendices

- **Appendix 4: Checklist for new product submissions**
  - Provides a one-page summary of the different sections for quick reference when compiling submissions

- **Appendix 5: Evidence of GMP certification recognised [working title]**
  - When finished, this Appendix will provide more detailed guidance regarding international GMP certificates, submission expectations, and other GMP-related information

Thank you!

New Zealand Food Safety
Haumaru Kai Aotearoa

Antibiotic Sales **Report**

- Why report it?
- How the data is compiled
- Recommendations to improve submission of data
- Trends from 2017 report

Why we report sales

- To encourage prudent use
- To support the interpretation of patterns and trends
- To assess the impact of use on animals and humans
- To identify which classes should be reserved for critical cases
- To satisfy international requirements including OIE – World Organisation for Animal Health

How the information is compiled

- Sales reported to MPI are converted to the amount of active sold

- Information is then converted to:
  - Sales per antibiotic class
  - Sales per species (information limited)
  - By route of administration

Industry Feedback

- A preliminary sales report is presented to industry for feedback
- Feedback helps explain the patterns and trends evident

Feedback is important for:

1. Providing context
2. Informing data analysis

Final Report

Following consultation with:

- Registrants
- The agricultural sectors and
- Veterinarians

1. The comments are collated and
2. Report is adjusted prior to publication

The future: improving data submission

What MPI will now do:

- We will now supply an excel spreadsheet

What we're asking of you:

- List products with multiple pack sizes separately
- Be careful with the use of decimal points and commas
- Report 'Nil' sales per month as '0'
- Make it clear if the product registration changed hands
- Make sure you submit the correct numbers!

Product name	Registration Number	Product Type	Quantity	Unit	January	February	….	Total	Notes
Example product, 100 per pack	A012345	Tablets	300	100	50	60		300000	De-registered in June 2019

2017 sales trends: summary

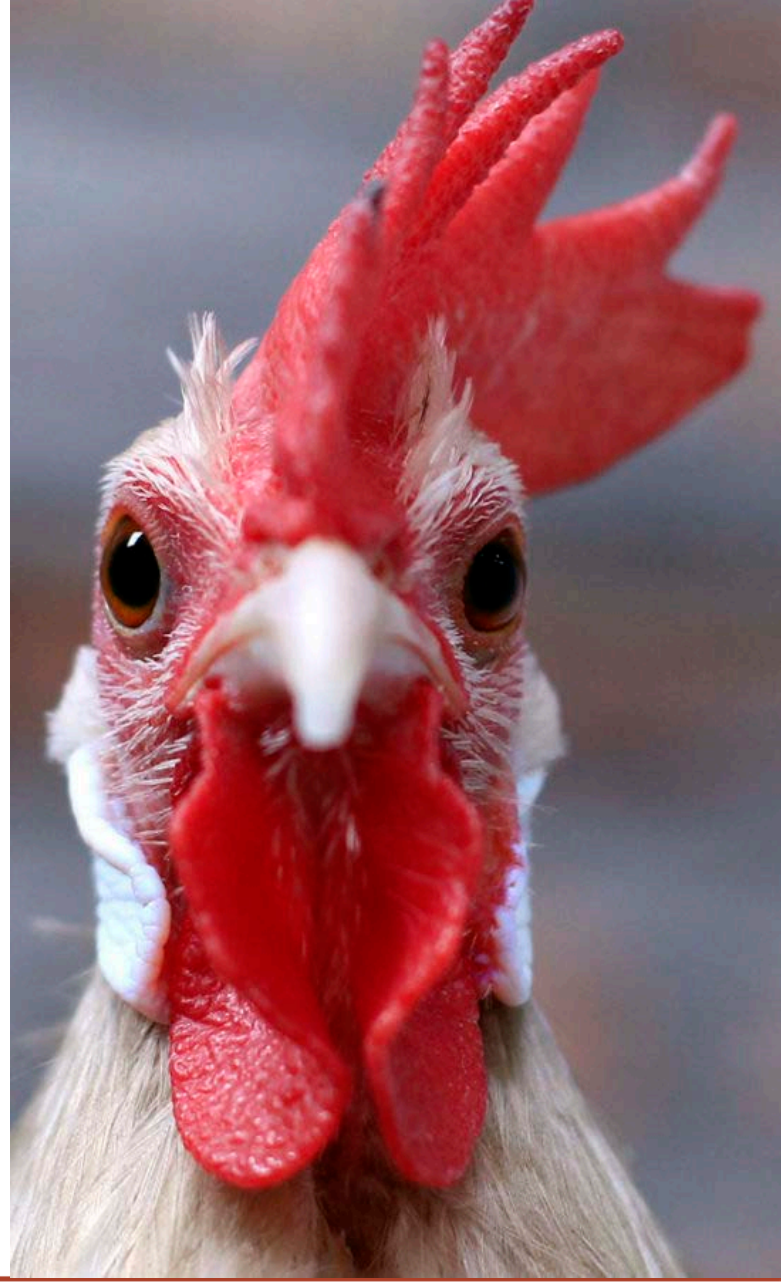
- The report covers the period from Jan 1st to Dec 31st 2017
- Data compiled came from 251 trade name products
- Compared to 2016, sales increased by 3%
- 4 of the 5 classes of antibiotic listed as ‘critical’ by WHO increased in quantities sold including:
    - 3rd and 4th Gen Cephalosporins
    - Macrolides
    - Fluoroquinolones
    - Penicillins
- Aminoglycosides decreased in sales by 17%, wholly due to a reduction in use in plants.

2017 sales trends: **Cephalosporins**

- **3rd generation cephalosporins increased by 16%**
  - Total sold was 303 kg
  - 90% sold contained ceftiofur
  - All ceftiofurs are injectables
  - Registered for use in multiple production species
- **4th generation cephalosporins increased by 58%**
  - Total sold was 2kg

2017 sales trends: **Macrolides**

- Sales increased by 5%
- Total of 7,262kg sold
- 96% sold included the active tylosin
    - 49% of tylosin-based products registered for use in pigs, poultry and cattle via feed
- Increase in sales due to an increase in the sales of the actives:
    - oleandomycin (↑213%)
    - spiramycin (↑113%)
    - tilmicosin (↑38%)
    - tylosin (↑3%)
- While the percentage increase of oleandomycin and spiramycin are large, the overall quantities sold were actually small at 36kg and 55kg respectively



2017 sales trends: **Fluoroquinolones**

- Sales of this class increased by 1%
- A total of 42.5kg was sold
- 15kg of that was registered for use in companion animals
    - There was an 11% reduction in quantities sold compared to 2016
- The remainder (27.5kg) was registered for use in cattle only or pigs and cattle
    - Sales of products registered for use in cattle increased by 28%
    - Those registered for use in pigs and cattle increased by 8%

2017 sales trends: **Critically important Penicillins**

This category includes:

Amoxycillin, ampicillin, penethamate, penicillin G Benzathine, Peniciliin G procaine

- 14,419kg sold in 2017
- That's a 9% increase compared to 2016
- Mostly injectables registered for use in multiple species and containing the active penicillin G
- Penicillins registered for use in companion animals comprised 3% of critically important penicillins sold and all contained the active amoxicillin
- Cloxacillin is the only penicillin active registered for use in New Zealand which is not considered critically important

In summary

- 58% sold registered for use in feed
- 28% sold injectable (an 11% reduction compared to 2016)
- Half sold are registered for use in pigs/poultry
- 20% sold was registered for use in multiple species
- It difficult to tell whether the increase in sales could be offset by an increase in the animal population

Next steps

The 2017 draft report was sent out at the end of June

We are seeking your comments on:

1. Changes in the national animal population which could influence sales
2. Specific disease challenges
3. Changes in management practices

Timeframes

- Comments are due soon: by **August 2nd**
- The report is due to be finalised and published **October 2019**
- The first draft of the 2018 report is due by the **first quarter of 2020**

New Zealand Food Safety
Haumaru Kai Aotearoa

Generic Applications

Establishing Therapeutic Equivalence based on Pharmaceutical Equivalence

ACVM Workshop
24 July 2019

Ministry for Primary Industries
Manatū Ahu Matua

Important definitions

Therapeutic equivalence:

- two TNPs are pharmaceutically equivalent; and
- after administration of the same molar dose, their effects with respect to both efficacy and safety are essentially the same, as determined by appropriate in vivo bioequivalence or in vitro studies

Important definitions

Pharmaceutical equivalence:

- two TNPs contain the same active ingredient(s) manufactured to meet the same or comparable compendial standards; and
- same dosage form; and
- administered via the same route; and
- and are identical in active concentration or strength

Important definitions

Similar Products:

- Pharmaceutically equivalent products, and
- are administered at the same dose rate to the same target animal for the same clinical indications with the same label instructions, and
- The non-active ingredients in the test formulation are likely to have similar properties and be present in similar proportions as the reference product

Important definitions

Closely similar products :

Similar products that also:

- contain the same or equivalent non-active ingredients at the same or equivalent concentrations, or
- *if* non-active ingredients are not the same or equivalent, differences are minor and will not affect product quality or biological activity,
- *and* the product specifications and physicochemical properties are the same or equivalent or, if different, will not adversely affect product quality or biological activity

Methods to establish equivalence

1. Chemical Equivalence
2. Biological Equivalence
3. Pharmaceutical Equivalence

Methods to establish equivalence

CHEMICAL EQUIVALENCE

- Quantitively and qualitatively identical formulations from same source, and
- formulated at the same manufacturing plant using the same manufacturing procedures, equipment and quality controls, and packaged in the same container material(s).

- ONLY difference is the trade name

Identical ACVM Act risk profiles

Methods to establish equivalence

BIOLOGICAL EQUIVALENCE

- Two veterinary medicines are bioequivalent when the rate and extent of absorption of the same molar dose of the active ingredient(s) or therapeutic moiety as determined by comparison of measured parameters (e.g. active concentration in blood or pharmacological effect) is demonstrated to be similar (within predefined limits), when administered under similar experimental conditions.

- Bioequivalence studies
    - Blood level
    - Pharmacological end-point
    - Clinical end-point

Methods to establish equivalence

PHARMACEUTICAL EQUIVALENCE

- For some dosage forms bioavailability/efficacy is minimally dependant on the product formulation and pharmaceutical equivalence together with *in vitro* data and robust scientific argument may be sufficient to support therapeutic equivalence and enable cross reference of efficacy data held by MPI for the reference product.

- For a limited number of dosage forms where bioavailability/efficacy is moderately formulation dependant (e.g some immediate release solid oral dosage units), an *in vitro : in vivo* correlation may exist negating the need for i*n vivo* studies.

Methods to establish equivalence

PHARMACEUTICAL EQUIVALENCE

- Most applicable to ‘closely similar’ products
- Where possible, differences in product formulation, manufacturing process, specifications or physiochemical properties must be identified.
- Data and argument must be provided supporting the conclusion that any differences observed will be clinically insignificant

The reference product

- ‘Similar’ product registered by MPI

- Innovator registration
  - First generic registration if innovator not available

  - BUT IN ALL CASES SHOULD have history of safe and effective field use in NZ.
  - Use in published clinical trials with confirmed efficacy for clinical indications sought is a good basis for use.

  - If uncertain, review available products and seek advice from a consultant once a candidate has been selected. If necessary MPI may be contacted.

Pharmaceutical equivalence – When it may apply

1. Reformulated generics
   - Same manufacturer
   - Differs *only* in dyes, flavours, preservatives, or any excipient that is recognised not to influence bioavailability.

2. Simple aqueous solution (when administered)
   - IV, IM, SC, oral, dermal, ophthalmic or aural route

3. Aqueous IV solution
   - Same API as reference product
   - No inactive ingredients that interact with API (complex) or otherwise alter disposition of API

Pharmaceutical equivalence – When it may apply

4. Solution – IM or SC injection or Systemically acting topical
   - Same API at the same concentration
   - Same type of solution
   - Identical or similar excipients at identical or similar concentrations.
   - PC properties need to be the same
   - *Must justify if there are any differences in excipients and/or their concentrations that they will* ***not*** *alter bioavailability*
5. Aqueous oral solution (at administration)
   - Same API at the same concentration
   - Standard excipients
   - Excipients that may affect GI transit, absorption, solubility or *in vivo* API stability must not be present or if present are to be the same as found in the reference product

Pharmaceutical equivalence – When it may apply

6. Medicated premix containing a soluble API
   - Acts as aqueous solution *in vivo*

7. Simple topical solution intended for local therapeutic effects
   - ophthalmic, otic, nasal, dermal

8. Inhalant volatile anaesthetic
9. Solution that does not contain pharmacological API's
   - Lubricants
10. Oral dosage form not intended to be systemically absorbed
    - Radio-opaque media

Pharmaceutical equivalence – When it may apply

11. Identical Products
    - Identical APIs, excipients, manufacturing processes and PC properties
    - Acts as an aqueous solution *in vivo*

12. Solid or Semi-solid oral immediate release dosage form with systemic action
    - Criteria *based upon* human BCS
    - API has high solubility and permeability (in Target animal) – Class I
    - (Maybe API has high solubility and low permeability) – Class III
    - Products are very rapidly dissolving (>85% in 15 minutes)
    - Excipients that may affect bioavailability are qualitatively and quantitively the same.

Pharmaceutical equivalence – When it may apply

13. Solid oral dosage forms with multiple strengths where BE has been shown for one (usually the highest) dose strength.
    - The products are manufactured using the same processes.
    - The composition of all formulations are qualitatively identical.
    - The ratio between concentrations of active ingredient(s) and excipients among the different strengths is identical (proportional formulations).

If not proportional composition may consider if:

- the amount of API(s) is less than 5 % of the tablet core weight/capsule content and,
    - the amounts of the different core excipients or capsule content are the same for the concerned strengths and only the amount of active substance is changed; or
    - the amount of a filler is changed to account for the change in amount of API. The amounts of other core excipients or capsule content should be the same for the concerned strengths.

Information requirements

1. Justify choice of nominated similar/closely similar reference product
   - documentation that active ingredient(s) plus strength/concentration, dosage form, administration route, and label clams for the test and reference product are the same
2. Where possible provide a side-by-side comparison of the test and reference product formulations, both quantitative and qualitative, if this information is available for the reference product;
3. Provide comparative physicochemical testing of a minimum of two batches of the test product and the NZ reference product using the proposed release specifications and test methods developed for the test product;

Information requirements

4. comparative impurity profiles for a minimum of two batches of test active ingredient, test product, and reference product using a methodology with adequate specificity;

5. active ingredient aqueous solubility;

6. additional testing for solutions could include comparative pH, viscosity, specific gravity determinations, or any test that may be relevant to compare the test and reference product;

Information requirements

7. Soluble powders and medicated premixes
   - FDA GFI # 171 (currently withdrawn and being rewritten)

8. Immediate release solid and semi-solid oral dosage forms
   - EMA /CVMP /016/2000-Rev 3 Appendix 1

     MUST PROVIDE
     pH-solubility profile for the API
     Data pertaining to absorption/permeability of the API
     In vitro dissolution data for test and reference product
     Excipients should be similar Esp for consideration of BCS - Class III APIs

Information requirements

9. scientific discussion should include the rate limiting steps in absorption of the active ingredient(s) for drugs with systemic action, or for the active ingredient achieving access to the site of effect if applicable;

10. provide relevant scientific argument to justify the case for equivalence based on pharmaceutical equivalence without in vivo studies and consider the clinical consequences of therapeutic inequivalence.

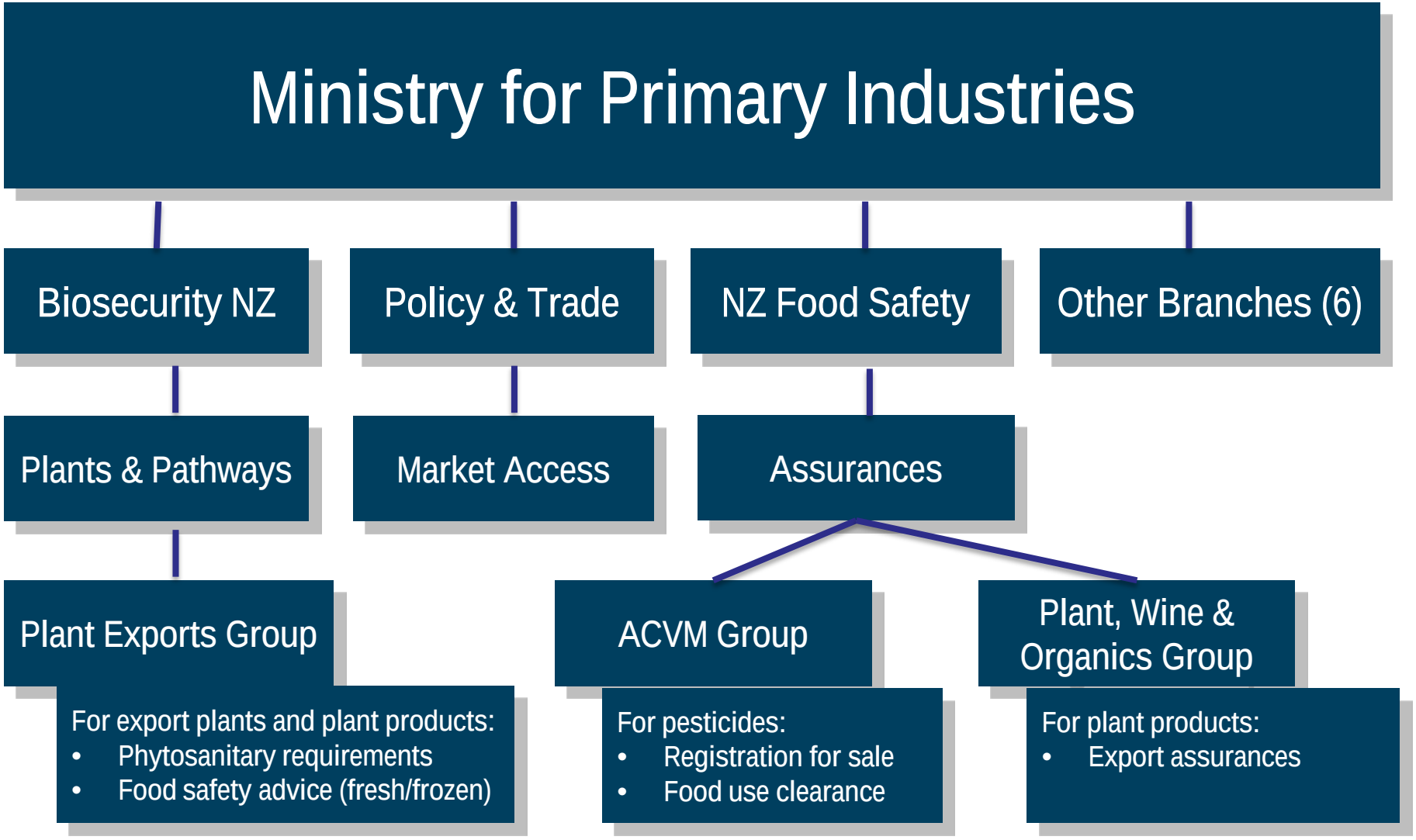
Questions?

Ministry for Primary Industries
Manatū Ahu Matua

Pesticide Residues in Food of Plant Origin MPI Involvement

ACVMG Workshop– July 2019

Dave Lunn
Principal Adviser (Residues)


Ministry for Primary Industries
Biosecurity NZ
Policy & Trade
NZ Food Safety
Other Branches (6)
Plants & Pathways
Market Access
Assurances
Plant Exports Group
For export plants and plant products:
• Phytosanitary requirements
• Food safety advice (fresh/frozen)
ACVM Group
For pesticides:
• Registration for sale
• Food use clearance
Plant, Wine & Organics Group
For plant products:
• Export assurances

ACVM Group - Food use clearance

For a new food use clearance (label claim), ACVMG:

- Confirms the proposed Good Agricultural Practice (GAP)
- Evaluates residue data to estimate expected residues at harvest when GAP is observed
- Decides if the dietary exposure to these residues is safe (below HBGVs)
- Promulgates NZ-MRLs to support GAP-compliance
  - Primarily for domestic food crops but also apply to exported food
- Approves the proposed label claim (GAP)

Plant Exports Group – Food safety advice (MRL Database)

- MRLs differ from country to country because:-
  - They are set to reflect (and enforce) national GAPs
  - These national GAPs differ from country to country
    - Depending on the range of pesticides available
    - What pests and diseases are present
    - Differing national growing and spraying practices
- NZ exporters need to comply with these MRLs
- MPI advice includes a database of MRLs for:
    - all NZ-registered pesticides, in 22 countries, for 56 plant commodities

Link: https://www.mpi.govt.nz/growing-and-harvesting/plant-products/pesticide-maximum-residue-levels-mrls-for-plant-based-foods/

MPI pesticide maximum residue limit database

This database has the maximum residue limits (MRLs) allowed for most pesticides used on our major fruit and vegetable export crops in New Zealand. Exporters can use this database to find out the residue limits in our main markets.

Select at least 2 criteria to search on:

Country:
Taiwan

Pesticide:
Select Pesticide

Crop:
Cherries

Select Criteria: Country - Taiwan; Crop - Cherries

Country	Pesticide	Crop	MRL (mg/kg)
Taiwan	1, 3-DICHLOROPROPENE	FRUIT	ND
Taiwan	1-NAPHTHYLACETIC ACID	FRUIT	Exempt
Taiwan	2,4-D	Cherries	0.20
Taiwan	ABAMECTIN	Cherries	0.09
Taiwan	ACEPHATE	STONE FRUIT	1.00
Taiwan	ALDRIN (Env contam)	FRUIT	ND
Taiwan	ALPHA-CYPERMETHRIN	STONE FRUIT	2.00 [15]
Taiwan	AZADIRACHTIN	FRUIT	Exempt
Taiwan	AZOXYSTROBIN	Cherries	1.00
Taiwan	BACILLUS SUBTILIS	FRUIT	Exempt

Items per page:
10

« ‹ 1 2 3 4 5 6 7 ... 12 › »

Note no	Note description
Taiwan	DoH MRL List - Appendix Table 1 - updated on 28 June 2019. Draft MRLs to SPS 503 (July 2019). Default MRL is Limit of Determination. Updated July 2019
6	MRL based on Limit set for peaches
7	Sum of isomers or enantiomers or diasteriomers
12	Expressed as MBC (Carbendazim)

National MRLs for Cherries

Country	Pirimicarb (mg/kg)	Boscalid (mg/kg)
Codex	3.0	3.0
Australia	0.5	3.5
Canada	0.1	1.7
China	0.5	None set
European Union	5.0	4.0
India	None set	None set
Japan	0.5	3.0
New Zealand	1.0	3.0
Singapore	None set	None set
Taiwan	3.0	1.7
Thailand	None set	None set
USA	None set	3.5

Plant Exports Group – Food safety advice (Suggested Export PHIs)

To comply with trading partner MRLs, growers need to know what pesticides to use and what pre-harvest intervals (PHIs) to observe

- Where trading partner MRLs are the same (or higher) than NZ MRLs, growers can base their pest management programmes on NZ label claims and withholding periods
- In many cases, trading partner MRLs are lower than NZ MRLs (or do not exist), and MPI offers advice on suggested Export PHIs
  - Based on assessments of available JMPR, EFSA, APVMA, PMRA, ACVMG residue summary reports
  - Provided to major producer groups for reference when designing pest management programmes for their growers

Support from pesticide registrants

To ensure growers get the best advice on how to comply with trading partner MRLs, registrants could:

- Include additional plot treatments in residue trials to show what PHI would be needed to comply with lowest trading partner MRL (maybe ‘zero’ or <0.01 mg/kg)
- Consider label claims that reflect domestic GAP and develop separate recommendations for export crops
- Support the CropLife globally harmonised GAP concept
  - Availability of a global supporting residue data set
  - Contribute to the establishment of Codex MRLs

Vertebrate Toxins

A Review of the Conditions and Controls imposed by ACVM on the Registration of Vertebrate Toxins

ACVM

Responsibilities lie with ensuring that VTA are

- manufactured,
- assigned "Trade Names",
- traded, and
- used in accordance with the requirements of the ACVM Act.

That the controls adequately manage the risk from an ACVM perspective i.e.

- public health (above and beyond the EPA),
- animal welfare,
- trade in primary produce & ag security, and also
- ensure use of ag compounds does not result in breaches to domestic food standards and ensure provision of appropriate consumer info.

EPA responsibilities centre on environmental protection and immediate safety of people and communities, and the use of VTA that it considers to be hazardous substances.

Rationale

- The conditions for the use of VTA's do not fully consider the extent to which these products would be used in areas that livestock are grazed.
- The conditions give little guidance on how to manage VTA, when used in on-farm situations.
- The current controls no longer adequately manage the risks involved with the use of VTA's as specified by the ACVM ACT.

Reviews & Audits

- Amounts of anticoagulant VTAs used in NZ are not accurately known
  - The ubiquitous sale of VTA by/to non approved persons
  - Registers of Sales not being kept
- More VTA bait is being applied than is needed to effectively control targeted pests
- High concentration bait formulations being used inappropriately or off-label
- Current label-compliant uses are resulting in detectable residues in some wildlife and livestock
- Failure by registrants / users to provide an notification of adverse events

Process

- Identify the gaps in the process that are used to manage the risks involved with the use of Vertebrate Toxins and propose changes.
- Brodifacoum reassessment
- Reassessment of all other anti-coagulant VTA’s
- Reassessment of VTA’s

End User Definitions

- Public Use – Non-professional users (e.g. householders)
- Professional – persons who normally uses VTAs as part of their business or for commercial purposes
- Conservation & TB eradication uses
  - Government Departments, Councils, Organisations operating conservation parks, mainland islands, island reserves, and national parks
  - Contractors and volunteers directly engaged and supervised by persons from the organisations listed above.
- Aerial Distribution – persons who normally uses VTAs as part of their business or for commercial or conservation purposes.

Highlights

- Classifications
  - Public Use – restricted to pack sizes less than 300g
  - Professional Use – restricted to 100 Kg
  - Conservation / TB – No size limit
  - Aerial Distribution – No size limit
- Sales
  - Quantities less than 300g can be sold by retail outlets
  - Quantities greater than 300g can only be sold by
    - The registrant of the product
    - An organisation holding an approved ACVM Operating Plan
    - Detailed records of sales are required (including photo ID)

Highlights

- Application
  - Bait stations only (Domestic use)
  - Bait stations (Professional & Conservation purposes)
  - Hand baiting of cyanide and pindone (Professional & Conservation purposes)
  - Aerial Delivery (Professional & Conservation purposes)
    - Hand baiting within 10 m of a boundary
- Certifications for sale to, or use of >300g
  - a Controlled Substance licence (mandatory for HSNO classes 6.1A and 6.1B e.g. sodium fluoroacetate, cyanide, Cholecalciferol, Zinc Phosphide, PAPP) and / or
  - NZQA unit standard XXXX (mandatory for vertebrate toxic agents not covered by 4a. e.g. the anticoagulant type VTA's and α-Chloralose). A CSL is also acceptable for these compounds.

Highlights

- Responsibility for VTA
  - Public Use – User
  - Professional – Applicator
  - Conservation / TB – Purchaser
  - Aerial – Purchaser
- Responsibilities Include
  - Compliance with all label requirements
  - Carcase removal
  - The position of all bait stations must be mapped
  - All bait stations / spilled baits must be monitored and removed at the end of the baiting program.
  - Adverse events notifications
  - Poison Use Statements

New Zealand Food Safety
Haumaru Kai Aotearoa

Ag Chem / VTA breakout session

ACVM Workshop
24 July 2019

Ministry for Primary Industries
Manatū Ahu Matua

Suggested Topics

SWNZ application rates – update

Draft labelling guide

Q & As

Application rates update

We understand that SWNZ has been requesting that registrants include a rate/100m row on their labels, as well as the rate/100L water that we recommend.

(See the Agricultural label rates position statement on our website)

Update: SWNZ has committed to providing us with their preferred application rate statement and we will seek advice and consult on this.

Labelling guide draft

Document history

Version Date	Section Changed	Change(s) Description
April 2017		
xxxx 2019	All	Change from Requirements to Guidance document Correction of residue statement Addition of 'date of manufacture' requirement Clarification of slaughter interval statement Clarification of application rate presentation for horticultural crops


New Zealand Food Safety
Haumaru Kai Aotearoa
Any other questions?
Ministry for Primary Industries
Manatū Ahu Matua

Common questions

-**Chemistry and Manufacturing**

We will ask about any changes from previous approval (i.e. batch size, manufacturing concentration) that may require explanation instead of remaining silent.

-**Residues, efficacy and crop safety**

Ensure you are providing arguments for any extrapolation (eg different claims, relevance of overseas data etc).

The registrant should make these arguments, not the data assessor.