WA Premier tells Port Hedland council 'stick to knitting' after anti-COVID vaccine motion passes

By Charlie McLean and Jessica Shackleton

ABC Pilbara Public Health

Mon 14 Oct 2024 at 8:22pm

In short:

A majority of councillors in Port Hedland, in WA's north-west, have voted in favour of a motion calling for an "immediate suspension" of mRNA COVID-19 vaccines.

The motion cited unverified claims that Pfizer and Moderna vaccines are contaminated with DNA fragments.

What's next?

The motion also called for council administrators to write to the Prime Minister and national health authorities over the issue.

The Western Australia Premier has told a council in the state's north to "stick to its knitting" after it passed a motion urging state and federal governments to suspend some COVID-19 vaccinations.

The Town of Port Hedland held a special council meeting on Friday and has instructed its chief executive to write to authorities nationwide to immediately stop the use of Pfizer and Moderna vaccines.

The council motion was centred on an unverified study from Canada in 2023 which found "high levels of residual plasmid DNA present in the Pfizer and Moderna COVID-19 modified mRNA vaccine".

The Canadian study claims to confirm earlier findings by US molecular biologist Dr Philip Buckhaultz, but those findings have been debunked by fact-checking organisation AAP FactCheck.

Premier Roger Cook said the Port Hedland council had gone "off the rails" by spreading the unverified claim.

"The Town of Port Hedland should stick to its knitting," the Premier said.

"It should stay focused on the services and people of that community.

"It's another example of that council lacking the focus on the issues which matter to their constituents ... making sure they look after the people, not get distracted by these silly ideological debates."

The Town of Port Hedland councillor who put forward the motion, Adrian McRae, ran as a candidate for the Great Australia Party, which campaigned against vaccine mandates at the 2022 federal election.

He made headlines earlier this year over his appearance on Russian state television endorsing the transparency of Vladimir Putin's election victory.

Cr McRae agreed that weighing in on national vaccine policy was not the council's job, but said state and federal governments had failed to take

community concerns about the safety of COVID vaccines seriously.

Councillor Adrian McRae made international headlines in March after appearing on Russian state television endorsing Vladimir Putin. *(ABC News: Charlie Mc Lean)*

Vote doesn't represent community, says Mayor

Mayor Peter Carter and councillor Ambika Rebello were the only two councillors to vote against the motion, which passed 5-2.

"It's not the place for local government to do this sort of work," Cr Carter said.

"They're saying, 'well, it's for the community', well, the community is 17,000 people and we had 50 odd people in the gallery. That does not represent the whole community."

The motion also asked the council's administrators to write to the Prime Minister and national health authorities drawing attention to the issue.

The council's administration warned proceeding with the letter was almost certain to result in extreme reputational and financial impact.

Port Hedland's Mayor said the motion wasn't a good look for the town, which is home to the country's most valuable export terminals. *(ABC News: Charlie Mc Lean)*

Cr Carter said the motion was not a good look for the town.

"You're trying to build relationships with the state government, the federal government," he said.

> **"We're a very important town and this motion that was put forward ... it shouldn't have even been there."**

Cr Carter has faced his own controversies in recent years, including corruption allegations over his personal business dealings, inappropriate comments about a woman's mental health, and is engaged in defamation action against a fellow councillor.

Editor's note 21/10/2024: This article has been updated to provide additional information about claims surrounding COVID-19 vaccines.


Australian Government
Department of Health
and Aged Care
TODAY'S NEWS
Tuesday, 15th October 2024

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MINISTER BUTLER

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Port Hedland Council carries vaccine contamination motion

Albany Advertiser, Other, 14/10/2024, Cain Andrews

Port Hedland Council has voted to call for the immediate suspension of Moderna and Pfizer COVID vaccines at a special council meeting. on Friday night (October 11). [...] The town's chief executive is also tasked with sending a letter to WA Health Minister Amber-Jade Sanderson and Commonwealth Health Minister Mark Butler requesting public responses to the claims of alleged DNA contamination in Pfizer and Moderna vaccines.

Also reported by: North West Telegraph (Online), Augusta-Margaret River Times (Online), West Australian (Online), South Western Times (Online), Busselton Dunsborough Times (Online), Countryman (Online), Albany Advertiser (Online), Geraldton Guardian (Online), Narrogin Observer (Online), Manjimup-Bridgetown Times (Online), Harvey-Waroona Reporter (Online), Pilbara News (Online), Great Southern Herald (Online), Broome Advertiser (Online), Augusta-Margaret River Times (Online), West Australian (Online)

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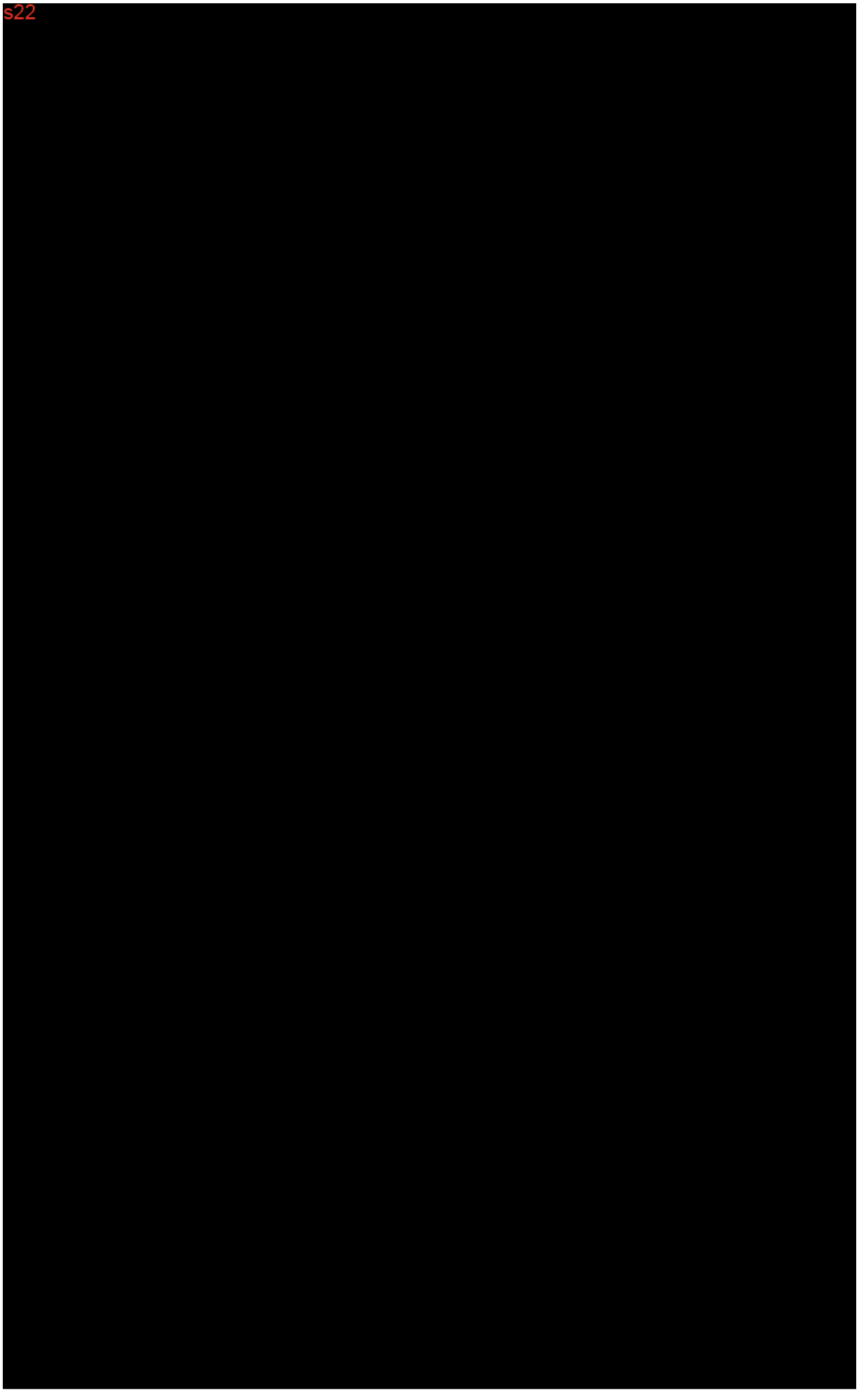
WA Premier tells Port Hedland council 'stick to knitting' after anti-COVID vaccine motion passes

Document 2

ABC Online, Other, 14/10/2024, Charlie Mclean & Jessica Shackleton

The Western Australia Premier has told a council in the state's north to "stick to its knitting" after it passed a motion urging state and federal governments to suspend some COVID-19 vaccinations. [...] The DNA argument surfaced during the pandemic and has been discredited by several international bodies and the Australian Department of Health and Aged Care.

Read More



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THERAPEUTIC GOODS ADMINISTRATION

s22

[redacted]

s22

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6PR, Afternoons, 14/10/2024, Julie-anne Sprague

The WA Premier has slammed the Port Hedland Council for passing a motion calling for the immediate suspension of COVID-19 vaccines. The motion, tabled by controversial councillor Adrian McRae, is based on a report from a Canadian virologist claiming DNA contamination in the Pfizer and Moderna vaccines can lead to cancer or altered DNA. The report has been debunked by the Therapeutic Goods Administration.

Play Now

Back to Top

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Document 2

Prepared by Isentia

isentia

From: s22
To: s22 ; s22
Cc: KERR, Lisa; s22 ; s22 ; s22 ; s22
Subject: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date: Wednesday, 9 October 2024 5:58:46 PM
Attachments: image001.png

Dear s22 and s22 (s22 and s22

Lisa has put together a draft statement (for publication), to address enquiries related to DNA contamination in mRNA vaccines (please see TRIM document D24-4291794)
The aim of this publication is so we can refer any future enquiries regarding this subject directly to this statement.

Please review and provide any input with track changes by **10am Thursday 10th October (tomorrow)**. Just to note, we will be seeking input from Tox, PVB and our legal team before it goes out.

Thank you!!

Kind regards

s22

s22
Laboratories Business Operations Section

Medical Devices and Product Quality Division | Health Products Regulation Group
Laboratories Branch
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: TGA, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

DRAFT Statement - mRNA vaccines are not contaminated with DNA

Allegations

The risks with residual DNA are greater for the COVID vaccines because the LNPs deliver the residual DNA straight into the cell.

Residual DNA integrates into the human genome causing transgenic babies, cancer and disrupted biological processes.

The TGA is aware of claims from individuals and medical societies that the COVID vaccines are allegedly contaminated with DNA. This is not the case.

History of Biotechnology Products

- DNA is an approved starting material for biotechnology products including recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies and vaccines.
- The first biotechnology products produced using recombinant DNA technology were marketed globally in the early 1980s.
- *Residual* DNA is the amount of DNA remaining after digestion and filtration of the medicine. It is present in small fragments in the final mRNA COVID-19 vaccines in very small quantities (less than 10 ng per dose as recommended by the World Health Organization, United States Food and Drug Administration and other regulatory agencies). Residual DNA in biotechnology products has been the topic of international regulatory discussions since the 1990s.

Safety of DNA in Biotechnology Products

- Manufacturers take steps in the manufacturing process to digest and purify out DNA.
- The ability of the manufacturer to remove DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other regulators prior to marketing approval.
- The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every batch of the mRNA vaccines released in Australia have met the requirements for residual DNA. To date we have also independently tested 27 batches of the vaccine by qPCR to monitor the residual DNA results from the manufacturers. Our results show that the amounts of residual DNA are below 10 ng per dose, which is the regulatory limit.
- Any residual DNA in the mRNA vaccine cannot integrate into human DNA without an enzyme called integrase. The mRNA vaccine does not contain integrase. Integrase is not present in mammalian species.
- Humans are exposed to much greater quantities of foreign DNA all the time from bacterial and viral infections, compared to the minute amount from DNA fragments in mRNA vaccines or biological medicines.
- The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There is no evidence to indicate that COVID-19 vaccines have increased rates of cancer at a population level.

Page: 2

Number: 1 Author: KERR, Lisa Date: 9/10/2024 5:03:00 PM

Needs comments from Tox and PVB about residual DNA not causing:
Transgenic babies
Cancer
Disrupted biological processes

Reports and publications alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amounts of DNA in the COVID vaccine. To date these reports fall short of the scientific rigor expected in pharmaceutical testing. Common concerns with these studies include:

- **Results interpretation**. Some laboratories have chosen to report DNA levels using test fluorometry, that is known to overestimate DNA levels in the presence of mRNA. The instructions for use for the components of this test actually warn the user of this problem [ref]
- **Small sample number**: some of these studies use a very small number, for example only three vials.
- **Suitable samples**: these studies have used samples that are well past their use by date. These samples are not suitable for testing. The TGA does not test expired samples for batch release.
- **Sample traceability**. It is unknown where vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- **No cold chain**. Vaccine vials are required to be shipped via cold chain, or in other words, the temperature must be within a specified range and it must be monitored. The vials that are shipped to Australia must adhere to these requirements and the TGA checks that this is done. The samples used in the small laboratory studies are not kept in cold chain and usually do not have temperature loggers with them.
- **Unvalidated method**. Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purposes. The guideline used by the TGA to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which provide performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity.
- **Inappropriate reference material**. The reference materials are not characterised.
- **Laboratory status**. The accreditation status the small laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor does it appear to have accreditation to ISO 17025, the international standard for testing and calibration laboratories.

The TGA is constantly reviewing the latest scientific evidence about the safety of vaccines and other biotechnology products. This statement represents the TGA's views on the scientific evidences as at [DATE]

From:	s22
To:	s22 ;s22
Cc:	KERR, Lisa; s22 ;s22 ; s22 ; s22
Subject:	RE: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 10 October 2024 10:05:38 AM
Attachments:	image001.png

Hi all,

We have added some comments to the document for Lisa's consideration.

Thanks

s22

From: s22 <s22 @health.gov.au>
Sent: Wednesday, October 9, 2024 5:59 PM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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Laboratories Branch

Australian Government Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted]@health.gov.au
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Summary of Comments on D24-4291794 (Revision 5) DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.pdf

Page: 1

Number: 1 Author: s22 [redacted] Date: 10/10/2024 10:03:00 AM
Digestion although correct technically - leaves it open to interpretation by the general public.
should we use cleaved or fragmented as an alternative.

Number: 2 Author: s22 [redacted] Date: 10/10/2024 8:34:00 AM
DNA digestion and purification

Number: 3 Author: s22 [redacted] Date: 10/10/2024 9:13:00 AM
Should we specifically include TGA as well before other agencies?

Number: 4 Author: s22 [redacted] Date: 10/10/2024 9:25:00 AM
COMIRNATY or SPIKEVAX? Or should it state 'mRNA COVID-19 vaccine'?

Number: 5 Author: KERR, Lisa Date: 9/10/2024 5:03:00 PM
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Page: 2

Number: 1 Author: s22 [redacted] Date: 10/10/2024 9:39:00 AM
Should add a few words like: ‘stated in the external studies’ ?

Number: 2 Author: s22 [redacted] Date: 10/10/2024 9:42:00 AM
Should it be ‘do they’ since there are multiple studies

From:	s22
To:	s22 ; s22
Cc:	KERR, Lisa; s22 ; s22 ; s22 ; s22
Subject:	RE: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 10 October 2024 9:44:58 AM
Attachments:	image001.png

Hi All,

I have provided my feedback using track changes and comments in the TRIM document. It is now checked into TRIM.

Please let me know if anything else is needed.

Regards

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Sent: Wednesday, October 9, 2024 5:59 PM
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Cc: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 s22 @Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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Commented s22 DNA digestion and purification

Commented s22 Should we specifically include TGA as well before other agencies?

Commented s22 COMIRNATY or SPIKEVAX? Or should it state *COVID-19 vaccine*"?

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Commented [KL4]: Needs comments from Tox and PVB about residual DNA not causing:
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Commented [s22]: Should add a few words like: *'stated in the external studies'* ?

Commented [s22]: Should it be *'do they'* since there are multiple studies

s22 [redacted]

From: s22 [redacted]
Sent: Monday, 14 October 2024 8:40 AM
To: HENDERSON, Nick; DUFFY, Tracey
Cc: KERR, Lisa; s22 [redacted]; s22 [redacted]; s22 [redacted]; s22 [redacted]; s22 [redacted]; s22 [redacted]; LAWLER, Tony
Subject: FW: URGENT: All 537 Australian Councils to Receive DNA Contamination Report [SEC=OFFICIAL]

FYI

s22 [redacted]

s22 [redacted]

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
☎: s22 [redacted] | 💻: s22 [redacted]@health.gov.au

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted] <s22 [redacted]@Health.gov.au>
Sent: Monday, October 14, 2024 8:34 AM
To: s22 [redacted]@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: FW: URGENT: All 537 Australian Councils to Receive DNA Contamination Report [SEC=OFFICIAL]

For information only.

From: s22 [redacted] s22 [redacted]@yahoo.com.au>
Sent: Sunday, October 13, 2024 7:45 PM
To: Minister Butler <Minister.Butler@Health.gov.au>; Minister. Sanderson <minister.sanderson@dpc.wa.gov.au>; COMLEY, Blair <Blair.COMLEY@Health.gov.au>; andrew.robertson_Contact <andrew.robertson@health.wa.gov.au>; webservices@pmc.gov.au; premier@dpc.wa.gov.au
Subject: URGENT: All 537 Australian Councils to Receive DNA Contamination Report

All 537 Australian Councils to Receive DNA Conta

JULIAN GILLESPIE

OCT 13

Document 6

All 537 Australian Councils to Receive DNA Contamination report

.. and much much more

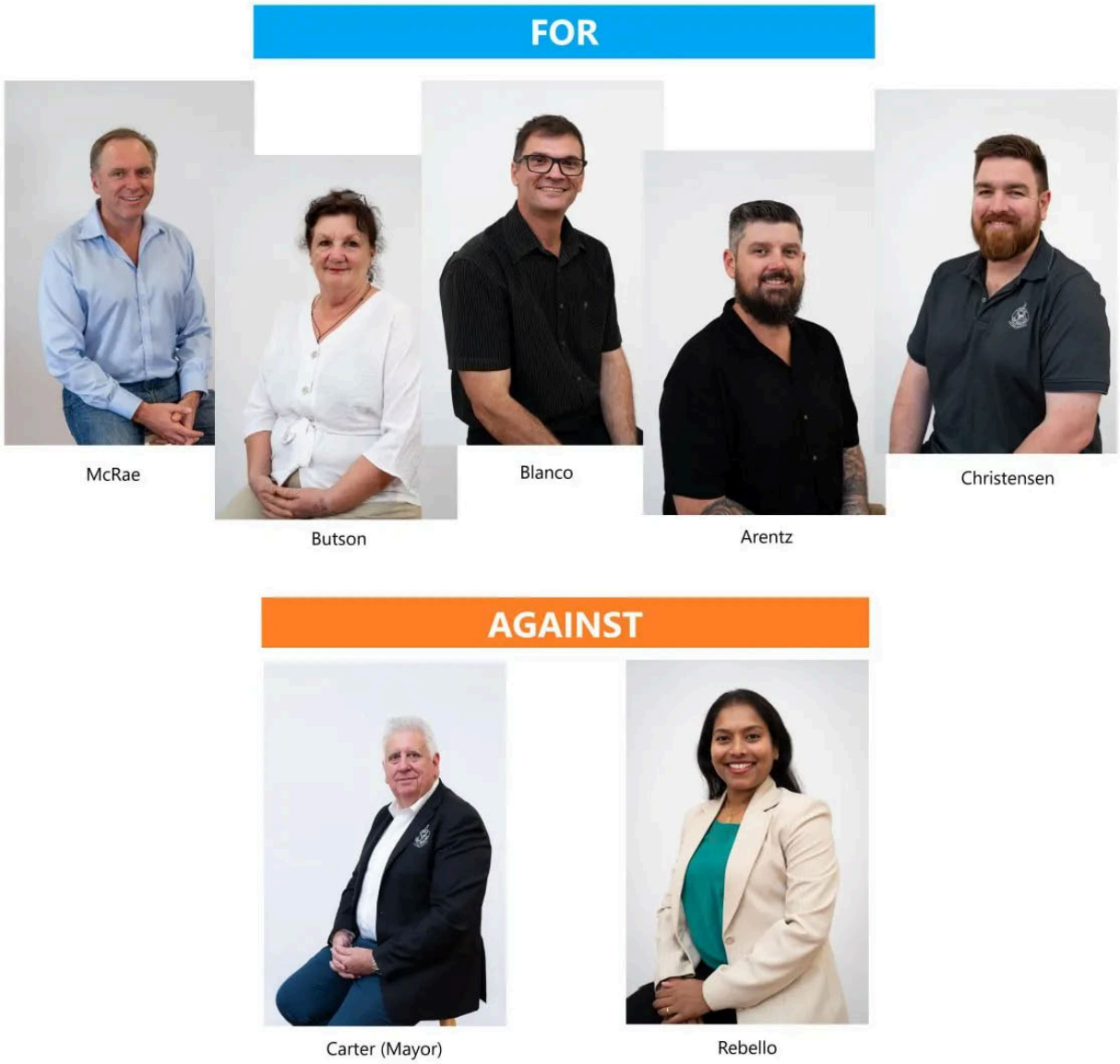
JULIAN GILLESPIE
OCT 13, 2024

good Substack Folk,

.. this pic is the TLDR

Document 6

Port Hedland Councillor Voting Record on the Motion to Provide Recipients of COVID mRNA Vaccinations Information on DNA Contamination
11th October 2024



Credit: @Jikkyleaks

but let me begin by asking ..

.. (please excuse the French)

How do you *piss off* 537 Australian Councils and their over 5,000 Councillors?

first .. you, as part of the Canberra Mob, lock down all their districts in 2020, 2021, and 2022

second .. being the Canberra Mob, you don't ask permission .. you don't pick up the phone to a single Council .. no, being the Canberra Mob, you just pay off all the State and Territory governments to tell the Councils and their Councillors to *heel* .. to *shut up* .. to *obey* .. *obey* the ***experts*** in Canberra .. the Canberra Mob

third .. being the Canberra Mob, orders are sent .. *coerce* .. *coercion* .. *coercing* all the residents of local Council districts to receive experimental gene therapies .. which the Canberra Mob do not tell anyone, are also GMOs

fourth .. you, as the Canberra Mob, send ***more*** orders .. mandate .. mandates .. mandating that a significant number of residents in every Council district **MUST** receive the experimental gene therapies if they want to keep their jobs .. if they want to see Grand Ma & Grand Pa .. while again, not telling anyone the vile vials contain GMOs

.. then later

.. after they forced these liquids into the bodies of over 20 million Australians

.. into the residents of your local Council district

.. the same Canberra Mob learn ***their*** needles contained grotesque amounts of synthetic DNA contamination

synthetic DNA contamination injected ..

---

into the Children of your local area

.. into the Babies born in your local area

Trillions of cancer causing fragments in every shot

Document 6

.. Trillions of cancer causing fragments multiplied by the over 63 million doses the Canberra Mob *caused* to be injected into the residents of every local Council district across the country, one dose after another .. after another .. and another

after telling everyone ***they*** .. and only ***they*** .. were **the** health experts

.. but then, a group of ***honest*** experts look .. really look .. at what was in those 63 million shots and find a ***sh*t ton*** of DNA contamination

.. then .. when that Canberra Mob learn about this grotesque DNA contamination from this group of honest experts, that Canberra Mob says

---

.. NOTHING

---

that, good Substack Folk, is soon going to be the realisation of over 5,000 Australian Councillors

.. soon to learn that Tony Albanese was fully briefed on Australia's DNA contamination crisis by Russell Broadbent MP and others, critical health information impacting all of Australia's local government residents

---

.. and Tony

Don of the Canberra Mob, currently

.. said .. nothing

.. is saying

Document 6

nothing

---

that, good Substack Folk, is how you *piss off* 537 Councils and their over 5,000 Councillors

---

the ire

the understandable anger

.. in others, rage

.. a sense of utter betrayal, good Substack Folk, is soon to manifest variously in over 5,000 Australian Councillors, after the successful efforts of Councillor Adrian McRae in Port Hedland Council on Friday night, in helping his neighbouring Councillor colleagues *near and far* to all understand ..

Tony Albanese went MIA on the DNA

.. where's Tony?

Document 6

.. enter Adrian McRae

Adrian McRae is no slouch .. now a successful industrialist in WA mining after starting with nothing, Adrian was earlier in the sciences as a specialist in horse medicine, dentistry no less, US qualified years ago, so he is no Johnny-come-lately for those unaware .. a very talented man

having seen the correspondence by Russell Broadbent MP to Tony .. the Prime Minister .. and especially the Science Summary contained in the letter of the 25th of September, Adrian knew more needed to be done

but first he contacted Dr David Speicher to ensure he was clearly understanding the true ramifications of Dr Speicher's DNA contamination findings .. then Councillor McRae made contact with several of the co-signatories and authors of the Science Summary to verify and clearly understand that the consequences, as stated, truly do represent a ***clear and present danger*** to all Australians

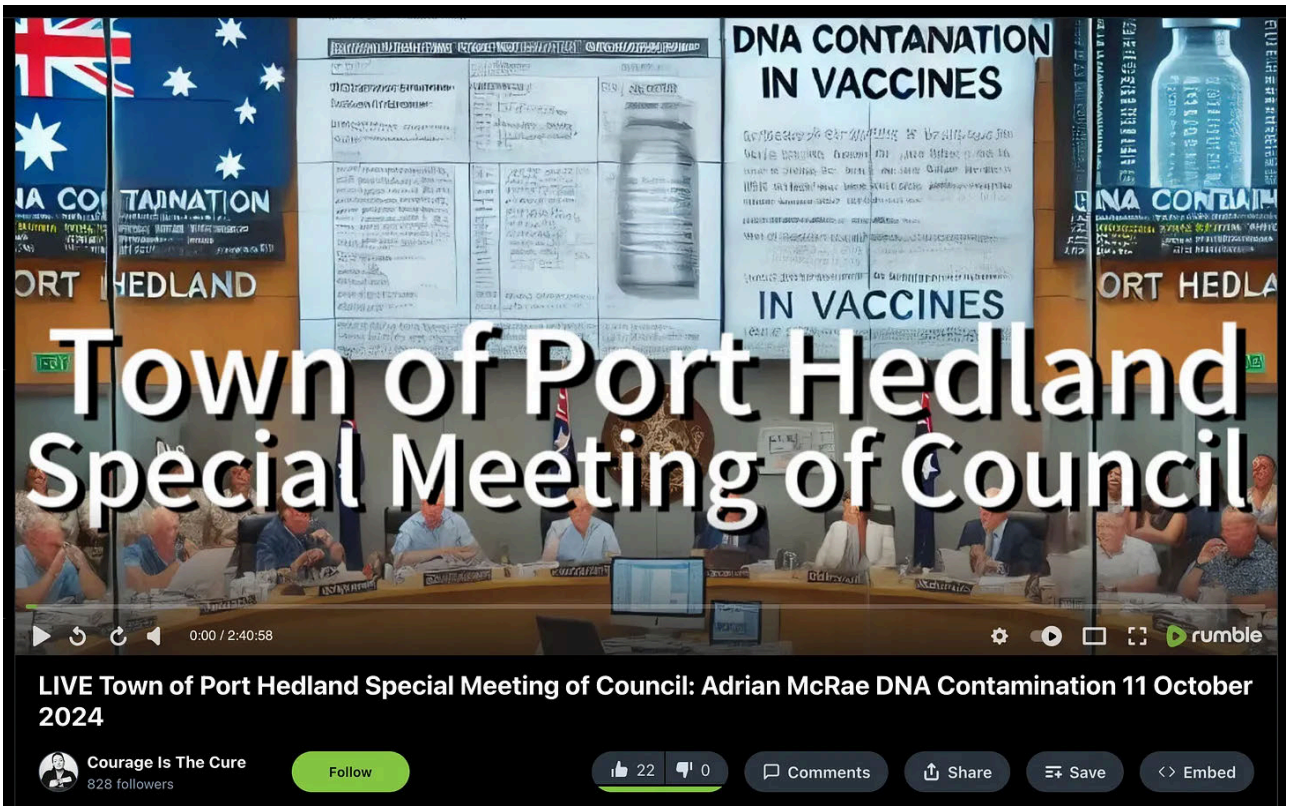
.. a threat that has unfortunately begun to materialise

armed with a thorough understanding of the situation **all** Australians now face .. whether vaxxed or unvaxxed .. as any rapid deterioration in the health of Australians impacts **all** Australians .. Councillor McRae knew the Special Meeting needed more than the Science Summary and contamination findings for getting the message understood in terms we can all understand .. and which the Councillors present needed for thoroughly understanding, so the urgency and purpose of the extensively documented Substantive Motion would become as clear as day

.. that required a Professor of renown who knows their stuff .. we shall return to this part later

.. the meeting

video of the entire Special Meeting will be made available on the Port Hedland Council website in coming days HERE .. but for now the meeting can be seen on Rumble .. *thank you* **Courage is The Cure**



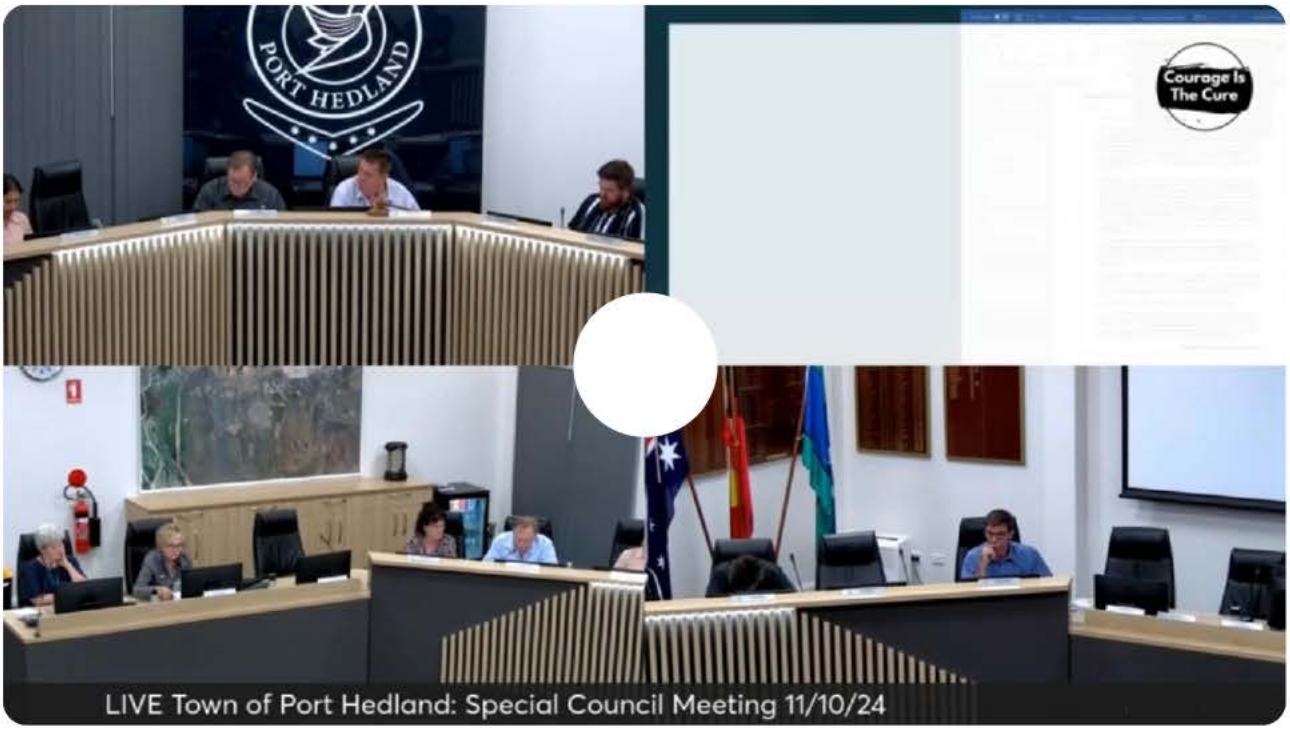
.. and it was a long one - at over 2 hours and 40 minutes - especially for you east coast Folk who stayed up burning the midnight oil

Document 6

.. the speech for Australia

for mine, and to assist everyone here with *getting to the nub* of Adrian's concern and why this meeting had to go ahead urgently, I have extracted Councillor McRae's speech in support of the Motion .. a little over 10 minutes

.. Albanese .. take notes



.. but wait .. let's roll it back a little .. Adrian mentioned Angus Dalgleish

before Councillor McRae delivered this extraordinary speech the meeting was closed to the attending public and online audience for nearly 30 minutes, as Mayor Carter called a *Confidential Session* so Councillors could watch a certain video Councillor McRae had brought along

.. so, what was that video all about?

.. enter Professor Angus Dalgleish

Professor Dalgleish, as the ***lead*** co-signatory of Mr Broadbent's letter of the 25th, stepped-up to break-down the Science Summary that letter contains, for the benefit of Port Hedland Councillors and the attending public

Document 6

here is what the Councillors were watching during that *Confidential Session* .. an address by Professor Dalgleish .. also a little over 10 minutes

.. I watch this testimony from Professor Dalgleish and only hear again and again and *again*

---

cancer

cancer

CANCER

---

this is the nature of the elephant in the room Councillor McRae has now - with the successful passing of the Motion - called upon all Australian Councils to see has been shown to the Prime Minister .. Tony .. weeks ago now .. about which Tony and the Canberra Mob are saying nothing

nada

zero

zip

.. a high-def version of Prof Dalgleish's video is available HERE

.. next steps

let's get into some of the detail of what the Motion succeeded in achieving for happening next

.. it short, the CEO of Port Hedland is now required to undertake the following:

> **(A)** Deliver the letter seen at **Annexure 1** to the Prime Minister, endorsing the letters of The Honorable Russell Broadbent MP dated 20 and 25 September 2024, in which Council repeats the call for an immediate suspension of the Pfizer and Moderna COVID-19 products under the same terms as expressed by Mr. Broadbent.
>
> **(B)** That Council forthwith circulate to all registered health practitioners and medical clinics operating within the Port Hedland Local Government Area a copy of the letter appearing at **Annexure 2**, to inform all local health practitioners of the report by Dr. Speicher and the findings of the Science Summary attached to Mr. Broadbent's letter of 25 September 2024. The Council strongly urges practitioners to share this information with patients contemplating receiving any Pfizer or Moderna COVID-19 vaccines. The goal is to ensure patients can provide legally valid informed consent. Copies of the letters from Mr. Broadbent MP and Town of Port Hedland to the Prime Minister will be attached.
>
> **(C)** That Council forthwith circulate to all other Australian Local Government Councils and Shires a copy of the letter appearing at **Annexure 3**. This letter will inform all Councils and Shires about the findings of Dr. Speicher's report and the

Science Summary, urging them to share the information with health practitioners and clinics in their areas to facilitate informed consent for their residents.

The letter will attach the letters from Mr. Broadbent MP and the Council's letter to the Prime Minister, urging all other Australian Local Government Councils and Shires to consider sending similar correspondence to the Prime Minister.

(D) Contact the Department of Health, Western Australia, and formally present Dr. Speicher's report, the letters from Mr. Broadbent MP, and the Council's letter to the Prime Minister, using a copy of the letter appearing at **Annexure 4**, requesting a public response and advice on steps the Department recommends for patients contemplating the receipt of any further Covid 19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.

(E) Contact the Minister for Health of Western Australia, Amber-Jade Sanderson, to formally present Dr. Speicher's report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council's letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 5**, seeking the Minister's public response and recommended actions for patients contemplating the receipt of any further Covid-19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.

(F) Contact the Commonwealth Department of Health and Aged Care, specifically Deputy Health Secretary Professor Lawler and Health Secretary Blair Comley, presenting Dr. Speicher's report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council's letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 6**, requesting a formal and public response from both officials, and recommended actions for patients contemplating the receipt of any further Covid 19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.

(G) Contact the Commonwealth Minister for Health and Aged Care, Mark Butler, presenting Dr. Speicher's report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council's letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 7**, requesting

Document 6

> a formal and public response from Minister Butler, and recommended actions for patients contemplating the receipt of any further Covid 19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.

.. all of the Annexures can be viewed HERE

.. but but but .. wait a minute

.. during the Special Meeting those annexures were **amended** to include additional paragraphs for heading off the canned BS excuses from the TGA and Health Department when asked about this contamination

.. the same canned BS they recently flicked back at Rebekah Barnett when she asked the TGA to comment on the report of Dr Speicher

.. well, that BS don't fly no more, and here's why

read the text in RED below to appreciate the problem the TGA has .. and as a consequence, the rest of Australia now has, because of the TGA's incompetence .. or perhaps, intentional acts of deception

.. this RED text in amended **Annexure 1** is contained in the other annexures now as well

Document 6

Annexure 1

Town of Port Hedland
[Date]

The Hon Anthony Albanese MP
Prime Minister
Parliament House
CANBERRA ACT 2600

By email: parliament@pm.gov.au

Dear Prime Minister,

Re: Urgent Request to Suspend Pfizer and Moderna COVID-19 Products Due to DNA Contamination

I write on behalf of the Town of Port Hedland to bring to your immediate attention a report by Dr. David Speicher PhD, which presents disturbing findings of synthetic DNA contamination in Pfizer and Moderna COVID-19 vaccines.

Dr. Speicher's report reveals that the contamination levels in the vaccines exceed Australia's Therapeutic Goods Administration (TGA) limit by up to 145 times, with DNA fragments capable of integrating into human cells. Alarmingly, the Pfizer vaccines also contain SV40 promoter-sequences, which were not disclosed to regulators, and are known to facilitate genomic integration, posing severe risks such as cancer and other long-term health consequences.

Council acknowledges the letters from the Honorable Russell Broadbent MP dated 20 September 2024 and 25 September 2024 which were co-signed by over fifty of the world's leading Doctors, Professors, Scientists and Legal Experts from Europe, North America and Australia. We extend our gratitude to Mr. Broadbent for raising awareness of Dr. Speicher's critical findings.

It has become increasingly clear that the testing methods employed by the Therapeutic Goods Administration (TGA) have failed to adequately address the risks posed by synthetic DNA contamination in Pfizer and Moderna vaccines. The TGA's reliance on outdated guidelines such as ICH Q2(R2), which do not account for the unique nature of modRNA platforms, has resulted in significant shortcomings. These guidelines were arbitrarily cited by the TGA to dismiss findings by scientists like Dr. Speicher, rather than embracing the necessary new scientific approaches to detect synthetic DNA in these products.

Notably, the TGA has been using testing methodologies—as documented in TGA FOI 5286—that only target a small segment of the plasmid DNA, failing to detect the bulk of the contamination, particularly those fragments under 200 base pairs where the highest risk lies. Alarmingly, Moderna, through its own patent filings, had specifically warned about the inadequacy of such testing methods for detecting residual DNA, especially DNA

Document 6

encapsulated in lipid nanoparticles (LNPs). Despite this warning, the TGA has relied on these insufficient methods, which grossly under-detect the true extent of contamination. Moderna's patents also highlighted the risks of insertional mutagenesis and carcinogenesis, yet these serious risks remain inadequately addressed by the TGA's current testing practices.

Further, despite prior warnings and international scrutiny, the TGA has not conducted proper tests to detect LNP-encapsulated DNA nor performed thorough investigations into the risks of DNA integration into human cells. This raises serious concerns about the TGA's capacity to protect the public from the known dangers of synthetic DNA contamination.

The only way to begin remedying this situation is for the TGA to acknowledge these failures and to urgently conduct comprehensive testing, in line with new scientific methods, to either confirm or disprove the findings of Dr. Speicher and other eminent scientists. Immediate action in the lab is necessary to prevent further harm.

Furthermore, after reviewing the Science Summary attached to Mr. Broadbent's letter of 25 September 2024, the Council shares grave concerns about the adverse health impacts that could arise from this contamination, including genomic instability, cancers, and potential effects on future generations.

In light of these findings, the Town of Port Hedland joins Mr. Broadbent and the multitude of global experts in urging the immediate suspension of these vaccines and calling for a thorough investigation into how this contamination has gone undetected by our regulatory agencies.

Additionally, the Council has taken steps to inform all Australian Local Government Councils, and health practitioners in the Port Hedland area, of these findings, ensuring that patients are provided the necessary information to warrant legally valid informed consent.

We respectfully request your urgent action to protect the health and safety of all Australians by suspending the use of these vaccines and commencing an investigation without delay.

Yours sincerely,
[Name]
CEO, Town of Port Hedland

.. a copy of amended Annexure 1 with functional hyperlinks is here:

Annexure 1 Amendment Letter To The Australian Prime Minister Download
37.6KB · PDF file

Download

so you can see what the TGA has not been doing

Document 6

.. it has not really been testing for DNA contamination

---

instead, these mugs have been using a test for DNA contamination which Moderna told them didn't work

.. yeah, you just read that right

.. yet somehow when Dr David Speicher produces world leading test methods that reveal the synthetic DNA contamination hidden in the LNPs, these mugs at the TGA instead start waving their hands in the air to misdirect everyone with outdated guidelines for validating test processes

---

yet the TGA never followed the same guidelines

the TGA instead has all along been using a test method

Moderna said was rubbish

yet the TGA has the hide to try .. try .. and say Dr David Speicher's work is rubbish

and not to be relied upon

.. when the only ones performing shyster science are the TGA ..

.. and they know we know it

Councillor Adrian McRae also cottoned on to the grift and BS flowing out of the TGA as spruiked by their media/propaganda department

and Adrian McRae broke this all down at the Special Meeting last Friday, and the Councillors there understood we have a lying TGA that has been caught out .. thus

Document 6

why they agreed to Councillor McRae's mini motion calling for the amendments to get the text in RED inserted above

these last moment amendments were super important, because now all this material is being sent to all 537 Australian Councils, they will all know too what BS ***to not accept*** from the lying and deceitful TGA, which is in nothing but damage control now

---

they've been caught out

---

special *thanks* go to Australia's most intrepid independent investigative journalist, Rebekah Barnett, because it was she who put in the right FOI application (5286) with the TGA, that saw them fumble with their black marker redactions, and leave just enough pages exposed for the world to see they are purposefully using the exact DNA contamination test that one of the manufacturers told them not to use

as Hoody and John Larter would say ..

You just couldn't make this stuff up

---

ok .. that's about it for now Folks

I together with Councillor Blanco will be following up with the Port Hedland CEO to ensure all the letters detailed in Annexures 1 through 7 above get sent properly, and don't end up in some mailbag by the side of the road, or lost to spam folders .. we will keep you apprised

apologies this post did not come sooner, but I needed to survey some issues before putting this note together, while I must also admit to labouring under a shell shocking hangover yesterday after tippling a few into the wee hours Friday night with Councillor McRae and Councillor for Karratha, Brenton Johannsen, who did the long drive up to attend the Special Meeting, noting the urgency of the Motion's information, so he came to lend a hand and his voice in support

Document 6

as too do we hope over 5,000 other Councillors will do across Australia soon .. get revved up if not down right angry as well .. probably enough to tell this Canberra Mob too, that Tony ol'boy better get to quickly doing something

yes .. as Angus Dalgleish has made clear .. we have already entered a health crisis and the Canberra Mob has to get off their collective ass*s and start fixing this mess they made .. if we are to survive, as a country

thank you .. please share widely, and restack if you can

745 Likes · 117 Restacks

Discussion about this post

Comments Restacks

Write a comment...

Matilda Bawden Matilda Bawden Oct 13

Please put the South Australian Health and Community Services Complaints Commissioner (HCSCC) on that list! He loves slapping innocent people with Prohibition Orders for "COVID misinformation and disinformation", while allowing South Australians to be injured or killed.

LIKE (78) REPLY SHARE

5 replies

Britta Christensen Oct 13

Thank you, for your great work and efforts. The world needs more people like you..

Document 6

LIKE (52) REPLY SHARE

202 more comments...

From: KERR, Lisa
To: s22
Cc: s22 ; VUCKOVIC, George; s22 s22
Subject: RE: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 6:12:00 PM
Attachments: image002.png
image003.png

Thanks s22 – I've reviewed and accepted almost all of the changes.

s22 and s22 – there are comments in there for you both.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 <s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 5:06 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: RE: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa

Thanks for sending through.

s22 in our comms team has reviewed and provided some comments, suggested edits and structural changes. s22 has alerted the Health media team that this is coming.

Back to you for review and further progression up the line.

Regards
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 2:08 PM
To: s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>
Subject: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22

As discussed, the draft statement is attached. It has AS cleared input from Toxicology and input from s22, SEB BSS and the Laboratories. May you please have a comms specialist review? This has not been past a FAS yet.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports which claims that the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, we believe they are invalid.

Many of our concerns are listed at [link to the heading at bottom of report – reports and publications alleging DNA contamination in the COVID 19 vaccines].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports that have been circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are causing the spread of misinformation.

Common concerns with these studies include:

- **Results interpretation**: Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.

- **Unvalidated method**: Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to

Commented s22 Perhaps this and the next dot point can be combined. I wonder if it might be better to create headings and maybe dot points withing them, such as 'results interpretation and unvalidated method', 'issues with samples' and 'laboratory accreditation' and have some dot points within those major headings

Commented [KL2R1]: Each dot point is a separate topic……

Commented [KL3R1]: They could be rearranged?

Commented [KL4R1]: Also, one of the studies performed the correct test and fluorometry but chose to include the incorrect results to the Prime Minister. So would like to keep this as is?

demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- **Suitable samples**: Some of these studies use a very small number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.

- **Sample traceability**: It is unknown where the vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.

- **No cold chain**: Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

- **Inappropriate reference material**: The reference materials were not adequately defined.

- **Laboratory status**: The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*.

Commented [KL5]: s22 changed from characterised - does this make it better?

Biotechnology medicines have been available since the 1980s

Medicines produced by biotechnology have been used by millions of patients for over 40 years, while medicines containing DNA have been made since the 1990s. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

Residual DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval. The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia.

Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to monitor the residual DNA concentration in the final product.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for lifetime treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Commented [s22]: Happy for the comms experts to comment on w this, or some similar representation may be useful

Commented [KL7R6]: [s22] - ok?

Commented [s22]: don't know if 'quality issue' is what people are worried about e.g. the AstraZeneca issue. Perhaps we remove opening line?

Commented [KL9R8]: [s22] - for you

Commented [s22]: Input from Tox. SEB AS cleared.

From: s22
To: KERR, Lisa
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:26:15 AM

No further changes from me. Its really good!

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>; s22 <s22@health.gov.au>
Cc: s22 <s22@Health.gov.au>; s22 s22@health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi all,

Attached is a copy of the draft web statement. I'm about to send it up for clearance. May you please review and let me know if any of it needs to be changed? Ideally I would hope it gets published today….. I would also like to use some of it for a media response due at 2 pm today….Please don't amend the TRIM version – use the attached doc.

FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: KERR, Lisa; s22 ; s22 ; s22 ; s22 ; s22 ; s22 ; s22
Cc: s22 ; s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:00:01 AM

Good morning Lisa,

I have read the statement, and it reads very well. No further changes from me.

Regards

s22

From: s22 s22 @health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi all,

Attached is a copy of the draft web statement. I'm about to send it up for clearance. May you please review and let me know if any of it needs to be changed? Ideally I would hope it gets published today..... I would also like to use some of it for a media response due at 2 pm today....Please don't amend the TRIM version – use the attached doc.

FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: KERR, Lisa; s22 ; s22 ; s22 ; s22 ; s22 ; s22 ; s22
Cc: s22 ; s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:52:57 AM
Attachments: image002.png

Hi Lisa,

I think it adequately represents our position.

s22
s22
Biotherapeutics
Laboratories Branch MDPQD HPRG
Not working Wednesdays
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
TGA Tindal Lane, Fairbairn ACT www.tga.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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Lisa

From: s22
To: s22 ; KERR, Lisa; s22 ; s22 ; s22 ; s22 ; s22
Cc: s22 ; s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:29:32 AM

Good morning, Lisa,

No changes from me either.

Kind regards,
s22

From: s22 <s22 @health.gov.au>
Sent: Thursday, October 17, 2024 8:00 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Good morning Lisa,

I have read the statement, and it reads very well. No further changes from me.

Regards

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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Lisa

From: s22
To: KERR, Lisa
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:29:31 AM

Thanks Lisa I should have said it reads great too!

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:28 AM
To: s22 <s22 @health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22 – Sample number done, but the sentence with fetal comes from Tox and has been past Comms. Once it is cleared I can ask s22 as it bothered me too.

From: s22 s22 @health.gov.au>
Sent: Thursday, October 17, 2024 9:20 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa – only minor suggestions (sorry if it seems picky!)

Page 2
Issues with samples:
Some of these studies use a very small sample number

Page 3
female fertility, foetal

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: KERR, Lisa
To: s22
Cc: s22 s22 ; s22 ; s22 s22 ; s22 ; VUCKOVIC, George
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 3:46:13 PM
Attachments: image003.png
image004.png
image005.png

Thanks s22 – got it. I'm primarily concerned with allaying fears in the public that this is actually something to worry about when it isn't - and that we all agree on what can be said.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 3:12 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 ris <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good afternoon Lisa,

Just chiming in to give a bit of clarity on the statements that were provided by the Tox section.

We agree with comments raised by BSS that the original dot point on the role of integrases should be deleted. There are papers implying that other enzymes/mechanisms are involved in

integrating SARS-CoV-2 sequences into the DNA of human cells (see Zhang et al 2021).

The comments and changes that were added by the Tox section were dot points regarding: (i) limits for residual DNA; (ii) the lack of evidence of adverse effects; and (iii) a recommendation to delete the statement on human exposure to foreign DNA.

The first dot point on limits for residual DNA is based verbatim on a previous response provided by the section.

> *"The limit for residual DNA in biological medicines is 10 ng/dose, as recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer."*

Its inclusion was intended to convey that the 10 ng/dose limit is effective at safeguarding against genomic integration (and cancers), evident by the long history of safe use of biotechnology products (including the more recent experiences with mRNA vaccines). There are several published papers that describe an improbable risk of oncogenicity from integration of host cell DNA from biological products, but they are considerably old (e.g. Krause & Lewis, 1998; Yang et al., 2010). In the event that some aspects of the statement are too speculative, we can also omit the following sentence "*There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer*."

We would also like to take this opportunity to simplify the statement on adverse developmental effects, which we will update once the document is checked back into TRIM.

> Original:
> ~~No adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in the combined reproductive and development study in animals administered 200 times the clinical dose of vaccine.~~
>
> Amendment:
> In safety studies (combined reproductive and developmental study in animals), no adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in in animals administered 200 times the clinical dose of vaccine.

I hope this clarification has cleared up any confusion.

Kind regards,

s22

s22
Senior Toxicologist – Toxicology Section
Scientific Evaluation Branch
Medicines Registration Division | HPRG
Australian Government, Department of Health and Aged Care
T: s22 | E s22 @health.gov.au | Location: Melbourne
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country

throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 11:14 AM
To: KERR, Lisa <
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for this.

With regard to adding the comment about plasmid DNA entering the human genome, I would be uncomfortable with that as I am unaware of studies which have tested this and so personally I have no experience in the matter.

I note however that s22 has added a comment about their being no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer. In this case s22 may be better placed to advise.

Regarding the intergrase dot point in the document, I recommend removal of that comment entirely. I don't believe it is correct and don't believe it adds anything, particularly in light of s22 comment.

Hope is helpful, happy to discuss.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 6:29 AM
To: s22 <s22 @health.gov.au>; s22
<s22 @health.gov.au>; s22 s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22
<s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks for looking at the document – may you please check it in as s22 needs to work on it now.

So from your comments below I take it that if I change the sentence to something like "there is no evidence that plasmid DNA has entered the human genome" that would sit better with you? I've looped s22 into this as it appears that BSS and Tox have different views? Should I

arrange a meeting for us all to discuss?

I also wanted to play devils advocate a little and ask BSS if you were asked by a member of the public who has received a recombinant protein therapeutic good if the products you have approved have altered the human genome, have caused cancer or have lead to transgenic babies - what would you say?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
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From: s22 s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 6:08 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for the call.

I have added some comments, I did rearrange the opening paragraph, I apologise if this is presumptuous on my part.

As noted, you may wish to consider the inclusion of viral gene therapies as examples of products which use high levels of DNA starting material. These are more analogous to the mRNA vaccines in that, for the one I am particularly similar with, large amounts of plasmid DNA are used in production which must be purified away from the therapeutic, in this case the viral vector. They also have the potential to package non-target sequences and be administered to patients. Note

that these do not have as long usage experience as some of the other examples.

Also as noted I do not believe the statement about integrases to be correct. As described below other mechanisms of DNA integration are possible, I would expect these to be rare events particularly in vivo with the cascade of circumstances required.

Hope is helpful.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Tuesday, October 15, 2024 4:45 PM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Just had a very interesting chat with s22 about all of this – with regards to the specific circumstances that I'm referring to – eg minute amounts of highly fragmented bacterial plasmid. We agreed that to integrate, there would need to be a series of highly improbably events to line up. s22 has kindly agreed to provide some input into the draft statement.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s22 s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 2:40 PM
To: s22 <s22 @health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks, with regard to the integration issue, foreign DNA can integrate into chromosomal DNA in the absence of an integrase in mammalian cells. This comes from the DNA damage/repair literature where breaks in DNA are repaired through processes called non-homologous end joining or homologous recombination. Exogenous DNA can potentially be incorporated using these processes.

Hope is helpful.

Cheers

s22

From: s22 <s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Confirm BSS does evaluate residual host cell DNA as part of the premarket assessment of recombinant products. The accepted limit as mentioned is 10ng/dose and the method is usually qPCR via EP **2.6.35. Quantification and characterisation of residual host-cell DNA**, see attached.

In regard to the statement re DNA integration and the need for integrase suggest this may need to be softened as understand, although unlikely, there are alternative mechanisms for DNA integration. s22 may have some additional thoughts/comments re this.

s22
s22
Biological Science Section
Scientific Evaluation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au

Location: Fairbairn ACT
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

- Integrates into the human genome
- Causes cancer
- Has/could result in transgenic babies

s22 – I know you sent me a summary of the SV40 primer issue – could you insert a paragraph for lay people in the document where indicated about margins of safety etc?

Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: KERR, Lisa
To: DUFFY, Tracey; s22 ; s22
Cc: s22 ; s22 ; s22 ; VUCKOVIC, George; s22 ; s22 ; HENDERSON, Nick; LAWLER, Tony
Subject: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 2:09:39 PM
Attachments: [D24-4399772] Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX
image002.png

Good afternoon,

The comments from Tracey, Nick and Tony have been worked through. The latest clean copy is attached and here: D24-4399772

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality, and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see:
www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which require evidence that those methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
    - where the vials were sourced
    - their location, custody, or temperature before or during testing.

  Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated, and results can be relied upon. Processes that do not ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. There is no evidence that these laboratories have Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies. Nor do the laboratories appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. These types of accreditations ensure that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product. The vaccines met the required limits for residual DNA.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome. This includes products such as insulin, which are injected multiple times a day for life-long treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billions of vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

From: s22
To: KERR, Lisa
Cc: s22 ; s22 ; s22 ; s22
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Friday, 18 October 2024 2:14:21 PM
Attachments: image001.png
image002.png
image004.gif
image005.png
image006.png

Thanks Lisa.

I've now published the statement: https://www.tga.gov.au/news/media-releases/addressing-misinformation-about-excessive-dna-mrna-vaccines

Regards,

s22

s22
Web Experience Section | HPRG Digital Transformation Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 1:34 PM
To: s22 <s22 @Health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22

I understand you are expecting the attached statement for publishing on the website – please find below Tony's clearance. Please note that there is a link and a date to be inserted – both are highlighted.

Would you please let me know once it is live?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

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From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Friday, October 18, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks Lisa
Looks great!
No further changes from me
T

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 11:14 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony,

Final statement attached as promised.

Lisa

------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Many of our concerns are listed below [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality, and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see:
www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which require evidence that those methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
    - where the vials were sourced
    - their location, custody, or temperature before or during testing.

  Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated, and results can be relied upon. Processes that do not ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. There is no evidence that these laboratories have Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies. Nor do the laboratories appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. These types of accreditations ensure that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product. The vaccines met the required limits for residual DNA.

The quality limits ensure that there is less than 10 ng present per dose – or less than ten billionths of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome. This includes products such as insulin, which are injected multiple times a day for life-long treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billion vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

s22

From: s22
Sent: Friday, 18 October 2024 2:16 PM
To: s22 ; TGA Social Media
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Totally fair.

From: s22 <s22 @health.gov.au>
Sent: Friday, October 18, 2024 2:13 PM
To: s22 s22 @Health.gov.au>; TGA Social Media <Social.Media@tga.gov.au>
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks for chance to review, I'd be inclined to keep exactly in the order as published, given sensitivity.

See below.

thx

From: s22 <s22 @Health.gov.au>
Sent: Friday, October 18, 2024 2:06 PM
To: TGA Social Media <Social.Media@tga.gov.au>; s22 s22 @health.gov.au>
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks s22

I'm hesitant to edit, as I think you've pulled out the right pieces.
But how do we (s22 included) feel about adding the red below?

From: TGA Social Media <Social.Media@tga.gov.au>
Sent: Friday, October 18, 2024 2:01 PM
To: s22 s22 @Health.gov.au>
Cc: TGA Social Media <Social.Media@tga.gov.au>
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hey s22

Here's what I've drafted for your approval please:

Facebook/Instagram/LinkedIn	X (Twitter)	Image
We are aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.	We are aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of	

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines. ~~DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies.~~ While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines. The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality, and efficacy. Read more: <LINK> [Instagram: Follow the link in our bio to find out more.]	DNA. This is not the case. Read more: <LINK> [Character count: 274 characters]	

Many thanks
s22

s22
s22
Regulatory Education and Communication Section | Regulatory Engagement Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Gulgana Building, Fairbairn
PO Box 100, Woden ACT 2606, Australia

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From: s22 s22 @Health.gov.au>
Sent: Friday, October 18, 2024 1:49 PM
To: TGA Social Media <Social.Media@tga.gov.au>
Subject: FW: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hold that thought.

From: s22 <s22 @health.gov.au>
Sent: Friday, October 18, 2024 1:44 PM
To: TGA Website <tga.website@tga.gov.au>; s22 <s22 @Health.gov.au>
Cc: s22 s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: FW: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi team

I did ask Lisa if there was someone in her team who does web publishing requests, but otherwise s22 was expecting it.

If it could be published asap please, as we're heading into the Friday deadzone.

Ta
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 1:34 PM
To: s22 s22 @Health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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Would you please let me know once it is live?

Kind regards,

Lisa

Lisa Kerr **PSM PhD MBA (Dr/she/her)**
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Friday, October 18, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 s22 @health.gov.au>;s22 s22 @health.gov.au>
Subject: RE: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks Lisa
Looks great!
No further changes from me
T

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 11:14 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

From: s22
To: s22 ; TGA Website
Cc: s22 ; s22
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Friday, 18 October 2024 2:15:52 PM
Attachments: image001.png
image002.png
image003.gif
image004.png
image005.png

Thanks so much s22

From: s22 @Health.gov.au>
Sent: Friday, October 18, 2024 2:15 PM
To: s22 <s22 @health.gov.au>; TGA Website <tga.website@tga.gov.au>
Cc: s22 s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks s22

This has now been published and I will send the Whispir alert out shortly.

Regards,

s22
s22
Web Experience Section | HPRG Digital Transformation Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606, Australia

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Sent: Friday, October 18, 2024 1:44 PM
To: TGA Website <tga.website@tga.gov.au>; s22 s22 @Health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: FW: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
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From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Friday, October 18, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: RE: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks Lisa
Looks great!
No further changes from me
T

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 11:14 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA

in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony,

Final statement attached as promised.

Lisa

------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

From: LAWLER, Tony
To: HENDERSON, Nick; KERR, Lisa; DUFFY, Tracey
Cc: s22 s22 s22 s22 ; VUCKOVIC, George; s22 ; s22 s22
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:24:16 AM
Attachments: image001.png
DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024NH_TL.docx

---

Thanks very much, this is great. Some corrections and comments from me in the attached (fortunately 25 people failed to board the plane!)
T

From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Thursday, October 17, 2024 10:05 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa
This looks good. Minor comment in TRIM version and attachment for me
Nick

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:55 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony – e copy attached

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Thursday, October 17, 2024 9:50 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the

mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi

Is the intent to get this online today? I will have TRIM access in a few hours and can have a look at it then.

Thansk

T

Sent from Workspace ONE Boxer

On 17 October 2024 at 6:38:43 am GMT+8, KERR, Lisa <Lisa.Kerr@health.gov.au> wrote:

> Ok I've had a go at fixing/responding….
>
> **From:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>
> **Sent:** Thursday, October 17, 2024 9:20 AM
> **To:** KERR, Lisa <Lisa.Kerr@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 <s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 s22 @Health.gov.au>
> **Subject:** RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
> Thanks – I have had a quick look and provided some comments/questions in the TRIM file to try and tighten our points.
>
> **From:** KERR, Lisa <Lisa.Kerr@health.gov.au>
> **Sent:** Thursday, October 17, 2024 8:56 AM
> **To:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 <s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>;s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 s22 @Health.gov.au>
> **Subject:** For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
> Good morning Nick and Tracey,
> In response to the recent spike in mis/disinformation about "DNA contamination" in the mRNA vaccines we've drafted a statement ([%20%20]D24-4291794) for the TGA website (as a media release). s22 , both SEB Tox and SEB BSS, and RPSD Regulatory Education and Comms have provided input and suggestions to this draft.
> Would you both please provide clearance for publication (or amendments…)
> Kind regards,
> Lisa
> **Lisa Kerr PSM PhD MBA (Dr/she/her)**

Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
[%20%20]www.tga.gov.au

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------< Content Manager Record Information >------

Record Number: D24-4291794

Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

[SEC=OFFICIAL]

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, ~~we believe they are invalid~~the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Commented [TD1]: Can we have another word?

Commented [TD2R1]: Or way of referring to the invalidity?

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death~~s~~ and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports ~~that have been~~ circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to ~~causing~~ the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which ~~that~~ is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in ~~COVID-19 vaccines~~these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which~~e~~ require evidence that those methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to ~~test~~ measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
  - ~~It is unknown~~ where the vials were sourced
  - ~~or~~ their location, custody or temperature before or during testing.
- Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated and results can be relied upon. Processes that do not ~~that~~ ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.~~.~~
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies.~~,~~ N~~n~~or do the laboratories~~y~~ appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. ~~Laboratories with t~~These types of laboratory accreditation ensures that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies~~,~~ and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after ~~digestion~~processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

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Commented [TL3]: Too strong?

Commented [HN4]: Can we say they "appear" not to have, if we acknowledge their accreditation status is unknown? Should we change wording to say "this means they may not have either GMP etc"

Commented [TL5R4]: Could we say instead "there is no evidence that…"?

Commented [TL6]: Is "processing" a more accessible term than "digestion"?

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

Commented [TL7]: Can we strengthen this to say not just that we have tested, but that they have met those stringent limits?

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for life-long~~time~~ treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Commented [TL8]: Would be good to have here our standard line of "over
x million doses and significant real world evidence has shown the risk/benefit ratio for vaccines remains overwhelmingly positive" or similar (don't have the words with me, sorry)

From: s22
To: s22
Cc: s22
Subject: FW: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 2:12:54 PM
Attachments: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.tr5
image002.png

Hi s22

As s22 would have flagged with you, could you please take a look at this and see how it lands from a comms perspective and make any edits or comments?

Once done, either you or s22 could also share with s22 /News team.

Please keep me CCed in.

ta

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 2:08 PM
To: s22 <s22 @health.gov.au>
Cc: s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>
Subject: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22

As discussed, the draft statement is attached. It has AS cleared input from Toxicology and input from s22, SEB BSS and the Laboratories. May you please have a comms specialist review? This has not been past a FAS yet.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation which claims that the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy. For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

Medicines made using biotechnology

Biotechnology has been used to make medicines for many decades. The first biotechnology products produced using recombinant DNA technology were marketed globally in the early 1980s.

DNA is an approved starting material for many biotechnology products. This includes mRNA vaccines, such as Comirnaty and Spikevax, as well as recombinant proteins such as the Novavax vaccine, insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines.

Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine. *Residual* DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Residual DNA in biotechnology products has been the topic of international regulatory discussions since the 1990s.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, World Health Organization, United States Food and Drug Administration and other regulatory agencies.

Commented [s22]: Happy for the comms experts to comment on wh r this, or some similar representation may be useful

Residual DNA in Biotechnology Products – quality controls

When medicines are made there are many controls to ensure the final product is as pure as possible. For biotechnology medicines that use DNA as a starting material there are steps in the manufacturing process which remove and/or minimise amounts of residual DNA in the final product.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other regulators prior to marketing approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia.

Every batch of the mRNA COVID-19 vaccines released in Australia have met the regulatory requirements for residual DNA concentration in the final product. To date, the TGA have also

independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to monitor the residual DNA concentration in the final product. Our results are in alignment with the manufacturers results and show that the amounts of residual DNA in the final product are below the **regulatory limit of 10 ng per dose**.

Residual DNA in Biotechnology Products – safety

The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There is no evidence to indicate that COVID-19 vaccines have increased rates of cancer at a population level.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for lifetime treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that levels of residual DNA below the required quality limits presents a very low risk to safety.

Reports and publications alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amounts of DNA in the COVID vaccine. To date, these reports fall short of the scientific rigor expected in pharmaceutical testing. If you are interested in the veracity of the information you are reading about DNA in the mRNA vaccines then there are some points to consider about the quality of the study that produced these reports. Common concerns with these studies include:

- **Results interpretation**: Some laboratories have chosen to report DNA levels using a test, fluorometry, that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA, which may be present in minute amounts and mRNA, which is the main ingredient in the COVID-19 vaccines.
- **Suitable samples**: Some of these studies use a very small number, for example only three vials. The studies used samples that were well past their use by date. These samples were not suitable for testing.
- **Sample traceability**: It is unknown where vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- **No cold chain**: Vaccine vials are required to be shipped via cold chain, or in other words, the temperature must be within a specified range, which must be monitored. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. The samples used in the small laboratory studies were not kept in cold chain and usually did not have temperature loggers with them.
- **Unvalidated method**: Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which provide performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry

Commented [KL2]: Needs comments from Tox and PVB about residual DNA not causing:
Transgenic babies
Cancer
Disrupted biological processes

Commented s22 Tox input provided (15 Oct).

Commented s22 Input from Tox. SEB AS cleared.

method to test residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- **Inappropriate reference material**: The reference materials were not characterised.
- **Laboratory status**: The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*.

The TGA is constantly reviewing the latest scientific evidence about the safety of vaccines and other biotechnology products. This statement represents the TGA's views on the scientific evidence as at [DATE]

From: KERR, Lisa
To: DUFFY, Tracey; HENDERSON, Nick
Cc: s22 ; LAWLER, Tony; s22 ; s22 ; s22 ; VUCKOVIC, George; s22 ; s22 ; s22
Subject: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 8:55:49 AM
Attachments: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.tr5
image003.png

Good morning Nick and Tracey,

In response to the recent spike in mis/disinformation about "DNA contamination" in the mRNA vaccines we've drafted a statement (D24-4291794) for the TGA website (as a media release). s22 , both SEB Tox and SEB BSS, and RPSD Regulatory Education and Comms have provided input and suggestions to this draft.

Would you both please provide clearance for publication (or amendments…)

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports which claims that the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, we believe they are invalid.

Many of our concerns are listed at [link to the heading at bottom of report – Common concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see:
www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports that have been circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are causing the spread of misinformation.

Common concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.
- Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals

for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.
- It is unknown where the vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. Laboratories with these types of accreditation ensures that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also

independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety
To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for lifetime treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable and are creating confusion.

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

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Concerns with these studies include:

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- Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.
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- The physical reference materials were not adequately defined.

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- Some of these studies use a very small sample number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.
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From: DUFFY, Tracey
To: KERR, Lisa; HENDERSON, Nick
Cc: s22 ; LAWLER, Tony; s22 ; s22 ; s22 VUCKOVIC, George; s22 ; s22 ; s22
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:19:39 AM
Attachments: image001.png

Thanks – I have had a quick look and provided some comments/questions in the TRIM file to try and tighten our points.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:56 AM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 <s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
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Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
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Therapeutic Goods Administration
Department of Health and Aged Care
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Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports that have been circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are causing the spread of misinformation.

Common concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.
- Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals

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- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.
- It is unknown where the vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. Laboratories with these types of accreditation ensures that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also

independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety
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To: DUFFY, Tracey; HENDERSON, Nick
Cc: s22 ; LAWLER, Tony; s22 ; s22 s22 ; VUCKOVIC, George; s22 ; s22 ; s22
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:38:43 AM
Attachments: image001.png

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Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

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While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, ~~we believe they are invalid~~the results are not robust or reliable.

Many of our concerns are listed at [link to the heading at bottom of report – Common concerns with these studies].

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Commented [KL4R3]: They occur in the three main reports from Konig, Speicher and McKernan

Commented [TD5]: Why are they common?

Commented [KL6R5]: As above

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Cc: s22 ; s22 ; s22 ; s22 ; VUCKOVIC, George; s22 ; s22 s22
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:49:35 AM
Attachments: image001.png
image001.png

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Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

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From: HENDERSON, Nick
To: KERR, Lisa; LAWLER, Tony; DUFFY, Tracey
Cc: s22 ; s22 s22 ; s22 VUCKOVIC, George; s22 ; s22 ; s22
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:05:56 AM
Attachments: image001.png
DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024NH.docx

---

Hi Lisa

This looks good. Minor comment in TRIM version and attachment for me

Nick

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:55 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
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Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony – e copy attached

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Thursday, October 17, 2024 9:50 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
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To: HENDERSON, Nick; KERR, Lisa; DUFFY, Tracey
Cc: s22 ; s22 ; s22 ; s22 ; VUCKOVIC, George; s22 ; s22 ; s22
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:24:16 AM
Attachments: image001.png
DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024NH_TL.docx

---

Thanks very much, this is great. Some corrections and comments from me in the attached (fortunately 25 people failed to board the plane!)
T

From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Thursday, October 17, 2024 10:05 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 s22 @Health.gov.au>
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa

This looks good. Minor comment in TRIM version and attachment for me

Nick

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:55 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 ari <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony – e copy attached

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Thursday, October 17, 2024 9:50 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>

Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi
Is the intent to get this online today? I will have TRIM access in a few hours and can have a look at it then.
Thansk
T

Sent from Workspace ONE Boxer
On 17 October 2024 at 6:38:43 am GMT+8, KERR, Lisa <Lisa.Kerr@health.gov.au> wrote:

> Ok I've had a go at fixing/responding….
>
> ---
>
> **From:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>
> **Sent:** Thursday, October 17, 2024 9:20 AM
> **To:** KERR, Lisa <Lisa.Kerr@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 <s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
> **Subject:** RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
>
> Thanks – I have had a quick look and provided some comments/questions in the TRIM file to try and tighten our points.
>
> ---
>
> **From:** KERR, Lisa <Lisa.Kerr@health.gov.au>
> **Sent:** Thursday, October 17, 2024 8:56 AM
> **To:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
> **Subject:** For clearance: DRAFT Statement - Addressing misinformation about DNA in the

mRNA vaccines - October 2024 [SEC=OFFICIAL]

Good morning Nick and Tracey,
In response to the recent spike in mis/disinformation about “DNA contamination” in the mRNA vaccines we’ve drafted a statement ([%20%20]D24-4291794) for the TGA website (as a media release). s22 , both SEB Tox and SEB BSS, and RPSD Regulatory Education and Comms have provided input and suggestions to this draft.
Would you both please provide clearance for publication (or amendments…)
Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
[%20%20]www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

------< Content Manager Record Information >------
Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

[SEC=OFFICIAL]

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, ~~we believe they are invalid~~the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Commented [TD1]: Can we have another word?

Commented [TD2R1]: Or way of referring to the invalidity?

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death~~s~~ and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports ~~that have been~~ circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to ~~causing~~ the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which ~~that~~ is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in ~~COVID-19 vaccines~~these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which~~e~~ require evidence that thosee methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to ~~test~~ measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
  - ~~It is unknown~~ where the vials were sourced
  - ~~or~~ their location, custody or temperature before or during testing.
- Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated and results can be relied upon. Processes that do not ~~that~~ ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.~~.~~
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies.~~,~~ N~~n~~or do the laboratories~~y~~ appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. ~~Laboratories with t~~These types of laboratory accreditation ensure~~s~~ that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies~~,~~ and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after ~~digestion~~processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

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Commented [TL3]: Too strong?

Commented [HN4]: Can we say they "appear" not to have, if we acknowledge their accreditation status is unknown? Should we change wording to say "this means they may not have either GMP etc"

Commented [TL5R4]: Could we say instead "there is no evidence that…"?

Commented [TL6]: Is "processing" a more accessible term than "digestion"?

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

Commented [TL7]: Can we strengthen this to say not just that we have tested, but that they have met those stringent limits?

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for life-long~~time~~ treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Commented [TL8]: Would be good to have here our standard line of "over
x million doses and significant real world evidence has shown the risk/benefit ratio for vaccines remains overwhelmingly positive" or similar (don't have the words with me, sorry)

From: s22
To: s22 ; LAWLER, Tony; DUFFY, Tracey; KERR, Lisa
Cc: s22 ;s22 ;s22 ; VUCKOVIC, George; s22 ; s22 ; HENDERSON, Nick; s22 s22
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 2:59:25 PM
Attachments: image001.png
image002.png
[D24-4399772] Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX

Good Afternoon s22

Following on from Tracey's phone call, Tracey has asked me to share the Draft Statement - Addressing misinformation about DNA in the mRNA vaccines.

Please note that Tony's flight is scheduled to land around 6pm, he will then provide final clearance when possible.

s22
s22

Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
P: s22

Please note that my working days and hours are Mon-Fri, 8am – 5pm
I do not check my emails outside of my working days and hours. Any contact outside of those hours will be actioned when I am next online.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 2:10 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Good afternoon,

The comments from Tracey, Nick and Tony have been worked through. The latest clean copy is attached and here: D24-4399772

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
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Concerns with these studies include:

Selective reporting and method validation

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- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

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Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billions of vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

From: s22
To: KERR, Lisa; DUFFY, Tracey; s22 ; s22
Cc: s22 ; s22 ; s22 ; VUCKOVIC, George; s22 ; HENDERSON, Nick; LAWLER, Tony
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 3:43:41 PM
Attachments: D24-4399772 Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 - PB edit.docx
image001.png

Hi Lisa,

I suggested a minor edit in the safety section, and a comment in the first section as I think there may have been some text missing.

Kind regards,
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 2:10 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>
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Lisa Kerr PSM PhD MBA (Dr/she/her)
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Commented s22 I think there may be some text missing here?

Should the sentence read 'Many of our concerns with these studies are listed below' (with the link to the section on 'below'

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Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product. The vaccines met the required limits for residual DNA.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome. This includes products such as insulin, which are injected multiple times a day for life-long treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billion~~s of~~ vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

From:	KERR, Lisa
To:	LAWLER, Tony
Cc:	DUFFY, Tracey; HENDERSON, Nick; s22 ; s22
Subject:	For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date:	Friday, 18 October 2024 11:14:33 AM
Attachments:	Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.tr5

Hi Tony,

Final statement attached as promised.

Lisa

------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Many of our concerns are listed below [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality, and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see:
www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which require evidence that those methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
    - where the vials were sourced
    - their location, custody, or temperature before or during testing.

  Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated, and results can be relied upon. Processes that do not ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. There is no evidence that these laboratories have Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies. Nor do the laboratories appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. These types of accreditations ensure that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product. The vaccines met the required limits for residual DNA.

The quality limits ensure that there is less than 10 ng present per dose – or less than ten billionths of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

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To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome. This includes products such as insulin, which are injected multiple times a day for life-long treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billion vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

From: s22
To: s22
Subject: FW: residual DNA notes regarding risk [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 9:38:28 AM
Attachments: image001.png

The links below might help as well

From: s22 s22 @health.gov.au>
Sent: Thursday, October 10, 2024 11:45 AM
To: s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>
Subject: RE: residual DNA notes regarding risk [SEC=OFFICIAL]

Hi s22

You can pass the information onto Lisa.

Additional info in regard to the SV40 region:

Not sure if f1 *ori* not recognised. May be required for replication in mammalian cells (vector appears to be dual expression vector). Does it require other components? (just thoughts) Regardless, the DNA is fragmented and this would be inconsequential.

The f1 *ori* SV40 promoter region is 813 bp. The probability of this region being intact is low given the random (?) fragmentation process to sizes <200 bp. This region compromises ~10% of the plasmid DNA. Therefore, assuming the residual DNA is solely due to plasmid DNA, this would equate to 1 ng/dose of the f1 *ori* SV40 promoter region, most of which is likely to be fragmented. The molecular weight of the plasmid is ~2.4 MDa. 10 ng of plasmid DNA equates to 4.2×10^{-6} nmol of DNA, a very low level.

No SV40 proteins are encoded by the plasmid.

The following articles also address the specific issue (thanks to s22 for finding):
https://assets.publishing.service.gov.uk/media/669e40cdce1fd0da7b592a11/FW__FOI_24_212_final_redaction.pdf

https://www.fda.gov/media/174875/download

https://www.scientificamerican.com/article/no-covid-mrna-vaccines-wont-damage-your-dna1/

https://science.feedback.org/review/claim-covid-19-mrna-vaccines-dna-contaminants-study-unknown-provenance-no-evidence-covid-19-mrna-vaccines-alter-dna-people/

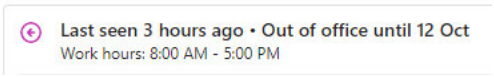
https://www.aap.com.au/factcheck/senate-hearing-used-to-propel-vaccine-dna-fears/

The submitted paper has not been published in a peer-reviewed journal. Nor have the following preprint papers:

McKernan, K., Y. Helbert, L.T. Kane and S. McLaughlin (2023) Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vectords DNA per dose (https://osf.io/preprints/osf/b9t7m)

Speicher, D.J., J. Rose, L.M. Gutschi, D. Wiseman and K. McKernan (2023) DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events.

As for s22 I haven't heard anything. He seems to be out of office until on Teams:



From: s22 s22 @health.gov.au>
Sent: Thursday, October 10, 2024 10:33 AM
To: s22 <s22 @health.gov.au>
Subject: RE: residual DNA notes regarding risk [SEC=OFFICIAL]

Thank you, s22 . You must have spent a lot of time on this. It is very useful for addressing concerns raised in the "science summary".

Do you mind me forwarding this to Lisa? Or you prefer to send her yourself?

s22 has logged on this morning, but his status is out of office. Hope he is better today.

Cheers

s22

From: s22 s22 @health.gov.au>
Sent: Thursday, October 10, 2024 8:02 AM
To: s22 s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>
Subject: residual DNA notes regarding risk [SEC=OFFICIAL]

Hi s2

I have put together some notes below. I thought I would let you know where I was up to.

Assumption that the 10 ng/dose and 200 bp fragments is met in the vaccine.

Consideration of the limit of 10 ng/dose is covered Grachev *et al.* (1998), attached. The limit was based on quality aspects rather than safety; residual DNA was considered as a contaminant rather than a significant risk factor. The WHO reported that a 10 µg dose of DNA (1000-fold higher than the maximum found in the vaccine) would result in the inactivation of two tumour-suppressor genes, by insertional mutagenesis, within a single cell of a vaccine recipient in only one of 10^7 recipients. Human blood contains 75–450 µg DNA per unit blood (i.e. 45000 times higher than the maximum residual DNA from a dose of the vaccine), associated with the death of

nucleated cells (Duxbury *et al.*, 1995, attached).

Therefore, a significant margin of safety exists with a limit of 10 ng/day. However, further considerations regarding safety are presented below.
The limit of 10 ng/dose was based on intact DNA. The safety margins are expanded further when the DNA is fragmented to <200 bp (FDA Guidance for Industry, 2010; and paper yet to get). Fragmentation of the DNA below the size of a functional gene such as this reduces the risk of expression of a functional gene.

Risks associated with components of the residual plasmid DNA:
The plasmid for expression of the Pfizer mRNA was based on a pCMV-TAG vector (I used BLAST analysis of sequence from Mod3 as not all info was placed in the plasmid map provided by the Sponsor).

- It contains a bacterial *ori* (origin of replication) to facilitate replication in bacterial cells. This *ori* would not be recognised in human cells.
- The plasmid also contains a SV40 promoter and f1 *ori* region (not shown in plasmid map presented by Sponsor but found in BLAST and reported in Speicher & McKernan papers). This is used in pCMV-Tag vectors for selection in mammalian cells. The SV40 enhancer region can promote nuclear transport of DNA. Risk that this will happen is low due to low level of DNA. Risk if does happen, low as integration events have low probability. The *ori* is not used for replication.

Given the vaccine plasmid is manufactured in bacterial cells and is a bacterial plasmid, the residual DNA would not encode any oncogenes.

Therefore:

- Risk of expression of genes from residual DNA low due to fragmented nature of DNA
- Risk of oncogene expression is negligible
- Risk of replication of DNA is negligible due to fragmented DNA (no intact plasmid) and lack of recognition of *ori*
- Risk of insertion is extremely low based on levels and probability indicated in data published by WHO, Yang etc. [still to get info re. direct injection into cells]

The TGA does not hold any evidence that the residual DNA is encapsulated in lipid nanoparticles. However, if it were, there is a low safety concern with the levels present as there is a sufficient safety margin.

Refs:

Duxbury M., Jezuit M., Letwin B. and Wright J. (1995) DNA in plasma of human blood for transfusion. *Biologicals* **23:** 229–231.

FDA Guidance for Industry [2010]: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications — https://www.fda.gov/media/78428/download

Grachev V., Magrath D. and Griffiths E. (1998) WHO requirements for the use of animal cells as in vitro substrates for the production of biologicals (Requirements for biological substances no. 50). *Biologicals* **26:** 175–193

Is there a container somewhere for papers re. residual DNA in vaccines/biological products.

Some questions for quality area:

- Confirm levels of residual DNA meet the 10 ng/dos and 200 bp limits (is this CIC info?)
- Is there any data on whether the residual DNA is encapsulated in lipid nanoparticles?
- Confirm what SV40 sequences are contained in the plasmid vector for Pfizer vaccine (promoter and enhancer?)

From: s22
To: s22
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 12:25:29 PM
Attachments: 241009 - LOD to Min. Butler Re DNA.pdf
FW URGENT All 537 Australian Councils to Receive DNA Contamination Report SECOFFICIAL.msg
Science Summary Consequences of DNA.docx
image002.png
RE URGENT Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child"s vial - SUSPENSION REQUEST SECOFFICIAL.msg
DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - SW 14102024.docx
Importance: High

Looks like a bit of discussion on integrase. This is a fact "Any residual DNA in the vaccine cannot integrate into human DNA without an enzyme called integrase. Integrase is not present in mammalian species. Instead, integration of viral DNA into host genome can occur naturally in viral infections from retroviruses (e.g. HIV), which make retroviral integrase. "

https://www.sciencedirect.com/science/article/abs/pii/S1879625712001319

From: s22
Sent: Monday, October 14, 2024 1:01 PM
To: s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Hi s22

Looks like we are asked to put together something related to DNA contamination misinformation.

Lisa's request:

"Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation"

Recently s22 answered a media question.

- My question is about what this section of the patent application means. Is it as is claimed an admission the vaccine could cause cancer — or is it pointing out the advantages of an mRNA vaccine as opposed to a DNA vaccine?

s22 response:

COVID-19 mRNA vaccines are mRNA vaccines, which are produced from plasmid DNA, and are not DNA vaccines. Residual DNA in small fragments might be present in the final mRNA vaccine product in very small quantality (less than 10 ng per dose). Residual DNA is a well-known manufacturing impurity in biotechnology products including recombinant proteins. Residual DNA has been the topic of international regulatory discussions since the 1990s. The limit for residual DNA in biological medicines is 10 ng/dose recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients

for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer.

Any residual DNA in the vaccine cannot integrate into human DNA without an enzyme called integrase. Integrase is not present in mammalian species. Instead, integration of viral DNA into host genome can occur naturally in viral infections from retroviruses (e.g. HIV), which make retroviral integrase.

I have used this information to add to the document. You will see Lisa's team copied stuff from this email as well.

Please see SW14102024 version attached to this email.

Thanks,
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 11:17 AM
To: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Dear s22 and s22

Lisa Kerr has asked if Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation.

Could I get you to put Tox input together into the TRIM-linked document and then let me so that I can get George's clearance? I have also attached s22 last input for your reference.

Timelines: Given Lisa's statement below, I would recommend COB today so I can get it to George asap.

With thanks

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

- Integrates into the human genome
- Causes cancer
- Has/could result in transgenic babies

s22 – I know you sent me a summary of the SV40 primer issue – could you insert a paragraph for lay people in the document where indicated about margins of safety etc?

Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr **PSM PhD MBA (Dr/she/her)**
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care

PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
To: s22 ; VUCKOVIC, George; s22 ; KERR, Lisa; s22
Cc: s22 ; s22 ; s22 ; s22 ; s22
Subject: RE: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child"s vial - SUSPENSION REQUEST [SEC=OFFICIAL]
Date: Friday, 11 October 2024 2:07:09 PM
Attachments: Tox response to Claim #4 in the letter to the minister.docx
image004.png
image005.png
image006.png
image007.png

Hi s22 s22 and Lisa

Attached is Tox's input to TGA's response to the letter to the Minister from PJ O'Brien & Associates.

I will be away from Monday. Please contact s22 for further input or information from the Tox team if required.

Kind regards,

s2

From: s22 <s22 @health.gov.au>
Sent: Thursday, October 10, 2024 9:58 AM
To: VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 <s22 @health.gov.au>s22 s22 @health.gov.au>
Cc: s22 <s22 @Health.gov.au>; s22 <s22 @Health.gov.au>
Subject: FW: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Good Morning,

Please see below email trail. MDPQD have indicated they will be reaching out to seek TOX input for the attached.

Please note the input does not require FAS clearance.

Kind Regards

s22
s22

Nick Henderson, First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health & Aged Care
T: s22 | E: s22 @health.gov.au
MDP 122, PO Box 100, Woden ACT 2606, Australia

From: s22 [redacted]
Sent: Thursday, October 10, 2024 10:47 AM
To: s22 [redacted] <s22 [redacted]@health.gov.au>; s22 [redacted] <s22 [redacted]@Health.gov.au>; s22 [redacted] s22 [redacted]@Health.gov.au>
Cc: s22 [redacted] s22 [redacted]@Health.gov.au>; s22 [redacted] s22 [redacted]@Health.gov.au>; s22 [redacted] s22 [redacted]@health.gov.au>; s22 [redacted] s22 [redacted]@health.gov.au>
Subject: FW: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Good Morning all,

Just an FYI below - upcoming D response that we will need your input into.

Warm regards,

s22 [redacted]
s22 [redacted]
Health Products Regulation Group
Australian Government Department of Health and Aged Care

Phone: s22 [redacted] Location: Scherger Drive, Fairbairn
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 9, 2024 5:01 PM
To: s22 [redacted] <s22 [redacted]@Health.gov.au>; s22 [redacted] <s22 [redacted]@Health.gov.au>
Cc: s22 [redacted] s22 [redacted]@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Subject: RE: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi,

This also needs input from Tox, RLSB and PVB.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

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working hours.

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From: s22 <s22 @health.gov.au>
Sent: Wednesday, October 9, 2024 1:13 PM
To: s22 s22 @Health.gov.au>
Cc: s22 s22 @Health.gov.au>; HPRG Parliamentary <HPRG.Parliamentary@Health.gov.au>
Subject: FW: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi s22

This one will be assigned to LB, so FYI for you and the team that OGTR will need to provide input.

Cheers,

s22

s22 s22

s22

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
☏: s22 | 💻: s22 @health.gov.au

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Wednesday, October 9, 2024 1:11 PM
To: MPS <MPS@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @Health.gov.au>

Subject: RE: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi
Looking at the last paragraph of the letter- although OGTR has repeatedly confirmed that there is no GMO element, can we please get their input too.
Thanks
T

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Wednesday, October 9, 2024 12:47 PM
To: MPS <MPS@health.gov.au>
Cc: Minister Butler <Minister.Butler@Health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @Health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Subject: RE: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi all

Confirming we'd like a D response for this one please, with a cc to Minister Butler.

Many thanks
s22

s22
s22
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
T: s22 | M: s22
E: Minister.Butler.DLO@health.gov.au
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT, 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 s22 @health.gov.au>
Sent: Wednesday, October 9, 2024 12:21 PM
To: s22 <s22 @Health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: Minister Butler <Minister.Butler@Health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi s22

Yes this is something we would be the relevant area to provide a response to if needed.

Cheers,

s22

s22

s22

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s2 @health.gov.au

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 <s22 @Health.gov.au>
Sent: Wednesday, October 9, 2024 12:18 PM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 s22 @health.gov.au>; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: Minister Butler <Minister.Butler@Health.gov.au>
Subject: FW: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST [SEC=OFFICIAL]

Hi Tony and team

Assume this will be one that your group responds to directly?

If you can confirm that would be great.

@Minister Butler DLO – Grateful for your advice as to whether the Minister should be cc:ed into the response.

Thanks, s22

s22
s22

Office of the Secretary
Australian Government, Department of Health and Aged Care
T: s22 | M: s22
E: s22 @health.gov.au
Location: Level 6 Yaradhang Building

PO Box 9848, Canberra ACT 2601, Australia

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From: s22 [redacted] <s22 [redacted]@pjob.com.au>
Sent: Wednesday, October 9, 2024 12:09 PM
To: Minister Butler <Minister.Butler@Health.gov.au>; Mark.Butler.MP@aph.gov.au
Cc: COMLEY, Blair <Blair.COMLEY@Health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: URGENT: Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child's vial - SUSPENSION REQUEST

Dear Minister Butler

Please find **attached** urgent letter for your attention following discovery of synthetic DNA contamination identified in Pfizer and Moderna vials sourced from Australia.

Given the nature of the information contained in this letter, we look forward to hearing from you as a matter of urgency.

--
Kind regards
s22 [redacted]
Lawyer
PJ O'Brien & Associates
s22 [redacted]

Claim (Point 4):

The contamination includes Simian Virus 40 (SV40) sequences in Pfizer's products, a viral sequence long known to present significant risks of cancer through insertional mutagenesis. It is well-established in scientific literature that as few as 3-to-10 SV40 fragments are enough to integrate foreign DNA into human cells, significantly increasing the risk of cancer. Dr. Speicher's findings indicate that a single dose of Pfizer's vaccine may contain as many as 575 billion SV40 fragments. Such contamination cannot be dismissed, especially given that 24 trillion synthetic DNA fragments could be present in just one shot, which drastically heightens the risk of serious long-term health consequences for the more than 20 million Australians who have received these products.

Commented s22 Input by the Labs

Response:

There is no scientific evidence supporting the statement "It is well-established in scientific literature that as few as 3-to-10 SV40 fragments are enough to integrate foreign DNA into human cells". The study cited by the group in their "Science Summary" showed SV40 enhancer facilitating nuclear import of plasmid DNA, but did not demonstrate integration of plasmid DNA into mammalian cells (Dean et al. 1999).

The plasmid used in the manufacture of COVID-19 mRNA vaccines contains a SV40 promoter sequence. The SV40 promoter region in the plasmid used in the manufacture of COVID-19 mRNA vaccines is only a very small fragment of the SV40 genome, and is not the SV40 T antigen sequence (which is thought to be responsible for SV40-induced cancer in some animal species) or the whole SV40 virus. No SV40 proteins are encoded by the plasmid. It is the SV40 virus that has been associated with cancer in animals, not the promoter fragment alone. The SV40 promoter sequence cannot act as a so-called insertional mutagen, i.e., integrate next to a cellular oncogene and activate its expression. Any residual SV40 promoter DNA fragments in the vaccine would be small (<200 bp), are inactive, and have no functional role.

The probability of the SV40 promoter region being intact in the vaccine is very low given the random fragmentation process of residual DNA to sizes <200 bp. This region compromises ~10% of the plasmid DNA. Therefore, assuming the residual DNA is solely due to plasmid DNA, this would equate to 1 ng/dose of the SV40 promoter region, most of which is likely to be fragmented. The molecular weight of the plasmid is ~2.4 MDa. 10 ng of plasmid DNA equates to 4.2×10^{-6} nmol of DNA, a very low level.

The limit of residual DNA in biological medicines was considered by a WHO working group on residual DNA, which recommended a limit of 10 ng/dose for residual DNA (Grachev et al. 1998). The limit was based on quality aspects rather than safety; residual DNA was considered as a contaminant rather than a significant risk factor. It was indicated that the risk of insertional mutagenesis that could lead to a neoplastic event is extremely small. A 10 µg dose of DNA (1000-fold higher than the maximum found in the vaccine) would result in the inactivation of two tumour-suppressor genes, by insertional mutagenesis, within a single cell of only one of 10^7 recipients. Furthermore, human blood contains 75–450 µg DNA per unit blood (i.e. 45000 times higher than the maximum residual DNA from a dose of the vaccine) (Duxbury et al., 1995). The safety margins are expanded further when the DNA is fragmented to <200 bp. Fragmentation of the DNA below the size of a functional gene such as this reduces the risk of expression of a functional protein.

Therefore, a significant margin of safety exists with a limit of 10 ng/day for residual DNA in the vaccine.

Dean DA *et al.* (1999) Sequence Requirements for Plasmid Nuclear Import. *Experimental Cell Research* **253:** 713–722.

Duxbury M *et al.* (1995) DNA in plasma of human blood for transfusion. *Biologicals* **23:** 229–231.

Grachev V *et al.* (1998) WHO requirements for the use of animal cells as in vitro substrates for the production of biologicals (Requirements for biological substances no. 50). *Biologicals* **26:** 175–193.

DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines

The TGA is aware that misinformation is circulating about DNA in the mRNA vaccines. The misinformation implies that appropriate health and safety checks of the vaccines have not been undertaken. The Therapeutic Goods Administration (TGA) is responsible for assessing all COVID-19 vaccines before they can be used in Australia. Both Comirnaty and Spikevax are fully registered in Australia. The TGA rigorously assesses any COVID-19 vaccine for safety, quality and efficacy. The TGA's decision to approve a new vaccine is always made on the basis that the benefits outweigh the risks for the intended population. The TGA is aware of claims from individuals and medical societies that the COVID-19 vaccines are allegedly contaminated with DNA. This is not the case.

History of Biotechnology Products

- DNA is an approved starting material for biotechnology products such as Comirnaty and Spikevax. This also includes recombinant proteins such as the Novavax vaccine, insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines.
- The first biotechnology products produced using recombinant DNA technology were marketed globally in the early 1980s.
- *Residual* DNA is the amount of DNA remaining after digestion and purification of the medicine. It is present in small fragments in the final mRNA COVID-19 vaccines and other biotechnology products in very small quantities (less than 10 ng per dose as recommended by the TGA, World Health Organization, United States Food and Drug Administration and other regulatory agencies). Residual DNA in biotechnology products has been the topic of international regulatory discussions since the 1990s.

Safety of DNA in Biotechnology Products

- Manufacturers take steps in the manufacturing process to purify starting materials, such as DNA, to remove and/or minimise amounts in the final product.
- The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other regulators prior to marketing approval.
- The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every batch of the mRNA COVID-19 vaccines released in Australia have met the regulatory requirements for residual DNA concentration in the final product. To date, the TGA have also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to monitor the residual DNA concentration in the final product. Our results are in alignment with the manufacturers results and show that the amounts of residual DNA in the final product are below the **regulatory limit of 10 ng per dose**.
- The limit for residual DNA in biological medicines is 10 ng/dose, as recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer
- Any residual DNA in the mRNA vaccine cannot integrate into human DNA without an enzyme called integrase. The mRNA vaccine does not contain integrase. Integrase is not present in mammalian species.
- ~~Humans are exposed to much greater quantities of foreign DNA all the time from bacterial and viral infections, compared to the minute amount from DNA fragments in mRNA vaccines or biological medicines.~~

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- The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There is no evidence to indicate that COVID-19 vaccines have increased rates of cancer at a population level.

Commented [KL1]: Needs comments from Tox and PVB about residual DNA not causing:
Transgenic babies
Cancer
Disrupted biological processes

Reports and publications alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amounts of DNA in the COVID vaccine. To date, these reports fall short of the scientific rigor expected in pharmaceutical testing. If you are interested in the veracity of the information you are reading about DNA in mRNA vaccines then there are some points to consider about the quality of the study that produced these reports. Common concerns with these studies include:

- **Results interpretation**: Some laboratories have chosen to report DNA levels using a test, fluorometry, that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA, which may be present in minute amounts and mRNA, which is the main ingredient.
- **Suitable samples**: Some of these studies use a very small number, for example only three vials. The studies used samples that were well past their use by date. These samples were not suitable for testing. The TGA does not test expired samples for batch release.
- **Sample traceability**: It is unknown where vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- **No cold chain**: Vaccine vials are required to be shipped via cold chain, or in other words, the temperature must be within a specified range, which must be monitored. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. The samples used in the small laboratory studies were not kept in cold chain and usually did not have temperature loggers with them.
- **Unvalidated method**: Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which provide performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity.
- **Inappropriate reference material**: The reference materials were not characterised.
- **Laboratory status**: The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to ISO/IEC 17025 , the international standard for testing and calibration laboratories.

The TGA is constantly reviewing the latest scientific evidence about the safety of vaccines and other biotechnology products. This statement represents the TGA's views on the scientific evidences as at [DATE]

From: s22
To: s22
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Monday, 14 October 2024 1:41:09 PM
Attachments: image001.png

Hi s22

Please call. We really want no impurities, but not possible, so need a cut off.

s22

Thanks so much s22 that looks great. The wording is very reasonable and puts it into context the existing experience and history of controlling for residual DNA.

One question I had (and only because this is new territory for me!): Is there's any use indicating what that limit represents relative to a contaminant DNA source of concern? In other words, is it even biologically possible for residual DNA at a limit of no more than 10 ng/dose to retain enough integrity from dosing to entering a cell and being enough to be incorporated into a genome for it to induce the effects that are being speculated about? What do you think? Is this something that helps or muddies the water?
I notice that there is no reference to a source – probably for lay understanding reasons. I think it might be fine, can refer it to s22 and see if he has any additional comments. Let me know if you have time to chat any time more about it.

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 1:01 PM
To: s22 s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Hi s22

Looks like we are asked to put together something related to DNA contamination misinformation.

Lisa's request:

"Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation"

Recently s22 answered a media question.

- My question is about what this section of the patent application means. Is it as is claimed an admission the vaccine could cause cancer — or is it pointing out the advantages of an mRNA vaccine as opposed to a DNA vaccine?

s22 response:

COVID-19 mRNA vaccines are mRNA vaccines, which are produced from plasmid DNA, and are not DNA vaccines. Residual DNA in small fragments might be present in the final mRNA vaccine product in very small quantality (less than 10 ng per dose). Residual DNA is a well-known manufacturing impurity in biotechnology products including recombinant proteins. Residual DNA has been the topic of international regulatory discussions since the 1990s. The limit for residual DNA in biological medicines is 10 ng/dose recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer.

Any residual DNA in the vaccine cannot integrate into human DNA without an enzyme called integrase. Integrase is not present in mammalian species. Instead, integration of viral DNA into host genome can occur naturally in viral infections from retroviruses (e.g. HIV), which make retroviral integrase.

I have used this information to add to the document. You will see Lisa's team copied stuff from this email as well.

Please see SW14102024 version attached to this email.

Thanks,
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 11:17 AM
To: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Dear s22 and s22

Lisa Kerr has asked if Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation.

Could I get you to put Tox input together into the TRIM-linked document and then let me so that I can get George's clearance? I have also attached s22 last input for your reference.

Timelines: Given Lisa's statement below, I would recommend COB today so I can get it to George asap.

With thanks
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

- Integrates into the human genome
- Causes cancer
- Has/could result in transgenic babies

s22 – I know you sent me a summary of the SV40 primer issue – could you insert a paragraph for lay people in the document where indicated about margins of safety etc?

Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
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From:	s22
To:	s22
Cc:	s22
Subject:	FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date:	Monday, 14 October 2024 2:13:00 PM
Attachments:	241009 - LOD to Min. Butler Re DNA.pdf FW URGENT All 537 Australian Councils to Receive DNA Contamination Report SECOFFICIAL.msg Science Summary Consequences of DNA.docx image002.png RE URGENT Australian Pfizer and Moderna COVID-19 Vaccines Contaminated with Synthetic DNA including child"s vial - SUSPENSION REQUEST SECOFFICIAL.msg DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - SW 14102024.docx
Importance:	High

Hi s22

Please see document DRAFT Statement – Addressing misinformation about DNA in the mRNA vaccines – SW 14102024.docx, which s22 has prepared in response to the request from Lisa.

We both discussed what is the best way to respond to this request (see below), going over various scenarios, and agreed that the statement prepared by her and s22 previously that refers to guideline limits for residual DNA and the extensive history of use of other biological products that are subject to this limit was appropriate. Please advise if you want us to expand on this statement, if there's anything else we should cover or want to discuss, noting that this is a lay person description with limited technical detail.

Thanks heaps,
s22

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- The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other regulators prior to marketing approval.
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Transgenic babies
Cancer
Disrupted biological processes

Reports and publications alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amounts of DNA in the COVID vaccine. To date, these reports fall short of the scientific rigor expected in pharmaceutical testing. If you are interested in the veracity of the information you are reading about DNA in mRNA vaccines then there are some points to consider about the quality of the study that produced these reports. Common concerns with these studies include:

- **Results interpretation**: Some laboratories have chosen to report DNA levels using a test, fluorometry, that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA, which may be present in minute amounts and mRNA, which is the main ingredient.
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- **Inappropriate reference material**: The reference materials were not characterised.
- **Laboratory status**: The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to ISO/IEC 17025 , the international standard for testing and calibration laboratories.

The TGA is constantly reviewing the latest scientific evidence about the safety of vaccines and other biotechnology products. This statement represents the TGA's views on the scientific evidences as at [DATE]

From: s22
To: s22
Cc: s22
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Monday, 14 October 2024 5:21:24 PM
Attachments: image001.png

Excellent. Thank you s22 and s22

The extra text and the comments should assist with the approval process as it works its way up the clearance pathway.

Regards
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 5:06 PM
To: s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

s22 and I discussed this, and revised it to have an additional dot point on nonclinical evidence of lack of adverse effects in repro studies at doses 200-fold the clinical dose of vaccine. Dot points are highlighted in yellow. s22 added a clarifying remark on the rationale for removing that statement about other inadvertent exposures and risks, which I agree with. Please advise if there is anything else or outstanding that you think should also be covered.

Thanks,
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 2:47 PM
To: s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22 and s22

Thanks for looking over this request and preparing a response (which looks good to me). Just a couple of follow-up questions from me.

Lisa has asked in one of the attached comments in the TRIM document:

> Needs comments from Tox and PVB about residual DNA not causing:
>
> Transgenic babies
>
> Cancer

Disrupted biological processes

1. Could we add to the following paragraph, something akin to our previous words about the finding from repro/dev toxicity studies in animals indicating no adverse effects at 100 times the human clinical dose ?

- The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There is no evidence to indicate that COVID-19 vaccines have increased rates of cancer at a population level.

2. The deleted text (~~Humans are exposed to much greater quantities of foreign DNA all the time from bacterial and viral infections, compared to the minute amount from DNA fragments in mRNA vaccines or biological medicines~~) – Is this incorrect or no longer needed? Would we be concerned if it was to be left in?

With thanks
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 2:14 PM
To: s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Hi s22

Please see document DRAFT Statement – Addressing misinformation about DNA in the mRNA vaccines – SW 14102024.docx, which s22 has prepared in response to the request from Lisa.

We both discussed what is the best way to respond to this request (see below), going over various scenarios, and agreed that the statement prepared by her and s22 previously that refers to guideline limits for residual DNA and the extensive history of use of other biological products that are subject to this limit was appropriate. Please advise if you want us to expand on this statement, if there's anything else we should cover or want to discuss, noting that this is a lay person description with limited technical detail.

Thanks heaps,
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 1:01 PM
To: s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Hi s22

Looks like we are asked to put together something related to DNA contamination misinformation.

Lisa's request:

"Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation"

Recently s22 answered a media question.

- My question is about what this section of the patent application means. Is it as is claimed an admission the vaccine could cause cancer — or is it pointing out the advantages of an mRNA vaccine as opposed to a DNA vaccine?

s22 response:

COVID-19 mRNA vaccines are mRNA vaccines, which are produced from plasmid DNA, and are not DNA vaccines. Residual DNA in small fragments might be present in the final mRNA vaccine product in very small quantality (less than 10 ng per dose). Residual DNA is a well-known manufacturing impurity in biotechnology products including recombinant proteins. Residual DNA has been the topic of international regulatory discussions since the 1990s. The limit for residual DNA in biological medicines is 10 ng/dose recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer.

Any residual DNA in the vaccine cannot integrate into human DNA without an enzyme called integrase. Integrase is not present in mammalian species. Instead, integration of viral DNA into host genome can occur naturally in viral infections from retroviruses (e.g. HIV), which make retroviral integrase.

I have used this information to add to the document. You will see Lisa's team copied stuff from this email as well.

Please see SW14102024 version attached to this email.

Thanks,
s22

From: s22 <s22 @health.gov.au>
Sent: Monday, October 14, 2024 11:17 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Importance: High

Dear s22 and s22

Lisa Kerr has asked if Tox could insert a paragraph for lay people into a draft web statement (link provided below) that she is putting together related to DNA contamination misinformation.

Could I get you to put Tox input together into the TRIM-linked document and then let me so that I can get George's clearance? I have also attached s22 last input for your reference.

Timelines: Given Lisa's statement below, I would recommend COB today so I can get it to George asap.

With thanks
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry

from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

- Integrates into the human genome
- Causes cancer
- Has/could result in transgenic babies

s22 – I know you sent me a summary of the SV40 primer issue – could you insert a paragraph for lay people in the document where indicated about margins of safety etc?

Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: s22
To: s22 ; s22
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 12:36:00 PM
Attachments: [16 Oct] Comparison of statements on integrases.docx
image001.png
image002.png

Hi s22

s22 and myself are discussing this at the moment. I have compiled a document of the statements of concern and the main issue is whether integrases are relevant. After discussing with s22 we agreed that its best to remove reference to integrases altogether. Is that possible?

Thanks, happy to chat,
s22

From: s22 <s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 12:33 PM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Dear s22 and s22

This has now become more urgent with George seeking our resolution sooner than later i.e. this afternoon.

Could we consider asap and work towards information George (and Lisa) by this afternoon, please.

Apologies for the late and urgent nature of this request.

Regards
s22

From: s22
Sent: Wednesday, October 16, 2024 12:06 PM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Dear s22 and s22

Just bringing some comments to your notice from s22 in BSS regarding plasmid DNA and integrase.

Lisa Kerr is likely to call a meeting to thrash out our statements to ensure consistency/scientific merit. Could you think further on these subjects and be prepared to put our case forward when the time comes?

With thanks
s22

From: s22 <s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 11:14 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for this.

With regard to adding the comment about plasmid DNA entering the human genome, I would be uncomfortable with that as I am unaware of studies which have tested this and so personally I have no experience in the matter.

I note however that s22 has added a comment about their being no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer. In this case s22 may be better placed to advise.

Regarding the intergrase dot point in the document, I recommend removal of that comment entirely. I don't believe it is correct and don't believe it adds anything, particularly in light of s22 comment.

Hope is helpful, happy to discuss.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 6:29 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks for looking at the document – may you please check it in as s22 needs to work on it now.

So from your comments below I take it that if I change the sentence to something like “there is no evidence that plasmid DNA has entered the human genome” that would sit better with you? I’ve looped s22 into this as it appears that BSS and Tox have different views? Should I arrange a meeting for us all to discuss?

I also wanted to play devils advocate a little and ask BSS if you were asked by a member of the public who has received a recombinant protein therapeutic good if the products you have approved have altered the human genome, have caused cancer or have lead to transgenic babies - what would you say?

Kind regards,

Lisa

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Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
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www.tga.gov.au

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Sent: Tuesday, October 15, 2024 6:08 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for the call.

I have added some comments, I did rearrange the opening paragraph, I apologise if this is presumptuous on my part.

As noted, you may wish to consider the inclusion of viral gene therapies as examples of products which use high levels of DNA starting material. These are more analogous to the mRNA vaccines

in that, for the one I am particularly similar with, large amounts of plasmid DNA are used in production which must be purified away from the therapeutic, in this case the viral vector. They also have the potential to package non-target sequences and be administered to patients. Note that these do not have as long usage experience as some of the other examples.

Also as noted I do not believe the statement about integrases to be correct. As described below other mechanisms of DNA integration are possible, I would expect these to be rare events particularly in vivo with the cascade of circumstances required.

Hope is helpful.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Tuesday, October 15, 2024 4:45 PM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Just had a very interesting chat with s22 about all of this – with regards to the specific circumstances that I'm referring to – eg minute amounts of highly fragmented bacterial plasmid. We agreed that to integrate, there would need to be a series of highly improbably events to line up. s22 has kindly agreed to provide some input into the draft statement.

Kind regards,

Lisa

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Medical Devices and Product Quality Division
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PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: s22 <s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 2:40 PM
To: s22 <s22 @health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks, with regard to the integration issue, foreign DNA can integrate into chromosomal DNA in the absence of an integrase in mammalian cells. This comes from the DNA damage/repair literature where breaks in DNA are repaired through processes called non-homologous end joining or homologous recombination. Exogenous DNA can potentially be incorporated using these processes.

Hope is helpful.

Cheers

s22

From: s22 <s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Confirm BSS does evaluate residual host cell DNA as part of the premarket assessment of recombinant products. The accepted limit as mentioned is 10ng/dose and the method is usually qPCR via EP **2.6.35. Quantification and characterisation of residual host-cell DNA**, see attached.

In regard to the statement re DNA integration and the need for integrase suggest this may need to be softened as understand, although unlikely, there are alternative mechanisms for DNA integration. s22 may have some additional thoughts/comments re this.

s22
s22
Biological Science Section
Scientific Evaluation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn ACT
PO Box 100, Canberra ACT 2601, Australia

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From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 s22 @health.gov.au>
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The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

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- Causes cancer
- Has/could result in transgenic babies

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Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

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Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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Statement added on Monday 14/10:

- The limit for residual DNA in biological medicines is 10 ng/dose, as recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer
- Any residual DNA in the mRNA vaccine cannot integrate into human DNA without an enzyme called integrase. The mRNA vaccine does not contain integrase. Integrase is not present in mammalian species.
- No adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in the combined reproductive and development study in animals administered 200 times the clinical dose of vaccine.
- ~~Humans are exposed to much greater quantities of foreign DNA all the time from bacterial and viral infections, compared to the minute amount from DNA fragments in mRNA vaccines or biological medicines.~~
- The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine. There is no evidence to indicate that COVID-19 vaccines have increased rates of cancer at a population level.

Previous response provided by Tox 19/9/2024 (Media response AAP):

COVID-19 mRNA vaccines are mRNA vaccines, which are produced from plasmid DNA, and are not DNA vaccines. Residual DNA in small fragments might be present in the final mRNA vaccine product in very small quantality (less than 10 ng per dose). Residual DNA is a well-known manufacturing impurity in biotechnology products including recombinant proteins. Residual DNA has been the topic of international regulatory discussions since the 1990s. The limit for residual DNA in biological medicines is 10 ng/dose recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer.

Any residual DNA in the vaccine cannot integrate into human DNA without an enzyme called integrase. Integrase is not present in mammalian species. Instead, integration of viral DNA into host genome can occur naturally in viral infections from retroviruses (e.g. HIV), which make retroviral integrase.

Comment from BSS:

As noted, you may wish to consider the inclusion of viral gene therapies as examples of products which use high levels of DNA starting material. These are more analogous to the mRNA vaccines in that, for the one I am particularly similar with, large amounts of plasmid DNA are used in production which must be purified away from the therapeutic, in this case the viral vector. They also have the potential to package non-target sequences and be administered to patients. Note that these do not have as long usage experience as some of the other examples.

Commented [s22]: I think the concern is for DNA in medicines, which we have covered by saying "the safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. " I don't think this sentence adds anything more. If anything it is irrelevant.

Commented [KL2]: Needs comments from Tox and PVB about residual DNA not causing:
Transgenic babies
Cancer
Disrupted biological processes

Commented [s22]: Cancer covered in the last sentence.

Commented [s22]: Cancer is covered here

Also as noted I do not believe the statement about integrases to be correct. As described below other mechanisms of DNA integration are possible, I would expect these to be rare events particularly in vivo with the cascade of circumstances required.

From: s22
To: s22
Cc: s22
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 2:51:00 PM
Attachments: image001.png
image002.png
image003.png

---

s22

This is what we'll send out shortly which you will be cc'd into too (as well as George)

———————————

Good afternoon all,

Just chiming in to give a bit of clarity on the statements that were provided by the Tox section.

We agree with comments raised by BSS that the original dot point on the role of integrases should be deleted. There are papers implying that other enzymes/mechanisms are involved in integrating e.g. SARS-CoV-2 sequences into the DNA of human cells (see https://www.pnas.org/doi/10.1073/pnas.2105968118).

Comments/changes that were added by the Tox section were the dot points regarding: limits for residual DNA; the lack of evidence of adverse effects; and a recommendation to delete the statement on human exposure to foreign DNA.

The following dot point is based verbatim on a previous response provided by the section.

> *The limit for residual DNA in biological medicines is 10 ng/dose, as recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer.*

Its inclusion was intended to convey that the 10 ng/dose limit is effective at safeguarding against genomic integration (and cancers), evident by the long history of safe use of biotechnology products (including the more recent experiences with mRNA vaccines). In the event that it is considered too speculative, the last statement can be removed "*There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer*."

We would also like to take this opportunity to simplify the statement on adverse developmental effects, which we will update once the document is checked back into TRIM.

> Original:
> ~~No adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in the combined reproductive and development study in animals administered 200 times the clinical dose of vaccine.~~

Amendment:
In safety studies (combined reproductive and developmental study in animals), no adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in in animals administered 200 times the clinical dose of vaccine.

I hope this is okay.

Kind regards,
s22

s22
s22
Scientific Evaluation Branch
Medicines Registration Division | HPRG
Australian Government, Department of Health and Aged Care
T: s22 E: s22 @health.gov.au | Location: Melbourne
PO Box 100, Woden ACT 2606, Australia

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Hope is helpful, happy to discuss.

Cheers

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To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
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Lisa

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Cc: s22 <s22 @health.gov.au>; s22
<s22 @health.gov.au>
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s22

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Kind regards,

Lisa

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From: s22 <s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 2:40 PM
To: s22 <s22 @health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks, with regard to the integration issue, foreign DNA can integrate into chromosomal DNA in the absence of an integrase in mammalian cells. This comes from the DNA damage/repair literature where breaks in DNA are repaired through processes called non-homologous end joining or homologous recombination. Exogenous DNA can potentially be incorporated using these processes.

Hope is helpful.

Cheers

s22

From: s22 <s22 @health.gov.au>
Sent: Tuesday, October 15, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Confirm BSS does evaluate residual host cell DNA as part of the premarket assessment of recombinant products. The accepted limit as mentioned is 10ng/dose and the method is usually qPCR via EP **2.6.35. Quantification and characterisation of residual host-cell DNA**, see attached.

In regard to the statement re DNA integration and the need for integrase suggest this may need to be softened as understand, although unlikely, there are alternative mechanisms for DNA integration. s22 may have some additional thoughts/comments re this.

s22
s22
Biological Science Section
Scientific Evaluation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn ACT
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these

if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

The misinformation in the flawed studies / communications includes:

The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

- Integrates into the human genome
- Causes cancer
- Has/could result in transgenic babies

s22 – I know you sent me a summary of the SV40 primer issue – could you insert a paragraph for lay people in the document where indicated about margins of safety etc?

Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

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