

17 October 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202009675

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 8 September 2022 for information relating to adverse test results. Manatū Hauora will respond to your request in turn.

For all adverse test results since 2017, please supply the following information, separately for each adverse test result.

MOH Reference

Date of adverse test result

What iHemp variety was subject to adverse test result

Name of approved lab doing the test

Type of Licence – General or R&B

DHB Location of crop with the adverse test result

Was this the first adverse test result for this grower

If not, list of seasons when adverse test results had been noted

Area actually grown by licence holder in the year of the adverse test result

Other iHemp cultivars grown at the location in the year of the adverse test result

Was the sample pollinated (seeded) or unpollinated (female only plant)

DHB region of supplier of the seed to the licensee with the adverse test result

DHB Region, of original grower of the seed - original source (if different from above)

Was this original seed source an import, or grown from NZ seed.

Age of original source of seed planted by the grower with the adverse test result

How long had the original source of seed been in New Zealand

Outcome of the adverse test result, details such as

Correspondence entered into with grower

Explanation received from Licensee

Was a Section 44 letter sent, what were the requirements

Was a crop destruction order sent?

Other comments from the MOH investigation into the adverse THC result, which would help industry understand the reason for the result.

Please see attached as document one a table for the information you have requested for adverse test results since 2017. This is released to you in full.

Copy of results panel of adverse test result supplied by Grower/Lab (an actual copy of the table or results as reported to Medicines Control)

There are 19 documents in scope of this part of your request. The results have been provided in a table for your reference as document two. Where information is withheld this is outlined in the appendix. Information withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely



Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	3 October 2022	Table 1: Adverse Test Results since 2017 Table	Released in full.
2	14 August 2019 – 25 May 2022	Table 2: Results Panel of Adverse Test Result supplied by Grower/Lab	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons. Some information deemed out of scope of your request.

Table 1

MOH Reference ¹	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Date of adverse test result	14-Aug-19	21-Feb-20	17-Apr-20	12-Jun-20	15-Jun-20	15-Jun-20	29-Jun-20	3-Feb-21	18-Mar-21	7-Apr-21	8-Apr-21	9-Apr-21	9-Apr-21	11-Mar-22	30-Mar-22	7-Apr-22	29-Apr-22	13-May-22	25-May-22
Copy of results panel of adverse test result supplied by Grower/Lab (an actual copy of the table or results as reported to Medicines Control) ²	See Table 2																		
What iHemp variety was subject to adverse test result	"Han varieties"	Finola	Kompolti	Kompolti	Kompolti	Yuma	Hemp No. 1	Yuma	Kompolti	Kompolti	CFX-2	Kompolti	Kompolti	Yuma	Kompolti	Hemp No. 1	Kompolti	Kompolti	Kompolti
Name of approved lab doing the test	ESR	ESR	ESR	Hill Laboratories	Hill Laboratories	Hill Laboratories	Hill Laboratories	ESR	ESR	Hill Laboratories	ESR	ESR	ESR	ESR	ESR	Hill Laboratories	ESR	ESR	ESR
Type of Licence – General or R&B	Research & Breeding	General	General	General	General	Research & Breeding	Research & Breeding	Research & Breeding	General	General	General	General	General	Research & Breeding	General	Research & Breeding	General	General	General
DHB Location of crop with the adverse test result	Northland	Waikato	Waikato	Whanganui	Nelson Marlborough	Nelson Marlborough	Midcentral	Northland	Waikato	Tairāwhiti	Lakes	Waitemata	Northland	Northland	Waikato	Midcentral	Waitemata	Nelson Mar borough	Northland
Was this the first adverse test result for this grower ³	Yes	Yes	Yes	Yes	Two adverse results received within the same report	Two adverse results received within the same report	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No
If not, list of seasons when adverse test results had been noted	NA	NA	NA	NA	NA	NA	NA	2019	NA	NA	NA	NA	NA	20-21	NA	NA	20-21	20-21	20-21
Area actually grown by licensee holder in the year of the adverse test result ⁴	Seed sown: Han NW 11g Han NE 10g Han-FN Q 13g Han FN H 17g	12ha	200g seed sown	50 square metres	180g seed sown over 100m ²	1kg seed sown	10kg seed sown over 1ha	158 plants	75m ²	1250 plants	2.16kg seed sown	20 seeds sown	6000 seeds sown	Approx. 40 affected plants	22kg of seed sown across 7-9ha	200m ²	60 plants	200g seed sown	410g seed sown

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⁵The licensee is not required to submit this information

⁶Information has been added to clarify instances where the licensee sowed seed that they harvested themselves

⁷The nature of industrial hemp seed registers makes it difficult to determine this information. For example, when registers combine seed from multiple sources.

⁸Information provided for seed known to be imported only

⁹Interpreted Section 44 letter as Regulation 44 Notice

¹⁰Requirements of Regulation 44 Notice: 1. Destroy the Affected Plants within 10 days of the date of this Notice. 2. Complete a Statutory Declaration (available at <https://www.govt.nz/browse/law-crime-and-justice/making-a-statutory-declaration>) confirming that the Affected Plants have been destroyed. 3. Provide the completed Statutory Declaration and supporting evidence (for example photographs) to demonstrate the destruction of the Affected Plants, by email to medicinescontrol@health.govt.nz.

MOH Reference ¹	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Other iHemp cultivars grown at the location in the year of the adverse test result	Kompolti & Yuma	None	None	None	Yuma	Kompolti	None	Kompolti	None	No	CRS-1 & Ferimon 12	None	None	Kompolti	None	None	None	Yuma	None
Was the sample pollinated (seeded) or unpollinated (female only plant) ⁵	*	Pollinated	Pollinated	*	*	*	Pollinated	*	Pollinated	Pollinated	Pollinated	*	*	*	*	Unpollinated	*	*	Pollinated
DHB region of supplier of the seed to the licensee with the adverse test result ⁶	Lakes	Imported	Counties Manukau	Canterbury (as reported by licensee)	Bay of Plenty and Whanganui	Whanganui	Imported	Lakes	Licensee sowed seed they harvested previous season. Licensee previously procured seed from Bay of Plenty.	Licensee sowed seed they harvested previous season. Licensee previously procured seed from Tairāwhiti.	Canterbury	Whanganui	Northland	Lakes	Lakes	Licensee sowed seed they harvested previous season. Licensee previously procured seed from Midcentral.	Whanganui	Bay of Plenty	Northland
DHB Region, of original grower of the seed - original source (if different from above) ⁷	Imported	NA	West Coast	*	*	Imported	NA	Whanganui	NA	NA	*	*	*	Whanganui	*	NA	*	*	*
Was this original seed source an import, or grown from NZ seed ⁷	Seed imported	Seed imported	Seed grown in NZ	*	*	Seed imported	Seed imported	Seed grown in NZ	Seed grown in NZ	Seed grown in NZ	*	*	*	Seed grown in NZ	*	Seed grown in NZ	*	*	*
Age of original source of seed planted by the grower with the adverse test result ⁷	*	*	*	*	*	*	*	*	Approx. 2 years	Approx. 1 year	*	*	*	*	*	*	*	*	*
How long had the original source of seed been in New Zealand ⁸	Seed arrived in NZ in 2018	Seed arrived in NZ in 2020	*	*	*	Seed arrived in NZ in 2018	Seed arrived in NZ in 2020	*	*	*	*	*	*	*	*	*	*	*	*
Outcome of the adverse																			

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MOH Reference ¹	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
test result, details such as correspondence entered into with grower	Medsafe contacts all licensee's affected by an adverse test result as soon as possible after receiving notification of the result from the lab. Regulation 44(2) of the Regulations states 'not later than 5 days after a licence holder receives an adverse test result, the licence holder must provide the Director-General with the following information: (a) particulars of the adverse test result: (b) the location of the affected plants and the name of the cultivar or variety of the affected plants: (c) the source of the seeds from which the affected plants were cultivated: (d) all relevant records in the cultivation register on the affected plants: (e) the name and address of any person to whom affected plants or seeds from affected plants have been supplied'. Following an adverse test result, Medsafe ensures that the licensee has complied with Regulation 44(2) and works with the licensee to manage the affected plants. If the THC content is less than 0.5%, Medsafe investigates the intended use for any seed from the affected plants, and discourage the seed being used for cultivation. If the THC content is greater than 0.5%, Medsafe requests a laboratory investigation report from the applicable laboratory to ensure the accuracy of the result before taking regulatory action.																		
Explanation received from Licensee	"Possible cause: the plants we are cultivated in the far north in the tropical heat the Han variety tends to like 39° 40° latitude this could possible have been the cause. The plants are all lumped together and it was a late season so the plants had matured postmaturity possible aged issue along with latitude".	*	*	*	*	*	"We suspect that this increase in THC content when grown in New Zealand may have been caused by the severe drought experienced in Dannevirke during the season as well as the significant increase in UV radiation in NZ when compared to China."	*	*	*	*	*	*	*	"have no reasonable explanation as to why the reading was high as we have done nothing different to what we have been doing the previous years, I realised the test in the first year also tested a high level (still under though?) the only explanation I could possibly have is Im wandering if we had purchased a bad batch of seed? I really don't have any other explanation."	*	"I'm beginning to think that potentially my soil type, growing conditions or fertilising techniques may be playing a part in this"	*	Suspected environmental
Was a Section 44 letter sent, what were the requirements⁹	No	No	Yes ¹⁰	No	No	Yes ¹⁰	No	Yes ¹⁰	Yes ¹⁰	No	No	Yes ¹⁰	Yes ¹⁰	Yes ¹⁰	Yes ¹⁰	No	Yes ¹⁰	Yes ¹⁰	No
Was a crop destruction order sent?	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No
Other comments from the MOH investigation into the adverse THC result,	All affected plants were already destroyed			Licensee noncooperative. Discrepancies identified regarding source of seed.			Crop died before result received. Licensee did not attend to the crop due to COVID-19 lockdown			The licence holder voluntarily destroyed all affected plants before a Regulation	Licensee destroyed affected plants voluntarily and provided evidence								

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MOH Reference ¹	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
which would help industry understand the reason for the result.										44 Notice could be actioned.	and a statutory declaration, before a Regulation 44 Notice could be actioned. The licensee had concerns about a staff member.								

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Table 2

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5	Sample Type: Hemp Flower (dry)				
	Sample Name:	General Licence MOH Sample 1		Specified Limit	Outside Limit
	Lab Number:	s 9(2)(a)			
	Hemp Tetrahydrocannabinol Analysis				
	Total Potential Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.439 ± 0.061	0.35	Yes
Δ ⁹ -Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.037 ± 0.021	-	-	
Δ ⁹ -Tetrahydrocannabinolic acid (THCA)	% (w/w) dry wt	0.459 ± 0.065	-	-	
6	Sample Name:	Research & Breeding MOH Sample 2		Specified Limit	Outside Limit
	Lab Number:	s 9(2)(a)			
	Hemp Tetrahydrocannabinol Analysis				
	Total Potential Tetrahydrocannabinol (THC)	% (w/w) dry wt	2.41 ± 0.32	0.35	Yes
	Δ ⁹ -Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.069 ± 0.022	-	-
Δ ⁹ -Tetrahydrocannabinolic acid (THCA)	% (w/w) dry wt	2.66 ± 0.36	-	-	
7	Sample Type: Hemp Flower (dry)				
	Sample Name:	s 9(2)(a)	- Hemp No.1 - s 9(2)(a)	Specified Limit	Outside Limit
	Lab Number:	05-Mar-2020 12:00 pm s 9(2)(a)			
	Hemp Tetrahydrocannabinol Analysis				
	Total Potential Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.536 ± 0.064	0.35	Yes
Δ ⁹ -Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.116 ± 0.026	-	-	
Δ ⁹ -Tetrahydrocannabinolic acid (THCA)	% (w/w) dry wt	0.479 ± 0.068	-	-	
8	Cultivar	MOH Licence No	%THC		
	Yuma	s 9(2)(a)	0.71		
	Out of scope		Out of scope		
9	Cultivar	MOH Licence No	%THC		
	Kompolti	s 9(2)(a)	1.14		

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Sample Type: Hemp Flower (dry)					
Sample Name:		Kompolti 09-Mar-2021		Specified Limit	Outside Limit
Lab Number:		s 9(2)(a)			
Individual Tests					
Antimony*	mg/kg as rcvd	Out of scope		-	-
Arsenic*	mg/kg as rcvd	Out of scope		-	-
Bismuth*	mg/kg as rcvd	Out of scope		-	-
Cadmium*	mg/kg as rcvd	Out of scope		-	-
Copper*	mg/kg as rcvd	Out of scope		-	-
Lead*	mg/kg as rcvd	Out of scope		-	-
Mercury*	mg/kg as rcvd	Out of scope		-	-
Silver*	mg/kg as rcvd	Out of scope		-	-
Tin*	mg/kg as rcvd	Out of scope		-	-
Total Heavy Metals*	mg/kg as rcvd	Out of scope		-	-
Yeasts & Moulds	cfu / g	Out of scope		-	-
Hemp Tetrahydrocannabinol Analysis					
Total Potential Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.579 ± 0.068		0.35	Yes
Δ ⁹ -Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.445 ± 0.063		-	-
Δ ⁹ -Tetrahydrocannabinolic acid (THCA)	% (w/w) dry wt	0.153 ± 0.029		-	-
11					
Cultivar		MOH Licence No		%THC	
Out of scope		s 9(2)(a)		Out of scope	
CFX-2				0.55	
Out of scope				Out of scope	
12					
Cultivar		MOH Licence No		%THC	
Kompolti		s 9(2)(a)		0.94	
13					
Cultivar		MOH Licence No		%THC	
Kompolti		s 9(2)(a)		0.51	
14					
Cultivar		MOH Licence No		%THC	Expanded Uncertainty (± %) ¹
Yuma		s 9(2)(a)		0.74	0.03
15					
Cultivar		MOH Licence No		%THC	Expanded Uncertainty (± %) ¹
Not supplied		s 9(2)(a)		0.76	0.04

*Information not available or uncertain

¹Unclear which reference number was requested. For the purposes of this request, the results have been assigned a number (in chronological order).

²Please refer to Table 2

³Grower interpreted as licensee

⁴Regulation 44(2)(d) of the Misuse of Drugs (Industrial Hemp) Regulations 2006 (the Regulations) requires the licensee to provide records from cultivation register. Regulation 50 (1)(a)(i) of the Regulations requires the amount by weight of seeds sown to be recorded in the cultivation register. Therefore, Medsafe generally receives this information as weight of seed sown.

⁵The licensee is not required to submit this information

⁶Information has been added to clarify instances where the licensee sowed seed that they harvested themselves

⁷The nature of industrial hemp seed registers makes it difficult to determine this information. For example, when registers combine seed from multiple sources.

⁸Information provided for seed known to be imported only

⁹Medsafe contacts all licensee's affected by an adverse test result as soon as possible after receiving notification of the result from the lab. Regulation 44(2) of the Regulations states 'not later than 5 days after a licensee holder receives an adverse test result, the licensee holder must provide the Director-General with the following information: (a) particulars of the adverse test result: (b) the location of the affected plants and the name of the cultivar or variety of the affected plants: (c) the source of the seeds from which the affected plants were cultivated: (d) all relevant records in the cultivation register on the affected plants: (e) the name and address of any person to whom affected plants or seeds from affected plants have been supplied'. Following an adverse test result, Medsafe ensures that the licensee has complied with Regulation 44(2) and works with the licensee to manage the affected plants. If the THC content is less than 0.5%, Medsafe investigates the intended use for any seed from the affected plants, and discourage the seed being used for cultivation. If the THC content is greater than 0.5%, Medsafe requests a laboratory investigation report from the applicable laboratory to ensure the accuracy of the result before taking regulatory action.

¹⁰Interpreted Section 44 letter as Regulation 44 Notice

¹¹Requirements of Regulation 44 Notice: 1. Destroy the Affected Plants within 10 days of the date of this Notice. 2. Complete a Statutory Declaration (available at <https://www.govt.nz/browse/law-crime-and-justice/making-a-statutory-declaration>) confirming that the Affected Plants have been destroyed. 3. Provide the completed Statutory Declaration and supporting evidence (for example photographs) to demonstrate the destruction of the Affected Plants, by email to medicinescontrol@health.govt.nz.

16	Sample Type: Hemp Flower (dry)					
	Sample Name:	Sample 1 - Hemp # 1 18-Mar-2022		Specified Limit	Outside Limit	
	Lab Number:	s 9(2)(a)				
	Hemp Tetrahydrocannabinol Analysis					
	Total Potential Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.392 ± 0.057	0.35	Yes	
Δ ⁹ -Tetrahydrocannabinol (THC)	% (w/w) dry wt	0.021 ± 0.020	-	-		
Δ ⁹ -Tetrahydrocannabinolic acid (THCA)	% (w/w) dry wt	0.422 ± 0.060	-	-		
17	Cultivar	MOH Licence No	%THC	Expanded Uncertainty (± %)¹		
	Kompolti	s 9(2)(a)	0.97	0.05		
18	Cultivar	MOH Licence No	%THC	Expanded Uncertainty (± %)¹		
	Kompolti	s 9(2)(a)	3.1	0.1		
19	Cultivar	MOH Licence No	%THC	Expanded Uncertainty (± %)¹		
	Kompolti	s 9(2)(a)	0.37	0.02		

*Information not available or uncertain

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²Please refer to Table 2

³Grower interpreted as licensee

⁴Regulation 44(2)(d) of the Misuse of Drugs (Industrial Hemp) Regulations 2006 (the Regulations) requires the licensee to provide records from cultivation register. Regulation 50 (1)(a)(i) of the Regulations requires the amount by weight of seeds sown to be recorded in the cultivation register. Therefore, Medsafe generally receives this information as weight of seed sown.

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