WRITTEN QUESTION TO THE MINISTER FOR THE ENVIRONMENT BY THE CONNÉTABLE OF ST. MARTIN QUESTION SUBMITTED ON MONDAY 21st JUNE 2021 ANSWER TO BE TABLED ON MONDAY 28th JUNE 2021

Question

With reference to Written Question 29/2021 will the Minister advise –

- (a) whether criteria required to be met for the granting of licences for commercial cultivation of medicinal cannabis will be published, including the use of Environmental Impact Assessments (E.I.A.s);
- (b) how many E.I.A.s have been carried out to date for this purpose, if any, and how many are scheduled to be undertaken before 31st December 2021;
- (c) on what date, and by whom, the decision was taken to include the requirement to undertake an E.I.A. in order to receive a licence and, if this occurred prior to 8th February 2021, why this was not communicated in the answer to Written Question 29/2021;
- (d) what consideration was given to the use of E.I.A.s in the licensing process prior to 11th January 2021, and what relevant policies and criteria, if any, relating to this subject were agreed prior to that date; and
- (e) if the use of E.I.A.s was agreed after 11th January 2021, whether licenses for the commercial cultivation of medicinal cannabis were suspended until an E.I.A. had been carried out?

Answer

The following answers have been prepared in consultation with officers for the Minister for Health and Social Services and officers in the Infrastructure, Housing and Environment Department. Please note that licencing for medicinal cannabis sits solely with the Minister for Health and Social Services and does not fall under the responsibility of the Minister for the Environment.

- (a) I am advised that yes, the application documentation will be published and made available on gov.je in due course.
 - See appendices which include licence guidance version 0.1 and version 1.1. These are not the conditions attached to any licence but serve to provide the applicants with guidance on the type of information they need to include in any application. Version 0.1 was the guidance that was being used when the two current licence holders applied. Version 1.1 is the current guidance which was agreed in March.

Please note that we are advised by the Minister for Health and Social Services that these are to be revised and reissued.

(b) I am advised that the term EIA was used as part of the licencing guidance in a more general sense of: what mitigating action, if any is required, would be taken by the applicant to reduce any and all impact on the environment as part of plans to cultivate cannabis. As part of the application process applicants have detailed, when deemed appropriate by the Minister for Health and Social Services, any impact on the surrounding environment in the intended general sense when the conditions were approved. No EIAs as described in planning related legislation have been carried out for that purpose as they have not been deemed required by the planning regulators which are independent from the licencing of medicinal cannabis.

- (c) I am advised that the decision to approve any and all requirements for a licence to cultivate cannabis was made by the Minister for Health and Social Services based on officer advice. The licence conditions were agreed at the time the first licences were granted, 10 December 2020. The requirement to assess any environmental impact was not in place prior to consideration of the two applications which were granted licence. Information has subsequently been received from both licence holders as their licences were conditional on receiving this.
 - My response to <u>WQ 29/2021</u> was prepared from a regulatory/planning perspective and so, in the sense of EIAs as required under planning laws, the answer was accurate in that no planning applications for sites intending to cultivate cannabis were deemed required.
- (d) No consideration was given to EIAs as they are to be interpreted from the planning law as this is a separate/independent regulatory process to that of the regulation of medicinal cannabis. As mentioned in (b), consideration was given to the impact on the environment in more general terms as part of the application for a licence to cultivate medicinal cannabis.
- (e) I am advised that no licenses for the commercial cultivation of medicinal cannabis were suspended until an EIA, as it is to be interpreted by the licence conditions, had been carried out.

As Minister for the Environment I have been advised that the Minister for Health and Social Services recognises that the use of the term EIA in his licencing conditions for medicinal cannabis was not correct and, as explained, requires clarification. I understand it is the Minister's intention to amend his licence conditions to clearly delineate the difference between the regulation of medicinal cannabis and the EIA's required by the Planning & Building Law to regulate development.

Cultivation and Processing of Cannabis – Draft Jersey Licence Application Guidance

- Your application should be in the form of a document that addresses the points laid out in the order of the guidance below.
- This guidance is still being developed and is subject to change.
- Any variety not listed in the EU Hemp plant variety database will be considered cannabis as its characteristics regarding THC content are not officially certified.
- The EU database can be found at EU Approved Hemp Seeds
- Applications should be sent to P.McCabe@health.gov.je

		Required Information	Additional Notes	Your Information/Notes
1	The Legal Entity or individual making the application.	Name and address of individual or Directors/Partners making application – please include CVs and refs. Address for correspondence Jersey residency required for the principles of the business or individual making application Building usage permission and ability to occupy agricultural sites/land For companies Name and address of those with a controlling interest (greater than 20%) CVs and refs Type of organisation (Partnership, LLP, PLC etc.) Copy of registration with Jersey Registry	 Licences will be considered for Jersey registered companies and individuals who can satisfy all the necessary requirements. Up to date (within the last 3 years) Enhanced DBS checks will be required for all those named on the application Significant changes in personnel or ownership should be reported to GoJ and can result in review/revocation of a licence. Licences cannot be traded. Licences cannot be transferred. Licences cannot be sold. FEES – fees for licences will be charged You must ensure correct planning permissions are in place for usage of buildings. To occupy agricultural land, glasshouses and polythene tunnels you must be a registered smallholder or bone fide agriculturalist. Contact s.surcouf@gov.je for details. 	

2	Proposed Operation	Give a description of the proposed operation	 This should be a narrative describing the broad aims of the operation including: description of what it is you propose to produce, and how, extraction methods, the intended target market, contracts in place, with whom, countries you will export to, how you will label products etc.
3	Importation	If you intend to import live plants/cuttings or cannabis raw material for processing you must state this as you will require an import licence. Import licences will only be issued on a consignment basis therefore you will need to apply for an Import licence each time you wish to import any controlled product.	 You will need to describe the source and supplier, prove their entitlement to export to you You will need to describe precisely what is to be imported. This should include Plant/cutting variety and total quantity For raw or processed cannabis plant material a description and total mass to be imported For refined or extracted cannabis products the total quantity and cannabinoid content. A batch specific certificate of analysis should be provided to confirm this Currently seed imports are not controlled
4	Security and Traceability	If you intend to grow cannabis not listed in the EU plant variety database you will need to demonstrate sufficient site security and material traceability measures are in place and provide proof of agreement from Jersey Law Enforcement that security controls are adequate.	If you intend to grow and possess cannabis you will need to demonstrate sufficient site security and product traceability measures are in place. Useful information can be found at https://www.gov.uk/government/publications/general-security-guidance-for-controlled-drug-suppliers A full description of site security arrangements should be provided If you intend to possess cannabis you will need to demonstrate sufficient secure storage of raw cannabis materials. You will need to provide proof of agreement from Jersey Law Enforcement that security controls are adequate. You will need to describe how you will comply with the necessary record keeping and safe custody requirements specified in the Misuse of Drugs (Jersey) Law and subordinate legislation.

5	Cultivation	You will need a licence to cultivate cannabis plant irrespective of the proposed end use See Section 10 The site(s) for cultivation should be carefully considered and should be away from schools or other child care facilities and other potential areas of concern	You will need to describe: Variety to be grown and seed/cutting source Location details with map Area under cultivation Indoor/outdoor/glass/polytunnel The projected output. Audit trail – e.g. tagging of each plant from cultivation to processing Final intended use.	
6	Possession	The intact cannabis plant and also the flowers and leaves of cannabis when separated from the plant are controlled substances If you intend to use whole plants or harvest flowers or leaves of cannabis you will need a licence to possess them. See Section 10	 You will need to describe the intended use of the plant and/or the flower/leaves. You will need to describe the projected output You will need to describe how you will comply with the necessary record keeping and safe custody requirements specified in the Misuse of Drugs (Jersey) Law 1978 and subordinate legislation. 	
7	Processing and Production of Products	If you intend process cannabis in any way you will need a licence to do so. See Section 10 Please note that this is not a licence to produce a cannabis based medicinal product. In order to manufacture or produce any medicinal product a manufacturing licence is required under the provisions of the Medicines (Jersey) Law 1995 This is in addition to licences under the Misuse of Drugs (Jersey) Law 1978 to produce, possess and supply a controlled drug	 You will need to describe the intended use of the flower/leaves or any other part of the plant You will need to describe the processing method. You will need to describe the projected output. You will need to describe the audit trail of plants/material used – e.g. tagging of each plant You will need to describe the disposal method of waste material You will need to describe how you will comply with the necessary record keeping and safe custody requirements specified in the Misuse of Drugs (Jersey) Law and subordinate legislation. You will need to describe: the final product including THC content and other cannabinoid content proposed market (e.g. local market or for export) packaging, labelling, marketing final destination quality control and quality assurance processes and methodology and its validation. 	

			 A full explanation, for Drug Control purposes, as to how the product can be legally made available to the customer. HACCP and other approvals needed for preparation of a food stuff if required. MHRA approvals (and other regulatory bodies where appropriate) Environmental health clearance for preparation of foodstuffs. If the final product is a CBD product for the food supplement market the combined total content of THC and other cannabinol derivatives must not exceed 3% of the total CBD content Unless the final product has been granted a marketing authorisation as a medicine by the MHRA any labelling or promotional material must not make any therapeutic or medicinal claims.
8	Supply	If you intend to supply cannabis (processed or unprocessed) to another party you will need a licence to supply such products. See Section 10	 You will need demonstrate sufficient site security and product traceability measures are in place. You will need demonstrate sufficient secure storage of cannabis products. You will need to provide proof of agreement from Jersey Law Enforcement that security controls are adequate. You will need to provide information on the product(s) to be supplied. You will need to provide information on final customer(s). You will need to provide proof of their legitimate legal authorisation to possess the product you are supplying.
9	Export	If you intend to export live plants/cuttings or raw or processed cannabis or any product controlled by the Misuse of Drugs (Jersey) Law 1978 you will need a licence to export such products.	 You will need to provide information on the product to be exported which should include details of the product and quantities of the controlled substances. You will need to provide information on final customer. You will need to provide proof of their legitimate legal authorisation to import the product from

		Export licences will only be issued on a consignment basis therefore you will need to apply for an export licence each time you wish to export any controlled product.	you into their jurisdiction. Normally this will be an import licence granted by the regulator in that jurisdiction. • You will need to provide proof of their legitimate legal authorisation to possess the product you are exporting.	
10	Licences required	Please indicate which licence(s) you require If you intend to cultivate cannabis you will need a cultivation licence. If you intend to use any controlled parts of the plant you will, in addition, also require a licence relevant to the activities you wish to undertake	Please clearly state which cultivation licence you will require Licence to cultivate plants of the genus cannabis with a THC content not exceeding 0.2% (Industrial Hemp) Licence to cultivate plants of the genus cannabis with a THC content exceeding 0.2% Please clearly state which of the following licences you will require – you only need to state one, which should be the one which covers all your intended activities Licence to produce, to supply, to offer to supply and to possess any controlled drug or any preparation or product containing a controlled drug Licence to produce any preparation or product containing a controlled drug and to supply, to offer to supply and to possess any controlled drug or such preparation or other product Licence to supply, to offer to supply and to possess any controlled drug Licence to possess any controlled drug.	

Further useful information is available at:

https://www.gov.uk/government/publications/domestic-licensing-application-guidance

https://www.gov.uk/government/publications/general-security-guidance-for-controlled-drug-suppliers

 $\underline{https://www.gov.uk/government/publications/transporting-controlled-drugs-guidance-on-security-measures}$

https://www.gov.uk/government/publications/guidelines-for-standard-operating-procedures

https://www.gov.uk/government/publications/industrial-hemp-licensing-guidance



Cultivation and Processing of Cannabis – Jersey Licence Application Guidance

- Your application should be in the form of a document that addresses all the points set out in the guidance below.
- If you are applying for a licence to cultivate cannabis, your application will be shared with the UK Home Office and you will be subject to a compliance visit by Home Office officials and the Government of Jersey's (GoJ) Chief Pharmacist.
- New/first time applications will take around 12-16 weeks to complete, dependent on arrangements for a Home Office compliance visit.
- Applications for renewal of existing licences should be submitted at least 6 weeks before expiry of the current licence.
- This guidance is relevant to applications for licences under the provisions of the Misuse of Drugs (Jersey) Law 1978 only.
- Applications should be sent to P.McCabe@health.gov.je

		Required information	Additional notes
1	The legal entity making the application	Name of company making application Address for correspondence Company website if there is one Copy of Certificate of Incorporation of a Limited Company Copy of business licence granted pursuant to the Control of Housing and Work (Jersey) Law 2012 Name, address, phone number and email address of the following individuals in relation to the application – please include CVs and references • Managing Director or person in charge of the company • Person responsible for the security of the premises to be licensed	 Licence applications will only be considered for Jersey-registered companies Up to date (within the last 3 years) enhanced DBS checks will be required for all those named on the application Any changes to the individuals named in the application must be notified to GoJ immediately and could result in review/revocation of a licence The person responsible for legal and regulatory compliance will be expected to ensure that there is full compliance with the statutory requirements of: The Misuse of Drugs (Jersey) Law 1978 The Misuse of Drugs (General Provisions) (Jersey) Order 2009 The conditions on any licence that may be issued and that there will be in place written operating procedures that should be available on request by the Chief Pharmacist

		Person responsible for legal compliance and regulatory affairs at the site relevant to the application	Licences cannot be traded, transferred, or sold
		 Person responsible for witnessing the destruction of controlled drugs for the site relevant to the application (this cannot be the same person that is responsible for legal and regularity compliance) List of shareholders in the applicant company 	You must ensure correct planning permissions are in place for usage of buildings. The approval or otherwise of any application for a licence under the provisions of the Misuse of Drugs (Jersey) Law 1978 is independent of, and without prejudice to, any decision under any other legislation or guidance
		Building usage permission and confirmation of ability to occupy agricultural sites/land	To occupy agricultural land, glasshouses and polythene tunnels you must be a registered smallholder or bona fide agriculturalist
2	Details of site relevant to this application	Address of site Is the site rented, leased or owned/owner occupied? Provide details of the owner	 Please provide a map of the intended site clearly indicating the boundaries Provide detailed plans for the layout of the site which should clearly illustrate any security arrangements
		Provide an Environmental Impact Assessment in relation to the site and the planned activities for the site	
3	Proposed operation	Explain why you are applying for a licence including the business reasons or purpose and what you plan to use the licence for State clearly what type(s) of licence you are applying for:	 This should be a narrative describing the broad aims of the operation including: description of what it is you propose to produce, and how, extraction methods if applicable, the intended target market, any contracts or letters of intent in place, with whom, countries you will seek to export to, how you will label products etc The intact cannabis plant and also the flowers and leaves of cannabis when separated from the plant are controlled substances. If you intend to use whole plants or harvest flowers or leaves of cannabis you will need a licence to possess them

- include any relevant bona fide information for potential customers
- where this is in a foreign language, please provide a certified translation

Provide details of your supplier(s) and source of raw materials or controlled substances

Provide details regarding your cultivation operation if applicable. You will need to describe:

- Variety to be grown and seed/cutting/tissue culture source
- Location details with map
- Area under cultivation
- Indoor/outdoor/glass/polytunnel
- The projected output
- Audit trail e.g. tagging of each plant from cultivation to processing
- Final intended use

If you intend to further process the cultivated botanical raw material in accordance with GMP standards, please include the following information where possible:

- You will need to describe the intended end use of the flower/leaves or any other part of the plant
- You will need to describe the processing method
- You will need to describe the projected output
- You will need to describe the audit trail of plants/material used e.g. tagging of each plant
- You will need to describe the disposal method of waste material
- You will need to describe:
 - the final product, including THC content and other cannabinoid content
 - o proposed market (e.g. local market or for export)
 - o packaging, labelling, marketing
 - final destination
 - quality control and quality assurance processes and methodology and its validation

Details of your projected output must include the likely annual yield of each product in kilograms and optionally the projected value in £

Please note that this is not an application for a licence to produce a finished cannabis-based medicinal product. In order to manufacture or produce any medicinal product, a manufacturing licence is required under the provisions of the Medicines (Jersey) Law 1995

Unless the final product has been granted a marketing authorisation as a medicine by the MHRA, any labelling or promotional material must not make any therapeutic or medicinal claims

		MHRA approvals (and other regulatory bodies where appropriate)	
4	Security and traceability	If you intend to grow or handle cannabis and/or its controlled extracts, you will need to demonstrate sufficient site security and material traceability measures are in place You should provide a security assessment report prepared by an independent security advisor/specialist A full description of site security arrangements should be provided. This should cover as a minimum: • CCTV • Perimeter fencing • Lockable physical security, e.g. prefabricated strong room, safe, cabinet • Presence/attendance of security guards Include the following details on any electronic alarm system: • name and address of installation company • is there a separate zone for the controlled drug store/safe? • is the alarm monitored by an offsite alarm receiving centre? • is/will the alarm be serviced annually? • does the alarm have a police unique reference number? • describe the level of police response if the alarm is activated	 Useful information can be found at: https://www.gov.uk/government/publications/general-security-guidance-for-controlled-drug-suppliers If you intend to possess cannabis, you will need to demonstrate sufficient secure storage of raw cannabis materials and controlled extracts You will need to describe how you will comply with the necessary safe custody requirements specified in the Misuse of Drugs (Jersey) Law and subordinate legislation: details of any electronic stock recording system will controlled substances be kept in a separate room or zone? are controlled substances kept in a safe or prefabricated strong room? are controlled drugs kept on site only?
5	Record keeping and substance traceability details	If you intend to grow or handle cannabis and/or its controlled extracts, you will need to demonstrate sufficient material traceability and record keeping measures are in place: • do you have on-site arrangements for the receipt, storage, assembly, picking, distribution, recording and destruction of controlled substances written down as a set of standard operating procedures • do you have an appropriate record keeping system in place?	You will need to describe how you will comply with the necessary record keeping requirements specified in the Misuse of Drugs (Jersey) Law and subordinate legislation

		describe in detail your record keeping system and procedures e.g. electronic stock recording system	
6	Import	If you intend to import live plants/cuttings, tissue cultures or cannabis raw material for cultivation or processing, you must state this as you will require an import licence Import licences will only be issued on a consignment basis, therefore you will need to apply for an Import licence each time you wish to import any controlled product	 You will need to describe the source and supplier, and prove their entitlement to export to you You will need to describe precisely what is to be imported. This should include: Plant/cutting/tissue culture variety and total quantity For raw or processed cannabis plant material, a description and total mass to be imported For refined or extracted cannabis products, the total quantity and cannabinoid content. A batch specific certificate of analysis should be provided to confirm this Currently seed imports are not controlled under misuse of drugs legislation
7	Export	If you intend to export live plants/cuttings/tissue cultures, or raw or processed cannabis, or any product controlled by the Misuse of Drugs (Jersey) Law 1978, you will need a licence to export such products Export licences will only be issued on a consignment basis, therefore you will need to apply for an export licence each time you wish to export any controlled product No export licence will be issued until a corresponding import licence has been issued by the competent authority in the destination jurisdiction	 You will need to provide information on the product to be exported, which should include details of the product and quantities of the controlled substances You will need to provide information on the final customer You will need to provide proof of their legitimate legal authorisation to import the product from you into their jurisdiction. Normally this will be an import licence granted by the regulator in that jurisdiction You will need to provide proof of their legitimate legal authorisation to possess the product you are exporting
8	Fees	Fees are payable in relation to any application for a licence Do not apply until you are confident that you are inspection ready and that you have all the necessary information and operating procedures in place including enhanced DBS checks. Please confirm the address for invoice purposes and any purchase order number you need us to quote	

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Further useful information is available at:

Home Office Licence Application Guidance

Home Office Guidance on Security Measures for Controlled Drugs

Home Office Guidance on Transporting Controlled Drugs

Home Office Guidelines on Standard Operating Procedures