Supplement No. 6 published with Extraordinary Gazette No. 31 dated 7 April, 2017.

THE NATIONAL CONSERVATION COUNCIL
GUIDANCE NOTE RISK ASSESSMENT OF ALIEN AND GENETICALLY ALTERED SPECIES, 2017
NATIONAL CONSERVATION LAW 2013
(LAW 24 OF 2013)

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GUIDANCE NOTE

Risk Assessment of alien and genetically altered species (consultations for import and applications to release) under section 35 of the National Conservation Law, 2017
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Definitions and Abbreviations

For the purposes of this Guidance Note, the following definitions apply:

The “Law” refers to the National Conservation Law, 2013.


“The Council” refers to the National Conservation Council established under the National Conservation Law 2013.

“DOA” means the Cayman Islands Department of Agriculture.

“MA” means the Management Authority established under the Endangered Species Trade and Transport Law 2004.

“alien” has the meaning given to it in the Law

“Artificial Hybrid” includes any organism arising from human-assisted hybridization between different taxa.

“Genetically altered organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; where:

“Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids; and

“Modern biotechnology” includes inter alia the application of:

- In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
“introduction” or “release” is deemed to have occurred if at any time the geographic location of the taxon in question ceases to be under the complete control of the person who is responsible for it.

“Selectively Bred Organism” includes any organism which has become genetically different from its wild ancestor as a result of human-mediated selection for useful or desired traits over successive generations.

“statutory consultation” means a consultation initiated in accordance with section 35(1).

“Taxon” (and its plural “Taxa”) means any living specimen, species, sub-species, artificial hybrid, selectively bred organism or genetically altered organism.

Introduction

The purpose of the National Conservation Law is to promote and secure biological diversity and the sustainable use of natural resources, to protect and conserve endangered threatened and endemic wildlife and their habitats; to provide for protected terrestrial, wetland and marine areas and to give effect to international agreements and conventions to which the Cayman Islands are a party.

The Cayman Islands are a party to the Convention on Biological Diversity however the Cayman Islands has not requested that the Cartagena Protocol on Biosecurity be extended to the territory. At present the Law is the only statute specifically addressing the regulation of genetically altered organisms in the Islands, although plants and animals laws1 administered by the Department of Agriculture and the law 2 implementing the Convention on International Trade in Endangered Species (CITES) speak to the import and export of living organisms. This Guidance Note does not address risk assessment for live viruses contained in vaccines, or for living micro-organisms such as bacteria and yeasts contained in generally available foods.

Section 35 of the Law provides that (1) Department of Agriculture and the Management Authority for ESTTL must consult with and take account of the views of the National Conservation Council before granting approvals relating to live or viable specimen of an alien or genetically altered species under their laws; and (2) any person who wishes to introduce or release in any part of the Islands a live or viable specimen of such species shall apply to the Council under the Law for a permit to do so.

Under section 3 (12) of the Law the National Conservation Council, subject to any directions of the Cabinet, may make orders and guidance notes and issue directives for the purpose of giving effect to the provisions of this Law which may include: procedures for regulating and controlling wild populations and the import, introduction, possession, transportation and release of alien or genetically altered specimens.

1 The Plants (Importation and Exportation) Law 1997 Revision, and the Animals Law 2015 Revision
2 The Endangered Species Trade and Transport Law 2004
Section 6(2) permits the Department of Environment to develop criteria for determining whether wild populations or proposed introductions of alien or genetically altered species might cause harm to any of the natural resources of the Islands and procedures for regulating and controlling such populations and introductions.

This Guidance Note provides details for assessment of consultations for import of, and applications to release, alien or genetically altered species under section 35 and forms a part of a wider strategy to be issued as Policy and Procedures for Management of Alien Invasive Species in the Cayman Islands. The Policy and Procedures document will address a management plan for the rapid assessment of routine horticultural and agricultural imports through the creation of system of Black and White Lists with the view to minimizing the instances of the application of the procedures outlined in this guidance.

Genetically altered organisms are increasingly being developed for use in agriculture and disease management. Risk analysis tools, including risk assessment, risk management and risk communication are integral to the process of regulating the use and release of these organisms, through examination of reasoned and replicable evidence in an openly-transparent forum.

This Guidance is expected to be a living document which may be updated regularly. Until such time as a separate directive is issued, it is intended to serve as directives for the benefit of statutory consultation by the DOA and MA as well as provide information to potential applicants for permits to release alien or genetically altered specimens.

**Evaluation of Alien Taxa**

In a statutory consultation, in the case of transactions not anticipating introduction or release, or in the case of an application to Council for permission for introduction or release no import permit or CITES permission may be granted before the Council provides its advice or permission, as the case may be.

The Department of Environment is delegated to make the following evaluations and determinations on behalf of the Council.

On receipt of a statutory consultation or an application for a permit under section 35 (2) the Department of Environment, on behalf of the Council, will evaluate whether the taxon is an alien taxon, and if so, determine whether it is potentially invasive and/or harmful. In performing the analysis a matrix assigning likelihood and consequences assessments will be used.

In making these evaluations and determinations the Department of Environment will observe the following criteria:

**Alien Taxa**

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A taxon shall be considered to be alien in the Cayman Islands if it unambiguously meets the definition of “alien species” in the Law, which states “alien species” means a species whose natural range does not include the Islands or, with reference to a specific Island, does not include that Island, and “alien” shall be construed accordingly.

This means that a taxon which is or was naturally restricted to less than all three of the Cayman Islands, should therefore be considered alien in the other island or islands where it does or did not naturally occur.

Genetically altered organisms, selectively bred organisms and artificial hybrids are all by definition considered to be alien.

In any case where the natural range of the taxon is unknown, is changing naturally, or has a boundary that may or may not be considered to include the Cayman Islands, its evaluation as an “alien species” may be uncertain or ambiguous. In this event the Director shall rule under authority of section 6(2)(k) whether or not the taxon’s natural range includes the Cayman Islands, and in reaching this ruling the Director shall consult as necessary, and shall observe the following guidelines:

a) A taxon whose periodic migratory range includes the Cayman Islands is not considered to be alien regardless of whether it breeds in the Cayman Islands or not.

b) A taxon which is considered to be an occasional vagrant in the Cayman Islands, and whose substantive range is geographically close enough to the Cayman Islands that proximity accounts for the occasional occurrence, is not considered to be alien.

c) A taxon whose range is expanding and has reached the Cayman Islands is considered to be alien if its range expansion is a consequence of human activity.

d) In any other case where these guidelines fail to determine if a taxon is alien, a precautionary approach shall apply and the Director shall make this determination with regard to any possible risk of harm the taxon may pose to the natural resources of the Islands.

**Invasive Taxa**

An alien taxon shall be considered to be Invasive or potentially invasive in the Cayman Islands if:

a) The climate in the Cayman Islands is similar enough to the climate in any part of its extant range that the taxon may be expected to survive in the wild;

and:

b) The taxon has biological characteristics and/or documented history that indicates that it has the potential to become invasive. In making this determination the Director should *inter alia* consider the following indicators:

- The taxon has been documented to reproduce and spread in the wild in other areas outside its natural range
- The taxon may be capable of breeding in the wild in the Cayman Islands
- The taxon has a high reproductive rate
- The taxon is fast growing
- The taxon is long lived
- The taxon is a generalist which does not depend on highly specific habitats or resources
The taxon is a pioneer species, quick to occupy disturbed habitats
- The taxon is adapted to heavier predation than is likely to occur in Cayman
- The taxon has the means to disperse in the Cayman Islands
- The taxon may be difficult to contain reliably within captivity/cultivation

Harmful Taxa

An alien taxon shall be considered to pose a risk of harm to natural resources in the Islands if:

a) It has any potential to hybridize with any native species
b) It is a predator that could potentially prey on native species
c) It is a parasite which could potentially parasitize native species
d) It is a herbivore which could potentially damage or defoliate native plants on a significant scale
e) It is potentially capable of displacing or suppressing native species
f) Its genome contains genetically altered components which could persist or spread in the environment
g) It may harbour pathogens which could infect any native species
h) It has potential to cause any other adverse effect on one or more protected areas, areas of critical habitat or the environment generally, where adverse effect is construed as defined in the Law.

The potential risk of an alien taxon causing harm to human interests, such as to human health, infrastructure, agriculture etc. should also be given consideration.

Risk Assessment

“Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and chance of harm”. 4

Risk Assessments will follow internationally accepted, objective, principles. Risk assessments will be carried out on a case by case basis taking all relevant circumstances pertaining to the protection of the natural environment and natural resources into account. In the case of genetically altered organisms Council has adopted a policy of regulating the organism in the context of the risks (and where relevant, potential benefits) of introduction or release, rather than seeking to regulate specific technology.

Risk Assessment is intended to provide the Council and the Department with structured support to make evidence-based decisions, whether as advice under a statutory consultation or permission to an applicant to release any such organism.

4 Monitoring and Compliance Risk Analysis Protocol. OGTR 2016
The National Conservation Council Guidance Note Risk Assessment of Alien and Genetically Altered Species, 2017

The Council and the Department of Environment may have regard to principles and guidance contained in, inter alia, the following, bearing in mind that the objectives of the National Conservation Law are not identical to the objectives underpinning these documents:

- Arthropod Containment Guidelines (Version 3.1) American Committee of Medical Entomology of the American Society of Tropical Medicine and Hygiene.

Upon receipt of a consultation for import of, and/or application to release, alien or genetically altered species under section 35, the Department on behalf of the Council will perform a screening in order to produce an initial evaluation in the form of a preliminary risk matrix for likelihood and consequence of harm using the following matrix\(^5\) for salient concerns relating to invasiveness and potential for harm:

<table>
<thead>
<tr>
<th>Likelihood Assessment</th>
<th>HIGHLY LIKELY</th>
<th>LOW</th>
<th>MODERATE</th>
<th>HIGH</th>
<th>HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Highly unlikely</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Low</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Marginal</td>
<td>Minor</td>
<td>Intermediate</td>
<td>Major</td>
<td></td>
</tr>
</tbody>
</table>

\[\textbf{CONSEQUENCES}\]

<table>
<thead>
<tr>
<th>CONSEQUENCES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal</td>
<td>Minimal or no damage to the environment or disruption to biological communities. Minimal adverse health or economic effects.</td>
</tr>
<tr>
<td>Minor</td>
<td>Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected. Adverse health or economic effects that are reversible.</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity. Adverse health or economic effects that are irreversible.</td>
</tr>
</tbody>
</table>

\(^5\) © Commonwealth of Australia
### Extensive damage to the environment or extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible. Adverse health or economic effects that are severe, widespread and irreversible.

In the event a taxon is determined to be alien and to score at a preliminary risk matrix estimate of low or negligible to be either potentially invasive or harmful, or both, then a Risk Assessment and subsequent ruling on the consultation or release application will be performed by the Department on behalf of the Council and communicated to the consulting body or applicant. The Department will report the issue of such consultations and permits regularly to the Council. It is anticipated that such assessments will contribute to the compilation of White Lists to be incorporated in the Policy and Procedures for Management of Alien Invasive Species in the Cayman Islands.

In the event a taxon is determined to be alien and to score at a preliminary risk matrix estimate of moderate or high to be either potentially invasive or harmful, or both, or where there is insufficient information to be confident in a score of negligible or low the Department will consult with the Council which will decide whether that Risk Assessment should be undertaken by the Department, or whether an Independent Risk Assessment should be carried out by a qualified consultant, at the cost of the applicant.

Where the release of an alien species may pose risks to human health, infrastructure and/or economic activity, issues which are all outside the remit of the National Conservation Law, the Department, or the independent consultant if appointed, should seek views from appropriate external agencies on these matters and take those views into account in formulating the risk assessment report; and the Council will take these same views into account when making a decision.

Screening and Risk Assessment are iterative processes and will include:

- An analysis of how the taxon may become invasive or harmful.
- A determination of the potential extent of harm to the natural environment in event the taxon does become invasive, including the magnitude of the adverse effect and the likelihood of its occurrence.
- An assessment of the benefits to the natural environment (if any) of the proposed release.
- A compilation of peer-reviewed scientific literature and evidence-based views on risks and benefits to human health, infrastructure and economic interests, as provided by external agencies consulted as appropriate. This compilation should include an assessment of the quality, relevance and degree of certainty of these information sources.
- A recommendation to Council to approve or deny, and recommendations on any conditions or risk management strategies that should apply if the application is approved.

The Council and the Department may have regard to any previous risk assessment for a taxon by a regulatory authority whether in the Cayman Islands or elsewhere. A Risk Assessment may also refer to the other components of risk analysis and make recommendations for risk management and risk communication as the case may require.
Information required of applicants

To facilitate the Risk Assessment, the applicant shall supply the following information.

For taxa which are not genetically altered, hybridized or selectively bred:

a) The full scientific name(s) of the specimen(s) proposed to be released.
b) The numbers and sex ratio of the specimen(s) proposed to be released.
c) The location(s) and date(s) of proposed releases.
d) The purpose of the proposed release.
e) The existing range of this taxon in the wild (including both its native range and its introduced range if any).
f) If the applicant is a business, a copy of the applicant’s current trade and business license is required.
g) The Council or DoE may request additional information before or during the risk assessment process.

For taxa which are hybridized or selectively bred, the same information will be required, but additionally the full identification of the variety or hybrid parentage of the taxon must be provided.

For taxa which are genetically altered, the applicant shall also provide the relevant technical and scientific details as laid out in Paragraph 9 of Annex III of the Cartagena Protocol on Biosafety, under the Convention on Biological Diversity. The applicant shall further provide:

h) a comprehensive statement of the benefits intended to result from the release.
i) a complete description of facilities and procedures for acquiring and handling the specimens before release, including biosecurity standards and procedures, including procedures for disposal of any substances that may affect the expression of altered gene or genes.
j) copies of any prior risk assessments that have already been carried out on the genetically altered taxon proposed for release.
k) copies of any scientific papers relating to risks and benefits associated with the genetically altered taxon proposed for release.

Independent Risk Assessment

If the Council determines on consultation with the Department that the Department does not have the resources or expertise to conduct a required Risk Assessment adequately, Council may instead require the applicant to engage suitable independent expertise to conduct the Risk Assessment at the applicant’s expense.

Procedure for Independent Risk Assessment

a) Council advises applicant of requirement for Independent Risk Assessment, and applicant may decide to go ahead, or withdraw their application.
b) If applicant wishes to proceed, Council appoints an Environmental Risk Assessment Board (ERAB) specific to the application, pursuant to its powers to appoint advisory committees.

c) The ERAB issues a scoping opinion. The opinion will identify those environmental impacts which are considered to have potential to be significant and which will need to be addressed as part of the Independent Risk Assessment. The scoping opinion will also indicate the range of technical competencies which the consultants selected to carry out the Independent Risk Assessment will need to possess; these competency requirements will be dependent upon the scale and complexity of the proposed release.

d) The applicant submits to the ERAB details of one or more consultancy firms/teams which possess the technical capacity to undertake the Independent Risk Assessment, based on the scoping opinion. The ERAB shall review and confirm if the proposed team(s) meet the competency requirements to carry out the Independent Risk Assessment. If details of more than one consultancy team are provided to the ERAB for review, and all teams meet the competency requirements, the selection of the preferred consultant shall be made by the proponent.

e) Should the ERAB determine that the proposed consultancy team(s) do not meet the competency requirements, the applicant shall engage further with consultancy teams until a team is identified that meets the requirements.

f) The applicant shall incur the costs associated with an Independent Risk Assessment.

g) Appointed consultant and ERAB develop and agree Terms of Reference for the Independent Risk Assessment. Terms of Reference will be developed on a case-by-case basis, depending on the nature and scale of the application and the risk profile of the taxon concerned as generated by the Department’s initial assessment and the scoping opinion. Council may in its discretion require the Terms of Reference to contain risk management and risk communication components.

h) The Terms of Reference are made publicly available.

i) The Independent Risk Assessment is conducted.

j) Public consultation is carried out, if required by the Terms of Reference.

k) Applicant submits draft Independent Risk Assessment report to the ERAB.

l) The Independent Risk Assessment report is finalized to ERAB’s satisfaction.

m) The final Independent Risk Assessment report is made publicly available.

n) ERAB considers final Independent Risk Assessment report, and makes a recommendation to Council.

o) Council rules on the application.

Made by the Council this 22nd day of March, 2017.

Christine Rose-Smyth

Chair