

SUBORDINATE LEGISLATION UNDER THE BIOSAFETY ACT, 2006

There are only 2 kinds of subordinate legislation required or permitted to be made under the Biosafety Act, 2006, namely:

- (a) Declaration of derivatives of GMO'S to be GMO products for the purposes of this Act; and
- (b) Regulations.

- **Declaration of GMO products for purposes of the Act.**

This is to be done by means of a Ministerial notice to be published in the *Government Gazette* under section 1(2) of the Act specifying articles, materials, substances or things derived from or containing GMO's which are to be regarded as GMO products under the Act. The effect of the notice will be that only articles, materials, substances and things listed in the notice will be subject to the provisions of the Act relating to GMO products.

The list can of course from time to time be adjusted by additions, deletions, variations, etc.

If there are any articles, etc. derived from GMO products which are to be regulated in accordance with the requirements of the Act from day 1 of the Act's commencement, (subject of course to the grace period provided for in section 51) then they need to be specified in a Government Notice under section 1(2) of the Act to take effect simultaneously with commencement date of the Act, or at least as soon thereafter as possible.

The list must be issued by the Minister only after consultation with the Council. That would mean that the draft Government Notice can be submitted to the Minister only after the Council is constituted and has had opportunity to consider the list.

The Council can of course be constituted, i.e its members appointed in accordance with the Interpretation Proclamation, 1920 even before the date the Act is to become of effect.

Please provide a list of any articles, etc. required to be declared GMO products.

- **Regulations**

Although all regulations are to be made under section 49 of the Act there are also various other provisions in the Act prescribing matters on which regulations must/may be made. Below is a list of all those provisions.

1. Section 21 (Exemptions)

The regulations may either prescribe exemptions from the provisions of the Act or give the Council power to grant exemptions, whether upon application or otherwise, of such nature and extent as must be stipulated in the regulations.

Exemptions will probably not be essential from day 1 unless it is known what exemptions should apply from day 1.

In the initial stages it would be sufficient to make general provision merely for powers of the Council to grant exemptions in accordance with a prescribed application procedure.

Comment Jacky Scholz: I agree with the above and support the view that regulations be made w.r.t. the Council giving them the power to exempt. If this is in the regulations then specific exemptions is not essential since the Council can then exempt any GMO they deem fit for exemption.

*A regulation to that effect should be in place on the commencement of the Act.

The regulation should make provision, in particular for the nature of exemptions that may be granted, the circumstances in which they may be granted, the period for which they may be granted, any conditions to apply in respect of exemptions etc. Also the procedure to be followed in connection with applications for exemptions, eg., form, advertisement, information to be provided, fee, etc.

2. Section 22 (Applications for permit)

(a) subsection (1)(a)

This provision requires that the information to be contained in an application for a permit must be prescribed:

How will applications be handled? What information must an applicant provide in an application, taking into account the different permits for the various kinds of dealings that can be applied for?

Will specially designed application forms be used for the different kinds of applications? If so, will the forms be obtainable from the Council's office? What documents/information should accompany the application, etc?

Comment by Jacky Scholz: Agree with the above and support that a specific application form be drafted as part of the regulations. The regulations can then specify the major information necessary and more detailed (administrative, etc) information can be required on the form. I propose (if possible) that a general clause also be inserted to state "such other information and the Council may require" to allow for additional information not contained in the regulations/form.

*Regulations in this regard are essential as from the date of commencement of the Act.

(b) subsection (1) (b):

This provision requires that the type of (applications) dealings for which the submission of a risk assessment report and risk management plan is required must be stipulated:

Is it known for which type of applications (i.e. dealings) a risk assessment report and risk management plan will be required?

It is of course not essential that the type of applications for which the submission of a report and plan need to be stipulated in the regulations because even if such a requirement is not stated in the regulations the Council can still require such submission when an application is made.

However, if it is known which kind of applications (dealings) always will be subject to the submission of a report and plan it will be expedient if it is provided for in the regulations. That would remove any doubt for prospective applicants.

It would of course also be possible to make a regulation stating for which kind of applications will never be required – if this can be stated without any doubt.

Comment by Jacky Scholz: Could another alternative not be that all applications must have this unless exempted by the Council under regulations under section 21?

(c) subsection (1) (c):

*The applications fees for the different kinds of applications must be prescribed. (regulation is essential from day 1 of commencement of the Act)

(d) subsection (2) (a):

The type of applications which are required to be advertised must be stipulated.

Comment by Jacky Scholz: Could another alternative not be that all applications must have this unless exempted by the Council under regulations under section 21?

*If it is known which kind of applications will always require advertisement they should be specified. It is however not essential that they must all be stipulated. The Council may still require that an application be advertised even if not so required by the regulations. However it is preferable that the regulation be in place from day 1 of the commencement of the Act.

It would of course also be possible to make a regulation stating for which kind of applications advertisement will never be required – if this can be stated without any doubt.

(e) subsection 4:

This provision requires the following matters to be prescribed:

- (i) In cases where advertisement of an application is required it is provided that the advertisement must run once a week for 2 consecutive weeks in at least 2 newspapers **"and by any other means as may be prescribed"**.

What other means of advertising must be stipulated and in respect of what type of applications (dealings)? If "other means" is necessary I would say that one must look at those people who have the greatest interest in GMOs (for example environmentalists, farmers, etc) and focus on media which reaches them more effectively than newspapers. And if this is at all necessary that there be "other means".

- (ii) What particulars must be contained in the advertisement of an application?

The particulars must be stipulated. When we consider this we must list those particulars which are necessary for a person who reads the advertisement to obtain the information necessary to sensibly consider the application and respond thereto. As the information may be too substantial to print in the newspaper, the applicant will also have to specify where full details can be obtained.

- (iii) The period for the making of submissions in relation to an advertised application must be stipulated, i.e. the number of days allowed for the submission of objections/comments, etc., after the date of publication of an advertisement.

Usually 30 days suffice – the period must be long enough to allow people to investigate and comment but not unnecessarily delay the application too long. One must also take into account and an interested party/organisation may wish to obtain an independent opinion on the application and that such an independent assessment of an application may take long.

*State the period (number of days) to be stipulated. It may of course differ according to the different kind of applications. (essential from day 1)

3. Section 23 (Risk assessment and risk management plan)

(a) subsection (1) (a):

The basic requirements with which a risk assessment report and a risk management plan must comply must be stipulated.

*What are those requirements according to the different kind of applications?
[Essential from day 1]

(b) subsection (2) (a):

The persons, bodies or institutions which an applicant must consult in the process of preparing a risk assessment report and risk management plan must be stipulated.

Are there any such persons, bodies or institutions to be stipulated and in respect of the different kind of applications?

Also, are there any specific matters to be stipulated in the regulations that must be taken into account by an applicant or other person in the preparation of a risk assessment report and management plan?

4. Section 26 (Permit conditions):

The conditions to attach to a permit are those that may be either be prescribed by regulation or those specifically imposed when the permit is granted, or both those so prescribed and those specifically imposed. The section enumerates in paragraphs (a) - (q) the matters which may be dealt with in conditions.

Some issues obviously will best be dealt with if determined and imposed in respect of an individual application, according to the prevailing circumstances. However, there may be some in respect of which standard/fixed conditions can be laid down in the regulations, for instance "records and documents to be kept".

*Are there any matters concerning the issues listed in paragraphs (a) - (q) which can at this stage be identified sufficiently to be stipulated in the regulations?

Another matter which may be prescribed under this section concerns the duties of biosafety officers, i.e. officers in charge of particular dealings authorised by a permit.

*What duties/functions of biosafety officers should be stipulated specifically in the regulations?

5. Section 27 (Activities that may only be carried out in a registered facility):

If there are certain activities relating to any GMO or GMO product which may be carried out only within a registered facility they must be stipulated in the regulations.

*Are there any such activities known that should be stipulated in the regulations?

Also, the information to be contained in an application for the registration of a place as a registered facility must be stipulated.

*What information should be stipulated? Will specially designed application forms be used? What documents/information should accompany the application, etc?

6. Section 28 (Conditions of registration)

The conditions to apply in respect of the registration of a place as a registered facility are those as prescribed by regulation and those specifically imposed upon the registration of a facility.

Are there any conditions which should be prescribed in the regulations?

7. Section 32(2) (Packaging, labelling and transport)

Requirements pertaining to the packaging or labelling of GMO's or GMO products may either be prescribed in the regulation or specifically specified in a permit condition.

*Is there anything which should be prescribed in the regulations in that regard?

One must just remember when these requirements are prescribed they are inflexible and must always be complied with. If they appear only in the permit it will be more flexible since permit from permit can differ and one will need to amend regulations if prescribed matters must be changed.

8. Section 32(2) (Procedures and safety measures for transport)

The provision provides for procedures and safety measures to be prescribed for the transport of GMO's or GMO products.

*Is there anything to be prescribed in the regulations in this regard?

9. Section 39(1) (Register)

This section requires that the particulars as prescribed in the regulations must be recorded in a register to be maintained by the Council in relation to –

- Permits issued under the Act and conditions to which they are subject
- Facilities registered under the Act and conditions of their registration
- The suspension, cancellation or variation of permits or registration certificates
- Exemptions granted under the Act or the regulations
- Any other matters as prescribed.

*Is there anything to be provided for in the regulations on particulars pertaining to the above to be recorded in the Register and are there any other matters to be dealt with in the Register?

10. Section 42 (Report to Minister of notifications given under Protocol)

In terms of this section the manner of reporting to the Minister notifications given under the Protocol of unintentional transboundary movements must be prescribed.

Any requirements/suggestions?

11. Section 43(5) (Commercially confidential information)

This provision stipulates (in paragraphs (a) – (e)) certain kinds of information that will not be protected by a declaration of confidential information and also “*any other information as may be prescribed*”.

Any suggestions?

12. Section 49 (Regulations)

This sections enumerates matters on which the Minister is authorised to make Regulations. The comments above probably cover all those issues, except the levying of fees and charges.

It is usually more practical/convenient to set out fees and charges payable under an Act and regulations in a schedule as an annexure to the regulations. The list of fees payable should therefore be considered. The following are suggestions on basic fees that can be included (some are explicitly provided for in the Act):

Application fee for issue of permit (differentiation can be made between the various kinds of permits for which application can be made and also in accordance with different gmo's or commodities)

Fees for issue of permit (differentiations as above can be made)

Application fee for registration of a facility

Fee for issue of registration certificate of facility

Inspection fees (inspections for different purposes, eg. premises before granting registration as a registered facility, routine inspection, others?)

Annual fee payable for renewal/retention of validity of permit

Annual fee payable for renewal/retention of registration of facility

Fee for issue of duplicate permit

Fee for issue of duplicate registration certificate

Fee for inspection of register or documents, or making extracts from or copies of register or documents

Any comments/suggestions in this regard. Also preliminary suggestions on the amounts of the fees?