SCHEDULE 2 Regulation 3(29)

NEW SCHEDULE 5A TO BE INSERTED

"SCHEDULE 5A Regulation 16(2)(g) and schedule 4

MONITORING PLAN

Introduction

1. This schedule describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in regulations 16(2)(g) and 28(f).

PART A

OBJECTIVE

2. The objective of a monitoring plan is to—

(a) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the genetically modified organism or its use in the environmental risk assessment are correct, and

(b) identify the occurrence of adverse effects of the genetically modified organism or its use on human health or the environment which were not anticipated in the environmental risk assessment.

PART B

GENERAL PRINCIPLES

3.—(1) Monitoring takes place after the consent to the placing of a genetically modified organism on the market.

(2) The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the genetically modified organism or its use, as such changes may be the result of environmental factors other than the placing of the genetically modified organism on the market.

(3) Experience and data gained through the monitoring of experimental releases of genetically modified organisms may assist in designing the post marketing monitoring regime required for the placing on the market of genetically modified organisms as or in products.

PART C

DESIGN OF THE MONITORING PLAN

4. The design of the monitoring plan should—

(a) be detailed on a case by case basis taking into account the environmental risk assessment,

(b) take into account the characteristics of the genetically modified organism, the characteristics and scale of its intended use and the range of relevant environmental conditions where the genetically modified organism is expected to be released,

(c) incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-)specific monitoring focusing on adverse effects identified in the environmental risk assessment—

(i) whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment, and

(ii) whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided,

(d) facilitate the observation, in a systematic manner, of the release of a genetically modified organism in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment,

(e) identify who (applicant, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the Scottish Ministers will be informed on any observed adverse effects on human health and the environment (time points and intervals for reports on the results of the monitoring must be indicated), and

(f) give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the Scottish Ministers, where appropriate, to take the measures necessary to protect human health and the environment."