



The basis of a GM-related monitoring program in South Africa: what to monitor and why?

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science
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OVERVIEW

- Role of different regulatory bodies
- Introduction to GMO environmental risk analysis
 - Monitoring as part of a risk analysis framework for GM crops
- An integrated regulatory system for monitoring GMOs in South Africa



REGULATIONS RELEVANT TO MONITORING GMOs IN SA

- **Genetically Modified Organisms Act (1997)**

To promote the responsible development , production, use and application of GMOs and to ensure that all activities involving the use of GMOs shall be carried out in a way that limits possible harmful consequences to the environment

Activities (including environmental releases) with GMOs go through a risk assessment to be granted a permit for that activity.

Permit conditions may include

- case specific monitoring (to be done by the applicant) as recommended by the AC (compliance monitoring)
- compliance to risk mitigation measures





REGULATIONS RELEVANT TO MONITORING GMOs IN SA cont.

National Environmental Management: Biodiversity Act (NEMBA, 2004)

- confers to SANBI the responsibility to monitor and report on the environmental impacts of GMOs commercially released in South Africa.

“ must monitor and report regularly to the Minister on the environmental impacts of all categories of genetically modified organism, post commercial release, based on research that identifies and evaluates risk”

- general surveillance and hypothesis based

National Environmental Management Act (NEMA, 1998)

- criteria that may trigger an EIA
- guidance for how an EIA may be conducted

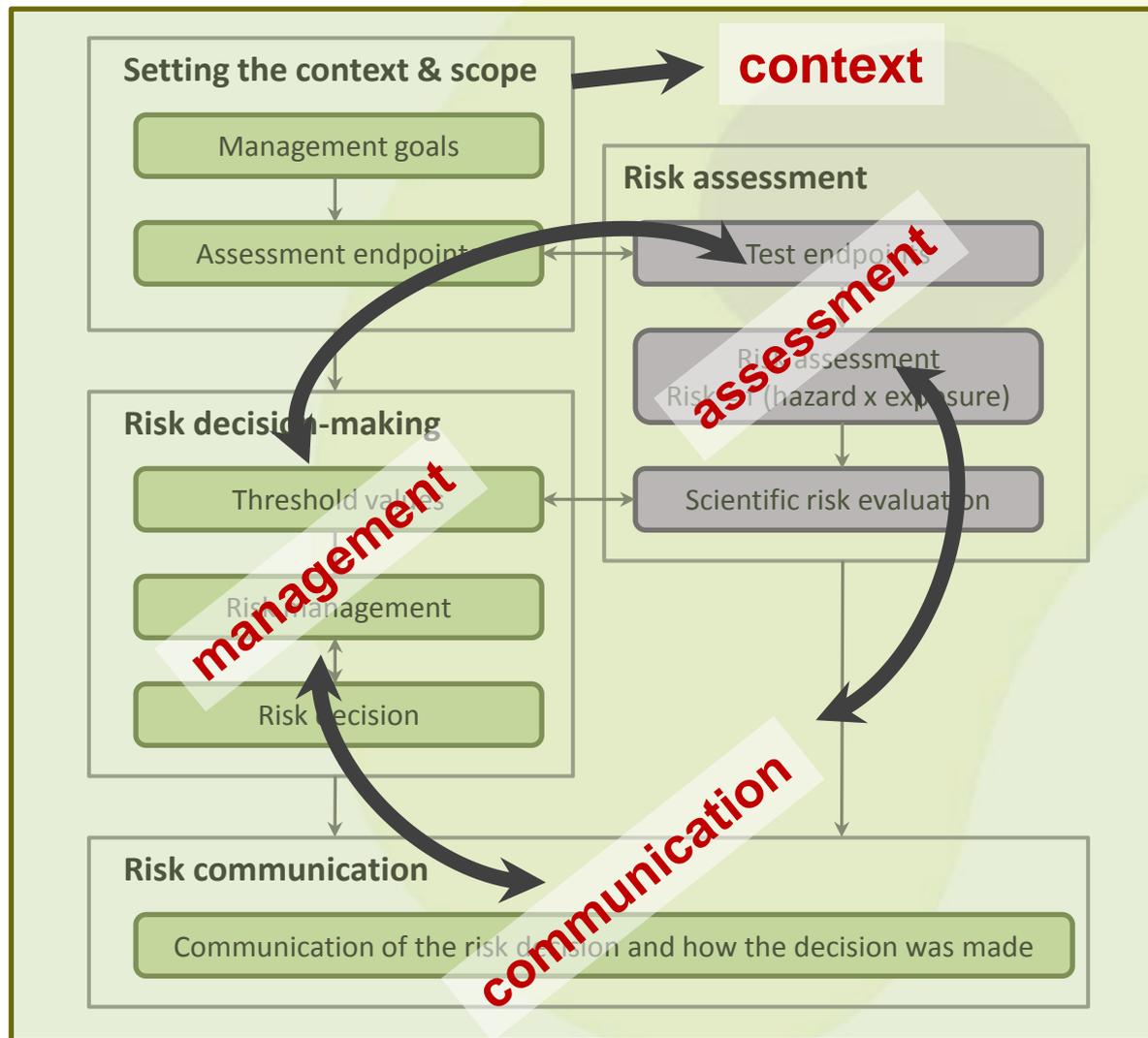
INTRODUCTION TO RISK ANALYSIS

- A comprehensive risk analysis is the basis of all regulatory activities associated with GMOs.
- Although there is some variation in how risk analysis frameworks are presented they always follow the same basic, iterative steps.
- Monitoring forms part of the risk management activities and is based on the initial steps of the risk analysis.



A FRAMEWORK FOR RISK ANALYSIS

Adapted from Johnson et al. 2007. Trends in Plant Science 12(1): 1-5.



Stages of risk analysis:

Key issue identification, risk assessment, risk decision-making and risk communication.

Progression through the system is not linear, but iterative

Green boxes - driven by society

Purple boxes - driven by science

A MONITORING FRAMEWORK FOR GM CROPS

- Monitoring can be defined as the systematic measurement of variables and processes over time, guided by specific, well defined reasons for collecting the data, for example, to ensure certain standards or conditions are being met or to examine potential changes.

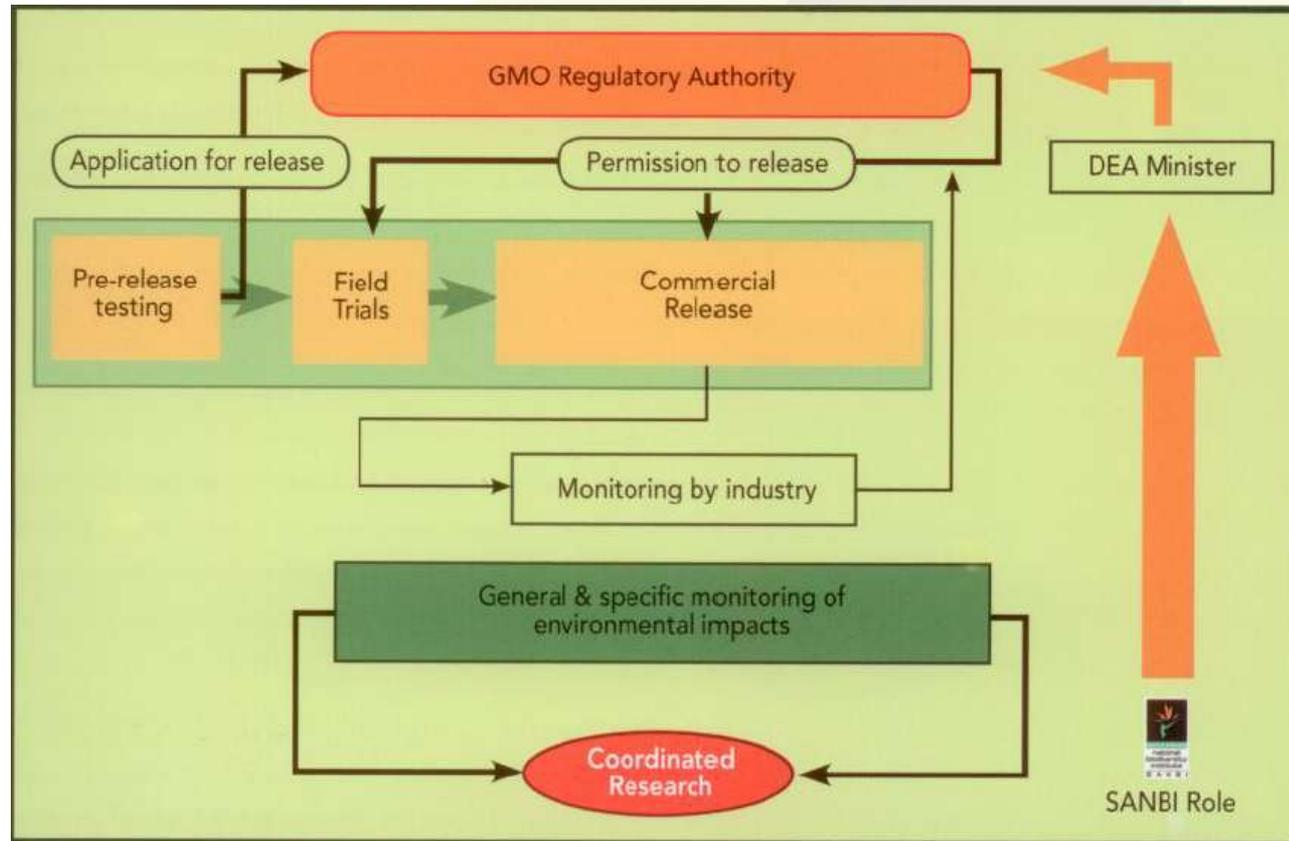
- Environmental monitoring includes:

- Case specific monitoring is well defined, hypothesis driven and is generally aimed at confirming that the assumptions used in the risk analysis are correct

- General surveillance on the other hand is aimed at identifying effects which were not anticipated in the risk analysis and is therefore based rather on consent than strict hypotheses



MONITORING INTEGRATED INTO RISK ANALYSIS

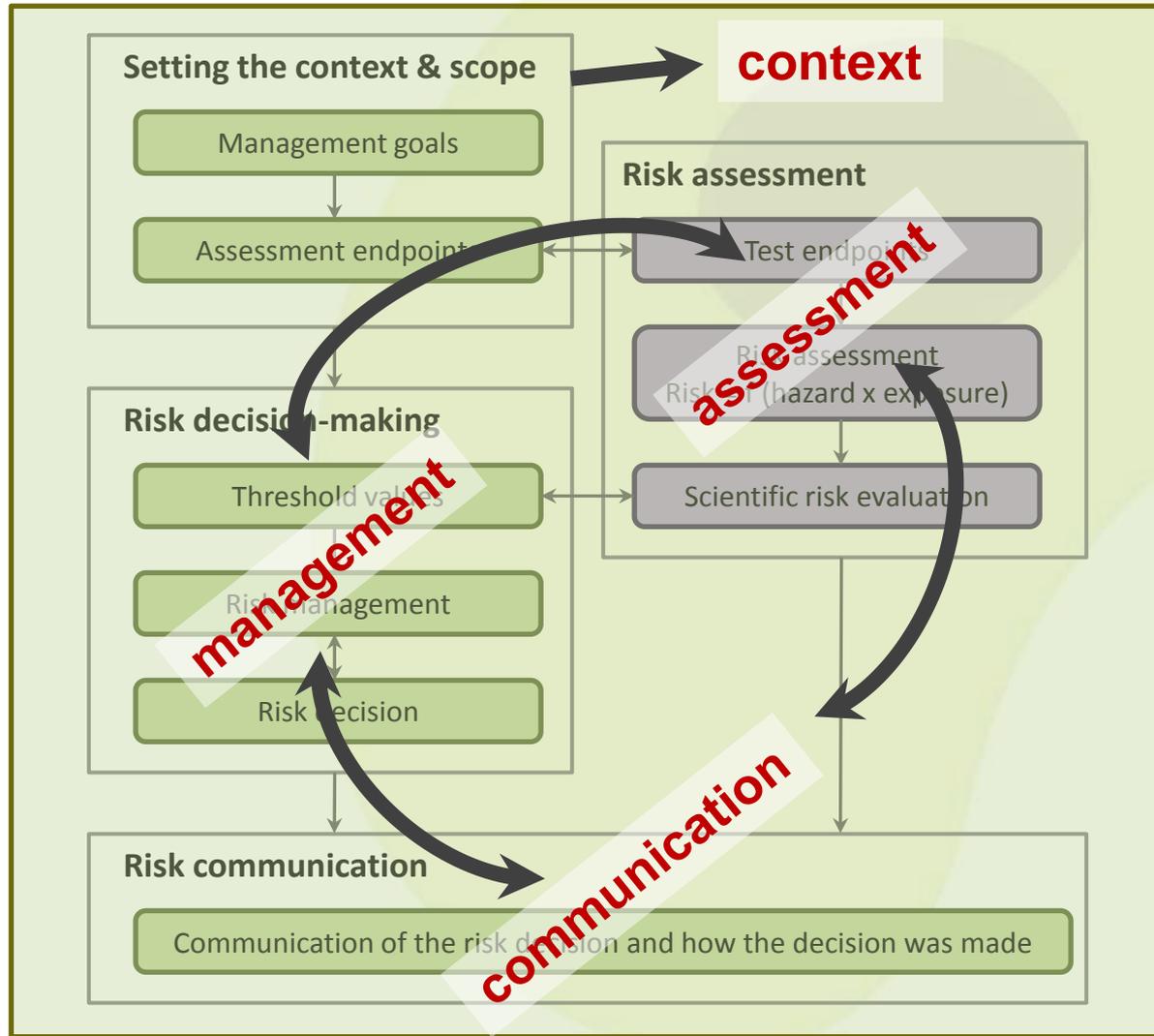


From "Monitoring the impacts of GM maize in South Africa". Department of Environmental Affairs and SANBI (2011).



MONITORING INTEGRATED INTO RISK ANALYSIS

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- Monitoring must be explicitly integrated into the risk analysis process i.e. the primary regulatory/decision making process.

- Possible harms, assessment endpoints, risk acceptance criteria, threshold values, risk management practices, etc. are all considered at a national level during the evaluation of a GMO for general release under the GMO Act and should be integrated into a possible monitoring plan for the particular GMO.

- Monitoring may become uncoupled from national policies and objectives and may not take into consideration already implemented risk management activities

- Uncoupling monitoring from national policies and objectives could lead to unnecessary duplication of efforts, the imprudent use of resources, divergence in priorities and conflict.



MONITORING INTEGRATED INTO RISK ANALYSIS

- Although SANBI's mandate to do monitoring stems from different legislation the best way of ensuring integration is to officially involve SANBI in the process of risk analysis under the GMO Act
- This would not take away SANBI's right to implement additional monitoring programs or strategies not identified during the risk analysis carried out under the GMO Act
- Ideally monitoring of GMOs (under the various legislation) will be based on the same risk analysis process including the risk decisions that were made.



TAKE HOME MESSAGES

- The basis of all regulatory activities associated with GMOs, including post-release monitoring, should be based on a comprehensive risk analysis.
- Monitoring forms part of the risk management activities under risk decision-making and its goals, endpoints and threshold values are based on the context, scope and assessment outcomes of the initial two steps.
- Monitoring must be fully integrated into the national decision making and management processes taking into consideration the responsibilities of the different role players.
- However when doing this within the South African national regulatory system care should be taken not to detach monitoring from the initial risk analysis process, as this could lead to duplication, divergence and/or conflict.





THANK YOU

