

# Seminar

## on Applications for Authorisation Non-Governmental Organisations and Trade Unions - Brussels, 7 July 2011

Appropriate and Effective Risk Management  
(Adequate Control)

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Legal framework and Implementation

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# Overview

1. Title VII Chapter 2  
Granting of Authorisations:  
Application – Decision – Review
2. Legal Considerations
3. Practical implementation (“Checklists“)

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## **Project**

- Two case studies on ES (“virtual authorisation”)
- Workshop with industry representatives



## 2. Legal Considerations

### Applicant

- obliged to set forth the facts relevant for the decision
  - REACH shifts “burden of proof”
  - Similar to licensing procedure IPPC/IED
- Art. 60 (2)/(4) + Art. 60 (9) f + Art. 60 (10)
- Risk Management + Monitoring Concept
- Art. 62 (4) d: interpreted in the light of Art. 60 and Art. 64

### Procedure ...

### Authorization Conditions ...

Guidance, p. 18: “In granting the authorisation and setting any conditions the Commission will take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, *known at the time of the decision.*”

### Monitoring (Actors in the Supply Chain/Authorities)

Guidance, p. ?:

### Review ....

# 3. Implementation

## Annex XVa: Monitoring Plan

(based on: Monitoring Plan in Annex VII of the Directive 2001/18/EC)  
... in the meantime: Additional Guidance [Technical Advice] on Monitoring

### Checklist I

Application

Art. 62:  
Inclusive Governance

### Checklist II

Granting of  
Authorisation

i.a.: Art. 60(9)f + (10):  
RM + Monitoring

### Checklist III

Review

*carpe diem ...*

*Art. 60 (et ...)*

*respice finem*

# Checklist I

## Points to be considered by the applicant in his application

1. Subject of the application for authorisation (“use applied for”)
  2. Description of the substance life-cycle / mass balance
  3. Data on point sources
  4. Estimate of emission from point sources
  5. Organization or technical measures for emission reduction
  6. Data on relevant diffuse emission sources
  7. Characterisation of emissions in the case of diffuse sources
  8. Mass balance for diffuse sources and point sources
  9. Surveillance and monitoring  
at a local or regional level for the duration of authorisation
  10. Information on research projects
  11. Data concerning the communication of substance related information down  
the supply chain
  12. Proposal for the revision period
- Mentioned – in  
general terms – in  
the Guidance, i.a.  
page 18,  
section 3.7.1 ...

**Thank you for your attention**

**more information:**

**[www.reach-helpdesk.info](http://www.reach-helpdesk.info)**

**[www.sofia-research.com](http://www.sofia-research.com)**