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# **Chemistry**

**Glyphosate / Acetochlor / Business Needs**

**Regulatory Leadership Meetings  
November 1 - 4, 2010**

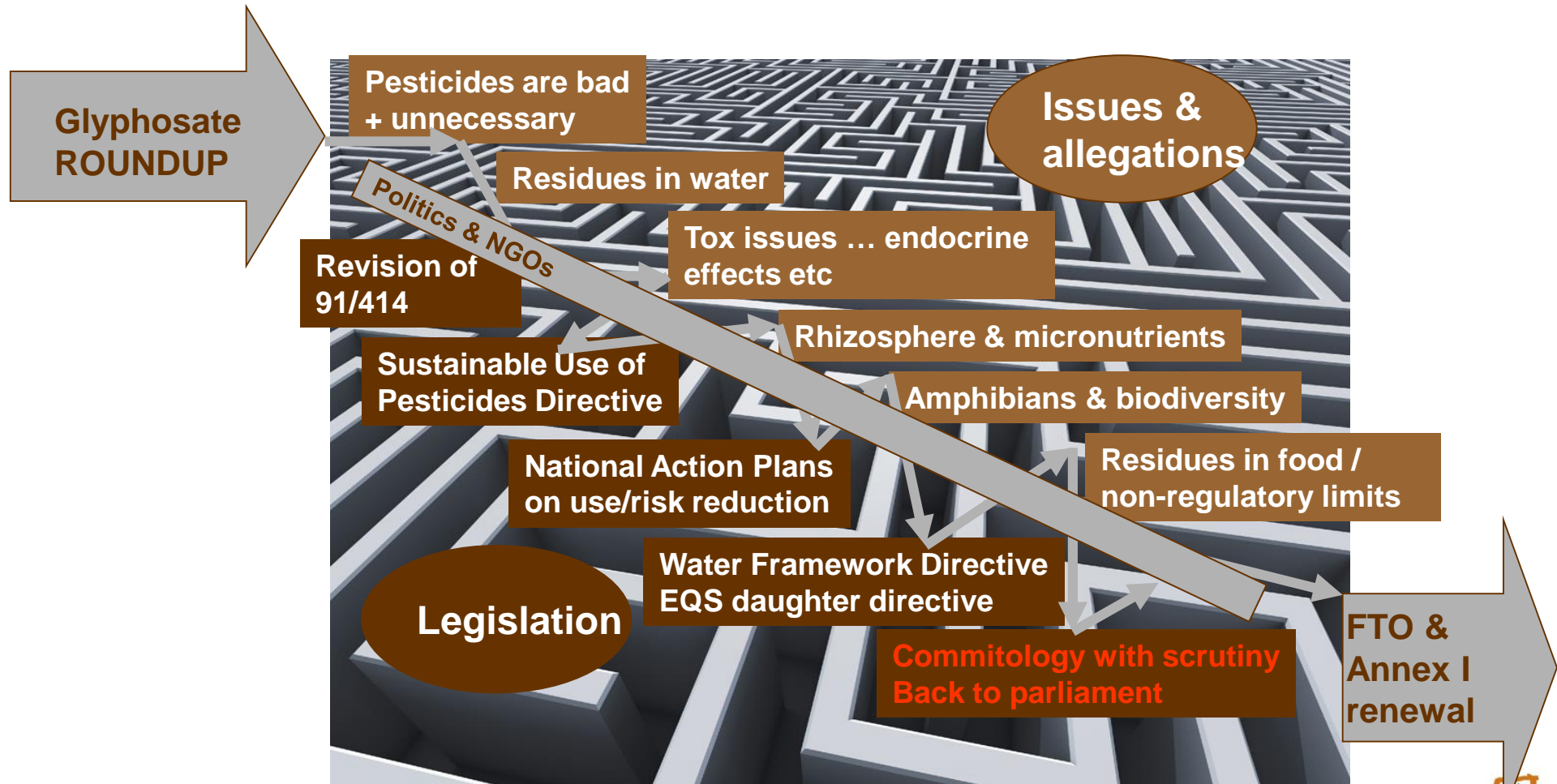
# Agenda

- Key Global Glyphosate Re-registrations, Reviews & Regulatory Actions
  - Emphasis on EU Annex I renewal
  - OTT in Brasil
- Roundup® Herbicide Surfactants
  - Attention/pressure increasing globally
  - Are we ready to move beyond POEA and defend surfactants/formulations broadly?
- Acetochlor
  - Situation in EU & Impact on ROW

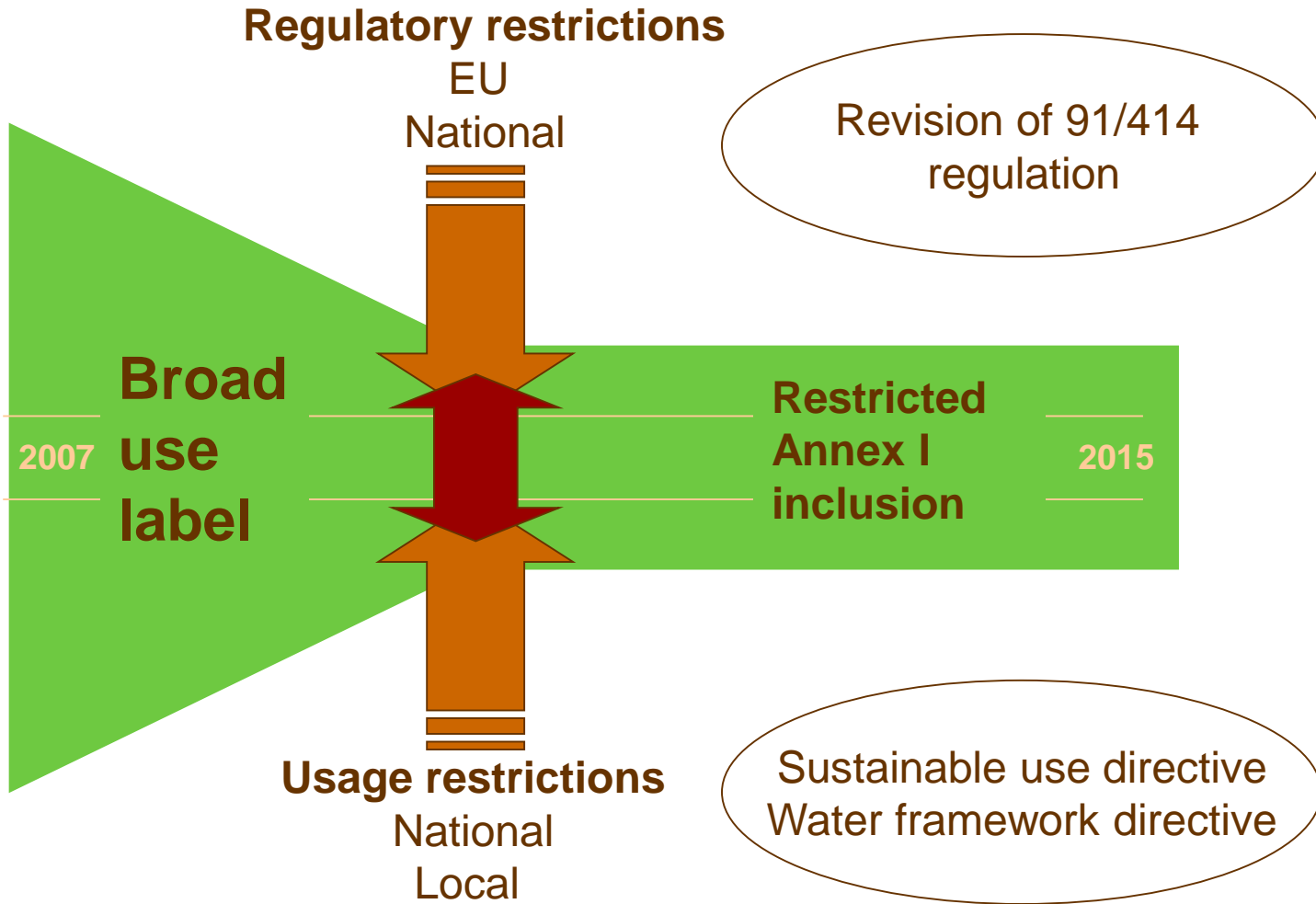
# Global Glyphosate Re-registrations, Reviews & Regulatory Actions

- EU – Annex I Renewal
- US/Canada Registration Review/Re-evaluation
  - EPA & PMRA DCIs received – overall favorable, no surprises
    - No PMRA request for chronic AMPA data
  - EDSP will likely lead to much work
    - EPA has only accepted 3/110 OSRI filings so far
- Japan – ADI Review (Toxicology & Residues)
  - Monsanto data reviewed – no questions; ADI = 0.75 mg/kg/day
  - 4 more databases from 5 companies; expect January completion
- Brazil – ANVISA Toxicology Review
  - Expect Technical Note any day

# Roundup Freedom to Operate (FTO) ... numerous barriers and traps



# Roundup use will be restricted the game is ... how restricted



# OTT in Brasil

- Update from Geraldo Berger

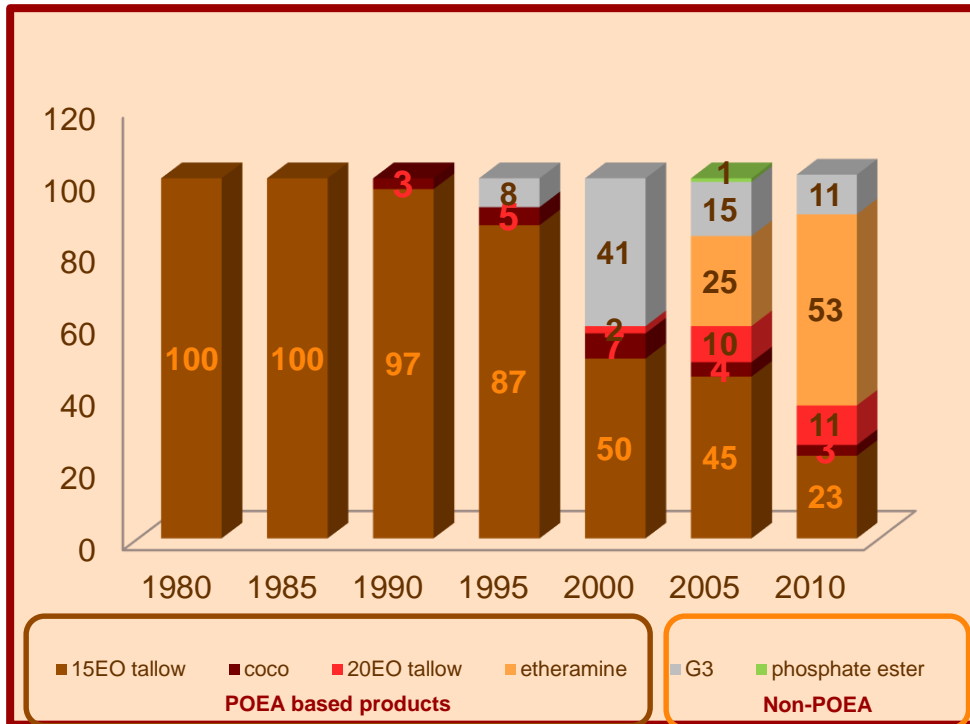


# **Roundup® Herbicide Surfactants**

## **POEA issues**



# EMEA Surfactant Status



## Business impact

- **POEA based products are business critical**
  - includes “new” generation, e.g. etheramine
- **Germany is major concern**
  - restrictions on POEA uses pre-harvest had significant negative impact on sales 2010
  - Bavaria guidance to extension services not to recommend any use in 2011
- **competition has alternatives**
  - APG (Syngenta) phosphate ester (many)
  - Cheminova registered hydrogenated tallow amine

## Product development

- **rapid re-launch of G3 for 2010 season**
- **liquid offer: register Zanussi (non-POEA) family of formulations**
  - potential access to other non-POEAs
- **dry offer: register MON 79991 (ex-Latin America)**
  - potential access to Cheminova dry

# Strategy in Germany

## 1. Defend POEAS (and science based regulation): industry consortium

- Build bridge to new registrations
  - Push back on data requests
  - Perform selected studies & risk assessments
- Understand the politics – low success
- Communicate disproportionate restrictions, data requests

### POEA manufacturers

Akzo, Clariant

### POEA product registrants

Agrichem, Albaugh, Barclay, Cheminova, DAS, Monsanto, Nufarm

## 2. Register non-POEA formulations: Monsanto

- **spring 2011** Zanussi mutual recognition with UK (limited label)
- **spring 2012** Zanussi national registration (full label)
- **winter 2011/12** Cheminova “Dakar” dry?
- **winter 2012/13** Sahara dry (submit registration Jan 2011)

## 3. Managed exit from POEA: Monsanto

- Avoid a ban
- Focus: voluntary non-renewal of registrations (e.g. MON 14420 end 2012)
- No sales of any POEA products after 2012

### Impact on the RoW

- driven by Seralini & Carrasco
- regulators looking to the EU

### EU Standing Committee (SCFCAH)

- European Parliament question on Carrasco
- Germany to review
- submitted position paper

### EU Member States

- Sweden – blocking new registrations
- France – defending POEAs

### Brazil & Argentina

### Canada/US

### Australia



# Questions – Surfactants / Roundup

## POEA

- Does each region have good 'Plan B' for moving away from POEA?

## Surfactants - General

- Is pressure increasing? Where is the risk highest?
- Is Monsanto the primary target?
- Are we effectively dealing with these challenges?
  - Responses, studies, publications, supporting expert scientists



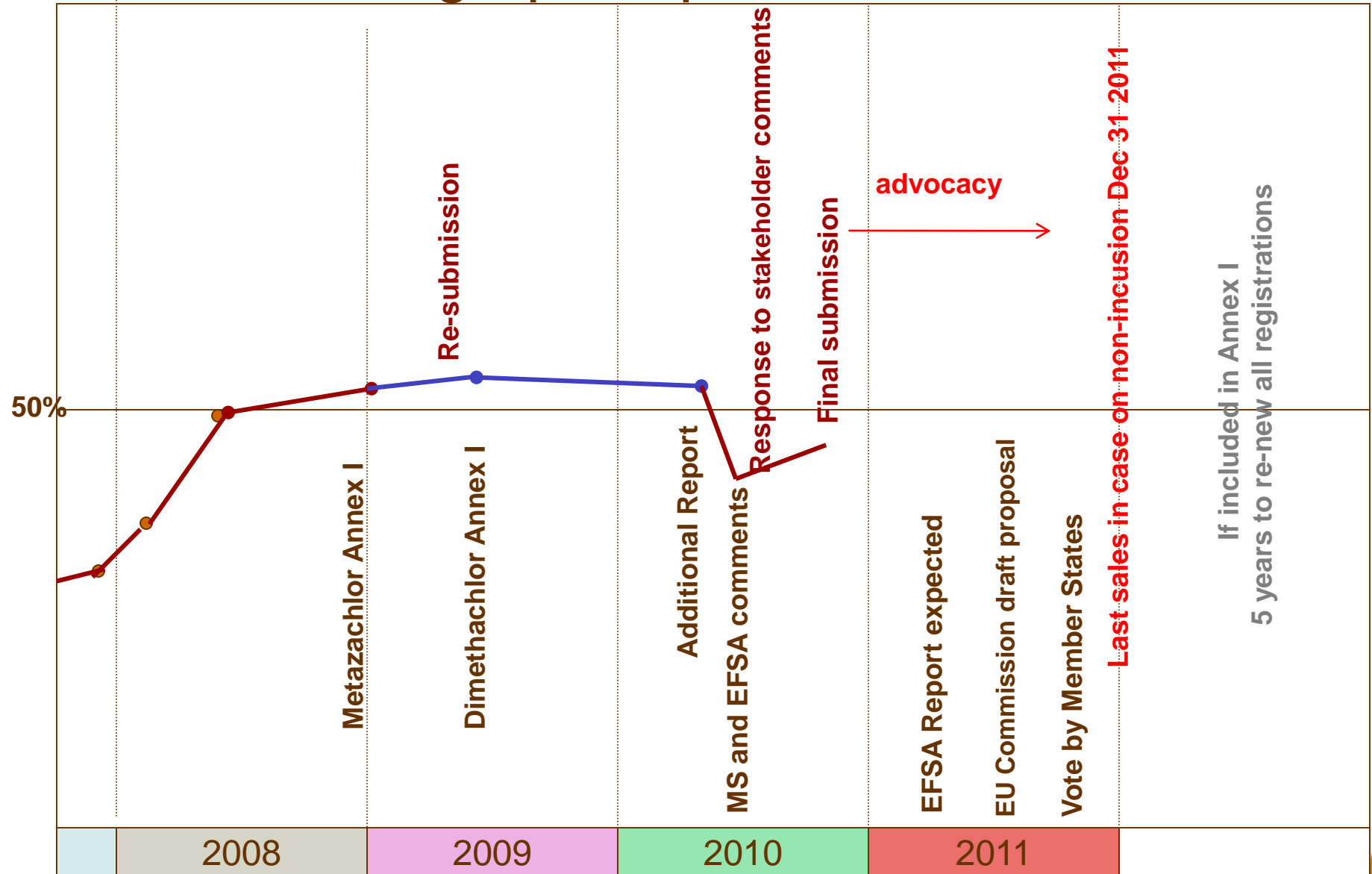
**Acetochlor strategies –  
current needs for global FTO**

# Maintain EU Sales of Acetochlor

- Strong and persistent scientific and regulatory responses to questions from the Rapporteur (RMS) and EFSA PRAPeR\*
  - Introduced risk mitigation options: reduced dose, use every second year *etc*
  - Last opportunity for new data submission was completed early October
  - Offer to revise Summary Report - avoid confusion amongst Member States
- Discussions with RMS & DG SANCO when possible
- Advocacy through maize growers (*DAS lead*)
  - Politicians: European (CEPM) & French maize growers ass'cns strongly supportive and active; engaging other country associations
  - Technical experts: focus on existing legal classification, *i.e.* not carcinogenic
  - Agronomists: favourable ARVALIS (French institute) study

\* The Pesticide Risk Assessment Peer Review (PRAPeR) is in the Scientific Cooperation and Assistance directorate, and does not have the same function or form as the GMO Panel (Risk assessment directorate). It is composed of EFSA staff who peer review pesticide active substances. In contrast, the independent experts as the GMO Panel provide scientific advice.

# The 'Acetograph' – part 2



# Can we do more?

All Member States understand that Acetochlor is:

- the most cost-effective maize herbicide
- a key component of weed resistance management
- NOT classified as a carcinogen

Target scientific advisors & politically influenced levels

DAS lead the advocacy – they have more country technical, regulatory and govt affairs staff

Monsanto's ability is severely restricted

Monsanto required resource

- toxicology expert tour to key experts (Q2 2011?)
- CA/GA/RA time to meet key influencers

# What if ... no Annex I Inclusion?

1. Defend ex-EU markets (East Europe, Africa)
  - Increasing reliance on EU decisions (not Russia)
  - Loss of alachlor has little impact after 5 years
  - Strategy to be developed with new EMEA team
2. Ability to register in Canada
  - Decision pending efficacy trial results
3. Central/South American markets
  - Much interest in expanding acetochlor use
  - Maintaining/obtaining registrations will be more difficult if no EU Annex I inclusion



# Acetochlor Strategy for ANVISA Review

## Dr. Zambrone's analysis (Mar-2010)

- Extremely complicated database needing many explanations
- R40 cancer classification in EU would be problematic in Brazil
- That said, MON & Dr. Zambrone successfully defended alachlor with ANVISA in 1999 using MOA data
  - May still be successful in Brazil even with unfavorable EU decision

## Dr. Zambrone's recommendations

- Start building stakeholder support soon
- Follow-up meeting with Dr. Zambrone to game-plan how EU-specific evaluations can be isolated
  - Default assumptions for metabolites and DW viewed differently in Brazil?

# Back-Up Slides

# Acetochlor Status in Brazil

- Registered for use on coffee, sugarcane, corn & soybean – but not currently sold/marketed
- DAS also has registrations for use on sugarcane & corn
  - Only have formulation registered; depend on MON's a.i. registration
- MON received request from ANVISA to submit all acetochlor Toxicology studies (25-Feb-2010)
  - Since existing dossier submitted in 1991, it did not include subsequent oncogenicity MOA studies, etc.
- Submitted requested studies & list of all Tox/MOA studies supporting U.S. registration and in EU Annex I dossier (May 14)

# Recent Publications - Roundup Formulations

- Seralini (Benachour) – Glyphosate formulations induces necrosis in human umbilical, embryonic and placental cells (*Chem. Res, Toxicol.*, January, 2009)
  - Monsanto only company specified; 4 Monsanto products tested
- Seralini (Gasnier) – Glyphosate formulations are toxic and endocrine disruptors in human cell lines (*Toxicology*, June, 2009)
  - Monsanto only company specified; 4 Monsanto products tested
- Carrasco (Paganelli - Univ. Buenos Aires) – Glyphosate formulations cause neural, intestinal & heart malformations in frog & chick embryos (*Chem. Res. Toxicol.*, Aug, 2010)
  - Associates herbicide use with GMOs; Monsanto's Roundup Classic tested
- Romano (Univ. Sao Paulo) – Glyphosate formulation alters Testosterone Levels and Testicular Morphology. (*Arch. Toxicol.*, 2010)
  - Monsanto only company specified; Roundup Transorb tested