Food Safety at MARS

So, why should we produce safe food?

Quality is the first of our principles. Excellence in Food Safety Management sits at the heart of that

and

- The consumer takes it for granted
- Mars reputation demands it
- Legal obligations and
- Unsafe food might result in illness or death
RESPONSABILITIES

- Food safety governance and strategic oversight
- Foster Quality culture throughout Mars
- Development and verification of Q&FS standards
- Food safety incident management
Dioxins and dioxin-like PCBs
<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Commodity</th>
<th>Contaminant</th>
<th>Exposure Assessment</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| 1968 | Japan (Yusho) | Rice Oil  | PCBs, PCDFs                                   | 10 mg/kg BW (PCBs)  
58 µg/kg BW (PCDFs)                           | 1700 victims                                                               |
| 1979 | Taiwan (Tucheng) | Rice Oil  | PCBs, PCDFs                                   | 17 mg/kg BW (PCBs)  
63 µg/kg BW (PCDFs)                           | 2000 victims                                                               |
| 1999 | Belgium     | Animal Feed | PCBs and dioxins                            | 25 µg/kg BW (PCBs, estimated)  
500 pg/kg BW (dioxins, estimated)             | Recall all meat products >25% fat content                                  |
| 2007 | Switzerland | Guar Gum   | Dioxins and pentachlorophenol                 | 406 pg WHO-TEQ/g product (PCDD/F)  
4 mg/kg product (PCP)                           | Recalls of guar gum and foodstuffs (esp. fruit, dairy) in at least 16 EC member states. |
| 2008 | Ireland     | Pork       | Dioxins                                       | Up to 200 pg WHO-TEQ/g fat                                | Withdrawn all pork products from Irish Republic and Northern Ireland    |
Dioxins and dioxin-like PCBs

- Polychlorinated dibenzodioxins (PCDDs)
- Polychlorinated dibenzofurans (PCDFs)
- 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD or TCDD)

Polychlorinated biphenyls (PCBs)
Dioxin contamination in food

Soil
Water

Soil
Water

7
Exposure to dioxin and dioxin-like PCBs

- Dioxins are not intentionally added to food or created during food processing

- By-products of waste incinerators (especially in the past), household heating, traffic, forest fires, and metal, pulp and paper industry

- In US, human body burden of TCDD and dioxin TEQ decreased 10-fold and 4- to 5-fold respectively between 70’s and 1999, leading to a decrease of exposure >95%
Dioxin and dioxin-like PCB exposure levels over time

Reductions in Average Exposure to Dioxins/Furans/PCBs Over Time

pg*/kg-body weight/day

1970
>15 TEQ**

1990
1-4 TEQ**

2010
<1 TEQ (Projected***)

PCBs
TCDD
Other dioxins/furans
Contribution of different food commodities to dioxin exposure levels in humans

Germany

- Milk and Dairy: 42%
- Meat: 17%
- Fish: 17%
- Poultry: 3%
- Eggs: 8%
- Fruit and Vegetables: 6%
- Oils and Fats: 7%

USA

- Milk and Dairy: 41%
- Meat: 32%
- Fish: 6%
- Poultry: 6%
- Eggs: 2%
- Fruit and Vegetables: 11%
- Oils and Fat: 2%
Toxic Equivalency Factor (TEF)

Congener toxic potency expressed relative to that of a reference compound, i.e. TCDD. Arbitrary $\text{TEF}_{\text{TCDD}} = 1$

WHO criteria for including a dioxin-like PCB compound in the TEF scheme

- show a structural relationship to the PCDDs and PCDFs
- bind to the Ah receptor
- elicit Ah receptor-mediated biochemical and toxic responses, and
- be persistent and accumulate in the food chain
### Toxic Equivalency Factor (TEF)

<table>
<thead>
<tr>
<th>PDDDs</th>
<th>TEF</th>
<th>'Non-ortho' PCBs</th>
<th>TEF</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCDD</td>
<td>1</td>
<td>3,3',4,4'-TCB</td>
<td>0.0001</td>
</tr>
<tr>
<td>1,2,3,7,8-PeCDD</td>
<td>1</td>
<td>3,4,4',5-TCB</td>
<td>0.0003</td>
</tr>
<tr>
<td>1,2,3,4,7,8-HxCDD</td>
<td>0.1</td>
<td>3,3',4,4',5-PeCB</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,6,7,8-HxCDD</td>
<td>0.1</td>
<td>3,3',4,4',5,5'-HxCB</td>
<td>0.03</td>
</tr>
<tr>
<td>1,2,3,7,8, 9-HxCDD</td>
<td>0.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,2,3,4,6,7,8-HpCDD</td>
<td>0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCDD</td>
<td>0.0003</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PCDFs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,3,7,8-TCDF</td>
<td>0.1</td>
<td>2,3,3',4,4'-PeCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>1,2,3,7,8-PeCDF</td>
<td>0.03</td>
<td>2,3,4,4',5-PeCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>2,3,4,7,8-PeCDF</td>
<td>0.3</td>
<td>2,3',4,4',5-PeCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>1,2,3,4,7,8-HxCDF</td>
<td>0.1</td>
<td>2,3,3',4,4',5-PeCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>1,2,3,6,7,8-HxCDF</td>
<td>0.1</td>
<td>2,3,3',4,4',5-HxCB</td>
<td>0.00003</td>
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<tr>
<td>1,2,3,7,8,9-HxCDF</td>
<td>0.1</td>
<td>2,3,3',4,4',5,5'-HxCB</td>
<td>0.00003</td>
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<td>2,3,4,6,7,8-HxCDF</td>
<td>0.1</td>
<td>2,3',4,4',5,5'-HxCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>1,2,3,4,6,7,8-HpCDF</td>
<td>0.01</td>
<td>2,3,3',4,4',5,5'-HpCB</td>
<td>0.00003</td>
</tr>
<tr>
<td>1,2,3,4,7,8,9-HpCDF</td>
<td>0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCDF</td>
<td>0.0003</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TEQ Approach – Dose Additivity

TEFs are based on toxicological evaluations of dose–response relationships between external exposure, i.e. the levels of intake of congeners, and toxicity in organs.

\[
\text{TEQ} = C_1 \text{TEF}_1 + C_2 \text{TEF}_2 + C_i \text{TEF}_i + \ldots
\]

TEQ = Toxic Equivalent of the mixture.
TEF$_i$ = Toxic Equivalency Factor for dioxin or dioxin-like PCB “$i$”
C$_i$ = Level of intake of Dioxin or dioxin-like PCB “$i$” in the mixture.
Children and breastfeeding

- Sweden, exposure estimates exceed TDI, high consumption of fish in the diet

- Belgium, breastfed babies, dioxin intake > 20 x TDI. First-3-months intake 6% lifetime dioxin intake

- US, exposure data indicates that children might exceed the WHO-TEQ limit

- Germany, breastfed babies, dioxin intake > 60 x TDI. 6-y old children, 50% dioxin body burden via breastfeeding
Dioxins and dioxin-like PCBs

Polychlorinated dibenzodioxins (PCDDs)

Polychlorinated dibenzofurans (PCDFs)

Dioxin

Polychlorinated biphenyls (PCBs)

2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD or TCDD)
MARS  Dioxins - Toxicity

- Wasting syndrome
- Impairment of immune responses
- Chloracne and related dermal lesions
- Reproductive Toxicity
- Carcinogenicity
- Teratogenicity
- Death

Ukraine President Viktor Yushchenko
MARS
Pesticides
## Food Safety Incidents - Pesticides

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Commodity</th>
<th>Pesticide</th>
<th>Route of Contamin.</th>
<th>Exposure Time</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1958</td>
<td>India</td>
<td>Flour</td>
<td>Parathion</td>
<td>Transport</td>
<td>1-2 months</td>
<td>360 people ill and 102 deaths</td>
</tr>
<tr>
<td>1971</td>
<td>Iraq</td>
<td>Wheat and Bread</td>
<td>Methyl mercury</td>
<td>Accidental use</td>
<td>6 months</td>
<td>6500 people ill and 459 deaths</td>
</tr>
<tr>
<td>1983</td>
<td>Senegal</td>
<td>Oil</td>
<td>Parathion</td>
<td>Unsafe use</td>
<td>1 day</td>
<td>25 people ill and 18 deaths</td>
</tr>
<tr>
<td>1985</td>
<td>USA</td>
<td>Watermelon</td>
<td>Aldicarb</td>
<td>Unsafe use</td>
<td>3 month</td>
<td>1350 people ill and no deaths</td>
</tr>
<tr>
<td>1989</td>
<td>Taiwan</td>
<td>Flour</td>
<td>Barium carbonate</td>
<td>Accidental use</td>
<td>1 day</td>
<td>13 people ill and 1 death</td>
</tr>
<tr>
<td>1997</td>
<td>India</td>
<td>Meal ingredients</td>
<td>Malathion</td>
<td>Unsafe use</td>
<td>1 day</td>
<td>60 people ill and 1 death</td>
</tr>
</tbody>
</table>
Pesticides

- Pesticide is any substance, preparation or organism prepared or used for controlling any pest

- Maximum Residue Level (MRL), maximum concentration of a pesticide residue permitted in or on food and feed

- MRLs, Good Agricultural Practice check

- MRLs are NOT safety limits. Exposure to residues in excess of an MRL does not imply a hazard to health → Acceptable Daily Intake (ADI)
<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Citrus fruit (orange)*</th>
<th>Tree Nuts (almonds)*</th>
<th>Root and tuber vegetables (potatoes)*</th>
<th>Bulb vegetables (garlic)*</th>
<th>Leaf vegetables and fresh herbs (lettuce)*</th>
<th>ADI**</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCB</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>Dichlorvos</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.00008</td>
</tr>
<tr>
<td>Diazinon</td>
<td>0.01</td>
<td>0.01-0.05</td>
<td>0.01-0.1</td>
<td>0.01-0.05</td>
<td>0.01</td>
<td>0.0002</td>
</tr>
<tr>
<td>Aldicarb</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.05</td>
<td>0.02</td>
<td>0.003</td>
</tr>
<tr>
<td>Endosulfan</td>
<td>0.05</td>
<td>0.1</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
<td>0.006</td>
</tr>
<tr>
<td>Alachlor</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05-0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* mg/kg commodity  
** mg/kg BW/d
Pesticides-Regulation (EC) No 396/2005

- Pesticide residues, MRLs, in food.
- Pesticides currently or formerly used in agriculture in or outside the EU (~1100)
- MRLs for fresh products (315), MRLs already in force before September 2008 (~45,000), harmonised MRLs previously set by the Member States (~100,000)
- A list of low risk substances for which MRLs are not necessary.
- EFSA, peer review programme, 1993, safety assessment of all active substances used in plant protection products.
**Pesticides - Toxicity**

- **Fungicides** - Low toxicity, irritating to skin, eyes, respiratory tract
- **Herbicides** - Low toxicity, irritating to skin, eyes, respiratory tract, diarrhea, vomiting
- **Insecticides** - Nervous system disorders, gastric symptoms, headache, dizziness, muscle weakness, coma and death

<table>
<thead>
<tr>
<th></th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD$_{50}$ (mg/kg BW)</td>
<td>≤ 50</td>
<td>50-500</td>
<td>500-5000</td>
<td>&gt;5000</td>
</tr>
<tr>
<td>Inhalation LC$_{50}$ (mg/l)</td>
<td>≤0.2</td>
<td>0.2-2</td>
<td>2-20</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Dermal LD$_{50}$ (mg/kg BW)</td>
<td>≤200</td>
<td>200-2000</td>
<td>2000-20000</td>
<td>&gt;20000</td>
</tr>
<tr>
<td>Ocular effects</td>
<td>Corrosive corneal opacity not reversible within 7 days</td>
<td>Corneal Opacity reversible within 7 days; irritation persisting for 7 days</td>
<td>No corneal opacity; irritation reversible within 7 days</td>
<td>No irritation</td>
</tr>
<tr>
<td>Dermal effects</td>
<td>Corrosive</td>
<td>Severe irritation at 72 h.</td>
<td>Moderate irritation at 72 h.</td>
<td>Middle or slight irritation at 72 h.</td>
</tr>
</tbody>
</table>
Material Quality Management Process

1. Material Risk Assessment
2. Draft Material Specification
3. Vendor Risk Assessment & approval for development
4. Material specification approval
5. Vendor Management

- Exception Management
- Continuous Improvement
- Performance Review
- Verification
Material Risk Assessment (MRA) – How to manage risks?

• The first step in the Mars Inc. Material Quality Management (MQM) standard.

• Identify inherent hazards related to a material

• Determine “severity of Effect” vs “Likelihood of Occurrence” => High / Medium / Low risk

Assess supplier controls vs own controls

• what must be controlled at the supplier

• what will be controlled at own site

• relationship between Supplier and own HACCP
Material Risk Assessment (MRA)

- What is the hazard? Chemical, Physical, Biological
- What does the supplier do to mitigate the risk?
- What do MARS do to mitigate the risk?
- Residual risk?
Thank you!
References


Commission Regulation(EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs


Electronic Code of Federal Regulations 40 CFR 156.62 [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=40:3A23.0.1.1.7&idno=40;sid=48302bcda20b542dd44746b6e576f543;cc=ecfr#40:23.0.1.1.7.3.1.2](last accessed February 11th 2010)

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Ministerial Council on Dioxin Policy of Japan (1999)

National Health & Medical Research Council (2002) Dioxins: Recommendation for a Tolerable Monthly Intake for Australians

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