Presentation on behalf of Grupa Azoty S.A., Tarnów
Seminar on Applications for Authorisation
Helsinki, 29-30 June 2015
Applicant and Consultants

- **Applicant:** Grupa Azoty S.A., Tarnów, Poland
- **Consultants assisting Grupa Azoty S.A. for its application for authorisation:**
  - Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG), Freiburg, Germany
  - Risk & Policy Analysis Ltd. (RPA), Loddon, UK
Grupa Azoty S.A., Tarnów, Poland
The subject of authorisation

✓ The subject of authorisation was trichloroethylene, which is used at Grupa Azoty S.A. in the production of caprolactam,

✓ caprolactam synthesis of the company is a pivotal part of the integrated production line leading to polyamide, which is the most important part of the business activity of the company,

✓ Trichloroethylene is the most important processing chemical involved the caprolactam purification process,

✓ The company buys the substance from a European supplier and is a downstream user,

✓ The authorisation referred to one use and one production site in Tarnów.
Guidelines resulting from the experience of Grupa Azoty S.A. recommended to be followed by the applicants

✓ Estimation, if your substance is subject to authorization. Some substances required for authorisation may be exempted from authorisation, e.g. due to its use as an intermediate. According to the REACH definition the substance is considered an intermediate, if it is “used for chemical processing in order to be transformed into another substance” (Definition, Art. 3, REACH).

✓ Contact with the manufacturer or supplier of the substance to inquire about the possibility of joint authorisation or including your use into his authorisation dossier,

✓ Searching for a consortium or other producers obliged to authorisation in order to share the costs,

✓ In all cases the dossier has to cover exactly your use of the substance,

✓ If you fail to find any of the above mentioned possibilities, you must assess, if you are able to prepare a successful application without the help of external consultants.
Employing external consultants

✔ Grupa Azoty S.A. decided to employ professional consultants:
  1. Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG), Germany,
  2. Risk & Policy Analysts Ltd, UK.

✔ Both companies possess considerable **expertise and EXPERIENCE** to elaborate the authorisation application. Grupa Azoty had already cooperated with them and they had been successful in previous projects.

✔ This was **not the cheapest possibility**, but caprolactam is the most important intermediate of the company used for polyamide production.

✔ The **company is very satisfied with the opinion of RAC and SEAC recommending a long review period of 12 years. It is a big success of both the consultants and the company.**
The main challenges resulting from the required authorisation:

✓ The first authorisation process, which required a lot of data, information and measurement results, e.g. air monitoring and biomonitoring,

✓ Involvement of a great number of employees to prepare and collect in time data and information required by the consultants as input data,

✓ Time and deadline pressure,

✓ Some factors were beyond the control of the company, because they were dependent from third parties,

✓ Pressure from the side of the board of directors, because caprolactam production is the core business of the company.
Thank you very much for your kind attention

More information: www.grupaazoty.com
Exposure assessments for Applications for Authorisation: An example

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www.fobig.com

Seminar on Applications for Authorisation, Helsinki, 29-30 June 2015
Outline

- Context
- Risk
- Exposure estimation
  - Workers – Dermal exposure
  - Workers – Inhalation exposure
  - Humans via the environment
- Communication aspects
- Discussion and conclusions
Context

- **The example**
  - Trichloroethene (TCE) in the industrial use as a process chemical in caprolactam purification
  - Grupa Azoty S.A., Tarnów (Poland)
  - Consultants: RPA (UK) and FoBiG (Germany)
  - 'Ideal case' (1 site, 1 use, biomonitoring method available)

- **CSR**
  - Reference values (dose-response, DNEL) established by RAC (own ERR)

-> Exposure assessment even more important
Risk: Exposure-risk relationship (ERR)  
Workers – inhalation

- Risk of $1 \times 10^{-5}$ for TCE at
  - 0.8 mg/m$^3$ (RAC (2014) based on AGS (2008))
  - 3 mg/m$^3$ (FoBiG (2014) derived in AfA CSR)  
    [LoQ: 0.069 mg/m$^3$ (bio-monitoring); 5 mg/m$^3$ (air monitoring)]

- ERR derived by RAC outdated
- ERR derived by FoBiG up-to-date, considering recent meta-analyses and re-evaluations

- Both ERRs presented in CSR and used for risk calculation  
  -> RAC used only their own ERR  
  -> RAC considers other ERRs only if RAC-ERR is not used
Exposure – Workers – Dermal exposure

- Starting point: High volatility
  - Evaporation (ECHA Guidance IR & CSA R.14) from gloves: 0.5-5 seconds
  - Complete glove penetration assumed
  - Dermal flux under occlusion
  -> Dermal exposure is <0.2% of total exposure (inhalation + dermal)

- Dermal absorption (NIOSH’s ‘Finite Dose Skin Permeation Calculator’): 0.01% (no gloves assumed)
- 0.1 % absorption assumed in an estimate based on ECETOC TRA
  -> Dermal exposure is <0.05% of total exposure (inhalation + dermal)

-> High volatility results in negligible dermal exposure (in this use)
-> RAC accepted this rationale

- Dermal exposure covered by bio-monitoring
Exposure – Workers – Inhalation exposure

- Available data: gas sensors set to Polish OEL (50 mg/m\(^3\))
- New bio-monitoring campaign
  - All workers from all 5 teams (end of workweek), n=15
  - Controls from administrative staff, n=5 (also for HvE)
- New air monitoring campaign (personal sampling)
  - All workers from 3 teams (during same workweek), n=9
- ART modelling (task-specific)
  - Small number of workers -> small number of samples
  - Identification of tasks associated with exposure
  - Also: get an idea prior to monitoring

-> But: three approaches will not always be possible
Exposure – Workers – Inhalation exposure

- Modelling results generally confirm measured data
- Air monitoring supportive, but some unexplained findings (processes under review)
- Bio-monitoring data considered most reliable
  - Do not assume RPE efficiency
  - Integrate exposure over the entire workweek (variability)
  - Considered more consistent
  - Also cover dermal exposure (although considered negligible)
  - Highest number of samples (all workers from all teams)

-> RAC followed these arguments, but considered the ‘dataset small (only a single measurement for each worker)’
### Exposure – Workers – Inhalation exposure

<table>
<thead>
<tr>
<th></th>
<th>TCE concentration [mg/m³]</th>
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<tbody>
<tr>
<td></td>
<td>AM</td>
<td>Biomonitoring</td>
<td>AM</td>
</tr>
<tr>
<td>Operators</td>
<td>8.5 (n=3)</td>
<td>5.7 (n=5)</td>
<td>7.6-9.1 (n=3)</td>
</tr>
<tr>
<td>Coordinators</td>
<td>5.1 (n=3)</td>
<td>0.89 (n=5)</td>
<td>2.5*-7.0 (n=3)</td>
</tr>
<tr>
<td>Lab staff</td>
<td>8.0 (n=3)</td>
<td>1.9 (n=5)</td>
<td>2.5*-11 (n=3)</td>
</tr>
<tr>
<td>All workers</td>
<td>7.2 (n=9)</td>
<td>2.8 (n=15)</td>
<td>2.5*-11 (n=9)</td>
</tr>
<tr>
<td>Controls</td>
<td>Not performed</td>
<td>0.034* (n=5)</td>
<td>Not performed</td>
</tr>
</tbody>
</table>

Data for comparison (N=469, DE, 2000-2010): AM = 110 mg/m³

<table>
<thead>
<tr>
<th></th>
<th>TCE concentration [mg/m³]</th>
<th></th>
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<th>Risk</th>
<th>Maximum</th>
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<tr>
<td></td>
<td>AM</td>
<td>Maximum</td>
<td>AM</td>
<td>This assessment*</td>
<td>ECHA**</td>
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<td>7.6E-06</td>
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<tr>
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<td>6.3E-06</td>
<td>2.3E-05</td>
<td>1.4E-05</td>
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<tr>
<td>Operators</td>
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<td>7.2</td>
<td>1.7E-05</td>
<td>6.1E-05</td>
<td>2.4E-05</td>
</tr>
</tbody>
</table>

All values rounded to two significant figures; * based on ERR derived in this CSR; ** based on ERR established by ECHA (2014)

-> RAC did not follow correction for frequency, but accepted estimate due to small difference (5.7 mg/m³ -> 5.1 mg/m³)
Exposure – Humans via the environment

- **Measured data**
  - Bio-monitoring controls (on-site, 250-300 m from unit, n=5)
  - Air monitoring (off-site, 1-4 km from the unit, n=5)

- **Modelling (local scale)**
  - Release in effluent based on E-PRTR data of municipal STP
  - Data on discharge rates etc. from GA (-> different units)
  - Release to air based on integrated permit
  - Details on Polish documents in Annex
  - EUSES modelling (simplified for one STP)
Exposure – Humans via the environment

- Risks very low even with extremely conservative modelling assumptions:
  - inhalation: continuous at 100 m from the source
  - oral exposure: all food comes from the vicinity of the site

- RAC acknowledges potential overestimates but calculates risk for entire population of the city of Tarnów
Communication aspects

- Intensive communication
  - 3 meetings/site visits within 6 months
  - Very detailed exchange of information (different units)
  - Languages: English (Polish)
Discussion and conclusions

- Exposure risk-relationships: RAC vs. own
- Several approaches to exposure estimation useful, but:
  - bio-monitoring methods exit for only few substances
  - air monitoring may be limited (e.g. LoQ for Cr(VI) >> concentration at 1 x 10^{-5} risk)
  - results typically require detailed discussion
  - costs involved
- Dermal exposure to high volatility solvents may be negligible for certain uses, but requires detailed justification
- Exposure HvE (local) potentially unrealistic
- Very good communication is crucial (of course...
Grupa Azoty S.A.
- Marek Pabis, Leszek Maciszewski, Andrzej Lewandowski, Przemysław Sutor, Łukasz Suślik
- All workers and staff taking part in air monitoring and bio-monitoring campaigns

FoBiG
- Klaus Schneider, Fritz Kalberlah

Risk & Policy Analysts
- Tom Persich, Paul Ylioja, Panos Zarogiannis
Thank you for your attention!