SPECIALITY ORGANIC CHEMICAL INDUSTRY

SYNOPSIS SHEET

Prepared in the frame work of EGTEI

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1. Activity description and EGTEI contribution

The speciality organic chemical industry covers the production of different types of chemicals as pharmaceutical active ingredients, biological products, food additives, photographic chemicals, dyestuffs and intermediates, pesticides and other speciality products… produced in campaign basis, in multipurpose and multiproduct plants.

The Directive 1999/13/EC [2] (or SED) aiming at limiting NMVOC emissions from solvent uses in some activities covers the pharmaceutical product manufacturing. The pharmaceutical product manufacturing covers:

- The production of primary pharmaceutical products: production of bulk pharmaceuticals, drug intermediates and active ingredients by means of synthesis, fermentation, extraction or other processes, in multipurpose and multiproduct plants and on a campaign basis.
- Activities related to formulation of finished drugs and medicines using the active ingredients supplied by the bulk plants (taking place in finishing plants). Active ingredients are converted into products suitable for administration. Physical formulation, filling and packaging are involved.

The sector considered in EGTEI is a larger sector covering both pharmaceutical and non pharmaceutical products. Only the pharmaceutical part of this sector is covered by the EC Directive though. This complicates the SED application, since due to multipurpose characteristic of installations, both pharmaceutical and non pharmaceutical products can be produced in the same installation. The entire activity, both pharmaceutical products and non pharmaceutical products, has been considered in EGTEI as processes are similar and the same plant may generate the two types of products (definition of a multipurpose and multiproduct plant).

This activity has been considered by EGTEI [1] as a priority sector. One part of it is covered by the SED. In many Member states, as in France, national regulations cover this activity as a whole (both pharmaceutical and non pharmaceutical applications).

This activity emits NMVOC. At a EU25 level for the year 2000 (according to the RAINS model: version CP_CLE_Aug04(Nov04)), NMVOC emissions were 52.4 kt representing 0.49% of total NMVOC emissions [10].These estimations could be modified in a near future due to information delivered by national experts during the bilateral consultation scheduled in 2005.

The methodology was developed with information collected by CITEPA for a study carried out for the SICOS (French Association of the Organic Chemistry and Biochemistry Industries) in 1998 [4] aimed at estimating the economical impact of the SED on this industry in France and data provided by SICOS [6], [7].

Pharmaceutical product production was considered as a unique sector in the previous RAINS version [5]. However EGTEI provides updated information on emission factors, efficiencies and costs. Data provided by EGTEI are presently used in the last RAINS version [11] for the modelling work carried in the scope of the CAFÉ programme and the revision of the Gothenburg Protocol and national emission ceiling directive.

The representative activity unit used is the annual solvent input (definition coherent with the SED: new solvents consumed + recycled solvents) expressed in kt solvent/year. Only one reference installation is considered.
Two combinations of primary and secondary measures are considered.
EGTEI provides default emission factors (EF) with abatement efficiencies, investments, variable and fixed operating costs (OC) as well as unit costs expressed in €/t NMVOC and €/kt solvent input for the two reduction measures.

Unit costs range from 1173 to 2305 €/t NMVOC abated according to the reduction measure considered and from 258 to 611 €/t solvent input.
National experts have no parameter to collect. In this activity, a unique solution for reducing emissions does not exist. Emissions are reduced through good house keeping, solvent management plants, replacements of production units, end of pipe techniques. It is why it has not been possible to derive a method enabling calculation of country specific costs. Data provided are based on examples. National

experts have however to provide the trends in activity level from 2000 to 2020 as well as the application and applicability rates of each abatement technique.
As the sector representation in RAINS is presently based on the EGTEI proposal, it is recommended to national experts to complete ECODAT with country specific parameters which are not known from CIAM.

In the future however, any new technology which could be developed should be considered by EGTEI in the background document to continuously improve the sector representation and the EGTEI capacity to describe new technologies. It should be necessary to review the considered efficiencies regularly to update them and perhaps define an additional reduction technique if necessary.

2. European regulation

As mentioned above, the European Directive 1999/13/EC [2] applies to this sector.
Operators can conform to the Directive in either of the following ways:

- by complying with the stack and fugitive emission limit values (option 1),
- by introducing a reduction scheme to obtain an equivalent emission level (option 2).

SED applies to installations with a solvent consumption larger than 50 t per year. Emission limit values implemented by the Directive are presented in table 2.1.

Table 2.1: Emission limit values for the manufacturing of pharmaceutical products

Option 1:

Solvent consumption threshold [t solvent / y]	NMVOC emission limit value in residual gases [mg C / Nm^3]	Fugitive emissions [% of solvent input*]
> 50	50 150 if use of a regenerative technique	New installations: 5 Existing installations: 10

Option 2:

Solvent consumption threshold [t solvent / y]	Total emission limit value [% of solvent input*]
> 50	New installations: 5 Existing installations: 10

* Solvent input: quantity of organic solvents used as input into the process in the time frame over which the mass balance is being calculated (purchased solvent) + quantity of organic solvents recovered and reused as solvent input into the process (The recycled solvent is counted every time it is used to carry out the activity).

For discharges of halogenated NMVOCs which are assigned the risk phrase R40, where the mass flow of the sum of the compounds is greater than, or equal to, 100 g/h, an emission limit value of 20 mg/Nm^3 shall be complied with. The emission limit value refers to the mass sum of the individual compounds. Methylene chloride, which is R40, is often used in this activity.
The compliance date for existing installations is 2007. Following the transcription of the directive in Member States, this date can be different from country to country. For example, in France, the compliance date is October 30th, 2005.

3. Methodology developed within EGTEI to represent the sector

3.1 Definition of the reference installation

In cooperation with the French Union of Chemical Industry (UIC) [6], it has been decided to consider the pharmaceutical product manufacturing as the representative activity for the whole speciality organic chemistry. It is consequently assumed that costs derived for the pharmaceutical product manufacturing are representative of the whole speciality organic chemistry. The reference installation and costs have been determined on the basis of information provided by SICOS for study [4].

In this activity, a reference installation cannot be characterised by its active ingredient production. This data is not available and most often, process routes for producing two active ingredients are totally different. The production rate ranges from some kilograms to several thousands tons of product.
In this activity, a reference installation can be characterised by its annual solvent input. This input corresponds to the quantity of solvents purchased (new solvents) plus the quantity of recycled solvent (see above). This definition is in accordance with the definition used by the SED [2].
Only one reference installation is taken into account for simplification and availability of data.

Table 3.1.1: Definition of the reference installation

Reference Installation Code (RIC)	Description
01	Medium Installation: annual solvent input (new + recycling) : 3 000 t/y representative for a range between 1 000 and 5 000 t/y

3.2 Definition of emission abatement techniques

In order to reduce solvent losses and emissions into the atmosphere, a wide range of best practices and process improvements are possible and have been implemented in plants several years ago. These measures aim at containing NMVOC emissions. Such measures include for example (the following list is not exhaustive):

- Work in concentrated environment in order to reduce the consumption of solvents,
- Increased use of low volatile solvents and of solvents easier to condense,
- Modification of certain operating conditions for distillation (e. g. distillation under ordinary pressure instead of vacuum distillation),
- Implementation of good housekeeping, increased condenser efficiency (increased exchanger surfaces and increased refrigerating capacities),
- Technology change: dry-sealed vacuum pumps instead of liquid ring vacuum pumps; closed pressure filters or vacuum filters more leak free than open filters; vacuum dryers leading to a better solvent condensation…

The above mentioned measures allow a significant NMVOC emission reduction.
Good housekeeping includes:

- Better controlling of feed rate, mixing, temperature as well as other reaction parameters (pressure control to minimize nitrogen consumption and associated losses from reactors…),
- Optimisation of process parameters,
- Effective production and maintenance scheduling,
- Improved material handling and storage procedures,
- …

No unique abatement technique can be implemented in a general way in all plants, due to the diversity of situations. Consequently, secondary abatement techniques which could be applied in pharmaceuticals production plants are not defined separately: since it is difficult to determine the implementation potential of each of these reduction technologies, secondary measure 01 takes into account the use of several techniques: thermal oxidation, condensation, activated carbon adsorption, absorption.

According to information received from [4, 7 and 8], three situations have been considered:

- Installations emitting more than 15 % of the solvent input: an average value of 30 % is taken into account. This corresponds to primary measure 00 where no specific primary controls nor secondary measures are used,
- Installations emitting between 5 to 15 % of the solvent input: an average value of 8 % is taken into account. This corresponds to primary measure 01 and secondary measures 01.
- Installations emitting less than 5 % of the solvent input: an average value of 3.5 % is taken into account. This corresponds to primary measure 02 and secondary measure 02 (see below).

In this case, the two options cannot be cumulated.

Table 3.1: Measures of reduction considered

Primary Measure Code PMC	Secondary Measure Code SMC	Description
00	00	Conventional primary measures and no secondary measure
01	01	Primary measure program 1 and low use of secondary measures
02	02	Primary measure program 2 and high use of secondary measures (both Incineration, adsorption and / or condensation)

4. Country specific data to be collected

Different types of country specific data have to be collected to give a clear picture of the situation in each Party. EGTEI proposes default values for these economical parameters which can be modified by the national expert if better data are available.
Activity levels from 2000 to 2020 as well as the description of the control strategy are necessary (these data can be directly entered in ECODAT). A full definition of the work to be done by national experts is provided in the general EGTEI methodology [10].
For this activity no country specific economical parameters are used to calculate variable operating costs. Only default costs have been defined.

The national expert can also modify the default unabated emission factor proposed by EGTEI to represent the reference situation of the coil coating for all Parties in a range of ± 10% (however justification has to be given).

Table 4.1: Unabated emission factor [kg NMVOC / t solvent]

Default emission factor	Country specific emission factor
300	To be provided by national experts

5. Default emission factors and cost data defined with the EGTEI methodology

Table 5.1 presents an overview of all data provided by the EGTEI methodology for the reference installation: default emission factors with abatement efficiencies, investments, variable and fixed operating costs as well as the cost efficiency and specific costs related to the fuel consumed.

Table 5.1: Emission factors (EF), abatement efficiencies, investments and operating costs (OC) and unit costs for each combination

RIC PMC SMC	NMVOC EF [kg/t solv.]	Abatement efficiency [%]	Investment [k€]	Variable OC [k€ / y]	Fixed OC [k€/y]	Unit cost [k€/t NMVOC abated]	Unit cost [k€/t solvent input]
01 00 00	300		0		0		
01 01 01	80	73	2 640	316.8	132.0	1.17	0.258
01 02 02	35	88	6 678	675.7	333.9	2.30	0.611

6. Relevance of EGTEI information for integrated assessment modelling (IAM)

In the previous RAINS version [5], the pharmaceutical industry was already covered.
The sector PHARMA represented the pharmaceutical product manufacturing with the activity level defined by the quantity of solvent consumed [5].
The module “pharma-SLV” in RAINS has been updated [11] to take into account the EGTEI proposal. For the time being, the activity covered in RAINS corresponds to the manufacture of pharmaceutical products. The speciality organic chemical industry considered in EGTEI covers a larger range of products, both pharmaceutical and non pharmaceutical. This is not yet reflected in RAINS.
Reduction measure definitions and their efficiencies are based on EGTEI proposals:

- pharma-SLV-PRM1+LEOP : primary measures package one + low level of end of pipe techniques

- pharma-SLV-PRM2+HEOP : primary measures package two + high level of end of pipe techniques

Data provided in EGTEI approach (emission factors and costs) have been implemented in the new version of the RAINS model [11] for the modelling work carried out in the scope of the CAFÉ programme and the revision of the Gothenburg protocol.

For this activity now, data provided by national experts through ECODAT can then be directly used by IIASA for introduction in the RAINS model.

7. Perspective for the future

For improving the representation of this activity, the definition of an additional reduction measure enabling to reduce more drastically NMVOC emissions should be necessary. Some new installations emit less than 3.5 % of NMVOC compared to the solvent input.

8. Bibliography

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Example of data collection and use of EGTEI data – Case of France

A. Country specific data collection and scenario CLE developed

The French national expert has been able to complete ECODAT for the speciality organic chemical industry with help of CITEPA [12] and consultation of the SICOS [13].
All data have been prepared by the French national expert for the bilateral consultations member state – CIAM which ended in March 2004.

Country and sector specific economic parameters

No country specific parameters have to be defined for this activity.

Activity level

The activity level from 2000 to 2020 has been defined by SICOS [13] and the increase is assumed to be 2.2 % per year. These data have been approved by the French national expert.
The total solvent input is assumed to increase as follows:

Table A.1: Activity levels on the reference Installation (t solvent input / year)

RIC	2000	2005	2010	2015	2020
01	232300	259002	288774	321968	358977

Unabated emission factor

The French emission factor used is equal to the default emission factor provided by EGTEI.

Table A.2: Unabated emission factor

Default unabated emission factor [kg NMVOC/t solvent input]	French unabated emission factor [kg NMVOC/t solvent input]
300	300

Current legislation control (CLE) scenario

In the current legislation control scenario (CLE), application rates of the different abatement techniques depend on regulation implemented and on dates of compliance required by this regulation but also internal development not driven by regulation.
In 2000, a large part of the solvent input is already carried out on plants equipped with one reduction measure. The rates of application have been defined from data provided by SICOS for study [4] and all data collected by CITEPA [12] in the scope of the elaboration of the French emission inventory [3]. The solvent input results from enquiry carried out for study [4].

Application rates of the two reduction techniques from 2005 to 2020 have been defined considering the requirement for compliance with the EC Directive (to be applied in France by 2005 instead of 2007)
The application rates for the current legislation scenario are presented in table A.3.

Table A.3: Application rates and applicability for each combination of reduction measures in CLE scenario

RIC PMC SMC	Application rate in 2000 [%]	Application rate in 2005 [%]	Appl. [%]	Application rate in 2010 [%]	Appl. [%]	Application rate in 2015 [%]	Appl. [%]	Application rate in 2020 [%]	Appl. [%]
01 00 00	5		0	0	0	0	0	0	0
01 01 01	39.8	45	100	37	100	25	100	20	100
01 01 02	55.2	55	100	63	100	75	100	80	100
Total RIC 01	100	100	-	100	-	100	-	100	-

B. Trends in emissions and total costs of the CLE scenario

Data shown in the table B.1 are directly provided by ECODAT and based on input parameters defined in chapter A.

Table B.1: trends in emissions and total annual costs of emission reductions is the CLE scenario

	2000	2005	2010	2015	2020
NMVOC emissions	**t COV**	**t COV**	**t COV**	**t COV**	**t COV**
CLE scenario	15369	14310	14915	14891	15795
Total annual costs	**k€/year**	**k€/year**	**k€/year**	**k€/year**	**k€/year**
CLE scenario	102205	117113	138727	168307	193987